

**ONTARIO  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST**

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985,  
c. C-36, AS AMENDED

AND IN THE MATTER OF THE COMPROMISE OR ARRANGEMENT OF  
ANTIBE THERAPEUTICS INC.

**RESPONDING AND CROSS-APPLICATION RECORD  
OF THE CROSS-APPLICANT, NUANCE PHARMA LTD.  
(Application Returnable April 18, 2024)**

April 15, 2024

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# TAB 1

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ANTIBE THERAPEUTICS INC.

**NOTICE OF CROSS-APPLICATION**

TO THE RESPONDENT:

A LEGAL PROCEEDING HAS BEEN COMMENCED by the applicant. The claim made by the applicant appears on the following page.

THIS APPLICATION will come on for a hearing

- In person
- By telephone conference
- By video conference

at the following location: 330 University Avenue, Toronto, Ontario

on April 18, 2024 at 10:00 a.m. (or as soon after such time as the application may be heard).

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or an Ontario lawyer acting for you must forthwith prepare a notice of appearance in Form 38A prescribed by the *Rules of Civil Procedure*, serve it on the applicant's lawyer or, where the applicant does not have a lawyer, serve it on the applicant, and file it, with proof of service, in this court office, and you or your lawyer must appear at the hearing.

IF YOU WISH TO PRESENT AFFIDAVIT OR OTHER DOCUMENTARY EVIDENCE TO THE COURT OR TO EXAMINE OR CROSS-EXAMINE WITNESSES ON THE APPLICATION, you or your lawyer must, in addition to serving your notice of appearance, serve a copy of the evidence on the applicant's lawyer or, where the applicant does not have a lawyer, serve it on the applicant, and file it, with proof of service, in the court office where the application is to be heard as soon as possible, but at least four days before the hearing.

IF YOU FAIL TO APPEAR AT THE HEARING, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO

OPPOSE THIS APPLICATION BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID  
MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date April 15, 2024

Address of court office: Superior Court of Justice  
330 University Avenue  
Toronto, ON M5G 1R8

**TO THE SERVICE LIST**

## CROSS-APPLICATION

1. Nuance Pharma Ltd. ("**Nuance**") objects to the motion of Antibe Therapeutics Inc. ("**Antibe**") seeking to extend its proceedings pursuant to the Companies' Creditors Arrangement Act ("**CCAA**") in the form of an amended and restated initial order, including, among other things, an extension of the initial statutory 10-day stay of proceedings.

2. Instead, Nuance makes application for:

- (a) an order abridging the time for service and the filing of this notice of application and the application record, validating serve effected to date, and an order dispensing with service on any person other than the persons served;
- (b) an order declaring that as of September 5, 2021 Antibe held US\$20 million (the "**Investment Payment Amount**") in funds in trust for Nuance;
- (c) an order declaring that as of April 8, 2024, Antibe held CAD\$19.6 million in trust for Nuance;
- (d) further to subparagraphs (b) and (c) above, a tracing and following order in respect of any assets, funds, effects and property arising from or relating to the Investment Payment Amount paid to Antibe by Nuance pursuant to the license agreement dated February 9, 2021 (the "**License Agreement**"), which was rescinded as of September 5, 2021, and other amounts Nuance is entitled to be paid pursuant to the Arbitral Award (as defined below);

- (e) an order appointing FTI Consulting Canada Inc. ("**FTI**") as receiver and manager (in such capacities, the "**Receiver**") without security of all the assets, undertakings, and properties of the respondent Antibe Therapeutics Inc. ("**Antibe**");
- (f) the costs of this cross-application on a substantial indemnity or other appropriate basis; and
- (g) such further or other relief as this Honourable Court may deem just and necessary.

3. In the alternative, if the Court is inclined to grant the relief sought by Antibe extending the CCAA process, Nuance is seeking an order lifting any stay of proceedings as against Antibe for the purposes of recognizing and making enforceable as a judgment of this Court the arbitral award rendered in the arbitration proceedings, SIAC Arbitration No. 021 of 2022 (the "**Arbitral Award**"), under the auspices of the Singapore International Arbitration Centre ("**SIAC**") by the arbitral tribunal (Ms. Catherine Amirfar, the "**Tribunal**") seated in the Republic of Singapore, dated February 27, 2024.

**THE GROUNDS FOR THE APPLICATION ARE:**

**A. Overview**

4. By operation of Nuance's September 5, 2021 rescission of the License Agreement, which rescission was expressly found to be valid in binding arbitration, Antibe holds its property, assets and undertakings up to the full amount of the Investment Payment Amount in trust for Nuance.



5. Antibe defensively sought, and asks this Court to exercise its discretion to extend, CCAA protection to avoid complying with the Arbitral Award that it publicly disclosed it would accept, and to continue to spend Nuance's funds in breach of trust.

6. Antibe's request to extend CCAA protection should be denied, and FTI should be appointed as Receiver. First, Antibe does not present any restructuring plan at all. Clinical trials for its only pharmaceutical product have been put on indefinite hold by the U.S. Food and Drug Administration ("**FDA**"). Even if the FDA's concerns can be addressed,

(a) Antibe does not have adequate financing to pursue further development of its drug, and Nuance refuses to become an involuntary lender to this failed enterprise; and

(b) It is still highly speculative that the Drug will ever make it to market, having regard to the significant safety issues that have been disclosed through clinical testing performed to-date, as well as the fact that very few products advance to market past the Phase II clinical trial stage.

7. Second, Antibe does not come to the Court with clean hands:

(a) Antibe's CEO, Dan Legault, who remains involved in the operations of Antibe, has been found to have made fraudulent misrepresentations and concealed material facts regarding the Drug, specifically in respect of the safety of the Drug; and

(b) Antibe refused to return Nuance's funds following the rescission of the License Agreement, again refused to return Nuance's funds after the rescission of the License Agreement was found to be valid by the Arbitrator, and instead ramped up spending of those funds in breach of trust.

8. Antibe in effect seeks this Court's blessing and CCAA protection to:
  - (a) have Nuance act as involuntary debtor-in-possession financier of Antibe, without Nuance's consent, and with none of the protections typically afforded to a debtor-in-possession financier; and
  - (b) continue depleting Nuance's funds in breach of trust and in breach of the Arbitral Award, to try and commercialize a drug that has been identified by regulators to present a serious risk of patient safety, and for which, even if commercialized, there are many market-established alternatives (e.g. Aspirin, Advil, Aleve, Celebrex and Voltaren).

That would be an improper use of the CCAA.

9. Furthermore, and in any event, Antibe has neither a restructuring plan, nor a germ of a restructuring plan. It instead proposes a "wait and see approach" based on Antibe's executives' belief that Antibe can address the concerns of the FDA, which concerns Antibe admits it does not yet fully understand, and which may, once understood may well be insurmountable.

10. The potential commercialization of the Drug is, at best, highly speculative, now even more so given Antibe's conduct. Antibe has already expended upwards of CAD\$124 million on the development of the Drug, the Drug is not close to coming to market, and likely will never come to market, given the concerns of Health Canada and the FDA.

11. The equities favour the appointment of FTI as Receiver, rather than any debtor-in-possession ("**DIP**") process, including given the past conduct of Antibe's senior management team, which remains actively involved in the management of Antibe's business.

12. FTI as Receiver is better placed to minimize Antibe's expenditures (preserving Nuance's trust property) and hibernate the business pending the clarification of the concerns of the FDA. If there is a viable path to continue development of the Drug, and if there is a party willing to finance such development, the Receiver is best placed to pursue a going-concern transaction for the benefit of stakeholders – however Antibe should not be permitted to deplete Nuance's trust property in a last-ditch speculative attempt to avoid the result of the Arbitral Award.

**B. The Parties**

13. Nuance is a Hong-Kong incorporated biopharmaceutical company focused on licensing, developing and commercializing medical therapies in the Greater China region, with its registered address at Unit 417 4/F, Lippo Centre Tower Two, No. 89 Queensway, Admiralty, Hong Kong. Nuance is the 100% subsidiary of Nuance Biotech, a Cayman Islands company, and the 100% shareholder of Nuance Pharma (Shanghai) Co. Ltd. It is a subsidiary of CBC Group, Asia's largest healthcare-dedicated investment firm.

14. Antibe is an insolvent biotech company registered under Ontario's *Business Corporations Act* (Ontario), with its registered office located at 15 Prince Arthur Avenue, Toronto, Ontario, M5R 1B2, Canada.

**C. Antibe has been Unjustly Enriched to Nuance's Detriment**

15. On February 19, 2021, Nuance paid the Investment Payment Amount of US\$20 million to Antibe in accordance with the License Agreement. Soon thereafter, Nuance realized that it had been induced to enter into the License Agreement based on material misrepresentations and

omissions on the part of Antibe and its management team, and, on September 5, 2021, issued a notice of rescission, rescinding the License Agreement *ab initio*.

16. On the basis of a robust evidentiary record, the Tribunal held that Nuance had "validly rescinded the License Agreement on the basis of [Antibe's] fraudulent inducement" and ordered Antibe to return the Investment Payment Amount to Nuance, together with interest, expenses and legal disbursements and costs.

17. Antibe has stated in its public disclosures that it "respects the final nature of the" Arbitral Award and "will accept the decision in good faith."

18. In absence of the License Agreement, which has been validly rescinded, there is no juristic reason for Antibe to retain the Investment Payment Amount that it has been ordered to return. Nuance's position is that a constructive trust arose by operation of law at the time the License Agreement was rescinded (i.e., September 5, 2021), and the Investment Payment Amount is therefore held in trust for Nuance, as beneficiary.

**D. The Appropriate Remedy for Unjust Enrichment is the recognition of a Constructive Trust in favour of Nuance**

19. The elements of unjust enrichment have been satisfied, and it is therefore appropriate that the Court recognize a constructive trust in favour of Nuance in the circumstances.

20. Antibe has stated that the Investment Payment Amount has been earmarked and reserved to finance Phase III clinical testing of the Drug – which, in light of the FDA's clinical hold, is unlikely to ever advance.

21. Accordingly, the nature of Nuance's claim is proprietary, which places it on a fundamentally different footing than Antibe's unsecured creditors.

22. There are no secured creditors disclosed in Antibe's balance sheet or court-filed materials.

**E. Antibe's Application is an Improper use of the CCAA and Should Not be Extended**

23. On March 28, 2024, Nuance brought an application seeking, among other things, to have the Arbitral Award recognized in Ontario, and the appointment of a receiver over the property of Antibe pursuant to section 101 of the Courts of Justice Act. A scheduling attendance for Nuance's application was set for the morning of April 9, 2024.

24. At 2:24am on the morning of April 9, 2024, Antibe delivered an application seeking relief under the CCAA which including an initial order, the appointment of Deloitte Restructuring Inc. as monitor, and the appointment of Black Swan Advisors as Chief Restructuring Officer in respect of Antibe. Nuance opposed Antibe's CCAA application, but the parties agreed to the terms of a limited initial order, with Nuance reserving all rights to object to any further extension of the CCAA proceedings at the comeback hearing.

25. Neither Antibe's initial CCAA application nor its motion for an amended and restated initial order disclose any kind of restructuring plan. Antibe's only viable product, the Drug, has been placed on indefinite clinical hold by the FDA.

26. Antibe asks the Court to exercise its discretion to extend the CCAA stay of proceedings so that it can "wait and see" if there is a viable path forward with the FDA. But it seeks to spend significant funds that are subject to Nuance's constructive trust to do so – effectively forcing Nuance to be an involuntary DIP financier of Antibe's CCAA proceedings.

27. Antibe's CCAA process is doomed to failure:

- (a) it is not apparent that there will be any ability to address concerns that FDA may raise;
- (b) even if the FDA's concerns can be addressed, there is no financing available to Antibe to advance further development, having regard to the Arbitral Award and Nuance's constructive trust;
- (c) even if financing were available, many drugs never make it past Phase 2 clinical testing, and there is no reason to believe the Drug will ever make it to the consumer market, particularly in light of the significant safety concerns that have been raised during the clinical trial phase of development;
- (d) even if the Drug did make it to market, the market for NSAID therapies is well-established with a number of name-brand incumbents having established significant market share. Citing information provided by Antibe's CEO, Daniel Legault, the Tribunal found that "NSAIDs are 'among the most common pain relief medicines in the world'". The Drug therefore does not appear to represent a significant economic opportunity, even if further development was viable;
- (e) the Drug is not novel – its development has not been fast tracked or otherwise facilitated by health authorities, as would be the case for a breakthrough therapy. Instead, the FDA has placed the Drug on clinical hold due to health and safety concerns;

- (f) Antibe has no prospect of raising funds from the equity markets. The trading in the securities of Antibe has been halted;
- (g) Antibe has no prospect of raising debt. Health Canada and the FDA have each expressed concerns about the safety of the Drug; and
- (h) given Nuance's mistrust of Antibe's management team, it cannot conceive of any possible proposal that Antibe might put forward that it could support.

28. Canadian Courts have consistently held that a CCAA debtor must have "a germ of a restructuring plan" at a minimum to avail itself of the benefits of the CCAA. Antibe has no such plan, and none is likely to be forthcoming, having regard to the above factors.

29. Canadian Courts have also held that CCAA applications brought for purely defensive measures, and without any viable restructuring plan, represent an inappropriate use of the CCAA. Antibe's CCAA application is clearly an attempt to evade the legal and operational effects of the Arbitral Award – which Antibe itself said it would respect.

**F. Antibe does not Come with Clean Hands and therefore does not Deserve the benefit of this Court's Discretion**

30. In the Arbitral Award, on the basis of an extensive evidentiary record submitted by Antibe and Nuance, the Tribunal held that Antibe fraudulently induced Nuance into entering the License Agreement, and that the License Agreement has been validly rescinded by Nuance.

31. Nuance's constructive trust arose by operation of law as of September 2021, i.e. at the time the License Agreement was rescinded. Antibe has therefore been engaged in a long-term plan to

deny Nuance the rightful return of the Investment Payment Amount, and is now asking this court to bless its inappropriate evasion by extending CCAA relief so that it may use funds it obtained from Nuance by fraudulent misrepresentation to continue development of the Drug.

32. If Nuance's constructive trust is not recognized and Antibe's CCAA process is permitted to proceed, the effect will be to deny the Tribunal's findings and effectively reward Antibe and its management team for its bad faith behaviour towards Nuance, while punishing Nuance by forcing it to be an involuntary DIP lender to a CCAA process that is doomed to fail.

33. Therefore, Antibe cannot show the requisite element of good faith necessary for this Court to exercise its discretion to extend the CCAA process.

**G. Nuance's Receiver is Just and Convenient in the Circumstances**

34. The appointment of a receiver to preserve Nuance's trust property is just and convenient in the circumstances, while Antibe's CCAA application is not appropriate.

35. As stated, by virtue of the constructive trust, Antibe holds its property in trust for Nuance as beneficiary. Section 67(1)(b) of the *Bankruptcy and Insolvency Act* ("**BIA**") provides that "the property of a bankrupt divisible by its creditors shall not comprise [...] property that is held in trust for any other person."

36. Accordingly, Nuance's position is that its trust property should not be subject to depletion by being maintained within a debtor-in-possession insolvency process. Nuance's receiver is better placed to preserve Nuance's trust property for the benefit of the beneficiary thereof (i.e. Nuance), with any remaining property (if any) to be marshalled for the benefit of Antibe's unsecured creditors.



37. As stated, Antibe's management team should not be rewarded seeking to avoid the consequences of its fraudulent inducement by being permitted to remain in control of a company that has no reasonable prospect of turnaround.

38. There is no prejudice to Antibe's other creditors if Nuance's trust is recognized and its receiver appointed:

- (a) Antibe has no secured creditors;
- (b) Antibe's unsecured creditors are left in the same position as possessing unsecured claims against an insolvent company;
- (c) Because Antibe's proposed restructuring is doomed to fail, the unsecured creditors are not being deprived of any certain recovery they might obtain through Antibe's CCAA. If anything, Nuance's receivership seeks to minimize Antibe's spending to the fullest extent possible, which may serve to enhance claims to unsecured creditors.

39. The equities therefore favour the appointment of Nuance's receiver, rather than any debtor-in-possession process where Antibe's management team retains control of the business.

40. Further, the balance of convenience also favours the appointment of Nuance's receiver in the circumstances.

41. The cash flow forecast put forward by Antibe for the requested extended stay period discloses a significant cash expenditure of over \$1.5 million over a 30-day period. Approximately 60% of this amount relates to professional fees, including the fees of a Chief Restructuring Offer

(whether by title or operation) – yet there is no restructuring plan to show despite this advisory team having completed over one month of work.

42. With respect to the 40% balance of the forecast expenditures, it is not at all apparent why Antibe's general and administrative expenditures are so high when its sole product under development is on pause (i.e., the Drug). Antibe has not disclosed what, if any, cost reduction measures have been implemented, and Nuance is not aware of any such cost saving initiatives.

43. Nuance's proposed receiver, FTI, is an industry-leading restructuring advisory firm with deep expertise in pharmaceutical industry turnarounds.

44. If appointed, FTI will undertake an expedited expense review with a view to hibernating Antibe's business to the fullest extent possible in order to preserve Nuance's trust property (and any residue) pending receipt of the FDA Hold Letter.

45. Should the FDA Hold Letter disclose a viable path forward for the Drug, FTI would be well positioned to engage with potentially interested parties to assess whether a sale or refinancing transaction might be available for Antibe's remaining assets and operations.

46. In all of the circumstances of this case, it is both just and convenient as well as necessary and appropriate for Nuance's receiver to be appointed.

#### **H. Alternative Argument – The Stay Must be Lifted**

47. If the Court is inclined to grant Antibe's requested amended and restated initial order, Nuance asserts that an order should be granted lifting the stay for the purpose of recognizing the Arbitral Award as a judgment of this Court.

48. In the circumstance where the CCAA process continues but the Arbitral Award is not recognized, Antibe will suffer significant and irreparable harm:

- (a) any recovery to Nuance would be depleted by the significant expenditures anticipated to be incurred in pursuing the CCAA, which, as stated, is doomed to fail;
- (b) Nuance ought to have the ability to assert its rights within Antibe's CCAA, should it be permitted to proceed, including by voting in respect of any plan of arrangement
- (c) Antibe had indicated that it would respect the Arbitral Award before pivoting to a defensive CCAA process that seeks to avoid such payment obligation.

49. No other creditors will be prejudiced if the stay is lifted for the purpose of recognizing the Arbitral Award – the Tribunal's determination already represents a liability of Antibe.

50. This is not a case where a viable proposal providing a creditor recovery is sought to be subverted by one creditor. Here, there is no viable proposal, and no reasonable prospect that one will be brought forward in the future.

## **I. General**

51. There is a real risk that Antibe will dissipate or deplete funds and assets held in trust for Nuance if the Court exercises its discretion to extend Antibe's CCAA proceedings.

52. Nuance wishes to any all necessary steps to preserve and protect amounts owing under the Arbitral Award and at equity and realize upon same.

53. Nuance has at all times acted in good faith towards Antibe.

54. Section 101 of the *Courts of Justice Act*.
55. Section 67(1)(a) of the BIA.
56. Section 11.02 of the CCAA.
57. Rules 1.04, 2.03, 3.02, 14.05, 16.04 and 38 of the *Rules of Civil Procedure*.
58. Such further or other relief as counsel may advise and this Honourable Court may permit.

**THE FOLLOWING DOCUMENTARY EVIDENCE** will be used at the hearing of the application:

- (a) the affidavit of Mark Lotter sworn April 15, 2024, and the exhibits thereto;
- (b) the consent of FTI Consulting Canada Inc. to act as receiver; and
- (c) such further and other evidence as counsel may advise and this Honourable Court may permit.

April 15, 2024

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Nuance Pharma Ltd.

IN THE MATTER OF *THE COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, C. C-36, AS AMENDED  
AND IN THE MATTER OF THE COMPROMISE OR ARRANGEMENT OF ANTIBE THERAPEUTICS INC. (the "Applicant")

Court File No. CV-23-00693758-00CL

*ONTARIO*  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST

PROCEEDING COMMENCED AT TORONTO

**NOTICE OF CROSS-APPLICATION**

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Lawyers for  
Nuance Pharma Ltd.

# TAB 2

**ONTARIO  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST**

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985,  
c. C-36, AS AMENDED

AND IN THE MATTER OF THE COMPROMISE OR ARRANGEMENT OF  
ANTIBE THERAPEUTICS INC.

**AFFIDAVIT OF MARK LOTTER  
(Sworn April 15, 2024)**

I, Mark Lotter, of the special administrative region of Macau, MAKE OATH AND SAY:

1. I am the founder and Chief Executive Officer of the Nuance group which comprises Nuance Biotech Inc., Nuance Pharma (Shanghai) Co. Ltd., and the cross-applicant, Nuance Pharma Ltd. (“**Nuance**”). As such, I have knowledge of the matters deposed herein except if I have indicated that my knowledge is based on information provided to me by others, and in which case, I verily believe such information to be true.

2. I swear this affidavit in support of the cross-application brought by Nuance for, among other things, the appointment of FTI Consulting Canada Inc. as receiver of Antibe Therapeutics Inc. (“**Antibe**”).

**A. My Prior Affidavit**

3. I previously swore an affidavit on March 28, 2024, in support of Nuance’s application for, among other things:



- (a) an order recognizing and making enforceable the arbitral award rendered in the arbitration proceeding SIAC Arbitration No. 021 of 2022 (the “**Arbitral Award**”);  
and
- (b) injunctive relief restraining Antibe from further dissipating assets held by it, including Nuance’s funds.

4. A copy of my March 28, 2024 affidavit is attached as **Exhibit “A”**. I repeat and rely upon that affidavit herein.

#### **B. The Current Status**

5. In all of the circumstances, including as described below and as set out in my March 28, 2024 affidavit, Nuance has no confidence in the management of Antibe. Antibe’s management has been found to have made fraudulent misrepresentations and concealed material facts regarding its only somewhat developed potential drug product - Otenaproxesul (the “**Drug**”).

6. In my view, it is highly unlikely that Antibe will be able to raise funds, either through debt or equity, where:

- (a) Antibe has been found to have fraudulently misled a commercial partner in order to obtain funds to develop the Drug;
- (b) Antibe has refused to comply with an arbitral award that it publicly disclosed to the market it would accept in good faith;
- (c) approximately 90% of drugs fail in the clinical trial stage of the drug development process of the U.S. Food and Drug Administration (the “**FDA**”);

- (d) the Drug's long-intended purpose for extended use has been found to present a serious risk to patient safety due to liver-related harm;
- (e) the Drug's current intended purpose (the treatment of acute pain) does not differentiate the Drug from established non-steroidal anti-inflammatory drugs, such as Advil, Aleve, Celebrex and Voltaren, which also present a risk of liver-related harm;
- (f) the Drug does not meet an unmet patient need;
- (g) Antibe does not have any other products close to being commercialized; and
- (h) the trading of securities of Antibe has been halted.

7. Based on the materials filed in the CCAA proceeding to date by Antibe, Antibe does not appear to have any restructuring plan or proposal other than to "wait and see", during which "wait and see" period it proposes to spend Nuance's funds, over Nuance's objections, on a large team of senior insolvency professionals at, in my view, a high burn rate, which insolvency professionals have been engaged for over a month, but have not presented a restructuring plan or proposal. Nuance unequivocally does not agree with such use of Nuance's funds.

8. Nuance should be repaid the funds that Antibe has been ordered to repay. A receiver should be appointed to control Antibe's spending, which should be minimized to the greatest extent possible.

### **C. Nuance & The Nuance Group**

9. Nuance has a good track record in cooperating with global biotech companies in ventures to commercialize innovation-focused biopharmaceuticals.

10. For example, in March 2021, Nuance entered into an in-license agreement with Bavarian Nordic A/S for the development and commercialization of life-saving vaccines against respiratory syncytial virus (RSV). Under the agreement, Nuance paid Bavarian Nordic an upfront payment of USD 12.5 million.

11. Unfortunately, the drug failed after its Phase 3 clinical trials revealed that the drug did not meet all the primary goals of preventing lower respiratory tract disease. Nuance accepted the failure of the drug. The risk that a drug fails at the clinical trial stage of the drug development process is well known. However, some drugs do succeed. Nuance successfully partnered with Verona Pharma in advancing Phase 3 studies in Asia of a first-in-class, novel solution Ensifentrine for the treatment of chronic obstructive pulmonary disease.

#### **D. The Arbitral Award**

12. The tribunal in SIAC Arbitration No. 021 of 2022 (the “**Tribunal**”) was Catherine Amirfar as sole arbitrator. Ms. Amirfar is a New York based lawyer at Debevoise & Plimpton, and Co-Chair of Debevoise’s International Dispute Resolution Group and the Public International Law Group, and a member of the firm’s Management Committee, ranking in Band 1 for International Arbitration (Global), Public International Law (Global) and International Arbitration (USA). Antibe consented to Ms. Amirfar’s appointment as arbitrator. A copy of Ms. Amirfar’s profile on the Debevoise & Plimpton website is attached as **Exhibit “B”**.

13. For ease of reference, I have reproduced below certain of the Tribunal’s more notable findings in the Arbitral Award, which is attached as Exhibit "C" to my March 28, 2024 affidavit, with bolding added.

- (a) “According to Mr. Legault, ‘**Antibe is relying on [the US\$ 20 million upfront payment] to conduct its Phase 3 testing of the Drug and bring it forward for regulatory approval in the USA and Canada.**’”<sup>1</sup>
- (b) “...**the Tribunal finds that the Respondent made misrepresentations and/or omissions leading up to the License Agreement, and that they were material.**”<sup>2</sup>
- (c) “In responding to specific questions from Nuance, the Respondent was already aware of the "serious concerns" raised by Health Canada, but did not provide the up-to-date information in its possession, and instead (i) omitted from the Data Room the most recent correspondence with Health Canada, even while prior correspondence with Health Canada and the FDA was included; and (ii) deliberately chose to put a version of the AME Protocol that had already been withdrawn on 22 January 2021, referring to it only as the "Draft AME protocol". **Taken together, Antibe's response to Nuance's inquiry can only be characterized as being so incomplete as to be affirmatively and deliberately misleading, evincing conscious misbehavior and recklessness, rather than an intent to be truthful or honest.** In addition, Antibe's report to its Board on 10 February 2021 belies the notion that the position of Health Canada on the AME Study was unimportant, such that this omission could have been inadvertent, as it was characterized to the Board as "still" the "main corporate risk" and the timing for the study initiation of January 2022 was inconsistent with the answer provided to Nuance just days earlier, on 4 February 2021. Also notable was the testimony of

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<sup>1</sup> Arbitral Award, paragraph 154.

<sup>2</sup> Arbitral Award, paragraph 260.

Antibe's Chief Executive Officer, Mr. Daniel Legault. As CEO, he was one of the senior executives who attended the meeting with Health Canada held on 22 January 2021 and throughout had direct knowledge of the events that resulted in Antibe withdrawing the AME Protocol to prevent receiving an official rejection from Health Canada. He also drafted and presented to the Antibe Board the slide presentation updating the Board on the AME Protocol. At the same time, he played a key role in the due diligence process, as one of the individuals who Ms. Korets-Smith testified she would go to for "regulatory communications, such as correspondence, meeting minutes" for purposes of the Data Room, and he specifically reviewed the response Antibe sent to Nuance with respect to the AME Study. Mr. Legault clearly acknowledged the importance and potential materiality of the position of Health Canada vis-a-vis the Drug, conceding at the hearing that Health Canada communications were "naturally requested by other potential partners" and testifying that if "Health Canada had issued a rejection on the merits of the CTA, or issued a decision that significantly affected the Drug's development time or costs, Antibe would have made that information public and informed Nuance." **His explanation of why the Health Canada communications were not placed in the Data Room – which as noted, involved circumstances in which Health Canada had advised that it would issue a rejection of the CTA absent Antibe's withdrawal – shifted at the hearing, from the position that "there was no deliberateness, we are just not turning our mind to it" and that the relevant correspondence "weren't left out. There was no request for it", and later, "we did not think the correspondence was material from a public company point of view and we were in a due diligence process and if they want ongoing**

**anything, they have to ask for it", and ultimately, "we are not going to provide you [Nuance] with anything unless you ask for it". It was only on 21 July 2021 that Antibe shared with Nuance the "final protocol for the AME study which is currently ongoing in Canada", and as noted, on 30 July 2021, the study hit the stopping criteria, and Antibe paused the AME Study, which fundamentally pivoted the development of the Drug towards an indication for acute (vs. chronic) pain. **As to motive to deceive, the Tribunal credits the Claimant's arguments and evidence as to Antibe's motivation to enter into the License Agreement in order to secure the necessary funding for the Drug's continued development, in circumstances where the Respondent admitted the development of the Drug could not go forward without Nuance's US\$20 million upfront payment.**"<sup>3</sup>**

- (d) “The Tribunal credits [Nuance's] evidence that [Nuance] did in fact review and request information on the regulatory communications and status of the pending studies and **that no amount of due diligence would have enabled [Nuance] to discover that Antibe had omitted/misled it with respect to key regulatory information...**which undercuts [Antibe’s] argument and evidence that [Nuance] could or should have done more in this regard.”<sup>4</sup>
- (e) “**Having found that Nuance has met its burden to establish its claim of fraudulent concealment / inducement, the Tribunal finds that the License Agreement has been validly rescinded by Nuance.** The Claimant is therefore entitled to be put in the situation in which it would have been but for the conclusion

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<sup>3</sup> Arbitral Award, paragraph 268.

<sup>4</sup> Arbitral Award, paragraph 269.

of the License Agreement. **On that basis, Antibe is ordered to return to Nuance the sum of US\$20 million that represented Nuance's upfront payment to Antibe, plus interest.**<sup>5</sup>

14. Based on Mr. Legault's evidence, reproduced and cited by the Arbitrator in the Arbitral Award, I understand that Antibe had earmarked and reserved Nuance's US\$20 million for Phase 3 testing of the Drug, which Phase 3 testing has not begun.

#### **E. My Responses to the Affidavit of Scott Curtis, COO of Antibe**

15. I have reviewed the affidavit of Scott Curtis affirmed April 8, 2024. In this section of my affidavit, I respond to certain of Mr. Curtis' statements, particularly those made by Mr. Curtis in the Overview of his affidavit.

16. At paragraph 9 of his affidavit, Mr. Curtis states that the Drug meets a significant unmet medical need. I disagree. When the FDA determines that a prospective drug is the first available treatment or if the drug has advantages over existing treatments (i.e. it meets a significant unmet medical need) the FDA has four expedited development and approval processes:<sup>6</sup> (i) fast track; (ii) breakthrough therapy; (iii) accelerated approval; or (iv) priority review. None of these have been granted for the Drug. I do not believe the Drug (as now pivoted to acute pain) meets any such unmet need and it appears that the FDA does not agree with Mr. Curtis that the Drug meets a significant unmet medical need.

17. At paragraph 10 of his affidavit, Mr. Curtis states that Antibe has made significant progress with mitigating potential liver-related harm from the chronic use of the Drug by developing the

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<sup>5</sup> Arbitral Award, paragraph 276.

<sup>6</sup> <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review>

Drug for acute use. This statement is misleading. NSAIDs like the Drug are commonly associated with increased oxidative stress, leading to liver transaminase elevations, as Antibe itself announced to the market on October 14, 2021 (see Exhibit "L" to this affidavit).

18. Developing the Drug for short-term use for acute pain is not “significant progress” with the Drug. Rather, the fact that the Drug causes liver transaminase elevations means that the Drug is no different in that regard from established NSAIDs, such as Aspirin, Advil, Aleve, Celebrex and Voltaren.

19. At paragraph 15 of his affidavit, Mr. Curtis states that the Arbitrator ordered the rescission of the License Agreement. That is not correct. The Arbitrator found that Nuance had validly rescinded the License Agreement on September 5, 2021. See, e.g., paragraph 276 of the Arbitral Award.

20. At paragraph 16 of his affidavit, Mr. Curtis states that Antibe put forth a good faith proposal to pay Nuance back in full over time. That mischaracterizes the proposal put forth by Antibe, but I will not go into the details of why, given that I understand the proposal was without prejudice. In any event, the terms of such proposal are not acceptable to Nuance.

21. At paragraph 20 of this affidavit, Mr. Curtis states that Antibe’s Chief Medical Officer believes that Antibe will be successful in having the clinical hold lifted by the FDA. I do not understand that statement, which appears to be aspirational, at best, given that Mr. Curtis himself concedes that he does not know the details of the reason for the FDA clinical hold.

22. At paragraph 21 of his affidavit, Mr. Curtis states that continuing to engage with the FDA is a “low-risk, high-reward endeavor”. I do not agree with that statement. There is significant risk to Antibe’s stakeholders, particularly Nuance, for Antibe to continue to spend funds (particularly



Nuance's funds) on a drug that appears to have, at best, a highly speculative prospect of ever being commercialized.

23. At paragraph 22 of his affidavit, Mr. Curtis states that there is an urgent unmet need for non-opioid acute pain alternatives. This is misleading. Multiple drug classes are used to treat acute post-operative pain. Mr. Curtis omits to mention the significant volume of NSAIDs already available to treat acute pain, including Aspirin, Advil, Aleve, Celebrex and Voltaren, among others. In addition, there are already short and long-acting non-opioids in the market, which have had limited impact on minimizing the market share of opioid-based therapies in the United States.

24. At paragraph 24 of his affidavit, Mr. Curtis states that "a successful Phase 2 Trial will preserve and maximize value for all stakeholders, including Nuance." That statement effectively presumes success, ignoring the fact that the majority of drugs fail at Phase 2 of the clinical trial stage (being the third of five stages of the FDA drug development process), as further described below.

25. Furthermore, it is clear from Mr. Curtis' affidavit, particularly paragraphs 24, 25, 26 and 97, that Antibe's proposed path forward is premised on Antibe being able to successfully completing Phase 2 of the clinical trial stage, which Phase 2 has not commenced and has been placed on hold. It is not apparent that Antibe will, in fact, be able to address the FDA's concerns.

26. At paragraph 29 of his affidavit, Mr. Curtis states that the requested stay of proceedings will put all stakeholder on an equal footing before this Court. That statement ignores the fact that Nuance is not on equal footing with Antibe's other unsecured creditors by virtue of the rescission of the License Agreement, which rescission was confirmed to be valid in the Arbitral Award.

27. At paragraph 55 of his affidavit, Mr. Curtis describes two “drug candidates” in addition to the Drug, ATB-352 and a “new molecule” to target inflammatory bowel disease, Crohn’s disease and ulcerative colitis. While Mr. Curtis does not provide further detail, it appears based on his description of ATB-352 and the “new molecule” that those drug candidates are likely at the first stage of the FDA’s drug development process, being discovery and development (research for a new drug in a laboratory). However, it is possible based on Mr. Curtis’ description that ATB-352 is at the second stage of the FDA’s drug development process, being preclinical research (laboratory and animal testing to address basic questions about safety).

28. In any event, I am not aware of Antibe having reported to the market that either ATB-352 or the “new molecule” have cleared the pre-clinical safety threshold for clinical trials, nor do I believe that they have.

29. Accordingly, neither ATB-352 nor the “new molecule” have yet reached the clinical trial stage, where approximately 90% of drug candidates fail.

30. At paragraphs 113-114, and 119 of his affidavit Mr. Curtis is critical of Nuance’s due diligence conducted prior to entering into the License Agreement, and critical of certain of the Tribunal’s findings. I note that Mr. Curtis’ comments in that regard are:

- (a) inconsistent with Antibe’s public disclosure that Antibe “respects...the final nature of the award and will accept the decision in good faith”; and
- (b) inconsistent with the findings of the Arbitrator that “[Nuance] did in fact review and request information on the regulatory communications and status of the pending studies and...**no amount of due diligence would have enabled Nuance Pharma to discover that Antibe had omitted/misled it with respect to key**

**regulatory information from the Data Room in these circumstances, which undercuts the Respondent's argument and evidence that the Claimant could or should have done more in this regard.”<sup>7</sup>**

#### **F. The Non-Steroidal Anti-Inflammatory Drug Market**

31. Non-steroidal anti-inflammatory drugs (i.e. NSAIDs) are the most widely used analgesics to relieve pain, reduce inflammation, and bring down a high temperature.

32. Some NSAIDs are sold over the counter, such as acetylsalicylic acid (Aspirin) and low doses of ibuprofen (Advil) and naproxen (Aleve) and. Other NSAIDs are only sold via prescription.

33. NSAIDs related to acute pain are very common and the market is saturated. Certain examples of commonly used NSAIDs, of which there are many others, include:

- (a) Acetylsalicylic acid (e.g. Aspirin);
- (b) Ibuprofen (e.g. Advil);
- (c) Naproxen (e.g. Aleve);
- (d) Celecoxib (e.g. Celebrex);
- (e) Diclofenac (e.g. Voltaren);
- (f) Acemetacin (e.g. Emflex);
- (g) Etodolac (e.g. Lodine);

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<sup>7</sup> Arbitral Award, paragraph 269, bolding added.

- (h) Meloxicam (e.g. Mobic, Metacam, and Anjeso);
- (i) Etoricoxib (e.g. Arcoxia);
- (j) Indometacin (e.g. Indocin and Tivorbex);
- (k) Ketoprofen (e.g. Orudis);
- (l) Tenoxicam (e.g. Mobiflex); and
- (m) Tiaprofenic acid (e.g. Surgam, Artiflam, and Flamirex).

34. NSAIDs are not recommended for extended use. A major issue associated with NSAIDs is that is that they can cause gastrointestinal (“GI”) ulcers and bleeding, and more rarely can contribute to heart and cardiovascular conditions, as well as kidney and liver symptoms. NSAIDs can put stress on the liver, evidenced by an elevation of liver transaminase elevations (“LTEs”).

#### **G. The FDA Drug Development Process**

35. In my role as Chief Executive Officer of a group of bio-tech companies, I am familiar with the FDA’s drug development process, which is described on the FDA’s website at <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process>.

36. The FDA has also published an infographic that provides an overview of the FDA’s Drug Approval process, which is attached as **Exhibit “C”**.

##### **i. The Fives Stages of Drug Development**

37. The FDA’s drug development process has five stages:

- (a) discovery and development (research for a new drug in a laboratory);

- (b) preclinical research (laboratory and animal testing to address basic questions about safety);
- (c) clinical research (testing on people to assess safety and efficacy);
- (d) FDA review (FDA review teams' thorough examination of all submitted data relating to the relevant drug to make a decision to approve or not approve the relevant drug);
- (e) FDA post-market safety monitoring (monitoring the safety of the drug after it is made available for use by the public).

**ii. The FDA's Clinical Trial Process**

38. As noted above, the third stage of the FDA's drug development process is clinical research. The FDA's clinical research stage is again described on the FDA's website at <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>.

39. The FDA's clinical trial stage, the third stage of the FDA's drug development process has multiple phases.

40. It has been reported that approximately 90% of drug candidates in clinical trials fail. A copy of an article authored by Duxin Sun, Professor of Pharmaceutical Sciences, University of Michigan, published on February 23, 2022, is attached as **Exhibit "D"**. In support of the 90% failure rate statistic, Mr. Sun cites a scientific journal article published in Nature Reviews Drug Discovery in 2016. A copy of that scientific journal article is attached as **Exhibit "E"**.

41. The 90% failure rate figure is generally consistent with my experience and understanding arising out of my involvement in the pharmaceutical industry.

42. Phase 1 of the clinical research stage generally involves studies with 20 to 100 healthy volunteers or people with the relevant disease or condition. The FDA reports that approximately 70% of drugs progress from Phase 1 to Phase 2.

43. Phase 2 of clinical research stage generally involves studies with up to several hundred people with the relevant disease or condition. The FDA reports that approximately 33% of drugs move progress Phase 2 to Phase 3.

44. Phase 3 of clinical research stage generally involves studies with 300 to 3,000 people with the relevant disease or condition. The FDA reports that approximately 25-30% of drugs progress from Phase 3 to Phase 4.

45. Phase 4 of clinical research stage generally involves studies with several thousand people who have the relevant disease or condition.

46. The FDA's published statistics of the proportion of drugs that progress through the various phases are generally consistent with other published research. In particular, BIO, the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations, has also conducted an analysis of clinical development success rates. It reports that:

- (a) approximately 52% of drugs progress from Phase 1 to Phase 2;
- (b) approximately 28.9% of drugs progress from Phase 2 to Phase 3;
- (c) approximately 57.8% of drugs progress from Phase 3 to Phase 4; and
- (d) the probability of success of FDA approval after Phases 1-4 are complete is 90.6%.

47. A copy of BIO's publication "Clinical Development Success Rates and Contributing Factors 2011-2020" is attached as **Exhibit "F"**.

48. Based on the FDA's published statistics, and BIO's analysis, the biggest hurdle in the clinical trial phase of the drug development is progressing a drug from Phase 2 to Phase 3, where a significant majority (70-75%) of drugs fail.

49. During the clinical trial stage, the FDA can place a planned trial on clinical hold. Reasons for a clinical hold include that:

- (a) human subjects are or would be exposed to an unreasonable and significant risk of illness or injury; and
- (b) the materials provided do not contain sufficient information needed to assess the risks to subjects of the proposed studies.<sup>8</sup>

**iii. Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review**

50. Where certain criteria are met, including that the relevant drug is the first available treatment or if the drug has advantages over existing treatments, the FDA has four distinct approaches to making such drugs available as soon as possible: Priority Review, Breakthrough Therapy, Accelerated Approval, and Fast Track.

51. These approaches are described on the FDA's website at <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review>.

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<sup>8</sup> <https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-clinical-hold>

- (a) Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need;
- (b) Breakthrough Therapy is a process designed to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy.
- (c) Accelerated Approval regulations allow drugs for serious conditions that fill an unmet medical need to be approved based on a surrogate endpoint.
- (d) A Priority Review designation means FDA's goal is to take action on an application within 6 months.

#### **H. The Status of the Drug**

52. According to Antibe, the Drug has been in development since 2004, or approximately 20 years. It has been reported that drugs can take 10-15 years to come to market.

53. To my knowledge, Antibe's lead product, the Drug, has not been granted any (i) fast track; (ii) breakthrough therapy; (iii) accelerated approval; or (iv) priority review.

54. Antibe's 2021 "pivot" from extended use to temporary acute pain management was significant. The Drug's supposed novelty (and commercial potential) lay with its (alleged) enhanced efficacy and safety for long-term (chronic) use as compared to other NSAIDs in the market.

55. The Drug is not close to coming to market. The Drug, as now conceptualized for acute pain management, is in the third stage (clinical trials) of five stages of the FDA's drug development process.



56. Within that third stage, it has yet to begin the Phase 2, of a total of four phases, because on March 28, 2024, the FDA placed the Drug on clinical hold, postponing the initiation of Antibe's planned Phase 2 trial in respect of the Drug. A copy of Antibe's news release dated April 1, 2024 confirming the FDA's clinical hold is attached as **Exhibit "G"**.

57. As noted above, Phase 2 is statistically the most challenging phase to complete in the clinical trial stage (being the third of five stages of FDA drug development).

58. While Phase 2 is statistically the most challenging phase to complete in the clinical trial stage, Phase 3 of the clinical trial stage is generally the most expensive.

59. In its June 26, 2020 short form prospectus, Antibe previously disclosed to the market that it anticipated that Phase 3 clinical trials of the drug (then anticipated to be in respect of extended use) would cost \$45-\$50 million in the aggregate. A copy of the June 26, 2020 short form prospectus is attached as **Exhibit "H"**.

60. I am aware from my review of the evidence given in the course of the Arbitration that Antibe's CEO, Mr. Legault, conceded that Phase 3 clinical trials would be the most expensive in the development path.

## **I. Antibe's Public Disclosure**

### **a. Antibe's Finances**

61. On February 24, 2021, Antibe announced to the market that it had closed its previously announced bought deal public offering of 6,727,500 units in the capital of Antibe at a price of \$6.00 per unit for aggregate gross proceeds of \$40,365,000. Antibe also announced that its cash balance was \$74,000,000 million, including the upfront payment received from Nuance and the

net proceeds of the Offering. A copy of Antibe's February 24, 2021 news release is attached as **Exhibit "I"**.

62. Antibe appears to have spent over \$40 million on bringing the Drug to the Phase 2 clinical trial stage for acute pain, which Phase 2 has been halted. On November 16, 2021 (around the time Antibe pivoted the Drug from extended use to acute pain management) Antibe announced to the market that it had ended its 2022 Q2 with a \$60 million cash position. A copy of Antibe's November 16, 2021 news release is attached as **Exhibit "J"**. According to Mr. Curtis, as of April 8, 2024, Antibe had a cash balance of \$19.6 million.

**b. News Releases regarding the Drug**

63. Between October 2015 and November 2021, Antibe issued 65 news releases tying the Drug (referred to as either Otenaproxesul or ATB-346) to the treatment of osteoarthritis, a chronic degenerative joint disease, causing pain, swelling, stiffness, and affecting a person's ability to move freely. The 65 Antibe news releases are collectively attached as **Exhibit "K"**.

64. On October 14, 2021, Antibe announced to the market that daily doses administered for longer treatment durations lead to increased hepatocellular oxidative stress, triggering LTEs. It further disclosed that increased oxidative stress is a "common finding associated with widely used medications, including nonsteroidal anti-inflammatory drugs ("NSAIDs") and acetaminophen." A copy of Antibe's October 14, 2021 press release is attached as **Exhibit "L"**.

65. On November 16, 2021, Antibe announced to the market that it launched an acute pain program for the Drug, and that it had "commenced collaboration" with acute pain specialists to optimize treatment regimens for the use of the Drug for post-operative pain (see Exhibit "J").

66. I am advised by my lawyer Alexander Payne of Bennett Jones LLP, and believe, that based on a search of Sedar +, none of Antibe’s post-November 2021 news releases refer to osteoarthritis.

67. On March 4, 2024, Antibe announced to the market that the Arbitral Award required “Antibe to refund the US\$20 million upfront payment and pay interest and costs of approximately US\$4 million” and that “[t]he decision is not subject to appeal.” Antibe further announced to the market that Antibe “respects...the final nature of the award and will accept the decision in good faith.” A copy of Antibe’s March 4, 2024 press release is attached as **Exhibit “M”**.

**J. Nuance Commenced an Application to Recognize and Enforce the Arbitral Award and Antibe filed for CCAA Protection**

68. On March 27, 2024, Nuance issued a Notice of Application seeking an order:

- (a) recognizing and making enforceable the Arbitral Award as a judgment of this Court;
- (b) restraining the Antibe from selling, removing, dissipating, alienating, transferring, assigning, encumbering, or similarly dealing with any of its assets, including, but not limited to, real property, bank accounts, insurance policies, annuities and other assets held by it or any other person or entity on its behalf; and
- (c) appointing a receiver of all the assets, undertakings and properties of Antibe pursuant to section 101 of the *Courts of Justice Act*.<sup>9</sup>

A copy of the Notice of Application is attached as **Exhibit “N”**.

---

<sup>9</sup> Notice of Application.

69. I am advised by my lawyer Alexander Payne of Bennett Jones LLP that on April 9, 2024, at 2:11 a.m., a matter of hours before a 9:45 a.m. attendance before Justice Black to set a schedule for the hearing of Nuance's Application, Antibe delivered an application record and other materials seeking CCAA protection. A copy of the email from Antibe's lawyers to Bennett Jones LLP is attached as **Exhibit "O"**.

70. I am further advised by my lawyer Alexander Payne of Bennett Jones LLP, and believe, that after the hearing on April 9, 2024, on the same day, Bennett Jones LLP sent a letter to Ken Rosenberg of Paliare Roland Rosenberg Rothstein LLP (counsel for Antibe) and Nigel Meakin of Deloitte (the Monitor) requesting information relating to Antibe's CCAA application. The letter is attached as **Exhibit "P"**.

#### **K. Trading in the Securities of Antibe has been Halted**

71. On April 9, 2024, the Canadian Investment Regulatory Organization ("CIRO") announced a suspension in trading in the securities of Antibe. A copy of the April 9, 2024 Newswire News Release regarding the halt of trading of securities of Antibe is attached as **Exhibit "Q"**.

#### **L. Nuance is Not Listed on Antibe's List of Creditors**

72. I have reviewed the list of Antibe's creditors as posted on Deloitte's website in respect of Antibe, a copy of which is attached as **Exhibit "R"**. I note that Nuance is not listed as one of Antibe's creditors at all, notwithstanding:

- (a) Antibe's public disclosure that it would accept the Arbitral Award "in good faith",  
and

- (b) Mr. Curtis' evidence that Antibe's current liabilities include a debt to Nuance in the approximate amount of CAD\$33 million, pursuant to the Arbitral Award.

**SWORN REMOTELY** by Mark Lotter in the special administrative region of Macau, in the People's Republic of China, before me at the City of Toronto, in the Province of Ontario on April 15, 2024, in accordance with *O. Reg 431/20*, Administering Oath or Declaration Remotely.

A handwritten signature in black ink, appearing to read "Mark Lotter". The signature is stylized with a large, looped "M" and "L".

---

**SIDNEY BREJAK**  
Commissioner for Taking Affidavits

---

**MARK LOTTER**

IN THE MATTER OF *THE COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, C. C-36, AS AMENDED  
AND IN THE MATTER OF THE COMPROMISE OR ARRANGEMENT OF ANTIBE THERAPEUTICS INC. (the "Applicant")

Court File No. CV-23-00693758-00CL

*ONTARIO*  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST  
PROCEEDING COMMENCED AT TORONTO

**AFFIDAVIT OF MARK LOTTER**  
**(Sworn April 15, 2024)**

BENNETT JONES LLP  
3400 One First Canadian Place  
P.O. Box 130  
Toronto ON M5X 1A4

**Lincoln Caylor (#37030L)**

Email: caylorl@bennettjones.com

**Jesse Mighton (#62291J)**

Email: mightonj@bennettjones.com

**Alexander C. Payne (#70712L)**

Email: paynea@bennettjones.com

**Sidney Brejak (#87177H)**

Email: brejaks@bennettjones.com

Telephone: 416.777.6121

Lawyers for the Responding Party  
Nuance Pharma Ltd.

This is Exhibit "A" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

---

Commissioner for Taking Affidavits  
SIDNEY BREJAK

**ONTARIO  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST**

B E T W E E N:

**NUANCE PHARMA LTD.**

Applicant

- and -

**ANTIBE THERAPEUTICS INC.**

Respondent

**AFFIDAVIT OF MARK LOTTER**  
(Sworn March 28, 2024)

I, Mark Lotter, of the City of London, in the United Kingdom, MAKE OATH AND SAY:

1. I am the founder and Chief Executive Officer of the Nuance group which comprises Nuance Biotech Inc., Nuance Pharma (Shanghai) Co. Ltd., and the applicant, Nuance Pharma Limited ("**Nuance**"). As such, I have knowledge of the matters deposed herein except where I have indicated that my knowledge is based on information provided to me by others and where so indicated I verily believe such information to be true.
2. I swear this affidavit in support of the application brought by Nuance for an order recognizing and making enforceable the arbitral award rendered in the arbitration proceeding



SIAC Arbitration No. 021 of 2022 (the “**Arbitral Award**”), under the auspices of the Singapore International Arbitration Centre (“**SIAC**”) by the arbitral tribunal (Ms. Catherine Amirfar, the “**Tribunal**”) seated in the Republic of Singapore, dated February 27, 2024, and for urgent injunctive relief restraining the respondent, Antibe Therapeutics Inc. (“**Antibe**”) from further dissipating assets held by it (including Nuance’s investment).

### **The Parties**

3. Nuance is a Hong-Kong incorporated biopharmaceutical company focused on licensing, developing and commercializing medical therapies in the Greater China region, with its registered address at Unit 417 4/F, Lippo Centre Tower Two, No. 89 Queensway, Admiralty, Hong Kong. Nuance is the 100% subsidiary of Nuance Biotech and the 100% shareholder of Nuance Pharma (Shanghai) Co. Ltd. It is a subsidiary of CBC Group, Asia’s largest healthcare-dedicated investment firm.

4. Antibe is a biotech company registered under Ontario's *Business Corporations Act*, R.S.O. 1990, c. B.16, with its registered office located at 15 Prince Arthur Avenue, Toronto, Ontario, M5R 1B2, Canada. Attached as **Exhibit "A"** is a copy of the Corporate Profile Report of Antibe.

### **The License Agreement**

5. Attached as **Exhibit "B"** is a duly certified copy of the License Agreement dated February 9, 2021 between Nuance and Antibe. Under the License Agreement, Nuance would provide Antibe an upfront payment of US\$ 20 million for an exclusive license to develop and commercialize the drug Otenaproxesul (the “**Drug**”) in China, Hong Kong, Macau, and Taiwan.

6. The development and purpose of the Drug, as defined by section 1 of the License Agreement, was for the "treatment of human disease conditions appropriate for [nonsteroidal anti-inflammatory drug] use, including without limitation [osteoarthritis], [rheumatoid arthritis], and [ankylosing spondylitis]." These conditions are all associated with chronic pain and is consistent with the Nuance and Antibe's intention for the Drug to address chronic pain.

### **The Arbitral Award**

7. Attached as **Exhibit "C"** is a duly certified copy of the Arbitral Award.

8. The Tribunal found that Antibe fraudulently misrepresented and concealed material information from Nuance leading up to the parties entering into the Licence Agreement. As a result, the Tribunal declared that Nuance had validly rescinded the License Agreement.

9. Specifically, it found that Health Canada had put Antibe on notice in January 2021 that it had "serious concerns" regarding the safety of the Drug which resulted in Antibe pausing its absorption, metabolism and excretion study ("**AME Study**") (a precursor to the absorption, distribution, metabolism and excretion study which is required for approval). All such communication and correspondence with Health Canada was intentionally not disclosed to Nuance, and such information was only produced for the first time through document production in the arbitration.

10. Moreover, the Tribunal found that on July 30, 2021, after it paused its AME Study, Antibe "fundamentally pivoted the development of the Drug towards an indication for acute (vs. chronic) pain" – a decision contrary to the License Agreement and the intentions of the parties that the Drug would be developed to address primarily and firstly chronic pain.

11. As for Antibe's motive, the Tribunal determined that Antibe had deceived Nuance to enter into the License Agreement in order to secure the necessary funding for the Drug's continued development. This is confirmed by Antibe's admission that the development of the Drug could not go forward without Nuance's US\$ 20 million upfront payment.

### **Antibe's Dissipation of Nuance's Investment**

12. On June 29, 2023, Antibe issued a public press release indicating that as of March 31, 2023, Antibe's cash position totaled CAN\$ 38.9 million (approximately US\$ 28.77 million). This represented a CAN\$ 3.5 million (approximately US\$ 2.577 million) decrease from the previous quarter which Antibe stated was CAN\$ 42.4 million. Attached as **Exhibit "D"** are copies of Antibe's press releases for June 29, 2023 and February 15, 2023.

13. Antibe also stated key upcoming milestones related to the Drug's Phase 2 development for acute pain. These milestones were:

- Complete clinical PK/PD study for otenaproxesul – calendar Q4 2023
- Initiate Phase II bunionectomy trial of otenaproxesul – calendar Q1 2024
- Deliver Phase II bunionectomy top-line data of otenaproxesul – calendar Q2 2024

14. On August 14, 2023, Antibe issued a press release indicating that as of June 30, 2023, it had an available cash balance and term deposits totalling CAN 34.3 million. This represented a CAN\$ 4.6 million (approximately US\$ 3.387 million) decrease from its position as of March 31, 2023. Antibe's upcoming milestones remained the same. Attached as **Exhibit "E"** is a copy of Antibe's August 14, 2023 press release.

15. Antibe's cash expenditures not only continued but increased thereafter. Antibe spent CAN\$ 6.4 million (approximately US\$ 5 million) in Q3 2023 – about 1.5 to 2 times its usual rate of spending in the previous quarters in 2022 and 2023. As a result, Antibe's cash position further dwindled to CAN\$ 27.9 million (approximately US\$ 20.4 million) as of September 30, 2023. This shows that Antibe has continued to ramp up spending to over CAN\$ 11 million (approximately US\$ 8 million) in the short span of 6 months (from March 31, 2023 to September 30, 2023), even before initiating Phase 2. Attached as **Exhibit "F"** is a copy of Antibe's November 13, 2023 press release. In the same press release, Antibe references the expected release of the Arbitral Award in Q4 2023, and so was fully aware that it could be ordered to return Nuance's US\$ 20 million plus costs and interest.

#### **Antibe's Deteriorating Financial Position and Continued Dissipation of Investment**

16. According to unaudited interim financial statements as of September 30, 2023, Antibe has a limited cash balance and term deposits. Additionally, it does not have any other substantial current or fixed assets which could conceivably be recovered by Nuance to satisfy the Arbitral Award. Attached as **Exhibit "G"** is a copy Antibe's unaudited interim financial statements.

17. In light of the foregoing, on November 20, 2023, Nuance's counsel in Singapore (WongPartnership LLP) wrote to Antibe's counsel seeking confirmation that it has not drawn down on Nuance's US\$ 20 million, and for an undertaking that, pending the outcome of the Arbitration and the satisfaction of the Arbitral Award in the event that the Tribunal finds in Nuance's favour, Antibe shall not spend Nuance's investment.

18. In a reply from counsel dated November 28, 2023, Antibe refused to provide either the confirmation or the undertaking, suggesting that it will continue to use Nuance's US\$ 20 million investment. Attached as **Exhibit "H"** is a copy of the email exchange between Nuance and Antibe.

19. On February 14, 2024, Antibe issued a press release indicating that it spent another CAN\$ 3 million (approximately US\$ 2.21 million) in Q4 of 2023. As of December 31, 2023, Antibe had an available cash balance and term deposits totaling CAN\$ 24.9 million (approximately US\$ 18.34 million). Notably, this amount is substantially short of the US\$ 20 million plus costs and interest owed to Nuance pursuant to the Arbitral Award. Despite this, Antibe indicated that it was "[o]n track to launch upgraded Phase II abdominoplasty trial in March 2024." Attached as **Exhibit "I"** is a copy of Antibe's February 14, 2024 press release.

20. After the release of the Arbitral Award, Nuance made demands for payment on March 1<sup>st</sup> and 13<sup>th</sup>, 2024. In a press release dated March 4, 2024, Antibe confirmed that it will not challenge the Arbitral Award and will "accept the decision in good faith." Attached as **Exhibit "J"** is a copy of Antibe's March 4, 2024 press release.

21. However, in response to the demands, on March 18, 2024, Antibe's representatives informed me during a call (which was conducted on an open basis and not stated to be without prejudice) that Antibe does not have sufficient cash to satisfy the Arbitral Award in full and instead proposed that the parties explore alternative options.

22. Despite its pronouncements and Nuance's repeated demands for payment, Antibe has not complied with the Arbitral Award. Instead, Antibe has confirmed that Phase 2 is underway and continuing. Which means it continues to deplete Nuance's US\$ 20 million investment to fund further development of the Drug to treat acute pain – not chronic pain as agreed to under the

License Agreement. Antibe confirmed that it "remain[s] committed to developing [the Drug]" and "priority remains conducting the Phase II trial as soon as possible."<sup>1</sup>

23. Antibe's fraudulent conduct coupled with Nuance's *prima facie* right to recover its monies/investment which are being dissipated supports the need for the preservation of assets held by Antibe.

24. In light of the foregoing, if Nuance does not obtain the urgent injunctive relief requested, Antibe will likely continue to dissipate Nuance's investment to the point where it will be unable to collect on the judgment of this Court recognising the Arbitral Award, causing Nuance to suffer irreparable harm.

25. Nuance will comply with any order regarding damages the Court may make in the future, if it ultimately appears that the injunction requested by the plaintiff ought not to have been granted.

**SWORN REMOTELY** by Mark Lotter in the City of London, in the United Kingdom, before me at the City of Toronto, in the Province of Ontario on March 28, 2024, in accordance with *O. Reg 431/20*, Administering Oath or Declaration Remotely.



*Sidney Brejak*

**Sidney Brejak**  
Commissioner for Taking Affidavits

**Mark Lotter**

<sup>1</sup> See Exhibit "J".

NUANCE PHARMA LTD.

-and-

ANTIBE THERAPEUTICS INC.

Applicant

Respondent

Court File No. CV-24-00717410-00CL

**ONTARIO  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST**

Proceeding Commenced at Toronto

**AFFIDAVIT OF MARK  
LOTTER (Sworn March 28, 2024)**

**BENNETT JONES LLP**  
3400 One First Canadian Place  
P.O. Box 130  
Toronto ON M5X 1A4

**Lincoln Caylor (#37030L)**  
Email: caylorl@bennettjones.com

**Alexander C. Payne (#70712L)**  
Email: paynea@bennettjones.com

**Sidney Brejak (#87177H)**  
Email: brejaks@bennettjones.com

Telephone: 416.777.6121

Lawyers for the Applicant

THIS IS **EXHIBIT "A"** REFERRED TO IN THE  
AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

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SIDNEY BREJAK  
Commissioner for Taking Affidavits





## Profile Report

ANTIBE THERAPEUTICS INC. as of March 14, 2024

Act	Business Corporations Act
Type	Ontario Business Corporation
Name	ANTIBE THERAPEUTICS INC.
Ontario Corporation Number (OCN)	5050248
Governing Jurisdiction	Canada - Ontario
Status	Active
Date of Amalgamation	June 03, 2021
Registered or Head Office Address	15 Prince Arthur Avenue, Toronto, Ontario, M5R 1B2, Canada

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

This report sets out the most recent information filed on or after June 27, 1992 in respect of corporations and April 1, 1994 in respect of Business Names Act and Limited Partnerships Act filings and recorded in the electronic records maintained by the Ministry as of the date and time the report is generated, unless the report is generated for a previous date. If this report is generated for a previous date, the report sets out the most recent information filed and recorded in the electronic records maintained by the Ministry up to the "as of" date indicated on the report. Additional historical information may exist in paper or microfiche format.

**Active Director(s)**

Minimum Number of Directors 1  
Maximum Number of Directors 12

**Name** RODERICK FLOWER  
**Address for Service** 14 Whitehill, Bradford-On-Avon Wiltshire, BA15 1SG, United Kingdom  
**Resident Canadian** No  
**Date Began** June 03, 2021

**Name** ROBERT HOFFMAN  
**Address for Service** 18264 Avenida Manantial, Rancho Santa Fe, California, 92067, United States  
**Resident Canadian** No  
**Date Began** June 03, 2021

**Name** AMAL KHOURI  
**Address for Service** 754 Upper Belmont Westmount, Montreal, Quebec, H3Y 1K4, Canada  
**Resident Canadian** Yes  
**Date Began** June 03, 2021

**Name** DANIEL LEGAULT  
**Address for Service** 276 Macpherson Avenue, Toronto, Ontario, M4V 1A3, Canada  
**Resident Canadian** Yes  
**Date Began** June 03, 2021

**Name** WALT MACNEE  
**Address for Service** 70 Rosehill Avenue, 705, Toronto, Ontario, M4T 2W7, Canada  
**Resident Canadian** Yes  
**Date Began** June 03, 2021

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

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**Name** JENNIFER MCNEALEY  
**Address for Service** 762 Marin Drive, Mill Valley, California, 94941, United States  
**Resident Canadian** No  
**Date Began** June 03, 2021

**Name** YUNG WU  
**Address for Service** 468 Wellington Street West, 601, Toronto, Ontario, M5V 1E3, Canada  
**Resident Canadian** Yes  
**Date Began** June 03, 2021

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

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**Active Officer(s)**

**Name** BETH CHIN  
**Position** Secretary  
**Address for Service** 130 Rockbluff Close Nw, Calgary, Alberta, T3G 5B2, Canada  
**Date Began** June 03, 2021

**Name** SCOTT WILSON CURTIS  
**Position** Chief Operating Officer  
**Address for Service** 280 Beech Avenue, Toronto, Ontario, M4E 3J2, Canada  
**Date Began** September 01, 2022

**Name** DANIEL LEGAULT  
**Position** Chief Executive Officer  
**Address for Service** 276 Macpherson Avenue, Toronto, Ontario, M4V 1A3, Canada  
**Date Began** June 03, 2021

**Name** DAVID JAMES VAUGHAN  
**Position** Other (untitled)  
**Address for Service** 456 Sheppard Avenue, Pickering, Ontario, L1V 1E5, Canada  
**Date Began** June 03, 2021

**Name** ALAIN THOMAS WILSON  
**Position** Chief Financial Officer  
**Address for Service** 230 Fairlawn Avenue, Toronto, Ontario, M4M 1T1, Canada  
**Date Began** June 03, 2021

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

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**Corporate Name History**

**Name**

ANTIBE THERAPEUTICS INC.

**Effective Date**

June 03, 2021

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

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Additional historical information may exist in paper or microfiche format.

**Amalgamating Corporations**

**Corporation Name**  
**Ontario Corporation Number**

ANTIBE THERAPEUTICS INC.  
2205405

**Corporation Name**  
**Ontario Corporation Number**

ANTIBE AMALCO INC.  
5050332

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

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### Active Business Names

This corporation does not have any active business names registered under the Business Names Act in Ontario.

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

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### Expired or Cancelled Business Names

This corporation does not have any expired or cancelled business names registered under the Business Names Act in Ontario.

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

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## Document List

Filing Name	Effective Date
Annual Return - 2023 PAF: BETH CHIN	September 25, 2023
CIA - Notice of Change PAF: BETH CHIN	February 22, 2023
CIA - Notice of Change PAF: Beth CHIN	September 13, 2022
CIA - Notice of Change PAF: Beth CHIN	June 09, 2022
CIA - Initial Return PAF: Beth CHIN	December 01, 2021
BCA - Articles of Amalgamation	June 03, 2021

All "PAF" (person authorizing filing) information is displayed exactly as recorded in the Ontario Business Registry. Where PAF is not shown against a document, the information has not been recorded in the Ontario Business Registry.

Certified a true copy of the record of the Ministry of Public and Business Service Delivery.

*V. Quintanilla W.*

Director/Registrar

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THIS IS **EXHIBIT "B"** REFERRED TO IN THE  
AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

---

SIDNEY BREJAK  
Commissioner for Taking Affidavits

# Katten

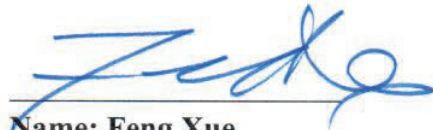
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I have seen and compared the original document and I hereby certify the attached document is a true and correct copy of the original.

Signature



**Name: Feng Xue**

Title: Managing Partner

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Email: feng.xue@katten.com

Date: March 27, 2024

## LICENSE AGREEMENT

This License Agreement (“**Agreement**”), effective February 9, 2021, by and between **ANTIBE THERAPEUTICS INC.**, a corporation formed under the laws of Ontario with a principal place of business at 15 Prince Arthur Avenue, Toronto, Ontario M5R 1B2 (“**Licensor**”) and **NUANCE PHARMA LIMITED**, a corporation formed under the laws of Hong Kong with a principal place of business at Room 639, East Tower, Shanghai Centre, 1376 West Nanjing Road, Shanghai, the PRC (“**Licensee**”). Each of Licensor and Licensee a “**Party**,” and collectively, the “**Parties**.”

### RECITALS

**WHEREAS** Licensor owns all right, title and interest in and to certain Trademarks and Know-How relating to the hydrogen sulfide-releasing non-steroidal anti-inflammatory drug product otenaproxesul (alternatively named ATB-346);

**WHEREAS** Licensor is the sole and exclusive licensee of the Existing Patents set out on Schedule 1, which Existing Patents relate to otenaproxesul and are registered in the name of Antibe Holdings Inc. (“**Holdings**”), under that certain license agreement between Antibe Holdings Inc. and Antibe Therapeutics Inc. dated December 22, 2009 as amended May 21, 2013 (“**Holdings License Agreement**”) and Licensor thereby Controls the Existing Patents;

**WHEREAS** Licensee wishes to obtain the exclusive rights to Develop and Commercialize otenaproxesul in the Territory and, to accomplish such purpose, Licensor is willing to grant Licensee an exclusive license to its Trademarks and Know-How, and an exclusive sub-license to the Existing Patents under the Holdings License Agreement;

**NOW THEREFORE** in consideration of the mutual promises and covenants contained herein, the Parties, intending to be legally bound, agree as follows:

### **1. DEFINITIONS**

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

**API** means an active pharmaceutical ingredient, being any substance intended to be used in a pharmaceutical product that, when used, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions in man or animal or to make a medical diagnosis; but excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies.

**Adverse Drug Reaction** means a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment, or prevention of a disease or the modification of an organic function.

**Adverse Drug Event** means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

**Affiliate** means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party, but for only so long as such control exists. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means:

- (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise;

- (b) the right to elect a majority of the members of the Board of Directors, or to appoint the chief executive officer, general manager or other senior management officials; or
- (c) the ownership, directly or indirectly, of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

**Agreement** has the meaning set forth in the preamble hereto.

**Alliance Manager** has the meaning set forth in Section 4.2(e) (Alliance Managers).

**Anti-Corruption Laws** has the meaning set forth in Section 11.4 (Compliance with Law).

**Applicable Law** means any law, regulation, rule, guidance, order, judgment or decree having the force of law, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time and applicable to a particular activity hereunder, including the FDC Act, DAL, the Provisions for Drug Registration of the NMPA and the Anti-Corruption Laws.

**Auditor** has the meaning set forth in Section 5.9 (Audit Dispute).

**Authorized Representatives** has the meaning set forth in Section 11.4 (Compliance with Law).

**Breaching Party** has the meaning set forth in Section 10.2(b) (Material Breach).

**Business Day** means any day other than (i) Saturday or Sunday or (ii) a day that is a legal holiday in the PRC on which the banks of the PRC are required to be closed.

**Calendar Quarter** means each successive period of three (3) calendar months commencing on 1 January, 1 April, 1 July and 1 October, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to 1 April, 2021.

**Calendar Year** means each successive period of twelve (12) calendar months commencing on 1 January and ending on 31 December except that the first Calendar Year of the Term shall commence on the Effective Date and end on 31 December, 2021.

**Change of Control** means with respect to a Party (a) any sale, exchange, transfer, or issuance to or acquisition in one transaction or a series of related transactions by one or more Affiliates or Third Parties of shares representing at least fifty percent (50%) of the aggregate ordinary voting power entitled to vote for the election of directors represented by the issued and outstanding stock of such Party or any Affiliate that directly or indirectly controls such Party, whether such sale, exchange, transfer, issuance or acquisition is made directly or indirectly, by merger or otherwise, or beneficially or of record, but excluding the issuance of shares in a financing transaction; (b) a merger or consolidation under Applicable Laws of such Party with an Affiliate or Third Party in which the shareholders of such Party or any Affiliate that directly or indirectly controls such Party immediately prior to such merger or consolidation do not continue to hold immediately following the closing of such merger or consolidation at least fifty percent (50%) of the aggregate ordinary voting power entitled to vote for the election of directors represented by the issued and outstanding stock of the entity surviving or resulting from such consolidation; or (c) a sale or other disposition of all or substantially all of the assets of such Party to which this Agreement relates to one or more Affiliates or Third Parties in one transaction or a series of related transactions.

**Clinical Trial Application** or CTA means an application to initiate a human clinical trial of a medical product, such as is required to be submitted to the NMPA under the Drug Administrative Law of China, the Drug Registration Management Measures (NMPA-No27-2020) (also called the DRR) and the Quality Management Standards (NMPA-GCP-No57-2020), as such may be amended from time to time, and similar applications such as may be filed under corresponding laws in other Jurisdictions. An IND is a type of CTA.

**Clinical Supply Agreement** has the meaning set forth in Section 3.4.

**Combination Product** means a Licensed Product that is comprised of or contains the Licensed Compound as an API together with one (1) or more other APIs and is sold either as a fixed dose or as separate doses in a single package.

**Commercialization** means any and all activities undertaken before and after Regulatory Approval directed to the preparation for sale, offering for sale, or sale of a product, including activities related to marketing, advertising, promoting, pricing, detailing, medical education, sales force training, scientific and medical affairs, correlative commercial activities conducted in preparation for the launch of a product, distributing (including without limitation importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering the product to customers), booking sales, and interacting with Regulatory Authorities regarding any of the foregoing; provided, however, that Commercialization does not include research, Development or Manufacturing. When used as a verb, **to Commercialize** and **Commercializing** means to engage in Commercialization and **Commercialized** has a corresponding meaning.

**Commercially Reasonable Efforts** means, with respect to the performance of Development or Commercialization activities with respect to the Licensed Compound or a Licensed Product, the carrying out of such activities using efforts and resources comparable to the efforts and resources commonly used in the biopharmaceutical industry by companies of a similar stage and size as the applicable Party in its respective Jurisdiction with resources and expertise similar to those of such Party for compounds or products of similar market potential at a similar stage in development or product life, taking into account, as applicable, relative safety and efficacy, product profile, the regulatory environment, payors' policies and regulations, competitiveness of the marketplace and the market potential of such products, the nature and extent of market exclusivity, including patent coverage and regulatory data protection, and price and reimbursement status, but not taking into account any payment obligations under this Agreement.

**Commercialization Plan** means the strategic commercialization plan for the Commercialization of Licensed Product in the Field in the Territory, as such plan may be amended or updated from time to time in accordance with this Agreement, which plan Licensee shall ensure is at all times consistent with the terms and conditions of this Agreement. The Commercialization Plan will include in reasonable detail (a) marketing principal strategies with respect to marketing and promoting the Licensed Product during the applicable time period, (b) the material activities to be conducted by Licensee in connection with the Commercialization of the Licensed Product during such time period, (c) a market access, pricing and reimbursement strategy which is to be consistent with corresponding strategy of Licensor outside of the Territory and (d) an estimate of all expenses associated with the activities set forth in such Commercialization Plan.

**Confidential Information** has the meaning set forth in Section 7.1 (Confidentiality Obligations).

**Control** means, with respect to any item of Know-How, Regulatory Documentation, material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 2.1 (Grants to Licensee), 2.2 (Grants to Licensor) or 10.4 (Consequences of Termination)), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Know-How, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

**Cost of Goods Sold** or **COGS** means, with respect to the Licensed Product, the production cost of such Licensed Product (for the avoidance of doubt, including, without limitation, manufacturing oversight, quality assurance and administrative costs) calculated in accordance with internal cost accounting methods consistently applied by Licensor for its other similar pharmaceutical products; provided, that such methods comply with IFRS. Cost of Goods shall include direct labor, direct materials (including taxes and duties).

Notwithstanding the foregoing, in the event a Licensed Product is manufactured by a Third Party supplier and procured by Licensor, the “Cost of Goods” shall include the costs charged for such Licensed Product by such Third Party supplier to Licensor, in each case as supported by reasonable evidence (such as contracts or invoice) that shall be provided to Licensee upon Licensee’s request.

**DAL** means the Drug Administrative Law of the PRC (Amended Law with effect from December 1, 2019).

**Development** means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, qualification and validation, quality assurance/quality control, in vitro microbiology, clinical studies, statistical analysis and report writing, the preparation and submission of Drug Registration Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval; provided, however, that Development excludes Manufacturing or Commercialization. When used as a verb, **Develop** and **Developing** means to engage in Development and **Developed** has a corresponding meaning.

**Development Plan** means the plan for the Development of the Licensed Product, including for Regulatory Approval and Post-Approval Research, in the Field in the Territory, including in reasonable detail (a) all material Development activities reasonably anticipated to be undertaken by Licensee to obtain Regulatory Approval of Licensed Product in the Field in the Territory (b) estimated dates on which Licensee expects to achieve certain Milestone Events, (c) an estimate of costs and expenses associated with the activities set forth therein as such plan may be amended or updated from time to time in accordance with this Agreement and (d) such other information set forth in Section 3.1(a) (Development Plan), which plan the Parties shall ensure is at all times consistent with the terms and conditions of this Agreement. The Development Plan will be appended to and become a part of this Agreement.

**Dollars** or **\$** means United States Dollars.

**Drug Registration Application** means with respect to any pharmaceutical product in any Jurisdiction, an application for Regulatory Approval for such pharmaceutical product in such Jurisdiction, including, as applicable, (a) a Drug Registration Application or any future equivalents thereof as defined in the DAL and the Provisions for Drug Registration, (b) any corresponding foreign application in a Jurisdiction; and (c) all renewals, supplements and amendments to any of the foregoing. For clarity, a Drug Registration Application corresponds to a New Drug Application (NDA) under the corresponding Applicable Law in the United States of America.

**Drug Registration Certificate** means a Drug Registration Certificate granted by the NMPA based on a Drug Registration Application or any future equivalents thereof as defined in the DAL and the Provisions for Drug Registration (such certificate corresponding in legal effect to an FDA approved New Drug Application (NDA) in the United States of America) (b) any corresponding application in a Jurisdiction; with respect to any pharmaceutical product in any Jurisdiction, an application for Regulatory Approval for such pharmaceutical product in such Jurisdiction, including, as applicable, (a) and (c) all renewals, supplements and amendments to any of the foregoing.

**Effective Date** has the meaning set forth in the preamble hereto.

**Existing Patents** means the Patents listed on Schedule 1.

**Exploit** means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of but does not include to Manufacture or have Manufactured. **Exploitation** means the act of Exploiting a compound, product or process.

**FDA** means the United States Food and Drug Administration and any successor agency thereto.



**FDC Act** means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

**Field** means use for treatment of human disease conditions appropriate for NSAID use, including without limitation Osteoarthritis (OA), Rheumatoid Arthritis (RA), and Ankylosing Spondylitis (AS).

**First Commercial Sale** means, with respect to a Licensed Product and a Jurisdiction in the Territory, the first arm's length sale by Licensee, its Affiliate(s) or Sublicensee(s) for monetary value for use or consumption by the end user of such Licensed Product in such Jurisdiction after Regulatory Approval for such Licensed Product has been obtained in such Jurisdiction (whether or not Reimbursement Approval has been received). Sales, for no charge, of reasonable amounts of such Licensed Product in such Jurisdiction prior to receipt of Regulatory Approval for such Licensed Product as so-called "treatment IND sales," "named patient sales," or "compassionate use sales" shall not be construed as a First Commercial Sale.

**PPFV** means the first patient's first screening visit in a clinical trial at or prior to which such subject signs an informed consent to participate in such clinical trial (if required under Applicable Law).

**GAAP** means, with respect to a Party or any of its Affiliates or Sublicensees, as applicable, United States generally accepted accounting principles as such Party, Affiliate or Sublicensee, as applicable, adopts, in each case, consistently applied as amended, supplemented or replaced from time to time.

**Generic Product** means, with respect to a particular mode of administration of a Licensed Product in a Jurisdiction, any other prescription pharmaceutical product (a) that is not produced, licensed or owned by Licensee, any of its Affiliates or any Sublicensee, (b) that contains the Licensed Compound and the same other API(s), if any, of such Licensed Product, (c) uses the same mode of administration as such Licensed Product, and (d) with respect to which a Third Party (other than a Sublicensee) has received Regulatory Approval for a Drug Registration Application for such other product in such Jurisdiction through an abbreviated regulatory pathway in reliance on the approved Drug Registration Application for such Licensed Product in such mode of administration in such Jurisdiction received by Licensee, any of its Affiliates or any Sublicensee.

**GCP and GLP** means, respectively, the current good clinical practice regulations set forth at 21 CFR Parts 50, 54, 56 and 312 and the current good laboratory practice regulations set forth at 21 CFR Part 58, each as amended from time to time, and other FDA regulations and guidelines issued under 21 CFR 10.90 otherwise relating to the conduct of laboratory studies for drug products regulated by the FDA, and equivalent standards of good clinical practice and good laboratory practice, respectively, under Applicable Law in the Territory.

**Government Official** means (a) any Person employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (b) any political party, party official or candidate, (c) any Person who holds or performs the duties of an appointment, office or position created by custom or convention or (d) any Person who holds himself out to be the authorized intermediary of or has a close relationship with any of the foregoing who can reasonably influence foregoing's decision making, including, but not limited to, the direct relatives of foregoing.

**Governmental Authority** means any federal, state, provincial, or municipal government body, commission, agency, board, court or tribunal having jurisdiction in the particular circumstances.

**IDL** means an imported drug license under the DAL and its relevant regulation and rules.

**IFRS** means, at any time, the International Financial Reporting Standards, promulgated by the International Accounting Standards Board, as amended, supplemented or replaced from time to time.

**Improvement** means any invention, discovery, development, Know-How or modification with respect to the Licensed Compound or a Licensed Product or relating to the Exploitation thereof, whether or not



patented or patentable, including any enhancement in the efficiency, operation, Manufacture, ingredients, preparation, presentation, formulation, means of delivery (including the development of any delivery system or enhancement thereto) or dosage of such Licensed Compound or Licensed Product, any discovery or development of any new or expanded indications for such Licensed Compound or Licensed Product, or any discovery or development that improves the stability, safety or efficacy of such Licensed Compound or Licensed Product; but excluding Licensee Development Data and Licensee Regulatory Documentation.

**IND** means (a) a filing with the NMPA that is equivalent to an Investigational New Drug application as would be filed with the US FDA under 21 USC Chp. 9, for authorization to commence clinical studies, and its equivalent in other Jurisdictions and (b) all supplements and amendments that may be filed with respect to the foregoing.

**Indemnification Claim Notice** has the meaning set forth in Section 9.3(a) (Notice of Claim).

**Indemnified Party** has the meaning set forth in Section 9.3(a) (Notice of Claim).

**Infringement** has the meaning set forth in Section 6.3(a) (Notice).

**Invoiced Sales** has the meaning set forth in the definition of **Net Sales**.

**Joint Development Committee** or **JDC** has the meaning set forth in Section 4.1 (Joint Development Committee).

**Jurisdiction** means, as applicable, a country, or a legally defined sub-region of a country.

**Know-How** means all scientific, technical, marketing, production, storage, sales and other information relating to the Licensed Compound, the Licensed Product and the Licensed Patents that is Controlled by Licensor as of the Effective Date or during the Term which is reasonably necessary for the Development and Commercialization of the Licensed Product in accordance with the terms of this Agreement.

**Knowledge** means the actual knowledge, without any duty to conduct any investigation with respect to such facts and information, of (a) with respect to Licensor, the Chief Executive Officer, Chief Scientific Officer, and General Counsel of Licensor or any personnel holding positions equivalent to such job title; and (b) with respect to Licensee, the Chief Executive Officer and Chief Medical Officer of Licensee or, as set forth herein, its relevant Affiliate, or any personnel holding positions equivalent to such job title.

**Licensed Compound** means the compound otenaproxesul (alternatively named ATB-346).

**Licensed Patents** means all of the Patents in the Territory Controlled by Licensor as of the Effective Date or during the Term, that are necessary or reasonably useful (or, with respect to a Patent application, would be necessary or reasonably useful if such Patent application were to issue as a Patent) for the Development or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory, including the Existing Patents.

**Licensed Product** means any product that is comprised of or contains a Licensed Compound alone or in combination with one or more other APIs.

**Licensed Product Agreement** means, with respect to a Licensed Product, any agreement entered into by and between Licensee (or any of its Affiliates or its or their Sublicensees) and one or more Third Parties that is necessary or reasonably useful for the Exploitation of such Licensed Product in the Field in the Territory, including (a) any agreement pursuant to which Licensee, its Affiliates or its or their Sublicensees receives any license or other rights to Exploit such Licensed Product, (b) clinical trial agreements, (c) contract research organization agreements, (d) sales agreements or distribution agreements, and (e) service agreements.

**Licensee Development Data** means any data relating in any way to otenaproxesul, and its uses, including but not limited to *in vivo* or *in vitro* pharmacology, toxicology, product stability, clinical data, safety data, efficacy data, raw patient data, clinical trial reports, and statistical analyses and statistical programs relating

thereto, other biological data and non-biological data whether or not included in or in support of the Regulatory Documentation in the Territory that is created or Controlled by Licensee, any of its Affiliates or any Sublicensee, or by a Third Party subcontractor on behalf of Licensee or any of its Affiliates or any Sublicensee.

**Licensors Development Data** means any of the following related to the Licensed Compound or a Licensed Product that is Controlled by Licensor and necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory: (a) pharmacology, toxicology and other biological data included in or in support of the Regulatory Documentation outside of the Territory that was created by Licensor or on behalf of Licensor and (b) clinical data included in or in support of the Regulatory Documentation outside of the Territory.

**Licensors Marks** means (a) the Trademarks, names and logos to be developed by Licensor pursuant to the protocol detailed in Section 6.6(a), (b) the Trademarks (in their native language or any translation thereof) with respect to any Licensed Product outside the Territory and (c) such other Trademarks, names and logos as Licensor may designate in writing from time to time.

**Licensors Regulatory Documentation** means (a) Regulatory Documentation Controlled by Licensor or any of its Affiliates as of the Effective Date relating to the Licensed Compound and (b) Regulatory Documentation Controlled by Licensor during the Term relating to the Licensed Compound that a Regulatory Authority in the Territory requires from Licensee in order for Licensee to submit a CTA or Drug Registration Application for a Licensed Product in the Territory.

**Losses** has the meaning set forth in Section 9.1 (Indemnification of Licensor).

**Manufacture and Manufacturing** means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, in-process and finished testing, shipping, storing, or release of a product or any ingredient or intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, test method development and stability testing, formulation, quality assurance and quality control of any compound, product or intermediate, and regulatory affairs with respect to the foregoing.

**Milestone Event** has the meaning set out in Section 5.2 (Milestones).

**Net Sales** means, with respect to Licensed Product, the gross amounts invoiced by Licensee, its Affiliates and Sublicensees, their distributors and (sub)contractors, for sales of Licensed Product in the Field of Use to Third Parties (“**Invoiced Sales**”), less the following deductions provided to such Third Parties:

- a) customary trade, quantity and/or cash discounts, charge-back payments, allowances or rebates actually taken and allowed, including promotional or similar discounts or rebates and discounts, rebates, or mandatory administrative fees to governmental or managed care organizations;
- b) customary discounts provided in connection with coupon, voucher or similar patient programs;
- c) customary credits or allowances given or made by reason of rejection, defects, recalls, returns, rebates, and retroactive price reductions;
- d) if any tax, tariff, duty or government charge (including any sales, value added, excise or similar tax or government charge, but excluding any income tax) levied on the sale, transportation or delivery of Licensed Product and borne by the Licensee thereof without reimbursement from any Third Party has been included in gross amounts invoiced, it may be deducted;
- e) any charges for freight, postage, shipping or transportation, or for insurance, in each case to the extent borne by the Licensee;

in each case to the extent consistent with Applicable Law.

All deductions shall only be allowable to the extent they are commercially reasonable and shall be determined, on a Jurisdiction-by-Jurisdiction basis, as incurred in the ordinary course of business in type and amount consistent with Licensee’s, its Affiliate’s, or a Sublicensee’s (as the case may be) business

practices consistently applied across its product lines and accounting standards. Any of the deductions listed above that involves a payment by Licensee, its Affiliates or its or their Sublicensees shall be taken as a deduction in the Calendar Year in which the payment is accrued by such entity; provided that, if the accrued amount with respect to such deduction is determined in a subsequent Calendar Year to have been greater than the actual amount of such deduction, the amount over-accrued shall be included in Net Sales in such subsequent Calendar Year. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when billed or invoiced and a sale shall not include transfers or dispositions of such Licensed Product for pre-clinical or clinical purposes or provided in good faith as samples or through patient assistance programs, in each case, without charge. Licensee's, its Affiliates' or its or their Sublicensees' transfer of any Licensed Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless such Licensed Product is consumed or administered by such Affiliate or Sublicensee in the course of its commercial activities, provided that the first sale to a Third Party thereafter is included in Net Sales. With respect to any unit of Licensed Product that is consumed or administered by Licensee or its Affiliates or its or their Sublicensees, Net Sales shall include the greater of (A) any amount billed or invoiced with respect to such consumption or administration, including any services provided directly in connection therewith or (B) the average per-unit Net Sales of such Licensed Product in the relevant Jurisdiction in the relevant Calendar Year.

In the event that a Licensed Product is sold in the form of a Combination Product, the Parties will discuss in good faith a proper methodology for adjusting Net Sales of such Combination Product.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among the relevant products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Licensee's, its Affiliates' or its or their Sublicensees' existing allocation method; provided that any such allocation to a Licensed Product shall be: (i) done in accordance with Applicable Law, including any price reporting laws, rules and regulations and (ii) subject to clause (i), in no event no greater than a pro rata allocation, such that the portion of each of the foregoing rebates, discounts and other forms of reimbursements shall not be included as deductions from Invoiced Sales hereunder in any amount greater than the proportion of the number of units of such Licensed Product sold by Licensee, its Affiliates or its or their Sublicensees to Third Parties hereunder compared to the number of units of all the products sold by Licensee, such Affiliates and such Sublicensees to Third Parties to which such foregoing rebate, discount or other form of reimbursement, as applicable, are granted.

If a Licensed Product is sold or otherwise commercially disposed of for consideration other than cash or in a transaction that is not at arm's length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length and for cash. Such amount that would have been invoiced shall be determined, wherever possible, by reference to the average selling price of the relevant Licensed Product in arm's length transactions in the relevant Jurisdiction in the relevant Calendar Year. Notwithstanding the foregoing, sales between or among Licensee, its Affiliate(s), its Sublicensees, its distributors and (sub)contractors shall be excluded from the computation of Net Sales, except where the buyer is an end user of the Product.

For any currency conversion for the calculation of Net Sales in Dollars that are based currencies other than Dollars, Licensee shall convert any amount expressed in a non-US currency into Dollar equivalents using its, its Affiliate's or Sublicensee's, as applicable, standard conversion methodology consistent with GAAP or IFRS, unless Licensor can demonstrate an alternative calculation based on commercially available conversion rates resulting in a greater than 1.0% difference in its favour, in which case the conversion rate shall be as calculated, or re-calculated by Licensor.

Subject to the above, Net Sales shall be calculated in accordance with generally accepted accounting practices in the relevant Jurisdiction in the Territory.

**NMPA** means the National Medical Products Administration of China (sometimes translated as “State Drug Administration”), or its predecessor China Food and Drug Administration (CFDA) or State Food and Drug Administration, and any successor agency thereto.

**Non-Breaching Party** has the meaning set forth in Section 10.2(b) (Material Breach).

**Notice Period** has the meaning set forth in Section 10.2(b) (Material Breach).

**Otenaproxesul Materials** means, as applicable, the Licensed Compound in bulk form manufactured for use as an API, intermediates required to Manufacture the finished product formulation of a Licensed Product, the finished product formulation of a Licensed Product, and any other components required to Manufacture any Licensed Product.

**Patents** means:

- a) all national, regional and international patents and patent applications, including provisional patent applications;
- b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications;
- c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, invention patents and design patents and certificates of invention;
- d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and
- e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

**Person** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a Governmental Authority.

**Phase 3 Clinical Trial** means a controlled clinical trial, or a portion of a controlled clinical trial, in humans of the efficacy and safety of a pharmaceutical product, which study (in its entirety or such portion, as applicable) is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a manner sufficient to file a New Drug Application, as described in Federal Regulation 21 C.F.R. §312.21(c) and its foreign equivalents. For the sake of clarity, with respect to what is commonly called a phase 2/3 trial, the Phase 3 Clinical Trial definition is met upon the FPFV in the portion of such study that is prospectively designed to demonstrate statistically whether such pharmaceutical product is effective and safe for use in a manner sufficient to file a Drug Registration Application, as described in Federal Regulation 21 C.F.R. §312.21(c) and its foreign equivalents. If a clinical trial does not constitute a Phase 3 Clinical Trial at the time of FPFV, but is later determined by the applicable Regulatory Authority to be sufficient to form the primary basis of an efficacy claim in a New Drug Application, then, such clinical trial shall be deemed to constitute a Phase 3 Clinical Trial, and the FPFV of such Phase 3 Clinical Trial shall be deemed to occur, on the date of such determination by the applicable Regulatory Authority.

**Post-Approval Research** means ongoing research and development of a Licensed Product after such Licensed Product has received Regulatory Approval in the Territory, including phase IV clinical studies and clinical studies in support of indications within the Field or labeling changes for such Licensed Product within the Field in the Territory during the Term.

**PRC** means the People's Republic of China; for the purpose of this Agreement, does not include Hong Kong Special Administrative Region, the Macau Special Administrative Region, and Taiwan.

**Prior CDA** has the meaning set forth in Section 7.1 (Confidentiality Obligations).

**Prohibited Payment** has the meaning set forth in Section 11.4 (Compliance with Law).

**Regulatory Approval** means, with respect to a Jurisdiction in the Territory, any and all approvals, and the process for obtaining such approvals, towards obtaining a Drug Registration Certificate from the NMPA, including licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a pharmaceutical product in such Jurisdiction, further including, where applicable, (a) pricing or reimbursement approval (**Reimbursement Approval**) in such Jurisdiction, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approval.

**Regulatory Authority** means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other Governmental Authority regulating or otherwise exercising authority with respect to the Exploitation of any compound or pharmaceutical product, including the NMPA.

**Regulatory Documentation** means (a) any IND, CTA, Drug Registration Application and Drug Registration Certificate, registration, license, authorization and approval (including Regulatory Approvals), and any application therefor; (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (c) clinical and other data contained or relied upon in any of the foregoing; in each case ((a), (b) and (c)) relating to the Licensed Compound or a Licensed Product.

**Regulatory Exclusivity Period** means, with respect to each Licensed Product in any Jurisdiction in the Territory, any period of data, market or other regulatory exclusivity (other than Patent exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such Jurisdiction that confers exclusive marketing rights with respect to such Licensed Product in such Jurisdiction or prevents another Person from using or otherwise relying on any data supporting the approval of the Drug Registration Application with respect to such Licensed Product in such Jurisdiction without the prior written consent of the Drug Registration Application-holder, as applicable.

**Representatives** has the meaning set forth in Section 7.1 (Confidentiality Obligations).

**Retained Rights** means, with respect to the Licensed Compound and Licensed Product, the rights of Licensor, its Affiliates and its and their licensors, (sub)licensees and contractors, but excluding the Licensee, to:

- a) perform its and their obligations and exercise its and their rights under this Agreement;
- b) Manufacture and research the Licensed Compound or any Licensed Product anywhere in the world solely for Exploitation outside the Territory or outside the Field; and
- c) Develop and otherwise use the Licensed Compound or Licensed Product for Exploitation outside the Territory or outside the Field.

**Royalty Term** means, with respect to each Licensed Product and each Jurisdiction in the Territory, the period beginning on the date of the First Commercial Sale and ending on the last to occur of:



- a) the expiration of the last-to-expire Valid Claim in any Licensed Patent in such Jurisdiction that that claims or covers (i) such Licensed Product, or its composition of matter, (ii) the Licensed Compound included in such Licensed Product as a composition of matter, or a method of treatment or other use of such Licensed Compound for any indication in the Field, or (iii) a method of use of or a method of Manufacturing such Licensed Product;
- b) the expiration of the Regulatory Exclusivity Period in such Jurisdiction for such Licensed Product; and
- c) the expiry of the Trademark and Know-How Term.

**Senior Officer** means, with respect to Licensor, its Chief Executive Officer, and, with respect to Licensee, its Chief Executive Officer.

**Sublicensee** means a Person, other than an Affiliate, that is granted a sublicense, directly or indirectly, by Licensee or its Affiliate under the grants in Section 2.1 (Grants to Licensee), as provided in Section 2.3 (Sublicenses).

**Term** has the meaning set forth in Section 10.1 (Term and Expiration).

**Termination Notice** has the meaning set forth in Section 10.2(b) (Material Breach).

**Territory** means any or all (as applicable) of the following: the PRC, the Hong Kong Special Administrative Region of the PRC, the Macau Special Administrative Region of the PRC, and Taiwan, each of which shall be considered a Jurisdiction in the Territory for purposes of this Agreement.

**Third Party** means any Person other than Licensor, Licensee and their respective Affiliates and authorized Sublicensees.

**Third Party Claims** has the meaning set forth in Section 9.1 (Indemnification of Licensor).

**Third Party Infringement Claim** has the meaning set forth in Section 6.5 (Infringement Claims by Third Parties).

**Trademark** means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration right, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source, origin or quality, whether or not registered, and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

**Trademark and Know-How Rights** has the meaning set forth in Section 5.3 (Royalties).

**Trademark and Know-How Term** has the meaning set forth in Section 5.3 (Royalties).

**Valid Claim** means (a) a claim of any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by (i) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (ii) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, Governmental Authority, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal or (b) a claim of a pending Patent application that has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.

**VAT** has the meaning set forth in Section 5.6(b) (Value Added Tax).

## 2. GRANT OF RIGHTS

2.1 Grants to Licensee. Subject to Section 2.5 (Retention of Rights) and the other terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive (including with regard to Licensor and its Affiliates) license, with the right to grant multiple tiers of sublicenses in accordance with Section 2.3 (Sublicenses), under the

Licensed Patents, the Know-How, and the Trademarks, to Develop and Commercialize, and to import for Development or Commercialization of, the Licensed Product in the Field in the Territory.

2.2 Grants to Licensor. Licensee hereby grants to Licensor a nonexclusive, royalty-free, perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Licensee Development Data solely to the extent necessary or reasonably required in connection with (a) Exploitation and Manufacturing of the Licensed Compound, Licensed Product(s) or any product containing the Licensed Compound, and any Improvements thereto outside the Territory or outside the Field, and (b) performing or exercising the Retained Rights within or outside the Territory or outside the Field; (c) seeking and obtaining protection for any Improvements within or outside the Territory. Licensee covenants that it shall not grant any further licenses to the Licensee Development Data to any Third Party maker of Generic Product.

2.3 Sublicenses.

- a) Licensee shall have the right to grant sublicenses, through multiple tiers of sublicensees, under the licenses granted in Section 2.1 (Grants to Licensee), to its Affiliates; *provided* that any such sublicenses shall be: (a) subject to the prior written consent of Licensor if granted to a Person other than an Affiliate of the Licensee, which consent shall not be unreasonably withheld, conditioned or delayed; and (b) consistent with, and expressly made subject to, the terms and conditions of this Agreement. Licensee shall cause each Affiliate and Sublicensee to comply with the applicable terms and conditions of this Agreement as if such Affiliate or Sublicensee were a Party to this Agreement. Third Party contract research organizations retained for Development (collectively, “CROs”) shall be mutually selected by the Parties, and Nuance is entitled to grant sublicense to such CROs.
- b) If Licensee entrusts certain activities related to Commercialization of the Licensed Product to Third Party distributors, sub-distributors or sales agents (collectively, “Distributors”), and grants such sublicense to the Distributors to the extent necessary or appropriate for them to conduct the so entrusted activities, the prior written approval of the Licensor shall be waived. All sublicense agreements (including those with Licensee’s Affiliates) shall be consistent with the terms and conditions of this Agreement.

2.4 Rights of Reference. Solely to the extent permitted under Applicable Law:

- a) Licensor hereby grants to Licensee and its Sublicensees a Right of Reference and Use, as that term is defined in 21 C.F.R. § 314.3(b) and any foreign counterpart to such regulation, to all Licensor Regulatory Documentation and the Licensor Development Data to the extent necessary or reasonably useful to Develop, obtain Regulatory Approval of, or Commercialize the Licensed Compound or Licensed Product in the Field in the Territory, in each case, subject to the terms and conditions of this Agreement.
- b) Without any additional consideration to Licensee, Licensee hereby grants to Licensor and its Affiliates, and any current or future direct or indirect (sub)licensee of Licensor with respect to the Licensed Compound or a Licensed Product, a Right of Reference and Use to the Licensee Development Data to the extent necessary or useful to (i) Exploit the Licensed Compound, Licensed Product(s) or any product containing the Licensed Compound, and any Improvements thereto, outside of the Territory or outside of the Field, or (ii) in support of Development, Manufacturing, Regulatory Approval, or Commercialization of the Licensed Compound, Licensed Product(s) or any product containing the Licensed Compound, and any Improvements thereto, outside of the Territory or outside the Field.
- c) Each Party will provide a signed statement to this effect, if requested by the other Party, for the limited purpose described in this Section 2.4 (Rights of Reference). For the avoidance of any doubt,

Licensee and its Affiliate(s) are not obliged to translate any information provided under this Section 2.4 into any language other than Chinese.

- d) Any information of a Party to which the other Party obtains access pursuant to this Section 2.4 shall be deemed the Confidential Information of such first Party. For clarity, Licensee's submission of such information to NMPA shall be governed by and subject to the terms of Article 7 (CONFIDENTIALITY AND NON-DISCLOSURE).

## 2.5 Retention of Rights

- a) **Retained Rights of Licensor.** Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted or reserved to Licensor pursuant to any other term or condition of this Agreement, Licensor hereby expressly retains, on behalf of itself and its Affiliates all right, title and interest in and to the Licensed Patents, the Know-How, Licensor Development Data, Licensor Regulatory Documentation and Licensor Marks, in each case, for purposes of performing or exercising the Retained Rights.
- b) **No Other Rights Granted by Licensor.** Except as expressly provided herein and without limiting the foregoing, Licensor grants no other right or license not otherwise expressly granted herein.

2.6 Restrictions on Licensee. Licensee shall not, and shall not permit any of its Affiliates or Sublicensees or distributors to, knowingly distribute, market, promote, offer for sale or sell the Licensed Product (i) to any Person outside the Territory or outside the Field or (ii) to any Person in the Territory that Licensee or any of its Affiliates or any of its or their licensees, Sublicensees or distributors has actual Knowledge that such Person (A) intends to distribute, market, promote, offer for sale or sell any Licensed Product for use outside the Territory or outside the Field, or to assist another Person to do so, or (B) has directly or indirectly distributed, marketed, promoted, offered for sale or sold any Licensed Product for use outside the Territory or outside the Field, or assisted another Person to do so. If Licensee or any of its Affiliates receives or becomes aware of the receipt by a licensee, Sublicensee or distributor of any orders for any Licensed Product for use outside the Territory or Field, such Person shall refer such orders to Licensor. Licensee shall cause its Affiliates and its and their licensees, Sublicensees and distributors to notify Licensor of any receipt of any orders for any Licensed Product for use outside the Territory or Field.

2.7 No Challenge. Licensee agrees not to bring any legal or administrative challenge to the validity, patentability, enforceability, ownership, and/or scope of any Licensed Patent, or otherwise to oppose the licensed patent. In the event Licensee brings any legal or administrative challenge to the validity, patentability, enforceability, ownership, and/or scope of any Licensed Patent, or otherwise to oppose the licensed patent, Licensee will reimburse Licensor for all of Licensor's expenses in connection with such challenge or opposition, including all legal expenses; any remaining milestone payments set forth in Section 5.2 will double; and the royalty rates set forth in Section 5.3 will double.

2.8 Restrictions on Licensor. Licensor shall not: (i) knowingly solicit or accept orders for distribution of Licensed Product to a Third Party for sale or distribution in the Territory in the Field; (ii) knowingly distribute any Licensed Product for sale or use in the Territory in the Field or assist any Third Parties to do so; or (iii) supply any Third Party that has distributed or offered to distribute Licensed Products in the Territory in the Field after Licensor has actual knowledge that said Third Party has distributed or offered to distribute Licensed Product obtained from Licensor in the Territory in the Field.

2.9 Non-Compete. During the Term of this Agreement and for two years following termination thereof, Licensee and its Sublicensees, shall not, and shall not enable or assist any Person that is not a Party to this Agreement to, Develop, Manufacture or Commercialize any product that is any Generic Product of the Licensed Product or any other oral NSAID product that is used for osteoarthritis (OA) pain in the Field in the Territory, other than the Licensed Compound and Licensed Product in accordance with this Agreement.



2.10 Transfer of Know-How. Promptly after the Effective Date but in any event within thirty (30) days thereafter, Licensor shall provide (a) the Know-How (other than any Manufacturing information, except such Know-How is reasonably necessary for obtaining Regulatory Approvals of any Licensed Product in the Territory) that, to Licensor's Knowledge, would be material or reasonably necessary to the Development or Commercialization of the Licensed Compound and Licensed Product in the Territory and (b) the Licensor Regulatory Documentation, in each case that has not, as of such time, already been made available to Licensee or any of its Affiliates. As soon as practicable upon Licensee's subsequent reasonable written request made during the Term from time to time, Licensor shall provide such additional information and technical assistance as may be reasonably needed for Licensee to interpret and use such Know-How or as may be otherwise reasonably needed for applications for Regulatory Approval of the Licensed Products in the Territory. Licensor acknowledges and agrees that its obligation of data transfer is essential to Licensee's performance of this Agreement.

### 3. DEVELOPMENT; REGULATORY AND COMMERCIALIZATION ACTIVITIES

#### 3.1 Development.

- a) **Development Plan.** Promptly after the Effective Date, the Parties will agree on a Development Plan for a Licensed Product in the Field in the Territory through the JDC. The Licensee or any of its Affiliates or any Sublicensee will conduct the Development of the Licensed Product according to the Development Plan as approved by the JDC and will conduct no other research, clinical, pre-clinical and other non-clinical testing, toxicology, formulation, or regulatory affairs with respect to the Licensed Compound or Licensed Product, without first obtaining the unanimous approval for such activities from the JDC. The Development Plan will include, among other things, the indications in the Field for which the Licensed Product are to be Developed and other exploratory indications in the Field for which the Licensed Product may be Developed, critical activities to be undertaken, certain timelines, go/no go decision points and relevant decision criteria. The Development Plan will be designed to efficiently obtain Regulatory Approval for Licensed Products in the Field in the Territory, while taking into consideration potential impacts on Development, Regulatory Approval or Commercialization of the Licensed Products other than in the Field in the Territory or outside the Territory. During the Term, the Parties will review the Development Plan from time to time and will amend such Development Plan on an ongoing basis as necessary. The Development Plan and its execution shall meet GCP and GLP standards. The then-current Development Plan will at all times contain at least that level of detail and cover at least the same matters (to the extent applicable) as the original Development Plan for the Licensed Product.
- b) **Diligence.** After the Effective Date, as between the Parties, Licensee shall, subject to Section 3.1(a) be solely responsible for all aspects of the Development of the Licensed Product in the Field in the Territory. Without limitation of Section 3.1(c) (Development Costs), Licensee shall use Commercially Reasonable Efforts to Develop, obtain and maintain Regulatory Approvals for Licensed Product for use in the Field in each Jurisdiction of the Territory. Licensee will be solely responsible for all clinical development activities conducted solely for the purpose of supporting and maintaining Regulatory Approval of the Licensed Product in the Field in the Territory in accordance with the Development Plan(s), with the intention that registration efforts in the Territory shall be consistent with the global approach of Licensor. The JDC is entitled to decide the timeline, methods and other details in the application for such Regulatory Approval. The JDC shall work diligently towards establishing an aspirational date for the following achievement, which date shall not in any event be before results from Licensor's initial pivotal Phase 3 trial are made available to the JDC.

Achievement
Filing of CTA by Licensee for a Phase 3 Clinical Trial with NMPA in China

- c) **Development Costs.** Licensee shall be solely responsible for all costs and expenses in connection with the Development of, and obtaining and maintaining Regulatory Approvals for, the Licensed Product in the

Field in the Territory. If the Development Plan includes multi-region clinical trials, Licensee shall be responsible for all direct clinical trial costs in the Territory and a pro rata portion of the indirect multi-region costs for such clinical trials outside of the Territory that are conducted by Licensor, its Affiliates or any of its other (sub)licensees based on the number of patients enrolled in each region, provided that such pro rata multi-region costs are reasonably incurred in accordance with the Development Plan (or amendment thereto), prior unanimous approval from the JDC, and are supported by reasonable evidence such as Third Party invoices.

- d) **Development Records.** Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, maintain, in good scientific manner, complete and accurate books and records pertaining to Development of Licensed Product hereunder, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (i) be appropriate for patent and regulatory purposes, (ii) be in compliance with Applicable Law, (iii) reasonably and properly reflect all work done and results achieved in the performance of its Development activities hereunder, (iv) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement and (v) be retained by Licensee for at least five (5) years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Licensor shall have the right, during normal business hours and upon fifteen (15) days prior written notice, to inspect and copy all such books and records maintained pursuant to this Section 3.1(e) (Development Records); *provided* that Licensor shall maintain such records and information disclosed therein in confidence to the extent set forth in Article 7 (CONFIDENTIALITY AND NON-DISCLOSURE).
- e) **Development Reports.** Without limiting Section 3.1(d) (Development Records), until the First Commercial Sale, within forty five (45) days following the end of each Calendar Year, Licensee shall provide the JDC with a detailed written report of such Development activities it has performed, or caused to be performed, since the preceding report, its Development activities in process and the future activities it expects to initiate during the following Calendar Year period. Each such report shall contain sufficient detail to enable the JDC to assess Licensee's compliance with its obligations set forth in Section 3.1(a) (Development Plan) and Section 3.1(b) (Diligence), including: (i) Licensee's, or its Affiliates' or its or their Sublicensees' activities with respect to achieving Regulatory Approvals of Licensed Product in the Territory; and (i) clinical study results and results of other Development activities, to the extent available and Controlled by Licensee and its Affiliate(s).

### 3.2 Regulatory Activities.

- a) **Regulatory Approvals.** Licensee shall have the responsibility and the right, at its cost, and subject to the Retained Rights and in accordance with this Agreement, to prepare, apply for, obtain, have, hold and maintain Drug Registration Applications, resulting Drug Registration Certificate(s), (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions (including INDs and CTAs) and to conduct communications with the Regulatory Authorities, for Licensed Product in the Field in the Territory in its name. Subject to meeting all obligations in accordance with this Agreement, Licensee shall be the Market Authorization Holder for such Drug Registration Certificate. All Regulatory Submissions of Licensee or any of its Affiliates or any Sublicensee, which obligates it or them to a specific clinical path with respect to the Licensed Compound or Licensed Product, requires unanimous approval in advance from the JDC. The intention of this provision is to ensure that registration efforts in the Territory are consistent with the global approach of Licensor. Subject to the foregoing, Licensee will lead and have control over preparing and submitting all regulatory filings related to Licensed Products for the Field in the Territory, including all applications for Regulatory Approval; provided, however, that it shall provide Licensor the ability to review all such filings and submissions prior to submission and shall take in good faith consideration Licensor's comments on such submission.

- b) **Regulatory Cooperation.** Licensor will use Commercially Reasonable Efforts to timely communicate to Licensee all Licensor Development Data and Licensor Regulatory Documentation. Licensee will use Commercially Reasonable Efforts to timely communicate to Licensor all Licensee Development Data and Licensee Regulatory Documentation. If the other Party reasonably requests additional information related to these material submissions, filings, notices or communications, the Party shall use Commercially Reasonable Efforts to provide relevant documents. Following the Effective Date, Licensor shall use Commercially Reasonable Efforts to promptly provide Licensee with all currently existing Licensor Development Data and Licensor Regulatory Documentation obtained in connection with the Development of the Licensed Product outside the Territory. Licensee will bear the reasonable costs related to Licensor's transferring the Licensor Development Data and Licensor Regulatory Documentation. For clarity, this Section 3.2(b) (Regulatory Cooperation) does not apply to any transfer of Manufacturing information, which shall be required of Licensor only as set forth in any relevant Clinical Supply Agreement and Commercial Supply Agreement, except such information is reasonably necessary for obtaining Regulatory Approvals of any Licensed Product in the Territory.
- c) **Recalls, Suspensions or Withdrawals.** Licensee shall notify Licensor promptly following its determination that any event, incident or circumstance has occurred that would reasonably be expected to result in the need for a recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Licensee shall have the right and obligation to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory; *provided* that prior to any implementation of such a recall, market suspension or market withdrawal, Licensee shall consult with Licensor and shall consider Licensor's comments in good faith. If a recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory is mandated by a Regulatory Authority in the Territory, as between the Parties, Licensee shall initiate such recall, market suspension or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 3.2(c) (Recalls, Suspensions or Withdrawals), as between the Parties, Licensee shall be solely responsible for the execution thereof. Licensee shall review with Licensor the proposed manner in which the recall is to be carried out and will give due consideration to any reasonable recommendation from Licensor as to the manner of conducting the recall, provided that it is agreeable to the applicable Governmental Authority. Subject to Article 9 (INDEMNITY), Licensee shall be responsible for all costs of any such recall, market suspension or market withdrawal.
- d) **Pharmacovigilance Agreement; Global Safety Database.** Licensor shall be responsible for maintaining the global safety database for the Licensed Product. Licensee shall be responsible for the collection and timely transfer of drug safety information to Licensor with respect to the Licensed Product in the Territory. On a date to be determined by the JDC, and in any event prior to the first filing by Licensee of an IND in the Territory, the Parties shall enter into a pharmacovigilance agreement promptly following the Effective Date providing for the terms pursuant to which (i) Licensor shall establish, hold and maintain (at Licensor's sole cost and expense) the global safety database for Licensed Product; (ii) Licensee shall timely, and shall ensure that its Affiliates and Sublicensees, provide Licensor with information in the Control of Licensee, its Affiliates or Sublicensees relating to adverse events and serious adverse events involving the Licensed Product and required or relevant to be disclosed to the NMPA (under NMPA-GCP-No57-2020 or other relevant regulation), such that Licensor may comply with its pharmacovigilance responsibilities outside the Territory, including, as applicable, any Adverse Drug Events and Adverse Drug Reactions (including those required to be reported to the FDA under 21 C.F.R. Sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States) with respect to any Licensed Product; and (iii) Licensor shall provide Licensee with access to data in such global safety database as necessary for Licensee to comply with its pharmacovigilance responsibilities in the Territory. In the event of any conflict between the terms and conditions of the pharmacovigilance agreement and the terms and conditions of this Agreement, the pharmacovigilance agreement shall govern and control with respect to all

drug safety information, pharmacovigilance matters, and the specific subject matter thereof, and this Agreement shall govern and control with respect to all other matters.

- e) **Regulatory Correspondence and Inspections.** Each Party shall promptly notify the other Party in writing of any inspection by or material correspondence received from any Governmental Authority in the Territory, and will provide copies of any such correspondence to the other Party. In the event that a Party receives any material regulatory letter requiring a response, the other Party will cooperate fully with the receiving Party in preparing such response and will promptly provide the receiving Party with any data or information required by the Receiving Party in preparing any such response.

### 3.3 Commercialization.

- a) **Commercialization Plan.** Licensee will prepare and provide to Licensor a Commercialization Plan for each Licensed Product in the Field in the Territory beginning approximately two years before the target launch date of the Licensed Product in the Territory, and in any event by the time of submission for approval of the Drug Regulatory Application. Licensee will take into account reasonable comments and suggestions of Licensor on the Commercialization Plan. Licensee shall provide periodic updates, at least annually, on the Commercialization Plan to Licensor. Without limiting Section 3.3(b) (Diligence), Licensee will be solely responsible for and pay for all Commercialization activities with respect to the Licensed Product in the Field in the Territory, which activities shall be conducted in accordance with the Commercialization Plan.
- b) **Diligence.** As between the Parties, and during the Term of this Agreement, Licensee shall be solely responsible for Commercialization of the Licensed Product in the Field throughout the Territory at Licensee's own cost and expense. Licensee, upon Regulatory Approval with respect to a Licensed Product in a Jurisdiction in the Territory, shall use Commercially Reasonable Efforts to Commercialize such Licensed Product in such Jurisdiction. The intention of this provision is to ensure that Commercialization efforts in the Territory are consistent with the global approach of Licensor. Parties acknowledge that the following achievements shall be included in the understanding of Commercially Reasonable Efforts to Commercialize:

<b>Achievement</b>
Submission of final application for Drug Registration Certificate for otenaproxesul in China
First sale of otenaproxesul in China (e.g., private pay market)
Net Sales of otenaproxesul of US\$100 M

- c) **Commercialization Costs; Booking of Sales; Distribution.** Licensee shall invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute the Licensed Product in the Field in the Territory and perform or cause to be performed all related Commercialization services. Subject to Section 3.2(c) (Recalls, Suspensions or Withdrawals), Licensee shall handle all returns, recalls or withdrawals, order processing, invoicing, collection, distribution and inventory management with respect to the Licensed Product in the Field in the Territory.
- d) **Commercialization Reports and Records.** Within forty five (45) following the end of each Calendar Quarter, commencing upon Licensee's, any of its Affiliates' or any Sublicensee's first filing for Drug Registration Application of a Licensed Product in the Territory and thereafter, Licensee shall provide Licensor with detailed written reports of such Commercialization activities it, any of its Affiliates or any Sublicensee has performed, or caused to be performed, since the preceding report and the future activities it expects to initiate during the following twelve (12)-month period. Each such report shall contain sufficient detail to enable Licensor to assess Licensee's compliance with its obligations set forth in Sections 3.3(a) (Commercialization Plan) and 3.3(b) (Diligence). Without limiting Section 5.9 (Audit), Licensee shall, and



shall require its Affiliates and the Sublicensees to, maintain complete and accurate books and records pertaining to Commercialization of Licensed Product hereunder, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be in compliance with Applicable Law. Such records shall be retained by Licensee for at least five (5) years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Licensor shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such books and records maintained pursuant to this Section 3.3(d) (Commercialization Reports and Records); provided that Licensor shall maintain such records and information disclosed therein in confidence to the extent set forth in Article 7 (CONFIDENTIALITY AND NON-DISCLOSURE).

3.4 Supply of Licensed Product – Clinical Trials. On a date to be determined by the JDC, and in any event prior to the first filing by Licensee of an IND in the Territory, the Parties will enter into a clinical supply agreement based on the principles illustrated in this Agreement (the “**Clinical Supply Agreement**”). Prior to the initiation of the Regulatory Approval process for a Licensed Product in the Territory, (i) Licensor will use Commercially Reasonable Efforts to supply, pursuant to the Clinical Supply Agreement, Licensed Product to Licensee; (ii) Licensor will provide all details of Manufacturing required or useful for the Drug Registration Application including but not limited to details of test method development, stability testing, toxicology, formulation, process development, qualification and validation, quality assurance/quality control, and in vitro microbiology, (iii) Licensee will purchase Licensed Product exclusively from Licensor; and (iv) Licensee will not Manufacture or have Manufactured the Licensed Compound or Licensed Product. Principal terms of the Clinical Supply Agreement shall further include:

- Cost: Licensor will supply Licensed Product to Licensee at a location designated by Licensee in Territory at a price equal to the Licensor’s Cost of Goods Sold plus shipping and insurance costs.
- Customary provisions concerning price adjustments, forecasting, ordering, product recall, and quality.

3.5 Supply of Licensed Product – Commercial Phase. On a date to be determined by the mutual agreement of Licensee and Licensor, and in any event prior to the first receipt of a Drug Regulatory Certificate for a Licensed Product in the Territory, the Parties will enter into a commercial supply agreement for Licensed Product based on the principles illustrated in this Agreement (the “**Commercial Supply Agreement**”). Under the Commercial Supply Agreement, (i) Licensor will use Commercially Reasonable Efforts to supply Licensed Product to Licensee; (ii) Licensor will provide all details of Manufacturing required or useful for obtain or maintain the Drug Registration Certificate; (iii) Licensee will purchase Licensed Product exclusively from Licensor; and (iv) Licensee will not Manufacture or have Manufactured the Licensed Compound or Licensed Product. Principal terms of the Commercial Supply Agreement shall further include:

- Cost: Licensee purchase price from Licensor will be the lower of 1) the lowest price offered by Licensor to any authorized licensee of Licensor for sales outside the Territory, plus shipping and insurance; and 2) COGS, plus shipping and insurance.
- Customary provisions concerning price adjustments, forecasting, ordering, product recall, and quality.

3.6 Subcontracting. Subject to Section 2.3 (Sublicenses) and Section 3.1(b) (Diligence) and 3.3(b) (Diligence), Licensee, any of its Affiliates or any Sublicensee may subcontract aspects of Development with one or more Third Parties with the approval of Licensor, and may, on written notice to Licensor have a Third Party perform aspects of its Commercialization obligations hereunder (including by appointing one or more distributors); provided that (a) no such permitted subcontracting shall relieve Licensee, its Affiliates or any Sublicensee of any obligation hereunder (except to the extent satisfactorily performed by such subcontractor) or any liability and Licensee shall be and remain fully responsible and liable therefor and

(b) the agreement pursuant to which Licensee, any of its Affiliates or any Sublicensee engages any Third Party subcontractor must (i) be consistent in all material respects with this Agreement, (ii) contain terms obligating such subcontractor to comply with the confidentiality, intellectual property and all other relevant provisions of this Agreement. Licensee shall use its Commercially Reasonable Efforts to ensure that each subcontractor accepts and complies with all of the applicable terms and conditions of this Agreement as if such permitted subcontractor were a Party to this Agreement. Licensee hereby waives any requirement that Licensor exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance under this Agreement prior to proceeding directly against Licensee. For clarity, nothing shall restrict Licensor's right to exercise any of the Retained Rights or any other rights of Licensor, or the performance of any obligation by Licensor, through any of its Affiliates or any Third Party.

- 3.7 Statements and Compliance with Applicable Law; Audit by Licensor of Clinical Trials and Data Privacy. Licensee shall and shall cause its Affiliates and Sublicensees to, comply with all Applicable Law with respect to the Exploitation of Licensed Product. Licensee shall avoid, and shall require and use Commercially Reasonable Efforts to cause its Affiliates and Sublicensees, and its Affiliates' and its and their Sublicensees', employees, representatives, agents, and distributors, to avoid, taking or failing to take, any actions, including public statements that Licensee, such Affiliates or Sublicensees know or reasonably should know would jeopardize the goodwill or reputation of Licensor, any of its Affiliates, or the Licensed Product or any Trademark associated therewith. At the request of Licensor, Licensee shall and shall cause its Affiliates and its and their Sublicensees to, permit Licensor or an independent auditor designated by Licensor and reasonably acceptable to Licensee, during regular business hours and upon at least fifteen (15) days prior written notice, no more than once during any Calendar Year unless required to investigate specific issues or follow up on a remediation action, to audit Licensee's compliance with Applicable Law, including but not limited to compliance in the performance of any clinical trial, and/or any data privacy controls thereunder, to identify areas of potential improvement consistent with the objectives of this Agreement.

#### 4. DEVELOPMENT COMMITTEE

4.1 Joint Development Committee. Within one (1) month after the Effective Date, the Parties shall establish a joint development committee ("**Joint Development Committee**" or "**JDC**"), which shall consist of two (2) representatives from each of the Parties, each with the requisite authority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JDC. From time to time, each Party may substitute one (1) or more of its representatives to the JDC on written notice to the other Party. Licensee shall select from its representatives the chairperson for the JDC, which chairperson may be changed from time to time, on written notice to Licensor, and which chairperson shall have no greater authority than any other representative on the JDC. The JDC shall:

- a) serve as a forum for discussing and supervising Development of the Licensed Compound and Licensed Product in the Field in the Territory, including by reviewing and approving Development Plans and any amendments thereto, and overseeing the conduct of the Development activities as provided in Section 3.1 (Development) (including as set forth in Development reports as provided in Section 3.1(e) (Development Reports)); and
- b) perform such other functions as are expressly set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

#### 4.2 General Provisions Applicable to the JDC.

- a) **Meetings and Minutes.** The JDC shall meet at least once each Calendar Quarter or as otherwise agreed to by the Parties, with the location of any in-person meetings alternating between reasonable locations designated by Licensee and reasonable locations designated by Licensor. Either Party shall have the right to call additional meetings on no less than forty-five (45) days notice unless exigent circumstances require shorter notice. Each Party shall make all proposals for agenda items at least twenty (20) days in advance of

the applicable meeting; provided that under exigent circumstances requiring input by the JDC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably withheld, conditioned or delayed). The chairperson of the JDC (or his or her designee) shall prepare and circulate the meeting agenda at least ten (10) days in advance of the meeting, and shall prepare and circulate for review and approval of the Parties minutes of each meeting as promptly as possible after the meeting. The JDC representatives shall comment on the minutes, and the Parties shall agree on the finalized minutes of each meeting promptly, but in no event later than fifteen (15) days after the applicable meeting.

- b) **Procedural Rules.** The JDC shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. Representatives of the Parties on the JDC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed. The JDC shall take action by unanimous vote of the representatives, with each representative having a single vote. If the JDC cannot, or does not, reach consensus on an issue which has been discussed during a meeting of the JDC, within five (5) Business Days after the matter has first been discussed by JDC, or any shorter term which is required by specific circumstances, such issue will be referred to the respective executive-level officers of the Parties for resolution. The respective executive-level officers of the Parties shall use good faith efforts to resolve any matter referred to them as soon as practicable, and any final decision that the executive-level officers of the Parties mutually agree to in writing shall be conclusive and binding on the Parties. In the event that the executive-level officers of the Parties are unable to resolve the issue within ten (10) Business Days after the issue has first been referred to them, or any shorter term which is required by specific circumstances, then with respect to issues relating to the Development of the Products, Licensee shall have the right to decide on actions with the Regulatory Authority that are necessary for meeting safety requirements under Applicable Law in the Territory. Licensor's view shall prevail if proposals of Licensee could reasonably be expected to have material adverse impacts on the Development or Commercialization of the Products outside the Field or outside the Territory. For clarity, Licensee's right to decide under this Section 4.2(b) shall not include authority for generation of any clinical data, even if ultimate clinical approval is at risk. Alliance Managers or other employees or consultants of a Party who are not representatives of the Parties on the JDC may attend meetings of the JDC; provided that such attendees shall not vote or otherwise participate in the decision-making process of the JDC. Each such attendee and each JDC representative must be bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 7 (CONFIDENTIALITY AND NON-DISCLOSURE).
- c) **Final Decision-Making.** If a decision of the JDC is not achieved on an issue under 4.2 (b), then such issue shall be resolved pursuant to Section 11.10 (Dispute Resolution).
- d) **Limitations on Authority.** Without limitation to the foregoing, the Parties hereby agree that, the JDC shall not have any authority other than that expressly set forth in Section 4.1 and matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement or other subsequent agreements between the Parties, are outside the jurisdiction and authority of the JDC. Specifically, the JDC shall have no authority in the following matters (i) amendment, modification or waiver of compliance with this Agreement, (ii) determination of whether or not Licensee has met its diligence or other obligations under this Agreement, (iii) determination of whether or not a breach of this Agreement has occurred; (d) determination of any commercial issues hereunder; or (iv) such other matters as are reserved to the consent, approval, agreement or other decision-making authority of either or both Parties in this Agreement that are not required by this Agreement to be considered by the JDC prior to the exercise of such consent, approval or other decision-making authority.

- e) **Alliance Managers.** Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters between meetings of the JDC and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an “**Alliance Manager**”), which person(s) may be replaced at any time by notice in writing to the other Party. The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

## 5. PAYMENTS AND RECORDS

5.1 **Upfront Payment.** In consideration of the rights granted to Licensee hereunder, within 15 (fifteen) Business Days following Licensee’s receipt of invoice from Licensor for such upfront payment to be issued on or after the Effective Date, Licensee shall pay Licensor a non-refundable and non-creditable upfront amount equal to twenty million US Dollars (\$20,000,000).

5.2 **Milestones.** As partial consideration for the rights granted to Licensee by the Licensor pursuant to Section 2.1 (Grants to Licensee), Licensee will notify the Licensor of the following one-time milestones after the first occurrence of each of the following events (each, a “**Milestone Event**”) within ninety (90) days of the initial achievement of such Milestone Event. Licensor shall promptly invoice Licensee for the corresponding amount below, and Licensee shall pay to the Licensor (in accordance with Sections 5.5, 5.6 and 5.7) the following one-time milestone payments within ninety (90) days of achievement of such Milestone Event, subject to receipt of the invoice issued by Licensor.

Milestone Event		Milestone Payment (US Dollars)
<b>Development Milestone</b>	a) Upon issuance by a Regulatory Authority of a Drug Registration Certificate for a Licensed Product in the first Jurisdiction in the Territory	10 Million
	<b>Development Milestone Total</b>	<b>10 Million</b>
<b>Commercial Milestones</b>	b) First Calendar Year with Net Sales in Territory of USD\$100 Million or higher.	5 Million
	c) First Calendar Year with Net Sales in Territory of USD\$200 Million or higher.	12 Million
	d) First Calendar Year with Net Sales in Territory of USD\$300 Million or higher.	21 Million
	e) First Calendar Year with Net Sales in Territory of USD\$400 Million or higher.	32 Million
	<b>Sales Milestone Total</b>	<b>70 Million</b>
<b>Total Upfront, Development, and Sales Milestones</b>		<b>100 Million</b>

For the avoidance of any doubt, Milestone Payment for achievement of each Milestone Event respectively shall be payable only once, regardless of the number of times such Milestone is achieved by any Product in the Territory. Once Licensee has made any particular milestone payment under this Section 5.2 (Milestones), Licensee will not be obligated to make any payment with respect to the re-occurrence or subsequent repeated achievement of the same Milestone Event. The Parties acknowledge that in certain scenarios, two or more Commercial Milestones may be met in the same Calendar Year, in which case both Milestone Payments become payable. The above milestone payments shall be one time only, non-creditable and non-refundable.



5.3 Royalties. As further consideration for the rights granted to Licensee by the Licensor hereunder, and in addition to the Milestones in Section 5.2, during the Royalty Term, Licensee shall pay to the Licensor during the Royalty Term a royalty on Net Sales of such Licensed Product in the Territory at the rate set forth below:

	<b>Royalty Rate</b>
Payable on Net Sales of Licensed Product	12.5%

The royalty rate above will be reduced by 50% in any Jurisdiction following the Date of Loss of Exclusivity in such Jurisdiction, meaning the later of:

- a) the expiration of the last-to-expire Valid Claim in any Licensed Patent in such Jurisdiction that claims or covers (i) such Licensed Product, or its composition of matter, (ii) the Licensed Compound included in such Licensed Product as a composition of matter, or a method of treatment or other use of such Licensed Compound for any indication in the Field, or (iii) a method of use of or a method of Manufacturing such Licensed Product;
- b) the expiration of the Regulatory Exclusivity Period in such Jurisdiction for such Licensed Product; and
- c) The entry of a Generic Product of a Third Party containing otenaproxesul and which results in a 50% reduction of market share compared to the previous year's corresponding Calendar Quarter.

(together the later of a), b) and c) meaning "the Date of **Loss of Exclusivity**" in such Jurisdiction).

For further clarity, the royalty rate subsequent to the Date of Loss of Exclusivity shall be the Trademark and Know-How Royalty, which shall be payable for practice of the Trademark and Know-How Rights during the Trademark and Know-How Term.

	<b>Royalty Rate</b>
Trademark and Know-How Royalty	6.25%

The Trademark and Know-How Rights includes that subset of rights granted under Section 2.1 which are useful or necessary to Commercialize the Licensed Product in the Territory after expiry of the Licensed Patents and the Regulatory Exclusivity Period. The "**Trademark and Know-How Term**" shall begin on the Date of Loss of Exclusivity in a Jurisdiction and shall continue until terminated under Section 10.2(a).

Licensee may request good faith negotiation of the Parties towards reduction of the Royalty Rate in the event that Licensee sales margin falls below expectations set forth in the Commercialization Plan due to significant and unexpected reimbursement price reduction event driven by Government Authority. The Commercialization Plan shall anticipate pricing requirements of the National Development and Reform Commission as part of the official National Reimbursement Drug List discussions in China where government will negotiate a reimbursement price for inclusion across China. Such inclusion is recognized as essential in allowing the Licensed Product full market access.

5.4 Royalty Payments and Reports. Licensee shall calculate all amounts payable to the Licensor pursuant to Section 5.3 (Royalties) at the end of each Calendar Quarter. Licensee shall pay to the Licensor the royalty amounts due with respect to a given Calendar Quarter within forty five (45) days following Licensee's receipt of invoice from Licensor for the royalty. Each payment of royalties due to the Licensor shall be accompanied by a statement

specifying, on a Licensed Product-by-Licensed Product and Jurisdiction-by-Jurisdiction basis, the amount of Invoiced Sales, Net Sales and deductions taken to arrive at Net Sales attributable to each Licensed Product in each Jurisdiction in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and Sublicensees to account for their Net Sales and to provide such reports with respect thereto, through Licensee, as if such sales were made by Licensee.

5.5 Mode of Payment. All payments to the Licensor under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account(s) as the Licensor may from time to time designate by notice to Licensee.

5.6 Taxes.

- a) **General.** Licensee will make all payments to Licensor under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by Applicable Law in effect at the time of payment. Any tax required to be withheld on amounts payable by Licensee under this Agreement will be timely paid by Licensee on behalf of Licensor to the appropriate Governmental Authority, and Licensee will furnish Licensor with the corresponding proof of payment of such tax, as may be required in order to enable Licensor to request reimbursement or deduction of the withheld amount, or to otherwise comply with its duties. Licensee and Licensor agree to cooperate to legally minimize and reduce such withholding taxes and provide any information or documentation required by any taxing authority. If (i) Licensee (A) had a duty to deduct, withhold and pay over any tax to any governmental authority in connection with any Payment it made to Licensor under this Agreement, but (B) failed to so deduct, withhold and timely pay over all or any portion of such tax, and (ii) such tax or portion thereof is assessed against Licensor, then Licensee will indemnify and hold harmless Licensor from and against any penalties imposed as a result thereof; provided, however, that no such indemnification shall be due from Licensee to the extent of any such penalties imposed solely as a result of or in connection with Licensee's reliance on Licensor's claim for reduced or no withholding hereunder that has been finally determined to have been incorrect.
- b) **Value Added Tax.** Notwithstanding anything contained in Section 5.6(a) (General), this Section 5.6(b) (Value Added Tax) shall apply with respect to value added tax (VAT) and all applicable local surcharges. All Payments are exclusive of VAT and all local surcharges. No Payments shall be deducted for any VAT or local surcharge. If any VAT or local surcharge is chargeable in respect of any Payments, Licensee shall pay and bear the VAT and the local surcharge at the applicable rate in respect of any such Payments following the receipt of an invoice issued by Licensor, illustrating the amounts of the Payments and applicable VAT and local surcharge(es) separately. Licensee shall make such VAT and local surcharge payments to the tax bureau timely in order to make the Payments by the due date of the Payments. Parties shall reasonably cooperate in accordance with Applicable Law to minimize indirect Taxes (such as VAT, sales tax, consumption tax and other similar taxes) in connection with this Agreement.

5.7 Interest on Late Payments. Except as expressly set forth herein, if any payment due to Licensor under this Agreement is not paid within sixty (60) days after the due date, then, in addition to any other rights and remedies available to Licensor under this Agreement, Licensee shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of the lesser of (a) three percent (3%) above the prime rate, as published in *The Wall Street Journal*, Eastern Edition, as adjusted from time to time on the first Business Day of each month or (b) the highest rate permitted under Applicable Law, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest. Any such interest payment that is itself such to withholding tax or VAT shall be subject to the provisions of Section 5.6 (Taxes).

5.8 Financial Records. Licensee shall, and shall cause its Affiliates and its and their Sublicensees, their distributors and other subcontractors, to keep complete and accurate financial books and records pertaining to the Development and Commercialization of Licensed Product hereunder, including books and records of Invoiced Sales

and Net Sales of Licensed Product, in sufficient detail to calculate and verify all amounts payable hereunder. Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, retain such books and records until the later of (a) 5 (five) years after the end of the period to which such books and records pertain, (b) the expiration of the applicable tax statute of limitations (or any extensions thereof) and (c) for such period as may be required by Applicable Law.

5.9 Audit. At the request of Licensor, Licensee shall and shall cause its Affiliates to permit Licensor or an independent auditor designated by Licensor and reasonably acceptable to Licensee, during regular business hours and upon at least fifteen (15) days prior written notice, no more than once during any Calendar Year unless required to investigate specific issues or follow up on a remediation action, to audit the books and records maintained pursuant to Section 5.8 (Financial Records), to ensure the accuracy of all reports and payments made hereunder. Except as provided below, the cost of this audit shall be borne by Licensor, unless the audit reveals, with respect to a period, a variance of more than five percent (5%) from the reported amounts for such period, in which case Licensee shall bear the cost of the audit. If such audit concludes that (i) additional amounts were owed by Licensee, Licensee shall pay the additional amounts with interest from the date originally due as provided in Section 5.7 (Interest on Late Payments) or (ii) excess payments were made by Licensee to Licensor, Licensor shall reimburse such excess payments (without interest), in either case ((i) or (ii)), within thirty (30) days after the date on which such audit is completed by Licensor.

5.10 Audit Dispute. In the event of a dispute with respect to any audit under Section 5.9 (Audit), Licensor and Licensee shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within sixty (60) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each such Persons' certified public accountants or to such other Person as such Persons shall mutually agree ("**Auditor**"). The decision of the Auditor shall be final and the costs of such audit as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than thirty (30) days after such decision and in accordance with such decision, Licensee shall pay the additional amounts or Licensor shall reimburse the excess payments without interest, as applicable.

## 6. INTELLECTUAL PROPERTY

### 6.1 Ownership.

- a) **Pre-Existing Intellectual Property**. Each Party shall own and retain all right, title and interest in and to any and all know-how and other inventions that are conceived, discovered, developed, authored or otherwise made by or on behalf of such Party or its Affiliates or its or their (sub)licensees (or Sublicensee(s)), as applicable), prior to the Effective Date or pursuant to activities outside the scope of this Agreement, whether or not patented or patentable, and any and all Patents and other intellectual property rights with respect thereto.
- b) **Improvements**. Licensee will promptly disclose all Improvements to Licensor. Licensor shall own all right, title and interest in and to any and all Improvements that are conceived, discovered, developed, authored or otherwise made by or on behalf of either Party or its Affiliates or its or their (sub)licensees (or Sublicensee(s)), as applicable) in the Development or Commercialization of Licensed Product under this Agreement. Licensee hereby assigns and agrees to assign all such Improvements to Licensor. Licensee shall cause all Persons who perform Development or Commercialization activities for Licensee under this Agreement or who conceive, discover, develop, author or otherwise make any applicable Improvement on behalf of Licensee or its Affiliates or its or their Sublicensees under or in connection with this Agreement to be under an obligation to assign their rights in any applicable Improvement and inventions resulting therefrom, and any Patent or intellectual property rights with respect thereto, to Licensee. In the case where Applicable Law prohibits assignment of such Improvements to Licensor, Licensee shall secure for the Licensor a suitable license or right to obtain or negotiate such a license, with Control, for such Improvements on terms as closely paralleling assignment as is possible in the circumstances.

- c) **Right to Exploit Improvements.** Licensor hereby grants a perpetual non-exclusive royalty-free license to Licensee to Exploit any and all Improvements contemplated under Section 6.1(b) in the Territory in the Field.
- d) **Ownership of Development Data.** Subject to the licenses granted under Article 2 (GRANT OF RIGHTS) or Section 10.3 (Consequences of Termination), as between the Parties, Licensee shall own the Licensee Development Data and Licensor shall own the Licensor Development Data.

## 6.2 Maintenance and Prosecution of Patents.

- a) **In General.** Licensor shall have the sole right, but not the obligation, through counsel of its choice at its discretion, to prepare and file the Licensed Patents (and Licensor will coordinate any such preparation and filing in the Territory with Licensee), and the first right, but not the obligation, through counsel of its choice at its discretion, to prepare, file, prosecute and maintain Patents covering any Improvement, including any related invalidation, appeals of invalidation, interference, re-issuance, re-examination, patent term extension and opposition proceedings with respect thereto. Licensor shall periodically inform Licensee of all material actions with regard to the preparation, filing, prosecution and maintenance of the Licensed Patents in the Territory, as applicable, including by providing Licensee with a copy of material communications to and from any applicable patent authority regarding such Patents and by providing Licensee drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Licensee to review and comment thereon. Licensor shall consider in good faith the requests and suggestions of Licensee with respect to such drafts and with respect to strategies for filing and prosecuting such Patents, including taking into consideration the commercial strategy of Licensee in the Territory.
- b) **Co-operation.** Licensee shall, and shall cause its Affiliates to, assist and co-operate with Licensor, as Licensor may reasonably request from time to time, in the preparation, filing, prosecution and maintenance of the Licensed Patents in the Territory and Patents covering any Improvements worldwide under this Agreement, including by providing access to relevant documents and other evidence and making any inventors available at reasonable business hours, provided that Licensor shall reimburse the Licensee for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Licensee will sign, or will use reasonable efforts to have signed, all legal documents as are reasonably necessary to prosecute and maintain Licensed Patents and Patents covering Improvements in accordance with this Section 6.2 (Maintenance and Prosecution of Patents).
- c) **Patent Term Extension and Supplementary Protection Certificate.** The Parties shall jointly make decisions regarding the application for patent term extensions, or any other extensions that are now or become available in the future, in the Territory, for the Licensed Patents with respect to the Licensed Compound and the Licensed Product, and in each case including whether or not to do so. Licensee shall have primary responsibility to notify Licensor and ensure Licensor is informed of any deadlines for filing such patent term extension application, or other extension application, which are dependent on the timing of the receipt of the Drug Regulatory Certificate or other regulatory process under the Control of Licensee. Licensee shall provide prompt and reasonable assistance, as requested by Licensor, for action as is required under any Applicable Law to obtain such extensions or supplementary protection certificates. Parties shall determine under Applicable Law in who's name to file such a mutually agreed patent term extension or supplementary protection certificate or equivalent thereof, and each Party shall promptly provide assistance to the other Party to enable such filing.

## 6.3 Enforcement.

- a) **Notice.** Each Party shall promptly disclose to the other in writing within ten (10) Business Days, any actual, alleged, or threatened Third Party infringement or misappropriation in the Territory of

any Licensed Patent and any actual, alleged or threatened infringement or passing off of a Licensor Mark (“**Infringement**”), of which such Party becomes aware.

- b) **Enforcement of Patents.** Licensor shall have the first right, but not the obligation, to respond to any Infringement of a Licensed Patent, a Licensor Mark or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods, or like offenses in the Territory relating to the Licensed Product. If Licensor elects to respond to any Infringement by initiating a proceeding, Licensor shall use legal counsel of its choice at its expense and shall have full control over the conduct of such proceeding. Licensor may settle or compromise any such proceeding without the consent of Licensee; provided, however, that if such settlement affects Licensee’s rights under this Agreement, or Licensee’s ability to Commercialize the Licensed Product within the Territory, or otherwise requires Licensee to admit wrongdoing, fault, or liability, Licensor will not settle or compromise any such proceeding without the consent of Licensee, such consent not to be unreasonably withheld, conditioned, or delayed. If Licensor elects not to respond to any Infringement of a Licensed Patent, a Licensor Mark or of any unfair trade practices, trade dress imitation, passing off of counterfeit goods, or like offenses in the Territory relating to the Licensed Product, then Licensee shall have the right, but not the obligation, to take action, at its sole expense, in which case Licensee shall have full control over the conduct of such proceeding and Licensee may settle or compromise any such proceeding without the consent of Licensor; provided, however, that if such settlement affects Licensor’s intellectual property rights or its rights under this Agreement, or Licensor’s ability to Commercialize the Licensed Product outside the Territory, outside the Field, or otherwise requires Licensor to admit wrongdoing, fault, or liability, Licensee will not settle or compromise any such proceeding without the consent of Licensor, such consent not to be unreasonably withheld, conditioned, or delayed. Licensee shall be solely responsible for any legal costs or damages awards made in any proceeding that is initiated by Licensee.
- c) **Co-operation.** The non-enforcing Party agrees to co-operate fully in any Infringement action pursuant to this Section 6.3 (Enforcement), including by making the inventors, applicable records and documents (including laboratory notebooks) with respect to the relevant Patents available to the enforcing Party on the enforcing Party’s reasonable request. With respect to an action controlled by the applicable enforcing Party, the other Party shall, and shall cause its Affiliates to, assist and co-operate with the enforcing Party, as the enforcing Party may reasonably request from time to time, in connection with its activities set forth in this Section 6.3 (Enforcement), including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that the enforcing Party shall reimburse such other Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith.
- d) **Recovery.** Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recovery realized as a result of such litigation described above in this Section 6.3 (Enforcement) (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses incurred with respect to such litigation (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the enforcing Party; provided that to the extent that any award or settlement (whether by judgment or otherwise) with respect to a Licensed Patent is attributable to loss of sales or profits with respect to a Licensed Product in the Field in the Territory, any amount that may be obtained by Licensee shall be considered Net Sales and subject to the royalty obligations under Section 5.3 (Royalties).

6.4 Invalidity or Unenforceability Defenses or Actions. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patents by a Third Party and of which such Party becomes aware. Licensor shall have the first right, but not the obligation, to



defend and control the defense of the validity and enforceability of any Licensed Patent, at its sole cost and expense, using counsel of Licensor's choice, including when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action. For purposes of this Section 6.4 (Invalidity or Unenforceability Defenses or Actions), the Party defending and controlling the defense of the validity and enforceability pursuant to the foregoing sentence with respect to a Patent shall be the "**Defending Party**." The non-Defending Party may participate in such claim, suit or proceeding with counsel of its choice at its sole cost and expense; provided that the Defending Party shall retain control of the defense in such claim, suit or proceeding. If the Defending Party elects not to defend the applicable Patents in a suit, then the Defending Party shall promptly notify the non-Defending Party of such election and the non-Defending Party may assume control of the defense of any such claim, suit or proceeding at its sole cost and expense. The non-Defending Party in such an action shall, and shall cause its Affiliates to, assist and co-operate with the Defending Party, as such Defending Party may reasonably request from time to time, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided that the Defending Party shall reimburse the non-Defending Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith.

6.5 Infringement Claims by Third Parties. If the Exploitation of a Licensed Product in the Field in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party against Licensee or any of its Affiliates or Sublicensees alleging infringement by Licensee or any of its Affiliates or its or their Sublicensees, distributors or customers of a patent right, know-how right or trademark owned by such Third Party, ("**Third Party Infringement Claim**"), including any defense or counterclaim in connection with an Infringement action initiated pursuant to Section 6.3 (Enforcement), the Party first becoming aware of such alleged infringement shall promptly notify the other Party thereof in writing. As between the Parties, subject to Article 9 (INDEMNITY), Licensor shall have the first responsibility for defending any such claim, suit or proceeding at its sole cost and expense, using counsel of Licensor's choice. Should Licensor fail to take suitably responsive action within 90 (ninety) days of the filing of a Third Party Infringement Claim in a court of putative jurisdiction, Licensee may assume control of responding to the Third Party Infringement Claim. The Parties shall co-operate fully regardless of which of them controls the action. If any damages, or award, including but not limited to royalties and legal fees, are incurred or awarded in connection with any Third Party Infringement Claim ("**Settlement Costs**"), the Parties agree to share such costs equally, upon presentation of reasonably detailed accounts and the legal basis for such Settlement Costs to the other Party. If Licensor is responsible for payment of Settlement Costs to the Third Party, Licensee shall add 50% of the Settlement Costs to payments made to Licensor by Licensee under Section 5.2 or 5.3, upon receipt of evidence of actual payment by Licensor to the Third Party. If Licensee is responsible for payment of the Settlement Costs to the Third Party, Licensee shall deduct 50% of the Settlement Cost from payments made to Licensor by Licensee under Section 5.2 or 5.3, upon evidence of actual payment by Licensee to the Third Party. Additional payment or deduction by Licensee in regards to Settlement Costs shall terminate when the Licensor's 50% portion of the Settlement Costs has been paid by Licensee.

6.6 Trademarks.

- a) **Trademark Development.** Licensor shall notify Licensee when it has commenced global development of trademark(s) applicable to the Licensed Product. Licensor shall provide Licensee with an opportunity to review and comment on the development of trademarks suitable for the Territory. Trademarks approved for use with otenaproxesul (ATB-346) by Licensor shall be deemed Licensor Marks.
- b) **Trademark License.** Licensor hereby grants to Licensee, for the Term, an exclusive authorized use license to the Licensor Marks in the Field in the Territory in association with the Licensed Product. All use of the Licensor Marks by Licensee, including goodwill, and rights to sue for past infringement, will inure to the benefit of Licensor.

c) **Ownership.** Licensee acknowledges that the Licensor Marks are owned by Licensor. The Licensor Marks shall be and remain the sole and exclusive property of Licensor. Licensee shall not contest the ownership of the Licensor Marks or the validity of any registration relating thereto. Licensee agrees, at the request of Licensor, to execute any and all proper documents appropriate to assist Licensor in obtaining and maintaining Licensor's rights in and to the Licensor Marks.

d) **Use of Marks.** Licensed Product distributed by Licensee under this Agreement shall bear the Licensor Marks together with a notice that the Licensor Marks are used under authorized license from Licensor, subject to the approval of such labeling by appropriate Governmental Authorities. Licensee shall submit to Licensor, for prior approval, which shall not be unreasonably withheld, a representative sample of any marketing, promotional or other materials to be used by Licensee, bearing the Licensor Marks. Licensor will communicate to Licensee its approval or disapproval within fifteen (15) Business Days of receipt of such sample. Upon Licensor's request, Licensee will immediately cease use of any unapproved trademarks. In the event Licensor modifies or changes any Licensor Marks, Licensee will use Commercially Reasonable Efforts to promptly institute such modifications or changes as requested by Licensor.

e) **No Similar Mark.** Licensee will not, without Licensor's prior written consent, register or use in connection with any product or service, any trademark that is confusingly similar to the Licensor Marks, as determined by the Licensor.

## 7. CONFIDENTIALITY AND NON-DISCLOSURE

7.1 **Confidentiality Obligations.** Each Party shall, and shall cause its Affiliates and its and their respective officers, directors, employees and agents (collectively, "**Representatives**") to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. "**Confidential Information**" means any technical, business or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, on or after the Effective Date, including the terms of this Agreement, information relating to the Licensed Compound or any Licensed Product (including any clinical data and Regulatory Documentation), any Know-How relating to the Development or Commercialization of the Licensed Compound or any Licensed Product developed by or on behalf of the disclosing Party or its Affiliates or the scientific, regulatory or business affairs or other activities of either Party. Confidential Information further includes any information of the disclosing Party that, as of the Effective Date, is considered "Confidential Information" under that certain Non-Disclosure Agreement by and between the Parties dated October 15, 2020 ("**Prior CDA**"). Notwithstanding the foregoing, Confidential Information does not include any information that the receiving Party can show by competent evidence:

- a) is or hereafter becomes part of the public domain or publicly known by public use, publication, general knowledge or the like through no breach of the Prior CDA or this Agreement by the receiving Party or any of its Representatives;
- b) can be demonstrated by documentation to have been in the receiving Party's or any of its Affiliates' possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;
- c) is subsequently received by the receiving Party or any of its Affiliates from a Third Party who is not bound by any obligation of confidentiality with respect to such information; or
- d) was independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information as shown by contemporaneous documentation.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party.

7.2 Permitted Disclosures. Notwithstanding the foregoing, each Party may disclose Confidential Information to the extent that such disclosure is:

- a) made in response to a valid order of a court of competent jurisdiction or other Governmental Authority or Regulatory Authority of competent jurisdiction or if such disclosure is otherwise required by Applicable Law or the rules of a securities exchange on which the securities of the disclosing Party or any of its Affiliates are listed (or to which an application for listing has been submitted), including by reason of filing with securities regulators or any securities exchange; provided, however, that, to the extent permitted under Applicable Law, the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to obtain a protective order or other remedy; and provided, further, that the Confidential Information disclosed in response to such court or Governmental Authority order or as required by Applicable Law shall be limited to that information which is legally required to be disclosed in response to such court or Governmental Authority order, as advised by outside counsel;
- b) made by or on behalf of the receiving Party, its Affiliates or (sub)licensees or Sublicensees, as applicable, to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval to the extent consistent with this Agreement; provided, however, that reasonable measures must be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;
- c) made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining, enforcing or defending a Patent in accordance with this Agreement; or
- d) made by or on behalf of the receiving Party to any of its Representatives or (ii) made by or on behalf of the receiving Party or any of its Affiliates to any of its or their potential or actual investors, acquirers, lenders, licensors, (sub)licensees or contractors as may be necessary in connection with their evaluation of, exercise of rights under or performance under such potential or actual investment, acquisition or applicable transaction; provided, however, that, in each case of (i) and (ii), such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information no less protective than the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 7 (CONFIDENTIALITY AND NON-DISCLOSURE) (provided, however, that, solely with respect to the individuals and entities described in clause (ii), the duration of confidentiality and non-use obligations need not exceed ten (10) years from the date of disclosure). Each Party shall be responsible for any breach of this Agreement by any Person to which Confidential Information of the other Party has been disclosed by or on behalf of such Party pursuant to this Section 7.2(d).

7.3 Publications. If Licensee, any of its Affiliates or any Sublicensee plans to publish or present the results of any studies regarding the Licensed Compound or Licensed Product conducted by Licensee, any of its Affiliates or any Sublicensee in the Territory, Licensee shall submit the draft of the publication to Licensor no later than sixty (60) days prior to the planned submission for publication for approval. Licensor shall have the right (a) to require modifications to the publication or presentation for patentability reasons or for the protection of Licensor's Confidential Information, and Licensee will remove all of Licensor's Confidential Information if requested by Licensor, and (b) to require a reasonable delay in publication or presentation in order to protect patentable information. If Licensor requests a delay, then Licensee shall, and shall ensure that its Affiliate(s) or the Sublicensee(s) shall, delay submission or presentation for an additional period of sixty (60) days (or such shorter period as may be mutually agreed by the Parties) to enable Licensor to file patent applications protecting Licensor's rights in such information. Licensor shall be named in the publication as required by academic standards.

7.4 Return of Confidential Information. Upon the effective date of the expiration or termination of this Agreement for any reason, the receiving Party will (a) promptly destroy all copies of Confidential Information in



its possession or control and confirm such destruction in writing to the requesting Party or (b) promptly deliver to the disclosing Party, at the disclosing Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the receiving Party. Notwithstanding the foregoing, the receiving Party (i) may retain such Confidential Information to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes and (ii) will not be required to delete electronic copies of Confidential Information that have been created solely by the receiving Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the receiving Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information retained under this Section 7.4 (Return of Confidential Information) shall continue to be subject to the terms of this Agreement for the period set forth in Section 7.5 (Confidentiality Survival).

7.5 Confidentiality Survival. The provisions of this Article 7 will survive the termination of this Agreement for a period of five (5) years.

## 8. REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Mutual Representations and Warranties. Licensor and Licensee each represents, warrants and covenants to the other that:

- a) It is a corporation or other entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform under this Agreement;
- b) The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action;
- c) This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);
- d) It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder; and
- e) Neither it nor any of its Affiliates has been debarred or is subject to debarment, and neither it nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred, in each case pursuant to Section 306 of the FDC Act (or any equivalent provision under Applicable Law) or who is the subject of a conviction described in such section or provision. It will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FDC Act (or any equivalent provision under Applicable Law) or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.

8.2 Additional Representations and Warranties of Licensor. Licensor further represents and warrants to Licensee, as of the Effective Date, that:

- a) Licensor and its Affiliates Control the Existing Patents and have the right to grant the licenses and sublicenses specified herein;
- b) Licensor has neither granted nor agreed to grant, whether or not contingent on future events or notices, any other licenses to the Existing Patents for the Field in the Territory

- c) Licensor has not received any written or, to Licensor's Knowledge, oral claim or demand alleging that (i) the issued patents within the Existing Patents are invalid or unenforceable or (ii) the Development or Commercialization of the Licensed Product as contemplated herein infringes any Patent owned by any Third Party in the Territory or (iii) any actions, suits, claims, disputes, or proceedings concerning the Existing Patents or the Licensed Products are currently pending or are threatened; and
- d) to Licensor's Knowledge, no Person is infringing or threatening to infringe the Existing Patents in the Field in the Territory.

### 8.3 Covenants of Licensor.

- a) Licensor will not modify, amend, or terminate the Holdings License Agreement in a manner that is materially adverse to Licensee, acknowledging that Licensor may amalgamate with Holdings to acquire ownership of Existing Patents. All rights granted to Licensee, its Affiliates and permitted Sublicensees under this Agreement will continue unaffected pursuant to such amalgamation.

### 8.4 Representations, Warranties, and Covenants of Licensee. Licensee represents, warrants, and covenants to Licensor that as of the Effective Date:

- a) there are no legal or administrative claims or actions brought by any private party or Governmental Authority, nor judgments or settlements against Licensee, its officers, directors, employees, or Affiliates, nor to Licensee's Knowledge, are any such legal or administrative claims or actions threatened, by any private party nor Governmental Authority, in each case, relating to antitrust, anti-competition, anti-bribery, sanctions under Applicable Law, or corruption violation, whether or not reportable in the US under the Foreign Corrupt Practices Act (FCPA); nor violations of any law or rule relating to health care compliance (including medical and scientific compliance).
- b) Licensee has not suffered a significant breach of data integrity in the previous 5 (five) years;
- c) Licensee has sufficient financial wherewithal to (i) perform all of its obligations pursuant to this Agreement, and (ii) meet all of its obligations that come due in the ordinary course of business;
- d) Licensee has, or will obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, Commercialization, and obtaining Regulatory Approvals; and
- e) Licensee will, and will cause its Affiliates and Sublicensees to, be bound by and comply with all obligations required of sub-licensees under this Agreement and under the Holdings License Agreement.

8.5 DISCLAIMER OF WARRANTIES. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE LICENSED PRODUCTS OR ANY TECHNOLOGY OR ANY LICENSE GRANTED BY EITHER PARTY HEREUNDER. LICENSOR DOES NOT WARRANT NOR REPRESENT THAT ANY OF THE LICENSOR PATENTS ARE VALID OR ENFORCEABLE.

## 9. INDEMNITY

9.1 Indemnification by Licensee. Licensee shall indemnify Licensor, its Affiliates, and its and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "Third Party Claims") to the extent arising from or occurring as a result of:

- a) the breach by Licensee of this Agreement;
- b) the gross negligence or willful misconduct on the part of Licensee or its Affiliates or its or their Sublicensees or its or their distributors or contractors or its or their respective directors, officers, employees or agents in performing its or their obligations under this Agreement; or
- c) the Exploitation by Licensee or any of its Affiliates or its or their Sublicensees or its or their distributors or contractors of any Licensed Product or the Licensed Compound in or for the Territory,

except, in each case, for those Losses for which Licensor has an obligation to indemnify Licensee pursuant to Section 9.2 (Indemnification by Licensor).

9.2 Indemnification by Licensor. Licensor shall indemnify Licensee, its Affiliates and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims to the extent arising from or occurring as a result of:

- a) the breach by Licensor of this Agreement;
- b) the negligence or willful misconduct on the part of Licensor or its Affiliates or its or their respective directors, officers, employees or agents in performing its obligations under this Agreement; or
- c) the Exploitation by Licensor or any of its Affiliates or its or their sublicensees or its or their distributors or contractors of the Licensed Compound or Licensed Product outside the Territory;

except, in each case, for those Losses for which Licensee has an obligation to indemnify Licensor pursuant to Section 9.1 (Indemnification by Licensee).

9.3 Indemnification Procedures.

- a) **Notice of Claim.** All indemnification claims in respect of a Party, its Affiliates or its or their Sublicensees (or (sub)licensees) or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (“**Indemnified Party**”). The Indemnified Party shall give the other Party (“**Indemnifying Party**”) a prompt written notice (“**Indemnification Claim Notice**”) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 9 (INDEMNITY), but in no event shall the Indemnifying Party be liable for any Losses to the extent that such Losses result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the Third Party Claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time).
- b) **Control of Defense.** The Indemnifying Party shall have the right to assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party’s receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party’s claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Any Indemnified Party shall be entitled to participate in the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided that such employment shall be at the Indemnified Party’s sole cost and expense unless the Indemnifying Party has failed to assume the defense in accordance with Section 9.3(b) (Control of Defense), in which case the Indemnified Party shall control the defense. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all reasonable and verifiable out-of-pocket costs and expenses (including attorneys’ fees and costs of suit)

incurred by the Indemnifying Party in accordance with this Article 9 (INDEMNITY) in its defense of the Third Party Claim.

- c) **Settlement.** With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim that shall not result in the applicable indemnitee(s) becoming subject to injunctive or other relief or otherwise adversely affect the business or interests of the Indemnified Party in any manner and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the applicable indemnitee hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.3(b) (Control of Defense), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss only with the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the Indemnified Party controls the defense of a Third Party Claim, the Indemnified Party may not settle any Third Party Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).
- d) **Co-operation.** If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall and shall cause each indemnitee to, co-operate in the defense or prosecution thereof and furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested by the Indemnifying Party in connection therewith. Such co-operation shall include access during normal business hours afforded to the Indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making the Indemnified Party, the indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the Indemnifying Party shall reimburse the Indemnified Party for all of its, its Affiliates' and its and their (sub)licensees' or their respective directors', officers', employees' and agents', as applicable, reasonable and verifiable out-of-pocket expenses in connection therewith.

9.4 Limitation of Liability. (a) EXCEPT IN THE EVENT OF THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY, OR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER SECTION 2.7 (NON-COMPETE) OR ARTICLE 7 (CONFIDENTIALITY AND NON-DISCLOSURE), AND (b) WITHOUT LIMITING A PARTY'S OBLIGATIONS UNDER SECTIONS 9.1 (INDEMNIFICATION BY LICENSEE) AND 9.2 (INDEMNIFICATION BY LICENSOR), NEITHER PARTY NOR ANY OF ITS AFFILIATES OR (SUB)LICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, CONSEQUENTIAL, MULTIPLE, INDIRECT, INCIDENTAL OR PUNITIVE DAMAGES OR FOR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

9.5 Insurance. The Parties shall maintain insurance, including product liability insurance, that is adequate to cover their obligations hereunder and that is consistent with normal business practices of prudent corporations engaged in the same or a similar business. The Parties acknowledge and agree that such insurance shall not be construed to create a limit with respect to their indemnification obligations.

## 10. TERM AND TERMINATION

10.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until 15 (fifteen) years from the date of the First Commercial Sale of Licensed Product in the last to approve Jurisdiction in the Territory (such period, the "Term").

## 10.2 Termination.

- a) **Termination for Convenience.** This Agreement may be terminated in its entirety at any time by Licensee effective upon at least ninety (90) days' prior written notice to Licensor for any reason. This Agreement may also be terminated by mutual written agreement of the Parties.
- b) **Material Breach.** In the event that either Party (the "**Breaching Party**") shall be in material breach in the performance of any of its obligations under this Agreement, in addition to any other right and remedy the other Party (the "**Non-Breaching Party**") may have, the Non-Breaching Party may terminate this Agreement by providing thirty (30) days (including a payment breach) (the "**Notice Period**") prior written notice (the "**Termination Notice**") to the Breaching Party and specifying the breach and its claim of right to terminate; *provided, however*, that (a) the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period; and (b) for any breach other than a payment breach, if such breach cannot be cured within the Notice Period, then, if the Breaching Party commences actions satisfactory to the Non-Breaching Party to cure such breach within the Notice Period and thereafter diligently continues such actions, the Breaching Party shall have an additional sixty (60) days after the end of the Notice Period to cure such breach (and, if the Breaching Party does not cure such breach by the end of such additional 60-day period, the termination shall become effective at the end of such additional 60-day period).
- c) **Material Breach for Licensee Failure of Commercially Reasonable Efforts in one or more Jurisdiction(s) of the Territory but not the entire Territory.** In the event that Licensee has not achieved Commercially Reasonable Efforts to Develop or Commercialize a Licensed Product in one or more Jurisdiction(s) of the Territory (a "**Failed Jurisdiction**"), but has not so failed in the whole Territory, Licensor may in its sole discretion terminate this Agreement with respect to the Failed Jurisdiction upon following the notification and cure periods set out in 10.2(b). The Termination Notice in this instance shall pertain to the Failure Jurisdiction only, and the consequences shall be as set out in Section 10.3 insofar as required to be adapted to the Failure Jurisdiction only, unless otherwise negotiated by the Parties.
- d) **Termination for Nonpayment.** Notwithstanding Section 10.2(b) (Material Breach), if Licensee fails to pay Licensor the upfront payment set forth in Section 5.1 (Upfront Payment) within the time period set out therein, the Licensor may terminate this Agreement immediately.
- e) **Termination for Insolvency.** In the event that either Party: (i) files for protection under bankruptcy or insolvency laws, (ii) makes an assignment for the benefit of creditors, (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within sixty (60) days after such filing, (iv) proposes a written agreement of composition or extension of its debts, (v) proposes or is a party to any dissolution or liquidation of such Party, (vi) voluntarily files a petition, or has any petition filed against it, under any bankruptcy or insolvency law that is not discharged within sixty (60) days of the filing thereof, or (vii) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

## 10.3 Consequences of Termination. Upon termination of this Agreement, as applicable,

- a) Licensee shall immediately inform Licensor of the units of Licensed Product or other Otenaproxesul Materials held by or on behalf of Licensee, any of its Affiliates or its or their Sublicensees, and the status of each unit of such Licensed Product or other Otenaproxesul Materials (including its remaining shelf-life and its compliance with GMP) ("**Remaining Product**"). For the Remaining Product, Licensee shall have a sell-off period of 6 (six) months from the effective date of termination ("**Sell-Off Period**") to dispose of the Remaining Product, with the applicable royalty and milestone obligations applicable to the resulting Net Sales.



- b) all rights and licenses granted by Licensor hereunder shall immediately terminate, including, for clarity, any sublicense granted by Licensee pursuant to Section 2.3 (Sublicenses), except for the rights necessary to dispose of the Remaining Product during the Sell-Off Period;
- c) Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, when and as requested by Licensor, assign to Licensor all of its right, title and interest in and to the Drug Registration Certificate and all Regulatory Documentation (including any Regulatory Approvals) applicable to any Licensed Compound or Licensed Product then owned or Controlled by Licensee or any of its Affiliates or Sublicensees; provided that if any such Drug Registration Certificate, Regulatory Documentation or Regulatory Approval is not immediately transferable in a Jurisdiction, Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, provide Licensor with all benefit of such Drug Registration Certificate, Regulatory Documentation or Regulatory Approval, as applicable, and such assistance and co-operation as necessary or reasonably requested by Licensor to timely transfer such Drug Registration Certificate, Regulatory Documentation or Regulatory Approval, as applicable, to Licensor or its designee or, at Licensor's option, to enable Licensor to obtain a substitute for such Drug Registration Certificate, Regulatory Documentation or Regulatory Approval, as applicable, or providing Licensor with a "right of reference" (as that term is defined in US 21 C.F.R. § 314.3(b), and any corresponding provision of the Drug Administration Law (DAL) of China) to support Licensor's use of and reliance on such Drug Registration Certificate, Regulatory Documentation or Regulatory Approval without disruption to Licensor's Exploitation of the Licensed Compound or applicable Licensed Product(s);
- d) The rights granted to Licensor under Sections 2.2 and 2.4 to Licensee Development Data shall continue in effect, and if necessary, Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, effective as of the effective date of termination, grant Licensor, an non-exclusive, royalty-free license, with the right to grant multiple tiers of sublicenses, in and to the Licensee Development Data to Exploit any Licensed Compound, Licensed Product or any product containing any Licensed Compound anywhere in the world, in any field;
- e) unless expressly prohibited by any Regulatory Authority, at Licensor's written request, Licensee shall, and shall cause its Affiliates and its and their Sublicensees to: (i) if Licensor notifies Licensee of its intent to assume control of ongoing clinical studies, transfer control to Licensor of any or all clinical studies involving Licensed Product being conducted by or on behalf of Licensee, an Affiliate or a Sublicensee as of the effective date of termination and (ii) if Licensor does not notify Licensee of any intent to assume control of ongoing clinical studies within thirty (30) days after the effective date of termination, promptly wind down such studies in accordance with Applicable Law; and
- f) Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, promptly provide a copy to Licensor of all Licensed Product Agreements, and, to the extent requested by Licensor in writing, assign to Licensor any Licensed Product Agreement, unless, with respect to any such Licensed Product Agreement, such Licensed Product Agreement expressly prohibits such assignment, in which case Licensee (or such Affiliate or Sublicensee, as applicable) shall cooperate with Licensor in all reasonable respects to secure the consent of the applicable Third Party to such assignment, at Licensee's expense, and if any such consent cannot be obtained with respect to a Licensed Product Agreement, Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, to the extent requested by Licensor in writing, obtain for Licensor substantially all of the practical benefit and burden under such Licensed Product Agreement, including by: (i) entering into appropriate and reasonable alternative arrangements on terms agreeable to Licensor, and (ii) subject to the consent and control of Licensor, enforcing, at Licensor's cost and expense and for the account of Licensor, any and all rights of Licensee (or such Affiliate or Sublicensee, as applicable) against the other party thereto arising out of the breach or cancellation thereof by such other party or otherwise.

10.4 Remedies. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

10.5 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Sections 1, 2.2, 2.4(b), 2.9, 3.1(c), 3.1(d), 3.2(c), 3.3(d), 5.4 to 5.10, 6.1, 6.2(b), 6.6(c), 7, 8.5, 9, 10 and 11 of this Agreement shall survive the termination or expiration of this Agreement for any reason.

## 11. MISCELLANEOUS

11.1 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their (sub)licensees (or Sublicensees) (or any abbreviation or adaptation thereof) in any publication, press release, marketing or promotional material or other form of publicity without the prior written approval of such other Party. The restrictions imposed by this Section 11.1 (Use of Name) shall not prohibit (a) either Party from making any disclosure identifying the other Party to the extent required in connection with its exercise of its rights or obligations under this Agreement or (b) either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a securities exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). Notwithstanding the above, solely following the issuance of the initial press releases described in Section 11.2 (Public Announcements), each Party and its Affiliates may disclose on its website and in its promotional materials that the other Party is a development partner of such Party and may utilize the other Party's name and logo in conjunction with such disclosure.

11.2 Public Announcements. Neither Party shall originate any publicity, news release, or public announcements relating to this Agreement (including, without limitation, its existence, its subject matter, the Parties' performance, any amendment hereto, or performance hereunder), whether to the public or press, stockholders, or otherwise, without the prior written consent of the other Party, save only such announcements that are required by law or the rules of any relevant stock exchange to be made or that are otherwise agreed to by the Parties. If a Party decides to make an announcement, whether required by law or otherwise, it shall give the other Party reasonable notice of the text of the announcement so that the other Party shall have an opportunity to comment upon the announcement. To the extent that such other Party reasonably requests the deletion of any information in any such announcement, the announcing Party shall delete such information unless, in the opinion of the announcing Party's legal counsel, such information is required by Applicable Law to be disclosed. The timing and content of the initial press release relating to this Agreement, if any, including its existence, the subject matter to which it relates and the transactions contemplated herein will, except as otherwise required by Applicable Law, be determined jointly by the Parties. To the extent that either Party reasonably determines that it is required to make a filing or any other public disclosure with respect to this Agreement or the terms or existence hereof to comply with Applicable Law (collectively, "**Disclosure Obligations**"), such Party shall promptly inform the other Party thereof and shall use reasonable efforts to maintain the confidentiality of the other Party's Confidential Information in any such filing or disclosure. Prior to making any such filing of a copy of this Agreement, the Parties shall mutually agree on the provisions of this Agreement for which the Parties shall seek confidential treatment, it being understood that if one Party determines to seek confidential treatment for a provision for which the other Party does not, then the Parties will use reasonable efforts in connection with such filing to seek the confidential treatment of any such provision. The Parties shall cooperate, each at its own expense, in such filing, including without limitation such confidential treatment request, and shall execute all documents reasonably required in connection therewith. The Parties will reasonably cooperate in responding promptly to any comments received from the applicable Regulatory Authority with respect to such filing in an effort to achieve confidential treatment of such redacted form; provided that a Party shall be relieved of such obligation to seek confidential treatment for a provision requested by the other Party if such treatment is not achieved after the second round of responses to comments from the applicable Governmental Authority.

11.3 Force Majeure. No Party shall be responsible for a failure or delay in performance of any of the obligations hereunder due to wars, insurrections, strikes, acts of God, power outages, storms, or actions of regulatory agencies (such events being defined as “**Force Majeure**”), provided that the Party seeking relief from its obligations advises the other Party forthwith of the Force Majeure. A Party whose performance of obligations has been delayed by force majeure shall use Commercially Reasonable Efforts to overcome the effect of the Force Majeure as soon as possible. The Parties hereby agree that the COVID-19 pandemic does not constitute a Force Majeure under this Section. The other Party will have no right to demand indemnity for damage or assert a breach against such Party, provided, however, that if the event of Force Majeure preventing performance shall continue for more than six (6) months and such underlying cause would not also prevent other parties from performing such obligations, then the Party not subject to the event of Force Majeure may terminate this Agreement with a written notice to the other without any liability hereunder, except the obligation to make payments due to such date.

11.4 Compliance with Law. Each Party agrees to conduct its activities under this Agreement in a manner that is consistent with Applicable Law, including the U.S. Foreign Corrupt Practices Act, the UK Bribery Act 2010, and the relevant provisions of the Criminal Law of the PRC and the Anti-Unfair Competition Law of the PRC, each as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, or money laundering (collectively, “**Anti-Corruption Laws**”). Each Party will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything of value (collectively, “**Prohibited Payment**”) to any Government Official where such Prohibited Payment would constitute a violation of any Anti-Corruption Law. In addition, regardless of legality, each Party will make no Prohibited Payment, directly or indirectly, to any Government Official if such Prohibited Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of the other Party’s business. Each Party acknowledges and agrees that none of it, or any of its Affiliates or its or their respective officers, directors, employees, agents and representatives (collectively, “**Authorized Representatives**”) is authorized to waive compliance with the provisions of this Section 11.4 (Compliance with Law) and that each Party will be solely responsible for its compliance with the provisions of this Section 11.4 (Compliance with Law) and the Anti-Corruption Laws irrespective of any act or omission of the other Party or any of its Affiliates, Sublicensees or its or their respective Authorized Representatives. Each Party’s failure to abide by the provisions of this Section 11.4 (Compliance with Law) shall be deemed a material breach of this Agreement.

11.5 Data Security, Data Protection and Supplier Code of Conduct; Audit Thereof. Licensee agrees to comply with Licensor’s data security, data protection and supply chain code of conduct requirements from time to time implemented by Licensor. At the request of Licensor, Licensee shall and shall cause its Affiliates and its and their Sublicensees to, permit Licensor or an independent auditor designated by Licensor and reasonably acceptable to Licensee, to audit data security controls, data protection and supply chain elements in use by any of them for Licensed Product. Should auditor or any competent authority deem that existing provisions are not sufficient and require additional documentation to be completed, or different standards to be applied, Licensee will do all the necessary acts and complete all necessary documents to put in place such additional documentation and standards.

11.6 Change of Control of Licensee. In the event of a Change of Control of Licensee or a Sublicensee, then such Licensee or Sublicensee and the acquiring Affiliate or Third Party shall provide within ten (10) days, a written assurance to Licensor, signed by duly authorized officers of Licensee or Sublicensee and the acquiring Affiliate or Third Party, as applicable, affirming that the acquiring Affiliate or Third Party, as applicable, will continue Commercially Reasonable Efforts in carrying out its obligations under this Agreement, and reaffirm all other rights, obligations, indemnities, representations, warranties and covenants of Licensee under this Agreement, and provide Licensor with evidence satisfactory to Licensor, of Affiliate or Third Party’s sufficient technical, clinical, and regulatory expertise and financial resources to maintain such Commercially Reasonable Efforts. Any defect in Commercially Reasonable Efforts outstanding by Licensee as of the date of Change of Control shall be attributed to the acquiring Affiliate or Third Party as of such date.

11.7 Assignment. This Agreement may not be, directly or indirectly, assigned or transferred, in whole or in part, by a Party to a Third Party without the prior written consent of the other Party, except that each Party may assign or otherwise transfer this Agreement to an Affiliate, or in connection with a merger or Change of Control of all of



its assets to which this Agreement relates subject to Section 11.7. The rights and obligations contained herein shall inure to the benefit of each Party's successors and permitted assigns, and shall be binding on and enforceable against the relevant Party's successors and permitted assigns. Any reference in this Agreement to any Party shall be construed accordingly.

11.8 Severability. In the event any portion of this Agreement shall be held illegal, void or ineffective, the remaining portion hereof shall remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such statute or rule of law.

11.9 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, USA, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

11.10 Dispute Resolution.

- a) Except as otherwise expressly provided herein, any dispute or claim arising out of or relating to this Agreement (except for any issues relating to the Development of the Products which must first be addressed as described under Section 4.2(b)), or to the breach, termination, or validity of this Agreement, will be resolved as follows: each Party shall discuss the matter and make reasonable efforts to attempt to resolve the dispute. If the Parties are unable to resolve the dispute, a Party may request that the Senior Officer of the Parties meet and attempt to resolve the dispute. Such meeting will occur within thirty (30) days of the written request. If the Senior Officers cannot resolve the dispute through good faith negotiations within sixty (60) days after such meeting, then the Parties will submit the dispute to binding arbitration before a single arbitrator using the arbitration procedures set forth under the international arbitration rules of the Singapore International Arbitration Centre ("SIAC"). Any hearing in the course of the arbitration shall be held in Singapore in the English language. The decision of the arbitrator shall be final and not subject to appeal. The arbitrator may apportion the costs of the arbitration, including the reasonable fees and disbursements of the parties, between or among the parties in such manner as the arbitrator considers reasonable. All matters in relation to the arbitration shall be kept confidential and subject to Article 7 (CONFIDENTIALITY AND NON-DISCLOSURE) to the full extent permitted by law, provided that either Party may disclose any such award or decision to the extent required to enforce such award or decision. No Person shall be appointed as an arbitrator unless he or she agrees in writing to be bound by such confidentiality obligations.
- b) Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 11.8(a) is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement to the extent possible in light of such pending arbitration proceeding.
- c) Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding or the provisions of Section 11.8(a).
- d) Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 11.9 (Notice) (or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with Section 11.9 (Notice) shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

11.11 Notices. Any notice or other communication required or permitted to be given hereunder shall be in writing and shall be given by facsimile or other means of electronic communication or by hand delivery as hereinafter

provided. Any such notice, if sent by fax or other means of electronic communication with delivery confirmation, shall be deemed to have been received on the day of sending, or if delivered by hand shall be deemed to have been received at the time it is delivered to the applicable address noted below. Notices of change of address shall also be governed by this Section 11.9 (Notices). Notices and other communications shall be addressed as follows:

In the case of Licensor:

Antibe Therapeutics Inc.  
15 Prince Arthur Avenue  
Toronto, ON  
M5R 1B2

Attention: Dan Legault  
E-mail: [dan@antibethera.com](mailto:dan@antibethera.com)

with a copy to:

66 Wellington Street West,  
Suite 4100, P.O. Box 35,  
TD Bank Tower,  
Toronto, Ontario,  
M5K 1B7

Attention: Robert Eberschlag  
Fax: +1 416.947.5076  
E-mail: [reberschlag@weirfoulds.com](mailto:reberschlag@weirfoulds.com)

In the case of Licensee:

Nuance Pharma Limited  
Room 639,  
East Tower, Shanghai Centre,  
No.1376 West Nanjing Road,  
Shanghai 200040, PRC

Attention: Mark Gavin Lotter  
E-mail: [mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)

11.12 Entire Agreement; Amendments. This Agreement together with the Clinical Supply Agreement and pharmacovigilance agreement, embodies all of the understandings and obligations between the Parties with respect to the Licensed Product and supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof. Any amendments or supplements to this Agreement shall not be valid unless executed in writing by duly authorized officers of both parties.

11.13 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the original English version shall prevail.

11.14 Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Article 6 (INTELLECTUAL PROPERTY) and Article 7 (CONFIDENTIALITY AND NON-DISCLOSURE) are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered

into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Sections may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Sections, the non-breaching Party shall be authorized and entitled to seek through arbitration or any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity.

11.15 Waiver and Non-Exclusion of Remedies. No failure to exercise and no delay in exercising any right or remedy hereunder shall operate as a waiver thereof. Any waiver granted hereunder shall only be applicable the specific acts covered thereby and shall not apply to any subsequent events, acts, or circumstances. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

11.16 No Benefit to Third Parties. Except as provided in Article 9 (INDEMNITY), covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

11.17 Relationship of the Parties. Each Party shall act as an independent contractor and shall not bind nor attempt to bind the other Party to any contract, nor any performance of obligations outside of the license agreement. Nothing contained or done under the Agreement shall be interpreted as constituting either Party the agent of the other in any sense of the term whatsoever or in the relationship of partners or joint venturers.

11.18 Further Assurances. Upon request by either Party and at such Party's expense, the other Party shall do such further acts and execute such additional agreements and instruments as may be reasonably necessary to give effect to the purposes of this Agreement

11.19 Construction.

- a) Unless otherwise specified, references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto (except to the extent any such amendment, replacement or supplement is not permitted in accordance with the terms thereof).
- b) Except where the context otherwise requires, wherever used, (i) the singular shall include the plural, the plural shall include the singular, (ii) the use of any gender shall be applicable to all genders, (iii) the word "or" is used in the inclusive sense (and/or), (iv) the words "herein", "hereof" and "hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, and (v) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner.
- c) Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.
- d) The captions and table of contents of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement.
- e) The term "including," "include," "includes" or "e.g." as used herein shall mean including, without limiting the generality of any description preceding such term.
- f) References to a "year" or "annual" mean a Calendar Year.
- g) References to an "indication" means, with respect to a product, any use to which such product is intended to be put for the treatment, prevention, mitigation, cure or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of

symptoms associated with a recognized disease or condition, in each case for any size patient population, which, if approved in the U.S., would be reflected in the “Indications and Usage” section of labeling pursuant to 21 C.F.R. §201.57(c)(2) or, to the extent applicable, any comparable labeling section outside the U.S., including any such use that is the subject to a clinical trial.

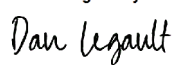
- h) Any reference to any law shall mean such law as in effect as of the relevant time, including all rules and regulations thereunder and any successor law in effect as of the relevant time, and including the then-current amendments thereto.
- i) The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.

11.20 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

*[Signature Page Follows]*

IN WITNESS WHEREOF, the Parties have signed this Agreement.

**ANTIBE THERAPEUTICS INC.**

DocuSigned by:  
By:  \_\_\_\_\_  
F47B5628B08A445...  
Name: Dan Legault  
Title: CEO

**NUANCE PHARMA LIMITED**

DocuSigned by:  
By:  \_\_\_\_\_  
1EF9439CEC52430...  
Name: Mark G. Lotter  
Title: Director

**SCHEDULE 1****EXISTING PATENTS**

<b><u>Jurisdiction</u></b>	<b><u>Application Filing Date</u></b>	<b><u>Application Number</u></b>	<b><u>Grant Date</u></b>	<b><u>Patent Number</u></b>
China	Feb 05, 2009	200780029321.2	Aug 27, 2014	101501018B
Hong Kong	Oct 28, 2009	09109992.0	Mar 21, 2014	HK1131973
United States of America (patent applic. to be filed in CN, HK)	Filing imminent	N/A		

THIS IS **EXHIBIT "C"** REFERRED TO IN THE  
AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

---

SIDNEY BREJAK  
Commissioner for Taking Affidavits

**AT THE SINGAPORE INTERNATIONAL ARBITRATION CENTRE**

**IN THE MATTER OF AN ARBITRATION UNDER THE ARBITRATION  
RULES OF THE SINGAPORE INTERNATIONAL ARBITRATION CENTRE  
(6<sup>TH</sup> EDITION, 1 AUGUST 2016)**

**SIAC ARBITRATION NO. 021 OF 2022**

Between

**NUANCE PHARMA LIMITED**  
*(Claimant)*

And

**ANTIBE THERAPEUTICS INC.**  
*(Respondent)*

**CERTIFIED TRUE COPY**

*WWE*  
**Goh Wei Wei**  
Advocate & Solicitor  
Singapore

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**FINAL AWARD**

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Dated this 27<sup>th</sup> day of February 2024

Registered in SIAC Registry of Awards as:  
**Award No. 024 of 2024**  
on 01 March 2024





**SIAC ARBITRATION NO. 021 OF 2022**

IN THE MATTER OF AN ARBITRATION UNDER THE ARBITRATION RULES OF  
THE SINGAPORE INTERNATIONAL ARBITRATION CENTRE  
(6<sup>TH</sup> EDITION, 1 AUGUST 2016)

BETWEEN

NUANCE PHARMA LIMITED (“**CLAIMANT**”)

AND

ANTIBE THERAPEUTICS INC. (“**RESPONDENT**”)

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**FINAL AWARD**

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27 February 2024

*Tribunal*  
Ms. Catherine Amirfar, Tribunal

*Administrative Secretary*  
Mr. Romain Zamour

*Seat of Arbitration*  
Singapore

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## I.

### INTRODUCTION

1. The Claimant in this arbitration is Nuance Pharma Limited (“**Nuance**” or the “**Claimant**”), a Hong-Kong incorporated biopharmaceutical company focused on licensing, developing and commercializing medical therapies in the Greater China region,<sup>1</sup> with its registered address at Unit 417 4/F, Lippo Centre Tower Two, No. 89 Queensway, Admiralty, Hong Kong. Nuance Pharma Limited is the 100% subsidiary of Nuance Biotech and the 100% shareholder of Nuance Pharma (Shanghai) Co. Ltd. It is a subsidiary of CBC Group, Asia’s largest healthcare-dedicated investment firm. The Claimant is represented in these proceedings by Ms. Wendy Lin, Ms. Goh Wei Wei, and Mr. Andrew Chen, WongPartnership LLP, 12 Marina Boulevard Level 28, Marina Bay Financial Centre Tower 3, Singapore 018982.

2. The Respondent is Antibe Therapeutics Inc. (“**Antibe**” or the “**Respondent**”) (together with the Claimant, the “**Parties**”), a biotech company registered under the laws of the Province of Ontario in Canada, with its registered office located at 15 Prince Arthur Avenue, Toronto, Ontario, M5R 1B2, Canada. The Respondent is represented in these proceedings by Mr. Chris G. Paliare, Ms. Karen Jones, and Ms. Kartiga Thavaraj, Paliare Roland Rosenberg Rothstein LLP, 155 Wellington Street West, 35<sup>th</sup> Floor, Toronto, ON M5V 3H1, Canada.

3. A dispute has arisen between Nuance and Antibe, in respect of which the Claimant commenced arbitration pursuant to a License Agreement dated 9 February 2021 between the Claimant and the Respondent (the “**License Agreement**”).<sup>2</sup>

4. The dispute concerns the Respondent’s alleged material misrepresentations and omissions, both pre-dating and post-dating the conclusion of the License Agreement, which are said to have (i) induced the Claimant to enter into the License Agreement and to continue to perform it, (ii) materially breached the License Agreement, and (iii) caused the License Agreement to be entered into by mistake.

## II.

### PROCEDURAL HISTORY

5. On 21 January 2022,<sup>3</sup> the Claimant filed with the Registrar (“**Registrar**”) of the Court of Arbitration of the Singapore International Arbitration Centre (“**SIAC**”) a Notice

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<sup>1</sup> Including the People’s Republic of China, the Hong Kong Special Administrative Region of the People’s Republic of China, the Macau Special Administrative Region of the People’s Republic of China, and Taiwan.

<sup>2</sup> Exhibit C-007, License Agreement dated 9 February 2021 by and between Antibe Therapeutics Inc. and Nuance Pharma Limited (the “**License Agreement**”).

<sup>3</sup> Dates reflected herein principally refer to the time zone of the Tribunal.

of Arbitration, pursuant to Section 11.10(a) of the License Agreement and Rule 3.1 of the Arbitration Rules of the Singapore International Arbitration Centre Arbitration Rules (6<sup>th</sup> Edition, 1 August 2016) (the “SIAC Rules”).

6. Pursuant to Rule 3.3 of the SIAC Rules, the arbitration is deemed to have commenced on 24 January 2022.

7. On 3 February 2022, the Respondent filed a Response to the Notice of Arbitration, pursuant to Rule 4.1 of the SIAC Rules. In the Response, the Respondent advanced a jurisdictional objection, arguing that “[a]ny arbitration that is constituted by Nuance prior to the fulfilment of the pre-conditions to arbitration outlined in the License Agreement is premature.”<sup>4</sup>

8. On 15 February 2022, the Claimant wrote to SIAC that pursuant to Rule 10.2 of the SIAC Rules, the Parties have agreed to extend the timeline for Parties to reach an agreement on the nomination of the sole arbitrator to 28 February 2022.

9. In Claimant’s Response to Respondent’s Jurisdictional Objection under Rule 28.1 of the SIAC Rules, dated 18 February 2022, the Claimant responded to the Respondent’s jurisdictional objection.

10. On 23 February 2022, the Respondent notified SIAC of the Parties’ agreement to nominate Ms. Catherine Amirfar as the sole arbitrator in this arbitration. The Claimant confirmed its agreement on the nomination by an email on 24 February 2022, Singapore time.

11. On 4 April 2022, the Registrar stated that it had determined, under Rule 28.1 of the SIAC Rules, that the objection shall not be referred to the SIAC Court for determination; and that, accordingly, SIAC was now proceeding with the constitution of the tribunal.

12. On 13 May 2022, SIAC informed the Parties that the President of the Court of Arbitration of SIAC had appointed the Tribunal, consisting of Ms. Catherine Amirfar (the “**Tribunal**”). SIAC enclosed a copy of the Letter of Appointment of Arbitrator dated 9 May 2022, made pursuant to Rule 9.3 of the SIAC Rules.

13. On 21 May 2022, the Tribunal wrote to the Parties, seeking to fix a date for a preliminary meeting by videoconference, and providing a draft Procedural Order No. 1 for the Parties’ comments. On 22 May 2022, the Claimant indicated that the Parties had conferred and were both available for a preliminary meeting by videoconference on 9 June 2022 7.30 pm EST / 10 June 2022 7.30 am Singapore time. On 7/8 June 2022, the Parties provided their respective positions on draft Procedural Order No. 1.

14. The preliminary meeting took place by videoconference on 9 June 2022 7.30 pm EST / 10 June 2022 7.30 am Singapore time.

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<sup>4</sup> See Response to Notice of Arbitration (“Response”) ¶¶ 13–20 (quotation at ¶ 20).

15. On 14 June 2022, further to the preliminary meeting, the Tribunal wrote to the Parties, seeking to fix dates for oral argument for the Respondent's jurisdictional objections, oral argument on objection in Redfern, and hearing in the arbitration. The Tribunal attached the CV of Mr. Romain Zamour, the proposed administrative secretary, confirmed the hourly rate of SGD 250, and sought the Parties' written consent to the use of a secretary for this matter. On 20 June 2022, the Claimant shared the Parties' common available dates for oral argument for the Respondent's jurisdictional objections, oral argument on objections in Redfern, and hearing in the arbitration. The Claimant also confirmed that both Parties consented to the appointment of Mr. Romain Zamour as administrative secretary. On 5 October 2023, the Tribunal shared with the Parties the declaration of independence, impartiality, and confidentiality of the administrative secretary. On 6 October 2023, the Parties confirmed that they had no objection.

16. On 25 June 2022, the Tribunal issued Procedural Order No. 1 to establish a procedural timetable for this case.

17. On 8 July 2022, pursuant to paragraph 2 of Procedural Order No. 1, the Claimant submitted its Statement of Claim, together with exhibits C-001 to C-028, and legal authorities CLA-001 to CLA-024.

18. On 27 July 2022, the Respondent wrote on behalf of the Parties, stating that "[t]he Parties are currently in the process of engaging in the dispute resolution procedure outlined at section 11.10 of the License Agreement," stating that as such the Parties have agreed to modify certain deadlines in the timetable set out in Procedural Order No. 1, and setting out the Parties' mutually agreed modifications. The letter stated that "Antibe has agreed to withdraw its motion with respect to the arbitrator's jurisdiction on the grounds that the Parties did not follow the dispute resolution procedure." On 11 August 2022, the Respondent wrote to follow-up on the letter of 27 July 2022.

19. On 12 August 2022, the Tribunal issued Procedural Order No. 2, ordering certain modifications to the procedural timetable in the light of the Parties' agreement.

20. On 18 September 2022, the Respondent wrote on behalf of the Parties, stating that "[t]he Parties are currently in the process of engaging in the dispute resolution procedure outlined at section 11.10 of the License Agreement," stating that as such the Parties have agreed to modify certain deadlines in the timetable set out in Procedural Order No. 2, and setting out the Parties' mutually agreed modifications. On 18 September 2022, the Tribunal indicated that the Parties' mutually agreed modifications to Procedural Order No. 2 were granted, and noted that a revised procedural order would be circulated in due course.

21. On 28 September 2022, the Tribunal issued Procedural Order No. 3, memorializing the agreed modifications to Procedural Order No. 2.

22. On 7 October 2022, pursuant to paragraph 1 of Procedural Order No. 3, the Respondent submitted its Statement of Defence, together with exhibits R-001 to R-051, and legal authorities RL-001 to RL-051.

23. On 9 December 2022, pursuant to paragraph 10 of Procedural Order No. 1, the Parties sent to the Tribunal their respective Redfern Schedules.

24. On 19 December 2022 (EST) / 20 December 2022 (SGT), pursuant to paragraph 11 of Procedural Order No. 1, the Tribunal conducted a videoconference with the Parties to discuss the objections in the Redfern Schedules. During the videoconference, the Tribunal requested the Parties to confer and revert on a number of outstanding points. On 29 December 2022, the Tribunal followed-up on this request.

25. On 1 January 2023, the Respondent wrote on behalf of the Parties, stating that the Parties had been unable to resolve any of the production issues except one. With the Respondent's consent, on 4 January 2023, the Claimant shared with the Tribunal the Parties' correspondence setting out their respective positions on the outstanding document requests.

26. On 5 January 2023, the Tribunal issued Procedural Order No. 4, containing her decisions on the Parties' outstanding disagreements in their respective Redfern Schedules (contained in Annex A and Annex B to the order).

27. On 13 January 2023, the Respondent wrote to seek reconsideration of request #6 of Antibe's request to produce. The Respondent's email also provided the text of the Claimant's response to the request for reconsideration. On 19 January 2023, the Tribunal denied the Respondent's request for reconsideration.

28. On 9 February 2023, the Claimant wrote on behalf of the Parties, advising an agreed revision to the due dates for the submission of the Reply and of the Rejoinder. On 10 February 2023, the Tribunal indicated that the agreed modifications were approved.

29. By emails of 15 February 2023 and 23 February 2023 from the Respondent, and 21 February 2023 from the Claimant, the Parties wrote regarding certain document production matters.

30. On 17 February 2023, pursuant to paragraph 15 of Procedural Order No. 1 as modified in the 10 February 2023 email, the Claimant submitted its Reply, together with exhibits C-029 to C-069, and legal authorities CLA-025 to CLA-031.

31. By emails of 22 February 2023 and 1 March 2023 from the Claimant, and 27 February 2023 from the Respondent, the Parties wrote regarding certain requested further adjustments to the procedural timetable. The 22 February 2023 communication also contained the Claimant's notification of its position with respect to the US\$ 20 million upfront payment under the License Agreement.

32. On 3 March 2023, the Tribunal issued Procedural Order No. 5, ordering certain further modifications to the procedural timetable in the light of the Parties' agreement, and addressing various other points, including certain document production matters, further requested modifications to the procedural timetable not agreed by the Parties, the date and time for the pre-hearing organizational meeting contemplated at paragraph 25 of Procedural Order No. 1, and the Parties' joint submission of points of agreement and disagreement.

33. On 7 March 2023, pursuant to paragraph 2(e) of Procedural Order No. 5, the Claimant provided certain confirmations regarding its document searches. The Claimant stated that, out of prudence, it had conducted a further search of its records with assistance from its IT department and had located additional responsive documents, which it provided in attachment. The Claimant further confirmed that "[t]here are no other documents connected to N-0004 and/or falling within the scope of the Tribunal's orders for Antibe's document requests" and "[t]he manner in which the Claimant previously conducted its document searches is consistent with the meaning of 'relevant' and 'internal' set out by the Tribunal at paragraph 2.d of the Procedural Order No. 5."

34. On 8 March 2023, pursuant to paragraph 1(b) of Procedural Order No. 5, the Respondent submitted its Rejoinder, together with exhibits R-052 to R-058, and legal authorities RL-052 to RL-065.

35. On 23 March 2023, the Claimant sought an extension for it to file its expert/technical evidence, as well as consequential adjustments. The same day, the Respondent opposed the Claimant's requested extension. On 23 March 2023, the Tribunal advised that the Claimant's requested extension and consequential adjustments to the timetable were granted.

36. On 24 March 2023, pursuant to paragraph 18 of Procedural Order No. 1 as modified on 23 March 2023, the Claimant submitted the Witness Statement of Mr Mark G. Lotter dated 24 March 2023 and the Witness Statement of Annie Lee dated 24 March 2023, together with exhibits C-070 to C-075. On 29 March 2023, pursuant to paragraph 18 of Procedural Order No. 1 as modified on 23 March 2023, the Claimant submitted the Witness Statement of Ms Cathleen Chan dated 29 March 2023.

37. By letter dated 5 April 2023 and email of 6 April 2023 from the Respondent, and email of 6 April 2023 from the Claimant, the Parties argued about certain document production matters. On 10 April 2023, the Tribunal directed Nuance to provide documents in its possession, custody or control in response to Category 2 of Antibe's requests that encompass not just the internal documents of Nuance but also documents, if any, exchanged with the CBC Group relating to "initial research on the Drug and Antibe based on publicly-available information" (paragraph 18 of Witness Statement of Annie Lee), and to do so by close of business on 12 April 2023.

38. On 12 April 2023 (following a request for a brief extension, which was granted), pursuant to the Tribunal's directions of 10 April 2023, the Claimant confirmed that,



to the best of its knowledge and belief, there are no further documents in Nuance's possession, custody or control falling within the scope of the Tribunal's directions. Further, and for completeness, the Claimant and Ms. Lee enclosed two further documents, numbered C-076 and C-077.

39. On 14 April 2023, pursuant to paragraph 19 of Procedural Order No. 1 as modified on 23 March 2023, the Respondent submitted the Witness Statement of Daniel Legault dated 13 April 2023 and the Witness Statement of Ella Korets-Smith dated 14 April 2023.

40. On 17 April 2023, the Tribunal issued Procedural Order No. 6, ordering certain further modifications to the procedural timetable, and addressing various other points, including certain document production matters, and the format that the Parties shall use in putting together a proposed hearing schedule (such format contained in Annex A to the order).

41. On 19 April 2023, pursuant to paragraph 19 of Procedural Order No. 1 as modified on 23 March 2023, the Respondent submitted the Witness Statement of Jeffrey Wayne, B.Sc., M.B.A. dated 18 April 2023 and the Witness Statement of Jonathan P Jarow, MD dated 19 April 2023, along with four un-numbered exhibits.

42. By emails of 21 April 2023 from the Claimant, and related emails of 21 April 2023 from the Respondent and 24 April 2023 from the Claimant, the Parties transmitted their statement of points of agreement and disagreement as contemplated at paragraph 6 of Procedural Order No. 5, together with the Parties' positions on the hearing schedule in the format of Annex A to Procedural Order No. 6.

43. On 24 April 2023, as contemplated at paragraph 5 of Procedural Order No. 5, the pre-hearing organizational meeting occurred via conference call.

44. On 26 April 2023, the Claimant wrote to indicate that the Parties were still conferring on the hearing schedule and would revert the following day, to confirm the identity of its party representatives, and to seek directions on the use of demonstratives at the hearing. On 27 April 2023, the Claimant wrote on behalf of the Parties, transmitting the Parties' proposed schedule in the form of a revised draft Annex A. On 29 April 2023, the Tribunal wrote to the Parties regarding the proposed schedule, to which the Claimant responded on behalf of the Parties on the same day. On 2 May 2023, the Respondent wrote on behalf of the Parties, transmitting a joint list of "Key Terms" and "Key Parties."

45. On 2 May 2023, the Tribunal issued Procedural Order No. 7, regarding the organization of the hearing (along with an Annex A containing the hearing schedule).

46. By emails of 7 May 2023, the Claimant and the Respondent shared demonstratives, which they intended to use at the hearing and which had raised no objection from the other party: the Claimant's Opening Statement (a set of slides) and the Respondent's

Timeline for Opening (a chronology with links to underlying documents referenced in the chronology).

47. From 8 to 12 May 2023, the hearing was held at Maxwell Chambers, Singapore. Over the course of the hearing, the following persons were in attendance:

**Tribunal**

Ms. Catherine Amirfar

**Claimant**

*Counsel*

Ms. Wendy Lin

Ms. Goh Wei Wei

Mr. Andrew Chen

Ms. Tan Ying Jenn

*Party Representatives*

Mr. Mark Lotter

Mr. Charlie Chen

**Respondent**

*Counsel*

Mr. Chris Paliare

Ms. Karen Jones

Ms. Kartiga Thavaraj

*Party Representative*

Mr. Daniel Legault

**Claimant's Witnesses**

Mr. Mark Lotter

Dr. Cathleen Chan

Ms. Annie Lee

**Respondent's Witnesses**

Ms. Ella Korets-Smith

Mr. Daniel Legault

Dr. Jonathan P Jarow

Mr. Jeffrey Wayne

**Administrative Secretary**

Mr. Romain Zamour

**Court Reporter**

Epiq Singapore Pte Ltd

48. Pursuant to paragraph 6 of Procedural Order No. 7, the Claimant prepared and provided a hard-copy set of submissions for the Tribunal. At the outset of the hearing, the Parties, by agreement, introduced into evidence a number of new exhibits and legal authorities, numbered C-078 to C-098, R-059, CLA-032 and CLA-033. In the course of the hearing, two additional exhibits were introduced into evidence: Hearing Exhibit 1 and Hearing Exhibit 2.

49. On 12 May 2023, as contemplated at paragraph 8 of Procedural Order No. 7, after the close of the evidence at the hearing, the Tribunal conferred with the Parties regarding potential post-hearing briefs.

50. On 21 May 2023, the Tribunal issued Procedural Order No. 8, regarding post-hearing briefs and costs submissions.

51. On 22 June 2023, the Respondent wrote to request an oral hearing after receipt of the post-hearing briefs. On 23 June 2023, the Claimant commented on the Respondent's request. On 24 June 2023, the Tribunal acknowledged receipt of the Parties' communications and stated that she reserved her decision on the request for now, and would advise the Parties of her decision after reviewing the post-hearing briefs.

52. On 6 July 2023, pursuant to paragraph 1 of Procedural Order No. 8, the Claimant and the Respondent simultaneously filed their post-hearing briefs. Together with its post-hearing brief, the Claimant adduced legal authorities CLA-034 to CLA-050. The Respondent appears to have submitted certain unnumbered legal authorities with its post-hearing brief.

53. On 13 July 2023, the Claimant wrote to the Tribunal on behalf of the Parties, stating that the Parties had agreed to a short extension until 17 July 2023 for the filing of the costs submissions, and seeking an extension from the Tribunal. By email of the same day, the Tribunal granted the agreed extension.

54. On 17 July 2023, pursuant to paragraph 3 of Procedural Order No. 8 as modified, the Claimant and the Respondent simultaneously filed their costs submissions, together with appendixes. The Claimant also noted that the Respondent had provided a hyperlinked version of its post-hearing brief, and proposed to do the same. By email of 18 July 2023, the Tribunal stated that she would welcome a hyperlinked version of the Claimant's post-hearing brief.

55. On 20 July 2023, the Respondent responded to the position that the Claimant took on interest in its costs submission and stated the Respondent's position on interest. On 29 July 2023, the Claimant provided a hyperlinked version of the Claimant's post-hearing brief. The Claimant also provided the proposed errata to the hearing transcripts, as agreed among the Parties.

56. On 8 August 2023, the Tribunal explained that she did not see a basis to revisit her direction that the Parties submit post-hearing briefs in lieu of oral closing submissions; consulted the Parties regarding the closure of the proceedings; and sought the Parties' consent to amending paragraph 28 of Procedural Order No. 1, to require submission of the draft Award to SIAC for its review no later than 60 days from the date on which the proceedings are declared closed (as opposed to 60 days from the end of post-hearing submissions), it being understood that such modification supersedes the timeframe set forth in SIAC Rule 32.3. On 9 August 2023, the Respondent stated that it had no objection to the closing of the

proceedings and that it also had no objection to the proposed amendment to paragraph 28 of Procedural Order No. 1. On 10 August 2023, the Claimant stated that similarly it had no objection to the closing of the proceedings and to the Tribunal's proposed amendment to Procedural Order No. 1. The Claimant also stated that it reserved the right to seek injunctive or other appropriate relief from the Tribunal in connection from the US\$ 20 million representing the Claimant's payment to the Respondent under the License Agreement. On 11 August 2023, the Respondent responded to the Claimant, stating that both Parties had consented to the close of the proceedings and that, once the Claimant had consented to the closing of the proceedings, it was precluded from bringing another proceeding against the Respondent.

57. On 6 October 2023, the Tribunal issued Procedural Order No. 9, denying the Respondent's request for an oral hearing after the post-hearing briefs, approving the Parties' agreed proposed modifications to the transcripts, confirming that with the Parties' agreement, the Tribunal would submit her draft Award to SIAC by 60 days from 6 October 2023, the date on which the proceedings were declared closed pursuant to Rule 32.1 of the SIAC Rules, and noting that no decision is required on the Claimant's purported reservation of rights in connection with the US\$20 million payment under the License Agreement.

58. On 4 December 2023, the Claimant wrote to the Tribunal, seeking the Tribunal's indication on the timing of the final Award and notifying the Tribunal of an "intended request" for interim relief. On the same day, the Respondent responded, emphasizing the closure of the proceedings. On the same day, the Tribunal wrote to the Parties, reminding the Parties that the Tribunal in Procedural Order No. 9 had declared the proceedings closed, and that as such the Tribunal had not reviewed the additional evidence attached to the Claimant's email. The Tribunal noted that the Claimant made no application and therefore no decision was required. As to the Claimant's query regarding the timing of the issuance of the Award, the Tribunal stated that, as agreed by the Parties and provided in Procedural Order No. 9, the Tribunal earlier on that day had submitted her draft Award to SIAC for its review. On 11 December 2023, the Claimant indicated that it would not be proceeding with the request for interim relief foreshadowed in the Claimant's communication of 4 December 2023.

59. On 30 January 2024, the Tribunal wrote to the Parties, updating them on the expected timing for the issuance of the final Award, and seeking the Parties' consent to treat the fees and expenses of the administrative secretary as part of the "costs of the arbitration" under SIAC Rule 35.2(c), as part of "the costs of . . . any other assistance reasonably required by the Tribunal." The Respondent and the Claimant so agreed on the same day.

### **III.**

#### **FACTUAL BACKGROUND**

60. This section sets out the summary of facts from the Parties' written and oral submissions, as well as the evidence presented at the hearing.

## A. Background on the Drug

61. The drug at issue in this case (the “**Drug**”) is called otenaproxesul.<sup>5</sup> It is also referred to as “ATB-346.” It is a “hydrogen sulfide releasing version of naproxen,” and a kind of nonsteroidal anti-inflammatory drug (“**NSAID**”).<sup>6</sup>

62. NSAIDs are “among the most common pain relief medicines in the world.”<sup>7</sup> Some NSAIDs are sold over the counter, such as Aspirin and low doses of naproxen (Aleve) and ibuprofen (Advil). Other NSAIDs are only sold via prescription. NSAIDs are indicated for multiple conditions, ranging from acute pain caused by injury or surgery to chronic pain and inflammation caused by diseases such as osteoarthritis.<sup>8</sup>

63. A major issue with NSAIDs is that they can cause gastrointestinal (“**GI**”) ulcers and bleeding, and more rarely can contribute to heart and cardiovascular conditions, as well as kidney and liver symptoms.<sup>9</sup>

64. In particular, NSAIDs can cause the elevation of certain enzymes in the liver, known as aminotransferase enzymes, and in particular alanine aminotransferase (“**ALT**”) and aspartate aminotransferase (“**AST**”). An elevation of either ALT or AST may indicate that the liver is stressed. Increases in either ALT or AST beyond three times the upper limit of normal (“**ULN**”) in the blood are commonly called “clinically significant increases” or “liver transaminase elevations” (“**LTEs**”).<sup>10</sup>

65. In the early and mid-2000s, Antibe’s founder discovered the anti-inflammatory properties of hydrogen sulfide and began combining hydrogen sulfide-releasing molecules with other molecules to create novel drugs with anti-inflammatory effects, such as the Drug. Antibe considers the Drug promising as it has demonstrated similar anti-inflammatory qualities to NSAID naproxen, with fewer side effects, especially those relating to GI issues.<sup>11</sup>

## B. Overview of Drug Development in the United States and Canada

66. Generally speaking, drug development is complex and highly regulated, and it is an expensive, risky, and time-consuming process.<sup>12</sup> Drug development proceeds in multiple steps or stages.<sup>13</sup> It begins in the laboratory, with the identification of a potentially

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<sup>5</sup> Witness Statement of Daniel Legault (“Legault”) ¶ 35.

<sup>6</sup> Legault ¶¶ 17, 35.

<sup>7</sup> Legault ¶ 18.

<sup>8</sup> Legault ¶¶ 18, 20.

<sup>9</sup> Legault ¶ 19.

<sup>10</sup> Legault ¶ 21.

<sup>11</sup> Legault ¶¶ 17, 35; *see* Statement of Defence of Antibe (“Defence”) ¶¶ 72–73.

<sup>12</sup> *See* Defence ¶¶ 53–54; Legault ¶¶ 26–27.

<sup>13</sup> Witness Statement of Jonathan P Jarow, MD (“Jarow”) ¶ 20.

therapeutic chemical entity. It then proceeds to nonclinical testing (for instance, testing in animals).<sup>14</sup>

67. Following nonclinical testing, the clinical investigation generally proceeds in three phases.<sup>15</sup> Phase 1 clinical studies are typically short-term, performed in a small number of healthy volunteers or patients, and primarily designed to assess the safety of the drug.<sup>16</sup>

68. Upon a satisfactory safety assessment in the Phase 1 clinical studies, drug development typically proceeds to Phase 2 clinical studies. These are “performed to assess proof of concept of a drug’s effectiveness, continue safety data collection, and help determine the dose(s) (and duration) to bring forward in clinical development.”<sup>17</sup> Typically, these are controlled studies performed on a larger number of patients than the Phase 1 studies.

69. Phase 3 clinical studies are “larger-scale clinical trials of longer duration performed in the intended treatment population.”<sup>18</sup> These are used “to provide substantial evidence of effectiveness while collecting additional safety information.”<sup>19</sup>

70. That said, multiple drug development programs are “not linear.”<sup>20</sup> Other studies may take place prior to or in parallel with Phase 3 studies, including absorption, distribution, metabolism and excretion (“ADME”) studies, dosage and safety studies, etc.<sup>21</sup>

71. The process and regulation for drug development varies by country.<sup>22</sup> In Canada, the regulator – Health Canada – must approve in advance each clinical trial conducted on humans. A drug developer must submit a Clinical Trial Application (“CTA”) to Health Canada, which must approve or reject the trial within 30 days. Health Canada can also seek additional information or request that changes be made to the clinical trial protocol.<sup>23</sup> Once a drug has completed all the required Phase 1, Phase 2, and Phase 3 (and any other) studies, the drug developer files a New Drug Application (“NDA”) with Health Canada to obtain approval to market the drug in Canada.<sup>24</sup>

72. In the United States, following nonclinical testing and before clinical testing may proceed, a drug developer must submit an Investigational New Drug (“IND”) application to the regulator – the Food and Drug Administration (“FDA”). The FDA has 30 days to provide clearance or request additional information. Upon clearance, the IND is considered

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<sup>14</sup> Jarow ¶ 20; *see also* Defence ¶ 56(a); Legault ¶ 28(a).

<sup>15</sup> Jarow ¶ 21; *see also* Defence ¶ 56(b)-(d); Legault ¶ 28(b)-(d).

<sup>16</sup> Jarow ¶ 22.

<sup>17</sup> Jarow ¶ 23.

<sup>18</sup> Jarow ¶ 24.

<sup>19</sup> Jarow ¶ 24.

<sup>20</sup> Jarow ¶ 25.

<sup>21</sup> Legault ¶ 29.

<sup>22</sup> Legault ¶ 30.

<sup>23</sup> Legault ¶ 30.

<sup>24</sup> Legault ¶ 31.

“open,” and a drug developer is allowed to administer the drug to humans in the United States. The IND must be regularly updated. When all studies have been completed, the drug developer files an NDA with the FDA in order to obtain approval to market the drug in the United States.<sup>25</sup> The FDA is often considered the most important regulatory body in the world, due to the size of the United States drug market and the respect that other regulators have for the FDA. In some cases, regulatory approvals in other countries may be based in large part on FDA approval in the United States.<sup>26</sup> Licensing is common in the drug development field. A drug licensor typically licenses a drug for a particular “territory” (or geographical region) and a particular “field” (or the specific “indications” or uses for a drug).<sup>27</sup>

### **C. Antibe’s Phase 1 and 2 Approval Process in Canada**

73. In mid-2014, Antibe completed preclinical studies for the Drug and applied to Health Canada for approval to do its first clinical study of the Drug. The CTA was approved and Antibe began the Drug’s first Phase 1 trial.<sup>28</sup>

74. In the fall of 2014, Antibe identified transient LTEs in 3 of 6 subjects within the second-highest cohort of 750mg/day for 14 days. “Transient” means that the elevated levels returned to normal without treatment or medical intervention. All the study volunteers remained asymptomatic. The principal investigator for the study concluded that the LTEs were likely due to influenza, and the study continued.<sup>29</sup>

75. Antibe then tested the Drug at 1,500mg/day for 14 days. Five of the 6 subjects showed LTEs. In 4, the LTEs were discovered post-treatment. In the fifth, the LTEs were thought to likely have been caused by factors unrelated to the Drug.<sup>30</sup> Antibe decided to pause the drug’s development until further investigation could be carried out as to the cause of the LTEs, a decision that it announced by press release dated 16 January 2015.<sup>31</sup>

76. In mid-March 2015, after two months of review of the safety data, Antibe concluded its Phase 1 trials, and issued a press release noting its intention to continue the clinical development of the Drug.<sup>32</sup>

77. In early 2016, Antibe applied to Health Canada for approval to do a 10-day Phase 2a study of 12 osteoarthritis patients to establish whether a lower 250 mg dose could deliver sufficient pain relief. Health Canada approved the CTA and Antibe conducted the trial. The patients rated the drug highly in treating their pain. One patient exhibited LTEs,

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<sup>25</sup> Legault ¶ 32.

<sup>26</sup> Legault ¶ 34.

<sup>27</sup> See Defence ¶ 64.

<sup>28</sup> Legault ¶ 36.

<sup>29</sup> Legault ¶ 38.

<sup>30</sup> Legault ¶ 39.

<sup>31</sup> Legault ¶ 40; see Exhibit R-001.

<sup>32</sup> Legault ¶ 41; see Exhibit R-0002.

which were attributed to a reaction to the chemotherapy that the patient was undergoing at the time.<sup>33</sup>

78. In the Fall of 2017, Antibe sought and received approval to conduct a large, 240-subject, 14-day GI safety study in healthy volunteers, comparing the outcomes of a daily dose of 250mg/day of the Drug to those of prescription-strength naproxen (the “**Phase 2B GI Safety Study**”). The Drug was found to have a significant GI safety advantage over naproxen. Drug-related LTEs were found in approximately 5% of subjects.<sup>34</sup>

79. In early 2019, Antibe sought and received approval to conduct a large, 14-day, placebo-controlled efficacy study involving 384 patients for Drug doses of 150, 200, and 250mg/day (the “**Phase 2B Efficacy Study**”). The study demonstrated impressive efficacy for both higher and lower doses. However, the drug-related LTE incidence for all study patients, regardless of dose, was in the 9-12% range. LTEs were only detected post-treatment.<sup>35</sup>

80. A clinical study report (“**CSR**”) dated 21 December 2020 reported on the trial results, recommending that future studies investigate doses at or less than 150mg/day considering the LTEs.<sup>36</sup>

81. With the completion of the Phase 2B Efficacy Study in the fall of 2020, Antibe completed its Phase 2 program.

82. Antibe planned to conduct the Phase 3 trials in the United States, and it began preparing an IND application.<sup>37</sup>

#### **D. Antibe’s 2021 AME Study in Canada**

83. As a result of the COVID-19 pandemic, Antibe believed it was unlikely to start its first planned Phase 3 trial until 2022. As a result, Antibe decided to conduct an absorption, metabolism and excretion study (“**AME Study**”) in Canada.<sup>38</sup> According to Antibe: “For the Canadian AME study submission is planned for April/May 2021 with study initiation late Q2 2021.”<sup>39</sup>

84. With this study, Antibe sought to identify lower effective doses of the Drug and to cover a longer dose administration period of 28 days (the longest previous clinical studies had been 14 days). The AME Study would also be a “precursor” to the ADME study

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<sup>33</sup> Legault ¶¶ 42–43; *see* Exhibit R-003.

<sup>34</sup> Legault ¶ 44; *see* Exhibit R-004.

<sup>35</sup> Legault ¶¶ 46–47.

<sup>36</sup> Legault ¶ 48; *see* Exhibit R-005, at 12.

<sup>37</sup> Legault ¶¶ 49–50.

<sup>38</sup> Legault ¶ 51.

<sup>39</sup> Exhibit R-035.



that is required in the United States and Canada and generally done in parallel with Phase 3 studies.<sup>40</sup>

85. Dr. Jarow (one of Antibe’s experts) at the hearing summarized the “very complex”<sup>41</sup> situation as follows:

So at this stage – so the company is kind of in a pickle, let’s be frank. They have a drug that is clearly shown in phase 2 studies that it appears to be efficacious to reduce symptoms in patients with osteoarthritis. It definitely or appears to decrease the GI toxicity seen with naproxen in the other phase 2 study. Yet they are having this very unusual liver toxicity. ... It was observed after the drug was stopped. They say that there is a dose dependency but it wasn’t clear that it was dose dependent, although the highest elevations in liver function tests were with the highest dose. And so – but they needed to find a window, if you will, where it was going to be both effective and safe, and so – and they needed longer durations of exposure. At that point they had only done 14 days.<sup>42</sup>

#### **E. The Parties’ Introduction and Execution of the Term Sheet in 2020-21**

86. The CBC Group connected the Parties in September 2020.<sup>43</sup> At the time, Nuance did not have any chronic-use NSAIDs in its portfolio.<sup>44</sup> It was looking for opportunities in the chronic pain field.<sup>45</sup> Following an introductory Zoom call on 6 October 2020, the Parties signed a non-disclosure agreement in mid-October 2020.<sup>46</sup>

87. The Parties had a lengthier introductory meeting on Zoom on 26 November 2020. Nuance shared its corporate pitch deck.<sup>47</sup>

88. The Parties had a further Zoom meeting on 17 December 2020. Antibe provided its corporate pitch deck (the “**Corporate Presentation**”).<sup>48</sup>

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<sup>40</sup> Legault ¶ 52.

<sup>41</sup> Tr. (5) 23:15 (Dr. Jarow).

<sup>42</sup> Tr. (5) 21:24–22:17 (Dr. Jarow).

<sup>43</sup> Exhibit R-010; Exhibit R-011.

<sup>44</sup> Witness Statement of Annie Lee (“Lee”) ¶ 11.

<sup>45</sup> Lee ¶ 16.

<sup>46</sup> Exhibit R-017.

<sup>47</sup> Exhibit R-018.

<sup>48</sup> Exhibit R-019; Exhibit C-001.

89. On 23 December 2020, Nuance wrote to Antibe, stating “we are very confident that ATB346 has great potential and Nuance has the team, resources and drive to make this a success.”<sup>49</sup> Nuance provided a draft non-binding term sheet and deal proposal.<sup>50</sup>

90. The draft term sheet concerned “Antibe’s otenaproxesul (ATB-346)”. It defined the “Field” as “The treatment of all human diseases and conditions, including, without limitation, osteoarthritis [“OA”], rheumatoid arthritis [“RA”], ankylosing spondylitis [“AS”],” and defined the “Territory” as “The Greater China Region, including mainland China, Hong Kong, Macau, and Taiwan”. The term sheet provided that “Antibe would grant Nuance an exclusive license” to develop and commercialize the Drug for the Field in the Territory, proposed an upfront payment of US\$ 20 million, development and commercial milestone payments potentially totaling US\$ 80 million, and an 8% royalty, and proposed a 90-day Exclusivity Period for negotiation.<sup>51</sup>

91. On 29 December 2020, Antibe responded, noting that “Antibe’s management team is enthusiastic about the opportunity to partner with Nuance for the China market,” and that “we are willing to put this negotiation ahead of the larger partnering process in China, with the understanding that we will move quickly to resolution, which is in the best interests of both parties.”<sup>52</sup>

92. As to the draft term sheet, Antibe requested, among other things, a 50-day exclusivity period (instead of the proposed 90 days) and a “royalty percentage to move towards a low double digit.”<sup>53</sup>

93. On 30 December 2020, Nuance responded, noting in two separate emails (one from Mr. Lotter and one from Ms. Lee) that “Nuance and the team is well prepared to move forward at pace and move quickly to a resolution,” “fully agree that this is in the interest of both parties,” and “we are very keen to move fast and meet your requirements.”<sup>54</sup> Nuance invited Antibe to send a proposed redline of the draft term sheet.

94. On the same day, Antibe sent a proposed redline of the draft term sheet. Antibe edited the definition of the “Field” to read “The treatment of disease conditions appropriate for NSAID use, including, without limitation, [OA], [RA], [AS]”; it proposed a royalty rate of 12.5%, and an Exclusivity Period of 50 days.<sup>55</sup>

95. On 31 December 2020, the Parties had a call. Nuance then sent the “latest [term sheet] reflecting our discussion just now.”<sup>56</sup> Nuance stated: “Please review and we

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<sup>49</sup> Exhibit C-004.

<sup>50</sup> Exhibit R-020.

<sup>51</sup> Exhibit R-020.

<sup>52</sup> Exhibit R-022.

<sup>53</sup> Exhibit R-022 (emphasis omitted).

<sup>54</sup> Exhibit R-022.

<sup>55</sup> Exhibit R-022.

<sup>56</sup> Exhibit R-024.

look forward to proceeding to the next steps and commencing our collaboration. For the data room, please provide access to the following Nuance team member: [list of five Nuance team members].”<sup>57</sup>

96. On 6 January 2021, the Parties signed the Term Sheet, which defined the Field as “The treatment of disease conditions appropriate for NSAID use, including, without limitation, [OA], [RA], [AS],” and the Territory as “The Greater China Region, including mainland China, Hong Kong, Macau, and Taiwan”. It provided for a License Grant, an upfront payment of US\$ 20 million, development and commercial milestone payments potentially totaling US\$ 80 million, a 12.5% royalty, and a 50-day Exclusivity Period for negotiation.<sup>58</sup>

97. Antibe wrote: “We are also working on preparing the Data Room and a draft of the Definitive Agreement, targeting the week of January 18<sup>th</sup> for having both of these available for your review.” Nuance responded: “Annie and the team are on standby for access to the data room as well to review the first draft of the Definitive Agreement. As mentioned on the call, Nuance is committed to concluding the agreement ideally before the Chinese New Year break i.e. end January 2021.”<sup>59</sup>

#### **F. Nuance’s Due Diligence and the Parties’ Draft Definitive Agreement in January to February 2021**

98. On 11 January 2021, the Parties had an introductory call with Antibe’s CEO (Mr. Legault). After the call, Nuance wrote: “Given the signed [term sheet] and planned next steps, we look forward to working with [ ] Ella, Rami and the team over the weeks ahead to get closure. ... On our side, the team is on full alert to conclude by the end of the month i.e. to coincide with the Chinese New Year. In China, closing a deal around the Chinese New Year represents a chance for partners to forge a long and lasting relationship and ensure a successful future for the parties involved.” Antibe responded: “we look forward to sleeves fully rolled up this month.”<sup>60</sup>

99. On 19 January 2021, Antibe shared a Draft Definitive Agreement.<sup>61</sup>

100. On 25 January 2021, Antibe opened the Data Room to Nuance, using ShareVault. Antibe stated: “We look forward to receiving the redline Definitive Agreement and entertaining any questions you may have with respect to the information in the data room, as we move forward in this process.”<sup>62</sup>

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<sup>57</sup> Exhibit R-024.

<sup>58</sup> Exhibit R-025.

<sup>59</sup> Exhibit R-025.

<sup>60</sup> Exhibit R-026.

<sup>61</sup> Exhibit R-029.

<sup>62</sup> Exhibit R-028.

101. Exhibit R-027 is the ShareVault index, showing 566 documents organized in nine categories: Non-Clinical (34 documents); CMC: Product Quality (51 documents); Regulatory (17 documents); Corporate Quality (one document); Clinical (314 documents); Market-Commercial (21 documents); IP (23 documents); Publications (41 documents); and Corporate (64 documents).<sup>63</sup>

102. The Regulatory category had 17 documents – 15 relating to Health Canada, dating back to 2014, and two relating to the FDA.<sup>64</sup>

103. On 28 January 2021, a member of the Nuance team wrote to Antibe: “Our clinical team has checked the data room folders and realized there is no information regarding to phase 3 studies. Could you help to upload the phase 3 study information (protocols, status ... etc) which is import for us to evaluate if the design and timeline are applicable in China.”<sup>65</sup>

104. On 29 January 2021, Antibe responded: “Thank you for your question. I wanted to let you know that we had a discussion with Mark and Annie earlier this week about the diligence process. Mark had made a very helpful suggestion to gather all of the diligence questions from Nuance and send over to Antibe for response at once. We would very much appreciate this format, as our team would like to take this list and answer thoughtfully and fulsomely.”<sup>66</sup>

105. On 3 February 2021, Nuance sent to Antibe a list of requests for information and documents:

Our team have reviewed the material in the data room. Below is the list of additional data/document required to complete DD from our side. It would be great if you can help to provide the info by end of this week. Thanks.

- Regulatory

1. Meeting minute of the End-of-phase 2 meeting minute
2. Risk management plan

- Clinical

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<sup>63</sup> See Exhibit R-027; *see also* Exhibit C-079.

<sup>64</sup> Exhibit R-027.

<sup>65</sup> Exhibit R-031.

<sup>66</sup> Exhibit R-031.

1. Protocols and timelines for 3 efficacy studies (study #1, #2, #3) and 2 GI safety studies (presented in the partnering presentation 2020.9 Page 14)
2. Asian population results and ethnic sensitivity in the completed studies
3. Plan number of Asian population to recruit in the proposed US or EU local studies
4. Protocol and timeline of the IND-opening Ph1 clinical AME study on metabolites
5. Plan to address the different exposure Naproxen displayed between female and male population after ATB-346 administered in Ph2B DRF study<sup>67</sup>

106. On 4 February 2021, Antibe responded to Nuance's questions and requests.<sup>68</sup>

107. In particular, on the AME Study, Antibe stated: "For the Canadian AME study submission is planned for April/May 2021 with study initiation late Q2 2021." And: "The Draft AME protocol has been added to ShareVault."<sup>69</sup>

108. As to the timeline for Phase 3, Antibe stated: "Assuming all goes accordingly, Antibe will be in a position to start the initial Phase 3 OA efficacy trial in H2 2021 and will be on an ambitious timeline to have the NDA submitted in 4Q 2024."<sup>70</sup>

#### **G. The Conclusion of the License Agreement in February 2021**

109. On 9 February 2021, the Parties entered into the License Agreement.<sup>71</sup> Pursuant to Section 2.1 of the License Agreement, Antibe grants to Nuance an exclusive license to Develop and Commercialize the Drug in the Field in the Territory.

110. The Field is defined in Section 1 as "use for treatment of human disease conditions appropriate for NSAID use, including without limitation [OA], [RA], and [AS]."

111. The Territory is defined in Section 1 as "any or all (as applicable) of the following: the PRC, the Hong Kong Special Administrative Region of the PRC, the Macau Special Administrative Region of the PRC, and Taiwan ...". Section 5.1 provides for a "non-refundable and non-creditable" upfront payment by Nuance to Antibe of US\$ 20 million.

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<sup>67</sup> Exhibit R-034.

<sup>68</sup> Exhibit R-035.

<sup>69</sup> Exhibit R-035.

<sup>70</sup> Exhibit R-035 (emphasis omitted).

<sup>71</sup> Exhibit C-007; Exhibit R-037.

Section 5.2 provides for development and commercial milestone payments, potentially up to US\$ 80 million. Section 5.3 provides for royalties, including a royalty rate of 12.5% on net sales. Section 3.1 provides that, “[p]romptly after the Effective Date, the Parties will agree on a Development Plan for a Licensed Product in the Field in the Territory through the JDC.”

112. On 19 February 2021, Nuance paid to Antibe the upfront payment of US\$ 20 million.

#### **H. The Canadian AME Study & Nuance’s Due Diligence**

113. In parallel to the due diligence and negotiations leading to the conclusion of the License Agreement, the Canadian AME Study proceeded.

114. On 27 December 2020, Antibe filed the CTA for the proposed AME Study with Health Canada.<sup>72</sup> Health Canada had 30 days to approve to reject the CTA.<sup>73</sup>

115. On 19 January 2021, Health Canada wrote to Antibe, seeking additional information and expressing “serious concerns regarding the potential risk of liver related AEs [adverse events]/SAEs [serious adverse events] in the proposed Phase 1b health human study, despite the low(er) ATB-346 doses (75mg, 100mg, 125 mg, and 150 mg), given that this is the first study with a 28-day treatment duration.”<sup>74</sup>

116. Health Canada specifically noted three points: (1) the “significance/relevance of the safety factor with respect to liver toxicity derived from most sensitive specie non-GLP minipig study is not clear”; (2) the “assessment of safety of the 150 mg dose in healthy humans is limited to a 7-day Phase 1 study. Liver AEs/SAEs have been observed at 250 mg administered for 14 days in healthy humans, and in patients with [OA] at 150 mg, 200 mg and 250 mg”; (3) “Continued dosing from Day 14-28 in the proposed 28-day study may increase the likelihood of a liver related AE/SAE. In both healthy human and OA patients treated for only 14 days, clinically significant elevation in transaminase (> 3x ULN) were observed during the post-treatment follow up period. Thus, the impact on the liver following 28 days of dosing, even at lower doses is not clear.”<sup>75</sup>

117. On 21 January 2021, Antibe responded in detail to Health Canada.<sup>76</sup> Among other things: on point (1), it referred to an “ongoing 13-week study” of minipigs; on point (2), it stated that before the 150 mg dose can be administered, “all lower doses must have first been completed and the Principal Investigator plus the company Safety Physician/Monitor must agree that in the absence of any liver or other safety signals the 150 mg dose can be administered”; on point (3), it emphasized that “[a]ll subjects will be under around-the-clock

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<sup>72</sup> Legault ¶ 53; Exhibit R-006.

<sup>73</sup> Legault ¶ 54.

<sup>74</sup> Exhibit C-035.

<sup>75</sup> Exhibit C-035.

<sup>76</sup> Exhibit C-036.

direct supervised care of study nurses and the in-house study physician during the entire 6 weeks of dosing/observation.”<sup>77</sup>

118. On 22 January 2021, Antibe met with Health Canada, as reflected in draft minutes of 26 January 2021 put together by a regulatory consultant working with Antibe.<sup>78</sup> The draft minutes state:

Dr. Alexa [of Health Canada] stated that the OCT [Office of Clinical Trials] agreed to have this meeting, not to discuss the file further, but to inform the sponsor about the regulatory decision based on the Information Request issued. The OCT cannot issue a favourable decision for this [CTA] at this time. A new review would need due to:

- Health Canada would like to have the data on the on-going 13 week mini-pig study, given the results seen in the previous non-GLP 30-day Dose Range Finding (DRF) study in mini-pigs.
- Proposed changes in the response are considered significant changes in the protocol design and therefore the protocol would require a full review.
- Health Canada remain uncertain about the study duration of 28 days.

Dr. Alexa offered to allow Antibe to withdraw the CTA by 11AM or a rejection would be issued. She also suggested that a pre-CTA meeting would be helpful to the sponsor before refileing the CTA, to discuss the study design regarding the safety signals regarding hepatic toxicity. ... Antibe agreed to withdraw the CTA from review.<sup>79</sup>

119. Antibe proceeded to send a withdrawal letter by 11 am on the same day.<sup>80</sup>

120. On 10 February 2021, Antibe in a board update stated the following about the AME Study:

- Our CTA (clinical trial application) file was considered (incorrectly) incomplete by Health Canada as our ongoing 13-week minipig tox study was referenced

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<sup>77</sup> Exhibit C-036.

<sup>78</sup> Exhibit C-037.

<sup>79</sup> Exhibit C-037.

<sup>80</sup> Exhibit C-038.

without providing data; we will provide the data and refile by mid-March

- They expressed concern over liver enzyme elevations for longer durations; we will thus propose to conduct the AME study with a dose escalation design. They suggested we request a pre-CTA meeting, which we view as helpful
- A ~120-day delay will result; this will only modestly impact our P3 plans, as Covid precludes an earlier start than the Fall. It might also modestly extend our partnering efforts, as we view the AME data as important in this regard)
- We continue to feel as if the issue is manageable as the elevations are dose-dependent, only occur post-treatment, are highly correlated with known, easy to manage liver stressors (primarily acetaminophen) and have no clinical sequelae (effects) at 150 mg. We also think we are likely to be effective at lower doses (see next slide) where PK analysis indicates that elevations would be rare. Still, this is our main corporate risk<sup>81</sup>

121. In another slide showing a timeline, Antibe indicated in the board update that Phase 3 would begin in January 2022.<sup>82</sup>

122. Antibe scheduled a pre-CTA meeting for 20 April 2021 and, in advance of the meeting, shared on 19 March 2021 a pre-CTA meeting package with Health Canada.<sup>83</sup> On 9 April 2021, Health Canada shared advance feedback on the pre-CTA package.<sup>84</sup> As summarized by Antibe's regulatory consultant:

Question #1 – they are suggesting a 14 day study with a 14 day follow up period.

Question #2 – they are requesting you to consider 1. A separate dosing cohort for each dose level, 2. Liver stopping rules and 3. dose-escalation stopping rules with a Notification to be submitted if the dose escalation stopping rules are met.

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<sup>81</sup> Exhibit C-040.

<sup>82</sup> Exhibit C-040.

<sup>83</sup> Exhibit C-047.

<sup>84</sup> Exhibit C-039.



Question #3 – they have various suggested changes to study design, inclusion/exclusion and subject monitoring, in addition to a list of prohibited medications.<sup>85</sup>

123. On 15 April 2021, Antibe wrote back to Health Canada. It confirmed that the suggested protocol revision recommendations offered by Health Canada in connection with Questions 2 and 3 were agreeable to Antibe and would be implemented. As to the suggestion of a 14-day study with a 14-day follow-up period in connection with Question 1, Antibe emphasized the need for and proposed to retain a 28-day administration period.<sup>86</sup>

124. On 20 April 2021, Antibe met with Health Canada for the pre-CTA meeting, as reflected in meeting minutes drafted by Antibe’s regulatory consultant (also reflecting Health Canada’s suggestions).<sup>87</sup> The focus of the meeting was the question of the length of the trial, in connection with Question 1.<sup>88</sup>

125. On 7 May 2021, Antibe submitted the revised CTA to Health Canada.<sup>89</sup> As noted in the “Revision History” section: “The protocol has been updated from Version 1.0 to Version 2.0 due to study design changes, including the age of the subjects, removal of a higher strength, and the addition of formal stopping criteria.”<sup>90</sup>

126. Health Canada approved the revised CTA on 2 June 2021.<sup>91</sup>

127. The AME Study began in July 2021.<sup>92</sup>

128. On 21 July 2021, Antibe shared with Nuance the “final protocol for the AME study which is currently ongoing in Canada.”<sup>93</sup>

129. On 29 July 2021, Antibe sought to amend the AME protocol, submitting a v3.0 including a naproxen comparator arm.<sup>94</sup>

130. As discussed further below, on 30 July 2021, the study hit the stopping criteria, and Antibe paused the AME Study.<sup>95</sup>

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<sup>85</sup> Exhibit C-039.

<sup>86</sup> Exhibit C-052.

<sup>87</sup> Exhibit C-053.

<sup>88</sup> Exhibit C-053.

<sup>89</sup> Exhibit R-007.

<sup>90</sup> Exhibit R-007.

<sup>91</sup> Exhibit C-055.

<sup>92</sup> Legault ¶ 62.

<sup>93</sup> Exhibit R-043.

<sup>94</sup> Exhibits C-062 & C-063.

<sup>95</sup> Legault ¶ 63.

## **I. The United States IND**

131. On 26 February 2021, Antibe submitted its IND application to the FDA.<sup>96</sup> The IND application “was very extensive and included all clinical and non-clinical reports on the Drug, which formed the basis of the submission.”<sup>97</sup>

132. On 17 and 19 March 2021, the FDA requested further information on the application, and suggested including stopping criteria and additional lab tests.<sup>98</sup>

133. Antibe responded to the FDA on 19 and 23 March 2023, agreeing with the FDA’s suggestions.<sup>99</sup>

134. On 29 March 2021, the FDA cleared Antibe’s IND application for the Drug.<sup>100</sup>

135. In June-July 2021, Antibe conducted its initial US-based clinical study. No adverse event occurred.<sup>101</sup>

## **J. From the Conclusion of the License Agreement to the Dispute**

136. As noted above, on 9 February 2021, the Parties entered into the License Agreement.<sup>102</sup>

137. On 25 February 2021, Nuance wrote to Antibe, asking for various actions “[t]o kick-off the ATB-346 project in China as soon as possible.”<sup>103</sup>

138. On 30 March 2021, the first Joint Development Committee (“**JDC**”) meeting was held.<sup>104</sup>

139. Antibe and Nuance agreed that: the JDC would meet every second week of each quarter; the regulatory affairs (“**RA**”) and medical teams from both sides would meet on a regular basis (bi-weekly/monthly); Antibe would provide updates on the latest progress of ATB-346; Antibe would need to provide download access to the data room; the parties would coordinate the first RA/medical meeting shortly.<sup>105</sup>

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<sup>96</sup> Exhibit C-043.

<sup>97</sup> Legault ¶ 64.

<sup>98</sup> Legault ¶ 65; Exhibits C-045 & C-046.

<sup>99</sup> Exhibits C-045 & C-046.

<sup>100</sup> Exhibit C-018; *see* Legault ¶ 66.

<sup>101</sup> *See* Legault ¶ 67; Exhibit R-009.

<sup>102</sup> Exhibit C-007; Exhibit R-037.

<sup>103</sup> Exhibit C-042.

<sup>104</sup> Exhibits C-014; C-049; R-038.

<sup>105</sup> Exhibit R-038.

140. Antibe shared draft minutes of the first JDC meeting on 2 April 2021, and followed-up on 11 April 2021, seeking to arrange an RA meeting soon, and requesting the latest update on ATB-346 as well as download access.<sup>106</sup>

141. The Parties agreed on a date for an RA/clinical meeting. Antibe followed-up on the request for download access on 21 April 2021.<sup>107</sup>

142. On 29 April 2021, Antibe asked Nuance to provide a summary of documents for which they required downloadable access. Nuance responded:

At this stage, we'd need to download

- all initial IND dossiers,
- Briefing book,
- all phase I- Phase III protocols, and
- all interaction files with FDA/EMA or othe[r] authority including (but not limited) EOP2 meeting dossiers, all FDA responses/comments. etc.
- In addition, all CMC validation reports, all individual preclinical reports, and all CSRs of phase I & Phase II which have already completed so far are requested as well.

Besides those documents, would you please share with us the current stage and next plan especially the timeline and strategy. We can then initiate the registration strategy, pathway and timeline of China accordingly. And the check list of documents for pre-IND and IND submission will be [definitely] created based on the regulatory strategy later on.<sup>108</sup>

143. On 5 May 2021, Antibe provided download access to the data room. Antibe stated that “[w]ith respect to the IND dossier, we are working on a way to be able to share this with you, as it is a very large document.”<sup>109</sup>

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<sup>106</sup> Exhibit C-008.

<sup>107</sup> Exhibit C-008.

<sup>108</sup> Exhibit C-008.

<sup>109</sup> Exhibit R-039.

144. The RA/clinical subcommittee meeting took place on 12 May 2021.<sup>110</sup> Both sides made presentations.<sup>111</sup>

145. On 19 July 2021, the second JDC meeting took place.<sup>112</sup>

146. As noted above, on 21 July 2021, Antibe shared with Nuance the “final protocol for the AME study which is currently ongoing in Canada.”<sup>113</sup>

147. On 30 July 2021, the AME Study hit the stopping criteria, and Antibe paused the AME Study.<sup>114</sup>

148. On 3 August 2021, Antibe issued a press release disclosing that the AME Study was placed on a required pause because a pre-specified safety threshold was exceeded.<sup>115</sup> Later on the same day, Antibe emailed Nuance to share the news.<sup>116</sup>

149. On 11 August 2021, Antibe and Nuance met to discuss the pause of the AME Study.<sup>117</sup> The CEOs of Antibe and Nuance (as well as Ms. Lee) also had a separate call.<sup>118</sup>

150. On 5 September 2021, Nuance, through counsel, wrote to Antibe: “My client hereby terminates the License Agreement with immediate effect and demands immediate refund of the \$20 million upfront fee it paid on February 19, 2021 with a \$10 million damages.”<sup>119</sup>

151. The Parties engaged in further exchanges and correspondence,<sup>120</sup> and the Claimant then filed its Notice of Arbitration in January 2022.

### **K. Antibe’s Continued Development of the Drug**

152. On 14 October 2021, Antibe issued a press release, stating that “[i]n our comprehensive review, it became apparent that otenaproxesul’s remarkable potency, GI protection and overall safety profile should be leveraged for acute pain use.”<sup>121</sup>

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<sup>110</sup> See Exhibits C-009 & R-040; *see also* Exhibit C-014.

<sup>111</sup> Exhibits C-009 & R-040.

<sup>112</sup> See Exhibits C-014 & C-059; *see also* Exhibit R-042.

<sup>113</sup> Exhibit R-043.

<sup>114</sup> Legault ¶ 63.

<sup>115</sup> Exhibit C-019.

<sup>116</sup> Exhibit C-013.

<sup>117</sup> Legault ¶ 108; *see also* Exhibit C-064.

<sup>118</sup> Legault ¶ 111.

<sup>119</sup> Exhibit R-045.

<sup>120</sup> See Exhibits R-048, R-049, R-050.

<sup>121</sup> Exhibit R-051.

153. In a November 2021 board presentation, Antibe described this as “the strategic pivot”: “Otenaproxesul for acute (vs chronic) pain.”<sup>122</sup> At the same time, Antibe maintains that it “has not abandoned its plans to develop the Drug for long-term use.”<sup>123</sup>

154. Mr. Legault in his witness statement and at the hearing provided evidence on the latest developments and Antibe’s plans for the Drug.<sup>124</sup> According to Mr. Legault, “Antibe is relying on [the US\$ 20 million upfront payment] to conduct its Phase 3 testing of the Drug and bring it forward for regulatory approval in the USA and Canada. Without the money, Antibe will not be able to develop and commercialize the Drug.”<sup>125</sup>

#### IV.

#### THE WITNESS EVIDENCE

155. In this proceeding, the Claimant submitted three statements or opinions from witnesses, and the Respondent submitted four statements or opinions from witnesses.<sup>126</sup> Each of the seven witnesses testified and was examined at the hearing.

156. In this section, the Tribunal provides an overview of the witness evidence.

##### A. The Claimant’s Witnesses

##### 1. Mr. Mark G. Lotter

157. The Claimant submitted a witness statement of Mr. Mark G. Lotter dated 24 March 2023.<sup>127</sup>

158. Mr. Lotter is the founder and Chief Executive Officer of the Nuance group, which comprises the Claimant.<sup>128</sup>

159. In his witness statement, Mr. Lotter addresses: the screening and evaluation of the Drug and of the Respondent by the Claimant’s Board; the JDC Meetings and the Drug’s development plan in China; the termination of the AME Study and the Respondent’s pivot to acute pain thereafter; the importance of the regulatory correspondence that the Respondent had withheld from the Claimant; and the loss that the Claimant alleges to have suffered as a result of the Respondent’s alleged wrongful conduct.<sup>129</sup>

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<sup>122</sup> Exhibit C-066.

<sup>123</sup> Legault ¶ 145.

<sup>124</sup> See Legault ¶¶ 129–147; see also Tr. (4) 181–182, 183–186 (Mr. Legault).

<sup>125</sup> Legault ¶ 147.

<sup>126</sup> See Tr. (1) 90:11–92:21 (Respondent’s Opening) (providing overview of the Respondent’s witness evidence).

<sup>127</sup> See generally Witness Statement of Mr Mark G. Lotter, 24 March 2023 (“Lotter”).

<sup>128</sup> Lotter ¶ 1.

<sup>129</sup> See Lotter ¶ 12.

160. At the hearing, Mr. Lotter testified, was examined, and answered the Tribunal's questions on 8 and 9 May 2023.<sup>130</sup>

## **2. Dr. Cathleen Chan**

161. The Claimant submitted a witness statement of Dr. Cathleen Chan dated 29 March 2023.<sup>131</sup>

162. Dr. Chan is the Managing Director, Regulatory Affairs, Joint Value Creation, of CBC Group, which is the controlling shareholder of the Claimant.<sup>132</sup>

163. In her witness statement, Dr. Chan sets out her opinion on the significance of the regulatory authorities' opinion in the drug development process and whether this may differ from the sponsors' own assessment; whether the liver safety results of the Drug in the presented data, without the regulatory authorities' feedback, is sufficient for an assessment of the potential/risks in respect of the Drug's approval, development and/or commercialization; and whether the changes introduced to the AME Protocol (v1.0) dated 16 December 2020 in the AME Protocol (v2.0) dated 30 April 2021 in respect of the Drug are material changes.<sup>133</sup>

164. At the hearing, Dr. Chan testified, was examined, and answered the Tribunal's question on 9 and 10 May 2023.<sup>134</sup>

## **3. Ms. Annie Lee**

165. The Claimant submitted a witness statement of Ms. Annie Lee dated 24 March 2023.<sup>135</sup>

166. Ms. Lee is the Managing Director of CBC Group, the controlling shareholder of the Claimant. From late 2020 to October 2021, she was also the Chief Operating Officer of the Claimant.<sup>136</sup>

167. In her witness statement, Ms. Lee addresses the circumstances leading up to the conclusion of the License Agreement (including the Claimant's due diligence), the conclusion of the License Agreement, the period post-signing of the License Agreement, the termination of the AME Study and the Respondent's pivot to acute pain, the Claimant's discovery that the Respondent withheld regulatory correspondence, and the Claimant's alleged loss.<sup>137</sup>

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<sup>130</sup> See generally Tr. (1) 147–204 (Mr. Lotter), (2) 4–170 (Mr. Lotter).

<sup>131</sup> See generally Witness Statement of Ms Cathleen Chan, 29 March 2023 (“Chan”).

<sup>132</sup> Chan ¶ 1.

<sup>133</sup> Chan ¶ 8.

<sup>134</sup> See generally Tr. (2) 171–203 (Dr. Chan); (3) 4–35 (Dr. Chan).

<sup>135</sup> See generally Witness Statement of Annie Lee, 24 March 2023 (“Lee”).

<sup>136</sup> Lee ¶¶ 1–2.

<sup>137</sup> See generally Lee.

168. At the hearing, Ms. Lee testified, was examined, and answered the Tribunal's questions on 10 May 2023.<sup>138</sup>

## **B. The Respondent's Witnesses**

### **1. Ms. Ella Korets-Smith**

169. The Respondent submitted a witness statement of Ms. Ella Korets-Smith dated 14 April 2023.<sup>139</sup>

170. Ms. Korets-Smith has been the Vice President, Business Development for the Respondent since January 2018. She was the Respondent's relationship manager with the Claimant for the licensing deal for the Drug.<sup>140</sup>

171. In her witness statement, Ms. Korets-Smith describes the communications and meetings with the Claimant prior to and following the signing of the License Agreement.<sup>141</sup>

172. At the hearing, Ms. Korets-Smith testified, was examined, and answered the Tribunal's questions on 10 and 11 May 2023.<sup>142</sup>

### **2. Mr. Daniel Legault**

173. The Respondent submitted a witness statement of Mr. Daniel Legault dated 13 April 2023.<sup>143</sup>

174. Mr. Legault is the Chief Executive Office of the Respondent.<sup>144</sup>

175. In his witness statement, Mr. Legault provides some background on the Drug and its development, and drug development in Canada and in the United States; discusses the introduction to the Claimant and the Claimant's due diligence; the work of the JDC, the Claimant's termination of the License Agreement, and the events following the Claimant's termination of the License Agreement; and addresses the ongoing development of the Drug.<sup>145</sup>

176. At the hearing, Mr. Legault testified, was examined, and answered the Tribunal's questions on 11 May 2023.<sup>146</sup>

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<sup>138</sup> See generally Tr. (3) 36–136 (Ms. Lee).

<sup>139</sup> See generally Witness Statement of Ella Korets-Smith, 14 April 2023 ("Korets-Smith").

<sup>140</sup> Korets-Smith ¶¶ 6–7.

<sup>141</sup> Korets-Smith ¶ 8.

<sup>142</sup> See generally Tr. (3) 138–199 (Ms. Korets-Smith); (4) 1–66 (Ms. Korets-Smith).

<sup>143</sup> See generally Witness Statement of Daniel Legault, 13 April 2023 ("Legault").

<sup>144</sup> Legault ¶ 1.

<sup>145</sup> See generally Legault.

<sup>146</sup> See generally Tr. (4) 66–193 (Mr. Legault).

### 3. Dr. Jonathan P. Jarow

177. The Respondent submitted a witness statement of Dr. Jonathan P. Jarow dated 19 April 2023.<sup>147</sup>

178. Dr. Jarow is a licensed medical doctor, surgeon, consultant to FDA regulated companies, and former medical officer at the FDA.<sup>148</sup>

179. In his witness statement, Dr. Jarow provided some background information (including on drug development and interactions with regulators), and provided his opinion on a number of points, including: whether there was sufficient data in the data room to identify risks in respect of the Drug's potential for regulatory approval from the FDA; whether a regulator's feedback is necessary to assess the potential and risks of a drug in development and the significance of the FDA's recommendations to the Drug's potential for regulatory approval from the FDA; the extent to which it can accurately be predicted whether a drug that has completed Phase 2 of testing will ultimately receive regulatory approval from the FDA; what information should generally be obtained to assess the potential benefits and risks of a drug in development based on his own work in due diligence; the opinions stated in Dr. Chan's witness statement.<sup>149</sup>

180. At the hearing, Dr. Jarow testified, was examined, and answered the Tribunal's questions on 12 May 2023.<sup>150</sup>

### 4. Mr. Jeffrey Wayne

181. The Respondent submitted a witness statement of Mr. Jeffrey Wayne dated 18 April 2023.<sup>151</sup>

182. Mr. Wayne is an independent consultant. He has worked in the pharmaceutical industry for over 40 years.<sup>152</sup>

183. In his witness statement, Mr. Wayne provides some background information on drug licensing in the drug development industry; his opinion as to whether the due diligence conducted by the Claimant in respect of the Drug was adequate in the circumstances; his opinion as to whether the Claimant was entitled to presume that the Respondent would provide it with all relevant and material documents about the Drug for due diligence purposes prior to Nuance signing the License Agreement, without any request from the Claimant; his opinion as to whether the Respondent was required as part of the due diligence process prior to signing the License Agreement, to provide the Claimant with

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<sup>147</sup> See generally Witness Statement of Jonathan P Jarow, MD, 19 April 2023 ("Jarow").

<sup>148</sup> Jarow ¶ 1.

<sup>149</sup> See Jarow ¶¶ 10–11.

<sup>150</sup> See generally Tr. (5) 1–46 (Dr. Jarow).

<sup>151</sup> Witness Statement of Jeffrey Wayne, B.SC., M.B.A., 18 April 2023 ("Wayne").

<sup>152</sup> See Wayne ¶ 4.



certain regulatory communications; his opinion as to whether the Respondent was required, after signing the License Agreement, to immediately provide the Claimant with certain regulatory communications, or to provide those communications at all; his opinion as to when the Respondent was required to provide Licensor Regulatory Documentation to the Claimant.<sup>153</sup>

184. At the hearing, Mr. Wayne testified and was examined on 12 May 2023.<sup>154</sup>

## V.

### JURISDICTION AND ADMISSIBILITY

185. Section 11.10(a) of the License Agreement contains a broad agreement to arbitrate. It provides:

Except as otherwise expressly provided herein, any dispute or claim arising out of or relating to this Agreement (except for any issues relating to the Development of the Products which must first be addressed as described under Section 4.2(b)), or to the breach, termination, or validity of this Agreement, will be resolved as follows: each Party shall discuss the matter and make reasonable efforts to attempt to resolve the dispute. If the Parties are unable to resolve the dispute, a Party may request that the Senior Officer of the Parties meet and attempt to resolve the dispute. Such meeting will occur within thirty (30) days of the written request. If the Senior Officers cannot resolve the dispute through good faith negotiations within sixty (60) days after such meeting, then the Parties will submit the dispute to binding arbitration before a single arbitrator using the arbitration procedures set forth under the international arbitration rules of the Singapore International Arbitration Centre (“SIAC”). Any hearing in the course of the arbitration shall be held in Singapore in the English language. The decision of the arbitrator shall be final and not subject to appeal. The arbitrator may apportion the costs of the arbitration, including the reasonable fees and disbursements of the parties, between or among the parties in such manner as the arbitrator considers reasonable. All matters in relation to the arbitration shall be kept confidential and subject to Article 7 (CONFIDENTIALITY AND NON-DISCLOSURE) to the full extent permitted by law, provided that either Party may disclose any such award or decision to the extent required to enforce such award or

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<sup>153</sup> See Wayne, Exhibit B.

<sup>154</sup> See generally Tr. (5) 47–66 (Mr. Wayne).

decision. No Person shall be appointed as an arbitrator unless he or she agrees in writing to be bound by such confidentiality obligations.<sup>155</sup>

186. The Parties do not contest, and the Tribunal finds, that the present dispute falls within the scope of the agreement to arbitrate in Section 11.10 of the License Agreement. Further, while the Respondent in these proceedings initially raised a jurisdictional objection, it then withdrew it.<sup>156</sup>

187. The Tribunal finds it has jurisdiction to hear and decide the present dispute.

188. The Parties have not raised any admissibility objection. The Tribunal sees no reason not to exercise her jurisdiction to hear and decide the present dispute. The Tribunal is satisfied that the pre-condition to arbitration in the arbitration agreement has been satisfied, in the light of the Respondent's withdrawal of its objection on that basis. Thus, the claims are admissible.

## VI.

### APPLICABLE LAW

189. The legal seat of the arbitration is Singapore.<sup>157</sup> Thus, the *lex arbitri* in this case is Singapore law. The SIAC Rules apply to this arbitration.<sup>158</sup>

190. Section 11.9 of the License Agreement provides: "This Agreement shall be governed and construed in accordance with the laws of the State of New York, USA, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction."<sup>159</sup>

## VII.

### THE PARTIES' ARGUMENTS ON THE MERITS AND THE TRIBUNAL'S DECISION

191. The dispute concerns the Claimant's allegations that the Respondent, *inter alia*: (i) made material misrepresentations and omissions pre-dating the conclusion of the License Agreement that induced the Claimant to enter into the License Agreement; (ii) made

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<sup>155</sup> Exhibit C-007, License Agreement, Section 11.10(a).

<sup>156</sup> See Letter from the Respondent dated 27 July 2022 ("Antibe has agreed to withdraw its motion with respect to the arbitrator's jurisdiction on the grounds that the Parties did not follow the dispute resolution procedure.").

<sup>157</sup> See Procedural Order No. 1 ¶ 25.

<sup>158</sup> See Exhibit C-007, License Agreement, Section 11.10(a); Procedural Order No. 1 ¶ 1.

<sup>159</sup> Exhibit C-007, License Agreement, Section 11.9.

material misrepresentations and omissions post-dating the entry into the License Agreement that induced the Claimant to continue to perform it; (iii) materially breached the License Agreement, and (iv) caused the License Agreement to be entered into by mistake.

192. The Tribunal's analysis and decision is set out below, following a summary of the Parties' respective positions, which is based on the Parties' own articulation of their claims and defenses, and which is not intended to be exhaustive. The Tribunal has carefully reviewed and considered all of the arguments and evidence presented by the Parties and has taken them into account in arriving at her decision.

**A. Whether Antibe Fraudulently Induced and/or Fraudulently Concealed Material Matters, or Made Negligent Misrepresentations, Which Induced Nuance To Enter into the License Agreement**

**1. The Claimant's Position**

193. In connection with matters pre-dating the conclusion of the License Agreement, the Claimant advances three claims: fraudulent concealment, fraudulent inducement, and negligent misrepresentation.<sup>160</sup>

**a. Legal Standard**

194. *First*, according to the Claimant, under New York law, the elements of a fraudulent concealment claim are "(1) a duty to disclose material facts; (2) knowledge of material facts by a party bound to make such disclosures; (3) failure to discharge a duty to disclose; (4) scienter; (5) reasonable reliance; and (6) damages."<sup>161</sup>

195. *Second*, as to the elements of a fraudulent inducement claim, the Claimant says that they are the following: "(1) the defendant made a material, false representation; (2) the defendant intended to defraud the plaintiff thereby; (3) the plaintiff reasonably relied upon the representation; and (4) the plaintiff suffered damage as a result of such reliance."<sup>162</sup>

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<sup>160</sup> See Claimant's Post-Hearing Brief ("Claimant's PHB") ¶ 99; Claimant's Opening Statement ("Hearing Opening Slide") 67; Statement of Reply ("Reply") ¶ 95; Statement of Claim ("Claim") ¶ 43; see also Notice of Arbitration ¶¶ 22–30.

<sup>161</sup> Claimant's PHB ¶ 103; Hearing Opening Slide 67 (citing to CLA-004, *De Sole v. Knoedler Gallery, LLC*, 139 F. Supp. 3d 618, 640 (S.D.N.Y. 2015); emphasis omitted); see also Claim ¶ 48 ("A fraudulent concealment claim shares the same elements as a fraudulent inducement claim, but with an additional requirement that a plaintiff must show that the defendant had a duty to disclose the material information.") (citing to CLA-019, *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011)); Tr. (1) 46:14–25 (Claimant's Opening).

<sup>162</sup> Claimant's PHB ¶ 150; Hearing Opening Slide 67 (citing to CLA-019, *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011)); see also Claim ¶¶ 44–47; Tr. (1) 46:14–25 (Claimant's Opening).

196. *Third*, according to the Claimant, the elements of a negligent misrepresentation claim under New York law are “(1) there exists a special relationship which imposes on the representor a duty to speak with care; (2) the representor knows or has reason to know that the information he provided is desired by the representee for a serious purpose; (3) the representor conveyed incorrect information; and (4) the representee reasonably relied on such information to his detriment.”<sup>163</sup> The Claimant contends that, in the commercial context, a duty to speak with care arises where persons “possess unique or specialized expertise, or are in a special position of confidence and trust with the injured party so that it would be expected that the other party would justifiably rely on the statement.”<sup>164</sup>

**b. Fraudulent Concealment/Misrepresentation**

197. The Claimant’s case on this point has evolved in the course of this proceeding. The Claimant says that this is because the Respondent’s acts were revealed through the disclosure process.<sup>165</sup>

198. In the Statement of Claim, paragraph 51, the Claimant focused on the following alleged express representations:

- a. The Drug has completed large Phase 2B studies for efficacy and gastrointestinal safety with strong results, and Phase 3 registration program initiation was expected in Q2 2021 [...];
- b. Recent third-party studies have validated the Drug’s commercial potential as an NSAID in the Chronic Pain Field [...];
- c. Antibe considered the assumptions on which the forward-looking statements and information it provided regarding the Drug and its development are based to be reasonable [...];
- d. Antibe believed that it had a reasonable scientific basis upon which it made statements of opinion or belief in respect of the Drug and its development [...].<sup>166</sup>

199. In paragraph 52, the Claimant also focused on the following alleged implied representations:

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<sup>163</sup> Claimant’s PHB ¶ 157; Hearing Opening Slide 68 (emphasis omitted); *see also* Claim ¶ 49 (citing to CLA-022, New York Contract Law, ¶¶ 21.26–21.27).

<sup>164</sup> Claimant’ PHB ¶ 158; Hearing Opening Slide 68 (citing to CLA-022, New York Contract Law, ¶¶ 21.27–21.28; emphasis omitted); *see also* Claim ¶ 50; Tr. (1) 47:1–22 (Claimant’s Opening).

<sup>165</sup> *See* Hearing Opening Slide 70; Tr. (1) 47:23–49:2 (Claimant’s Opening); *see also* Reply ¶ 11 (“It was only in November 2022 that Antibe was forced to disclose these material communications that it had previously concealed in the document production phase of the Arbitration”).

<sup>166</sup> Claim ¶ 51.

- a. The Drug could / would be approved, developed and commercialised in the Chronic Pain Field [...]. Corollary to this, the Drug could / would complete the AME Study and secure the relevant approvals from the FDA and Health Canada for the Drug to be developed and commercialised in the Chronic Pain Field [...];
- b. Antibe honestly believed and/or had reasonable grounds to believe that the Drug could / would be so approved, developed and/or commercialised [...];
- c. For the purposes of Nuance Pharma's due diligence, Antibe has provided all material information relating to the Drug and its development to Nuance Pharma [...];
- d. The information provided by Antibe to Nuance Pharma (including by way of the Data Room) relating to the Drug and its approval, development and/or commercialisation was when given, true, up-to-date, complete and accurate in all material respects, and Antibe has not omitted any matter / information, the omission of which would make such information untrue, inaccurate or misleading in any material respect, up to the time of the License Agreement. Antibe honestly held and/or had reasonable grounds for holding the intention to promptly notify Nuance Pharma if at any time Antibe becomes aware of any matter / information which results in or may reasonably result in any of the information disclosed being untrue, inaccurate or misleading in any material respect [...];
- e. Antibe was not aware of any matter / information which would or may reasonably adversely affect the Drug's approval, development and/or commercialisation in the Chronic Pain Field, including (i) completion of the AME Study; and (ii) securing the relevant approvals including from the FDA and Health Canada. If at any time Antibe becomes aware of any such matter / information, Antibe honestly held and/or had reasonable grounds for holding the intention to promptly notify Nuance Pharma of the same [...];
- f. Antibe honestly held and/or had reasonable grounds for holding the intention to submit the Draft AME Protocol to Health Canada for approval [...].<sup>167</sup>

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<sup>167</sup> Claim ¶ 52.

200. According to the Claimant, these pre-License Agreement representations were false or incorrect.<sup>168</sup> *First*, the Claimant said that the Respondent “was admittedly aware of potential issues which could / would adversely affect the Drug’s approval, development and/or commercialisation in the Chronic Pain Field prior and up to the conclusion of the License Agreement.”<sup>169</sup> *Second*, the Claimant contended that the Respondent “could not have honestly believed and/or have reasonable grounds to represent that it intended to submit the Draft AME Protocol to Health Canada for approval as it knew or ought to have known that the Protocol was liable to material change in view of the Liver Toxicity Issue (as was indeed the case).”<sup>170</sup> *Third*, the Claimant argued that the Respondent “did not provide information (including by way of the Data Room) that was true, up-to-date, complete and accurate when given, and omitted material information which would or may reasonably affect the Drug’s approval, development and/or commercialisation in the Chronic Pain Field.”<sup>171</sup>

201. In the Statement of Reply, paragraph 96, the Claimant referred to paragraphs 51 and 52 of the Statement of Claim, and focused on the following alleged representations:

- a. The Drug has completed large Phase 2B studies for efficacy and gastrointestinal safety with strong results, and Phase 3 registration program initiation was expected in Q2 2021.
- b. Following from (a) above, Antibe was not aware of any matter that could or would reasonably adversely affect the Drug’s Phase 3 of development.
- c. The information provided by Antibe to Nuance Pharma (including by way of the Data Room) relating to the Drug and its approval, development and/or commercialisation was when given, true, up-to-date, complete and accurate in all material respects, and Antibe has not omitted any matter / information, the omission of which would make such information untrue, inaccurate or misleading in any material respect, up to the time of the License Agreement.
- d. Antibe honestly held and/or had reasonable grounds for holding the intention to promptly notify Nuance Pharma if at any time Antibe becomes aware of any matter / information which results in or may reasonably result in any of the information disclosed being untrue, inaccurate or misleading in any material respect.

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<sup>168</sup> Claim ¶ 54.

<sup>169</sup> Claim ¶ 55; *see also id.* ¶¶ 56–58.

<sup>170</sup> Claim ¶ 59.

<sup>171</sup> Claim ¶ 60.

e. Antibe was not aware of any matter / information which would or may reasonably adversely affect the Drug's approval, development and/or commercialisation in the Chronic Pain Field, including: (i) completion of the AME Study; and (ii) securing the relevant approvals including from the FDA and Health Canada. If at any time Antibe becomes aware of any such matter / information, Antibe honestly held and/or had reasonable grounds for holding the intention to promptly notify Nuance Pharma of the same.<sup>172</sup>

202. The Claimant in the Statement of Reply reiterated that these alleged representations were false.<sup>173</sup> To show this, the Claimant also relied on the correspondence between the Respondent and Health Canada, "only produced **for the first time** through document production in this Arbitration."<sup>174</sup>

203. At the hearing and in its post-hearing brief, the Claimant articulated the fraudulent concealment claim as its primary claim,<sup>175</sup> focusing on the following alleged concealments of material facts:

a. Antibe's Health Canada communications in January 2021, which reveal that Health Canada had "serious concerns" about LTEs and the AME Study's 28 day dosing period.

b. The draft AME Protocol (v1.0) placed in the Data Room for due diligence purposes had effectively been rejected, and was not the version that would ultimately be submitted for Health Canada's approval (and in fact it was not).

c. Due to Health Canada's concerns, Phase 3 trials would start (at the earliest) in January 2022, instead of H2 2021.<sup>176</sup>

204. The Claimant contended that the Respondent was under a duty to speak because there was a disparity of knowledge between the Parties, as the Respondent had "exclusive" knowledge of the regulatory communications, "which Nuance Pharma had no means of knowing about."<sup>177</sup>

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<sup>172</sup> Reply ¶ 96; *see also id.* ¶¶ 97–100 (including argument at ¶ 100 that "[i]t is trite that under New York law, an actionable representation need not be express and may be implied by conduct.").

<sup>173</sup> *See generally* Reply ¶¶ 101–108.

<sup>174</sup> Reply ¶ 107 (emphasis in the original); *see also id.* ¶¶ 104–106.

<sup>175</sup> *See* Hearing Opening Slide 67 ("Nuance Pharma's primary claim is for fraudulent **concealment** of material facts prior to entering into the license Agreement") (emphasis in the original); Claimant's PHB ¶ 99 ("Nuance's submission for its primary claim for fraudulent concealment").

<sup>176</sup> Hearing Opening Slide 78 (emphasis omitted); *see also* Claimant's PHB ¶ 104.

<sup>177</sup> *See* Hearing Opening Slides 91–93 (quotations at slides 92 & 93, emphasis omitted); Tr. (1) 67:24–69:11 (Claimant's Opening); *see also* Claimant's PHB ¶¶ 107–110.

205. Also at the hearing and in its post-hearing brief, the Claimant argued “alternatively” that the Respondent “made material misrepresentations,” “by its statements and conduct”:

a. For the purposes of Nuance Pharma’s due diligence, Antibe had provided all material information relating to the Drug and its development to Nuance Pharma.

b. The information provided by Antibe to Nuance Pharma (including by way of the Data Room) relating to the Drug and its approval, development and/or commercialisation was when given, true, up-to-date, complete and accurate in all material respects, and Antibe had not omitted any matter / information, the omission of which would make such information untrue, inaccurate or misleading in any material respect, up to the time of the License Agreement

c. Antibe honestly held and/or had reasonable grounds for holding the intention to submit the Draft AME Protocol v1.0 – the version placed in the Data Room on 4 February 2021 – to Health Canada for approval.<sup>178</sup>

206. As to its alternative claim for negligent misrepresentation, the Claimant contends that the Parties’ relationship was “not a case of a single arms-length commercial transaction,” as the Parties were contracting into a long-term relationship; and “information disparity between the parties rendered the licensing deal inherently unfair without disclosure.”<sup>179</sup>

### **c. Materiality**

207. In the Statement of Claim, the Claimant stated that “[t]he information and documents for due diligence were meant to provide crucial and material information on the Drug’s approval and development,” and “[i]n particular, regulatory information and documentation ... were key milestone information and documents that would most directly apprise Nuance Pharma of any potential adverse issues affecting the Drug’s approval and development in the Chronic Pain Field.”<sup>180</sup>

208. Similarly, in the Statement of Reply, the Claimant asserted that the “previously-concealed documents have revealed that Antibe was well aware at all times that there was a material risk that the Drug could / would not be approved, developed and/or

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<sup>178</sup> Claimant’s PHB ¶ 152; *id.* ¶¶ 153–154; Hearing Opening Slide 94 (emphasis omitted); *see also* Hearing Opening Slides 95–96 (discussing CLA-33, *Raiffeisen Bank International v. Asia Col Energy* [2020] EWHC 2602 (Comm)); Tr. (1) 69:12–71:22 (Claimant’s Opening).

<sup>179</sup> Claimant’s PHB ¶ 159 (emphasis omitted).

<sup>180</sup> Claim ¶ 27.



commercialised in the Chronic Pain Field due to the regulatory authorities' serious concerns arising from the Liver Toxicity issue."<sup>181</sup>

209. At the hearing, the Claimant argued that "[t]he concealed Health Canada communications were material."<sup>182</sup> The Claimant asserted that the Respondent itself in a board update identified Health Canada's concerns as its "main corporate risk."<sup>183</sup> It argued that "[r]egulatory authorities are the key decision makers in the drug development process"<sup>184</sup>; because the Parties contemplated that the Claimant would in-license the Drug by building on the Drug's development process in the United States and Canada, the Claimant needed to have complete and up-to-date regulatory information<sup>185</sup>; when the Claimant reviewed the data room, it focused on regulatory interactions<sup>186</sup>; the Respondent's subsequent communications with Health Canada in March-April 2021 confirm the materiality of the communications in January 2021, as they ultimately led to "material study design changes" to the AME Protocol.<sup>187</sup>

210. In its post-hearing brief, the Claimant argues that the facts "revealing / stemming from Health Canada's serious concerns ... would have been important to a reasonable potential licensee."<sup>188</sup> The Claimant contends that (i) the Parties are agreed that potential licensees regard regulatory feedback to be important in assessing the risk of investing in a drug; (ii) Dr. Jarow's evidence shows that it was Health Canada's January 2021 communications that provided the first indication of an issue with duration (as opposed to dosage); and (iii) it was always understood that Nuance would leverage on the Drug's development in the United States and Canada in developing the Drug in China and therefore the delay to the Drug's development timeline would impact the Drug's development in China.<sup>189</sup>

#### **d. Scierter**

211. In the Statement of Claim and Statement of Reply, the Claimant asserted that the Respondent "could not have honestly believed" certain statements it made and "deliberately omitted" certain information from the due diligence process.<sup>190</sup>

212. At the outset of its arguments with respect to scierter at the hearing<sup>191</sup>, the Claimant contended that the heightened pleading standard mandated by United States Federal

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<sup>181</sup> Reply ¶ 11; *see also id.* ¶ 31.

<sup>182</sup> Hearing Opening Slides 79–90; Tr. (1) 59:24–67:23 (Claimant's Opening).

<sup>183</sup> Hearing Opening Slide 79 (quoting Exhibit C-040).

<sup>184</sup> Hearing Opening Slide 80.

<sup>185</sup> Hearing Opening Slide 81.

<sup>186</sup> Hearing Opening Slides 82–83.

<sup>187</sup> Hearing Opening Slides 84–90.

<sup>188</sup> Claimant's PHB ¶ 106 (emphasis omitted).

<sup>189</sup> Claimant's PHB ¶ 106; *see generally* Claimant's PHB ¶¶ 59–87.

<sup>190</sup> *See, e.g.*, Claim ¶¶ 59–60; Reply ¶¶ 106, 116.

<sup>191</sup> *See* Hearing Opening Slides 97–101; Tr. (1) 71:23–76:7 (Claimant's Opening).

Rule of Civil Procedure 9(b) is a procedural rule not applicable in the present proceeding.<sup>192</sup> It then argued that: (a) the concealments/misrepresentations were made by the Respondent with a view to concluding the License Agreement; (b) the Respondent's failure to provide the latest regulatory communications with Health Canada was "a deliberate omission" and "no explanation has been provided for this omission"; (c) the Respondent not only withheld the Health Canada communications but also "misleadingly represented that it planned to submit the draft AME Protocol (v1.0) to Health Canada in April/May 2021"; (d) the Respondent continued to conceal these material communications after the execution of the License Agreement; (e) the Respondent was motivated to enter into the License Agreement and obtain the US\$ 20 million upfront payment quickly.<sup>193</sup>

213. In its post-hearing brief, the Claimant argues that Antibe possessed the requisite scienter (or intent to defraud).<sup>194</sup> The Claimant first refers to its detailed factual argument in section II.C of its post-hearing brief that "Antibe knowingly withheld from Nuance its latest, up-to-date [January 2021 communications with Health Canada ("**Jan 2021 HCA Communications**")], which it further covered up with misleading responses to Nuance's due diligence queries,"<sup>195</sup> and to its argument on materiality in section II.D.<sup>196</sup>

214. The Claimant avers that "Antibe has never once said in its pleadings or witness statements that its omission of the 3 Health Canada communications dating 19 to 22 Jan 2021 ... was accidental."<sup>197</sup> According to the Claimant, "Antibe not only consciously omitted from the Data Room (only) the latest Jan 2021 HCA Communication, it then made positive but incomplete / partial disclosures."<sup>198</sup> The Claimant says that Antibe's own contemporaneous conduct from January up to July 2021 showed that Antibe attached importance to Health Canada's concerns.<sup>199</sup> The Claimant also relies on "Antibe's clear motivation – to move the licensing deal 'quickly to resolution' in order to secure the necessary funding for the Drug's continued development" and Antibe's "continued concealment of the relevant communications with Health Canada even after the parties had entered into the License Agreement" and more generally "Antibe's post-agreement conduct."<sup>200</sup>

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<sup>192</sup> Hearing Opening Slide 97.

<sup>193</sup> See Hearing Opening Slides 97–100; see also *id.* Slide 101 (addressing CLA-029, *Siegel v. Ford*, 2017 WL 4119654 (S.D.N.Y. 2017)).

<sup>194</sup> Claimant's PHB ¶¶ 111–116.

<sup>195</sup> See generally Claimant's PHB ¶¶ 27–58.

<sup>196</sup> See generally Claimant's PHB ¶¶ 59–87.

<sup>197</sup> Claimant's PHB ¶ 27 (emphasis in the original).

<sup>198</sup> Claimant's PHB ¶ 112(a) (emphasis omitted).

<sup>199</sup> Claimant's PHB ¶ 112(b).

<sup>200</sup> Claimant's PHB ¶ 113 (emphasis omitted); see also Claimant's PHB ¶¶ 21–26 ("Antibe was keen to move and secure the licensing deal which would provide the necessary, valuable funding for the Drug's continued, expensive development").

215. Alternatively, the Claimant says that “scienter is also satisfied by recklessness” and that proof of scienter is not necessary “if the Tribunal only finds for negligent misrepresentation.”<sup>201</sup>

**e. Inducement and/or Reasonable Reliance**

216. In the Statement of Claim, the Claimant argued that it relied on the pre-License Agreement representations in arriving at its decision to enter into the License Agreement, and that “[i]f [the Claimant] knew the Representations were false . . . , it goes without saying that it would not have entered into any (much less a long-term) licensing relationship with Antibe, or forked up the hefty US\$ 20 million upfront payment.”<sup>202</sup>

217. In the Statement of Reply and at the hearing, the Claimant developed this argument and responded to the Respondent’s arguments that the Claimant could not reasonably rely on the Respondent’s representations.<sup>203</sup>

218. In response to the Respondent’s argument that the Claimant is a sophisticated business party that had access to the information but failed to take advantage of that access, the Claimant contends that “the representee must have had the means to discover the truth to begin with.”<sup>204</sup> According to the Claimant, this is reflected in New York law, which provides that a party may rely on representations where they relate to matters “peculiarly within the other party’s knowledge” or where the truth is discoverable but only with “extraordinary effort or great difficulty.”<sup>205</sup>

219. The Claimant contends, *first*, that it was impossible for it to have discovered the concealment or that the Respondent’s representations were false, because the crucial information was exclusively in the Respondent’s possession<sup>206</sup>; *second*, the Claimant did specifically request further regulatory communications but the Respondent “willfully withheld this information.”<sup>207</sup> In other words, “[n]o amount of due diligence would have enabled Nuance Pharma to discover that Antibe had omitted material information from the Data Room.”<sup>208</sup> *Third*, in any case, the Claimant did conduct sufficient due diligence.<sup>209</sup>

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<sup>201</sup> Claimant’s PHB ¶¶ 115–116.

<sup>202</sup> Claim ¶¶ 68–69.

<sup>203</sup> See generally Reply ¶¶ 109–122; Hearing Opening Slides 102–121; Tr. (1) 76:8–84:25 (Claimant’s Opening).

<sup>204</sup> Reply ¶ 112.

<sup>205</sup> Reply ¶¶ 113–114 (collecting authorities at ¶ 114); see also Hearing Opening Slides 102–105.

<sup>206</sup> Reply ¶¶ 116–119.

<sup>207</sup> Reply ¶ 120; see also Hearing Opening Slide 109.

<sup>208</sup> Reply ¶ 121; see also Hearing Opening Slides 106–108.

<sup>209</sup> Reply ¶ 122; see also Hearing Opening Slides 110–121.

220. In its post-hearing brief, the Claimant argues that “Antibe’s primary defence is ... a red herring” as Nuance “could not have discovered the key concern identified in the (concealed) Health Canada Communications.”<sup>210</sup>

221. In any event, the Claimant argues that Nuance did exercise reasonable due diligence in relation to LTEs generally.<sup>211</sup> The Claimant also specifically objects to what it characterizes as the introduction by the Respondent of new allegations and evidence on this point at the hearing.<sup>212</sup>

#### **f. Merger/Disclaimer Clauses in the License Agreement**

222. The Claimant contends that the Respondent’s reliance on Clause 8.5 (Disclaimer of Warranties) and Clause 11.12 (Entire Agreement) of the License Agreement is misplaced.<sup>213</sup> In its post-hearing brief, the Claimant asserts that these clauses in any event “do not deal with / have no effect on Nuance’s claim for fraudulent concealment.”<sup>214</sup>

223. As to Clause 11.12, the Claimant argues that such clauses “only operate where it has been shown that there is a valid enforceable written agreement, and such clauses would generally not preclude reliance on misrepresentations (whether fraudulent or negligent).”<sup>215</sup> The Claimant says that “[i]t is not seriously contested that Antibe cannot rely on this Clause.”<sup>216</sup>

224. As to Clause 8.5, the Claimant contends that, *first*, it is qualified “[e]xcept as expressly set forth in the Agreement”<sup>217</sup>; and, *second*, generally-worded disclaimer clauses such as Clause 8.5 are insufficient to preclude reliance on misrepresentations (whether fraudulent or negligent) and cannot preclude reliance on misrepresentations concerning facts peculiarly within the defendant’s knowledge.<sup>218</sup>

#### **g. Rescission of the License Agreement and/or Damages**

225. The Claimant contends that it has suffered injury due to the pre-License Agreement representations, including (a) the US\$ 20 million it paid to the Respondent after the conclusion of the License Agreement, (b) the incidental expenditures incurred in

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<sup>210</sup> Claimant’s PHB ¶ 119 (emphasis omitted); *see also id.* ¶¶ 117–123, 88–92.

<sup>211</sup> *See generally* Claimant’s PHB ¶¶ 124–148.

<sup>212</sup> *See* Claimant’s PHB ¶¶ 139–142.

<sup>213</sup> *See generally* Hearing Opening Slides 122–124; Tr. (1) 85:1–14 (Claimant’s Opening); Reply ¶¶ 124–129; Claim ¶¶ 61–67.

<sup>214</sup> Claimant’s PHB ¶ 160 (emphasis omitted).

<sup>215</sup> Claim ¶¶ 63–64.

<sup>216</sup> Hearing Opening Slide 122 (citing to Rejoinder ¶ 107, which only refers to Clause 8.5).

<sup>217</sup> Hearing Opening Slide 123; Reply ¶ 125.

<sup>218</sup> Claimant’s PHB ¶¶ 161–162; Hearing Opening Slide 124; Reply ¶¶ 126–129; Claim ¶¶ 65–67.

performing the License Agreement, and (c) the opportunities lost as a result of the non-compete in Clause 2.9 of the License Agreement.<sup>219</sup>

226. The Claimant submits that, accordingly, it is “entitled to rescind the License Agreement so as to recover the sum of US\$ 20 million it paid to Antibe and/or damages (to be assessed) for all incidental expenditure it incurred in performing the License Agreement.”<sup>220</sup>

## **2. The Respondent’s Position<sup>221</sup>**

227. The Respondent submits that the Claimant’s claims are fundamentally based in fraud and that the Claimant has failed to substantiate its fraud allegations.<sup>222</sup>

### **a. Legal Standard**

228. The Respondent says that, to make out a claim for fraudulent inducement, the Claimant must show: “(a) that Antibe made a materially false representation, (b) that Antibe intended to defraud Nuance with that representation, (c) that Nuance reasonably relied upon the representation, and (d) that Nuance suffered damage as a result of such reliance.”<sup>223</sup>

229. According to the Respondent, fraudulent concealment requires proof of the same elements, plus that the Respondent had a duty to disclose material information.<sup>224</sup>

230. The Respondent contends that negligent misrepresentation involves the same elements “with two modifications”: there is “an additional requirement of a special relationship between the parties” and “the fraud scienter/intent requirement is replaced with a negligence standard.”<sup>225</sup>

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<sup>219</sup> Claimant’s PHB ¶ 149; Reply ¶ 123; Claim ¶¶ 70–71.

<sup>220</sup> Claim ¶ 71 (citing to CLA-024, Richard A. Lord, *Williston on Contracts* (4<sup>th</sup> ed. 2021), §69:47, §69:48, §69:61; CLA-020, *New York Law of Torts*, § 1.74).

<sup>221</sup> The Tribunal notes footnote 63 of the Statement of Defence, in which the Respondent states: “Antibe assumes that the legal claims by Nuance outlined in the Statement of Claim, which are narrower than those outlined in its Notice of Arbitration, are its claims in this proceeding and therefore has not responded to any allegations contained in Nuance’s Notice of Arbitration that are not contained in the Statement of Claim.”

<sup>222</sup> See generally Closing Submission of Antibe (“Respondent’s PHB”) ¶¶ 110–116; Rejoinder of Antibe (“Rejoinder”) ¶¶ 65–75; see also Response ¶ 46.

<sup>223</sup> Statement of Defence of Antibe (“Defence”) ¶ 180 (citing to RL-001, *Baker-Rhett v. Aspiro AB*, 324 F. Supp. 3d 407, 418-19 (S.D.N.Y. 2018)).

<sup>224</sup> Defence ¶ 181 (citing to RL-002, *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011)).

<sup>225</sup> Defence ¶ 182 (citing to RL-003, *DeBlasio v. Merrill Lynch & Co.*, 2009 WL 2242605, at \*32 (S.D.N.Y. July 27, 2009)).

231. According to the Respondent, to pursue a claim for fraudulent inducement, fraudulent concealment or negligent misrepresentation under New York law, Nuance must meet the heightened pleading requirements of Federal Rules of Civil Procedure 9(b).<sup>226</sup>

**b. No Material Misrepresentations or Concealment by Antibe**

232. The Respondent defines a representation as “an assertion of a fact, which is given by one party to induce another party to enter into a contract or take some other action.”<sup>227</sup> The Respondent says that it “did not make any representations to Nuance,” and in the alternative that it did not make any misrepresentations or omissions.<sup>228</sup>

233. In response to the Claimant’s list of alleged express representations at paragraph 51 of the Statement of Claim,<sup>229</sup> the Respondent contends that:

(a) Antibe made no representation that the Drug would be approved, developed, or commercialized, at all, or in the Field or Territory, or in respect of its “commercial potential as an NSAID in the Chronic Pain Field”. [...]

(b) The Corporate Presentation plainly did not comprise a representation by Antibe. The Corporate Presentation, as Nuance highlights in its Statement of Claim at paragraph 19(a), specifically included the following words: we “caution the reader that these assumptions regarding future events, many of which are beyond our control, may ultimately prove to be incorrect since they are subject to risks and uncertainties that affect us”. [...]

(c) The Drug did complete its Phase 2B studies for efficacy and GI safety with strong results and, at the time, Antibe expected the Phase 3 registration program to be initiated in Q2 2021 (and regardless, this was not a representation by Antibe).

(d) None of the information provided in the presentation slides ... referred to in paragraph 19 of the Statement of Claim constitute representations by Antibe. [...]<sup>230</sup>

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<sup>226</sup> Defence ¶ 183.

<sup>227</sup> Defence ¶ 185.

<sup>228</sup> Defence ¶¶ 186–187.

<sup>229</sup> See Claim ¶ 51 (quoted at paragraph 196 above).

<sup>230</sup> Defence ¶ 188; see also *id.* ¶ 189 (“Further and in the alternative, Antibe did in fact have reasonable grounds to believe and honestly believed any statements it made to be reasonable.”).

234. In response to the Claimant's list of alleged implied representations at paragraph 52 of the Statement of Claim,<sup>231</sup> the Respondent contends that:

(a) As stated previously, Antibe never made representations or promises to Nuance regarding the Drug's development or commercialization. Again, drug development is a highly risky field. While Antibe had reasonable grounds to and honestly believed the Drug could and would be approved, developed and/or commercialized, these did not constitute representations by Antibe.

(b) Antibe further did not represent that it had provided Antibe with all material information related to the Drug. However, Antibe did provide all material information to Nuance [...].

(c) Antibe made no representations advising that its documents were "up-to-date" or "complete and accurate in all material respects" and never represented that it had not "omitted any matter" or any information. ... Regardless, the information provided by Antibe was up-to-date, and complete and accurate. [...]

(d) Antibe made no representations in respect of completing the AME Study or securing relevant approvals, including from Health Canada or the FDA. [...]

(e) As noted above, Antibe had reasonable grounds for holding the intention to submit the AME Protocol to Health Canada. In fact, Antibe did submit the AME Protocol to Health Canada for approval on December 27, 2020. Regardless, this did not constitute a representation by Antibe.<sup>232</sup>

235. The Respondent in its post-hearing brief reiterates that "Antibe never made these or any other representations."<sup>233</sup>

236. The Respondent in any event denies the Claimant's assertions of falsity of the Respondent's statements.<sup>234</sup>

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<sup>231</sup> See Claim ¶ 52 (quoted at paragraph 197 above).

<sup>232</sup> Defence ¶ 190; *see also id.* ¶¶ 191 ("Further and in the alternative, a breach of an implied representation is not an actionable claim under New York law."), 192 ("Further and in the alternative, Antibe did in fact have reasonable grounds to believe and honestly believed any statements it made to be reasonable."); Rejoinder ¶ 92 ("there is no independent action for a 'breach of an implied representation' under New York law").

<sup>233</sup> Respondent's PHB ¶¶ 157–160 (quotation at ¶ 158).

<sup>234</sup> See Defence ¶¶ 193–194.

237. The Respondent reiterates the same points in the Rejoinder,<sup>235</sup> in response to the Claimant's identification of alleged misrepresentations in paragraphs 96–97 of the Reply.<sup>236</sup>

238. As to the fraudulent concealment claim, the Respondent notes that the Claimant must prove that there was a duty to disclose, that such duty arises “where one party possesses superior knowledge, not readily available to the other, and knows that the other is acting on the basis of mistaken knowledge,” and that this requirement is not met in this case.<sup>237</sup> The Respondent reiterates the point in its post-hearing brief.<sup>238</sup> Further, according to the Respondent in its post-hearing brief: Antibe never concealed evidence, “Nuance just never asked for them.”<sup>239</sup>

239. As to the negligent misrepresentation claim, the Respondent says that the Claimant must prove “a special relationship exists,” and that whether a special relationship exists turns on “(1) whether the person making the representation held or appeared to hold unique or special expertise; (2) whether a special relationship of trust or confidence existed between the parties; and (3) whether the speaker was aware of the use to which the information would be put and supplied if for that purpose.”<sup>240</sup> “Crucially,” according to the Respondent, “the parties must enjoy a relationship of trust and reliance closer than that of the ordinary buyer and seller, and an arm’s length business relationship is not enough.”<sup>241</sup> The Respondent submits that there was no special relationship between the Parties.<sup>242</sup> It reiterates the point in its post-hearing brief.<sup>243</sup>

### c. No Materiality

240. In its post-hearing brief, the Respondent argues that the Jan 2021 HCA Communications were not material.<sup>244</sup> The Respondent contends, relying in particular on the evidence of Dr. Chan and Dr. Jarow, that “the documents that were material to assessing the

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<sup>235</sup> See Rejoinder ¶¶ 86–88; see also *id.* ¶ 91 (“Nuance could have bargained for representations or warranties of particular issues, including the trajectory of the development of the Drug, if it wanted to. It chose not to.”).

<sup>236</sup> See Reply ¶¶ 96–97 (paragraph 96 quoted at paragraph 199 above).

<sup>237</sup> Defence ¶¶ 197–198 (quoting RL-009, *Brass v. Am. Film Tech., Inc.*, 987 F.2d 142, 150 (2d Cir. 1993)); see also Rejoinder ¶¶ 89–90 (“there was no significant disparity of information between Nuance and Antibe, and Antibe did not have ‘exclusive’ knowledge and access to information”).

<sup>238</sup> Respondent’s PHB ¶¶ 152–154.

<sup>239</sup> Respondent’s PHB ¶¶ 125–126.

<sup>240</sup> Defence ¶ 199 (internal quotation marks omitted) (quoting RL-010, *Kimmell v. Schaefer*, 89 N.Y.2d 257, 264 (N.Y. 1996)).

<sup>241</sup> Defence ¶ 199 (international quotation marks omitted) (quoting RL-012, *Fraternity Fund Ltd. v. Beacon Hill Asset Mgmt. LLC.*, 376 F. Supp. 2d 385, 411 (S.D.N.Y. 2005)).

<sup>242</sup> Defence ¶ 200.

<sup>243</sup> Respondent’s PHB ¶¶ 155–156.

<sup>244</sup> See Respondent’s PHB ¶¶ 127–134.



Drug’s risks were available in the Data Room” and that Nuance “did not need the January 2021 Health Canada communications to know or understand this information.”<sup>245</sup>

241. And the Respondent contends that Antibe’s other allegations of concealment are unfounded or trivial.<sup>246</sup>

**d. No Scienter**

242. As set out in further detail below, the Respondent says that the Claimant has neglected to adduce any facts on “the key element of fraud: intent/scienter.”<sup>247</sup> The Respondent contends that the Claimant’s “bare assertions of fraud” fail to support “any motive to deceive or manipulate” (the first prong of the test above), “beyond possibly implying generalized economic self-interest or securing profit,” which the Respondent says is insufficient.<sup>248</sup> As to recklessness (the second prong of the test above), the Respondent contends that it is conduct that is “highly unreasonable and which represents an extreme departure from the standards of ordinary care,” and that, again, the Claimant alleges no facts meeting that standard.<sup>249</sup> In its post-hearing brief, the Respondent contends that “Nuance has provided no evidence that Antibe intended to deceive Nuance” and “Nuance also has not established that Antibe had a motive to deceive Nuance.”<sup>250</sup>

**e. No Reasonable Reliance**

243. The Respondent contends that the Claimant “has not provided any evidence that it relied, reasonably or otherwise, on Antibe’s alleged representations.”<sup>251</sup> In its post-hearing brief, the Respondent argues that Nuance did not rely on regulatory communications.<sup>252</sup>

244. According to the Respondent, the Claimant is a “sophisticated industry professional” that “was obliged to do its own due diligence.”<sup>253</sup> The Respondent highlights the following statement from *Grumman Allied Industries*: “Where sophisticated businessmen engaged in major transactions enjoy access to critical information but fail to take advantage of

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<sup>245</sup> Respondent’s PHB ¶¶ 127–134 (quotations at ¶¶ 128 & 134).

<sup>246</sup> Respondent’s PHB ¶¶ 141–145.

<sup>247</sup> Rejoinder ¶ 93; *see also id.* ¶¶ 76–84.

<sup>248</sup> Rejoinder ¶ 79 (citing to RL-057, *Prickett v. New York Life Ins. Co.*, 896 F. Supp. 2d 236, 246 (S.D.N.Y. 2012) (“However, a general profit motive, such as the motive to earn fees, is not a sufficient motive to commit fraud.”)).

<sup>249</sup> Rejoinder ¶ 80 (quoting RL-058, *Barrett v. PJT Partners Inc.*, 2017 WL 3995606 (S.D.N.Y. Sept. 8, 2017) at 7).

<sup>250</sup> Respondent’s PHB ¶¶ 147–149 (quotations at ¶¶ 148 & 149 and emphasis in the original).

<sup>251</sup> Defence ¶ 201 (emphasis omitted); *see generally id.* ¶¶ 202–208; Rejoinder ¶¶ 94–104; *see also* Tr. (1) 121:9–133:23 (Respondent’s Opening) (addressing the Claimant’s due diligence).

<sup>252</sup> Respondent’s PHB ¶¶ 135–137.

<sup>253</sup> Defence ¶ 204.

that access, New York courts are particularly disinclined to entertain claims of justifiable reliance.”<sup>254</sup>

245. The Respondent argues that the Claimant “was certainly in a position to acquire additional information, including by requesting information from Antibe, or by reviewing information that was available to the public.”<sup>255</sup> The Respondent emphasizes that it was not responsible for the Claimant’s due diligence.<sup>256</sup>

246. In the Rejoinder, the Respondent seeks to distinguish the cases on which the Claimant relied in the Statement of Reply.<sup>257</sup> The Respondent further submits that the Claimant’s assertion that it conducted sufficient due diligence “alone negates its claims in respect of reasonable reliance.”<sup>258</sup>

247. More generally, the Respondent faults the Claimant for conducting a deficient due diligence.<sup>259</sup> It argues the point in detail in its post-hearing brief.<sup>260</sup> In particular, the Respondent argues that Nuance failed to identify obvious safety and dose risks.<sup>261</sup>

248. In its post-hearing brief, the Respondent puts its argument on this point as follows:

4. Contrary to Nuance’s assertions, [Nuance] did not require regulatory communications to identify and assess the risks associated with the Drug. The main risk associated with the Drug was liver toxicity, which was identified through [LTEs]. Antibe provided Nuance with all of the non-clinical and clinical study reports about the Drug in the Data Room and, even before then, had alerted Nuance in December 2020 to the LTEs seen in the most recent clinical study. Nuance’s own witness, Dr. Cathleen Chan, testified that the LTEs documented in the Drug’s most recent clinical study report alone should have been

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<sup>254</sup> Defence ¶ 206 (quoting RL-015, *Grumman Allied Industries, Inc. v. Rohr Industries, Inc.*, 748 F.2d 729, 737 (2d Cir. 1984)) (emphasis omitted); *see also* Respondent’s PHB ¶¶ 150–151.

<sup>255</sup> Defence ¶ 207.

<sup>256</sup> Defence ¶ 208; *see also* Respondent’s PHB ¶¶ 119–120 (“Nuance was Responsible for Its Due Diligence”).

<sup>257</sup> *See* Rejoinder ¶¶ 95–104.

<sup>258</sup> Rejoinder ¶ 94.

<sup>259</sup> *See, e.g.*, Rejoinder ¶¶ 19 (“On December 23, 2020, after three ZOOM meetings, an exchange of corporate presentations, and some email correspondence, Nuance sent Antibe a draft term sheet and a deal proposal in which it offered to pay Antibe US\$ 100 million plus a royalty ...”), 38 (“Nuance has indicated that, in the course of the arbitration, it has provided all of the documents in its possession that are relevant to its due diligence. There are six documents in total.”).

<sup>260</sup> *See generally* Respondent’s PHB ¶¶ 121–124, 56–64, 65–70.

<sup>261</sup> Respondent’s PHB ¶¶ 65–70.

a red flag for Nuance and would have been of particular concern to the Chinese regulator.

5. Ironically, the evidence demonstrates conclusively that Nuance was aware of the LTEs. It either failed to appreciate that the LTEs posed significant risks or chose to ignore the obvious risks and take a calculated risk that the Drug would succeed, and high rewards would follow. Dr. Chan testified she recognized the LTEs as a safety risk and that any doctor should have been able to do the same. Regulatory expert Dr. Jonathan Jarow testified there was another risk that was obvious from the data Antibe provided to Nuance at the start of its due diligence: that Antibe may not be able to find an ‘effective’ dose of the Drug—that is, a dose that was both efficacious and safe.

6. Nuance knew Antibe had not been able to identify an effective dose for 14-day use of the Drug. Unusually high liver enzyme elevations had been documented in all groups of study patients who had taken the Drug in the most recent clinical study, regardless of dose. The patients had taken the Drug for just 14 days. In order to have the Drug approved for chronic use, such as the osteoarthritis indication it was pursuing, Antibe would have to successfully complete a minimum 12-week study, with patients followed for a year after the study ended. There were real risks that even if Antibe could identify an effective dose for a 14-day period, that dose either would not be efficacious (because it was too low) or could cause serious liver toxicity (because the dose was too high, or the duration was too long) if administered over the duration required to get the Drug approved for a chronic condition indication.

7. Nuance never took any steps to understand the nature and extent of the risks related to the LTEs. It never asked Antibe a single question about the LTEs. The evidence suggests it did not obtain or review publicly available information on the significance of the LTEs, such as the naproxen label or Antibe’s 2015 press release announcing it was pausing the Drug’s clinical study because of LTEs. It never completely reviewed any of Antibe’s clinical study reports.

8. Now, Nuance blames Antibe for its failure to obtain and review regulatory communications and, in particular, Antibe’s January 2021 correspondence with Health Canada. Nuance also blames Antibe for its failure to recognize and assess the risks associated with the Drug. These failings are the direct result of

Nuance’s inadequate due diligence and Nuance alone is responsible for the consequences.<sup>262</sup>

**f. Antibe Can Rely on the Merger/Disclaimer Provision**

249. The Respondent relies on the “merger clause” (the entire agreement clause at Clause 11.2 of the License Agreement) and the “disclaimer clause” (the representations and warranties clause at Section 8 of the License Agreement).<sup>263</sup>

250. The Respondent underlines that Clause 8.5 expressly disclaims any express or implied warranties of “fitness for a particular purpose.”<sup>264</sup>

251. The Respondent contends that “[d]espite the lack of an explicit disclaimer of alleged representations that form the basis of a fraudulent inducement claim, courts may disregard a fraudulent inducement claim and give effect to a contract when sophisticated parties who negotiated at arms length could have easily protected themselves either through obtaining readily available information or alternatively including a protective clause in the agreement.”<sup>265</sup>

**g. No Injury and Rescission Is Not Available**

252. The Respondent submits that the Claimant has not alleged any injury: the Drug “was and remains a promising drug, it continues to be developed, it remains an effective NSAID for use in the Field, and Antibe remains committed to a partnership with Nuance in respect of the Drug.”<sup>266</sup>

253. The Respondent further contends that, even if the Claimant had suffered injury, the Claimant’s “crucial lack of due diligence” is a “direct intervening factor in said injury,” breaking the causation chain.<sup>267</sup>

254. In its post-hearing brief, the Respondent argues that Nuance was not induced to enter into the License Agreement, and therefore there is no evidence that the alleged concealment “is linked to the alleged harm.”<sup>268</sup> The Respondent points to the testimony of Mr. Lotter, which according to the Respondent demonstrates that Nuance would have entered into the License Agreement regardless of the January 2021 Health Canada communications.<sup>269</sup>

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<sup>262</sup> Respondent’s PHB ¶¶ 4–8.

<sup>263</sup> Defence ¶ 233.

<sup>264</sup> Defence ¶ 236; *see also* Rejoinder ¶ 107.

<sup>265</sup> Defence ¶ 238; *see also* Respondent’s PHB ¶¶ 161–162.

<sup>266</sup> Defence ¶ 210; *see also* Rejoinder ¶ 105.

<sup>267</sup> Defence ¶ 211.

<sup>268</sup> Respondent’s PHB ¶¶ 138–140.

<sup>269</sup> Respondent’s PHB ¶ 140 (citing to Tr. (2) 161:25 to 162:8 (Mr. Lotter)).

255. Thus, according to the Respondent, the Claimant is not entitled to rescission, repayment of the upfront payment it provided to the Respondent, or to any damages.<sup>270</sup>

### 3. The Tribunal's Analysis and Decision

#### a. Fraudulent Misrepresentation / Concealment

256. The Tribunal starts with what Claimant now characterizes as its primary claim for fraudulent concealment of material facts that induced Claimant into entering the Licensing Agreement<sup>271</sup> or fraudulent inducement based on Respondent's "material misrepresentations," "by its statements and conduct."<sup>272</sup>

257. For purposes of its fraudulent concealment claim, the Claimant places particular emphasis on the correspondence between the Respondent and Health Canada<sup>273</sup> and focuses on the following alleged concealments of material facts:

- a. Antibe's Health Canada communications in January 2021, which reveal that Health Canada had "serious concerns" about LTEs and the AME Study's 28 day dosing period.
- b. The draft AME Protocol (v1.0) placed in the Data Room for due diligence purposes had effectively been rejected, and was not the version that would ultimately be submitted for Health Canada's approval (and in fact it was not).
- c. Due to Health Canada's concerns, Phase 3 trials would start (at the earliest) in January 2022, instead of H2 2021.<sup>274</sup>

258. For purposes of its fraudulent misrepresentation/inducement claim, the Claimant focuses on the following alleged material misrepresentations/omissions:

- a. For the purposes of Nuance Pharma's due diligence, Antibe had provided all material information relating to the Drug and its development to Nuance Pharma.
- b. The information provided by Antibe to Nuance Pharma (including by way of the Data Room) relating to the Drug and

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<sup>270</sup> Defence ¶ 212; *see also* Rejoinder ¶ 106.

<sup>271</sup> *See* Hearing Opening Slide 67 ("Nuance Pharma's primary claim is for fraudulent **concealment** of material facts prior to entering into the license Agreement") (emphasis in the original); Claimant's PHB ¶ 99 ("Nuance's submission for its primary claim for fraudulent concealment").

<sup>272</sup> *See, e.g.*, Claimant's PHB ¶ 152; *id.* ¶¶ 153–154; Hearing Opening Slide 67. Claimant's claim for negligent misrepresentation is made "alternatively." Hearing Opening Slide 67.

<sup>273</sup> *See* Hearing Opening Slides 71–78; Tr. (1) 49:3–59:18 (Claimant's Opening).

<sup>274</sup> Hearing Opening Slide 78 (emphasis omitted); *see also* Claimant's PHB ¶ 104.

its approval, development and/or commercialisation was when given, true, up-to-date, complete and accurate in all material respects, and Antibe had not omitted any matter / information, the omission of which would make such information untrue, inaccurate or misleading in any material respect, up to the time of the License Agreement

c. Antibe honestly held and/or had reasonable grounds for holding the intention to submit the Draft AME Protocol v1.0 – the version placed in the Data Room on 4 February 2021 – to Health Canada for approval.<sup>275</sup>

259. Under New York law, the elements of a fraudulent misrepresentation/ inducement claim, are the following: “(1) the defendant made a material, false representation; (2) the defendant intended to defraud the plaintiff thereby; (3) the plaintiff reasonably relied upon the representation; and (4) the plaintiff suffered damage as a result of such reliance.”<sup>276</sup> The elements of a fraudulent concealment claim are “(1) a duty to disclose material facts; (2) knowledge of material facts by a party bound to make such disclosures; (3) failure to discharge a duty to disclose; (4) scienter; (5) reasonable reliance; and (6) damages.”<sup>277</sup> A fraudulent concealment claim thus shares the same elements as a fraudulent inducement claim, but with an additional requirement that a plaintiff must show that the defendant had a duty to disclose the material information. On these points, the Parties appear to agree.<sup>278</sup>

260. With respect to the Claimant’s claim of fraudulent misrepresentation / inducement, the Tribunal finds that the Respondent made misrepresentations and/or omissions leading up to the License Agreement, and that they were material. Importantly, the Claimant’s allegations and evidence in this regard are not fairly characterized as just about the risks associated with LTEs or effective dosage with respect to the Drug, as Respondent argues<sup>279</sup>, but rather the specific positions of regulatory authorities actively assessing the Drug as part of the ongoing regulatory review and approval process.<sup>280</sup> The Tribunal credits the

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<sup>275</sup> Claimant’s PHB ¶ 152; *id.* ¶¶ 153–154; Hearing Opening Slide 94 (emphasis omitted); *see also* Hearing Opening Slides 95–96 (discussing CLA-33, *Raiffeisen Bank International v. Asia Col Energy* [2020] EWHC 2602 (Comm)); Tr. (1) 69:12–71:22 (Claimant’s Opening).

<sup>276</sup> Hearing Opening Slide 67 (citing to CLA-019, *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011)); *see also* Claimant’s PHB ¶ 150; Claim ¶¶ 44–47; Tr. (1) 46:14–25 (Claimant’s Opening).

<sup>277</sup> Hearing Opening Slide 67 (citing to CLA-004, *De Sole v. Knoedler Gallery, LLC*, 139 F. Supp. 3d 618, 640 (S.D.N.Y. 2015); emphasis omitted); *see also* Claimant’s PHB ¶ 103.

<sup>278</sup> Hearing Opening Slide 67; Claim ¶ 48 (citing to CLA-019, *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011)); Tr. (1) 46:14–25 (Claimant’s Opening); Defence ¶ 181 (citing to RL-002, *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011)).

<sup>279</sup> *See, e.g.*, Respondent’s PHB ¶¶ 4–8; Respondent’s PHB ¶¶ 127–134.

<sup>280</sup> Hearing Opening Slides 79–90; Tr. (1) 59:24–67:23 (Claimant’s Opening).

evidence presented by the Claimant that the Respondent had “exclusive” knowledge of the regulatory communications, “which Nuance Pharma had no means of knowing about”.<sup>281</sup>

261. Here, the positions taken by Health Canada vis-à-vis the Drug, and specifically its “serious concerns” expressed on 19 January 2021 in the context of the AME Study<sup>282</sup> were so significant that they: warranted a meeting between Antibe’s top executives and Health Canada on 22 January 2021 during which Health Canada advised it “cannot issue a favorable decision” for Antibe’s CTA “at this time” and “proposed changes in the response are considered significant changes in the protocol design”; caused the Respondent to withdraw its CTA the same day; and ultimately led to design changes to the AME Protocol that included the age of the subjects, removal of a higher strength, and the addition of formal stopping criteria.<sup>283</sup> Notably, the Respondent itself in an update to its Board identified Health Canada’s concerns as its “main corporate risk”.<sup>284</sup> The Tribunal also credits the Claimant’s evidence, including the testimony of its witnesses, that the Parties contemplated that the Claimant would in-license the Drug in China by building on the Drug’s development process in the United States and Canada<sup>285</sup>, and thus complete and up-to-date regulatory information was a material consideration in entering into the Licensing Agreement.<sup>286</sup> Such consideration notably was echoed by the Respondent’s own expert, Dr. Jarow, who conceded at the hearing that it was Health Canada’s January 2021 communications that provided the first indication of an issue as to duration (as opposed to dosage),<sup>287</sup> and that as a general matter regulatory feedback is “very important”.<sup>288</sup>

262. This takes the Tribunal to the Respondent’s argument that the Claimant has failed to adduce facts sufficient to demonstrate “the key element of fraud: intent/scienter.”<sup>289</sup>

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<sup>281</sup> See Hearing Opening Slides 91–93 (quotations at slides 92 & 93, emphasis omitted); Tr. (1) 67:24–69:11 (Claimant’s Opening); see also Claimant’s PHB ¶¶ 107–110.

<sup>282</sup> Exhibit C-035 (Health Canada’s Request for Additional Information expressing “serious concerns regarding the potential risk of liver related AEs/SAEs in the proposed Phase 1b health human study”).

<sup>283</sup> See, e.g., Exhibits C-037 & C-038; Hearing Opening Slides 84–90.

<sup>284</sup> Exhibit C-040.

<sup>285</sup> See, e.g., Hearing Opening Slide 81; Claimant’s PHB ¶ 106; see generally Claimant’s PHB ¶¶ 59–87.

<sup>286</sup> See, e.g., Lotter ¶¶ 52 (“I have reviewed these documents and have no doubt that, if they had been disclosed to Nuance in the Data Room, these would have been flagged as regulatory / safety ‘showstoppers’ and I would not have recommended the licensing deal to the Board at the time, much less on the terms that were eventually agreed on.”), 54 (“I can only surmise that Antibe must have known that these regulatory correspondence would have been red flags to Nuance Pharma as well [as] the Chinese regulatory authorities. Antibe therefore concealed them as it know (or was concerned) that, if these were disclosed, they would spook Nuance Pharma from the deal.”).

<sup>287</sup> Tr. (5) 41:14–42:5, 43:18–44:2 (Dr. Jarow).

<sup>288</sup> Tr. (5) 15:12–16:8 (Dr. Jarow); see Claimant’s PHB ¶ 3.

<sup>289</sup> Rejoinder ¶ 93; see also *id.* ¶¶ 76–84.

Under New York law, the Claimant must adduce “clear and convincing evidence that the misrepresentations were made with the intent to deceive.”<sup>290</sup>

263. The Respondent says that the Claimant must “give rise to a strong inference of fraudulent intent” by “alleging facts that 1) show that Antibe had both motive and opportunity to commit fraud, or that 2) constitute strong circumstantial evidence of conscious misbehavior or recklessness, and [the Claimant] must do so with respect to *each* alleged act or omission.”<sup>291</sup> The Respondent contends that the Claimant’s “bare assertions of fraud” fail to support “any motive to deceive or manipulate” (the first prong of the test above), “beyond possibly implying generalized economic self-interest or securing profit,” which the Respondent says is insufficient.<sup>292</sup> As to recklessness (the second prong of the test above), the Respondent contends that it is conduct that is “highly unreasonable and which represents an extreme departure from the standards of ordinary care,” and that, again, the Claimant alleges no facts meeting that standard.<sup>293</sup> According to the Respondent, Health Canada’s “serious concerns” were “alleviated” and the Final AME Protocol was submitted to Health Canada in May of 2021 and was approved “with what was essentially an administrative change from the draft protocol submitted the previous December”: “There was no material change.”<sup>294</sup> In its post-hearing brief, the Respondent contends that “Nuance has provided no evidence that Antibe intended to deceive Nuance” and “Nuance also has not established that Antibe had a motive to deceive Nuance.”<sup>295</sup>

264. As an initial matter, while the Tribunal agrees with the Claimant that the heightened pleading standard mandated by United States Federal Rule of Civil Procedure 9(b) is a procedural rule not applicable in the present proceeding<sup>296</sup>, the cases adduced and addressed by both Parties that deal with the pleading standard are helpful in delineating the showing necessary to establish scienter under New York law. In this regard, the *Siegel v. Ford* case, cited by both Parties, is instructive.<sup>297</sup> In that case, the district court for the Southern District of New York rejected the respondent’s motion to dismiss for failure to state a claim the plaintiffs’ common law fraud claim under New York law. In finding that the plaintiffs had adequately pleaded scienter, the court found that “the allegations in the

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<sup>290</sup> See *E-21 Glob., Inc. v. Second Renaissance, LLC*, 360 F. App’x 172, 175 (2d Cir. 2009) (cited to at Respondent’s PHB ¶ 147 n. 181 (unnumbered legal authority submitted with Respondent’s PHB)).

<sup>291</sup> Rejoinder ¶ 78 (emphasis in the original) (quoting RL-053, *Tellabs, Inc. v. Makor issues & Rights, Ltd.*, 551 US. 308, 310, 334 (2007)); see also Defence ¶ 195.

<sup>292</sup> Rejoinder ¶ 79 (citing to RL-057, *Prickett v. New York Life Ins. Co.*, 896 F. Supp. 2d 236, 246 (S.D.N.Y. 2012) (“However, a general profit motive, such as the motive to earn fees, is not a sufficient motive to commit fraud.”)).

<sup>293</sup> Rejoinder ¶ 80 (quoting RL-058, *Barrett v. PJT Partners Inc.*, 2017 WL 3995606 (S.D.N.Y. Sept. 8, 2017) at 7).

<sup>294</sup> Rejoinder ¶ 81; see *id.* at ¶ 82.

<sup>295</sup> Respondent’s PHB ¶¶ 147–149 (quotations at ¶¶ 148 & 149 and emphasis in the original).

<sup>296</sup> Hearing Opening Slide 97.

<sup>297</sup> CLA-029, *Siegel v. Ford*, 2017 WL 4119654 (S.D.N.Y. 2017); see, e.g., Reply ¶¶ 117–118, Rejoinder ¶¶ 100–104.



complaint, when taken as true permit the inference that [the respondent] either knowingly or recklessly” engaged in misrepresentation.<sup>298</sup> The issue is factual in nature, centering on when an inference can be established that a defendant knowingly or recklessly misrepresented or failed to disclose a material fact.<sup>299</sup>

265. The *Meda* case<sup>300</sup>, on which both Parties rely<sup>301</sup>, is particularly analogous. In that case, the court applied New York law to dismiss the plaintiff’s case after a bench trial on the basis that the plaintiff “did not establish” that the defendant’s failure to place a certain drug pricing agreement that it had with the French government in the data room “was intentional or reckless.”<sup>302</sup> Notably, the court found that the plaintiff “failed to show by clear and convincing evidence that anyone at [defendant company] knowingly or recklessly made any fraudulent misrepresentation or omissions” where, *inter alia*: the documentary and testimonial evidence adduced established that the defendant company’s “executives in Minnesota put time and care into preparing what they reasonably believed to be truthful, conservative, and honest offering materials”; “[n]o European country’s drug pricing agreements were in the data room, and [plaintiff] appears never to have noticed that absence”; and “there was no specific effort to hide a French drug pricing agreement.”<sup>303</sup>

266. On the basis of the documentary and testimonial evidence presented—including in assessing the credibility of the testimony from the Parties’ respective witnesses at the hearing—the Tribunal finds that the Claimant has met its burden to establish that Antibe acted with the requisite scienter under New York law with respect to its misrepresentations and omissions involving the correspondence and discussions with Health Canada.

267. As detailed further above, the following key events took place prior to the execution of the License Agreement:

- € On 25 January 2021, Antibe opened the Data Room to Nuance, which included 17 regulatory documents, including 15 relating to Health Canada dating back to 2014. The Data Room did not include:

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<sup>298</sup> CLA-029, *Siegel v. Ford*, 2017 WL 4119654 (S.D.N.Y. 2017) at \*10 (emphasis added). *See also* the *Loreley* case, cited by the Claimant in its Post-Hearing Brief, which itself relies on a case from the New York Court of Appeal (the highest court in New York). CLA-044, *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 175 (2d. Cir 2015) (“Under New York law, Plaintiffs must ultimately prove that Defendants possessed ‘knowledge of [their misstatements]’ falsity’ and ‘an intent to induce reliance.’”) (quoting *Eurycleia Partners, LP v. Seward & Kissel, LLP*, 12 N.Y.3d 553, 559 (N.Y. 2009)).

<sup>299</sup> *See* CLA-004, *De Sole v. Knoedler Gallery, LLC*, 139 F. Supp. 3d 618, 641 (S.D.N.Y. 2015) (“Whether a given intent existed is generally a question of fact, appropriate for resolution by the trier of fact.”) (internal quotation and citation omitted).

<sup>300</sup> RL-052, *Meda AB v. 3M Co.*, 969 F. Supp. 2d 360 (S.D.N.Y. 2013).

<sup>301</sup> *See, e.g.*, Rejoinder ¶¶ 69–73; Claimant’s PHB ¶ 114.

<sup>302</sup> RL-052, *Meda AB v. 3M Co.*, 969 F. Supp. 2d 360, 376 (S.D.N.Y. 2013).

<sup>303</sup> RL-052, *Meda AB v. 3M Co.*, 969 F. Supp. 2d 360, 385–386 (S.D.N.Y. 2013).

The 19 January 2021 correspondence sent the week before from Health Canada, in which Health Canada failed to approve the AME Study CTA that Antibe had filed on 27 December 2020<sup>304</sup> and instead sought additional information, raising “serious concerns regarding the potential risk of liver related AEs [adverse events]/SAEs [serious adverse events] in the proposed Phase 1b health human study, despite the low(er) ATB-346 doses (75mg, 100mg, 125 mg, and 150 mg), given that this is the first study with a 28-day treatment duration.”<sup>305</sup>

The 21 January 2021 detailed response from Antibe to Health Canada providing information on dosage and safety protocols.<sup>306</sup>

Information relating to the 22 January 2021 meeting between senior executives of Antibe—including Daniel Legault, the Chief Executive Officer—and Health Canada, including draft minutes of 26 January 2021 put together by a regulatory consultant working with Antibe<sup>307</sup>, which memorialize, among other things, that Health Canada took the position that (1) “The [Office of Clinical Trials] cannot issue a favourable decision for this [CTA] at this time”; (2) the “[p]roposed changes in the response are considered significant changes in the protocol design and therefore the protocol would require a full review”; and (3) Health Canada “offered to allow Antibe to withdraw the CTA by 11AM or a rejection would be issued”.<sup>308</sup>

Antibe accordingly sent a letter later that day on 22 January 2021 withdrawing the CTA.<sup>309</sup>

- € On 28 January 2021, Nuance wrote to Antibe specifically to note the absence of phase three studies in the Data Room and requested that Antibe “help to upload the phase 3 study information (protocols, status ... etc) which is import for us to evaluate if the design and timeline are applicable in China.”<sup>310</sup>
- € Antibe did not respond immediately, and instead suggested the next day (29 January) that Nuance “gather all of the diligence questions from Nuance and send over to Antibe for response at once. We would very much appreciate this format, as our team would like to take this list and answer thoughtfully and fulsomely.”<sup>311</sup>

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<sup>304</sup> Legault ¶ 53; Exhibit R-006.

<sup>305</sup> Exhibit C-035.

<sup>306</sup> Exhibit C-036.

<sup>307</sup> Exhibit C-037.

<sup>308</sup> Exhibit C-037.

<sup>309</sup> Exhibit C-038.

<sup>310</sup> Exhibit R-031.

<sup>311</sup> Exhibit R-031.

- € On 3 February 2021, Nuance sent to Antibe a list of requests for information and documents, including “Protocols and timelines for 3 efficacy studies (study #1, #2, #3) and 2 GI safety studies (presented in the partnering presentation 2020.9 Page 14)”.<sup>312</sup>
- € On 4 February 2021, Antibe responded to Nuance’s questions and requests, and on the AME Study, Antibe stated: “For the Canadian AME study submission is planned for April/May 2021 with study initiation late Q2 2021.” And: “The Draft AME protocol has been added to ShareVault.”<sup>313</sup> Also on 4 February 2021, Antibe stated: “Assuming all goes accordingly, Antibe will be in a position to start the initial Phase 3 OA efficacy trial in H2 2021 and will be on an ambitious timeline to have the NDA submitted in 4Q 2024.”<sup>314</sup>
- € Five days later, on 9 February 2021, the Parties entered into the License Agreement.
- € The next day, on 10 February 2021, Antibe updated its Board with information that while Antibe “continue[d] to feel as if the issue is manageable... Still, this is our main corporate risk”, and because the AME Study was not yet approved, Phase 3 would be “modestly delayed” and begin in January 2022.<sup>315</sup>

268. In responding to specific questions from Nuance, the Respondent was already aware of the “serious concerns” raised by Health Canada, but did not provide the up-to-date information in its possession, and instead *(i)* omitted from the Data Room the most recent correspondence with Health Canada, even while prior correspondence with Health Canada and the FDA was included; and *(ii)* deliberately chose to put a version of the AME Protocol that had already been withdrawn on 22 January 2021, referring to it only as the “Draft AME protocol”. Taken together, Antibe’s response to Nuance’s inquiry can only be characterized as being so incomplete as to be affirmatively and deliberately misleading, evincing conscious misbehavior and recklessness, rather than an intent to be truthful or honest. In addition, Antibe’s report to its Board on 10 February 2021 belies the notion that the position of Health Canada on the AME Study was unimportant, such that this omission could have been inadvertent, as it was characterized to the Board as “still” the “main corporate risk” and the timing for the study initiation of January 2022 was inconsistent with the answer provided to Nuance just days earlier, on 4 February 2021. Also notable was the testimony of Antibe’s Chief Executive Officer, Mr. Daniel Legault. As CEO, he was one of the senior executives who attended the meeting with Health Canada held on 22 January 2021<sup>316</sup> and throughout had direct knowledge of the events that resulted in Antibe withdrawing the AME Protocol to prevent receiving an official rejection from Health Canada<sup>317</sup>. He also drafted and presented

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<sup>312</sup> Exhibit R-034.

<sup>313</sup> Exhibit R-035.

<sup>314</sup> Exhibit R-035 (emphasis omitted).

<sup>315</sup> Exhibit C-040.

<sup>316</sup> Tr. (4) 99:5–15 (Mr. Legault).

<sup>317</sup> See generally Tr. (4) 99:5–119:20 (Mr. Legault).

to the Antibe Board the slide presentation updating the Board on the AME Protocol.<sup>318</sup> At the same time, he played a key role in the due diligence process, as one of the individuals who Ms. Korets-Smith testified she would go to for “regulatory communications, such as correspondence, meeting minutes” for purposes of the Data Room<sup>319</sup>, and he specifically reviewed the response Antibe sent to Nuance with respect to the AME Study.<sup>320</sup> Mr. Legault clearly acknowledged the importance and potential materiality of the position of Health Canada vis-à-vis the Drug, conceding at the hearing that Health Canada communications were “naturally requested by other potential partners”<sup>321</sup> and testifying that if “Health Canada had issued a rejection on the merits of the CTA, or issued a decision that significantly affected the Drug’s development time or costs, Antibe would have made that information public and informed Nuance.”<sup>322</sup> His explanation of why the Health Canada communications were not placed in the Data Room—which as noted, involved circumstances in which Health Canada had advised that it would issue a rejection of the CTA absent Antibe’s withdrawal—shifted at the hearing, from the position that “there was no deliberateness, we are just not turning our mind to it” and that the relevant correspondence “weren’t left out. There was no request for it”<sup>323</sup>, and later, “we did not think the correspondence was material from a public company point of view and we were in a due diligence process and if they want ongoing anything, they have to ask for it”<sup>324</sup>, and ultimately “we are not going to provide you [Nuance] with anything unless you ask for it”.<sup>325</sup> It was only on 21 July 2021 that Antibe shared with Nuance the “final protocol for the AME study which is currently ongoing in Canada”<sup>326</sup>, and as noted, on 30 July 2021, the study hit the stopping criteria, and Antibe paused the AME Study<sup>327</sup>, which fundamentally pivoted the development of the Drug towards an indication for acute (vs. chronic) pain.<sup>328</sup> As to motive to deceive, the Tribunal credits the Claimant’s arguments and evidence as to Antibe’s motivation to enter into the License Agreement in order to secure the necessary funding for the Drug’s continued development, in circumstances where the Respondent admitted the development of the Drug could not go forward without Nuance’s US\$20 million upfront payment.<sup>329</sup>

269. With respect to the elements of reasonable reliance and damages, i.e., whether the fraudulent misrepresentation is linked to the alleged harm in that Nuance was induced to enter into the License Agreement, the Tribunal also credits the Claimant’s arguments and evidence, including in circumstances reflecting the significance to Nuance of the Drug’s

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<sup>318</sup> Tr. (4) 118:15–119:2 (Mr. Legault).

<sup>319</sup> Tr. (4) 7:1–8 (Ms. Korets-Smith).

<sup>320</sup> Tr. (4) 20:11–25:7 (Ms. Korets-Smith); 64:5–66:14 (Ms. Korets-Smith); 134:7–16 (Mr. Legault).

<sup>321</sup> Tr. (4) 133:14–16 (Mr. Legault); *see also* Tr. (3) 144:24–145:23 (Korets-Smith).

<sup>322</sup> Legault ¶ 58; *see also* Tr. (4) 192:17–193:8 (Mr. Legault).

<sup>323</sup> Tr. (4) 126:9–21, 129:11–130:1 (Mr. Legault).

<sup>324</sup> Tr. (4) 132:5–18 (Mr. Legault).

<sup>325</sup> Tr. (4) 133:2–5 (Mr. Legault).

<sup>326</sup> Exhibit R-043.

<sup>327</sup> Legault ¶ 63.

<sup>328</sup> *See* Legault ¶¶ 129–133; Exhibit C-066, slide 4; Tr. (4) 176:13–177:7 (Mr. Legault); Exhibit C-095.

<sup>329</sup> *See, e.g.*, Defence ¶ 274; Legault ¶ 147.

potential indication for chronic (vs. acute) pain and the development timeline as understood by Nuance when it signed the License Agreement.<sup>330</sup> The Tribunal also finds that the Claimant's reliance on the Respondent in this regard was reasonable as a matter of New York law, which provides that a party may rely on representations where they relate to matters "peculiarly within the other party's knowledge" or where the truth is discoverable but only with "extraordinary effort or great difficulty"<sup>331</sup>, and Antibe's actions here did not put Nuance on notice of the "true nature" of the serious concerns expressed by Health Canada<sup>332</sup>. The Tribunal credits the Claimant's evidence that the Claimant did in fact review and request information on the regulatory communications and status of the pending studies<sup>333</sup> and that no amount of due diligence would have enabled Nuance Pharma to discover that Antibe had omitted/misled it with respect to key regulatory information from the Data Room in these circumstances<sup>334</sup>, which undercuts the Respondent's argument and evidence that the Claimant could or should have done more in this regard.

270. Accordingly, and for the avoidance of doubt, the Tribunal also rejects the Respondent's arguments, *inter alia*, that the Claimant's alleged lack of due diligence breaks the causation chain and that Nuance, but for the fraudulent misrepresentation of the communications with Health Canada, would have nonetheless entered into the License Agreement.

271. Finally, with respect to the Respondent's argument that the License Agreement's "merger" or "disclaimer" clauses preclude relief here, the Tribunal credits the arguments and evidence of Claimant that Clause 8.5 (Disclaimer of Warranties) and Clause 11.12 (Entire Agreement) of the License Agreement do not affect Nuance's claim for fraudulent misrepresentation/inducement in entering into the License Agreement in the first place and do not preclude reliance on misrepresentations, especially for facts peculiarly within a Respondent's knowledge.<sup>335</sup>

272. Having found for the Claimant on its "Claim 1" with respect to its fraudulent misrepresentation / inducement claim, the Tribunal does not address the additional element of a duty to disclose for purposes of the Claimant's fraudulent concealment claim, nor the

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<sup>330</sup> See generally, *e.g.*, Claimant's PHB ¶¶ 117–148.

<sup>331</sup> See, *e.g.*, Reply ¶¶ 113–114 (collecting authorities at ¶ 114); see also Hearing Opening Slides 102–105.

<sup>332</sup> Claimant's PHB ¶¶ 121–122 (discussing CLA-032, *CP Kelco U.S., Inc. v. Pharmacia Corp.*, 2002 U.S. Dist. LEXIS 19139 (D. Del. 2002)), 135.

<sup>333</sup> See generally Reply ¶¶ 79–82, 122; see also Hearing Opening Slides 110–121.

<sup>334</sup> See, *e.g.*, Reply ¶ 121; see also Hearing Opening Slides 106–108; Claimant's PHB ¶¶ 117–123, 88–92.

<sup>335</sup> See, *e.g.*, CLA-040, *HealthNow N.Y., Inc. v. APS Healthcare Bethesda, Inc.*, 2006 U.S. Dist. LEXIS 13148 at \*16–17 ("where the alleged misrepresentations supporting a claim of fraud arise from facts within the 'peculiar knowledge' of a party, even a specific disclaimer as to reliance on those representations does not bar a fraud claim") (internal quotations and citations omitted); see also Claimant's PHB ¶¶ 160–162; Hearing Opening Slides 122–124; Reply ¶¶ 126–129; Claim ¶¶ 65–67.

Claimant's alternative claims (Claims 2-4) for material breach of the License Agreement, unilateral mistake, or fraudulent concealment/fraudulent or negligent misrepresentations post-License Agreement.<sup>336</sup>

**b. Relief**

273. The Claimant seeks the following relief<sup>337</sup>:

- a. A declaration that the License Agreement has been validly rescinded or is void or is terminated;
- b. In the alternative to (a) above, rescission of the License Agreement or a declaration that the License Agreement is void or is terminated;
- c. Return of the sum of US\$20,000,000;
- d. Further and/or in the alternative to (c) above, damages in the sum of US\$20,000,000 in respect of Nuance's upfront payment plus Nuance's management time costs in negotiating for and performing the License Agreement, estimated to be US\$101,500;
- e. Interest;
- f. Costs; and
- g. Such further or other relief as the Tribunal deems fit.

274. The Respondent requests that the Tribunal<sup>338</sup>:

- a. Dismiss Nuance's claim in its entirety on the grounds that it is without merit;
- b. Order Nuance to pay Antibe's arbitration costs, including Antibe's representative's costs and expenses;
- c. Order Nuance to pay interest on all of the above amounts as of the date these amounts were due, until the date of their effective payment; and

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<sup>336</sup> See Claimant's PHB ¶¶ 98–101 (summarizing Claims 1 to 4).

<sup>337</sup> Claimant's PHB ¶ 198; *see also* Reply ¶ 166; Hearing Opening Slide 139.

<sup>338</sup> Statement of Defence ¶ 275.

d. Order any further and/or additional relief as the Tribunal may deem appropriate.

275. Under New York law, rescission of a contract is available in circumstances where “there is fraud or duress in the inducement of the contract, failure of consideration, inability to perform, or a breach of the contract so substantial that it defeats the object of the parties in making the contract.”<sup>339</sup> Courts generally permit rescission of a contract only when it appears reasonably feasible to return the parties to their respective positions prior to the contract.<sup>340</sup> As explained in the leading treatise *Williston on Contracts*, one of the reliefs open to a defrauded party is “rescission of the fraudulent transaction and restoration of the situation that the parties occupied before the fraudulent transaction was entered into.”<sup>341</sup>

276. Having found that Nuance has met its burden to establish its claim of fraudulent concealment / inducement, the Tribunal finds that the License Agreement has been validly rescinded by Nuance. The Claimant is therefore entitled to be put in the situation in which it would have been but for the conclusion of the License Agreement. On that basis, Antibe is ordered to return to Nuance the sum of US\$20 million that represented Nuance’s up-front payment to Antibe, plus interest, as discussed in the next section of this Award. Nuance also seeks to recover Nuance’s management time costs in negotiating for and performing the License Agreement, estimated to be US\$101,500. The Tribunal agrees with the Respondent’s argument at the hearing<sup>342</sup> that the Claimant’s estimate is too speculative and declines to award the Claimant’s requested relief in this respect.

## VIII.

### INTEREST

#### A. The Claimant’s Position

277. The Claimant sets out its position on interest in its costs submission.<sup>343</sup>

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<sup>339</sup> RL-037, *Creative Waste Mgmt., Inc. v. Capitol Envtl. Servs., Inc.*, 429 F. Supp 2d 582, 599, 606 (S.D.N.Y. 2006) (emphasis added); *see also* RL-046, *K.M.L. Laboratories Ltd. v. Hopper*, 830 F. Supp. 159, 163 (E.D.N.Y. 1993) (“Under New York law, a breach in a contract which substantially defeats the purpose of that contract can be grounds for rescission. Rescission is not permitted for a slight, casual or technical breach, but, as a general rule, only for such as are material and willful, or, if not willful, so substantial and fundamental as to strongly tend to defeat the object of the parties in making the contract.”) (internal quotations and citations omitted).

<sup>340</sup> RL-046, *K.M.L. Laboratories Ltd. v. Hopper*, 830 F. Supp. 159, 164 (E.D.N.Y. 1993) (“Courts generally permit rescission of a contract only when it appears reasonably feasible to return the parties to their respective positions prior to the contract.”) (internal quotations and citations omitted).

<sup>341</sup> CLA-024, Richard A. Lord, *Williston on Contracts* (4<sup>th</sup> ed.), Section 69:47 (Remedies for fraud and misrepresentations, generally).

<sup>342</sup> *See* Tr. (3) 116:20–123:23 (Ms. Lee).

<sup>343</sup> Claimant’s Costs Submissions ¶¶ 24–29.

278. The Claimant submits that the Tribunal has the power to award pre-Award interest on the sums awarded pursuant to Section 20(1)(c) of the International Arbitration Act, and to award post-Award interest pursuant to Section 20(3) of the same act.<sup>344</sup>

279. According to the Claimant, interest falls to be determined by Singapore law as the law of the arbitral seat as it is a matter of procedure, and the default statutory rate in Singapore is 5.33% per annum.<sup>345</sup>

280. The Claimant seeks both pre-Award and post-Award interest on all sums awarded at the default rate of 5.33% per annum, from the date the Claimant's cause of action arose/costs were incurred.<sup>346</sup>

### **B. The Respondent's Position**

281. The Respondent stated its position on interest in its email of 20 July 2023, in the following terms: "Antibe agrees with Nuance that costs and damages ordered by the arbitrator should carry interest of 5.33% from the date of the award. Antibe disagrees that, in the circumstances of this case, pre-award interest should be ordered on costs or damages."<sup>347</sup>

### **C. The Tribunal's Analysis and Decision**

282. As the Claimant notes, the Tribunal has the power under the International Arbitration Act to award both pre-Award and post-Award interest. Further, pursuant to Article 32.9 of the SIAC Rules: "The Tribunal may award simple or compound interest on any sum which is the subject of the arbitration at such rates as the parties may have agreed or, in the absence of such agreement, as the Tribunal determines to be appropriate, in respect of any period which the Tribunal determines to be appropriate."

283. Here, while the Claimant seeks both pre-Award and post-Award interest and the Respondent only post-Award interest, both Parties agree on the applicable rate of interest. According to the Claimant, the applicable rate is "the default rate of 5.33% per annum."<sup>348</sup> And the Respondent says that "costs and damages ordered by the arbitrator should carry interest of 5.33% from the date of the award."<sup>349</sup>

284. In the light of the agreement of the Parties, the Tribunal will use a rate of interest of 5.33% per annum. The Claimant's position on the applicable rate, with which the Respondent agrees, is based on Order 17 rule 5(1)(b) of the Singapore Rules of Court 2021,<sup>350</sup>

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<sup>344</sup> Claimant's Costs Submissions ¶¶ 24–25.

<sup>345</sup> Claimant's Costs Submissions ¶ 26.

<sup>346</sup> Claimant's Costs Submissions ¶¶ 27–29.

<sup>347</sup> Email of 20 July 2023 from the Respondent to the Tribunal.

<sup>348</sup> Claimant's Costs Submissions ¶ 27 (with respect to pre-Award interest); *see also id.* ¶ 29 ("same default rate" for post-Award interest).

<sup>349</sup> Email of 20 July 2023 from the Respondent to the Tribunal.

<sup>350</sup> *See* Claimant's Costs Submissions ¶ 26 n. 31.



which provides for “simple interest at 5.33% per year.”<sup>351</sup> The Tribunal therefore orders simple interest.

285. As to pre-Award interest, the Tribunal agrees with the Claimant that pre-Award interest shall be awarded. The Tribunal has found that the Claimant validly rescinded the License Agreement and is entitled to be put back in the situation in which it would have been but for the conclusion of the License Agreement. In particular, on 19 February 2021, the Claimant made an upfront payment of US\$ 20 million to the Respondent. The Claimant is entitled to the return of this sum. It is also entitled to pre-Award interest on this sum: but for the conclusion of the License Agreement, the Claimant would have been in possession of this sum from 19 February 2021 to the date of this Award and would have been in a position to earn interest on this sum.

286. Thus, the Tribunal awards pre-Award interest at the rate of 5.33% per annum, from 19 February 2021 to the date of this Award, on the US\$ 20 million that the Respondent is ordered to return to the Claimant.

287. As to post-Award interest, the Parties argue in favor of post-Award interest, and the Tribunal concurs. The Tribunal sees no reason to depart from the rate of interest used for purposes of pre-Award interest. Thus, the Tribunal awards post-Award interest at the rate of 5.33% per annum, from the date of this Award to the date of full compliance with the Award, on all sums awarded under the Award.

## IX.

### COSTS

#### A. The Claimant’s Position

288. The Claimant submits that (i) in the event that the Tribunal finds that Nuance is substantially or wholly successful in this arbitration, costs should follow the event and Nuance should be awarded in full its legal costs and its share of the costs of the arbitration (US\$ 1,200,811.55); (ii) in the event Nuance does not substantially or wholly succeed in this arbitration but the Tribunal determines that Antibe had concealed material information and/or made material misleading representations to Nuance, Nuance should be awarded its legal costs and its share of the costs of the arbitration incurred up to the completion of document production (US\$ 444,728.75 and US\$ 93,126.24), and save for the foregoing, the Parties should bear their own costs.<sup>352</sup> Annex 1 of the Claimant’s costs submission contains a detailed schedule of costs and fees.<sup>353</sup>

289. The Claimant refers to Rule 35 of the SIAC Rules, which provides that, unless otherwise agreed by the Parties, the Tribunal shall specify in the Award the total amount of

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<sup>351</sup> See Claimant’s Costs Submissions, Annex 12.

<sup>352</sup> Claimant’s Costs Submissions ¶¶ 8(a)-(b), 30(a)-(b).

<sup>353</sup> Claimant’s Costs Submissions, Annex 1.

the costs of the arbitration, and their apportionment among the Parties; and to Rule 37, which further empowers the Tribunal to order in its Award that all or part of the legal or other costs of a party be paid by another party.<sup>354</sup>

290. The Claimant contends that “costs follow the event” is a starting point.<sup>355</sup> It says the rule may be displaced in some circumstances, leading the Tribunal to consider relative success and failure on specific issues.<sup>356</sup> The Tribunal should also consider the conduct of the Parties and the reasonableness of the costs claimed.<sup>357</sup>

291. The Claimant argues that it should be awarded its legal costs and its share of the costs of the arbitration in full, in the event that it wholly or substantially succeeds in the arbitration.<sup>358</sup> The Claimant submits that (i) its costs are highly reasonable considering the importance and significance of the dispute; (ii) its costs are also reasonable considering the number and complexity of the issues in dispute; (iii) it kept its legal costs as reasonably low as possible by staffing each phase of the arbitration appropriately; (iv) it offered discounts on its legal fees; (v) and its costs are reasonable “in view of Antibe’s unreasonable conduct in the proceedings.”<sup>359</sup>

292. The Claimant further argues that it should be awarded its legal costs and its share of the costs of the arbitration up to the document production phase in the event that it is partially successful in the arbitration, which was reasonably brought to uncover material information otherwise concealed by Antibe up to the document production phase.<sup>360</sup> This is on the basis that “Nuance had no option but to commence the Arbitration to uncover the truth” and that Nuance’s claims were “deservedly brought.”<sup>361</sup> According to the Claimant, in allocating post-document production costs, the Tribunal should take into consideration Antibe’s “unreasonable conduct” in the arbitration.<sup>362</sup>

## **B. The Respondent’s Position**

293. The Respondent submits that costs should be awarded on a full indemnity basis to the winner of the arbitration, but if Nuance is only partially successful and its fraud claims are dismissed, it ought not to be awarded more than 25% of its costs.<sup>363</sup>

294. The quantum of the costs sought by Antibe, set out in detail in Appendix A to its submission on costs, is as follows:

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<sup>354</sup> Claimant’s Costs Submissions ¶¶ 1–2.

<sup>355</sup> Claimant’s Costs Submissions ¶ 3.

<sup>356</sup> Claimant’s Costs Submissions ¶ 3.

<sup>357</sup> Claimant’s Costs Submissions ¶¶ 4–5.

<sup>358</sup> Claimant’s Costs Submissions ¶¶ 9–15.

<sup>359</sup> Claimant’s Costs Submissions ¶¶ 9–15.

<sup>360</sup> Claimant’s Costs Submissions ¶¶ 16–23.

<sup>361</sup> Claimant’s Costs Submissions ¶¶ 17–18 (emphasis omitted).

<sup>362</sup> Claimant’s Costs Submissions ¶ 23.

<sup>363</sup> Costs Submissions of the Respondent ¶ 1.

(a) Legal fees in the amount of USD 1,641,163.21 (including [Harmonized Sales Tax or HST]);

(b) Disbursements in the amount of USD 258,698.68 (including HST); and

(c) Costs of the arbitration, being USD 144,855.55 (including HST);

(d) For a total of USD 2,044,717.44.<sup>364</sup>

295. The Respondent contends that the Tribunal's jurisdiction to award costs comes from the SIAC Rules (and in particular Rules 35 and 37), Procedural Order No. 1, and the arbitration agreement itself.<sup>365</sup>

296. The Respondent argues that the basic principle of costs is that costs follow the event.<sup>366</sup> The Respondent says that the Tribunal should take into account as factors the importance of the issues to the Parties, the causes of action in fraud, the merits of the Parties' case and the conduct of the Parties in the arbitration, as well as the reasonableness of the costs claimed.<sup>367</sup>

297. According to the Respondent, (i) Nuance's fraud claims were serious to Antibe; (ii) Nuance's fraud claims were unsubstantiated; (iii) Nuance's claims were unmeritorious; (iv) Nuance's conduct of the litigation prolonged the proceeding; and (v) Antibe conducted its case efficiently.<sup>368</sup>

298. As to its claimed costs, the Respondent submits that they were reasonable, proportionate and warranted, and that they are consistent with the reasonable expectations of the Parties.<sup>369</sup>

### **C. The Tribunal's Analysis and Decision**

299. Section 11.10 of the License Agreement provides that "[t]he arbitrator may apportion the costs of the arbitration, including the reasonable fees and disbursements of the parties, between or among the parties in such manner as the arbitrator considers reasonable."<sup>370</sup> Pursuant to SIAC Rule 35.1, "the Tribunal shall specify in the Award the total amount of the costs of the arbitration." Further, "the Tribunal shall determine in the Award the apportionment of the costs of the arbitration among the parties."

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<sup>364</sup> Costs Submissions of the Respondent ¶ 2; *see also id.* ¶ 45; *id.* Appendix A.

<sup>365</sup> Costs Submissions of the Respondent ¶¶ 5–8.

<sup>366</sup> Costs Submissions of the Respondent ¶¶ 9–12.

<sup>367</sup> Costs Submissions of the Respondent ¶ 13.

<sup>368</sup> Costs Submissions of the Respondent ¶¶ 14–36.

<sup>369</sup> Costs Submissions of the Respondent ¶¶ 37–44.

<sup>370</sup> See Exhibit C-007, License Agreement, Section 11.10(a).

300. SIAC Rule 35.2 makes clear that the term “costs of the arbitration” includes (a) the Tribunal’s fees and expenses; (b) SIAC’s administration fees and expenses; and (c) the costs of any assistance reasonably required by the Tribunal. The Registrar determines the costs of arbitration in accordance with Rule 34.7 of the SIAC Rules as follows:

<u>Tribunal’s Fees &amp; Expenses</u>	<u>SGD</u>
<b>Catherine Amirfar</b>	
Sole Arbitrator’s Fees	191,398.86
Sole Arbitrator’s Expenses	30,043.80
GST	N/A
<b>TOTAL TRIBUNAL’S FEES &amp; EXPENSES</b>	<b>221,442.66</b>
<u>Administrative Secretary’s Fees &amp; Expenses</u>	<u>SGD</u>
<b>Romain Zamour</b>	
Administrative Secretary’s Fees	23,750.00
Administrative Secretary’s Expenses	15,445.61
GST	N/A
<b>TOTAL ADMINISTRATIVE SECRETARY’S FEES &amp; EXPENSES</b>	<b>39,195.61</b>
<u>SIAC Fees &amp; Expenses</u>	
Administration Fee	46,644.35
SIAC Expenses	150.00
<b>TOTAL SIAC ADMINISTRATION FEES &amp; EXPENSES</b>	<b>46,794.35</b>
<b>TOTAL COSTS OF ARBITRATION</b>	<b>307,432.62</b>

301. The Claimant and the Respondent paid SG\$ 153,816.14 and SG\$ 153,936.14 respectively, the deposits held by the SIAC towards these costs, and these deposits have been applied by the SIAC towards the costs of arbitration (with any balance amount refunded to the Parties in the same proportions as those in which the deposits were made pursuant to Rule 34.7 of the SIAC Rules).

302. SIAC Rule 37 further provides that the Tribunal “shall have the authority to order in its Award that all or a part of the legal or other costs of a party be paid by another party.” Here, the total amount of legal or other costs is as follows:

(a) the Claimant claims US\$ 1,025,374.12 in legal fees, as well as US\$ 43,745.02 in disbursements.<sup>371</sup> The Respondent claims US\$ 1,641,163.21 in legal fees, as well as US\$ 258,698.68 in disbursements.<sup>372</sup>

(b) further costs relating to the transcription charges and charges for the hearing rooms at Maxwell Chambers: the Claimant claims US\$ 6,885.21 (corresponding to S\$ 9,099.00 using the exchange rate used by the Claimant<sup>373</sup>) (transcription charges) plus US\$ 8,399.39 (corresponding to S\$ 11,100.02 using the exchange rate used by the Claimant) (charges for hearing rooms at Maxwell Chambers)<sup>374</sup>; and the Respondent claims US\$ 7,497.57 (as “Epiq”) plus US\$ 22,743.64 (as “Arbitrator”), plus “HST” (Harmonized Sales Tax).

303. The Tribunal now turns to the issue of the allocation of costs. The Parties agree that the baseline principle of allocation of costs is “costs follow the event.” The Tribunal concurs. The Parties further agree that other factors are relevant, such as the conduct of the Parties and the reasonableness of the costs claimed. The Tribunal concurs on this as well.

304. Here, the Claimant has prevailed on its claim (fraudulent inducement leading to rescission of the License Agreement), and on its principal request for relief (return of the upfront payment under the License Agreement). The Tribunal considers that the costs claimed by both Parties are reasonable, in light of the complexity of the case and the serious nature of fraud allegations. The Tribunal further considers that both Parties behaved reasonably in the course of the proceedings, generally conducting litigation fairly and efficiently.

305. Thus, on balance, the Tribunal sees no reason to depart from the principle of “costs follow the event.” The Tribunal therefore holds that the Respondent shall reimburse the Claimant for the Claimant’s portion of the costs of the arbitration, namely SG\$ 153,716.31.

306. The Tribunal further holds that the Respondent shall reimburse the Claimant for the totality of its legal fees (US\$ 1,025,374.12), disbursements (US\$43,745.02), US\$ 6,885.21 in transcription charges paid for by the Claimant, and US\$ 8,399.39 in charges for hearing rooms at Maxwell Chambers, paid for by the Claimant.

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<sup>371</sup> Claimant’s Costs Submissions, Annex 1.

<sup>372</sup> Costs Submissions of the Respondent, Appendix A.

<sup>373</sup> Claimant’s Costs Submissions, Annex 1, at 1 n. 1.

<sup>374</sup> Claimant’s Costs Submissions, Annex 1.

**X.**

**DISPOSITIF**

307. For the reasons set forth above, the Tribunal:

- (a) HOLDS that the present dispute is within the Tribunal's jurisdiction and that the Claimant's claims are admissible;
- (b) DECLARES that the Claimant validly rescinded the License Agreement on the basis of the Respondent's fraudulent inducement of the Claimant to enter into the License Agreement;
- (c) ORDERS the Respondent to pay to the Claimant US\$ 20,000,000.00, representing the sum that the Claimant had paid to the Respondent as upfront payment under the License Agreement, plus pre-award simple interest on this sum at the rate of 5.33% per annum, from 19 February 2021 to the date of this Award;
- (d) ORDERS the Respondent to pay to the Claimant SG\$ 153,716.31, as reimbursement for the costs of the arbitration;
- (e) ORDERS the Respondent to pay to the Claimant US\$ 1,025,374.12, as the legal fees of the Claimant in the arbitration; US\$ 43,745.02, as the disbursements of the Claimant in the arbitration; US\$ 6,885.21 in transcription charges paid for by the Claimant; as well as US\$ 8,399.39 in charges for hearing rooms at Maxwell Chambers, paid for by the Claimant;
- (f) ORDERS the Respondent to pay to the Claimant, if the Respondent fails to pay in full within 7 business days the amounts set forth in paragraphs (c), (d), and (e) above, simple post-award interest on any outstanding amounts at the rate of 5.33% per annum, from the date of this Award to the date of full and complete payment; and
- (g) DISMISSES all other claims or requests.

Tribunal: Ms. Catherine Amirfar



Dated: 27 February 2024  
Seat of Arbitration: Singapore

THIS IS **EXHIBIT "D"** REFERRED TO IN THE  
AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

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SIDNEY BREJAK  
Commissioner for Taking Affidavits



**ANTIBE THERAPEUTICS INC.**

**ANNUAL INFORMATION FORM**

**FOR THE FISCAL YEAR ENDED MARCH 31, 2023**

**JUNE 28, 2023**



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## GLOSSARY

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“**AIF**” means Annual Information Form;

“**AME**” means Absorption, Metabolism and Excretion;

“**Antibe**” or the “**Company**” means Antibe Therapeutics Inc., the Company filing this AIF;

“**Antibe Board**” or “**Board**” means the board of directors of the Company, as constituted from time to time;

“**Antibe Holdings**” or “**Holdings**” means Antibe Holdings Inc., a corporation existing under the *Business Corporations Act* (Alberta);

“**BRIC**” means, collectively, Brazil, Russia, India and China;

“**CAGR**” means compound annual growth rate;

“**CEO**” means Chief Executive Officer;

“**Common Shares**” means the common shares of the Company;

“**COX**” means cyclo-oxygenase;

“**CRO**” means contract research organization;

“**FDA**” means U.S. Food and Drug Administration;

“**GI**” means gastrointestinal;

“**GLP**” means Good Laboratory Practices;

“**GMP**” means Good Manufacturing Practices;

“**H<sub>2</sub>S**” means hydrogen sulfide;

“**ICFR**” means Internal Controls over Financial Reporting;

“**ICH**” means International Conference on Harmonization;

“**IFRS**” means International Financial Reporting Standards;

“**IND**” means investigational new drug;

“**IPO**” means the initial public offering of Common Shares of the Company completed on June 18, 2013;

“**License Agreement**” has the meaning given under the heading “Interests of Management and Other in Material Transactions”;

“**MD&A**” means Management Discussion and Analysis;

“**NCE**” means new chemical entity;

“**NDA**” means new drug application;

“**NI 52-109**” means National Instrument 52-109 – “Certification of Disclosure in Issuers' Annual and Interim Filings”;

“**NI 52-110**” means National Instrument 52-110 – “Audit Committees” of the Canadian Securities Administrators;

“**NSAID**” means nonsteroidal anti-inflammatory drug;

“**OA**” means osteoarthritis;

“**OBCA**” means the *Business Corporations Act* (Ontario) and the regulations thereunder, as amended;

“**OSC**” means the Ontario Securities Commission;

“**IP**” mean intellectual property;

“**RA**” means rheumatoid arthritis;

“**SEDAR**” mans the System for Electronic Document Analysis and Retrieval;

“**SR&ED**” means Scientific Research and Experimental Development;

“**TSX**” means the Toronto Stock Exchange;

“**UGI**” means upper gastrointestinal.

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## FORWARD-LOOKING STATEMENTS

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Certain statements in this AIF about the Company's current and future plans, expectations and intentions, results, levels of activity, performance, goals or achievements or any other future events or developments constitute forward-looking statements. The words "may", "will", "would", "should", "could", "expect", "plan", "intend", "trend", "indication", "anticipate", "believe", "estimate", "predict", "likely" or "potential", or the negative or other variations of these words or other comparable words or phrases, are used to identify forward-looking statements. Forward-looking statements are based on estimates and assumptions made by the Company in light of management's experience and perception of historical trends, current conditions and expected future developments, as well as other factors that the Company believes are appropriate and reasonable in the circumstances.

Many factors could cause the Company's actual results, level of activity, performance or achievements or future events or developments to differ materially from those expressed or implied by the forward-looking statements. The purpose of the forward-looking statements is to provide readers with a description of management's expectations regarding, among other things, the Company's financial performance and research and development plans and may not be appropriate for other purposes. Readers should not place undue reliance on forward-looking statements.

Furthermore, unless otherwise stated, the forward-looking statements are made as of the date of this AIF, and the Company has no intention and undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. New factors emerge from time to time, and it is not possible for the Company to predict which factors may arise. In addition, the Company cannot assess the impact of each factor on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Without limitation, this AIF may contain forward-looking statements pertaining to the following:

- the Company's research and development plans (including the persons expected to oversee, coordinate and participate in such plans), business model, strategic objectives and growth strategy;
- the Company's current and future capital requirements and the need for additional financing;
- the continuation of the Company as a going concern;
- the payment of dividends;
- the Company's expectations regarding net losses and revenue generation; and
- the Company's expectations regarding increases in research and development costs and general and administrative expenses.

With respect to forward-looking statements, assumptions have been made regarding, among other aspects:

- the Company's future research and development plans proceeding substantially as currently envisioned;
- expected research and development tax credits;
- future expenditures to be incurred by the Company;
- research and development and operating costs;
- the Company's ability to find partners in the pharmaceutical industry;
- additional sources of funding, including the Company's ability to obtain funding from partners;

- the impact of competition on the Company; and
- the Company being able to obtain financing on acceptable terms.

Because the factors discussed in this AIF could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by the Company, readers should not place undue reliance on any such forward-looking statements. These statements are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such risks and uncertainties relate, among other factors, to:

- the Company's history of operating losses;
- the Company's ability to obtain additional capital in the future to conduct operations, research and development activities and develop its products;
- the availability of tax credits;
- the Company's ability to find partners in the pharmaceutical industry;
- the Company's ability to license its products on terms and conditions acceptable to the Company;
- the Company's ability to compete against other companies and research institutions with greater financial and other resources;
- the Company's ability to secure and maintain adequate protection for its intellectual property;
- the Company's ability (or the ability of the Company's partners) to obtain regulatory approvals for the Company's products;
- the Company's ability to attract and retain key personnel; and
- the potential impact of the COVID-19 pandemic on the Company's operations.

The Company's actual results could differ materially from those discussed in the following AIF.

*Except where otherwise indicated or where the context otherwise requires, all references in this annual information form (“AIF”) to the “Company” or “Antibe” are to Antibe Therapeutics Inc. Unless otherwise indicated, all dollar amounts are expressed in thousands of Canadian dollars and the statistical and financial data and other information contained in this AIF are presented as at March 31, 2023.*

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## **CORPORATE STRUCTURE**

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### ***General***

The Company was incorporated under the Business Corporations Act (Ontario) on May 5, 2009. The Company was originally established under the legal name 2205405 Ontario Inc. On December 16, 2009, the Company changed its name to Antibe Therapeutics Inc. On June 18, 2013, the Company completed its initial public offering and was listed on the TSX Venture Exchange. On November 12, 2020, the Company graduated to the Toronto Stock Exchange. The Company trades over-the-counter in the United States on the OTCQX market. The address of the Company's registered office and principal place of business is 15 Prince Arthur Avenue, Toronto, Ontario, Canada, M5R 1B2.

### ***Intercorporate Relationships***

The Company was incorporated as a wholly-owned subsidiary of Antibe Holdings (“Holdings”) with an exclusive Intellectual Property (“IP”) license from Holdings to develop and commercialize the Company’s pipeline drugs. The license obligated the Company to pay royalties to Holdings on future revenues derived from this IP. On June 3, 2021, the Company completed a transaction with Holdings by way of a three-corner amalgamation. Pursuant to the transaction, the Company acquired full ownership of Holdings’ patent portfolio, eliminating the royalty liability on future revenues. In consideration, Antibe issued an aggregate of 5,873,092 common shares in the capital of the Company to acquire all of the issued and outstanding shares of Holdings.

In 2016, the Company completed the acquisition of Citagenix Inc., a Montreal-based sales and distribution company with a focus on regenerative medicine. In November 2022, the Company announced the closing of its sale of Citagenix to HANSAméd Limited. (Please see “Fiscal 2023 Developments” for further detail.)

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## **GENERAL DEVELOPMENTS OF THE BUSINESS**

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This section describes the important developments for the Company in general and for its drug candidates and regenerative medicine products over the last three completed financial years. Additional details related to the Company’s drug development and commercial activities are included in the “The Business” section of this document. On December 1, 2020, the Company completed a share consolidation of the Company’s issued and outstanding common shares on the basis of one (1) new common share for every ten (10) common shares issued and outstanding. All common shares, options, restricted share units, warrants and per share amounts have been restated to give retrospective effect to the share consolidation.

### ***Fiscal 2021 Developments***

#### ***Financial and Operational***

On May 6, 2020, the Company announced the hiring of Dr. Joseph Stauffer in the new role of Chief Medical Officer (“CMO”). An experienced anesthesiologist, Dr. Stauffer has served as CMO in public and private drug therapy companies for nearly 20 years, building teams of physicians, scientists, regulators and safety experts to drive clinical success for a number of chronic and acute pain assets. Dr. Stauffer will assume a leadership role in Antibe’s clinical development strategy and its increasing engagement with global regulatory agencies and potential large market partners.

On June 30, 2020, the Company announced that it closed a bought deal public offering of 6,250,000 units of the Company (the “Units”) at a price of \$4.00 per Unit plus the exercise in full of the Underwriters’ over-allotment option of 937,500 units for aggregate gross proceeds of \$28,750. Each Unit was comprised of one common share of the Company and one-third of one common share purchase warrant. Each full warrant is exercisable to purchase one common share at any time prior to June 30, 2022 at a price of \$6.00 per common share.

On November 12, 2020, the Company completed its graduation to the Toronto Stock Exchange (“TSX”) and the Common Shares began trading on the TSX under the symbol “ATE”. In connection with the Company’s graduation to the TSX, concurrently, the Company’s common shares (the “Common Shares”) have been voluntarily delisted from the TSX Venture Exchange. The Common Shares will continue to trade on the OTCQX market under the symbol “ATBPF”.

On November 24, 2020, the Company announced the appointment of Robert E. Hoffman and Jennifer McNealey to its Board of Directors. Mr. Hoffman is President, CEO and Chairman of Kintara Therapeutics and formerly the Chief Financial Officer of San Diego-based Heron Pharmaceuticals, a NASDAQ-listed commercial stage drug developer with a pipeline of acute pain therapeutics. Ms. McNealey is Chief Financial Officer of Abdera Therapeutics and a senior financial and strategy executive with a considerable breadth of experience in the biotechnology sector, as an analyst, portfolio manager, information provider and expert in corporate communications and investor relations.

On February 9, 2021, the Company licensed otenaproxesul to Nuance Pharma Limited (“Nuance”) for commercialization in the Greater China region. The license provides Nuance with exclusive rights to commercialize otenaproxesul in China, Hong Kong, Macau, and Taiwan. Under the terms of the agreement, Antibe is entitled to US\$100 million in milestone payments, including US\$20 million upfront and US\$80 million in development and sales milestones, in addition to a double-digit royalty on sales. Clinical development and regulatory costs for the region will be borne by Nuance.

On February 24, 2021, the Company announced that it has closed a bought deal public offering of 6,727,500 units (the “Offered Securities”) in the capital of the Company at a price of \$6.00 per Offered Security (the “Offering Price”) for aggregate gross proceeds to the Company of \$40,365, which included the full exercise of the over-allotment option by the underwriters. Each Offered Security consisted of one common share and one-half of one common share purchase warrant (each whole warrant, a “Warrant”). Each Warrant entitles the holder thereof to acquire one common share at an exercise price of \$7.50 for a period of 36 months from closing.

#### *Developmental*

On June 1, 2020 the Company announced that otenaproxesul met the primary endpoint in the Phase IIB dose-ranging, efficacy study. Both the 250 mg and 200 mg doses of otenaproxesul demonstrated superiority to placebo in reducing OA pain with a high level of statistical significance. The 150 mg dose of otenaproxesul, although not powered for statistical significance, demonstrated an efficacy signal with the lowest effective dose yet to be established. The drug was safe and well tolerated during this study. Transient liver transaminase elevations between 7.2% to 12.9% were noted across the three otenaproxesul treatment arms. No clinically meaningful gastrointestinal, renal or measured cardiovascular safety outcomes were reported. A total of 384 patients with OA of the knee were randomized to either placebo or otenaproxesul administered once daily: 250 mg, 200 mg or 150 mg. The primary objective in the study was to demonstrate the statistically significant superiority of otenaproxesul versus placebo in reducing OA pain as measured by the change from baseline in the WOMAC pain subscale score over a 14-day treatment period. (See “Phase IIB Dose-Ranging, Efficacy Study” for further detail.)

On March 29, 2021, Antibe announced that the U.S. FDA had cleared the Company’s Investigational New Drug (“IND”) application for otenaproxesul for the treatment of osteoarthritis pain. This enables Antibe to undertake human clinical trials in the U.S.

#### ***Fiscal 2022 Developments***

##### *Financial and Operational*

On June 3, 2021, the Company completed a transaction with Holdings by way of a three-corner amalgamation. Pursuant to the transaction, the Company acquired full ownership of Holdings’ patent portfolio, eliminating the royalty liability on future revenues. In consideration, Antibe issued an aggregate of 5,873,092 common shares in the capital of the Company to acquire all of the issued and outstanding shares of Holdings.

##### *Developmental*

In July 2021, the Company completed a single-dose pharmacokinetic (“PK”) and pharmacodynamic (“PD”) study in 24 healthy volunteers in the U.S. subsequent to its IND filing with the U.S. FDA. Subjects were administered the single dose of either 150 mg or 100 mg of otenaproxesul, tolerating the drug without incident and successfully completing on-

study and follow-up assessments with no clinically meaningful adverse events or clinically significant laboratory abnormalities.

On August 3, 2021, the Company announced that it had placed its absorption, metabolism and excretion (“AME”) study of otenaproxesul on a required pause because a pre-specified safety threshold was exceeded. On October 14, 2021, the Company completed a scientific and strategic review and launched an acute pain program for otenaproxesul; clinical studies commenced in calendar Q1 2022.

### ***Fiscal 2023 Developments***

#### *Financial and Operational*

On May 25, 2022, the Company announced the appointment of Robert E. Hoffman, a Director of Antibe, as the new Chair of its Board of Directors. The Company also created two corporate Vice Chair positions to recognize the contributions of Walt Macnee, the outgoing Chair, and Dr. John L. Wallace, Chief Scientific Officer and Director since he founded the Company. As Vice Chairs, they will provide ongoing counsel to the Company on key business initiatives while also both continuing to serve on its Board of Directors. Dr. Wallace is also taking the opportunity to return to his vocation as a research scientist, with a continued focus on enriching the Company’s pipeline.

In calendar Q3 2022, a third-party commercial assessment of otenaproxesul was completed, indicating potential robust sales and strong market adoption rates (see accompanying MD&A for further details). Antibe has also concluded a comprehensive strategic positioning assessment of otenaproxesul for acute pain in the U.S. market.

On November 1, 2022, the Company announced the closing of the sale of Citagenix to HANSAmEd Limited in an all-cash transaction. The transaction involves a guaranteed \$3.5 million, divided into four equal payments over three years, with an additional \$4 million subject to Citagenix achieving sales milestones in the four year period following closing. The purchase price is also subject to working capital adjustments. In accordance with the agreement, the Company received proceeds totaling approximately \$1.4 million, comprising the first of the four guaranteed payments of \$875 thousand and an adjustment of approximately \$0.5 million in estimated excess working capital. In addition, prior to the closing Citagenix paid the Company \$1.1 million to retire Preferred Shares in Citagenix.

#### *Developmental*

On October 12, 2022, Antibe announced otenaproxesul’s transition to a faster-absorbing formulation to accelerate onset of action; also enabling treatment regimens with lower drug doses, providing additional safety buffer and a potential pathway to address chronic pain indications. A patent application was filed for this new formulation, strengthening IP protection to 2043.

In late calendar Q4 2022, the Company selected lead and back up candidates for its IBD program; a patent application was filed in calendar Q2 2023.

On February 15, 2023, Antibe announced results from DILIsym, a sophisticated software model widely used to predict liver safety, suggesting that all envisioned acute pain treatment regimens of the new formulation are liver-safe for five-day treatment durations (including ten days post treatment follow up).

### ***Subsequent Developments***

In May 2023, arbitration proceedings were held with Nuance Pharma Limited (“Nuance”), one of the Company’s license partners. Nuance holds a license from Antibe respecting the commercialization of otenaproxesul in China, Macau, Hong Kong and Taiwan. (Please see “Legal Proceedings” for further information.)

### ***Expected Future Developments***

Going forward into the fiscal 2024 period, Antibe expects to commence Phase II development of otenaproxesul for acute pain indications in calendar Q1 2024. If the Phase II program is successful, the Company will request an End of Phase 2 meeting with the U.S. FDA to discuss the Phase III program. It is anticipated that the full Phase III program for otenaproxesul can be completed within 12-18 months from initiation. If the Phase III program is successful, the Company intends to apply for marketing approval for a broad acute pain indication. Upon marketing approval, Antibe



plans to initiate a series of studies to further investigate the effectiveness of otenaproxesul in a range of additional and promising acute pain indications. The Company also expects to commence IND-enabling studies in the fiscal 2024 period for at least one of its other pipeline assets.

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## **THE BUSINESS**

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### **Overview**

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Antibe is a clinical stage biotechnology company leveraging its proprietary hydrogen sulfide (“H<sub>2</sub>S”) platform to develop next-generation therapies to address inflammation arising from a wide range of medical conditions. The Company’s current pipeline includes therapies that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”). Antibe’s lead drug, otenaproxesul, is in development for the treatment of acute and chronic pain. The Company’s second pipeline drug is a GI-sparing alternative to ketoprofen. The Company’s next target is inflammatory bowel disease (“IBD”), a condition long in need of safer, more effective therapies.

The Company’s overall strategy is to monetize otenaproxesul and its drug pipeline at the optimal time through partnering or mergers and acquisitions (“M&A”) activity. Antibe’s primary regulatory focus is to obtain United States Food and Drug Administration (“U.S. FDA”) approval for otenaproxesul given that the United States is the world’s largest pharmaceutical market. The Company is also planning to pursue regulatory approval in major markets in Europe and Asia.

In March 2018, otenaproxesul met its primary endpoint in a 14-day Phase IIB double-blind trial vs naproxen showing a statistically significant difference in the incidence of ulcers, a measure of gastrointestinal safety (2.5% versus 42.1% ulceration rate of at least 3 mm in diameter).

In June 2020, otenaproxesul met its primary endpoint in a Phase IIB dose-ranging, efficacy study by demonstrating superiority to placebo in reducing osteoarthritis pain with a high degree of statistical significance. At the post-treatment assessment, patients had clinically significant, transient liver transaminase elevation (“LTE”) incidences ranging from 7.2% to 12.9%. It is standard for pain trials to allow the use of other medications, commonly acetaminophen. Especially in the post-treatment assessment period, acetaminophen use, pre-existing liver conditions and concomitant statin use were associated with a majority of the LTE incidents. Given the efficacy signal observed with the lowest dose in this trial, future development would examine use of lower doses.

In August 2021, LTEs were observed in a subset of subjects in an AME study conducted at lower doses, presenting a challenge for daily drug administration over longer treatment durations. The Company then undertook and completed a scientific and strategic review leading to the launch of an acute pain program for otenaproxesul; clinical studies commenced in calendar Q1 2022. The Company continues to investigate alternative formulations and dosing regimens as a potential path forward for chronic indications.

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### **Novel Drug Development Platform**

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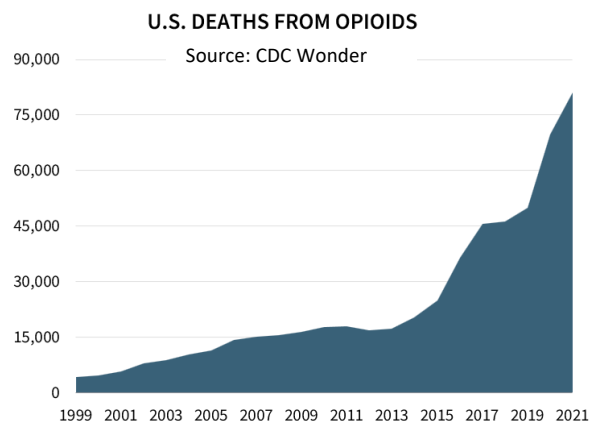
Antibe’s drug development platform originates, develops and out-licenses patent protected new pharmaceuticals that are improved versions of existing drugs. These improvements arise from Nobel Prize-winning medical research<sup>(1)</sup> highlighting the crucial role of gaseous mediators: chemical substances produced in the human body to regulate a range of fundamental cellular processes. The Company’s drug design methodologies involve chemically linking a base drug to a hydrogen sulfide-releasing moiety; in short, improving existing inflammation-targeted therapies with the goal of making them safer and/or more effective.

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<sup>1</sup> The 1998 Nobel Prize in Physiology or Medicine was awarded jointly to Robert F. Furchgott, Louis J. Ignarro and Ferid Murad "for their discoveries concerning nitric oxide as a signaling molecule in the cardiovascular system". Dr. Ignarro is a member of the Company's Scientific Advisory Board.

### ***Opioid Crisis Drives Need for New Non-Addictive Pain Medications***

As the resurgent global opioid crisis drives prescribers, patients, payors and policymakers toward non-addictive alternatives, NSAIDs are increasingly used to treat acute pain, especially post-operative pain. However, today's NSAIDs can cause gastrointestinal ("GI") ulcers and bleeding, especially at the higher doses often employed in acute indications. Given the lack of innovation in oral analgesics in the last 20 years, this represents a significant opportunity, as these drugs are only category of medications suitable for the transition to home recovery. This issue was emphasized in 2022 by new draft guidance from both the CDC and the FDA highlighting the urgent need for new non-opioid pain medications.<sup>(2)</sup>



The largest segment of the US\$25 billion acute pain market<sup>(3)</sup> is the US\$13 billion post-operative pain segment,<sup>(4)</sup> with opioids and NSAIDs accounting for the majority share. In the U.S., there are 76 million surgical procedures annually<sup>(5)</sup> and more than two million Americans may become persistent opioid users each year.<sup>(6)</sup>

### ***The Global NSAID Market***

NSAIDs are one of the largest classes of drugs worldwide, with sales of US\$18 billion,<sup>(7)</sup> representing a significant portion of the US\$52 billion global pain management market for pharmaceuticals and medical devices.<sup>(8)</sup> In treating post-operative pain, NSAIDs are employed to replace opioids and as a component of multimodal analgesia, a growing practice whereby multiple drugs are administered to achieve optimal pain reduction. Market leaders include well-known prescribed medicines such as Pfizer Inc.'s Celebrex® (US\$1.2 billion in 2019 annual sales (GlobalData)) and Novartis International AG's Voltaren® (US\$417 million in 2019 annual sales (GlobalData)). Leaders in the over-the-counter segment include Advil® and Aleve®.

This class of drugs has been widely used for decades to treat acute and chronic pain, fever and inflammation from conditions such as osteoarthritis ("OA"), rheumatoid arthritis ("RA") and gout. They have also been used to treat acute or chronic pain associated with injuries, surgical and dental procedures, back pain and headaches.

<sup>2</sup> New York Times, C.D.C. Proposes New Guidelines for Treating Pain, Including Opioid Use (Feb 10, 2022).

<sup>3</sup> GlobalData, Statista, DataBridge, DelveInsight, Allied Market Research, Biotech Advisors, Antibe internal estimates.

<sup>4</sup> Transparency Market Research (2019), 2021 estimate.

<sup>5</sup> Gan et al., *Journal of Pain Research* (2017).

<sup>6</sup> Brummett et al., *JAMA Surgery* (2017).

<sup>7</sup> Fortune Business Insights (2020), 2022 estimate.

<sup>8</sup> BCC Research (2017), 2022 estimate.

### **GI Safety – The Unmet Medical Need**

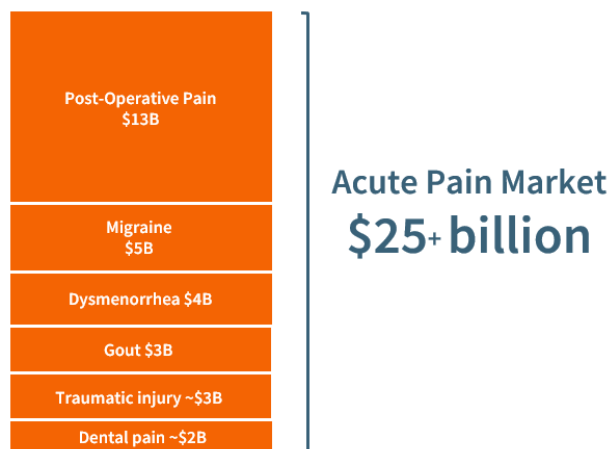
The therapeutic anti-inflammatory effects of NSAIDs are attributable to the inhibition of cyclooxygenase (“COX”) enzymes. However, NSAIDs have well-known and serious adverse side effects, including the bleeding and ulceration in the gastrointestinal tract. In severe cases, NSAID usage can result in fatal GI ulceration and bleeding. Even in short-term use, they triple the risk of serious GI outcomes.<sup>(9)</sup> These side effects occur at an even higher rates in patients with other common disorders (e.g. arthritis, hypertension and obesity) and in the elderly. A second-generation of NSAIDs, known as selective COX-2 inhibitors, including Vioxx, Celebrex and Bextra, were developed with GI safety in mind.

These drugs have only been marginally effective in reducing such side effects but carry additional cardiovascular toxicity risks. Such increased risks of adverse cardiovascular events resulted in the removal of Vioxx and Bextra from global markets in 2004. Notably, opioids also can cause adverse GI effects, including nausea, vomiting and severe constipation – leading to patient discomfort and the costs of extended hospitalization.<sup>(10)</sup>

Antibe’s drug design represents a significant opportunity for the development of a new class of NSAID-based compounds, which exhibit equal or greater efficacy than currently marketed drugs while drastically reducing adverse GI side effects. No current drug appears to meet these criteria, resulting in a significant unmet medical need. Furthermore, there are few novel NSAIDs in development, most being reformulations or combinations of existing drugs.

### **Otenaproxesul: Antibe’s Lead Drug**

Otenaproxesul (formerly ATB-346) combines a moiety that releases a gaseous mediator (H<sub>2</sub>S) with naproxen, a widely used NSAID, to create a novel therapeutic compound. Antibe is leveraging the drug’s remarkable potency, GI protection, and its overall safety profile to position otenaproxesul as the NSAID-of-choice for acute pain. Antibe plans to seek a broad acute pain label that will enable prescribers to use otenaproxesul for a range of indications including post-operative pain, acute musculoskeletal pain, dysmenorrhea, migraine, gout and dental pain – all large markets with an ongoing medical need for safe and effective therapies.



<sup>9</sup> Fine M, *American Journal of Managed Care* (2013).

<sup>10</sup> Whitman CJ et al., *Journal of Opioid Management* (2015).

**Table 1. Otenaproxesul Product Profile (Acute Pain)**

<p>Disease Condition(s):</p>	<p>Acute pain; the drug is being positioned as the NSAID-of-choice for acute pain, including post-operative pain, acute musculoskeletal pain, dysmenorrhea, migraine, gout and dental pain.</p> <p>Antibe continues to investigate alternative formulations and dosing regimens as a potential path forward for chronic indications.</p>
<p>Product Description:</p>	<p>Otenaproxesul is a hydrogen sulfide-releasing derivative of naproxen (naproxen is among the most commonly used and most cardiovascular-safe of the NSAID class). The drug’s new formulation (announced in October 2022) is a faster-absorbing version of the original formulation.</p>
<p>Target Segment(s) and Marketplace:</p>	<p>The Company intends to apply for marketing approval for a broad acute pain indication, a US\$25+ billion market that includes post-operative pain, acute musculoskeletal pain, dysmenorrhea, migraine, gout and dental pain, all large segments with few safe and effective therapies.</p>
<p>Preclinical Studies:</p>	<p>The drug remained GI-safe when given to animals with compromised mucosal defense or pre-existing ulcers—situations in which selective COX-2 inhibitors cause ulcers and bleeding in humans. It also remained safe when co-administered with aspirin. In addition, otenaproxesul did not elevate blood pressure when administered to hypertensive rats, in contrast to a hypertensive effect with naproxen in rats. Antibe has an extensive database of preclinical data collected from studies using a variety of validated animal models to assess the effectiveness and safety of otenaproxesul.</p>
<p>Clinical Studies (chronic pain):</p>	<p>In March 2018, otenaproxesul met its primary endpoint in a Phase IIB double-blind trial vs naproxen, showing a statistically significant difference in the incidence of ulcers, a measure of gastrointestinal (“GI”) safety (2.5% versus 42.1% ulceration rate of at least 3 mm in diameter).</p> <p>In June 2020, otenaproxesul met its primary endpoint in a Phase IIB dose-ranging, efficacy study by demonstrating superiority to placebo in reducing osteoarthritis pain with a high degree of statistical significance. Transient liver transaminase elevations ranging from 7.2% to 12.9% were noted across the three otenaproxesul treatment arms. It is standard for pain trials to allow the use of other medications, commonly acetaminophen. Especially in the post-treatment assessment period, acetaminophen use, pre-existing liver conditions and concomitant statin use were associated with a majority of the LTE incidents. Given the efficacy signal observed with the lowest dose in this trial, future development would examine the use of lower doses.</p> <p>In August 2021, LTEs were observed in a subset of subjects in an AME study conducted at lower doses, presenting a challenge for daily drug administration over longer treatment durations. While continuing to investigate alternative formulations and dosing regimens as a potential path forward for chronic indications, the Company has launched an acute pain program for otenaproxesul.</p>
<p>Development Status:</p>	<p>The Company has received clearance for an IND application with the U.S. FDA to allow clinical testing of otenaproxesul in the United States. The Company launched otenaproxesul’s clinical program for post-operative pain in calendar Q1 2022 and anticipates delivering top-line data from the Phase II program in calendar Q2 2024.</p>

### *Development Plan and Recent Activity*

By leveraging otenaproxesul's existing comprehensive clinical data package, including its demonstrated efficacy and GI safety profile, the Company launched its acute pain clinical program in calendar Q1 2022. This program began with a series of short pharmacokinetic/pharmacodynamic ("PK/PD") studies to identify optimal treatment regimens for post-operative pain before entering Phase II. Although four such studies were planned, the Company concluded that the results from the first two studies warranted moving into a Phase II program.

In late calendar 2021, the Company began intensive research to improve the immediate post-treatment bioavailability of otenaproxesul while concomitantly accelerating onset of cyclooxygenase inhibition, seeking tablet dosages much lower in strength than would be needed with the existing drug formulation. In October 2022, Antibe announced a new formulation of otenaproxesul that aims to increase the drug's therapeutic benefit and commercial potential. Its intended benefits include: (i) rapid dissolution mechanics, accelerating otenaproxesul's onset of action, a key benchmark for acute pain medications; and (ii) enhanced bioavailability, enabling a significant dose reduction compared to its current formulation. The lower dose provides an additional safety buffer as well as a potential pathway to address chronic pain indications. The new formulation was developed in collaboration with Antibe's global manufacturing partner; all related IP is owned exclusively by Antibe.

The transition to the new formulation enabled Antibe to bypass the Phase II molar extraction study originally planned for calendar Q4 2022. Instead, the Company captured the necessary data via a set of de-risking animal studies that recently concluded. To confirm the optimal dosing regimens for the upcoming Phase II bunionectomy trial, a relatively small PK/PD study in healthy volunteers is expected to complete in calendar Q4 2023. The Phase II bunionectomy trial is slated to initiate in calendar Q1 2024 at leading U.S. sites for this type of surgery. The surgical bunionectomy model is recognized as one of the most reliable methods for evaluating analgesic efficacy in post-operative pain.

If the Phase II program is successful, the Company will request an End of Phase 2 meeting with the U.S. FDA to discuss the Phase III program. Given the short treatment durations employed in acute pain trials, it is anticipated that the full Phase III program for otenaproxesul can be completed within 12-18 months from initiation. This includes two concurrent, pivotal efficacy trials to assess post-operative pain relief for the following surgical procedures: (i) the hard tissue model of bunionectomy, replicating the second Phase II trial with a larger sample size; and (ii) abdominoplasty, a widely accepted soft-tissue surgical model. The Company intends to apply for marketing approval for a broad acute pain indication. Upon marketing approval, Antibe plans to rapidly initiate a series of studies to further investigate the effectiveness of otenaproxesul in a range of promising acute pain indications. The Company also intends to utilize the characteristics of the acute pain dosing regimen to identify an optimal dosing regimen for chronic pain indications.

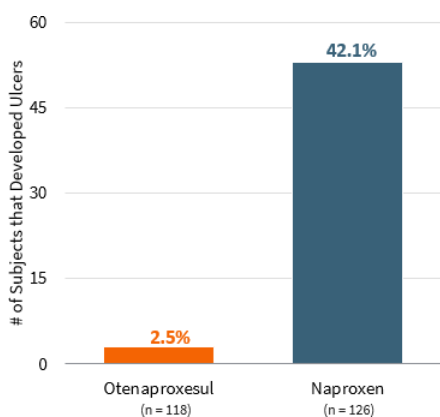
Given the extensive animal studies already performed in support of otenaproxesul's chronic pain program, the Company anticipates a requirement for only two additional animal studies for the acute pain program. These studies are expected to be conducted in parallel with the drug's Phase III program.

The following summarizes the Company's estimated timeline for otenaproxesul:

- Complete clinical PK/PD study for otenaproxesul – calendar Q4 2023
- Initiate Phase II bunionectomy trial of otenaproxesul – calendar Q1 2024
- Deliver Phase II bunionectomy top-line data of otenaproxesul – calendar Q2 2024

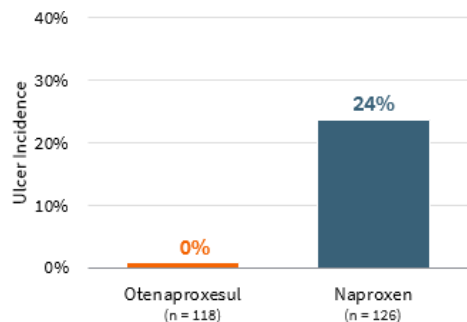
**Phase IIB GI Safety Study (Completed in March 2018).** Antibe received approval from Health Canada in August 2017 to conduct a Phase II, double-blind GI safety trial of otenaproxesul in 244 healthy volunteers. The study was designed to demonstrate the superiority of otenaproxesul in GI safety compared to naproxen, the most prescribed NSAID in the United States. One group was treated for 14 days with otenaproxesul (250 mg once daily) while the other group was treated for 14 days with the standard prescription dose of naproxen (550 mg twice daily). The primary endpoint for the study was the incidence of gastric or duodenal ulcers of at least 3 mm diameter with unequivocal depth, considered the gold standard in assessing the GI safety of NSAIDs. On March 20, 2018, Antibe announced that otenaproxesul successfully met the primary endpoint in the study. Subjects on otenaproxesul exhibited an ulceration rate of 2.5% (3/118) versus an ulceration rate of 42.1% (53/126) for subjects on naproxen at the end of the treatment period (*Figure 1*), with a very high degree of statistical significance ( $p < 0.0001$ ). Otenaproxesul was also safe and well tolerated.

**Figure 1. Gastric Ulcer Incidence of Otenaproxesul Versus Naproxen During Two-Week Treatment Period**

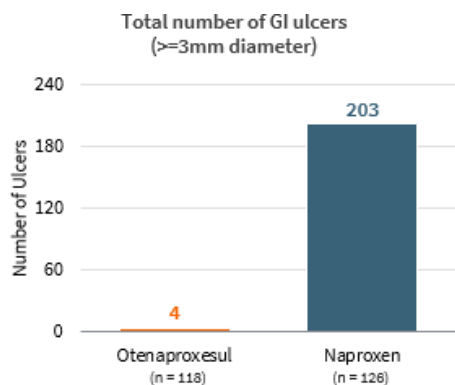


On July 3, 2018, the Company announced the secondary endpoint data from the Phase IIB GI safety study for otenaproxesul. The secondary endpoints were: incidence of gastric or duodenal ulcers of at least 5 mm diameter with unequivocal depth; number of gastric and/or duodenal erosions and/or ulcers; incidence of dyspepsia leading to discontinuation of study treatment; changes from baseline in hematocrit levels; and changes from baseline in ex vivo whole blood thromboxane B2 (TXB2) synthesis, a known biomarker for cyclo-oxygenase (COX) inhibition. No subjects treated with otenaproxesul exhibited ulcers of more than 5 mm diameter (0% ulcer incidence) versus 30 subjects treated with naproxen (24% ulcer incidence), with an average of 2.5 ulcers per subject (*Figure 2*). Furthermore, there were a total of 4 gastric ulcers and 0 duodenal ulcers in the otenaproxesul group, versus a total of 203 gastric and duodenal ulcers in the naproxen group (*Figure 3*). Both naproxen and otenaproxesul inhibited TXB2 synthesis by more than 94% (*Figure 4*).

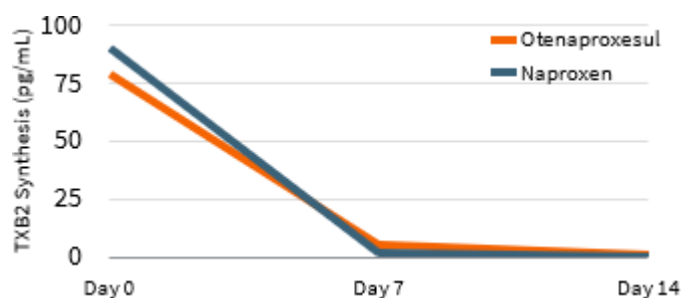
**Figure 2. Incidence of Large GI Ulcers ( $\geq 5$ mm diameter)**



**Figure 3. Total Number of GI Ulcers ( $\geq 3$ mm diameter)**



**Figure 4. COX Inhibition**



**Phase IIB Dose-Ranging, Efficacy Study (Completed in June 2020).** On June 1, 2020, the Company announced that otenaproxesul met the primary endpoint in the Phase IIB dose-ranging, efficacy study. Both the 250 mg and 200 mg doses of otenaproxesul demonstrated superiority to placebo in reducing osteoarthritis (“OA”) pain with a high level of statistical significance. The 150 mg dose of otenaproxesul, although not powered for statistical significance, demonstrated an efficacy signal. A total of 384 patients with OA of the knee were randomized to either placebo or otenaproxesul administered once daily: 250 mg, 200 mg or 150 mg. The primary objective in the study was to demonstrate the statistically significant superiority of otenaproxesul versus placebo in reducing OA pain as measured by the change from baseline in the WOMAC pain subscale score over a 14-day treatment period.

The drug was safe and well tolerated during this study. Transient liver transaminase elevations (“LTEs”) ranging from 7.2% to 12.9% were noted across the three otenaproxesul treatment arms. It is standard for pain trials to allow the use of other medications, commonly acetaminophen as a pain rescue medication. Notably, in the post-treatment assessment period, acetaminophen use, pre-existing liver conditions and concomitant statin use were associated with a majority of the LTE incidents. No clinically meaningful gastrointestinal, renal or measured cardiovascular safety outcomes were reported.

Otenaproxesul demonstrated superiority to placebo at doses of 250 mg (p-value of 0.01) and 200 mg (p-value of 0.007). Similar efficacy was observed between these doses (Figure 5), suggesting that the upper range of the dose-response curve has been reached. The 150 mg dose demonstrated an efficacy signal and had it been equivalently powered to the other treatment arms, the Company believes it would have achieved statistical significance. Given the efficacy signal observed with the 150 mg dose, future development at doses of 150 mg and lower warranted further investigation.

**Figure 5. Phase IIB Efficacy Study – Primary Efficacy Endpoint Data (Symptomatic Benefit)**

	Placebo	Otenaproxesul		
		250 mg	200 mg	150 mg
WOMAC pain score at baseline (day 0)	325.7	318.5	325.2	325.8
WOMAC pain score at day 4	261.4	229.8	237.4	230.2
Reduction versus baseline at day 4 (%)	20.3%	28.3%	27.3%	29.3%
WOMAC pain score at day 14	228.2	183.2	183.8	203.4
Reduction versus baseline at day 14 (%)	32.7%	43.6%	43.7%	39.3%
<b>Primary endpoint: p-value versus placebo (day 14)</b>	-	<b>0.01</b>	<b>0.007</b>	<b>0.13</b>

WOMAC scores based on 500-point Likert scale; reduction figures normalized to 100mm WOMAC pain subscale  
 Study population: 250 mg = 132 patients; 200 mg = 125 patients; 150 mg = 61 patients; placebo = 66 patients

In addition, both the 250 mg and 200 mg doses of otenaproxesul demonstrated a highly statistically significant reduction in the WOMAC stiffness subscale score (p<0.001 for both doses) and both doses were superior to placebo in the WOMAC difficulty performing daily activities (DPDA) subscale score (p-value of 0.004 and 0.001, respectively). While not statistically powered, the 150 mg dose of otenaproxesul nonetheless demonstrated a statistically significant improvement in stiffness compared to placebo (p-value of 0.03) and displayed an efficacy response in DPDA (Figure 6).

**Figure 6. Phase IIB Efficacy Study – Secondary Efficacy Endpoint Data (Therapeutic Benefit)**

	Placebo	ATB-346 (250 mg)	ATB-346 (200 mg)	ATB-346 (150 mg)
WOMAC stiffness reduction versus baseline (%)	23.8%	41.7%	40.5%	36.2%
<b>p-value versus placebo (day 14)</b>	-	<b>&lt; 0.001</b>	<b>&lt; 0.001</b>	<b>0.03</b>
WOMAC DPDA reduction versus baseline (%)	24.3%	38.4%	40.1%	32.5%
<b>p-value versus placebo (day 14)</b>	-	<b>0.004</b>	<b>0.001</b>	<b>0.106</b>



Adverse events typically associated with NSAID use, such as dyspepsia, acid reflux and dizziness, were comparable across placebo and all three treatment arms of otenaproxesul (Figure 7). There were very few serious adverse events or events leading to withdrawal of treatment.

**Figure 7. Phase IIB Efficacy Study – Summary of Adverse Events**

Patient-reported adverse event (>= 2%)	Placebo	ATB-346 (150 mg)	ATB-346 (200 mg)	ATB-346 (250 mg)
Dyspepsia	1.5%	1.6%	4.8%	4.5%
Constipation	0.0%	4.9%	1.6%	1.5%
Diarrhea	7.6%	1.6%	1.6%	1.5%
Nausea	1.5%	1.6%	1.6%	3.0%
Dizziness	0.0%	0.0%	1.6%	3.8%
Gastroesophageal reflux disease	3.0%	3.3%	0.8%	3.0%
Abdominal pain	0.0%	0.0%	0.8%	2.3%
Abdominal pain upper	1.5%	1.6%	0.8%	2.3%
Faeces soft	3.0%	0.0%	0.0%	0.8%
Pain	3.0%	0.0%	0.8%	2.3%
Headache	3.0%	3.3%	3.2%	7.6%
Nasopharyngitis	4.5%	1.6%	0.8%	3.0%
Urinary tract infection	0.0%	3.3%	3.2%	0.0%

Only 1 out of 318 patients administered otenaproxesul had clinically significant, transient liver transaminase elevations (LTEs) during the 14-day treatment period. At the post-treatment assessment (day 24), patients in the 250 mg, 200 mg and 150 mg treatment arms had clinically significant, transient LTE incidences of 12.9%, 7.2% and 9.8%, respectively. It is standard for pain trials to allow the use of other medications, commonly acetaminophen. Acetaminophen use, especially in the post-treatment assessment period, pre-existing liver conditions and concomitant statin use were associated with a majority of the LTE incidents. The study was conducted by Veristat, LLC in 39 clinical sites across Canada.

Trial participants treated with otenaproxesul experienced neither an increase nor decrease in blood pressure in contrast with other non-aspirin NSAIDs, which often increase blood pressure. The absence of an increase in blood pressure has been a consistent finding in all of otenaproxesul’s clinical trials to-date.

On March 29, 2021, Antibe announced that the U.S. FDA had cleared the Company’s Investigational New Drug (“IND”) application for otenaproxesul. This enables Antibe to undertake human clinical trials for otenaproxesul in the United States. In July 2021, the Company completed a single-dose pharmacokinetic (“PK”) and pharmacodynamic (“PD”) study in 24 healthy volunteers in the U.S. subsequent to its IND filing with the U.S. FDA. Subjects administered a single dose of either 150 mg or 100 mg of otenaproxesul, tolerated the drug without incident and successfully completed on-study and follow-up assessments without the development of clinically meaningful adverse events or clinically significant laboratory abnormalities. The results are being used to guide future development of otenaproxesul.

**Absorption, Metabolism and Excretion (“AME”) Study.** In July 2021, the Company commenced an AME study using lower doses (i.e., ≤150 mg per day), which was expected to conclude in calendar Q4 2021. On August 3, 2021, the Company announced that it had placed the AME study on a required pause because a pre-specified safety threshold was exceeded. At that point, the study had enrolled a total of 42 subjects on either a 75 mg or 100 mg daily dose of otenaproxesul, of whom 35 had completed the 28-day drug administration period, with seven subjects having been administered the drug for 21 days. Three subjects in the 100 mg cohort, who had completed the full drug administration period, exhibited liver transaminase elevations (“LTEs”) exceeding five times the upper limit of normal, triggering the required pause. Other indicators of liver function for these subjects were normal. Following the 4-week drug administration period, a further three subjects exhibited similar LTEs. All six subjects, including five in the 100 mg cohort and one in the 75 mg cohort, completed their in-clinic observation period without any additional safety findings. All LTEs were transient and self-limiting and required no clinical intervention. While continuing to investigate

alternative formulations and dosing regimens as a potential path forward for chronic indications, the Company has launched an acute pain program for otenaproxesul.

### *Regulatory Considerations*

In the United States, otenaproxesul will be regulated by FDA's Center for Drug Evaluation and Research. Antibe is pursuing U.S. marketing approval via an FDA new drug application ("NDA") enabling path. An NDA-enabling path is generally considered the gold standard path for drug development. The Company intends to work closely with the FDA and coordinate with the regulatory agencies of other large global markets to ensure that the development plan satisfies each of their respective requirements while minimizing redundancies.

### ***ATB-352: Analgesic for Specialized Indication***

ATB-352 is an H<sub>2</sub>S-releasing derivative of ketoprofen, a potent NSAID commonly prescribed for acute pain. Preclinical studies have revealed a potential application in a specialized indication with high unmet need. The Company has filed a patent application related to this indication.

Antibe has confirmed the non-addictive properties of ATB-352. Preclinical studies have demonstrated that ATB-352 causes negligible GI damage compared to ketoprofen.<sup>(11)</sup> The Company has completed animal proof-of-concept studies with encouraging results and is pursuing additional such studies.

### ***New Chemistry Initiatives***

In calendar 2021, Antibe engaged a full-service contract research organization ("CRO"), Dalriada Drug Discovery, to undertake new chemistry initiatives to identify additional H<sub>2</sub>S-releasing compounds that show promise in the treatment of acute pain, chronic pain and other inflammatory conditions. This project has been successfully completed, with results that include the IBD lead and backup candidates. Antibe retains ownership rights to any new IP filed as a result of this project.

The Company has selected lead and back up candidates for inflammatory bowel disease ("IBD") and is pursuing animal efficacy studies. Comprising treatments for Crohn's disease and ulcerative colitis, the IBD market is expected to nearly double between 2019 and 2029 to US\$25 billion.<sup>(12)</sup> The Company's new IBD candidates are being designed to maintain the efficacy, safety and pharmacokinetics of ATB-429, a hydrogen sulfide-releasing IBD drug (acquired via the recent amalgamation with Holdings) that has extensive and promising animal data but diminishing patent life.

### ***Commercial Strategy for Otenaproxesul***

The global market for acute pain therapeutics is estimated to be more than US\$25 billion, with opioids and NSAIDs accounting for the majority share.<sup>(13)</sup> In the U.S., there are 76 million surgical procedures annually<sup>(14)</sup> and more than two million Americans may become persistent opioid users each year.<sup>(15)</sup> The resurgent opioid crisis is pressuring prescribers, payors and policymakers to reduce the use of opioids across medical practice. In particular, the treatment of post-operative pain continues to rely on opioids, with little innovation in orally administered acute pain drugs, the only category of medications suitable for the transition to home recovery.

Antibe has completed a comprehensive third-party commercial assessment involving more than 60 U.S. clinicians and payors. This assessment reflects extensive primary and secondary research, including focus groups and an in-depth survey of medical specialists, involving orthopedic and general surgeons, anesthesiologists, internists, general practitioners and emergency physicians, all of whom treat acute pain on a daily basis. The assessment considered post-operative pain, acute musculoskeletal pain, dysmenorrhea, migraine and gout – the potential adoption of otenaproxesul for other acute pain indications (e.g., dental pain) was not investigated. Pricing and reimbursement, which drive a drug's adoption and ability to gain market share, were favourable, with minimal reimbursement hurdles

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<sup>11</sup> Gemici et al., *Nitric Oxide* (2015).

<sup>12</sup> Global Data, 2020.

<sup>13</sup> GlobalData, Statista, DataBridge, DelveInsight, Allied Market Research, Biotech Advisors, Antibe internal estimates.

<sup>14</sup> Gan et al., *Journal of Pain Research* (2017).

<sup>15</sup> Brummett et al., *JAMA Surgery* (2017).

expected. For the U.S. market alone, the assessment projects peak annual sales exceeding US\$1 billion.<sup>(16)</sup> Consistent with industry practice, an adjustment factor was applied to build conservatism into the sales projections. Physician responses indicate strong adoption rates, exceeding 50% for post-operative pain where opioids are widely used and surpassing 30% in all cases. Interest in otenaproxesul was highest for doctors prescribing NSAIDs and opioids, with gastrointestinal safety the principal safety concern for those prescribing NSAIDs. The assessment was conducted by Shift Health, a leading life science strategy consultancy.

Antibe has also concluded a comprehensive strategic positioning assessment of otenaproxesul for acute pain in the U.S. market. The assessment identified a compelling commercial strategy and validated the drug's best-in-class positioning in a market with few novel therapies in development. In addition, new opportunities for competitive differentiation were identified and are being pursued. The assessment was conducted by a leading life science-focused marketing and commercialization agency.

### ***Partnering***

The Company has concluded four regional licensing deals to date. On February 9, 2021, the Company licensed otenaproxesul to Nuance Pharma Limited (“Nuance”) for commercialization in the Greater China region. The license provides Nuance with exclusive rights to commercialize otenaproxesul in China, Hong Kong, Macau, and Taiwan. Under the terms of the agreement, Antibe is entitled to US\$100 million in milestone payments, including US\$20 million upfront and US\$80 million in development and sales milestones, in addition to a double-digit royalty on sales. Clinical development and regulatory costs for the region will be borne by Nuance. (In May 2023, arbitration proceedings were held with Nuance. Please see “Legal Proceedings” for further information.)

On September 5, 2018, Antibe entered into an exclusive licensing agreement with Kwang Dong Pharmaceutical Co., Ltd. (“Kwang Dong”) for the development and commercialization of otenaproxesul in South Korea. Kwang Dong is a leading pharmaceutical company in South Korea, with net sales in excess of US\$600 million and over 500 sales representatives. Under the terms of the agreement, Antibe is entitled to receive US\$10 million in non-dilutive development and commercial milestone payments, including an upfront payment of US\$1 million, and a royalty on net sales in the region.

On February 24, 2017, Antibe entered into an exclusive long-term license and distribution agreement (the "License Agreement") with Laboratoires Acbel SA (“Acbel”) for otenaproxesul in Albania, Algeria, Bulgaria, Greece, Jordan, Romania and Serbia (the “Territory”). Acbel is a pharmaceutical company with a strong sales and distribution presence in the Balkan region. Acbel, through its affiliates and partners, is the largest seller of naproxen in this region, which represents approximately 1% of the global market for NSAIDs. Under the terms of the license agreement, Antibe received an upfront, non-dilutive payment of \$1.1 million (€800,000) and is entitled to receive a 5% royalty on net sales of otenaproxesul in the Territory.

In addition, Antibe is also party to a license agreement with Knight Therapeutics Inc. (“Knight”), which was entered into in conjunction with Knight's investment in Antibe by way of convertible debenture in November 2015. Knight was granted commercial rights for Antibe's drug candidates and other future prescription drugs in Canada, Israel, Russia and sub-Saharan Africa. Antibe is entitled to royalties from Knight on annual sales, along with the potential for \$10 million in payments for sales-based milestones.

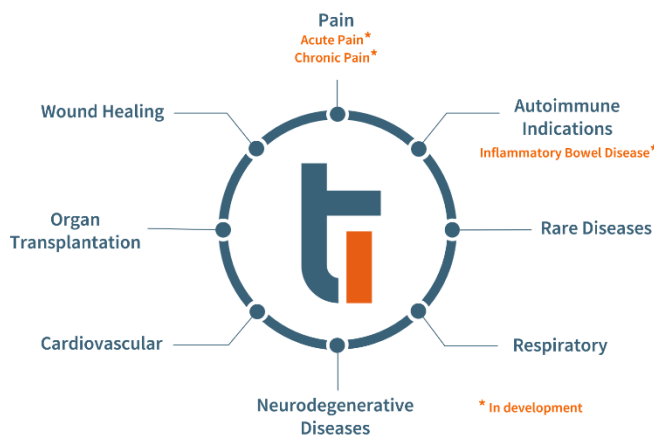
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<sup>16</sup> The U.S. accounts for 47% of the global pharmaceutical market (IQVIA, 2021).

### Pipeline Expansion Opportunities

Antibe has built a development platform that exploits the therapeutic potential of hydrogen sulfide (“H<sub>2</sub>S”) in the treatment of inflammation. Leveraging the unique properties of H<sub>2</sub>S by molecularly attaching a moiety that releases H<sub>2</sub>S to a known, off-patent base drug can result in a potential new drug that may have a significantly improved drug profile compared with the base drug. Ideal candidates to investigate as possible base drugs are expected to have the following characteristics:

- they can be distributed in large, growing markets;
- they are going or have gone off patent; and
- they exhibit weaknesses, such as low efficacy or certain toxicities, which could be significantly improved by the properties of H<sub>2</sub>S.



### Summary of Development Pipeline

The Company has determined that a number of targets meet these characteristics. It currently has two drugs in its pipeline (otenaproxesul and ATB-352) and additional candidates that are in process or have completed medicinal chemistry. Compared with de novo development, improving an existing base drug as described above may shorten the development period and time to market, and reduce development risk and cost. The improved drug also benefits from physician, regulatory and sales force familiarity with the base drug. Importantly, since Antibe creates new chemical entities, the improved drugs obtain new composition of matter patent protection.

Antibe is pursuing blockbuster drug opportunities in the areas of pain and inflammation with a pipeline of novel drug candidates that leverage its hydrogen sulfide-releasing technology.

Candidate	Target Indication	Markets/Segments	Est. Market Size	Development Status
Otenaproxesul (formerly ATB-346)	Acute & chronic pain	Post-operative pain, acute musculoskeletal pain, dysmenorrhea, migraine, gout and dental pain; chronic pain	US\$25+ billion <sup>(17)</sup>	Entering Phase II program in calendar Q1 2024
ATB-352	Specialized pain indication	Not disclosed	Not disclosed	Preclinical studies
Discovery program	Inflammatory Bowel Disease	Ulcerative colitis, Crohn’s disease	US\$16 billion <sup>(18)</sup>	Animal efficacy studies

### Corporate Strategy

The Company’s overall strategy is to monetize its pipeline at the optimal time through partnering or M&A activity. In parallel, the Company will continue to advance candidates to maximize both value and negotiating leverage with strategic partners.

<sup>17</sup> GlobalData, Statista, DataBridge, DelveInsight, Allied Market Research, Biotech Advisors, Antibe internal estimates.

<sup>18</sup> Global Data, 2020.

### ***Pursue a Broad Label for Otenaproxesul to Address Overall Acute Pain Market***

Otenaproxesul’s clinical development plan is designed to enable the Company to pursue regulatory approval for broad acute pain indication. Antibe is using the post-operative pain development path as a springboard to the much larger overall acute pain opportunity, including acute musculoskeletal pain, dysmenorrhea, migraine, gout and dental pain, all large segments with few safe and effective therapies. The Company continues to investigate alternative formulations and dosing regimens as a potential path forward for chronic indications.

### ***Leverage Development Platform to Expand Pipeline***

Antibe has built a development platform that exploits the therapeutic potential of hydrogen sulfide in the treatment of inflammation. In calendar June 2021, the Company entered into a strategic collaboration with Dalriada Drug Discovery to accelerate the identification of new drug candidates (including for its IBD program) and to fortify the IP position of its pipeline drugs.

### ***Opportunistically Pursue Strategic Partnerships***

Antibe will opportunistically pursue strategic partnerships to unlock and maximize value of its pipeline, with more activity expected as the otenaproxesul approaches human proof-of-concept for acute pain indications. The Company plans to initiate a partner targeting study to support strategic outreach as the drug’s therapeutic and commercial potential is fully validated.

### ***Leverage Human and Financial Resources***

The Company's HR strategy is to recruit and leverage a small senior team of highly experienced executives, supported by contract research organizations (“CROs”) and specialized regulatory and technical consultants. This approach delivers efficient and agile decision-making and strategy execution in all aspects of the business. The Company will continue to take a disciplined approach to spending to focus its resources on developing otenaproxesul while advancing multiple earlier-stage programs in parallel.

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## **Intellectual Property**

### ***Patents***

The Company was incorporated as a wholly owned subsidiary of Antibe Holdings with an exclusive IP license from Holdings to develop and commercialize the Company’s pipeline drugs. The license obligated the Company to pay royalties to Holdings on future revenues derived from this IP. On June 3, 2021, the Company completed a transaction with Holdings by way of a three-corner amalgamation. Pursuant to the transaction, the Company acquired full ownership of Holdings’ patent portfolio, eliminating the royalty liability on future revenues. In consideration, Antibe issued an aggregate of 5,873,092 common shares in the capital of the Company to acquire all of the issued and outstanding shares of Holdings.

The Company maintains a vigorous intellectual property prosecution and protection program. Patents are filed in key global markets, including the BRIC countries. Detailed and specific patents are filed by creating individual molecules and generating molecule-specific data. The NSAID program has successfully undergone extensive IP due diligence in Canada, the United States and Europe with respect to both validity and freedom to operate, and the patents have already issued in most major markets, including Canada, the United States and Europe. Specifically, the Company holds a patent in "Hydrogen sulfide releasing derivatives of nonsteroidal anti-inflammatory drugs" that is valid in: Australia, Brazil, Canada, China, the EU, Great Britain, Japan, Hong Kong, Israel, Mexico, Norway, Russia, South Africa, Singapore, South Korea, Turkey, and the United States, with an expiration date for all jurisdictions of July 18, 2027. Patent approval is pending in India.

The Company has filed two new patent applications covering uses of otenaproxesul for treatment of acute pain and for a specialized pain indication for ATB-352, offering the potential for IP protection to extend to the 2043 for both drugs. In October 2022, the Company filed a patent application for otenaproxesul’s new formulation, strengthening the drug’s IP protection to 2043.

## ***Trademarks***

The Company has filed trademark applications in all major markets for two proprietary brand names, with registration completed for Australia, Canada, China, the EU, Japan, Russia and the UK.

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## **Operations**

### ***Manufacturing, Supply & Production***

Antibe does not own or operate manufacturing facilities for the production of its products. The Company currently relies on its supply partners for all of its required raw materials, active ingredients and finished products.

Development and commercial quantities of any products that the company develops and/or markets will need to be manufactured in facilities, and by processes, that comply with the requirements of Health Canada, the U.S. FDA and in other jurisdictions in which the Company is seeking marketing approval. Antibe employs internal resources to manage its suppliers and plays an active role in working with suppliers to maintain the quality of the products that the Company expects to supply to its distribution partners. The manufacturers of Antibe's products have advised that they are compliant with both current Good Laboratory Practices ("cGLP") and Good Manufacturing Practices ("cGMP").

The Company and its suppliers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. Antibe and its suppliers must ensure that all of the processes, methods and equipment are compliant with cGMP and cGLP for drugs and medical devices on an ongoing basis, as mandated by the U.S. FDA and foreign regulatory authorities. (Please see "Risk Factors" for further detail.)

### ***Specialized Skill and Knowledge***

The Company has extensive knowledge in scientific research, clinical development and commercialization of drugs and therapies in the areas of pain, inflammation and regenerative medicine. By enlisting the support of experienced clinical trial, regulatory and legal consultants, the Company is able to use expert knowledge to assist in the successful development of its products and the protection of its intellectual property. Antibe continually evaluates its internal resources and may add talented senior professionals to its team as needed to support growth.

### ***Employees***

At March 31, 2023, the Company had 11 employees. The Company also uses senior consultants, hired on a contract basis and outsources its clinical development programs to various Contract Research Organizations ("CROs"), as needed. The Company has never experienced any employment-related work stoppages and believes its relationships with its employees are good.

### ***Facilities***

Antibe's corporate headquarters are located in Toronto, Ontario. The Company renewed its twelve-month lease for the use of its 15 Prince Arthur Ave. office space effective September 6, 2019 and continues to renew it on an ongoing basis. The lease carries a six-month notice period.

### ***Environmental, Health & Safety Matters***

Currently, the Company does not manufacture any of its products. However, the operations of its subcontractors and suppliers are subject to various laws and regulations relating to environmental, health and safety matters, and their failure to comply with such laws and regulations could have a material adverse effect on its business and reputation, result in an interruption or delay in the development or manufacture of its products and development candidates, or increase the costs for the development or manufacture of its products and development candidates.

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**Liquidity and Capital Resources**

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The Company is a drug development company as well as a regenerative medicine marketer and seller of products and will continue to operate at a loss for the foreseeable future. The Company is dependent on continued access to capital markets to acquire the resources it needs to achieve its business objectives.

The Company's future capital requirements will depend on many factors including, without limitation, the scope of the Company's research and development efforts, the results of the studies that comprise those efforts, the Company's ability to successfully manage its development partners and the Company's ability to grow its regenerative medicine business. If the development of otenaproxesul proceeds as planned, and the scientific results of the planned development work are positive, the Company expects to be in a strong position to attract new investment and/or obtain additional financing at attractive rates. However, financial market and other conditions may result in the Company not being able to secure the additional financing needed to complete the development of any of its assets on terms acceptable to the Company, or at all.

As at March 31, 2023, the Company had cash and term deposits totalling \$38.9 million and working capital of \$38.8 million.

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**RISK FACTORS**

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Any investment in the Company involves a number of risks. In addition to the information contained elsewhere in this AIF and in the referenced 2023 audited consolidated financial statements and related notes, investors and prospective investors should give careful consideration to the following risk factors. These are not the only risks and uncertainties that the Company faces. If any of the following events described as risks or uncertainties actually occurs or others occur, the Company's business, prospects, financial condition and operating results would likely suffer, possibly materially. In that event, the market price of the Common Shares could decline and investors could lose part or all of their investments. Additional risks and uncertainties presently unknown to the Company, or that the Company believes not to be material at this time, may also impair or have a material adverse effect on the Company's operations.

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**Start-up and Basis of Presentation**

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The Company's pharmaceutical development operations currently consist of preparing for Phase II clinical trials of otenaproxesul. Additionally, the Company conducts pre-clinical research on other of its assets in order to assess them as potential future pre-clinical and clinical development candidates. Almost all research and development, administration and capital expenditures incurred by the Company since the commencement of operations are associated with the development described above.

The Company is subject to a number of risks and material uncertainties associated with the successful development and acquisition of new products and their marketing, the conduct of its clinical studies and their results and the establishment of strategic alliances as needed. The Company will have to acquire the financing needed to conduct its research and development operations. To achieve the objectives of its business plan, the Company plans to raise capital and enter into development partnerships as needed. The products developed by the Company will require approval from regulatory bodies including the U.S. FDA, Health Canada, and similar organizations in other countries before their sale can be authorized.

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**Risks Related to the Company's Business**

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***Ability to Continue as a Going Concern***

The audited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As at March 31, 2023, the Company had working capital of \$38,782 (2022 – \$56,670), incurred a net comprehensive loss for the year then ended of \$19,402 (2022 – \$25,060), had negative cash flows from operations of \$16,149 (2022 – \$16,920) and an accumulated deficit of \$130,418 (2022 – \$111,016).

Until such time as the Company's pharmaceutical products are patented and approved for sale, the Company's liquidity requirements are dependent on its ability to raise additional capital by selling additional equity, from proceeds from the exercise of stock options and common share warrants or by obtaining credit facilities. The Company's future capital requirements will depend on many factors, including, but not limited to, the market acceptance of its products and services. No assurance can be given that any such additional funding will be available or that, if available, it can be obtained on terms favourable to the Company.

All of the factors above indicate the existence of a material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern, which assumes the Company will continue its operations for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the ordinary course of business. Management's plans to address these issues involve actively seeking capital investment and generating revenue and profit from the commercialization of its products. The Company's ability to continue as a going concern is subject to management's ability to successfully implement this plan. Failure to implement this plan could have a material adverse effect on the Company's financial condition and financial performance.

If the going concern assumption were not appropriate for the audited consolidated financial statements, then adjustments would be necessary to the carrying value of assets and liabilities, the reported revenue and expenses, and the classifications used in the consolidated statements of financial position. The audited consolidated financial statements do not include adjustments that would be necessary if the going concern assumption were not appropriate.

### ***Lack of Supporting Clinical Data***

The clinical effectiveness and safety of any of the Company's developmental products is not yet supported by clinical data and the medical community has not yet developed a large body of peer reviewed literature that supports the safety and efficacy of the Company's products. If future studies call into question the safety or efficacy of the Company's products, the Company's business, financial condition, and results of operations could be adversely affected.

### ***Research and Development Risk***

A principal component of the Company's business strategy is to expand its product offering to fully exploit its core science and related technologies. As such, the Company's organic growth and long-term success is dependent in part on its ability to successfully develop new and current products and it will likely incur significant research and development expenditures to do so. The Company cannot be certain that any investment in research and development will yield feasible or commercially viable products. Furthermore, its ability to discover and develop products will depend on its ability to:

- retain key scientists and executives as employees or partners;
- identify high quality therapeutic targets and unmet medical needs;
- identify potential drug candidates;
- develop products internally and assist its partners with development;
- successfully complete laboratory testing and clinical trials on humans;
- manufacture drug candidates and products that meet regulatory and industry standards;
- obtain and maintain necessary intellectual property rights to the Company's products;
- obtain and maintain necessary U.S. and other regulatory approvals for its products;
- collaborate with third parties to assist in the development of its products; and
- enter into arrangements with third parties to co-develop, license, and commercialize its products.

The Company may not be successful in discovering and developing drug products. Failure to introduce and advance new and current products could materially and adversely affect the Company's operations and financial condition.

### ***Clinical Development Risks***

The Company must demonstrate the safety and efficacy of otenaproxesul (and potentially other products it develops) through, among other things, extensive clinical testing. The Company's drug research and development programs are at an early stage of development. Numerous unforeseen events during, or as a result of, the testing process could delay or prevent commercialization of any products the Company develops, including the following:



- the results of clinical studies may be inconclusive, may demonstrate potentially unsafe drug characteristics, or may not be indicative of results that will be obtained in later human clinical trials;
- the safety and efficacy results attained in the early clinical studies may not be indicative of results that are obtained in later clinical trials; and
- after reviewing clinical study results, the Company or its partners or collaborators may abandon projects that were previously thought to be promising.

Clinical studies are very expensive, can run into unexpected difficulties and the outcomes are uncertain. The data collected from studies the Company conducts may not be sufficient to support the regulatory approval of additional human testing of such product(s). Clinical studies of the Company's products may not be completed on schedule or on budget. The Company's failure to complete any of its clinical studies on schedule or on budget, or its failure to adequately demonstrate the safety and efficacy of any of the products it develops, could delay or prevent regulatory approval of such products, which could adversely affect the Company's business, financial condition and results of operations.

### ***Negative Cash Flow from Operating Activities***

The Company reported negative cash flow from operating activities for the year ended March 31, 2023, and expects to experience negative operating cash flows for the foreseeable future. Until such time as the Company's drug products are approved for sale, the Company's working capital requirements are dependent on the Company's ability to raise capital by selling additional equity or from proceeds from the exercise of stock options and Common Share purchase warrants, by obtaining business development revenue (milestone payments for licensing agreements), or by obtaining credit facilities. No assurance can be given that any such additional funding or revenue will be available or that, if additional funding is available, it can be obtained on terms favourable to the Company.

### ***Operational Risk***

In the normal course of business, the Company's operations continue to be influenced by a number of internal and external factors and are exposed to risks and uncertainties that can affect its business, financial condition and operating results. The Company's activities are subject to ongoing operational risks, including the performance of key suppliers, product performance, and government and other industry regulations, all of which may affect its ability to meet its obligations. In addition, and although the Company believes it has prudently adopted conservative assumptions in its business planning and related cost estimations, no assurances can be given that such assumptions will prove to be accurate.

### ***Reliance on Partners and Suppliers***

Antibe works with a number of third parties to develop its products (and finance such development) and expects its reliance on third party partnerships and suppliers to increase in the future. If the Company's current or future strategic partners and suppliers do not devote adequate resources to product development, or if they experience financial difficulties, change their business strategy, decide to not pursue commercialization of our drug, have their licensing rights terminated by court or arbitrator, or undergo a business combination that affects their willingness or ability to fulfill their obligations to the Company, the result could be a material adverse effect on the Company's financial condition, results of operations and/or cash flow. Furthermore, if the Company is unable to enter into additional partnerships and supplier relationships in the future, or if the current or future partnerships and supplier relationships fail, the Company's ability to develop and sell products could be impacted negatively and the Company's business could be adversely affected. There can be no assurances that the Company will be able to establish these future strategic relationships, or, if established, that the relationships will be maintained.

### ***Disruptions in Production***

Factors that could affect the production and sale of the Company's products which could result in decreases in profitability include: (a) Acts of God; (b) the expiration or termination of leases, contracts, permits or licenses; (c) sales price redeterminations; (d) future litigation; (e) work stoppages or other labour difficulties; (f) disputes with suppliers, distributors and subcontractors; (g) political risk with offshore suppliers; (h) reliance on suppliers with highly technical and not easily replaceable expertise; and (i) changes in the market and general economic conditions.

Weather conditions, equipment replacement or repair and fires can have a significant impact on operating results.

### ***Fluctuations in Exchange Rates***

The Company is exposed to the financial risk related to the fluctuation of foreign exchange rates. The Company operates in Canada and the United States. The Company's costs are primarily in Canadian and U.S. dollars. The Company has not hedged its exposure to currency fluctuation.

### ***Income Taxes***

Income taxes are accrued based on current taxes expected to be paid or recovered for the period, and deferred taxes applicable in respect of the temporary differences that will reverse in subsequent periods. The tax rates and tax laws used to compute the amounts are those that are enacted or substantively enacted at the reporting date in the countries where the Company operates.

Estimation of income taxes includes evaluating the recoverability of deferred tax assets based on an assessment of the Company's ability to utilize the underlying future tax deductions against future taxable income before they expire. The Company's assessment is based upon existing tax laws and estimates of future taxable income. If the assessment of the Company's ability to utilize the underlying future tax deductions changes, the Company would be required to recognize more or fewer of the tax deductions as assets, which would decrease or increase the income tax expense in the period in which this is determined.

Significant judgment is required in determining the global provision for taxation. There are transactions and calculations during the ordinary course of business for which the ultimate tax determination is uncertain. The Company maintains provisions for uncertain tax positions that it believes appropriately reflect its risk with respect to tax matters under active discussion, audit, dispute or appeal with tax authorities, or which are otherwise considered to involve uncertainty. These provisions for uncertain tax positions are made using the best estimate of the amount expected to be paid based on a qualitative assessment of all relevant factors. The Company reviews the adequacy of these provisions at each balance sheet date. However, it is possible that at some future date an additional liability could result from audits by taxing authorities. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will affect the tax provisions in the period in which such determination is made.

### ***Worsened General Economic Conditions***

The decline in the global economic environment in recent years and the continuing economic instability in certain parts of the world resulted in increasing uncertainty regarding future revenue and third party commitments, both in terms of timing and magnitude. If the global economic climate does not recover, the Company may not generate the commercial activity required to support its operations resulting in requirement for additional restructurings and erosion of its existing capital resources which may hinder the future viability of the Company.

### ***Acquisitions***

The Company in the future may acquire businesses, products or technologies that it believes complement or expand its existing business. Acquisitions of this type involve a number of risks, including the possibility that the operations of the acquired business will not be profitable or that the attention of the Company's management will be diverted from the day-to-day operation of its business. An unsuccessful acquisition could reduce the Company's margins or otherwise harm its financial condition.

### ***Product Liability and Medical Malpractice Claims***

The Company may be exposed to risks associated with product liability claims if the use of the Company's products results in injury or property damage. In addition, medical malpractice claims may be brought against the Company. The Company carries what it believes to be adequate product liability insurance as well as clinical studies insurance, but the Company may not have adequate resources to satisfy a judgment if a successful claim is brought. The assertion of product liability or medical malpractice claims may also significantly damage the Company's reputation.

### ***Management of Growth***

The Company's future results of operations will depend in part on the ability of its officers and other key employees to implement and expand operational, customer support and financial control systems and to expand, train and manage its employee base. The Company's future performance will also depend to a significant extent on its ability to identify, attract, train and retain highly skilled sales, technical, marketing and management personnel.

### ***Dependence on Key Personnel***

Antibe's success is dependent on certain key management personnel, primarily its scientists and executives, who are key to the existence and continuity of the Company. Furthermore, competition for qualified employees among biotechnology industry companies is intense, and the loss of key personnel or inability to attract and retain additional highly skilled employees required for the expansion of activities could adversely affect Antibe's business. There can be no assurance that these persons will remain available to Antibe, forcing Antibe to attract and retain additional qualified employees and key executives for the achievement of Antibe's business goals.

### ***Protection of Intellectual Property***

The Company's success depends in part on its ability to maintain or obtain and enforce patent and other intellectual property ("IP") protections for its processes and technologies and to operate without infringing upon the proprietary rights of third parties or having third parties circumvent the rights that the Company owns or licenses. The Company has applications and registrations in the United States, Canada, and other jurisdictions, and has received some patents and expects others, and may, in the future, seek additional patents and registrations or file patent applications and registrations.

Patents may provide some degree of protection for intellectual property; however, patent protection involves complex legal and factual determinations and is therefore uncertain. The Company cannot be assured that its patents or patent applications will be valid or will issue over prior art, or that patents will issue from the patent applications it has filed or will file. Additionally, the Company cannot be assured that the scope of any claims granted in any patent will be commercially useful or will provide adequate protection for the technology used currently or in the future. The Company cannot be certain that the creators of its technology were the first inventors of inventions and processes covered by its patents and patent applications or that they were the first to file. Accordingly, it cannot be assured that its patents will be valid or will afford protection against competitors with similar technology or processes. Despite its efforts to protect its proprietary rights, unauthorized parties may attempt to copy or otherwise obtain and use its proprietary information. Monitoring unauthorized use of confidential information is difficult and the Company cannot be certain that the steps taken to prevent unauthorized use of confidential information will be effective. In addition, the laws governing patent protection continue to evolve and are different from one country to the next, all of which causes further uncertainty in the usefulness of a patent. In addition, issued patents or patents licensed to the Company may be successfully challenged, invalidated, circumvented or may be unenforceable so that the Company's patent rights would not create an effective competitive barrier.

Moreover, the laws of some countries may not protect the Company's proprietary rights to the same extent as do the laws of the United States and Canada. There are also countries in which the Company intends to sell its products, but has no patents or pending patent applications, or trademark registrations. The Company's ability to prevent others from making or selling duplicate or similar technologies will be impaired in those countries in which there is weaker or no intellectual property protection. If the Company is not able to adequately protect its intellectual property and proprietary technology, its competitive position, future business prospects and financial performance will be adversely affected.

Unpatented trade secrets, technological innovation and confidential know-how are also important to the Company's success. Although protection is sought for proprietary information through confidentiality agreements and other appropriate means, these measures may not effectively prevent disclosure of proprietary information, and, in any event, it cannot be assured that others will not independently develop the same or similar information or gain access to the same or similar information. In view of these factors, the Company's intellectual property positions have a degree of uncertainty.

Setbacks in these areas could negatively affect the Company's ability to compete and materially and adversely affect its business, financial condition and results of operations.

### ***Inability to Implement the Business Strategy***

The growth and expansion of the Company's business is heavily dependent upon the successful implementation of the Company's business strategy. There can be no assurance that Antibe will be successful in the implementation of its business strategy.

### ***Large Accumulated Deficit***

Antibe has a large accumulated deficit, expects future losses, and may never achieve or maintain profitability. It has incurred substantial losses since inception and expects to incur additional operating losses in the future as a result of research and development costs and ongoing operating costs including the additional costs of operating as a public company. The extent of the Company's future losses is highly uncertain, and its prospects must be considered in light of the risks and uncertainties encountered by a company in the early stage of product development in the continuously evolving human pharmaceutical market, including the risks described throughout this AIF. If the Company cannot successfully address these risks, its business and financial condition will suffer.

### ***Competitive Market for Antibe's Products***

The pharmaceutical and biotechnology industries are highly competitive. Overall, most of Antibe's competitors in the pharmaceutical and biotechnology industries are larger and have greater financial and other resources, which enable them to invest significant amounts of capital and other resources in their businesses, including expenditures for research and development and sales and marketing. If one of Antibe's current or future competitors develops innovative proprietary products, some or all of Antibe's products could be rendered obsolete.

### ***Intellectual Property Litigation***

Patents issued or licensed to the Company and trademarks registered or licensed to the Company may be infringed upon by the products or processes of others. The cost of enforcing intellectual property rights against infringers, if such enforcement is required, could be significant, and the time demands could interfere with normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. Antibe may become a party to intellectual property litigation and other proceedings. The cost of any intellectual property litigation, even if resolved in the Company's favour, could be substantial. Some of the Company's competitors may be able to sustain the costs of such litigation more effectively than the Company can because of their substantially greater financial resources. Litigation may also absorb significant time and could divert management's attention from Antibe's core business. Litigation also puts the Company's intellectual property at risk of being invalidated or interpreted narrowly, and puts patent applications at risk of not being issued.

Additionally, it is possible that patents issued or licensed to Antibe may be challenged successfully by third parties in patent litigation. Patent applications which relate to or affect the business may have been filed by others and may conflict with the Company's technologies or patent applications; this could reduce the scope of patent protection which could otherwise be obtained or even lead to refusal of patent applications. It is also possible for others, on an independent basis, to develop products which have the same effect as the Company's products or to design around the technology protected by the Company's patents. In any event, if the Company is unable to secure or to continue to maintain a preferred position, its products could become subject to competition from the sale of generic or equivalent products. Antibe could also become involved in interference proceedings in connection with one or more of its patents or patent applications to determine priority of invention.

Antibe cannot be certain that it is the creator of inventions covered by pending patent applications or that it was the first to file patent applications for any such inventions. It cannot be assured that the Company's patents, once issued, would be declared by a court to be valid or enforceable, or that a competitor's technology or product would be found to infringe upon the Company's products. In the event that a court were to find that the Company was infringing upon a valid patent of a third party, it could be required to pay a substantial damage award, develop non-infringing technology, enter into royalty-bearing licensing agreements or stop selling its products. It cannot be assured that the Company could enter into licensing arrangements at a reasonable cost, or at all. Any inability to secure licenses could result in delays in the introduction of some of the Company's products or even lead to prohibition of the development, manufacture or sale of certain of its products.

Although no claims against the Company are, to its knowledge, currently pending, it may be subject to claims. Litigation may be necessary to defend against these claims. Even if the Company is successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

### ***Non-IP Litigation***

Any unfavourable court or arbitration judgment or other cases could affect Antibe's cash flow. One of the Company's license partners, Nuance Pharma Limited, has commenced arbitration proceedings related to their license agreement. (Please see "Legal Proceedings" for further detail.) As of the date hereof, the Company has no other legal matters pending.

### ***The Company's Licensees may not Perform or may Terminate the Licenses***

The Company is party to license agreements for certain of its drug candidates with various counterparties for various geographical jurisdictions. And the Company may enter into additional license agreements in the future, including with smaller or medium-sized pharmaceutical companies in regions that represent smaller market opportunities (i.e., outside of the United States and Western Europe). Licensees generally have the right to terminate license agreements and/or may not perform as expected or in accordance with the terms and conditions of a license agreement. The actions or inactions of licensees relating to the Company's licenses or otherwise could negatively impact the Company's products, reputation and results of operations. In addition, disputes may arise between the Company and its licensees that may result in the delay or termination of the research, development or commercialization of drug candidates, as applicable, or that result in costly litigation. While the Company intends to be selective in choosing financially strong and experienced licensees, it will have little or no ability to control the business practices or other actions of its licensees beyond specific matters relating to license set forth in each license agreement.

### ***Regulatory Risk***

Antibe will require approval from the U.S. FDA and Health Canada to conduct future human clinical studies in the U.S. and Canada respectively, and will require approval from these regulatory agencies and equivalent organizations in other countries before any of its products can be marketed. There is no assurance that such approvals will be forthcoming. Furthermore, the exact nature of the studies these regulatory agencies will require is not known and can be changed at any time by the regulatory agencies, increasing the financing risk and potentially increasing the time to market the Company faces, which could adversely affect the Company's business, financial condition or results of operations.

### ***Regulatory Compliance***

In both domestic and foreign markets, the development, formulation, manufacturing, packaging, labeling, handling, distribution, import, export, licensing, sale and storage of pharmaceuticals are affected by a body of laws, governmental regulations, administrative determinations, including those by U.S. FDA and Health Canada, court decisions and similar constraints. Such laws, regulations and other constraints can exist at the federal, provincial or local levels in Canada and at all levels of government in foreign jurisdictions. There can be no assurance that Antibe and Antibe's partners are in compliance with all of these laws, regulations and other constraints. Antibe and its partners may be required to incur significant costs to comply with such laws and regulations in the future, and such laws and regulations may have an adverse effect on the business. The failure of the Company or its partners to comply with current or future regulatory requirements could lead to the imposition of significant penalties or claims and may have a material adverse effect on the business. In addition, the adoption of new laws, regulations or other constraints or changes in the interpretations of such requirements might result in significant compliance costs or lead Antibe and its partners to discontinue product development and could have an adverse effect on the business.

### ***International Operations***

Antibe's international operations expose it and its representatives and agents to risks inherent to operating in foreign jurisdictions that could materially adversely affect its operations and financial position. These risks include:

- Country specific taxation policies;
- Imposition of additional foreign governmental controls or regulations;
- Export license requirements; and

- Changes in tariffs and other trade restrictions.

Moreover, applicable agreements relating to business in foreign jurisdictions are governed by foreign laws and are subject to dispute resolution in the courts of, or through arbitration proceedings in, the country or region in which the parties are located or another jurisdiction agreed upon by the parties. Antibe cannot accurately predict whether such jurisdictions will provide an effective and efficient means of resolving disputes that may arise. Even if it obtains a satisfactory decision through arbitration or a court proceeding, Antibe could have difficulty in enforcing any award or judgment on a timely basis or at all.

### ***Reliance on Information Technology***

Despite the implementation of security measures, the Company's internal computer systems, and those of third parties on which the Company relies, are vulnerable to damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the internet, attachments to emails, or persons inside the Company. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Should a material system failure or security breach occur and cause interruptions in Antibe's operations, it could result in a material disruption of the Company's development programs and business operations. For example, the loss of clinical trial data from ongoing, completed or future clinical trials could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Likewise, the Company relies on third parties for a range of services and products including the manufacture of product candidates and conduct of studies and trials; similar events relating to third parties' computer systems could also have a material adverse effect on the Company's business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, Antibe could incur liability and the further development and commercialization of product candidates could be delayed.

### ***Financial Instruments***

The Company is exposed to a variety of financial risks by virtue of its activities: credit risk, liquidity risk, foreign currency risk and interest rate risk. The Company's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on financial performance.

Risk management is carried out by the officers of the Company as discussed with the Board of Directors. The officers of the Company are charged with the responsibility of establishing controls and procedures to ensure that financial risks are mitigated in accordance with the expectation of the Board of Directors as follows:

#### *Credit risk*

The Company's credit risk is primarily attributable to receivables and the excess of cash held in one financial institution in excess of the amount covered by the deposit insurance by Canadian Deposit Insurance Corporation.

#### *Liquidity risk*

Liquidity risk is the risk that the Company is not able to meet its financial obligations as they become due or can do so only at excessive cost. The Company manages its liquidity risk by forecasting cash flows and anticipated investing and financing activities. Officers of the Company are actively involved in the review and approval of planned expenditures, including actively seeking capital investment and pursuing the commercialization of its products.

As of March 31, 2023, the Company's financial obligations, including applicable interest, are due as follows:

	Less than 1	1–2	After 2	Total
	\$	\$	\$	\$
Accounts payable and accrued liabilities	2,764	-	-	2,764

#### *Foreign currency risk*

The functional and reporting currency of the Company is the Canadian dollar. The Company undertakes transactions denominated in foreign currencies, including U.S. dollars, and, as such, is exposed to currency risk due to fluctuations in foreign exchange rates against the Canadian dollar. The Company does not use derivative instruments to reduce exposure to foreign currency risk.

#### *Interest rate risk*

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. Financial assets and financial liabilities with variable interest rates expose the Company to cash flow interest rate risk.

#### **COVID-19 Pandemic**

The COVID-19 pandemic did impact the Company's business to some extent. The Company's Phase IIB dose ranging, efficacy trial in 2020 took an additional six weeks to complete due to factors such as the COVID-19 related closure of medical clinics, doctors becoming ill from COVID-19, and staff working from home, all of which slowed the collation of the trial data. COVID-19 could further impact the Company's expected timelines, operations and the operations of its third-party suppliers, manufacturers, and contract research organizations as a result of quarantines, facility closures, travel and logistics restrictions and other limitations in connection with the outbreak. The most significant risk posed by the COVID-19 pandemic is that it could also significantly impact the progress and completion of animal and clinical studies.

Whatever further impact, if any, the COVID-19 pandemic may have on the Company is unpredictable. The future extent of future COVID-19 outbreaks is uncertain and, therefore, it is not possible to estimate its impact on the Company's business, operations or financial results; however, the impact could be material.

If the Company's quarterly operating results fall below the expectations of investors or securities analysts, the market price of the Common Shares could decline substantially. Furthermore, any quarterly fluctuations in the Company's operating results may, in turn, cause the market price of the Common Shares to fluctuate substantially. The Company believes that quarterly comparisons of the Company's financial results are not necessarily meaningful and should not be relied upon as an indication of its future performance.

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#### **Disclosure Controls and Procedures**

The Company's management is responsible for establishing and maintaining disclosure controls and procedures, as defined in National Instrument 52-109 – Certification of Disclosure in Issuers' Annual and Interim Filings ("NI 52-109") and have designed such disclosure controls and procedures to provide reasonable assurance that material information with respect to the Company is made known to them and information required to be disclosed by the Company in its annual filings, interim filings or other reports filed or submitted by it under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation.

The Company's management is responsible for establishing and maintaining internal controls over financial reporting ("ICFR"), as defined in NI 52-109 and have designed such ICFR to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with IFRS.

There have been no changes in the Company's ICFR during the 12 months ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, the Company's ICFR.

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## **Risks Related to Financing**

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### ***Active Liquid Market for Common Shares***

There may not be an active, liquid market for the Common Shares. There is no guarantee that an active trading market for the Common Shares will be maintained on the TSX. Investors may not be able to sell their Common Shares quickly or at the latest market price if trading in the Common Shares is not active.

### ***Forward-Looking Information May Prove Inaccurate***

Investors are cautioned not to place undue reliance on forward-looking statements and forward-looking information. By its nature, forward-looking statements and forward-looking information involve numerous assumptions, known and unknown risks and uncertainties, of both a general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking statements and forward-looking information or contribute to the possibility that predictions, forecasts or projections will prove to be materially inaccurate. Additional information on the risks, assumptions and uncertainties are found in this Prospectus under the heading "Forward-Looking Information".

### ***Dilution to Existing Shareholders, Restrictions on Operations and Relinquishment Rights to Technologies or Product Candidates***

The Company may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interests of the Company's shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of the Company's shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on the Company's ability to incur additional debt, limitations on the Company's ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact the Company's ability to conduct its business. If the Company raises additional funds through strategic partnerships and alliances and licensing arrangements with third parties, the Company may have to relinquish valuable rights to its technologies or product candidates, or grant licenses on terms unfavourable to the Company.

### ***Price of the Company's Common Shares May Fluctuate***

Market prices for securities in general, and that of pharmaceutical companies in particular, tend to fluctuate. Factors such as the announcement to the public or in various scientific or industry forums of technological innovations; new commercial products; patents, exclusive rights obtained by the Company or others; disputes or other developments relating to proprietary rights, including patents and data exclusivity, litigation matters and the Company's ability to obtain patent protection and data exclusivity for the Company's technologies; the commencement, enrollment or results of future clinical trials the Company may conduct, or changes in the development status of the Company's product candidates; results or delays of non-clinical and clinical studies by the Company or others; any delay in the Company's regulatory filings for its product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings; a change of regulations; additions or departures of key scientific or management personnel; overall performance of the equity markets; general political and economic conditions; publications; failure to meet the estimates and projections of the investment community or that the Company may otherwise provide to the public; research reports or positive or negative recommendations or withdrawal of research coverage by securities analysts; actual or anticipated variations in quarterly operating results; announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by the Company or its competitors; public concerns over the risks of pharmaceutical products and dietary supplements; unanticipated serious safety concerns; future sales of securities by the Company or its shareholders; and many other factors, many of which are beyond the Company's control, could have considerable effects on the price of the Company's securities. There can be no assurance that the market price of the Common Shares will not experience significant fluctuations in the future. As a result of any of these factors, the market price



of the securities of the Company at any given point in time may not accurately reflect the value of the Company or its securities.

In addition, the stock market in general, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of the Company's Common Shares, regardless of the Company's actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm the Company's business, operating results or financial condition.

### ***Decline of Market Price of the Common Shares***

The Company's net losses and expenses may fluctuate significantly and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in the price of the Company's Common Shares. The Company's net losses and expenses have fluctuated in the past and are likely to do so in the future. These fluctuations could cause the market price of the Common Shares to decline. Some of the factors that could cause the Company's net losses and expenses to fluctuate include the following:

- results of non-clinical studies and clinical trials, or the addition or termination of non-clinical studies, clinical trials or funding support;
- the timing of the release of results from any non-clinical studies and clinical trials;
- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize the Company's products;
- the outcome of any litigation or arbitral proceedings;
- changes in foreign currency fluctuations;
- competition;
- the timing of achievement and the receipt of milestone payments from current or future third parties;
- payments due from HANSAmед related to their purchase of Citagenix Inc.;
- failure to enter into new or the expiration or termination of current agreements with third parties;
- failure to manufacture drug candidates and products that meet regulatory and industry standards;
- failure to introduce the Company's products to the market in a manner that generates anticipated revenues;
- the Company's execution of any new collaboration, licensing or similar arrangement, and the timing of payments the Company may make or receive under such existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which the Company may become involved;
- additions and departures of key personnel;

- strategic decisions by the Company or its competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of the Company's product candidates receives regulatory approval, market acceptance and demand for such product candidates;
- regulatory developments or determinations affecting the Company's product candidates or those of its competitors; and
- changes in general market and economic conditions.

### ***Future Sales or Issuances of Securities***

The Company may sell additional Common Shares or other Securities in subsequent offerings to finance future activities or issue shares as consideration for acquisitions. The Company cannot predict the size of future issuances of securities or the effect, if any, that future issuances and sales of securities will have on the market price of the Common Shares. Sales or issuances of substantial numbers of Common Shares, or the perception that such sales could occur, may adversely affect prevailing market prices of the Common Shares. With any additional sale or issuance of Common Shares, investors will suffer dilution to their voting power and the Company may experience dilution in its earnings per share.

### ***Internal Controls over Financial Reporting***

As a public company, Antibe is required to comply with the internal control evaluation and certification requirements of securities laws in Canada. The Company's financial reporting internal controls are currently in compliance with those requirements. Ensuring compliance with reporting and other obligations places significant demands on management, administrative, operational and accounting resources. The Company anticipates that it will need to continue to upgrade systems, implement additional financial and management controls, reporting systems and procedures. If it is unable to accomplish these objectives in a timely and effective fashion, its ability to continue to comply with the financial reporting requirements and other rules that apply to reporting issuers could be impaired. Moreover, any failure to maintain effective internal controls, including a failure to implement new or improved controls in response to identified weaknesses in its system of internal controls, could cause the Company to fail to meet its reporting obligations or result in material misstatements in its financial statements. If the Company cannot provide reliable financial statements or prevent fraud, its reputation and operating results could be materially harmed, its current and future shareholders could lose confidence in the reported financial information and in the Company, and the Company's share price could be affected negatively.

### ***Prior Losses***

It is expected that the Company will continue to experience operating losses until product sales and/or licensing rights income generate sufficient revenues to fund its continuing operations, including research and product development. There is no assurance that Antibe will be able to realize such revenues.

Antibe has incurred net losses from operations since inception. If, in the future, Antibe needs but cannot raise additional funds, it may not be able to continue as a going concern and realize its assets and pay its liabilities as they fall due. The financial statements have been prepared on a going concern basis, which assumes Antibe will continue its operations in the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the ordinary course of business.

### ***Ability to Secure Additional Financing & Dilution of Common Shares***

Antibe expects that its current cash and cash equivalent reserves will be sufficient to meet its anticipated needs for working capital and capital expenditures for the near future. If estimates of revenue, expenses, or capital or liquidity requirements change or are inaccurate, or if cash generated from operations is insufficient to satisfy liquidity requirements, the Company may arrange additional financings. In the future, the Company may also arrange financings to give it the financial flexibility to pursue attractive acquisition or investment opportunities that may arise. The Company may pursue additional financing through various means, including equity investments,

issuances of debt, joint venture projects and licensing arrangements or through other means. The Company cannot be certain that it will be able to obtain additional financing on commercially reasonable terms or at all. The Company's ability to obtain additional financing may be impaired by such factors as the status of capital markets, both generally and specifically in the pharmaceutical industry, and by the fact that it is an enterprise without a proven operating history. If the amount of capital raised from additional financing activities, together with revenues from operations (if any), is not sufficient to satisfy the Company's capital needs, it may not be able to develop or advance its products, execute its business and growth plans, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer or partner requirements. If any of these events occur, the Company's business, financial condition, and results of operations could be adversely affected. Any future equity financings undertaken are likely to be dilutive to existing shareholders. Finally, the terms of securities issued in future capital transactions may include preferences that are more favourable to new investors.

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## **DIVIDENDS**

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Antibe has not paid dividends on the Common Shares in the past and has no plans to pay dividends on the Common Shares for the foreseeable future. The Company's current intention is to retain earnings to fund the development and growth of the business and it does not anticipate declaring or paying any cash dividends in the near to medium term. The Board will determine if and when dividends should be paid in the future based on all relevant circumstances, including the desirability of financing future growth and the financial position at the relevant time.

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## **DESCRIPTION OF CAPITAL STRUCTURE**

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### *Authorized Capital*

The Company's authorized share capital currently consists of an unlimited number of Common Shares without nominal or par value.

### *Common Shares*

Each holder of a Common Share is entitled to (i) notice of and the right to vote at all meetings of shareholders of the Company, (ii) receive any dividend declared by the Board, and (iii) receive the remaining property of the Company in the event of the voluntary or involuntary liquidation, dissolution or winding up of the Company, or any other distribution of its assets among its shareholders for the purposes of winding up its affairs. The foregoing description may not be complete and is subject to, and qualified in its entirety by reference to, the terms and provisions of the Company's constituting documents, as amended. As at March 31, 2023, there were 52,617,092 Common Shares issued and outstanding.

## MARKET FOR SECURITIES

The Common Shares of the Company trade on the TSX under the symbol “ATE” and on the OTCQX under the symbol “ATBPF”. The following table sets forth the reported high and low prices and the trading volume for the periods indicated (all data adjusted for the share consolidation that took effect on December 1, 2020):

Month	Toronto Stock Exchange (CDN\$)			OTC Market (US\$)		
	High	Low	Volume	High	Low	Volume
June 1-27, 2023	0.52	0.46	331,264	- 0.38	0.35	30,200
May 2023	0.56	0.47	476,395	0.41	0.35	168,174
April 2023	0.61	0.52	301,805	0.43	0.38	31,949
March 2023	0.65	0.48	811,301	0.47	0.35	390,646
February 2023	0.62	0.48	1,012,697	0.46	0.36	63,502
January 2023	0.69	0.47	555,136	0.53	0.36	142,910
December 2022	0.59	0.41	838,700	0.40	0.28	108,308
November 2022	0.55	0.46	450,612	0.39	0.35	101,854
October 2022	0.64	0.50	395,062	0.47	0.37	49,846
September 2022	0.71	0.59	373,889	0.54	0.42	130,221
August 2022	0.68	0.58	412,500	0.53	0.46	145,621
July 2022	0.69	0.56	570,945	0.49	0.42	37,240
June 2022	0.75	0.60	644,580	0.59	0.46	145,792
May 2022	0.72	0.66	648,025	0.57	0.50	137,556
April 2022	0.82	0.66	408,692	0.64	0.52	98,395

## DIRECTORS AND OFFICERS

The following table provides the names and jurisdictions of residence of the executive officers and the directors of the Company as at the date of this AIF as well as their offices held with the Company, the date they were first appointed to the Board and their principal occupation and positions.

Name and Jurisdiction of Residence	Current Position and/or Office Held	Director Since	Principal Occupation
Robert E. Hoffman <sup>(1)(2)</sup> <i>San Diego, California USA</i>	Chair of the Board	November 24, 2020	President, CEO and Chairman, Kintara Therapeutics, Inc.
Amal Khouri <sup>(2)</sup> <i>Montréal, Québec Canada</i>	Director	March 19, 2018	Chief Business Officer, Knight Therapeutics Inc.
Daniel Legault <i>Toronto, Ontario Canada</i>	President, Chief Executive Officer, Secretary & Director	May 5, 2009	President, Chief Executive Officer, Secretary & Director of Antibe
Roderick Flower <sup>(1)(2)</sup> <i>London, England United Kingdom</i>	Director	February 26, 2013	Emeritus Professor of Pharmacology at William Harvey Research Institute, Queen Mary University (London, UK)

Walt Macnee <sup>(3)</sup> <i>Toronto, Ontario Canada</i>	Vice Chair & Director	February 26, 2013	Former Vice Chairman, MasterCard Worldwide; former Chair of the Board, Antibe
Jennifer McNealey <sup>(1)(3)</sup> <i>Mill Valley, California USA</i>	Director	November 24, 2020	Chief Financial Officer, Abdera Therapeutics
Yung Wu <sup>(3)</sup> <i>Toronto, Ontario Canada</i>	Director	July 18, 2016	Chief Executive Officer, MaRS Discovery District
Scott Curtis <i>Toronto, Ontario Canada</i>	Chief Operating Officer	-	Chief Operating Officer, Antibe
Joseph Stauffer <i>Sarasota, Florida USA</i>	Chief Medical Officer	-	Chief Medical Officer, Antibe
Ana Stegic <i>Oakville, Ontario Canada</i>	Director, Clinical Operations	-	Director, Clinical Operations, Antibe
David Vaughan <i>Pickering, Ontario Canada</i>	Chief Development Officer	-	Chief Development Officer, Clinical Operations, Antibe
Alain Wilson <i>Toronto, Ontario Canada</i>	Chief Financial Officer	-	Chief Financial Officer, Antibe

- (1) Member of the Audit Committee, of which Mr. Hoffman is the Chair.  
(2) Member of the HR & Compensation Committee, of which Dr. Flower is the Chair.  
(3) Member of Governance and Nomination Committee, of which Ms. McNealey is the Chair.

The directors listed above shall hold office for a term expiring at the conclusion of the next annual meeting of shareholders of the Company, or until their successors are duly elected or appointed pursuant to the Business Corporations Act (Ontario). Each director devotes the amount of time as is required to fulfill his or her obligations to the Company. The Company's officers are appointed by, and serve at the discretion of, the Board.

### ***Share Ownership by Directors and Officers***

As at June 28, 2023, as a group, the Company's directors and officers beneficially owned or exercised control or direction over, directly or indirectly, 2,964,751 Common Shares representing approximately 5.6% of the issued and outstanding Common Shares (on an undiluted basis) or approximately 9.5% of the issued and outstanding Common Shares on a fully diluted basis.

## **LEGAL PROCEEDINGS**

The Company received notice of arbitral proceedings from Nuance Pharma Limited ("Nuance"), one of the Company's license partners, on January 21, 2022. Nuance holds a license from Antibe respecting the commercialization of otenaproxesul in China, Macau, Hong Kong and Taiwan. Pursuant to the license agreement (the "License Agreement"), Nuance is obligated to make up to US\$80 million in payments to Antibe upon certain development and sales milestones, in addition to an upfront payment of US\$20 million which has been paid. Nuance seeks to have the license rescinded and the upfront payment returned, alleging in essence that Antibe failed to adequately share information concerning the risks of transaminase elevations related to otenaproxesul. Well in advance of the execution of the License Agreement Antibe provided Nuance with extensive documentation, including all IND-enabling non-clinical study reports and all clinical study reports. Transaminase elevations concerns were outlined extensively in those documents. The Company considers Nuance's claims to be without merit. The Company has engaged counsel to assist it with the arbitration proceedings, which have been brought under the Arbitration Rules of the Singapore International Arbitration Centre. Arbitration proceedings were held in May 2023 and a decision is pending; the Company will provide disclosure concerning significant developments when they occur.

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**INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

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There are no material interests, direct or indirect, of the directors or executive officers of the Company, or any shareholders who beneficially own, control or direct, directly or indirectly, more than 10% of the Company's outstanding Common Shares, or any known associates or affiliates of such persons, in any transaction within the last three years before the date of this AIF that has materially affected or is reasonably expected to materially affect the Company or a subsidiary of the Company, except as disclosed below or as otherwise disclosed in this AIF.

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**TRANSFER AGENT AND REGISTRAR**

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Computershare Limited is the registrar and transfer agent of the Common Shares at its principal offices in Toronto, Ontario.

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**MATERIAL CONTRACTS**

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The following are the material contracts, other than contracts in the ordinary course of business, and material contracts in the ordinary course of business required to be listed, that were entered into by the Company in the fiscal 2023 period or prior to this period and are still in effect:

1. Amended and Restated Employee Stock Option Plan and Restricted Share Unit Plan (collectively the "Incentive Plans") dated effective September 9, 2022 to encourage ownership of the Common Shares by directors, officers and employees of the Company, and its subsidiaries thereof, consultants and management Company employees, who are primarily responsible for the management and profitable growth of its business and to advance the interests of the Company by providing additional incentive for superior performance by such persons and to enable the Company and its subsidiaries to attract and retain valued directors, officers, employees, consultants and management Company employees. The maximum number of Common Shares reserved and set aside for issued under the Incentive Plans shall not exceed 12.5% of the Company's issued and outstanding Common Shares from time to time. Options and restricted share units granted under the plan are granted at the discretion of the board of directors of the Company.
2. Licensing and Distribution Agreement entered into with Nuance Pharma Limited ("Nuance") on February 9, 2021 for the development and commercialization of otenaproxesul in the Greater China region.
3. Licensing and Distribution Agreement entered into with Kwang Dong Pharmaceutical Co., Ltd. ("Kwang Dong") on September 5, 2018 for the development and commercialization of otenaproxesul in South Korea.
4. Licensing and Distribution Agreement entered into with Laboratoires Acbel SA ("Acbel") on February 24, 2017 for the exclusive commercial rights for otenaproxesul in the following territories: Greece, Romania, Serbia, Bulgaria, Albania, Algeria and Jordan.
5. Licensing and Distribution Agreement entered into with Knight Therapeutics Inc. on November 16, 2015 for the exclusive commercial rights for otenaproxesul, ATB-352 and ATB-340 (including future Antibe prescription drugs) in the following territories: Canada, Israel, Russia and sub-Saharan Africa.

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**AUDIT COMMITTEE INFORMATION**

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***Audit Committee Mandate***

The Board has established an Audit Committee and adopted a written mandate for the Audit Committee, which sets out the Audit Committee's responsibility for (among other things) reviewing the Company's financial statements and public disclosure documents containing financial information and reporting on such review to the Board, ensuring the Company's compliance with legal and regulatory requirements, overseeing qualifications, engagement, compensation, performance and independence of the Company's external auditors, and reviewing, evaluating and approving the internal control and risk management systems that are implemented and maintained by management. A copy of the Charter of the Audit Committee is attached to this AIF as Appendix "A".

***Composition of the Audit Committee and Relevant Education and Experience***

The Audit Committee consists of Mr. Hoffman (Chair), Dr. Flower and Mr. McNealey. Each member of the Audit Committee is considered to be "financially literate" and "independent" within the meaning of NI 52-110.

The Company believes that each of the members of the Audit Committee possesses: (i) an understanding of the accounting principles used by the Company to prepare its financial statements; (ii) an ability to assess the general application of such accounting principles in connection with the accounting for estimates, accruals and provisions; (iii) experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the Company's financial statements, or experience actively supervising one or more individuals engaged in such activities; and (iv) an understanding of internal controls and procedures for financial reporting.

The following is a brief summary of the education and experience of each member of the Audit Committee relevant to the performance of his responsibility as a member of the Committee.

**Audit Committee Member      Relevant Education & Experience**

Robert E. Hoffman (Chair)      Mr. Hoffman is President, CEO and Chairman of Kintara Therapeutics, Inc. (San Diego, California). Earlier, he was CFO of San Diego-based Heron Pharmaceuticals, a NASDAQ-listed commercial stage drug developer with a pipeline of acute pain therapeutics. During his tenure at Heron, the company raised more than \$650 million and launched its second commercial drug product. His career in the sector began in 1997 at Arena Pharmaceuticals, where he rose to become CFO, holding that position for ten years. While at Arena, he was involved with its IPO and financings raising more than \$1.5 billion. Mr. Hoffman is currently a member of the boards of ASLAN Pharmaceuticals and privately held FibroBiologics; he has served as a board member for several publicly listed biotechnology companies. For 10 years until 2020, he was a member of the Small Business Advisory Committee of the Financial Accounting Standards Board (FASB). Mr. Hoffman is also a founding board member of Day for Change, which has funded charities serving underprivileged and abused children in the San Diego area for 20 years.

Roderick Flower      Dr. Flower is Emeritus Professor, Pharmacology at William Harvey Research Institute, Queen Mary University (London, UK). He has spent much of his career researching inflammation and anti-inflammatory drugs; he was a member of the original group that demonstrated the mechanism of action of NSAIDs. Dr. Flower has also made significant advances in understanding how the glucocorticoids and cromone drugs produce their anti-inflammatory and anti- allergic actions. He has published more than 400 papers and is a co-author of a best-selling pharmacology textbook. He is also the recipient of several awards and honorary degrees, including the William Withering Prize of the Royal College of Physicians, the Wellcome Gold Medal of the British Pharmacological Society and the Lifetime Achievement Award of the International Association of Inflammation Societies. Dr. Flower is the former President of the British Pharmacological Society.

Jennifer McNealey      Ms. McNealey is the Chief Financial Officer of Abdera Therapeutics (Vancouver, British Columbia). She is a senior financial and strategy executive with a considerable breadth of experience in the biotechnology sector, as an analyst, portfolio manager, information provider and expert in corporate communications and investor relations. Ms. McNealey began her career as a healthcare equity analyst, transitioning to management of biopharmaceutical-focused investment funds. She has managed investment funds for Morgan Stanley Dean Witter Advisors, Amerindo Investment Advisors and latterly at Franklin Templeton, where she co-managed the Franklin Biotechnology Discovery Fund. She is also the founder of Laurient LLC, an independent equity research and competitive intelligence platform analyzing publicly traded biopharmaceutical companies.

**Audit Fees**

The following table summarizes the fees paid by the Company to its auditor for external audit and other services provided to the Company in each of the last two fiscal years.

Year	Audit Fees <sup>(1)</sup>	Audit Related Fees	Tax Fees <sup>(2)</sup>	All Other Fees <sup>(3)</sup>
Fiscal 2023	\$375	-	\$12.7	-
Fiscal 2022	\$364.5	-	\$76	-



- (1) Fees in respect of services performed in order to comply with Canadian generally accepted auditing standards (“GAAS”). In some cases, these may include an appropriate allocation of fees for tax services or accounting consultations, to the extent such services were necessary to comply with GAAS. Also includes fees in respect of reviews of the interim financial statements, the reports of which are provided to the Audit Committee.
- (2) Fees in respect of services performed by the auditor’s tax professionals, except those services required in order to comply with GAAS which are included under “Audit Fees”. Tax services include assistance with tax compliance and tax planning and advice.
- (3) Fees in respect of all services not falling under any of the foregoing three categories.

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**INTEREST OF EXPERTS**

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The financial statements for the financial years ended March 31, 2022 and March 31, 2023 have been audited by Ernst & Young (“EY”) LLP, Chartered Accountants, the Company’s auditors. EY is independent within the meaning of the Rules of Professional Conduct of the Chartered Professional Accountants of Ontario.

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**ADDITIONAL INFORMATION**

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Additional information relating to the Company may be found on SEDAR at [sedar.com](http://sedar.com). Additional information, including directors’ and executive officers’ remuneration and indebtedness and principal holders of the Company’s securities is contained in the Company’s management information circular for its upcoming September 8, 2023 annual meeting of shareholders at which directors will be elected. Additional financial information is available in the Company’s financial statements and MD&A for its most recently completed financial year.

**APPENDIX “A”  
CHARTER OF THE AUDIT COMMITTEE**

**NAME**

There shall be a committee of the board of directors (the “Board”) of Antibe Therapeutics Inc. (the “Company”) known as the Audit Committee.

**PURPOSE OF AUDIT COMMITTEE**

The Audit Committee has been established to assist the Board in fulfilling its oversight responsibilities with respect to the following principal areas:

- (a) the Company’s external audit function; including the qualifications, independence, appointment and oversight of the work of the external auditors;
- (b) the Company’s accounting and financial reporting requirements;
- (c) the Company’s reporting of financial information to the public;
- (d) the Company’s compliance with law and regulatory requirements;
- (e) the Company’s risks and risk management policies;
- (f) the Company’s system of internal controls and management information systems; and
- (g) such other functions as are delegated to it by the Board.

Specifically, with respect to the Company’s external audit function, the Audit Committee assists the Board in fulfilling its oversight responsibilities relating to: the quality and integrity of the Company’s financial statements, including the Company’s management’s discussion & analysis (“MD&A”); the independent auditors’ qualifications; and the performance of the Company’s independent auditors.

**MEMBERSHIP**

The Audit Committee shall consist of as many members as the Board shall determine. Except as may otherwise be permitted under National Instrument 52-110 - *Audit Committees* (“NI 52-110”), each member of the Audit Committee must, to the satisfaction of the Board, be “financially literate” (as such term is defined in NI 52-110) and each member shall be “independent” (as such term is defined in NI 52-110). Each member of the Audit Committee shall continue to be a member until a successor is appointed, unless the member resigns, is removed or ceases to be a director of the Company. The Board may fill a vacancy that occurs in the Audit Committee at any time.

**CHAIR AND SECRETARY**

The Chair of the Audit Committee shall be designated by the Board. If the Chair is not present at a meeting of the Audit Committee, the members of the Audit Committee may designate an interim Chair for the meeting by majority vote of the members present. The Secretary of the Audit Committee shall be such member of the Audit Committee as may be designated by majority vote of the Audit Committee from time to time, provided that if the Secretary is not present, the Chair of the meeting may appoint any person who need not be a member, to act as secretary at any meeting. A member of the Audit Committee may be designated as the liaison member to report on the deliberations of the Audit Committees of affiliated companies (if applicable).

## **MEETINGS**

The Chair of the Audit Committee, in consultation with the Audit Committee members, shall determine the schedule and frequency of the Audit Committee meetings provided that the Audit Committee will meet at least four times in each fiscal year and at least once in every fiscal quarter. The Audit Committee is to meet prior to the filing of quarterly financial statements in order to review and discuss the unaudited financial results for the preceding quarter and the related MD&A and is to meet prior to filing the annual audited financial statements and MD&A in order to review and discuss the audited financial results for the year and related MD&A. The Audit Committee shall have the authority to convene additional meetings as circumstances require.

Notice of every meeting shall be given to the external and internal auditors of the Company, and meetings shall be convened whenever requested by the external auditors or any member of the Audit Committee in accordance with applicable law. The Audit Committee shall meet separately and periodically with management, legal counsel and the external auditors. The Audit Committee shall meet separately with the external auditors at every meeting of the Audit Committee at which external auditors are present.

A quorum for the transaction of business at any meeting of the Audit Committee is (the presence in person or by telephone or other communication equipment of) a simple majority of the total number of members of the Audit Committee or such greater number as the Audit Committee may by resolution determine. If within one hour of the time appointed for a meeting of the Audit Committee, a quorum is not present, the meeting shall stand adjourned to the same hour on the second business day following the date of such meeting at the same place. If at the adjourned meeting a quorum as hereinbefore specified is not present within one hour of the time appointed for such adjourned meeting, the quorum for the adjourned meeting will consist of the members then present.

Should a vacancy arise among the members of the Audit Committee, the remaining members of the Audit Committee may exercise all of its powers and responsibilities so long as a quorum remains in office.

Meetings of the Audit Committee are to be held from time to time at such place as the Audit Committee or the Chair of the Audit Committee may determine, within or outside Ontario, Canada, upon not less than 48 hours prior notice to each of the members. Meetings of the Audit Committee may be held without 48 hours prior notice if all of the members entitled to vote at such meeting who do not attend, waive notice of the meeting and, for the purpose of such meeting, the presence of a member at such meeting shall constitute waiver on his or her part. Any member of the Audit Committee, the Chairman of the Board, the Company's external auditors, or the Chief Executive Officer or Chief Financial Officer of the Company are entitled to request that the Chair of the Audit Committee call a meeting. A notice of a meeting of the Audit Committee may be given verbally, in writing or by telephone, fax or other means of communication, and need not specify the purpose of the meeting.

The Audit Committee shall keep minutes of its meetings which shall be submitted to the Board.

All decisions of the Audit Committee will require the vote of a majority of its members present at a meeting at which quorum is present. Action of the Audit Committee may be taken by an instrument or instruments in writing signed by all of the members of the Audit Committee, and such actions shall be effective as though they had been decided by a majority of votes cast at a meeting of the Audit Committee called for such purpose. Such instruments in writing may be signed in counterparts each of which shall be deemed to be an original and all originals together shall be deemed to be one and the same instrument.

## **MEETING AGENDAS**

Agendas for meetings of the Audit Committee shall be developed by the Chair of the Audit Committee in consultation with management and the corporate secretary, and shall be circulated to Audit Committee members as far in advance of each Audit Committee meeting as is reasonable.

## **RESOURCES AND AUTHORITY**

The Audit Committee shall have the resources and the authority to discharge its responsibilities, including the authority, in its sole discretion, to engage, at the expense of the Company, outside consultants, independent legal counsel and other advisors and experts as it determines necessary to carry out its duties, without seeking approval of the Board or management.

The Audit Committee shall have the authority to conduct any investigation necessary and appropriate to fulfilling its responsibilities, and has direct access to and the authority to communicate directly with the internal and external auditors, the counsel of the Company and other officers and employees of the Company.

The members of the Audit Committee shall have the right for the purpose of performing their duties to inspect all the books and records of the Company and its subsidiaries and to discuss such accounts and records and any matters relating to the financial position, risk management and internal controls of the Company with the officers and external and internal auditors of the Company and its subsidiaries. Any member of the Audit Committee may require the external or internal auditors to attend any or every meeting of the Audit Committee.

## **RESPONSIBILITIES**

The Company's management is responsible for preparing the Company's financial statements and the external auditors are responsible for auditing those financial statements. The Audit Committee is responsible for overseeing the conduct of those activities by the Company's management and external auditors, and overseeing the activities of the internal auditors.

The specific responsibilities of the Audit Committee shall include those listed below. The enumerated responsibilities are not meant to restrict the Audit Committee from examining any matters related to its purpose.

### **1. Financial Reporting Process and Financial Statements**

The Audit Committee shall:

- (a) in consultation with the external auditors and the internal auditors, review the integrity of the Company's financial reporting process, both internal and external, and any major issues as to the adequacy of the internal controls and any special audit steps adopted in light of material control deficiencies;
- (b) review all material transactions and material contracts entered into between (i) the Company or any subsidiary of the Company, and (ii) any subsidiary, director, officer, insider or related party of the Company, other than transactions in the ordinary course of business;
- (c) review and discuss with management and the external auditors: (i) the preparation of Company's annual audited consolidated financial statements and related MD&A and its interim unaudited consolidated financial statements and related MD&A; (ii) whether the financial statements present fairly (in accordance with Canadian generally accepted accounting principles) in all material respects the financial condition, results of operations and cash flows of the Company as of and for the periods presented; (iii) any matters required to be discussed with the external auditors according to Canadian generally accepted auditing standards; (iv) an annual report by the external auditors describing: (A) all critical accounting policies and practices used by the Company; (B) all material alternative accounting treatments of financial information within generally accepted accounting principles that have been discussed with management of the Company, including the ramifications of the use of such alternative treatments and disclosures and the treatment preferred by the external auditors; and (C) other material written communications between the external auditors and management;
- (d) following completion of the annual audit, review with each of: (i) management; (ii) the external auditors; and (iii) the internal auditors, any significant issues, concerns or difficulties encountered during the course of the audit;
- (e) resolve disagreements between management and the external auditors regarding financial reporting;

- (f) review the financial statements, MD&A and annual and interim press releases prior to public disclosure of this information; and
- (g) review and be satisfied that adequate procedures are in place for the review of the public disclosure of financial information by the Company extracted or derived from the Company's financial statements, other than the disclosure referred to in (f), and periodically assess the adequacy of those procedures.

## **2. External Auditors**

The Audit Committee shall:

- (a) require the external auditors to report directly to the Audit Committee;
- (b) recommend to the Board the external auditors to be nominated for approval by the shareholders and the compensation of the external auditor;
- (c) be directly responsible for the selection, nomination, compensation, retention, termination and oversight of the work of the Company's external auditors engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company;
- (d) approve all audit engagements and must pre-approve the provision by the external auditors of all non-audit services, including fees and terms for all audit engagements and non-audit engagements, and in such regard the Audit Committee may establish the types of non-audit services the external auditors shall be prohibited from providing and shall establish the types of audit, audit related and non-audit services for which the Audit Committee will retain the external auditors. The Audit Committee may delegate to one or more of its independent members the authority to pre-approve non-audit services, provided that any such delegated pre-approval shall be exercised in accordance with the types of particular non-audit services authorized by the Audit Committee to be provided by the external auditor and the exercise of such delegated pre-approvals shall be presented to the full Audit Committee at its next scheduled meeting following such pre-approval;
- (e) review and approve the Company's policies for the hiring of partners and employees and former partners and employees of the present and former external auditors of the Company;
- (f) consider, assess and report to the Board with regard to the independence and performance of the external auditors; and
- (g) request and review the audit plan of the external auditors as well as a report by the external auditors to be submitted at least annually regarding: (i) the external auditing firm's internal quality-control procedures; (ii) any material issues raised by the external auditor's own most recent internal quality-control review or peer review of the auditing firm, or by any inquiry or investigation by governmental or professional authorities within the preceding five years respecting one or more independent audits carried out by the external auditors, and any steps taken to deal with any such issues.

### **3. Accounting Systems and Internal Controls**

The Audit Committee shall:

- (a) oversee management's design and implementation of and reporting on internal controls. The Audit Committee shall also receive and review reports from management, the internal auditors and the external auditors on an annual basis with regard to the reliability and effective operation of the Company's accounting system and internal controls; and
- (b) review annually the activities, organization and qualifications of the internal auditors and discuss with the external auditors the responsibilities, budget and staffing of the internal audit function.

### **4. Legal and Regulatory Requirements**

The Audit Committee shall:

- (a) receive and review timely analysis by management of significant issues relating to public disclosure and reporting;
- (b) review, prior to finalization, periodic public disclosure documents containing financial information, including the Company's MD&A and Annual Information Form, if required;
- (c) prepare the report of the Audit Committee required to be included in the Company's periodic filings;
- (d) review with the Company's counsel legal compliance matters, significant litigation and other legal matters that could have a significant impact on the Company's financial statements; and
- (e) assist the Board in the oversight of compliance with legal and regulatory requirements and review with legal counsel the adequacy and effectiveness of the Company's procedures to ensure compliance with legal and regulatory responsibilities.

### **5. Additional Responsibilities**

The Audit Committee shall:

- (a) discuss policies with the external auditor, internal auditor and management with respect to risk assessment and risk management;
- (b) establish procedures and policies for the following
  - i. the receipt, retention, treatment and resolution of complaints received by the Company regarding accounting, internal accounting controls or auditing matters; and
  - ii. the confidential, anonymous submission by directors or employees of the Company of concerns regarding questionable accounting or auditing matters;
- (c) discuss, prepare and review with the Board an annual performance evaluation of the Audit Committee;
- (d) report regularly to the Board, including with regard to matters such as the quality or integrity of the Company's financial statements, compliance with legal or regulatory requirements, the performance of the internal audit function, and the performance and independence of the external auditors; and

(e) review and reassess the adequacy of the Audit Committee's Charter on an annual basis.

**6. Limitation on the Oversight Role of the Audit Committee**

Nothing in this Charter is intended, or may be construed, to impose on any member of the Audit Committee a standard of care or diligence that is in any way more onerous or extensive than the standard to which all members of the Board are subject.

Each member of the Audit Committee shall be entitled, to the fullest extent permitted by law, to rely on the integrity of those persons and organizations within and outside the Company from whom he or she receives financial and other information, and the accuracy of the information provided to the Company by such persons or organizations.

While the Audit Committee has the responsibilities and powers set forth in this Charter, it is not the duty of the Audit Committee to plan or conduct audits or to determine that the Company's financial statements and disclosures are complete and accurate and in accordance with international financial reporting standards and applicable rules and regulations. These are the responsibility of management and the external auditors.

## **Antibe Reports Q3 2023 Interim Financial and Operating Results**

- *Recent animal data on otenaproxesul's new formulation confirm rapid drug uptake and potential for effective pain management*
- *Targeting first clinical dose in calendar Q3 2023; Phase II top-line data within 12 months*
  - *Ended quarter with \$42.4 million in cash and equivalents, providing over two years of runway*

TORONTO--(BUSINESS WIRE)--February 15, 2023--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical-stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies to target inflammation, has filed its financial and operating results for the fiscal quarter ended December 31, 2022.

"As we prepare for the Phase II bunionectomy trial, we're increasingly excited about the potential of otenaproxesul's new formulation," noted Dan Legault, Antibe's CEO. "Recent animal data have confirmed both its potential for effective pain management at dramatically lower doses and a rapid onset profile ideally suited for acute pain. To de-risk the translation of this data to human doses, we've planned a confirmatory study in healthy volunteers upon release of the new drug tablets. We look forward to delivering Phase II top-line data in the next 12 months."

The Company also announced that its founder, Dr. John L. Wallace, has decided to retire from the Board of Directors. Dr. Wallace will remain a corporate Vice Chair, enabling the Company to continue to benefit from his wisdom and expertise. Robert E. Hoffman, Antibe's Board Chair, commented: "From elucidating how today's NSAIDs injure the digestive tract to conceiving our novel hydrogen sulfide platform, John's pioneering science has underpinned our emergence as a publicly traded biotech pursuing a major advance in anti-inflammatory therapeutics. We thank him for his extraordinary service as a Director."

### **Business Highlights and Operational Update**

#### *Progress for otenaproxesul on formulation and IP*

- Transitioned to faster-dissolving formulation that accelerates onset of action; also enables treatment regimens with lower drug doses, providing additional safety buffer and a potential pathway to address chronic pain indications
- Filed patent application for new formulation, strengthening IP protection to 2043
- Initiated animal de-risking studies for new formulation; saved resources by bypassing previously planned molar extraction clinical study
- Finalized study design for upcoming pharmacokinetic/pharmacodynamic ("PK/PD") study in healthy volunteers to confirm dose selection for upcoming Phase II bunionectomy trial; PK/PD study anticipated to take 2 – 3 months
- Results from DILIsym, a sophisticated software model widely used to predict liver safety, suggest that all envisioned acute pain treatment regimens of the new formulation are liver-safe for five-day treatment durations (including ten days post treatment follow up)
- Retained Klick Health, a leading life science-focused marketing and commercialization agency, to conduct a comprehensive strategic positioning assessment of otenaproxesul for



acute pain in the U.S. market; based on the recent third-party commercial assessment projecting U.S. market peak annual sales exceeding \$1 billion, the purpose of the current study is to validate the drug's positioning and formulate a commercial launch strategy to support partnering discussions

- Continued investigation of alternative formulations and treatment regimens as potential paths forward for chronic pain indications

#### *Inflammatory bowel disease program lead selection*

- Completed animal colitis model with positive efficacy results for several potential candidates
- Lead and back-up candidates selected with patent application filing expected next quarter

#### *Corporate*

- Closed the previously announced sale of Citagenix subsidiary in an all-cash transaction involving a guaranteed \$3.5 million, divided into four equal payments over three years, with the remaining \$4.0 million subject to Citagenix achieving sales milestones over four years (the milestone formula was amended subsequent to the closing, including a one-year term extension and an additional \$1.0 million of potential milestone payments; the amendment is available on SEDAR)

### **Upcoming Milestones**

The following summarizes the Company's estimated timeline for its key upcoming milestones:

- Ready tablets of otenaproxesul's new formulation – calendar Q2 2023
- Initiate clinical PK/PD study for otenaproxesul – calendar Q3 2023
- Initiate Phase II bunionectomy trial of otenaproxesul – calendar Q4 2023
- Deliver Phase II bunionectomy top-line data of otenaproxesul – calendar Q1 2024

### **Financial Results**

**Cash Position:** As of December 31, 2022, the Company had available cash balance and term deposits totaling \$42.4 million, compared to \$54.8 million as at March 31, 2022. This provides the Company with over two years of runway, which includes the cost of the upcoming Phase II bunionectomy trial.

**Net Loss:** For the quarter ended December 31, 2022, Net Loss and Comprehensive Loss totaled \$4.3 million (\$0.08 per share), an decrease of \$0.5 million compared to \$4.8 million (\$0.09 per share) in fiscal Q3 2022.

**Research and Development Expenses:** Research and development expenses for the quarter, net of research tax credits, amounted to \$2.2 million, compared to \$2.5 million in fiscal Q3 2022.

**General and Administrative Expenses:** General and administrative expenses were \$1.6 million for the quarter, compared to \$1.3 million in fiscal Q3 2022.

The Company's unaudited fiscal Q3 2023 condensed interim financial statements and MD&A are available on SEDAR.

### **About Antibe Therapeutics Inc.**

Antibe is a clinical-stage biotechnology company leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to target inflammation arising from a wide range of medical conditions. The Company's current pipeline includes assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids and today's NSAIDs for acute pain. Antibe's second pipeline drug, ATB-352, is being developed for a specialized pain indication. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

### **Forward Looking Information**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, the amounts, timing and receipt of the portion of the Citagenix sale price that is subject to the achievement of sales milestones, the anticipated scope, timing, duration and completion of certain of the Company's clinical trial programs and studies and the anticipated timing for seeking market approval for certain of the Company's drugs and therapies for certain additional indications. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, Citagenix not achieving sales milestones, the Company's inability to timely execute on its business strategy and timely and successfully complete its clinical trials and studies, the Company's inability to obtain the necessary regulatory approvals related to its activities, risks associated with drug and medical device development generally and those risk factors set forth in the Company's public filings made in Canada and available on [sedar.com](http://sedar.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

### **Contacts**

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VP Investor Relations  
+1 416-577-1443  
[christina@antibetherapeutics.com](mailto:christina@antibetherapeutics.com)

THIS IS **EXHIBIT "E"** REFERRED TO IN THE  
AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

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SIDNEY BREJAK  
Commissioner for Taking Affidavits

## **Antibe Reports Q1 2024 Interim Financial and Operating Results**

*- Otenaproxesul new formulation tablets manufactured for upcoming PK/PD study*

*- PK/PD study results expected next quarter with Phase II initiation in calendar Q1 2024*

*- Ended quarter with \$34.3 million in cash and equivalents*

TORONTO--(BUSINESS WIRE)--August 14, 2023--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical-stage company leveraging its hydrogen sulfide platform to develop next-generation therapies to target inflammation, has filed its financial and operating results for the fiscal quarter ended June 30, 2023.

“With tablets in hand, we’re excited to be approaching several near-term catalysts,” commented Dan Legault, Antibe’s CEO. “We’ll kick off our otenaproxesul clinical program in the fall with a short PK/PD study to confirm liver safety and inform the doses for the Phase II trial, which is slated to start in the first quarter of 2024. Top-line Phase II data are expected late next spring – positive results would set the stage for an End of Phase 2 meeting with the FDA later in 2024. All of this reflects a tremendous behind-the-scenes effort by our scientific, manufacturing and regulatory teams, supported by our global manufacturing partner. The opportunity to capture share in a market roiled by the opioid epidemic has never been greater.”

### **Business Highlights and Operational Update**

The following covers fiscal Q1 2024 and subsequent events:

#### *Progress for otenaproxesul on formulation, IP and commercial potential*

- Completed transition to faster-absorbing formulation, including manufacturing scale up and production of tablets for upcoming PK/PD study; new formulation accelerates onset of action, also enabling lower drug doses
- Finalized study design and selected CRO for upcoming PK/PD (pharmacokinetic/ pharmacodynamic) study in healthy volunteers to confirm the dosing regimens for the Phase II bunionectomy (foot bone surgery) trial
- Received results from DILIsym, a sophisticated software model widely used to predict liver safety, suggesting that all envisioned acute pain treatment regimens of the new formulation are liver-safe for five-day treatment durations (including a ten-day post-treatment follow up)
- Embarked on a DILIsym program of the new formulation to explore potential chronic treatment regimens

#### *Emerging discovery program progressing*

- Selected lead and back-up candidates for IBD program, currently undergoing evaluation in animal efficacy models; filed patent application, providing protection to 2043

- Selected lead and back-up candidates for a family of new anti-inflammatory compounds with effectiveness demonstrated in two animal models; comprehensive announcement expected in the current quarter

### *Corporate*

- Annual General Meeting set for September 8, 2023; materials have been mailed to shareholders
- Completed in-person arbitration proceeding with Nuance Pharma; decision now expected in the upcoming quarter

### **Upcoming Milestones**

The following summarizes the Company's estimated timeline for its key upcoming milestones:

- Complete clinical PK/PD study for otenaproxesul – calendar Q4 2023
- Initiate Phase II bunionectomy trial of otenaproxesul – calendar Q1 2024
- Deliver Phase II bunionectomy top-line data of otenaproxesul – calendar Q2 2024

### **Financial Results**

**Cash Position:** As of June 30, 2023, the Company had available cash balance and term deposits totaling \$34.3 million, compared to \$38.9 million as at March 31, 2023.

**Net Loss:** For the quarter ended June 30, 2023, Net Loss and Comprehensive Loss totaled \$5.8 million (\$0.11 per share), an increase of \$0.3 million compared to \$5.5 million (\$0.10 per share) in fiscal Q1 2023.

**Research and Development Expenses:** Research and development expenses for the quarter, net of research tax credits, amounted to \$3.6 million, compared to \$3.8 million for fiscal Q1 2023.

**General and Administrative Expenses:** General and administrative expenses were \$2.2 million, compared to \$1.1 million in fiscal Q1 2023.

The Company's unaudited fiscal Q1 2024 condensed interim financial statements and MD&A are available on SEDAR.

### **About Antibe Therapeutics Inc.**

Antibe is a clinical-stage biotechnology company leveraging its proprietary hydrogen sulfide platform to develop next-generation therapies to target inflammation arising from a wide range of medical conditions. The Company's current pipeline includes assets that seek to overcome the gastrointestinal ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids and today's NSAIDs for acute pain. Antibe's second pipeline drug, ATB-352, is being developed for a specialized pain indication. The Company's next target is inflammatory bowel

disease (“IBD”), a condition long in need of safer, more effective therapies. Learn more at [antibethera.com](http://antibethera.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, the anticipated scope, timing, duration and completion of certain of the Company’s clinical trial programs and studies including the PK/PD study, the Phase II trial and the anticipated timing for seeking market approval for certain of the Company’s drugs and therapies for certain additional indications. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions “will”, “anticipate”, “believe”, “plan”, “estimate”, “expect”, “intend”, “propose” and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company’s inability to timely execute on its business strategy and timely and successfully complete its clinical trials and studies, the Company’s inability to obtain the necessary regulatory approvals related to its activities, risks associated with drug development generally and those risk factors set forth in the Company’s public filings made in Canada and available on [sedar.com](http://sedar.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

## **Contacts**

### **Contact Information**

Antibe Therapeutics Inc.  
Christina Cameron  
VP Investor Relations  
+1 416-577-1443  
[christina@antibethera.com](mailto:christina@antibethera.com)

THIS IS **EXHIBIT "F"** REFERRED TO IN THE  
AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

---

SIDNEY BREJAK  
Commissioner for Taking Affidavits

## **Antibe Reports Q2 2024 Interim Financial and Operating Results**

- Completed successful PK/PD study for otenaproxesul's new formulation**
- Phase II initiation on track for upcoming quarter**
- Ended quarter with \$28 million in cash and equivalents**

TORONTO--(BUSINESS WIRE)--November 13, 2023--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical-stage biotechnology company leveraging its hydrogen sulfide platform to develop next-generation therapies to target inflammation, has filed its financial and operating results for the fiscal quarter ended September 30, 2023.

“Last quarter capped two years of preparation for otenaproxesul’s successful PK/PD study,” commented Dan Legault, Antibe’s CEO. “With human safety addressed and encouraging PK data in hand, we’re excited to be nearing another inflection point in otenaproxesul’s value and partnering potential. We’re looking forward to the Phase II trial, on track to launch in calendar Q1 2024.”

### **Business Highlights and Operational Update**

The following covers fiscal Q2 2024 and subsequent events:

#### *Progress for otenaproxesul on formulation, IP and commercial potential*

- Completed first-in-human pharmacokinetic/pharmacodynamic (“PK/PD”) study of faster-absorbing formulation, enabling selection of treatment regimens for the upcoming Phase II trial
- Strong PK/PD safety results validated DILIsym liver safety modeling results showing envisioned acute pain treatment regimens of the new formulation to be liver-safe
- PK/PD data confirm linear, dose-proportional pharmacokinetics
- Filed and supplemented patent applications, strengthening IP protection for new formulation to 2043
- DILIsym program underway to explore potential chronic treatment regimens

#### *Emerging discovery program progressing*

- Filed patent applications covering a family of new anti-inflammatory compounds with effectiveness demonstrated in three animal models; announcement expected in calendar Q1 2024

#### *Corporate*

- Arbitration decision with Nuance Pharma expected in calendar Q4 2023
- Dr. Joseph Stauffer, Antibe’s Chief Medical Officer, to chair the USA Clinical Trials Innovation & Outsourcing Programme conference on November 15, 2023 (New York, NY)



- Second guaranteed payment of \$875,000 received in accordance with the Citagenix sale agreement

## **Upcoming Milestones**

In light of the strong safety and PK data from otenaproxesul's recent clinical PK/PD study, Antibe is upgrading the design of the upcoming fully-funded Phase II trial. While trial initiation remains set for calendar Q1 2024, the Company now anticipates top-line results in calendar Q3 2024.

## **Financial Results**

**Cash Position:** As of September 30, 2023, the Company had available cash balance and term deposits totaling \$27.9 million, compared to \$34.3 million as at June 30, 2023.

**Net Loss:** For the quarter ended September 30, 2023, Net Loss and Comprehensive Loss totaled \$5.0 million (\$0.10 per share), a decrease of \$1.1 million compared to \$6.1 million (\$0.12 per share) in fiscal Q2 2023.

**Research and Development Expenses:** Research and development expenses for the quarter, net of research tax credits, amounted to \$3.5 million, compared to \$3.9 million in fiscal Q2 2023.

**General and Administrative Expenses:** General and administrative expenses were \$1.9 million, compared to \$1.7 million in fiscal Q2 2023.

The Company's unaudited fiscal Q2 2024 condensed interim financial statements and MD&A are available on SEDAR.

## **About Antibe Therapeutics Inc.**

Antibe is a clinical-stage biotechnology company leveraging its proprietary hydrogen sulfide platform to develop next-generation therapies to target inflammation arising from a wide range of medical conditions. The Company's current pipeline includes assets that seek to overcome the gastrointestinal ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids and today's NSAIDs for acute pain. Antibe's second pipeline drug, ATB-352, is being developed for a specialized pain indication. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, the anticipated scope, timing, duration and completion of certain of the Company's clinical trial programs and studies including the Phase II trial and the anticipated timing for seeking market approval for certain of the Company's drugs and therapies for certain additional indications. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to timely execute on its business strategy and timely and successfully complete its clinical trials and studies, the Company's inability to obtain the necessary regulatory approvals or intellectual property rights related to its products and activities, risks associated with drug development generally and those risk factors set forth in the Company's public filings made in Canada and available on [sedar.com](http://sedar.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

## **Contacts**

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AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

---

SIDNEY BREJAK  
Commissioner for Taking Affidavits



**ANTIBE THERAPEUTICS INC.**

**UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS**

**For the Three and Six Months ended September 30, 2023 and 2022**

**ANTIBE THERAPEUTICS INC.**  
**Interim Consolidated Statements of Financial Position**  
**As at September 30, 2023 and March 31, 2023**  
(Expressed in thousands of Canadian dollars)  
(Unaudited)

	September 30, 2023	March 31, 2023
	\$	\$
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents	4,143	6,755
Term deposits <i>[note 4]</i>	23,733	32,137
Other receivables <i>[note 5]</i>	1,639	1,655
Prepaid expenses <i>[note 9]</i>	1,584	999
Total current assets	<b>31,099</b>	41,546
<b>Non-current assets</b>		
Deferred contract costs	1,283	1,283
Deferred consideration receivable <i>[note 3]</i>	1,471	1,380
Intangible assets	26,352	26,352
Total non-current assets	<b>29,106</b>	29,015
<b>TOTAL ASSETS</b>	<b>60,205</b>	70,561
<b>LIABILITIES</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	2,865	2,764
Total current liabilities	<b>2,865</b>	2,764
<b>Non-current liabilities</b>		
Deferred revenue	27,631	27,631
Total non-current liabilities	<b>27,631</b>	27,631
<b>TOTAL LIABILITIES</b>	<b>30,496</b>	30,395
<b>SHAREHOLDERS' EQUITY</b>		
Share capital	141,582	141,489
Common Share purchase warrants <i>[note 7(c)]</i>	10,264	10,264
Contributed surplus	19,148	18,904
Deficit	(141,285)	(130,491)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>29,709</b>	40,166
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>60,205</b>	70,561

Commitments and contingencies *[note 16]*

*(Signed) Daniel Legault* Daniel Legault, Director

*(Signed) Robert Hoffman* Robert Hoffman, Director

**ANTIBE THERAPEUTICS INC.****Interim Consolidated Statements of Loss and Comprehensive Loss****For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts)

(Unaudited)

	<b>Three months ended September 30, 2023</b>	Three months ended September 30, 2022	<b>Six months ended September 30, 2023</b>	Six months ended September 30, 2022
	\$	\$	\$	\$
<b>EXPENSES</b>				
Research and development <i>[note 9]</i>	<b>3,492</b>	3,857	<b>7,059</b>	7,685
General and administrative <i>[note 10]</i>	<b>1,941</b>	1,729	<b>4,091</b>	2,860
Stock-based compensation <i>[notes 7 and 11]</i>	<b>(80)</b>	806	<b>337</b>	1,549
Selling and marketing <i>[note 12]</i>	<b>96</b>	114	<b>243</b>	208
Total expenses	<b>5,449</b>	6,506	<b>11,730</b>	12,302
<b>LOSS FROM CONTINUING OPERATIONS</b>	<b>(5,449)</b>	(6,506)	<b>(11,730)</b>	(12,302)
Finance income and related costs <i>[note 13]</i>	<b>(443)</b>	(258)	<b>(936)</b>	(453)
<b>NET LOSS FROM CONTINUING OPERATIONS</b>	<b>(5,006)</b>	(6,248)	<b>(10,794)</b>	(11,849)
<b>DISCONTINUED OPERATIONS</b>				
Income from discontinued operations <i>[note 3]</i>	-	169	-	239
<b>NET LOSS AND COMPREHENSIVE LOSS</b>	<b>(5,006)</b>	(6,079)	<b>(10,794)</b>	(11,610)
<b>Basic and diluted loss per share <i>[note 8]</i></b>	<b>(0.10)</b>	(0.12)	<b>(0.21)</b>	(0.22)
<b>Basic and diluted weighted average number of shares outstanding <i>[note 8]</i></b>	<b>52,637,091</b>	52,129,929	<b>52,633,703</b>	52,143,116

**ANTIBE THERAPEUTICS INC.**
**Interim Consolidated Statements of Changes in Shareholders' Equity  
For the Six Months Ended September 30, 2023 and 2022**

 (Expressed in thousands of Canadian dollars, except share amounts)  
(Unaudited)

	Number of Common Shares	Share capital	Common Share(s) purchase warrants	Contributed surplus	Deficit	Total shareholders' equity
		\$	\$	\$	\$	\$
Balance, March 31, 2022	52,099,276	139,547	10,264	18,038	(111,016)	56,833
Shares issued for redeemed restricted share units <i>[note 7(b)]</i>	41,779	124	-	(124)	-	-
Stock-based compensation	-	-	-	1,549	-	1,549
Net loss from continuing operations for the period	-	-	-	-	(11,849)	(11,849)
Income from discontinued operations	-	-	-	-	239	239
<b>Balance, September 30, 2022</b>	<b>52,141,055</b>	<b>139,671</b>	<b>10,264</b>	<b>19,463</b>	<b>(122,626)</b>	<b>46,772</b>
Balance, March 31, 2023	52,617,092	141,489	10,264	18,904	(130,491)	40,166
Shares issued for redeemed restricted share units <i>[note 7(b)]</i>	<b>19,999</b>	<b>93</b>	-	<b>(93)</b>	-	-
Stock-based compensation	-	-	-	<b>337</b>	-	<b>337</b>
Net loss from continuing operations for the period	-	-	-	-	<b>(10,794)</b>	<b>(10,794)</b>
<b>Balance, September 30, 2023</b>	<b>52,637,091</b>	<b>141,582</b>	<b>10,264</b>	<b>19,148</b>	<b>(141,285)</b>	<b>29,709</b>

**ANTIBE THERAPEUTICS INC.**  
**Interim Consolidated Statements of Cash Flows**  
**For the Six Months Ended September 30, 2023 and 2022**  
(Expressed in thousands of Canadian dollars)  
(Unaudited)

	2023	2022
	\$	\$
<b>OPERATING ACTIVITIES</b>		
Net loss from continuing operations for the period	(10,794)	(11,849)
Income from discontinued operations <i>[note 3]</i>	-	239
Items not affecting cash:		
Stock-based compensation <i>[notes 7 and 11]</i>	337	1,549
Interest on capitalized lease payments	-	4
	<b>(10,457)</b>	<b>(10,057)</b>
Changes in non-cash balances:		
Other receivables	(75)	878
Inventory	-	(298)
Prepaid expenses	(585)	14
Accounts payable and accrued liabilities	101	(113)
Deferred tax liability	-	260
Net change in non-cash balances	<b>(559)</b>	<b>741</b>
<b>Cash flows used in operating activities</b>	<b>(11,016)</b>	<b>(9,316)</b>
<b>INVESTING ACTIVITIES</b>		
Purchase of term deposits	(13,422)	(28,109)
Redemption of term deposits	21,826	16,299
<b>Cash flows provided by (used in) investing activities</b>	<b>8,404</b>	<b>(11,810)</b>
<b>FINANCING ACTIVITIES</b>		
Lease payments	-	(78)
<b>Cash flows used in financing activities</b>	<b>-</b>	<b>(78)</b>
<b>Net decrease in cash and cash equivalents during the period</b>	<b>(2,612)</b>	<b>(21,204)</b>
Cash and cash equivalents, beginning of the period	6,755	34,807
<b>Cash and cash equivalents, end of the period</b>	<b>4,143</b>	<b>13,603</b>



## ANTIBE THERAPEUTICS INC.

### Notes to the Condensed Interim Consolidated Financial Statements

#### For the Three and Six Months Ended September 30, 2023 and 2022

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

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## 1. DESCRIPTION OF BUSINESS

Antibe Therapeutics Inc. (the “Company” or “Antibe”) was incorporated under the *Business Corporations Act* (Ontario) on May 5, 2009. The Company’s common shares (the “Common Share(s)”) trade on the Toronto Stock Exchange under the symbol “ATE”, and on the OTCQX market under the symbol “ATBPF.”

The Company originates, develops and out-licenses new pharmaceuticals. Antibe’s lead compound, otenaproxesul (previously known as ATB-346), combines a moiety that releases hydrogen sulfide with naproxen, an approved, marketed and off-patent, non-steroidal, anti-inflammatory drug. The Company’s main objectives are to develop otenaproxesul by satisfying the requirements of the relevant drug regulatory authorities while also satisfying the commercial licensing objectives of prospective global partners. The Company has also established a development plan for its lead compound through to the end of Phase III human clinical studies for regulatory discussion purposes. Additionally, the Company continues to investigate other research projects as well as additional development opportunities.

The Company was also, through its wholly owned subsidiary, Citagenix Inc. (“Citagenix” or “CGX”), a seller of tissue regenerative products servicing the orthopaedic and dental marketplaces. Citagenix’s portfolio consists of branded biologics and medical devices that promote bone regeneration. Citagenix operates in Canada through its direct sales force, and in the United States and internationally via a network of distributors. On November 1, 2022, the Company completed the sale of Citagenix to HANSAmEd Limited (see note 3).

The address of the Company’s registered head office and principal place of business is 15 Prince Arthur Avenue, Toronto, Ontario, Canada, M5R 1B2.

These unaudited condensed interim consolidated financial statements were authorized for issuance by the Board of Directors on November 10, 2023.

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## 2. BASIS OF PRESENTATION

### (a) Statement of compliance –

These unaudited condensed interim consolidated financial statements were prepared using the same accounting policies and methods as those used in the Company’s audited consolidated financial statements as at and for the year ended March 31, 2023. These unaudited condensed interim consolidated financial statements have been prepared in accordance with International Accounting Standard 34, *Interim Financial Reporting*. Accordingly, these unaudited condensed interim consolidated financial statements do not include all the disclosures required for annual financial statements and should be read in conjunction with the annual consolidated financial statements of the Company as at and for the year ended March 31, 2023, which are available on SEDAR. Several amendments apply for the first time in 2023, but do not have an impact on the unaudited condensed interim consolidated financial statements of the Company. The Company has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

### (b) Consolidation –

These unaudited condensed interim consolidated financial statements reflect the accounts of the Company and its previously wholly owned subsidiary, Citagenix.

Prior to November 1, 2022, the Company operated as two operating segments: Antibe (research and development of new pharmaceuticals) and Citagenix (a seller of tissue regenerative products servicing the orthopaedic and dental marketplaces). On November 1, 2022, the Company closed the sale of Citagenix.

The results of the operations of Citagenix in the comparative period are recorded within income from discontinued operations in the interim consolidated statements of loss and comprehensive loss (note 3).

All intercompany balances and transactions have been eliminated on consolidation.

**ANTIBE THERAPEUTICS INC.**

**Notes to the Condensed Interim Consolidated Financial Statements**

**For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

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**2. BASIS OF PRESENTATION (continued)**

**(c) Going concern –**

The unaudited condensed interim consolidated financial statements have been prepared assuming that the Company will continue as a going concern. For the six months ended September 30, 2023, the Company incurred a net loss from continuing operations of \$10,794, had negative cash flows from operations of \$11,016 and an accumulated deficit of \$141,285.

Until such time as the Company's pharmaceutical products are patented and approved for sale, the Company's liquidity requirements are dependent on its ability to raise additional capital by selling additional equity, from licensing agreements of its lead compound, from proceeds from the exercise of stock options and Common Shares purchase warrants or by obtaining credit facilities. The Company's future capital requirements will depend on many factors, including, but not limited to, the market acceptance of its products and services. No assurance can be given that any such additional funding will be available or that, if available, it can be obtained on terms favourable to the Company.

All of the factors above indicate the existence of a material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern, which assumes the Company will continue its operations for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the ordinary course of business. Management's plans to address these issues involve actively seeking capital investment and generating revenue and profit from the commercialization of its products. The Company's ability to continue as a going concern is subject to management's ability to successfully implement this plan. Failure to implement this plan could have a material adverse effect on the Company's financial condition and financial performance.

If the going concern assumption were not appropriate for these unaudited condensed interim consolidated financial statements, then adjustments would be necessary to the carrying value of assets and liabilities, the reported revenue and expenses, and the classifications used in the interim consolidated statements of financial position. The unaudited condensed interim consolidated financial statements do not include adjustments that would be necessary if the going concern assumption were not appropriate.

**(d) Use of estimates –**

The preparation of these unaudited condensed interim consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, if any, as at the date of the unaudited condensed interim consolidated financial statements, and the reported amounts of expenses during the reporting period. Actual results may vary from the current estimates. These estimates are reviewed periodically and, as adjustments become necessary, they are reported in income in the year in which such adjustments become known. Significant estimates in these unaudited condensed interim consolidated financial statements include the completeness of the accrual for research and clinical trial expenses, and accruals and inputs related to the calculation of stock-based compensation.

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**3. SALE OF CGX**

On November 1, 2022, the Company completed the sale of its wholly owned subsidiary, CGX. The \$6,500 transaction involves a guaranteed \$3,500, and a further \$3,000 subject to Citagenix achieving sales milestones over the three-year period following closing. On February 15, 2023, the agreement was amended to include an additional \$1,000 of contingent consideration and a one-year extension, bringing the total consideration to \$7,500. The fair value of the contingent consideration was determined to be \$nil as of the date of the sale and \$nil as of September 30, 2023. The present value of the deferred consideration was determined to be \$2,255 as of the date of the sale and \$2,346 as of September 30, 2023, using a discount rate of 8%.

**ANTIBE THERAPEUTICS INC.****Notes to the Condensed Interim Consolidated Financial Statements****For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

**3. SALE OF CGX (continued)**

The results of Citagenix for the three and six months ended September 30, 2022 are included in the interim consolidated statements of loss and comprehensive loss as income from discontinued operations, and are presented below:

	<b>Three months ended September 30, 2022</b>	<b>Six months ended September 30, 2022</b>
	\$	
Revenue	2,879	6,022
Cost of goods sold	1,761	3,566
Gross profit	1,118	2,456
Expenses	949	1,957
Income before tax from discontinued operations	169	499
Provision for income taxes	-	260
<b>Income from discontinued operations</b>	<b>169</b>	<b>239</b>

**4. TERM DEPOSITS**

As at September 30, 2023, the Company held investments of \$23,733 (March 31, 2023 – \$32,137) in four separate Canadian currency guaranteed investment certificates (“GICs”) having terms of six, nine and twelve months, and one USD currency GIC having a term of six months. Interest rates range from 4.85% to 5.90%.

**5. OTHER RECEIVABLES**

	<b>September 30, 2023</b>	March 31, 2023
	\$	\$
SR&ED	-	46
Deferred consideration receivable [note 3]	875	875
Interest receivable	449	508
Harmonized Sales Tax receivable	271	186
	<b>1,595</b>	1,615
Employee advances [note 6]	44	40
	<b>1,639</b>	1,655

**6. RELATED PARTY TRANSACTIONS**

Employee cash advances as at September 30, 2023, totalled \$44 (March 31, 2023 – \$40). Currently, the Company has one officer receiving cash advances.

**ANTIBE THERAPEUTICS INC.****Notes to the Condensed Interim Consolidated Financial Statements****For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

**7. SHARE CAPITAL****(a) Stock options –**

On September 12, 2023, the Company granted options of 667,500 Common Shares with an exercise price of \$0.56 per share to its directors, officers, employees, and certain consultants. The total fair value of these options, calculated using the BSM, is \$224. All options are subject to a service condition: one third (1/3) of the options granted will vest on each of the first, second and third anniversaries of the grant date.

On September 12, 2023, the Company also granted 357,500 performance options with an exercise price of \$0.56 per share to key senior executives. Vesting of these options is subject to the successful achievement of certain goals that are designed to reflect the successful execution of the Company's business plan and strategy. The estimated fair value of these performance options, calculated using the BSM, is \$120. As at September 30, 2023, it was determined that the probability and timing of achieving the performance criteria was more likely than not and, as such, \$3 was expensed during the period and included in contributed surplus.

The following is a summary of all options to purchase Common Shares that are outstanding as at September 30, 2023 and 2022, as well as details on exercise prices and expiry dates:

	<b>Six months ended September 30, 2023</b>		<b>Six months ended September 30, 2022</b>	
	<b>Options</b>	<b>Weighted average price</b>	<b>Options</b>	<b>Weighted average price</b>
<b>Balance, beginning of the period</b>	<b>1,430,112</b>	<b>\$ 1.83</b>	1,274,435	2.93
Granted during the period	<b>1,025,000</b>	<b>0.56</b>	-	-
Forfeited during the period	-	-	(55,000)	3.40
<b>Balance, end of the period</b>	<b>2,455,112</b>	<b>1.30</b>	1,219,435	2.08

<b>Number of options</b>	<b>Exercise price</b>	<b>Expiry date</b>
	\$	
15,000	5.50	October 21, 2023
66,000	0.68	January 11, 2024
80,500	6.60	March 4, 2024
20,000	0.91	November 15, 2024
36,000	1.40	July 13, 2025
156,272	1.45	March 9, 2026
687,000	2.00	March 31, 2027
15,152	4.95	April 11, 2028
4,188	4.00	May 8, 2028
10,000	2.90	March 11, 2029
340,000	0.48	November 15, 2032
1,025,000	0.56	September 12, 2033
<b>2,455,112</b>		

The number of options exercisable as at September 30, 2023, is 1,090,112 and the weighted average exercise price of these options is \$2.25.

The total fair value of options not yet recognized as an expense is \$614.

**ANTIBE THERAPEUTICS INC.****Notes to the Condensed Interim Consolidated Financial Statements****For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

**7. SHARE CAPITAL (continued)**

For the three and six months ended September 30, 2023, totals of \$37 and \$59, respectively (2022 – \$3 and \$6, respectively) related to stock options have been included within stock-based compensation in the interim consolidated statements of loss and comprehensive loss.

The following assumptions were used in the BSM to determine the fair value of stock options granted in the period:

	<b>Six months ended September 30, 2023</b>	Six months ended September 30, 2022
Weighted average risk-free interest rate	<b>3.69%</b>	-
Weighted average expected volatility	<b>119%</b>	-
Expected dividend yield	-	-
Weighted average expected life of options	<b>10 years</b>	-
Weighted average share price	<b>\$0.56</b>	-
Weighted average exercise price	<b>\$0.56</b>	-

**(b) Restricted share unit plan –**

The following is a summary of all restricted share units (“RSUs”) for Common Shares that are outstanding as at September 30, 2023 and 2022:

	<b>Six months ended September 30, 2023</b>	Six months ended September 30, 2022
	RSUs	RSUs
<b>Balance, beginning of the period</b>	<b>3,537,265</b>	2,438,445
Redeemed during the period	<b>(19,999)</b>	(41,779)
Forfeited during the period	-	(5,083)
<b>Balance, end of the period</b>	<b>3,517,266</b>	2,391,583

Based on the share price on the date of granting, the total fair value of RSUs not yet recognized as an expense is \$448.

For the three and six months ended September 30, 2023, totals of \$(111) and \$283, respectively (2022 – \$803 and \$1,543, respectively) related to RSUs have been included within stock-based compensation in the interim consolidated statements of loss and comprehensive loss.

**ANTIBE THERAPEUTICS INC.****Notes to the Condensed Interim Consolidated Financial Statements****For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

**7. SHARE CAPITAL (continued)****(c) Common Share purchase warrants –**

The following is a summary of all warrants to purchase Common Shares that are outstanding as at September 30, 2023 and 2022, as well as details on exercise prices and expiry dates:

	<b>Six months ended September 30, 2023</b>		<b>Six months ended September 30, 2022</b>	
	<b>Warrants</b>	<b>Weighted average price</b>	<b>Warrants</b>	<b>Weighted average price</b>
		\$		\$
<b>Balance, beginning of the period</b>	<b>6,485,706</b>	<b>4.76</b>	7,389,166	6.31
Expired during the period	-	-	(499,810)	3.96
<b>Balance, end of the period</b>	<b>6,485,706</b>	<b>4.76</b>	6,889,356	4.83

<b>Number of warrants</b>	<b>Exercise price</b>	<b>Expiry date</b>
	\$	
3,121,956	1.80	December 31, 2023
3,363,750	7.50	February 24, 2024
<b>6,485,706</b>		

**8. LOSS PER SHARE**

Basic loss per share is calculated by dividing the net loss attributable to common shareholders by the weighted average number of Common Shares outstanding during the period. All unexercised share options and warrants were excluded from calculating diluted loss per share as the effect of their issuance would be anti-dilutive.

**9. RESEARCH AND DEVELOPMENT EXPENSES**

The nature of the research and development expenses for the three and six months ended September 30, 2023 and 2022, is summarized as follows:

	<b>Three months ended September 30, 2023</b>	<b>Three months ended September 30, 2022</b>	<b>Six months ended September 30, 2023</b>	<b>Six months ended September 30, 2022</b>
	\$	\$	\$	\$
Salaries and wages	<b>561</b>	516	<b>1,222</b>	1,197
Professional and consulting fees	<b>306</b>	320	<b>567</b>	938
Research and clinical trial costs	<b>2,625</b>	3,021	<b>5,270</b>	5,550
<b>Total research and development expenses</b>	<b>3,492</b>	3,857	<b>7,059</b>	7,685

Non-refundable advance payments for goods and services that will be used or rendered in future research and development activities are recorded as a prepaid expense and recognized as an expense within "Research and development" in the period that the related goods are consumed or services are performed. As at September 30, 2023, \$1,292 (2022 – \$570) was recorded as a prepaid expense.

**ANTIBE THERAPEUTICS INC.****Notes to the Condensed Interim Consolidated Financial Statements****For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

**10. GENERAL AND ADMINISTRATIVE EXPENSES**

The nature of the general and administrative expenses for the three and six months ended September 30, 2023 and 2022, is summarized as follows:

	<b>Three months ended September 30, 2023</b>	Three months ended September 30, 2022	<b>Six months ended September 30, 2023</b>	Six months ended September 30, 2022
	\$	\$	\$	\$
Salaries and wages	<b>781</b>	722	<b>1,188</b>	1,065
Professional and consulting fees	<b>1,002</b>	842	<b>2,604</b>	1,479
Office expenses	<b>86</b>	76	<b>173</b>	162
Other expenses	<b>72</b>	89	<b>126</b>	154
<b>Total general and administrative expenses</b>	<b>1,941</b>	1,729	<b>4,091</b>	2,860

**11. STOCK-BASED COMPENSATION**

The function of the stock-based compensation expense for the three and six months ended September 30, 2023 and 2022, is summarized as follows:

	<b>Three months ended September 30, 2023</b>	Three months ended September 30, 2022	<b>Six months ended September 30, 2023</b>	Six months ended September 30, 2022
	\$	\$	\$	\$
General and administrative	<b>(18)</b>	506	<b>224</b>	984
Research and development	<b>(62)</b>	300	<b>113</b>	565
<b>Total stock-based compensation</b>	<b>(80)</b>	806	<b>337</b>	1,549

During the three months ended September 30, 2023, the Company revised its estimate of achieving a particular performance metric resulting in a reversal of previously expensed stock-based compensation.

**12. SELLING AND MARKETING EXPENSES**

The nature of the selling and marketing expenses for the three and six months ended September 30, 2023 and 2022, is summarized as follows:

	<b>Three months ended September 30, 2023</b>	Three months ended September 30, 2022	<b>Six months ended September 30, 2023</b>	Six months ended September 30, 2022
	\$	\$	\$	\$
Advertising and promotion	<b>30</b>	11	<b>40</b>	63
Travel and entertainment	<b>66</b>	103	<b>203</b>	145
<b>Total selling and marketing expenses</b>	<b>96</b>	114	<b>243</b>	208

**ANTIBE THERAPEUTICS INC.****Notes to the Condensed Interim Consolidated Financial Statements****For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

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**13. FINANCE INCOME AND RELATED COSTS**

The components of the finance income and related costs for the three and six months ended September 30, 2023 and 2022, are as follows:

	<b>Three months ended September 30, 2023</b>	Three months ended September 30, 2022	<b>Six months ended September 30, 2023</b>	Six months ended September 30, 2022
	\$	\$	\$	\$
Interest and bank charges	2	2	5	4
Foreign currency transactions	19	59	7	83
Finance income	(464)	(319)	(948)	(540)
<b>Total finance income and related costs</b>	<b>(443)</b>	<b>(258)</b>	<b>(936)</b>	<b>(453)</b>

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**14. CAPITAL RISK MANAGEMENT**

The Company's primary objective with respect to its capital management is to ensure that it has sufficient cash resources to fund the research, development and patent of drugs. To secure the additional capital necessary to pursue these plans, the Company may attempt to raise additional funds through the issuance of equity.

The Company includes the following in its definition of capital: share capital, Common Share purchase warrants, contributed surplus and accumulated deficit, which, as at September 30, 2023, totalled \$29,709 (March 31, 2023 – \$40,166). The Company is not subject to externally imposed capital requirements.

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**15. FINANCIAL RISK MANAGEMENT**

The Company is exposed to a variety of financial risks by virtue of its activities: credit risk, liquidity risk, foreign currency risk and interest rate risk. The overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on financial performance.

Risk management is carried out by the officers of the Company as discussed with the Board of Directors. The officers of the Company are charged with the responsibility of establishing controls and procedures to ensure that financial risks are mitigated in accordance with the expectation of the Board of Directors as follows:

**Credit risk**

The Company's credit risk is primarily attributable to other receivables and the excess of cash held in one financial institution over the deposit insurance limit set by the Canadian Deposit Insurance Corporation.

**Liquidity risk**

Liquidity risk is the risk that the Company is not able to meet its financial obligations as they become due or can do so only at excessive cost. The Company manages its liquidity risk by forecasting cash flows and anticipated investing and financing activities. Officers of the Company are actively involved in the review and approval of planned expenditures, including actively seeking capital investment and generating revenue and profit from the commercialization of its products (note 2(c)).



**ANTIBE THERAPEUTICS INC.****Notes to the Condensed Interim Consolidated Financial Statements****For the Three and Six Months Ended September 30, 2023 and 2022**

(Expressed in thousands of Canadian dollars, except share and per share amounts and where noted)

(Unaudited)

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**15. FINANCIAL RISK MANAGEMENT (continued)**

As at September 30, 2023, the Company's financial obligations, including applicable interest, are due as follows:

	<b>Less than 1 year</b>	<b>1–2 years</b>	<b>After 2</b>	<b>Total</b>
	\$	\$	\$	\$
Accounts payable and accrued liabilities	2,865	-	-	2,865

**Foreign currency risk**

The functional and reporting currency of the Company is the Canadian dollar. The Company undertakes transactions denominated in foreign currencies, including US dollars and euros, and, as such, is exposed to currency risk due to fluctuations in foreign exchange rates against the Canadian dollar. The Company does not use derivative instruments to reduce exposure to foreign currency risk.

**Interest rate risk**

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company is not currently incurring any debt and is, therefore, not exposed to changes in interest rates.

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**16. COMMITMENTS AND CONTINGENCIES**

On February 9, 2021, Antibe entered into an exclusive licensing agreement with Nuance Pharma (Shanghai) Co. Ltd. ("Nuance") for the development and commercialization of otenaproxesul in the Greater China region. The license provides Nuance with exclusive rights to commercialize otenaproxesul in China, Hong Kong, Macau, and Taiwan.

The Company received notice of arbitral proceedings from Nuance relating to this license agreement on January 21, 2022. Pursuant to the license agreement, Nuance is obligated to make up to US\$80 million in payments to Antibe upon certain development and sales milestones, in addition to an upfront payment of US\$20 million, which has been paid. Nuance seeks to have the license rescinded and the upfront payment returned, alleging that Antibe failed to adequately share information concerning the risks of transaminase elevations related to otenaproxesul. The Company considers Nuance's claims are unlikely to succeed. Management has determined that the occurrence of a loss is not probable and, therefore, there is no accrual in the condensed interim consolidated financial statements as at September 30, 2023 and March 31, 2023. The Company has engaged counsel to assist it with the arbitration proceedings, which have been brought under the Arbitration Rules of the Singapore International Arbitration Centre. Arbitration proceedings were held in May 2023 and a decision is pending.

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THIS IS **EXHIBIT "H"** REFERRED TO IN THE  
AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

---

SIDNEY BREJAK  
Commissioner for Taking Affidavits

**From:** kartiga.thavaraj@paliareroland.com  
**Sent:** Tuesday, November 28, 2023 9:32 AM  
**To:** Andrew CHEN  
**Cc:** Wendy LIN; GOH Wei Wei; Chris.Paliare@paliareroland.com; Karen.Jones@paliareroland.com  
**Subject:** Re: SIAC Arb 021 of 2022 - Undertaking [WP-LDR.FID367531]  
**Attachments:** ~WRD0002.jpg; image001.png

USE CAUTION: External Email

Counsel,

In our view, there is no legal basis for Nuance to make the request made in your November 20, 2023 email and nothing to suggest Nuance would suffer irreparable harm if Antibe uses its money as it sees fit. Antibe will not be providing the confirmation or undertaking you suggest.

Further, the advice or information provided by us to any officers and directors of Antibe in respect of your email is protected by solicitor client privilege. Any attempt by you to write to our clients would be inappropriate, as they are represented by counsel. All communication with Antibe, or its officers and directors, must be directed to our office.

Kartiga

---

From: Karen Jones <Karen.Jones@paliareroland.com>  
Sent: Monday, November 20, 2023 3:26:13 PM  
To: 'Andrew CHEN' <Andrew.Chen@wongpartnership.com>  
Cc: Wendy LIN <wendy.lin@wongpartnership.com>; GOH Wei Wei <weiwei.goh@wongpartnership.com>; Kartiga Thavaraj <kartiga.thavaraj@paliareroland.com>; Chris Paliare <Chris.Paliare@paliareroland.com>  
Subject: RE: SIAC Arb 021 of 2022 - Undertaking [WP-LDR.FID367531]

Dear Mr. Chen:

We will respond to your email early next week.

Regards

Karen Jones

[cid:image001.png@01DA1BC5.E4F35330]Paliare Roland

Karen Jones

Phone: 416. 646. 4339

Email: karen.jones@paliareroland.com

155 Wellington St. West, 35th Floor

Toronto, ON M5V 3H1

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From: Andrew CHEN <Andrew.Chen@wongpartnership.com>

Sent: Monday, November 20, 2023 12:01 AM

To: Chris Paliare <Chris.Paliare@paliareroland.com>; Karen Jones <Karen.Jones@paliareroland.com>; Kartiga Thavaraj <kartiga.thavaraj@paliareroland.com>

Cc: Wendy LIN <wendy.lin@wongpartnership.com>; GOH Wei Wei <weiwei.goh@wongpartnership.com>

Subject: SIAC Arb 021 of 2022 - Undertaking [WP-LDR.FID367531]

Dear Colleagues It has come to Nuance's attention that Antibe's latest press release titled "Antibe Reports Q2 2024 Interim Financial and Operating Results" dated 13 November 2023 reports that, "

NkdkJdXPPEBannerStart

External Sender - From: (Andrew CHEN <Andrew.Chen@wongpartnership.com>)

This message came from outside your organisation.

NkdkJdXPPEBannerEnd

Dear Colleagues

1. It has come to Nuance's attention that Antibe's latest press release titled "Antibe Reports Q2 2024 Interim Financial and Operating Results" dated 13 November 2023 reports that, "[a]s of September 30, 2023, [Antibe] had available cash

balance and term deposits totaling \$27.9 million [i.e., approximately US\$20.4 million], compared to \$34.3 million as at June 30, 2023”.

1. This is a significant change in circumstances from that set out in our previous correspondence including our email of 25 January 2023 where Nuance noted that, among other things:

1. Antibe’s previous filings, announcements and/or projections including those made as at end 2022; which had indicated that it will have sufficient funding to continue with the Drug’s development at least for 2023 without having to draw down on Nuance’s US\$20 million.

2. Antibe’s Statement of Defence stated that it intends to rely on these monies for its Phase 3 testing of the Drug and bring it forward for regulatory approval in the US and Canada. However, Antibe has not yet reached that stage of development. Further, based on Antibe’s Management’s Discussion and Analysis dated 14 November 2022, it is only “[i]f the Phase II trial is successful” that Antibe will “request an End of Phase 2 meeting with the U.S. FDA to discuss the registration program (including Phase III trials)”. (We note these statements were repeated in Mr Dan Legault’s witness statement dated 13 April 2023.)

3. Antibe’s cashflow projection provided to Nuance in August 2022 is that “at the end of Dec 2023 Antibe will have more than \$20 mil in available funds (not including an additional \$10 mil available from an existing source)”.

4. Antibe’s announcement dated 15 November 2022 disclosing that Antibe had an available cash balance and term deposits totaling C\$45.4 million which would provide Antibe with “over two years of runway, including the cost of the upcoming Phase II bunionectomy trial”.

1. In the circumstances, Nuance has strong grounds to believe that Antibe will soon (or has already begun to) draw down on Nuance’s US\$20 million upfront payment, for the ostensible purposes of furthering the Drug’s development in acute pain (instead of chronic pain) in disregard of Nuance’s interests as a creditor of Antibe.

1. We therefore write to seek:

1. Antibe’s confirmation that it has not drawn down on Nuance’s US\$20 million and the statements at [2.b] above remain accurate; and

2. Antibe’s confirmation and undertaking that pending the outcome of the Arbitration and the satisfaction of the award in the event that the Tribunal awards the same in Nuance’s favour (rescinding the License Agreement and/or ordering damages), Antibe, whether by itself or by its servants or agents or howsoever otherwise, shall not dispose of, deal with and/or otherwise diminish the value of the sum of US\$20 million representing Nuance’s upfront payment to Antibe under the License Agreement. This confirmation / undertaking is necessary to maintain the status quo and to ensure any award that is ultimately issued in Nuance’s favour in the Arbitration would not be rendered nugatory, causing irreparable harm to Nuance.

1. We trust Antibe will have no objections to providing the abovementioned confirmation / undertaking. Antibe will not suffer any real prejudice in providing the said confirmation / undertaking given that the Tribunal is to submit the award to the SIAC for its review by, at the latest, 4 December 2023 (i.e., in less than a month’s time) and Antibe’s latest press release confirms that its Phase 2 trials for acute pain treatment is scheduled to initiate only in Q1 2024.

1. Please let us know by 5pm (SGT) on 23 November 2023 whether Antibe is agreeable to providing the abovementioned undertaking. We will thereafter circulate a draft Deed of Undertaking for Antibe's signature.

1. We also formally put Antibe and its officers on notice that if Nuance is successful in the Arbitration and Antibe is unable to satisfy the award, Nuance will be compelled to proceed as it deems appropriate to enforce its rights and interests against Antibe and/or its officers, in particular, Mr Dan Legault, who directed and authorised Antibe's fraudulent inducement, misrepresentation and/or concealment in relation to the License Agreement and thereafter Antibe's running down of Nuance's US\$20 million upfront payment / incurring further liabilities despite the pending Arbitration / award. If you are not able to convey this message to Antibe's officers, please let us know and we will write separately to them in that regard.

1. All Nuance's rights are reserved.

Regards,

Andrew CHEN  
Associate

WongPartnership LLP

12 Marina Boulevard Level 28  
Marina Bay Financial Centre Tower 3

018982

d +65 65178737 | t +65 64168000 | f +65 65325722

e Andrew.Chen@wongpartnership.com

<https://url.us.m.mimecastprotect.com/s/Pw8cC9rgKWUo0IBMcoPt3C?domain=wongpartnership.com><<https://url.us.m.mimecastprotect.com/s/-SskCDk8gvHg9EVnFW9kzMw?domain=urldefense.proofpoint.com>> | Connect with us on LinkedIn<<https://url.us.m.mimecastprotect.com/s/-LmsCERxjwSR7vDguNjRujO?domain=urldefense.proofpoint.com>>

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<<https://url.us.m.mimecastprotect.com/s/ixixCJ6QoBt0J6Y1cVoRc7M?domain=urldefense.proofpoint.com>>

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SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

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SIDNEY BREJAK  
Commissioner for Taking Affidavits



## **Antibe Reports Q3 2024 Interim Financial and Operating Results**

*- Successful PK/PD study confirms liver safety, sets stage for upgraded Phase II trial launch next month*

*- Phase II trial enhancements include placebo arm, increased sample size and adaptive design*

*- Ended quarter with \$25 million in cash and equivalents*

TORONTO--(BUSINESS WIRE)--February 14, 2024--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical-stage biotechnology company leveraging its hydrogen sulfide platform to target pain and inflammation, has filed its financial and operating results for the fiscal quarter ended December 31, 2023.

“The results of November’s successful PK/PD study have empowered us to make considerable enhancements to the Phase II trial,” commented Dan Legault, Antibe’s CEO. “These upgrades may enable it to qualify as pivotal, potentially unlocking value by simplifying and shortening otenaproxesul’s remaining path to approval. Even with these enhancements, the trial remains on track to initiate next month – we’re looking forward to an exciting year.”

### **Business Highlights and Operational Update**

The following covers fiscal Q3 2024 and subsequent events:

#### *Progress for otenaproxesul on formulation, IP and commercial potential*

- On track to launch upgraded Phase II abdominoplasty trial in March 2024; tablets manufactured and preparation of clinical sites in process
- Phase II trial enhancements include the use of a placebo arm, an increased sample size (300 patient exposures), and the use of adaptive design methodology – these enhancements may enable it to qualify as a pivotal trial for the U.S. FDA
- Completed first-in-human pharmacokinetic/pharmacodynamic (“PK/PD”) study of faster-absorbing formulation:
  - Strong safety results validated DILIsym liver safety modeling results showing acute pain treatment regimens of the new formulation to be liver-safe (DILIsym is a sophisticated software model widely used to predict liver safety in drug development)
  - Confirmed the new formulation’s linear, dose-proportional kinetics, with substantially lower doses needed to achieve target plasma levels compared to the original formulation
  - More rapid elimination also observed, expanding the drug’s safety envelope
  - Taken together, these results provide the basis for upgrading the Phase II trial
- Filed and supplemented patent applications, strengthening IP protection for new formulation to 2043
- DILIsym program underway to explore potential chronic treatment regimens

## *Corporate*

- Arbitration with Nuance Pharma: the parties have been advised that the decision has been filed and will be released following the completion of remaining administrative matters
- Antibe named to the 2024 OTCQX Best 50, a ranking of the top performing companies traded on the OTCQX Best Market. Selected from more than 575 companies, Antibe is the only biotech to achieve this designation in the last two years
- Mayo Clinic-trained neuroscientist and pain researcher, Svetlana Kurklinsky, PhD, hired in the new role of Director of Clinical Science
- Second guaranteed payment of \$875,000 received in accordance with the Citagenix sale agreement

## **Upcoming Milestones**

The following summarizes the Company's estimated timeline for its key upcoming milestones for otenaproxesul:

- Initiate Phase II abdominoplasty trial – calendar Q1 2024
- Deliver Phase II abdominoplasty top-line data – calendar Q3 2024
- Request End of Phase II meeting with the U.S. FDA – calendar Q4 2024

## **Financial Results**

**Cash Position:** As of December 31, 2023, the Company had available cash balance and term deposits totaling \$24.9 million, compared to \$27.9 million as at September 30, 2023.

**Net Loss:** For the quarter ended December 31, 2023, Net Loss and Comprehensive Loss totaled \$4.2 million (\$0.08 per share), a decrease of \$0.1 million compared to \$4.3 million (\$0.08 per share) in fiscal Q3 2023.

**Research and Development Expenses:** Research and development expenses for the quarter, net of research tax credits, amounted to \$2.3 million, compared to \$2.2 million in fiscal Q3 2023.

**General and Administrative Expenses:** General and administrative expenses were \$2.3 million, compared to \$2.2 million in fiscal Q3 2023.

The Company's unaudited fiscal Q3 2024 condensed interim financial statements and MD&A are available on SEDAR.

## **About Antibe Therapeutics Inc.**

Antibe is a clinical-stage biotechnology company leveraging its proprietary hydrogen sulfide platform to develop next-generation therapies to target pain and inflammation arising from a wide range of medical conditions. The Company's current pipeline includes assets that seek to overcome the gastrointestinal ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids and today's NSAIDs for acute pain. Antibe's second pipeline drug, ATB-352, is being developed for a specialized pain indication. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

## **Forward Looking Statements**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, the anticipated scope, timing, duration and completion of certain of the Company's clinical trial programs and studies including the Phase II trial and the anticipated timing for seeking market approval for certain of the Company's drugs and therapies for certain additional indications including chronic pain. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to timely execute on its business strategy and timely and successfully complete its clinical trials and studies, the Company's inability to obtain the necessary regulatory approvals or intellectual property rights related to its products and activities, the timing and outcome of the arbitration decision with Nuance Pharma, risks associated with drug development generally and those risk factors set forth in the Company's public filings made in Canada and available on [sedar.com](http://sedar.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

## **Contacts**

Antibe Therapeutics Inc.  
Christina Cameron  
VP Investor Relations  
+1 416-577-1443  
[christina@antibetherapeutics.com](mailto:christina@antibetherapeutics.com)

THIS IS **EXHIBIT "J"** REFERRED TO IN THE  
AFFIDAVIT OF MARK LOTTER  
SWORN BEFORE ME THIS 28TH DAY OF  
MARCH, 2024

*Sidney Brejak*

---

SIDNEY BREJAK  
Commissioner for Taking Affidavits

## **Antibe Announces Unfavorable Decision in Arbitration With Nuance Pharma**

TORONTO--(BUSINESS WIRE)--March 4, 2024--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical-stage biotechnology company leveraging its hydrogen sulfide platform to target pain and inflammation, today announced that the arbitrator has found in favor of Nuance Pharma in the dispute regarding the license agreement for the commercialization of otenaproxesul in the Greater China region. The confidential ruling from the Singapore International Arbitration Centre rescinds the license agreement and requires Antibe to refund the US\$20 million upfront payment and pay interest and costs of approximately US\$4 million. The decision is not subject to appeal. Antibe views this unexpected result as highly unusual based on best practices for licensing deals in the biotech industry.

“We strongly disagree with this decision,” commented Dan Legault, Antibe’s CEO. “Nonetheless, we acknowledge the fact that we agreed to binding arbitration in a foreign jurisdiction. Antibe respects the confidentiality and final nature of the arbitration proceedings and will accept the decision in good faith. We continue to believe that the comprehensive data package shared with Nuance for the previous chronic pain formulation fully reflected the drug’s safety and efficacy characteristics. Although this ruling presents a significant short-term challenge, we remain committed to developing otenaproxesul -- particularly due to the strength of recent clinical results for acute pain that have significantly de-risked its final trials.”

In light of the arbitral ruling, the Company is evaluating its development and milestone plans for the balance of 2024, which may include adjusting timelines as circumstances require. The strong data from the recent PK/PD study highlight otenaproxesul’s potential and the priority remains conducting the Phase II trial as soon as possible. More information will be shared as the Company determines the best path forward for all stakeholders.

### **About Antibe Therapeutics Inc.**

Antibe is a clinical-stage biotechnology company leveraging its proprietary hydrogen sulfide platform to develop next-generation therapies to target pain and inflammation arising from a wide range of medical conditions. The Company’s current pipeline includes assets that seek to overcome the gastrointestinal ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”). Antibe’s lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids and today’s NSAIDs for acute pain. Antibe’s second pipeline drug, ATB-352, is being developed for a specialized pain indication. The Company’s next target is inflammatory bowel disease (“IBD”), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

## **Forward Looking Statements**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, statements concerning the payment of amounts due to Nuance under the arbitral award, the anticipated scope, timing, duration and completion of certain of the Company's pre-clinical and clinical trial programs and studies and the anticipated timing for seeking market approval for certain of the Company's drugs and therapies for certain additional indications. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to timely execute on its business strategy and timely and successfully complete its clinical trials and studies, the Company's inability to obtain the necessary regulatory approvals related to its activities, risks associated with drug development generally and those risk factors set forth in the Company's public filings made in Canada and available on [sedarplus.com](http://sedarplus.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

## **Contacts**

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VP Investor Relations  
+1 416-577-1443  
[christina@antibethera.com](mailto:christina@antibethera.com)

NUANCE PHARMA LTD.

-and-

ANTIBE THERAPEUTICS INC.

Applicant

Respondent

Court File No. CV-24-00717410-00CL

**ONTARIO  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST**

Proceeding Commenced at Toronto

**AFFIDAVIT OF MARK LOTTER**  
(Sworn March 28, 2024)

**BENNETT JONES LLP**  
3400 One First Canadian Place  
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Toronto ON M5X 1A4

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**Sidney Brejak (#87177H)**  
Email: brejaks@bennettjones.com

Telephone: 416.777.6121

Lawyers for the Applicant

This is Exhibit "B" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK





## Catherine Amirfar

Partner

New York

---

Tel: +1 212 909 7423

Catherine Amirfar is Co-Chair of Debevoise’s International Dispute Resolution Group and the Public International Law Group, and a member of the firm’s Management Committee. Her practice focuses on public international law, international commercial and treaty arbitration, and complex international commercial litigation.

With over twenty years of experience, Ms. Amirfar has argued before federal and state courts throughout the United States, the International Court of Justice (ICJ) and arbitration tribunals sitting around the world. She has deep expertise representing states, international organizations, nongovernmental organizations and multinational companies.

Ms. Amirfar is consistently recognized at the very top of her field by the major legal directories, ranking in Band 1 for International Arbitration (Global), Public International Law (Global) and International Arbitration (USA). In *Chambers Global* (2024), clients declare that she is “the best of the best,” “truly exceptional” and “a real leader in the field.” According to *Chambers USA* (2023), she is “brilliant, innovative and a superb advocate with an unrivaled sophistication in international matters.” She is also said to be “an excellent advocate, fierce in her delivery and mature in her judgment.” *The Legal 500 US* (2023), which lists her in its Hall of Fame for international arbitration, notes that she enjoys “a prominent global reputation for her record in landmark disputes” and has described her as “an amazing advocate for her clients” and “one of the best litigation/arbitration specialists in her field.” She receives praise for her “subject matter expertise, tactical abilities, and grounded demeanor.” *Who’s Who Legal* (2024) names her as a Global Elite Thought Leader, and has described her as “an extremely skillful advocate” and “a leading practitioner with broad experience” of international arbitration. *Benchmark Litigation* (2021) recognized her as International Arbitration Litigator of the Year. In 2021, she also has been named a Litigator of the Week by *The American Lawyer*, an award which recognizes achievements in “the nation’s most complex high-profile cases” which impact “the biggest breakthrough decisions in America’s courtrooms.”

Ms. Amirfar has a long history of wider involvement in her field beyond client work. Ms. Amirfar is Immediate Past President of the American Society of International Law (ASIL), for which she has been co-hosting a podcast called “International Law Behind the Headlines.” ASIL is one of the most prestigious organizations within the field of international law, with 4,000 members from more than 100 nations. She also serves as a member of the U.S. Department of State’s Advisory Committee on International Law, the Council on Foreign Relations, the Advisory Committees of the American Law Institute for the Restatement (Fourth) of Foreign Relations Law of the United States and for the Restatement of the U.S. Law of International Commercial Arbitration. Ms. Amirfar is also a member of the Governing Board of the International Council for Commercial Arbitration (ICCA), the leading global organization of international arbitrators and arbitration practitioners, the Court of Arbitration of the Singapore International Arbitration Centre, and serves as Co-Chair of the ICCA-ASIL Task Force on Damages in International Arbitration. In 2021, Ms. Amirfar was appointed Deputy Co-Chair of the High Level Panel of Legal Experts on Media Freedom, an independent body that was established in July 2019 at the request of the United Kingdom and Canadian governments to provide advice to countries that are members of the Media Freedom Coalition of States.

Ms. Amirfar maintains a highly active pro bono practice, advising NGOs and individuals in a wide variety of human rights matters. Most recently, she has led work in conjunction with the Clooney Foundation for Justice on a number of high-profile cases seeking the release of unlawfully imprisoned journalists around the world. She is also representing plaintiffs in Alien Tort Statute and Torture Victims Protection Act cases in U.S. courts with co-counsel the Center for Justice and Accountability. These include civil suits against the alleged commander of the Lutheran Church massacre of approximately 600 unarmed civilians in Liberia, and the former Secretary of Defense of Sri Lanka for his alleged involvement in the attack, torture, and murder of a journalist. In 2014, Ms. Amirfar was selected by *Chambers USA* as the Pro Bono Private Practice Lawyer of the Year.

Prior to rejoining Debevoise in 2016, Ms. Amirfar spent two years as the Counselor on International Law to the Legal Adviser at the U.S. Department of State, and received the State Department’s Superior Honor Award in recognition of her contributions. During her tenure as Counselor, Ms. Amirfar advised the State Department on its most significant litigation matters involving international law and foreign relations, and liaised with senior officials of the Departments of Justice and Defense, the National Security Council and the Office of White House Counsel. She represented the United States before international bodies and advised the State Department on international legal issues arising in the areas of human rights, armed conflict, sovereign and diplomatic immunity, international arbitration and claims settlement, and the intersection of U.S. and international law.

Ms. Amirfar has written extensively on international arbitration, the relationship between international law and U.S. domestic law, international human rights and humanitarian law; investor-state disputes; and the law of consular and diplomatic immunities. She is a frequent lecturer on international law and has guest-lectured at Yale Law School and NYU Law School, among others.

Ms. Amirfar originally joined the firm in 2002 and became a partner in 2008. From 2000 to 2002, she clerked for the Hon. D.A. Batts, Southern District of New York. She received a J.D. *cum laude* from New York University Law School in 2000, where she was a Root-Tilden-Snow Scholar. She served as an editor for the *NYU Law Review* and was awarded top honors in the NYU Orison S. Marden Moot Court Competition. She received a B.A., with honors, in International Relations from Stanford University in 1995.

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## Education

New York University School of Law, 2000, J.D.

Stanford University, 1995, B.A.

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## Bar Admissions

New York

## Practices

Litigation

---

Arbitration & International Disputes

---

Commercial Arbitration

---

Investor-State Arbitration

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Public International Law

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Business Integrity

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Energy & Natural Resources Arbitration

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## Regions

US/North America

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Middle East/Africa

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This is Exhibit "C" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK



U.S. Food and Drug Administration

# Drug Approval Process

## PRE-CLINICAL

### Drug Sponsor's Discovery and Screening Phase



#### Drug Developed

Drug sponsor develops a new drug compound and seeks to have it approved by FDA for sale in the United States.



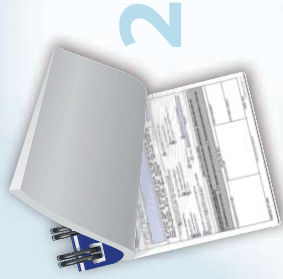
#### Animals Tested

Sponsor must test new drug on animals for toxicity. Multiple species are used to gather basic information on the safety and efficacy of the compound being investigated/researched.

**FDA's Center for Drug Evaluation and Research (CDER) evaluates new drugs before they can be sold.**



The center's evaluation not only prevents quackery, but also provides doctors and patients the information they need to use medicines wisely. CDER ensures that drugs, both brand-name and generic, are effective and their health benefits outweigh their known risks.



#### IND Application

The sponsor submits an Investigational New Drug (IND) application to FDA based on the results from initial testing that include, the drug's composition and manufacturing, and develops a plan for testing the drug on humans.

#### IND REVIEW

FDA reviews the IND to assure that the proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm. FDA also verifies that there are adequate informed consent and human subject protection.

## CLINICAL

### Drug Sponsor's Clinical Studies/Trials

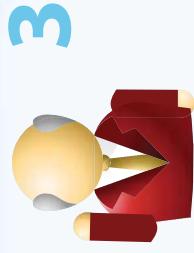
#### What is a drug as defined by the FDA?

A drug is any product that is intended for use in the diagnosis, cure mitigation, treatment, or prevention of disease, and that is intended to affect the structure or any function of the body.

#### PHASE 1

# 20-80

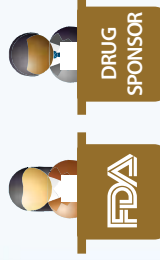
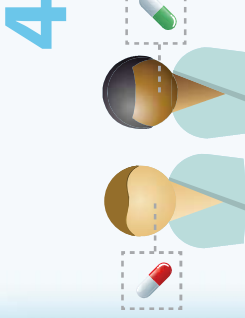
The typical number of healthy volunteers used in Phase 1; this phase emphasizes safety. The goal here in this phase is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted.



#### PHASE 2

# 100's

The typical number of patients used in Phase 2; this phase emphasizes effectiveness. This goal is to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment—usually a placebo, or a different drug. Safety continues to be evaluated, and short-term side effects are studied.

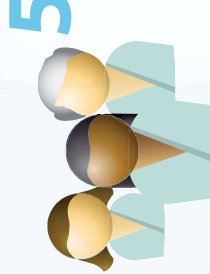


At the end of Phase 2, FDA and sponsors discuss how large-scale studies in Phase 3 will be done.

#### PHASE 3

# 1000's

The typical number of patients used in Phase 3. These studies gather more information about safety and effectiveness, study different populations and different dosages, and uses the drug in combination with other drugs.





## Who reviews new drug submissions?

A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists review the drug sponsor's data and proposed labeling of drugs.



## What other drug products are regulated by FDA?

Drugs include more than just medicines. For example, fluoride toothpastes, antiperspirants (not deodorant), dandruff shampoos, and sunscreens are all considered drugs.



# NDA REVIEW

## FDA's New Drug Application (NDA) Review

### 10 Drug Labeling

FDA reviews the drug's professional labeling and assures appropriate information is communicated to health care professionals and consumers.



10

### 8-9 Application Reviewed

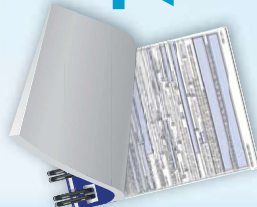
After an NDA is received, FDA has 60 days to decide whether to file it so it can be reviewed. If FDA files the NDA, the FDA Review team is assigned to evaluate the sponsor's research on the drug's safety and effectiveness.



8-9

### 7 NDA Application

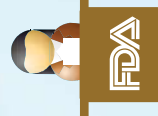
The drug sponsor formally asks FDA to approve a drug for marketing in the United States by submitting an NDA. An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured.



7

### 6 Review Meeting

FDA meets with a drug sponsor prior to submission of a New Drug Application.



6

### FASTER APPROVALS

The Accelerated Approval program allows earlier approval of drugs that treat serious diseases and that fill an unmet medical need. The approval is faster because FDA can base the drug's effectiveness on a "surrogate endpoint," such as a blood test or X-ray result, rather than waiting for results from a clinical trial.

The Fast Track program helps reduce the time for FDA's review of products that treat serious or life-threatening diseases and those that have the potential to address an unmet medical need. Drug sponsors can submit portions of an application as the information becomes available ("rolling submission") instead of having to wait until all information is available.



## PHASE 4

Because it's not possible to predict all of a drug's effects during clinical trials, monitoring safety issues after drugs get on the market is critical. The role of FDA's post-marketing safety system is to detect serious unexpected adverse events and take definitive action when needed.



Once FDA approves a drug, the post-marketing monitoring stage begins. The sponsor (typically the manufacturer) is required to submit periodic safety updates to FDA.

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)  
(800) FDA-1088 (322-1088) phone  
(800) FDA-0178 (322-0178) fax



FDA's MedWatch voluntary system makes it easier for physicians and consumers to report adverse events. Usually, when important new risks are uncovered, the risks are added to the drug's labeling and the public is informed of the new information through letters, public health advisories, and other education. In some cases, the use of the drug must be substantially limited. And in rare cases, the drug needs to be withdrawn from the market.

# 12 FDA

### Drug Approval

FDA reviewers will approve the application or issue a response letter.

## PDUFA

### Prescription Drug User Fee Act

Since the PDUFA was passed in 1992, more than 1,000 drugs and biologics have come to the market, including new medicines to treat cancer, AIDS, cardiovascular disease, and life-threatening infections.

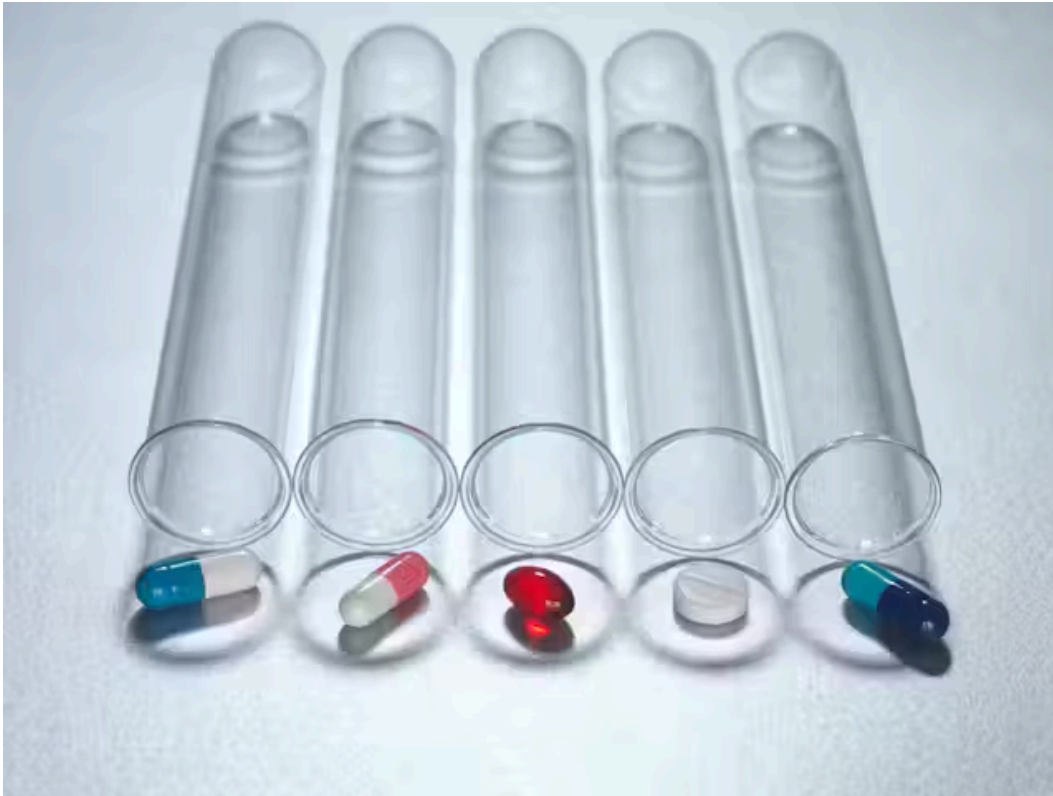
PDUFA has enabled the Food and Drug Administration to bring access to new drugs as fast or faster than anywhere in the world, all while maintaining the same thorough review process. Under PDUFA, drug companies agree to pay fees that boost FDA resources, and FDA agrees to time frames for its review of new drug applications.

This is Exhibit "D" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK



The majority of drug failures are attributed to lack of clinical efficacy and high toxicity. Andrew Brookes/Image Source via Getty Images

## 90% of drugs fail clinical trials – here's one way researchers can select better drug candidates

Published: February 23, 2022 2.30pm EST

### Duxin Sun

Professor of Pharmaceutical Sciences, University of Michigan

It takes 10 to 15 years and around US\$1 billion to develop one successful drug. Despite these significant investments in time and money, 90% of drug candidates in clinical trials fail. Whether because they don't adequately treat the condition they're meant to target or the side effects are too strong, many drug candidates never advance to the approval stage.

As a pharmaceutical scientist working in drug development, I have been frustrated by this high failure rate. Over the past 20 years, my lab has been investigating ways to improve this process. We believe that starting from the very early stages of development and changing how researchers select potential drug candidates could lead to better success rates and ultimately better drugs.

### How does drug development work?



Over the past few decades, drug development has followed what's called a classical process. Researchers start by finding a molecular target that causes disease – for instance, an overproduced protein that, if blocked, could help stop cancer cells from growing. They then screen a library of chemical compounds to find potential drug candidates that act on that target. Once they pinpoint a promising compound, researchers optimize it in the lab.

## GCSE Biology - Drug Development and Testing - Clinical Trials #45



Drugs go through a number of stages of development and testing before they're given to people in clinical trials.

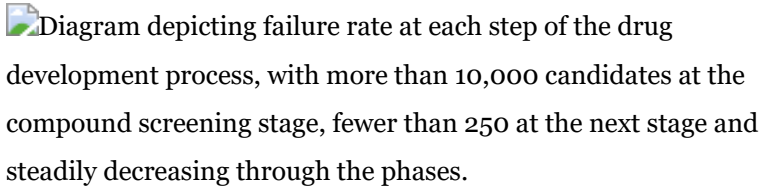
Drug optimization primarily focuses on two aspects of a drug candidate. First, it has to be able to strongly block its molecular target without affecting irrelevant ones. To optimize for potency and specificity, researchers focus on its structure-activity relationship, or how the compound's chemical structure determines its activity in the body. Second, it has to be “druglike,” meaning able to be absorbed and transported through the blood to act on its intended target in affected organs.

Once a drug candidate meets the researcher's optimization benchmarks, it goes on to efficacy and safety testing, first in animals, then in clinical trials with people.

### **Why does 90% of clinical drug development fail?**

Only 1 out of 10 drug candidates successfully passes clinical trial testing and regulatory approval. A 2016 analysis identified four possible reasons for this low success rate. The researchers found between 40% and 50% of failures were due to a lack of clinical efficacy, meaning the drug wasn't able to produce its intended effect in people. Around 30% were due to unmanageable toxicity or side effects, and 10%-15% were due to poor pharmacokinetic properties, or how well a drug is absorbed by and excreted from the body. Lastly, 10% of failures were attributed to lack of commercial interest and poor strategic planning.

This high failure rate raises the question of whether there are other aspects of drug development that are being overlooked. On the one hand, it is challenging to truly confirm whether a chosen molecular target is the best marker to screen drugs against. On the other hand, it's possible that the current drug optimization process hasn't been leading to the best candidates to select for further testing.

Diagram depicting failure rate at each step of the drug development process, with more than 10,000 candidates at the compound screening stage, fewer than 250 at the next stage and steadily decreasing through the phases.

With each successive step of the drug development process, the probability of success gets increasingly smaller. Duxin Sun and Hongxiang Hu

Drug candidates that reach clinical trials need to achieve a delicate balance of giving just enough drug so it has the intended effect on the body without causing harm. Optimizing a drug's ability to pinpoint and act strongly on its intended target is clearly important in how well it's able to strike that balance. But my research team and I believe that this aspect of drug performance has been overemphasized. Optimizing a drug's ability to reach diseased body parts in adequate levels while avoiding healthy body parts – its tissue exposure and selectivity – is just as important.

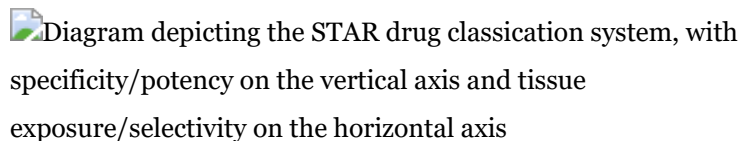
For instance, scientists may spend many years trying to optimize the potency and specificity of drug candidates so that they affect their targets at very low concentrations. But this might be at the expense of ensuring that enough drug is reaching the right body parts and not causing harm to healthy tissue. My research team and I believe that this unbalanced drug optimization process may skew drug candidate selection and affect how it ultimately performs in clinical trials.

## **Improving the drug development process**

Over the past few decades, scientists have developed and implemented many successful tools and improvement strategies for each step of the drug development process. These include high-throughput screening that uses robots to automate millions of tests in the lab, speeding up the process of identifying potential candidates; artificial intelligence-based drug design; new approaches to predict and test for toxicity; and more precise patient selection in clinical trials. Despite these strategies, however, the success rate still hasn't changed by much.

My team and I believe that exploring new strategies focusing on the earliest stages of drug development when researchers are selecting potential compounds may help increase success. This could be done with new technology, like the gene editing tool CRISPR, that can more rigorously confirm the correct molecular target that causes disease and whether a drug is actually targeting it.

And it could also be done through a new STAR system my research team and I devised to help researchers better strategize how to balance the many factors that make an optimal drug. Our STAR system gives the overlooked tissue exposure and selectivity aspect of a drug equal importance to its potency and specificity. This means that a drug's ability to reach diseased body parts at adequate levels will be optimized just as much as how precisely it's able to affect its target. To do this, the system groups drugs into four classes based on these two aspects, along with recommended dosing. Different classes would require different optimization strategies before a drug goes on to further testing.

Diagram depicting the STAR drug classification system, with specificity/potency on the vertical axis and tissue exposure/selectivity on the horizontal axis

The STAR system provides a systematic way to approach drug candidate selection, taking into account different factors that play a role in how clinically successful a drug may be. Duxin Sun and Hongxiang Hu

A Class I drug candidate, for instance, would have high potency/specificity as well as high tissue exposure/selectivity. This means it would need only a low dose to maximize its efficacy and safety and would be the most desirable candidate to move forward. A Class IV drug candidate, on the other hand, would have low potency/specificity as well as low tissue exposure/selectivity. This means it likely has inadequate efficacy and high toxicity, so further testing should be terminated.

Class II drug candidates have high specificity/potency and low tissue exposure/selectivity, which would require a high dose to achieve adequate efficacy but may have unmanageable toxicity. These candidates would require more cautious evaluation before moving forward.

Finally, Class III drug candidates have relatively low specificity/potency but high tissue exposure/selectivity, which may require a low to medium dose to achieve adequate efficacy with manageable toxicity. These candidates may have a high clinical success rate but are often overlooked.

## **Realistic expectations for drug development**

Having a drug candidate reach the clinical trial stage is a big deal for any pharmaceutical company or academic institution developing new drugs. It's disappointing when the years of effort and resources spent to push a drug candidate to patients so often lead to failure.

Improving the drug optimization and selection process may significantly improve success of a given candidate. Although the nature of drug development may not make reaching a 90% success rate easily achievable, we believe that even moderate improvements can significantly reduce the cost and time it takes to find a cure for many human diseases.

[*Get fascinating science, health and technology news. Sign up for The Conversation's weekly science newsletter.*]

This is Exhibit "E" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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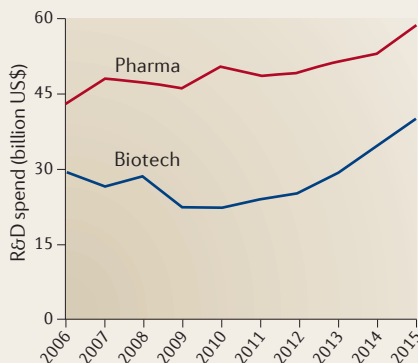
Commissioner for Taking Affidavits  
SIDNEY BREJAK

## NEWS IN BRIEF

**Biotech R&D spend jumps by more than 15%**

Two reports show big increases in R&D spending among both biotech and pharmaceutical drug developers.

In an [annual review](#) of the biotech sector, analysts at EY (formerly Ernst & Young) found that biotech companies spent US\$40.1 billion on R&D in 2015, up 16% from their 2014 spend (see FIG. 1). For the second year in a row this increase was led by the sector's smaller companies, which cumulatively increased their R&D budgets by 28% (to \$15 billion). Established



**Figure 1 | R&D spend.** Biotech R&D spending data are from the EY Biotechnology Reports 2008–2016. Where annual reports provided inconsistent R&D spending data, data from the latest report were used. Pharmaceutical R&D spending data are from the PhRMA 2016 Profile.

companies with revenues of at least \$500 million per year increased their R&D spend by a lower level of 10%. R&D expenses grew more quickly than revenues, the analysts write, “suggesting a continued willingness to bet on the industry pipeline.”

The analysts note that, although the biotech sector enjoyed a record performance in 2015, revenue and market cap growth slowed in 2015. These data suggest that “biotech’s wave of unprecedented success may have crested,” they write.

A [separate report](#) by the industry lobby group PhRMA, meanwhile, showed that pharmaceutical companies spent \$58.8 billion on R&D in 2015, up 10% from their 2014 spend.

The R&D budgets of some companies are captured in both cohorts.

Asher Mullard

and antibodies) together with ‘non-NME’ development projects such as reformulations and combinations of approved drugs (but not generics). When the analysts focused on the NMEs to assess only the most innovative therapies, the overall success rate was 6.2%. Novel biologics, including antibodies and gene therapies, performed better, with an overall success rate of 11.5%.

A second study shed further light on the clinical trial success rates and provides cause for optimism. Analysts at the consulting firm McKinsey & Company tracked the progress of 9,200 compounds that were developed between 1996 and 2014. When they calculated a rolling 3-year average, they found that success rates are on the rise. They calculated a cumulative success rate of 11.6% in 2011–2014, up from a low of 7.5% in 2008–2011 ([Nat. Rev. Drug Discov.](#) **15**, 379–380; 2016).

Several of their findings mirrored those of the BIO study. McKinsey calculated an above-average overall success rate for rare disease drugs, hitting 29% over the past 3 years. Biologics had an overall success rate of 18%, twice that of the 9% success rate for small-molecule drugs.

Asher Mullard

**Parsing clinical success rates**

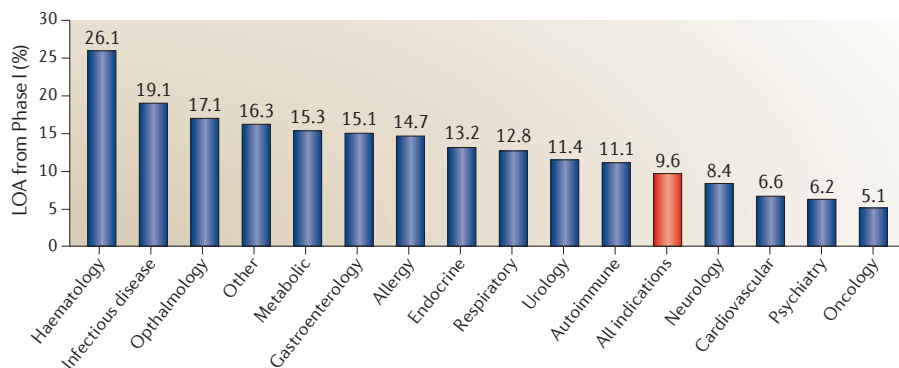
Conventional wisdom holds that only around 10% of drug development projects make it all the way from Phase I to approval. Two studies of clinical trial success rates now provide updated granularity to this rule of thumb, and show considerable variation by therapeutic area and drug modality.

In a [first report](#), the industry lobby group BIO, along with analysts at BioMedTracker and Amplion, analysed 7,455 drug development programmes that moved through the clinic between 2006 and 2015. They found that

the probability of success was 63% in Phase I trials, 31% in Phase II trials, 58% in Phase III trials and 85% during the regulatory review process, for an overall success rate of 9.6% ( $63\% \times 31\% \times 58\% \times 85\% = 9.6\%$ ). But when they analysed the data by therapeutic area, the overall success rates ranged from 26% for haematology projects to 5% for oncology projects (see FIG. 1).

Rare disease drugs for non-cancer indications out-performed the average, with an overall success rate of 25%. Projects that included biomarkers fared similarly well, achieving an overall success rate of 26%.

The overall analysis lumped new molecular entities (NMEs; including small molecules



**Figure 1 | Likelihood of approval (LOA) from Phase I.** Data from Clinical Development Success Rates 2006–2015 by BIO, BioMedTracker and Amplion.

**EMA provides first glimpse of PRIME candidates**

In March, the [European Medicines Agency \(EMA\)](#) launched the PRIME programme, a variation of the FDA’s breakthrough designation programme aimed at speeding up the development of promising medicines with high potential to address unmet needs. They have now [disclosed the first four PRIME candidates](#). Only one of these drugs (KTE-C19) has been publicly disclosed as having breakthrough designation.

The first four PRIME candidates are: Biogen’s aducanumab, a beta-amyloid targeting antibody for Alzheimer disease; Kite Pharma’s KTE-C19, a chimeric antigen receptor (CAR) T cell therapy for diffuse large B cell lymphoma; ChemoCentryx’s CCX168, a C5a receptor inhibitor for a set of rare autoimmune diseases called ANCA-associated vasculitis; and Novimmune’s NI-0501, an anti-interferon-γ antibody for the rare autoimmune disease haemophagocytic lymphohistiocytosis.

The agency denied PRIME designation to 14 submissions.

The EMA will disclose further PRIME candidates on a monthly basis.

Asher Mullard

This is Exhibit "F" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK





# Clinical Development Success Rates and Contributing Factors 2011–2020



## About BIO

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members, from the entrepreneurial to the Fortune 500 multinationals, are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. BIO also produces industry-leading investor and partnering events to strengthen the innovator ecosystem.



## About Informa Pharma Intelligence

Biomedtracker, a subscription-based product of Informa Pharma Intelligence, tracks the clinical development and regulatory history of investigational drugs to assess their Likelihood of Approval (LOA) by the FDA. Biomedtracker is populated in near real-time with updated information from press releases, corporate earnings calls, investor and medical meetings, and numerous other sources. These data can be visualized, analyzed, and interpreted in the specifically designed R&D benchmarking tool Pharmapremia. This provides an exclusive window into drug development pipelines and paints a fuller, clearer picture of how the industry is performing. For more information visit [www.pharmaintelligence.informa.com](http://www.pharmaintelligence.informa.com).



## About QLS Advisors

QLS Advisors LLC is a technology and advisory company based in Cambridge, MA, dedicated to fostering innovation in the life sciences. QLS employs a unique blend of fundamental and quantitative tools to help clients manage risk, assess reward, and develop investment and financing strategies for portfolios of healthcare-related assets. For more information visit [www.qlsadvisors.com](http://www.qlsadvisors.com).





## Executive Summary

This is both an updated study of clinical drug development success rates from our 2016 report, and an expansion into the drivers of success with the addition of machine learning modeling to analyze the predictive factors contributing to drug development. A total of 12,728 clinical and regulatory phase transitions were recorded and analyzed from 9,704 development programs over the last decade (2011–2020), across 1,779 companies in the Biomedtracker database. Phase transitions occur when a drug candidate advances into the next phase of development or is suspended by the sponsor. By calculating the number of programs progressing to the next phase vs the total number progressing and suspended, we assessed the success rate at each of the four phases of development: Phase I, II, III, and regulatory filing. Having phase-by-phase data in hand, we then compared groups of diseases, drug modalities, and other attributes to generate the most comprehensive analysis yet of biopharmaceutical R&D success.

This work was made possible due to the years of clinical program monitoring and data entry by Informa Pharma Intelligence's Biomedtracker, which subsequently populates the purpose-built Probability of Technical Success (PTS) tool, Pharmapremia. BIO has long worked with Biomedtracker to calculate success rates based on this data. More recently, BIO and Biomedtracker teamed up with QLS Advisors, a team of expert data scientists who apply machine learning (ML) and artificial intelligence (AI) to clinical trials data and drug properties to assess the features that contribute the most amount, positively or negatively, to the probability of approval. The computational analyses of over 200 different drug, trial, indication, and sponsor metrics that influence clinical success rates were applied in a predictive capacity to produce risk assessments and evaluations of R&D assets with increased accuracy.

### Key Takeaways

- The overall likelihood of approval (LOA) from Phase I for all developmental candidates over 2011–2020 was 7.9%.
- Phase II development remains the largest hurdle in drug development, with just 28.9% of candidates achieving this critical phase transition.
- Of the 14 major disease areas, Hematology therapies had the highest LOA from Phase I (23.9%), representing a seven-fold increase over the least successful group, Urology (3.6%).
- Immuno-oncology therapies provide a rare pocket of success in oncology R&D with an overall LOA of 12.4% vs 5.3% for all oncology approaches.
- Rare disease therapies were notably successful with an overall LOA of 17.0%.
- Chronic, high prevalence disease therapies were less successful with an overall LOA of 5.9%.
- Biological complexity in drug modalities generally leads to higher LOA, with CAR-T and RNA interference achieving the highest LOAs of 17.3% and 13.5%, respectively.
- Development programs with trials employing patient preselection biomarkers have two-fold higher LOAs (15.9%), driven by a Phase II success rate of nearly one-in-two.
- The top contributing factors toward phase success are disease indication, target, modality, and drug novelty.
- On average, it takes 10.5 years for a Phase I asset to progress to regulatory approval. Disease areas with above-average LOAs tend to have the shortest development timelines.

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## Introduction

This study aimed to measure clinical development success rates, contributing factors to those outcomes, and timelines of clinical trials. With the goal of providing current benchmarking metrics for drug development, this study covers the most recent decade of individual drug program phase transitions from January 1, 2011, to November 30, 2020. A phase transition is defined as the movement out of a clinical phase – for example, advancing from Phase I to Phase II development, or being suspended after completion of Phase I development.

Three separate analyses were conducted. Part 1 of this report includes clinical development success rates based on 12,728 transitions in the Biomedtracker database. These transitions occurred in 9,704 clinical drug development programs over the last decade. Within this broad set of data, we segmented and analyzed success in drug development across levels of novelty, molecular modalities, and disease indications. As this study cuts across 1,779 companies, roughly the entire spectrum of biopharma companies was included. This is illustrated with 15 companies each contributing more than 100 transitions, while 748 smaller biotechs contributed just one transition each. Only company-sponsored, FDA registration-enabling development programs were included in this analysis. Investigator-sponsored studies and combinations with other investigational drugs were excluded. A more detailed description of the data collection, composition, and analysis methodologies is provided in the “Methods” section.

The second analysis applies big data analytics to uncover the underlying drivers of drug development success. Despite the successful application of machine learning techniques to libraries of billions of chemical and biological compounds in order to identify potential drug candidates, most drug developers and financial analysts still rely on historical observation to derive estimates of the clinical trial success rate when analyzing pipelines of investigational drugs. QLS Advisors, a technology and advisory company dedicated to fostering innovation in the life sciences, applies machine-learning techniques to predict the outcomes of randomized clinical trials. In Part 2 of this report, QLS Advisors explores how investors in the biopharma industry can use machine learning to characterize the probability of success for regulatory approval of a novel therapy.

An analysis of clinical timelines is included in Part 3. Here we measure the time it takes for drug development programs at each clinical phase to transition upon success to the next phase.

## Part 1. Phase Transition Success and Likelihood of Approvals

Success rates for individual phases of the drug development process were determined by dividing the number that successfully advanced to the next phase by the total number advanced and suspended. This “advanced and suspended” number is often referred to as “n” in this report and should be taken into account when drawing conclusions from the success rate results.

Consistent with previous studies of drug development phase transition success rates, we found Phase II success rates to be far lower than any other phase.<sup>1,2</sup> Phase I and III rates were substantially higher than Phase II, with Phase I slightly lower than Phase III. The highest success rate of the four development phases was the New Drug Application (NDA)/ Biologic License Application (BLA) filing phase (**Figure 1**).

The Phase I transition success rate was 52.0% (n=4,414). As this phase is typically conducted for safety testing and is not dependent on efficacy for candidates to advance, it is common for this phase to have a higher success rate among the clinical phases across most categories analyzed in this report. However, Phase I success rates also may benefit from delayed reporting or omission bias, as some larger companies may not deem failed Phase I programs as material and thereby not report them in the public domain.

The Phase II transition success rate (28.9%, n=4,933) was substantially lower than Phase I, and the lowest of the four phases studied. As this is generally the first stage where proof-of-concept is deliberately tested in human subjects, Phase II consistently has the lowest success rate of all phases. This is also the point in development where industry must decide whether to pursue large, expensive Phase III studies, or to terminate development – this may be done for multiple reasons, including commercial viability. The second-highest phase transition success rate was found in Phase III (57.8%, n=1,928). This is significant as most company-sponsored Phase III trials are the longest and most expensive trials to conduct.

The probability of FDA approval after submitting an NDA or BLA, taking into account re-submissions, was 90.6% (n=1,453).

### Overall phase transition success rates

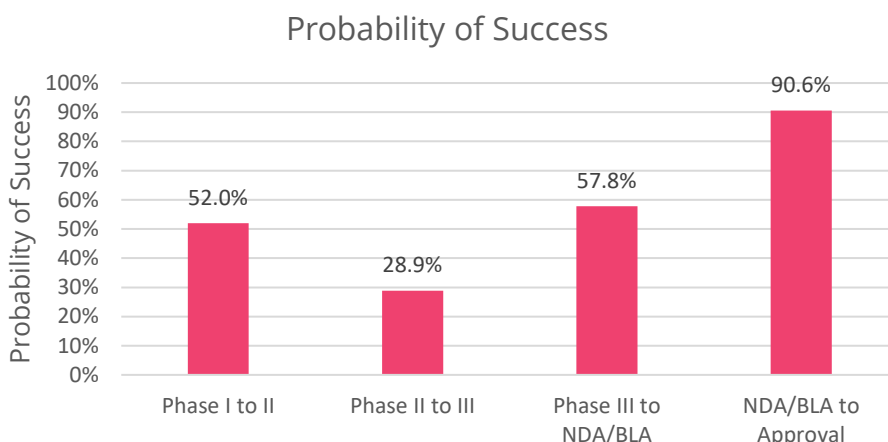


Figure 1: Phase transition success rates from Phase I for all diseases, all modalities. Source: Biomedtracker® and Pharmapremia®, 2020.

<sup>1</sup> Hay M, Thomas D, Craighead JL, Economides C, Rosenthal J (2014). Clinical development success rates for investigational drugs. *Nature Biotechnology*, 32(1), 40–51. doi: 10.1038/nbt.2786

<sup>2</sup> Thomas D, Burns J, Audette J, Carroll A, Dow-Hygelund C, Hay M (2016) Clinical Development Success Rates 2006-2015. Available [here](#) [Accessed 15 January 2021].

## Phase Transition Success – By Disease Area

Major disease areas were segmented according to the convention used by Biomedtracker and categorized into 21 major diseases and 623 indications for the 2011–2020 timeframe. For reporting at the disease area level, in **Figure 2** we analyzed 14 major groupings: Allergy, Autoimmune, Cardiovascular, Endocrine, Gastroenterology (non-IBD), Hematology, Infectious disease, Metabolic, Neurology, Oncology, Ophthalmology, Psychiatry, Respiratory, and Urology. The remaining disease areas were placed into the “Other” category. This includes Dermatology, Renal, Obstetrics, Rheumatology (for non-autoimmune indications), ENT/Dental, and Orthopedics. Beneath these major disease areas are 573 indications, which will be analyzed and discussed in subsequent reports.

**Phase transition success rates by disease area**

Phase Success	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	n	Phase POS	n	Phase POS	n	Phase POS	n	Phase POS
Hematology	92	69.6%	106	48.1%	82	76.8%	72	93.1%
Metabolic	136	61.8%	149	45.0%	66	63.6%	48	87.5%
Infectious disease	403	57.8%	414	38.4%	197	64.0%	156	92.9%
Others	154	63.6%	228	38.6%	90	60.0%	69	88.4%
Ophthalmology	88	71.6%	200	35.5%	82	51.2%	45	91.1%
Autoimmune	413	55.2%	471	31.4%	219	65.3%	202	94.1%
Allergy	55	56.4%	92	28.3%	34	64.7%	20	100.0%
Gastroenterology	45	46.7%	73	34.2%	35	57.1%	33	90.9%
All indications	4414	52.0%	4933	28.9%	1928	57.8%	1453	90.6%
Respiratory	179	55.9%	215	21.9%	62	64.5%	45	95.6%
Psychiatry	150	52.7%	164	26.8%	71	56.3%	57	91.2%
Endocrine	319	43.3%	293	26.6%	151	66.2%	124	86.3%
Neurology	516	47.7%	504	26.8%	226	53.1%	165	86.7%
Oncology	1628	48.8%	1732	24.6%	495	47.7%	324	92.0%
Cardiovascular	214	50.0%	252	21.0%	105	55.2%	80	82.5%
Urology	22	40.9%	40	15.0%	13	69.2%	13	84.6%

**Figure 2:** Phase transition success rates by disease area. The n value is the total ‘Advanced or Suspended’ transitions of all phases used to calculate LOA. ‘POS’ is the probability of successfully advancing to the next phase. The ordering of disease areas is consistent with the overall likelihood of approval from Phase I, which is analyzed later in Figure 5. Source: Biomedtracker® and Pharmapremia®, 2020

## Phase I Transition Success Rates

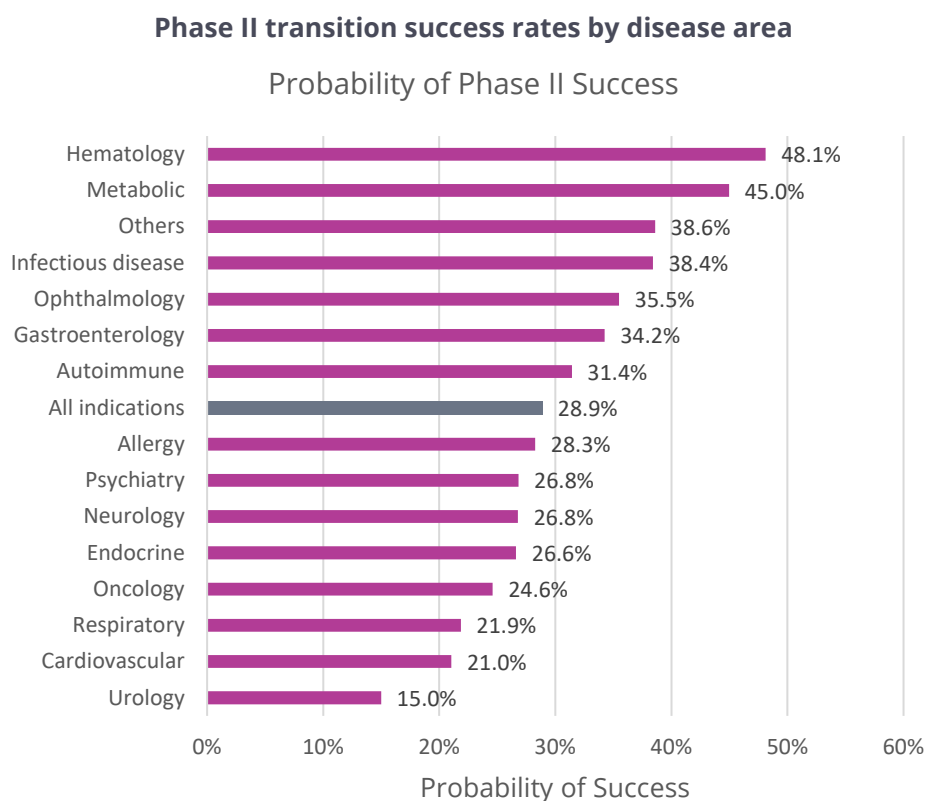
Success rates by disease area for Phase I ranged from 40.9% to 71.6%, with the average for all disease indications coming in at 52.0%. Ophthalmology and Hematology were both well above the average rate, achieving respective successful Phase I transitions of 71.6% (n=88) and 69.6% (n=92). With the exception of these two major disease areas, the remainder were all within a reasonable distance from the mean.

## Phase II Transition Success Rates

In every disease area, Phase II had the lowest transition success rate of the four phases. As shown in **Figure**

3, Phase II success rates ranged from a high of 48.1% (Hematology, n=106) to a low of 15.0% (Urology, n=40). This 33% range of disparity between major disease areas at the Phase II transition is the major contributor to the observed divergences in overall likelihood of approval (LOA), as discussed in the next section. With only Hematology and Metabolic (45.0%) coming close to achieving a one-in-two success rate, these two disease areas are also the leaders when calculating the overall LOA from Phase I, as shown later in **Figure 5**.

Similar to Phase I transition success, the lowest-performing disease groups were Urology, Cardiovascular (21.0%), and Oncology (24.6%). Relative to its placement for Phase I success rate, the Gastroenterology category performed better in Phase II (34.2%), above the average for all indications.



**Figure 3:** Phase II transition success rates by disease area. Source: Biomedtracker® and Pharmapremia®, 2020

### Phase III Transition Success Rates

For Phase III transition success rates, Oncology had the lowest transition success rate (47.5%, n=495). As seen in Figure 4, the Phase III success rates for the remaining 13 specific disease areas were each above 50%.

Five other disease groups besides Oncology ranked below the average Phase III transition success rate of 57.8%, including Ophthalmology (51.2%, n=82) which in the earlier phases performed better than the average across all diseases. Conversely, Urology, which had the lowest transition rates in Phase I and II, had the second-highest Phase III success rate behind Hematology at 69.2%, albeit with a very low n of 13 transitions. All of the disease groups with below-average Phase III success rates had disease indications with large patient populations. Later in this report, we will analyze these high prevalence diseases and compare their success rates to those of therapies for rare diseases.

### Phase III transition success rates by disease area

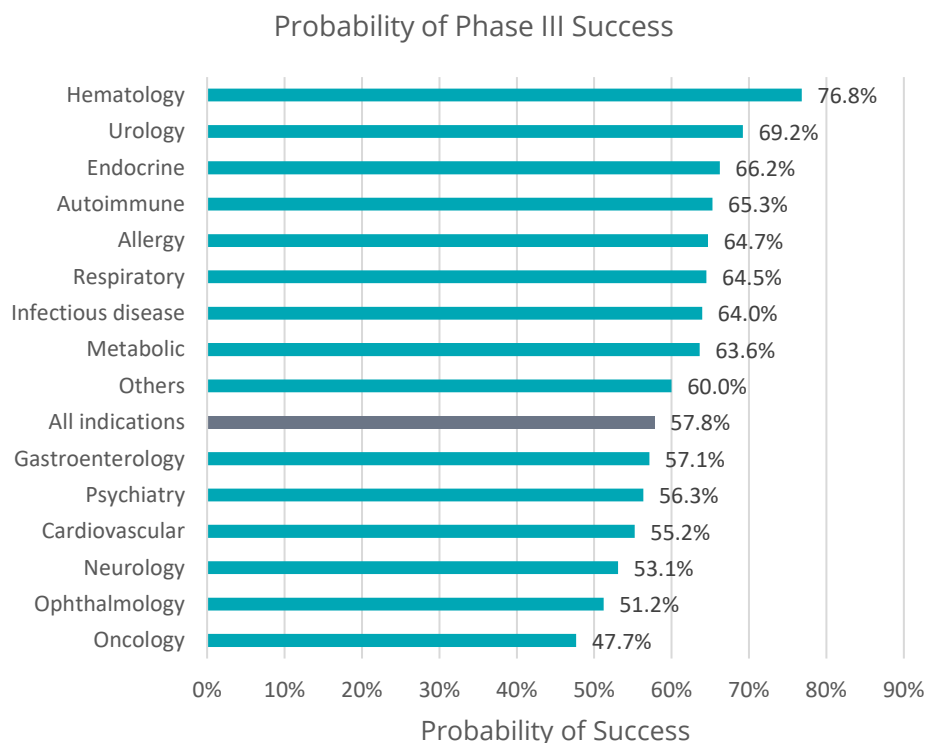


Figure 4: Phase III transition success rates by disease area. Source: Biomedtracker® and Pharmapremia®, 2020

### NDA/BLA Submission Success Rates

NDA/BLA transition success rates (approval rates) for the major disease areas ranged from the low end of 82.5% (Cardiovascular) to a high of 100.0% (Allergy). This distribution had the tightest range among the four phases analyzed in this report. These rates are the result of eventual success, not success on the first review. In some cases, programs have more than two Complete Response Letters (CRLs) and attempts at approval. This unlimited allowance of submission attempts pushes the overall success above 90.6% across all diseases, with only 137 drugs suspended by their sponsors at the regulatory transition over 2011–2020 (thus, 1,316 approved).

Among the clinical development programs analyzed, there was an approximately even split of innovative drugs and non-originator products that were successful in obtaining regulatory approval. These included 740 innovative drug programs (435 new molecular entities (NMEs), 278 new biologics, and 27 vaccines) and 576 non-originator products (453 non-NMEs and 123 biosimilars). There is a more detailed discussion about success rates by for drug modality and classification later in the report.

### Likelihood of Approval (LOA) – By Disease Area

One of the key measures of success used in this report is the LOA from Phase I. The LOA success rate is simply a multiplication of success rates from all four phases, a compounded probability calculation. For example, if each phase had a 50% chance of success, then the LOA from Phase I would be  $0.5 \times 0.5 \times 0.5 \times 0.5 = 6.25\%$ .



Multiplying the individual phase probabilities across all disease areas (found in Figure 1), the compounded probability of progressing from Phase I to U.S. FDA approval reveals that only 7.9% of drug development programs (n=12,728) successfully make it to market.

As can be seen in Figure 5, there is a wide range of LOAs from Phase I. At the high end, Hematology towers over the other disease groups at 23.9% (n=352). Hematology therapies had an LOA from Phase I seven times higher than Urology therapies, which had the lowest Phase I LOA of all the major disease areas (3.6%, n=88).

After Hematology, the next highest LOA from Phase I was Metabolic with 15.5% (n=399). Five other disease areas were above the overall average of 7.9% (Infectious Disease > Ophthalmology > Autoimmune > Allergy > Gastroenterology) which ranged from 13.2% down to 8.3%. Falling under the overall LOA of 7.9%, but very close, were Respiratory (7.5%) and Psychiatry (7.3%). Therapies for five disease categories were well below the average (Endocrine > Neurology > Oncology > Cardiovascular > Urology). The fact that Oncology and Neurology have the two largest n values, while also having low LOA values, indicates that these two disease categories are significant contributors in bringing down the overall industry LOA.

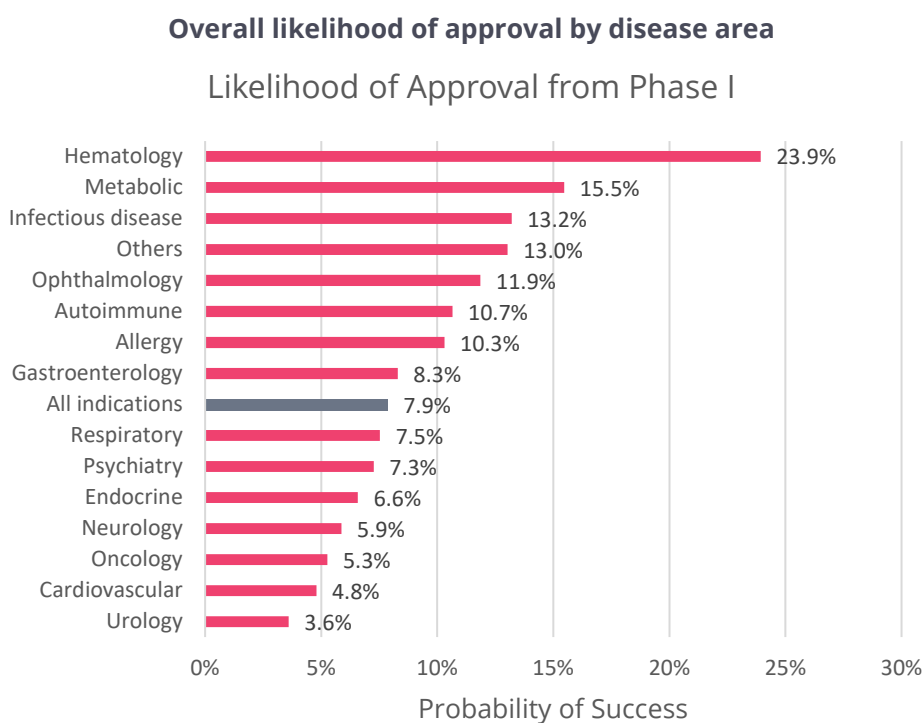


Figure 5a: Chart of LOA from Phase I, displayed highest to lowest by disease area. Source: Biomedtracker® and Pharmapremia®, 2020



Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Hematology	352	23.9%	260	34.4%	154	71.5%	72	93.1%
Metabolic	399	15.5%	263	25.0%	114	55.7%	48	87.5%
Infectious disease	1170	13.2%	767	22.8%	353	59.4%	156	92.9%
Others	541	13.0%	387	20.5%	159	53.0%	69	88.4%
Ophthalmology	415	11.9%	327	16.6%	127	46.7%	45	91.1%
Autoimmune	1305	10.7%	892	19.3%	421	61.4%	202	94.1%
Allergy	201	10.3%	146	18.3%	54	64.7%	20	100.0%
Gastroenterology*	186	8.3%	141	17.8%	68	51.9%	33	90.9%
All indications	12728	7.9%	8314	15.1%	3381	52.4%	1453	90.6%
Respiratory	501	7.5%	322	13.5%	107	61.6%	45	95.6%
Psychiatry	442	7.3%	292	13.8%	128	51.4%	57	91.2%
Endocrine	887	6.6%	568	15.2%	275	57.1%	124	86.3%
Neurology	1411	5.9%	895	12.3%	391	46.0%	165	86.7%
Oncology	4179	5.3%	2551	10.8%	819	43.9%	324	92.0%
Cardiovascular	651	4.8%	437	9.6%	185	45.6%	80	82.5%
Urology	88	3.6%	66	8.8%	26	58.6%	13	84.6%

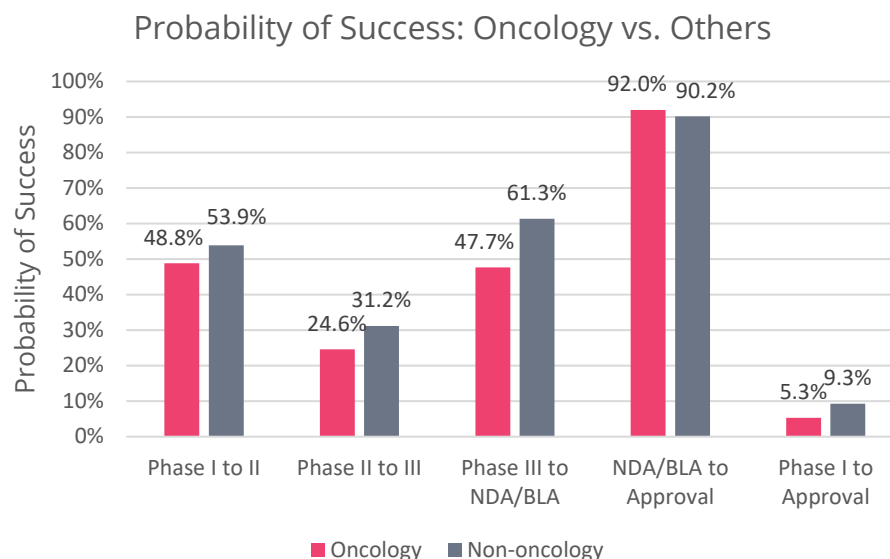
**Figure 5b:** Table likelihood of approval by disease area with corresponding n values. The n value is the total 'Advanced or Suspended' transitions of all phases used to calculate LOA. 'Phase LOA' is the probability of FDA approval for drugs from this phase of development. Source: Biomedtracker® and Pharmapremia®, 2020

### Oncology and Non-Oncology Diseases

Oncology drug development program transitions in the 2011–2020 period accounted for 33% of the 12,728 total transitions. With the third-lowest LOA from Phase I (5.3%, n=4,179), Oncology had an outsized effect on the overall industry success rate. To further understand this contribution, we compared phase transition success rates and LOA for non-oncology development programs against oncology development programs (Figure 6).

The LOA from Phase I across non-oncology indications, 9.3% (n=8,549), was nearly twice that for Oncology alone, at 5.3% (n=4,179). Comparing individual phase transition success rates in Figure 2, Oncology consistently had one of the lowest success rates compared to the other 14 disease categories for every developmental clinical transition. In particular, there were relative differentials of approximately 20% between Oncology and non-oncology groupings at the Phase II and III stages. One notable exception was the NDA/BLA to approval success rate. Oncology performed slightly better than non-oncology at the regulatory transition between NDA/BLA and approval, with a 92.0% (n=324) success rate, as opposed to 90.2% (n=1,129).

## Oncology vs. non-oncology phase transition success rates and LOA



Phase Success	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS
Oncology	1628	48.8%	1732	24.6%	495	47.7%	324	92.0%
Non-oncology	2786	53.9%	3201	31.2%	1433	61.3%	1129	90.2%

Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Oncology	4179	5.3%	2551	10.8%	819	43.9%	324	92.0%
Non-oncology	8549	9.3%	5763	17.2%	2562	55.3%	1129	90.2%

**Figure 6:** Oncology vs non-oncology phase transition success rates and LOA. Top: Chart of phase transition success rates and LOA from Phase I for Oncology vs non-Oncology. Bottom: Table of phase transition success and likelihood of approval by Oncology vs non-Oncology with corresponding n values. The n value is the total 'Advanced or Suspended' transitions of all phases used to calculate LOA. 'POS' is the probability of successfully advancing to the next phase, whereas 'Phase LOA' is the probability of FDA approval for drugs from this phase of development. Source: Biomedtracker® and Pharmapremia®, 2020

Oncology drugs were further categorized into two main types of cancer: solid tumors and hematologic cancers. Drugs for solid tumors had more than twice as many transitions in the data set (2,982 vs 1,094), but a much smaller LOA from Phase I vs hematological cancers (4.6% vs 7.5%).

The 2011–2020 time period witnessed the rise of drugs that harness the immune system to treat the underlying cancer, spanning both solid and hematologic types. The first successful immuno-oncology (IO) drugs spawned intense growth in this field over a short period of time, with 679 total phase transitions included in the Biomedtracker database. The success rates of IO drugs far exceed the traditional oncology averages, with a Phase I LOA of 12.4%. The notably high Phase II transition rate of 42.0% for IO drugs – contrasting 24.6% as a whole for oncology – is the main factor underpinning the overall LOA success for the IO class. These oncology groupings are shown in **Figure 7**.

## Oncology sub-category phase transition success rates and LOA

Phase Success	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS
Hematologic	425	50.1%	449	27.8%	120	60.0%	100	90.0%
Solid	1145	48.9%	1261	23.4%	364	42.9%	212	92.9%
IO	275	64.0%	244	40.2%	98	49.0%	62	98.4%

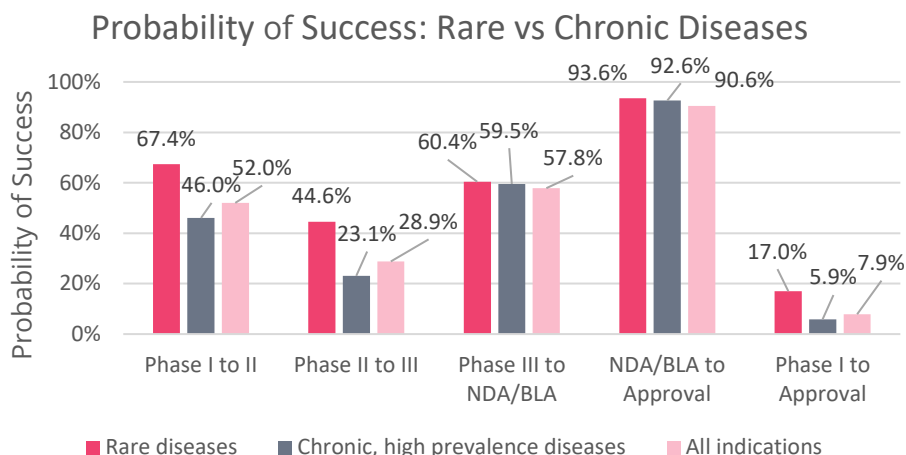
Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Hematologic	1094	7.5%	669	15.0%	220	54.0%	100	90.0%
Solid	2982	4.6%	1837	9.3%	576	39.8%	212	92.9%
IO	679	12.4%	404	19.4%	160	48.2%	62	98.4%

**Figure 7:** Oncology sub-category phase transition success rates and LOA. The n value is the total 'Advanced or Suspended' transitions of all phases used to calculate LOA. 'POS' is the probability of successfully advancing to the next phase, whereas 'Phase LOA' is the probability of FDA approval for drugs from this phase of development. Note: Hematologic and solid tumor types are mutually exclusive categories, while the IO drug class includes transitions from across both categories. IO drugs for solid tumors had 3x the transitions as IO hematological cancers but have similar success rates. Source: Biomedtracker® and Pharmapremia®, 2020

### Rare and Chronic High Prevalence Diseases

Within the Biomedtracker database, rare diseases can be identified based on meeting either or both of the following standard criteria: affecting fewer than 200,000 people in the US, or prevalence of 1 in 2,000 people in the EU. As 43% of the Oncology transitions are for rare indications, all Oncology indications were removed to make this rare disease analysis more concentrated on inborn genetic disorders. For chronic diseases, we first obtained a list of conditions from the CMS Chronic Conditions Data Warehouse (CCW). We removed any cancer indications, then identified those diseases with greater than 1 million patients affected in the United States.

### Rare disease vs. highly prevalent chronic disease success rates



**Figure 8a:** Non-oncology rare disease and highly prevalent chronic disease phase transition success rates and LOA. Chart of phase transition success rates and LOA from Phase I. Source: Biomedtracker® and Pharmapremia®, 2020

Phase Success	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS
Rare diseases	380	67.4%	464	44.6%	240	60.4%	172	93.6%
Chronic, high prevalence diseases	745	46.0%	737	23.1%	279	59.5%	217	92.6%
All diseases	4414	52.0%	4933	28.9%	1928	57.8%	1453	90.6%

Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Rare diseases	1256	17.0%	876	25.2%	412	56.6%	172	93.6%
Chronic, high prevalence diseases	1978	5.9%	1233	12.7%	496	55.1%	217	92.6%
All diseases	12728	7.9%	8314	15.1%	3381	52.4%	1453	90.6%

**Figure 8b:** Non-oncology rare disease and highly prevalent chronic disease phase transition success rates and LOA. Table of phase transition success and likelihood of approval by disease prevalence with corresponding n values. The n value is the total 'Advanced or Suspended' transitions of all phases used to calculate LOA. 'POS' is the probability of successfully advancing to the next phase, whereas 'Phase LOA' is the probability of FDA approval for drugs from this phase of development. Source: Biomedtracker® and Pharmapremia®, 2020

After identifying programs for non-oncology rare diseases and highly prevalent chronic diseases, we compared their phase transition success rates and LOA as shown in **Figure 8**. At 17.0%, the overall LOA from Phase I for rare diseases (17.0%) was almost three times higher than for chronic, high prevalence diseases (5.9%). As both of these groups exclude Oncology indications, we can compare these results with those of the overall non-oncology figures. The 9.3% LOA (n=8,549) value for all non-oncology indications is meaningfully higher than for chronic, high prevalence diseases, suggesting that these indications are having a negative impact on overall success rates outside Oncology. Chronic, high prevalence diseases accounted for 16% of total transitions, with Oncology providing a further 33%. These two groups, having LOAs well below average, together comprise half of the total dataset, thus negatively affecting the overall industry LOA of 7.9%.

Although excluded from the above analysis, rare disease Oncology indications had a higher LOA than non-rare Oncology indications (6.8% vs 4.4%), largely driven by the higher overall success for hematologic malignancies. Blood cancers typically have lower prevalence and are classified as rare diseases.

Success rates for all four transitions were higher for the rare disease group than any of the overall transition success rates. The largest difference was found in Phase II transition success rates (44.6% for rare disease vs 28.9% overall). There was also a notable gap between Phase I transition success rates (67.4% vs 52.0%), although success in Phase III and in the NDA/BLA to Approval transitions were broadly comparable.

Conversely, the success rates for transitions in the highly prevalent chronic disease group were lower than the overall transition success rates in Phase I (46.0% vs 52.0%) and Phase II (23.1% vs 28.9%). The opposite was seen in Phase III and NDA/BLA transitions, where slightly higher success rates were observed: 59.5% vs 57.8% for Phase III and 92.6% vs 90.6% for NDA/BLA.

## Drug Classes and Modalities

Drugs in the dataset were annotated as novel or off-patent, with the novel category including new molecular entities (NMEs; mainly small molecules), biologics, and vaccines; and the off-patent group comprised of non-NMEs and biosimilars. As noted in **Figure 9**, transition success rates for novel drugs confirm that they face a more difficult pathway to approval than for off-patent products. The overall Phase I LOA for off-patent therapies (14.7%, n=2,161) was twice as high as that for novel therapies (6.8%, n=10,527). This two-fold increase in success for non-originator products was driven by higher success rates in all three clinical phase transitions, with the greatest divergence observed during Phase III (52.9% vs 70.3%).

Within the novel drugs segment, NMEs had a lower probability of approval from Phase I than either biologics or vaccines. While there was a 5.7% (n=6,803) chance of a Phase I NME gaining approval, the probabilities for biologics and vaccines were 9.1% (n=3,412) and 9.7% (n=312), respectively. Vaccines in particular have been 100% successful in the NDA/BLA to Approval stage (n=27). In the off-patent category, biosimilars performed well, with an overall Phase I LOA of 32.3% (n=277).

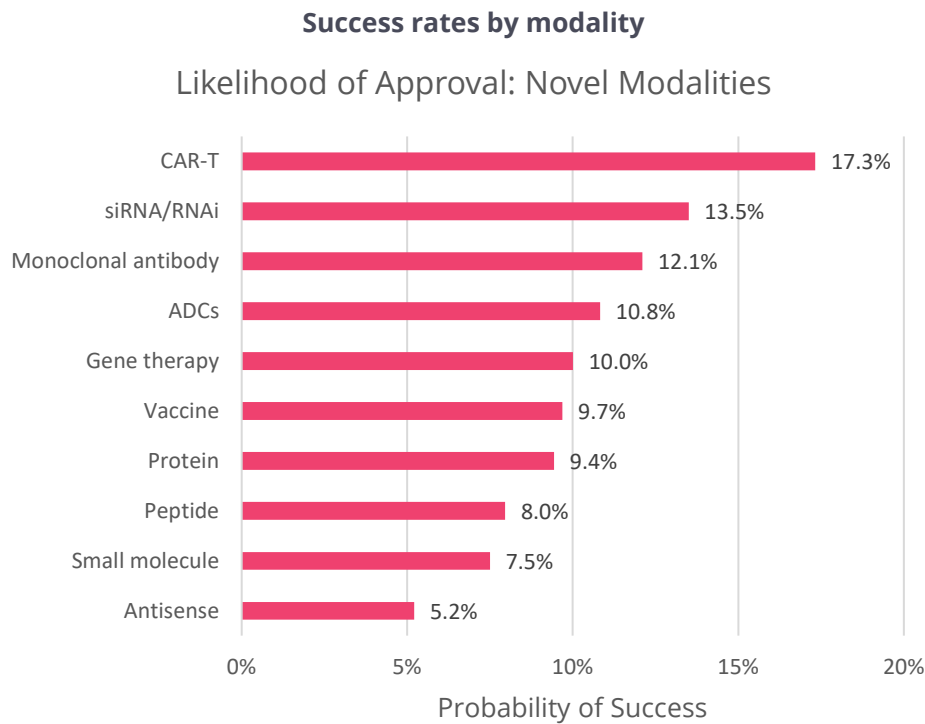
### Phase transition success rates and LOA from Phase I for drugs based on class and novelty

Phase Success	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS
"Novel"	3933	51.3%	4394	27.9%	1374	52.9%	826	89.6%
NME	2505	50.6%	2924	25.6%	869	50.6%	505	86.1%
Biologic	1301	52.5%	1355	32.4%	462	56.7%	294	94.6%
Vaccine	127	52.0%	115	32.2%	43	58.1%	27	100.0%
"Off-Patent"	455	60.4%	527	37.6%	552	70.3%	627	91.9%
Non-NME	395	57.5%	523	37.5%	471	67.5%	495	91.5%
Biosimilar	60	80.0%	4	50.0%	81	86.4%	132	93.2%

Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
"Novel"	10527	6.8%	6594	13.2%	2200	47.4%	826	89.6%
NME	6803	5.7%	4298	11.2%	1374	43.6%	505	86.1%
Biologic	3412	9.1%	2111	17.4%	756	53.6%	294	94.6%
Vaccine	312	9.7%	185	18.7%	70	58.1%	27	100.0%
"Off-Patent"	2161	14.7%	1706	24.3%	1179	64.6%	627	91.9%
Non-NME	1884	13.3%	1489	23.2%	966	61.8%	495	91.5%
Biosimilar	277	32.2%	217	40.3%	213	80.5%	132	93.2%

**Figure 9:** Phase transition success rates and LOA from Phase I for drugs based on class and novelty. The n value is the total 'Advanced or Suspended' transitions of all phases used to calculate LOA. 'POS' is the probability of successfully advancing to the next phase, whereas 'Phase LOA' is the probability of FDA approval for drugs from this phase of development. Source: Biomedtracker® and Pharmapremia®, 2020

Looking a little deeper into drug modality, chimeric antigen receptor T cell (CAR-T) development has seen the most success among selected novel modalities (**Figure 10**). At 17.3% (n=67), the Phase I LOA for CAR-T therapies is more than twice the 7.9% average across all diseases, and more than three times higher than the 5.3% Phase I LOA for all of oncology. Since 2017, three separate CAR-Ts have gained approval, with a total of four successful BLA transitions. The strong R&D progress in RNA interference (RNAi) therapies is reflected in the Phase I LOA for this category, second behind CAR-T at 13.5% (n=70). This class includes three approvals as of December 31, 2020, the first of which came in 2018. Monoclonal antibodies, antibody drug conjugates (ADCs), and gene therapies also each have over a 10% likelihood of approval at the Phase I stage.



**Figure 10a:** LOA from Phase I for drugs based on modality. Chart of LOA from Phase I, displayed highest to lowest by drug modality.

Phase Success	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS
CAR-T	43	44.2%	17	58.8%	3	66.7%	4	100.0%
siRNA/RNAi	40	70.0%	38	28.9%	6	66.7%	3	100.0%
Monoclonal antibody	804	54.7%	740	34.1%	310	68.1%	282	95.4%
ADCs	103	41.7%	53	41.5%	16	62.5%	12	100.0%
Gene therapy	27	51.9%	57	38.6%	10	50.0%	2	100.0%
Vaccine	129	52.7%	117	31.6%	43	58.1%	27	100.0%
Protein	246	51.6%	288	33.0%	149	61.7%	117	89.7%
Peptide	234	53.0%	218	28.4%	100	60.0%	67	88.1%
Small molecule	2308	52.6%	2896	28.0%	1118	56.9%	849	89.5%
Antisense	69	60.9%	70	20.0%	14	64.3%	9	66.7%

Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
CAR-T	67	17.3%	24	39.2%	7	66.7%	4	100.0%
siRNA/RNAi	87	13.5%	47	19.3%	9	66.7%	3	100.0%
Monoclonal antibody	2136	12.1%	1332	22.1%	592	64.9%	282	95.4%
ADCs	184	10.8%	81	25.9%	28	62.5%	12	100.0%
Gene therapy	96	10.0%	69	19.3%	12	50.0%	2	100.0%
Vaccine	316	9.7%	187	18.4%	70	58.1%	27	100.0%
Protein	800	9.4%	554	18.3%	266	55.4%	117	89.7%
Peptide	619	8.0%	385	15.0%	167	52.8%	67	88.1%
Small molecule	7171	7.5%	4863	14.3%	1967	50.9%	849	89.5%
Antisense	162	5.2%	93	8.6%	23	42.9%	9	66.7%

**Figure 10b:** LOA from Phase I for drugs based on modality. Table of phase transition success and likelihood of approval by modality with corresponding n values. The n value is the total 'Advanced or Suspended' transitions of all phases used to calculate LOA. 'POS' is the probability of successfully advancing to the next phase, whereas 'Phase LOA' is the probability of FDA approval for drugs from this phase of development. \*n values for vaccine differs slightly from Figure 9 owing to variable classification of cellular vaccines. Source: Biomedtracker® and Pharmapremia®, 2020

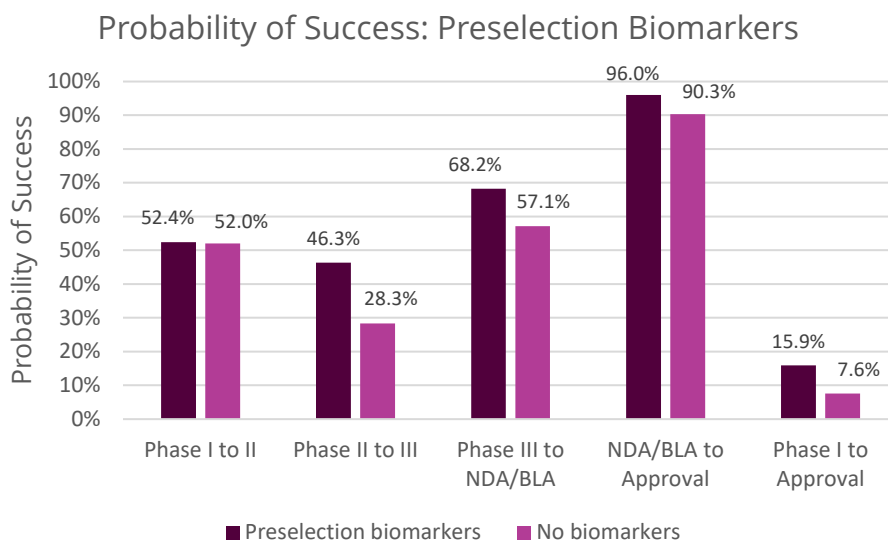
### Patient Preselection Biomarkers

A greater understanding of human disease – whether at the molecular or genomic level – ultimately leads to the investigation of personalized medicine. Indications are increasingly segmented by biomarkers in order to match patients with the treatments most likely to show the greatest benefit, according to the underlying drug mechanism and disease pathophysiology. We identified 767 phase transitions out of 12,728 (6%) that incorporated patient preselection biomarkers in their corresponding clinical trial design. This was accomplished by mapping Informa Pharma Intelligence's Biomedtracker and Trialtrove databases, to provide the supplemental level of clinical trial detail. For a detailed description please refer to the Methods section.

The LOA from Phase I segmented by biomarkers can be found in **Figure 11**. Drug development programs with trials employing patient preselection biomarkers have a two-fold higher LOA (15.9%) than those that do not (7.6%).



## Success rates by use of patient preselection biomarkers



Phase Success	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS	POS n	Phase POS
Preselection biomarkers	414	52.4%	149	46.3%	129	68.2%	75	96.0%
No biomarkers	4000	52.0%	4784	28.3%	1799	57.1%	1378	90.3%

Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Preselection biomarkers	767	15.9%	353	30.3%	204	65.5%	75	96.0%
No biomarkers	11961	7.6%	7961	14.6%	3177	51.5%	1378	90.3%

**Figure 11:** Patient preselection biomarker phase transition success rates and LOA. Top: Chart of phase transition success rates and LOA from Phase I. Bottom: Table of phase transition success and likelihood of approval by biomarker status with corresponding n values. The n value is the total 'Advanced or Suspended' transitions of all phases used to calculate LOA. 'POS' is the probability of successfully advancing to the next phase, whereas 'Phase LOA' is the probability of FDA approval for drugs from this phase of development. Source: Biomedtracker®, Pharmapremia®, and Trialtrove®, 2020

The advantage of patient preselection biomarkers varies according to the trial stage. At Phase I, there is no discernible difference between the two discrete sets, with both biomarker and non-biomarker programs achieving close to the average success rate of 52.0%. The benefit is clearly greatest at Phase II, where the use of preselection biomarkers enables 46.3% of programs to advance (n=149), compared to just 28.3% of those without. A similar advantage, albeit smaller in magnitude, is also observed with Phase III transitions – 68.2% for biomarker-supported programs vs 57.1% for those without. Success at the NDA/BLA transition is largely contingent on Phase III trial design and so this benefit carries over from the largest clinical phase.

While this analysis only represents a small subset of the overall data, the degree of difference between individual phase success rates and overall LOA from Phase I builds confidence in the pursuit of drug development programs targeted at biomarker-enriched patient populations. Such assets are likely to advance through clinical development with lower levels of attrition, and should in theory improve patient outcomes via the advent of increasingly personalized medicine.



## Part 2. Predictive Analysis of Clinical Success

In Part 1, we estimated success rates using the drug-indication pathways gathered from the Biomedtracker database. We can now incorporate additional information, called “features,” for each drug development program using machine learning methods to produce forward-looking measures—forecasts—of the outcome of ongoing programs. This type of analysis provides more timely and relevant estimates than standalone analyses of historical success rates.

Some examples of features included in this predictive analysis are the characteristics of the drug, its indication, its sponsor, and its clinical trial design. There are more than 200 features used in the QLS forecasts, a sample of which can be found in **Figure 12**. In much the same way that linear regression models employ regressors, or “right-hand-side” variables, to predict the “left-hand-side” or the dependent variable, these features contain useful signals about drug development that allow the outcomes of drug development programs to be more accurately predicted than before.

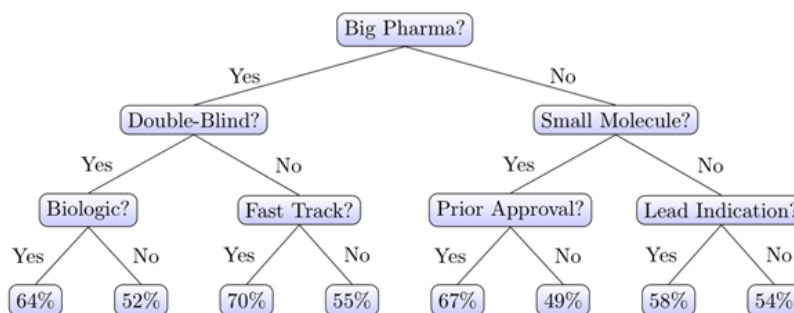
**Sample of the 200-plus features driving success rate probabilities**

Drug Features	Indication Features	Sponsor Features	Trial Features
Drug classification	Therapeutic area	Entity type	Phase
Compound type	Disease subgroup	Headquarters location	Status
Biological target	Prevalence	Number of approvals	Site locations
Mechanism of action	Incidence	Therapeutic area track record	Actual-to-target accrual ratio
Prior approvals	Prior approvals	Phase success track record	Intervention model

**Figure 12:** Sample of the 200-plus features extracted from Pharmaprojects, Trialtrove, and Biomedtracker.

The QLS approach uses state of the art machine-learning techniques to analyze clinical trial data. While the details of the QLS model are proprietary, an example of a commonly used machine-learning algorithm is a random forest classifier. The random forest classifier is an algorithm that takes the average prediction from a multitude of yes-no decision trees (i.e., a “forest”) that are applied to the features (see **Figure 13**).

When training a decision tree, one task is to learn the most informative questions to ask at each branch point of the tree. For example, the algorithm might ask, “Is the drug sponsor a big pharma company?” If the answer is “yes,” then the algorithm would move to the “yes” branch of the decision tree and then ask, “Is the trial double-blind?” On the other hand, if the answer is “no,” then the algorithm would move to the “no” branch of the decision tree, and ask, “Is the drug a small molecule?” and so on, until enough information has been collected about the drug-program to make a prediction about its success or failure. By identifying subtle patterns in a large enough database of historical drug transitions, machine-learning algorithms can often make remarkably accurate predictions. Additional details on these techniques can be found in the Methodology section.



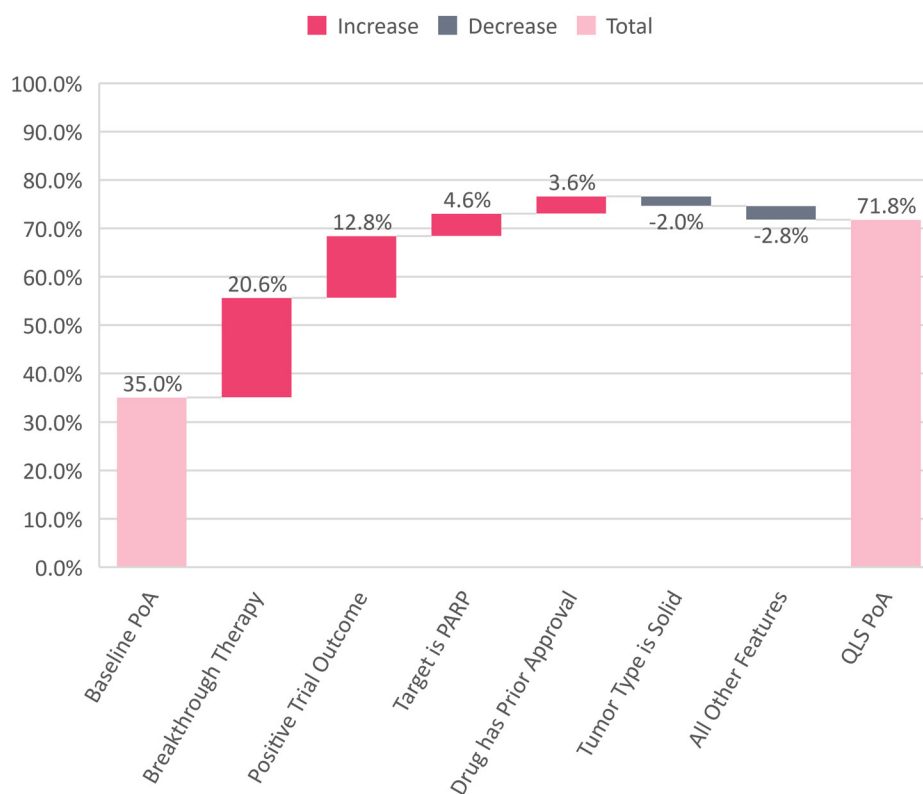
**Figure 13:** A hypothetical representation of a single, simplified decision tree. The percentages at the “leaves” of the tree denote the fraction of training data samples that are categorized by a given pathway.

## Feature Importance

Given the stakes involved in the drug development process, machine learning forecasts must not only be accurate, but also interpretable to stakeholders charged with the responsibility of making go/no-go decisions. These decision-makers need to understand why a given forecast differs from the historical average, and which features were most important in driving the difference or delta with respect to the disease-group baseline LOA. To increase the transparency of our forecasts, the QLS machine learning algorithm reports the most important features and their individual contributions to the forecast's delta.

As an illustration, we decompose our probability of approval (POA) prediction of an oncology drug that is currently in phase 3 clinical trials into its key components. (Note that we use the term POA for the QLS machine-learning forecasts to differentiate from the empirical "LOA" presented in Part I.) **Figure 14** reports the top five features that increase this program's estimated probability of approval from its therapeutic area historical baseline of 35.0% from phase 3 to approval, to 71.8%. The top positive feature driving this higher than average probability is its breakthrough therapy designation (+20.6%). This designation is granted when the FDA has determined that preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. Further positive clinical evidence in phase 2 increases the estimate by an additional +6.4%. Next, because it is a PARP inhibitor (+4.6%) that has been previously approved for another indication (+3.6%), the POA is augmented by an additional 8.2%. Finally, its treatment of a solid tumor type (-2.0%) and the net aggregate contribution of other features (-2.8%) penalize the overall POA score slightly.

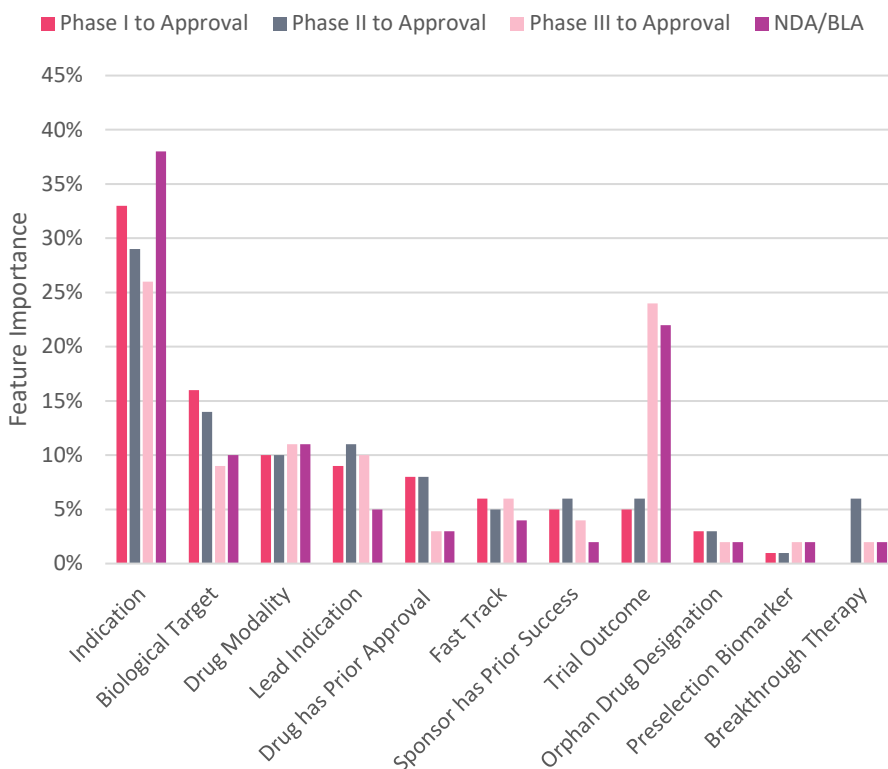
### Example of probability decomposition



**Figure 14:** Decomposition of the probability of approval estimate for an anti-cancer drug that is currently in phase 3 clinical trials for prostate cancer. The top five features that increase this program's estimated probability of approval from the historical phase 3 to approval baseline in oncology of 35.0% to 71.8% are reported. Abbreviations: POA=probability of approval; PARP= poly ADP-ribose polymerase.

Although each *individual* prediction may have unique drivers, we can also extract the most informative variables across *all* predictions to gain insight into some of the most common predictors of success. **Figure 15** summarizes our results.

### Feature importance by phase to approval



**Figure 15:** The most important features of our random forest classifier across all predictions. Feature importance is normalized to sum to 100%. Note that individual predictions may have unique drivers specific to a given therapeutic area, trial design, or drug profile that are not listed here. Source: QLS Advisors.

The indication was consistently ranked the top variable across all clinical development phases. Indeed, success rates vary substantially across indications even within a therapeutic area. For example, in oncology, the overall phase 1 to approval LOA ranges from a minimum of 1.1% (n=275) for pancreatic cancer to a maximum of 15.2% (n=33) for alimentary cancers. We also observe that lead indication status, prior approval of a drug for another indication, and biological target validation all have a significant impact on the probability of approval. In some cases, developing an already approved drug for a new indication—one that has a controlled manufacturing process, and has already been shown to be safe in humans—has a greater likelihood of success than a novel indication. In other cases, the success rates for lead indications may be higher if a sponsor initiates clinical trials for multiple follow-on indications for which the drug was not originally intended, and many of the initiated clinical trials for the same drug fail.

Analysis showed that the trial outcome (whether the trial was completed, with its primary endpoints met) has significant associations with late-stage clinical success. It is easy to imagine that a drug-indication pair whose trial failed to meet its endpoints has a low probability of success in advancing to approval. For example, as of December 31, 2020, our algorithm predicts that one specific BLA for Alzheimer’s disease has only a 65% chance of progressing from regulatory review to approval, even though historically 83% of neurology drugs have made the transition to approval once they have reached this stage. The observation that the biologic failed to meet its primary endpoints in phase 3 is the top contributor (-15%) to this adjustment from the

baseline. In contrast, candidates that achieve positive outcomes have a higher probability of success.

The use of patient pre-selection biomarkers in clinical trials has become more common, and it has been reported that trials using biomarkers are more likely to succeed.<sup>3</sup> Consistent with these findings, **Figure 15** shows that the use of patient pre-selection biomarkers has an important impact on success rates. For example, in the past decade, the number of non-targeted therapies in oncology has declined, while the use of targeted agents and pre-selection biomarkers has risen dramatically. Between 2016 and 2020, 85% (n=136) of oncology approvals were targeted agents. Moreover, 37% (n=51) involved either pre-selection against a driver mutation (26%; n=36) or pre-selection using a tumor-specific antigen (11%; n=15).

In **Figure 15**, drug modality can be seen as another important predictor of success. As an illustrative example, monoclonal antibodies have had higher phase-1-to-approval success rates (5.9%; n=935) than other modalities within oncology. Moreover, immunotherapies focused on PD-1 or PD-L1 have been tremendously successful from phase I (23.9%; n=71). In contrast, other immunotherapies, while numerous, have been much more likely to result in failure from phase I (1.9%; n=945).

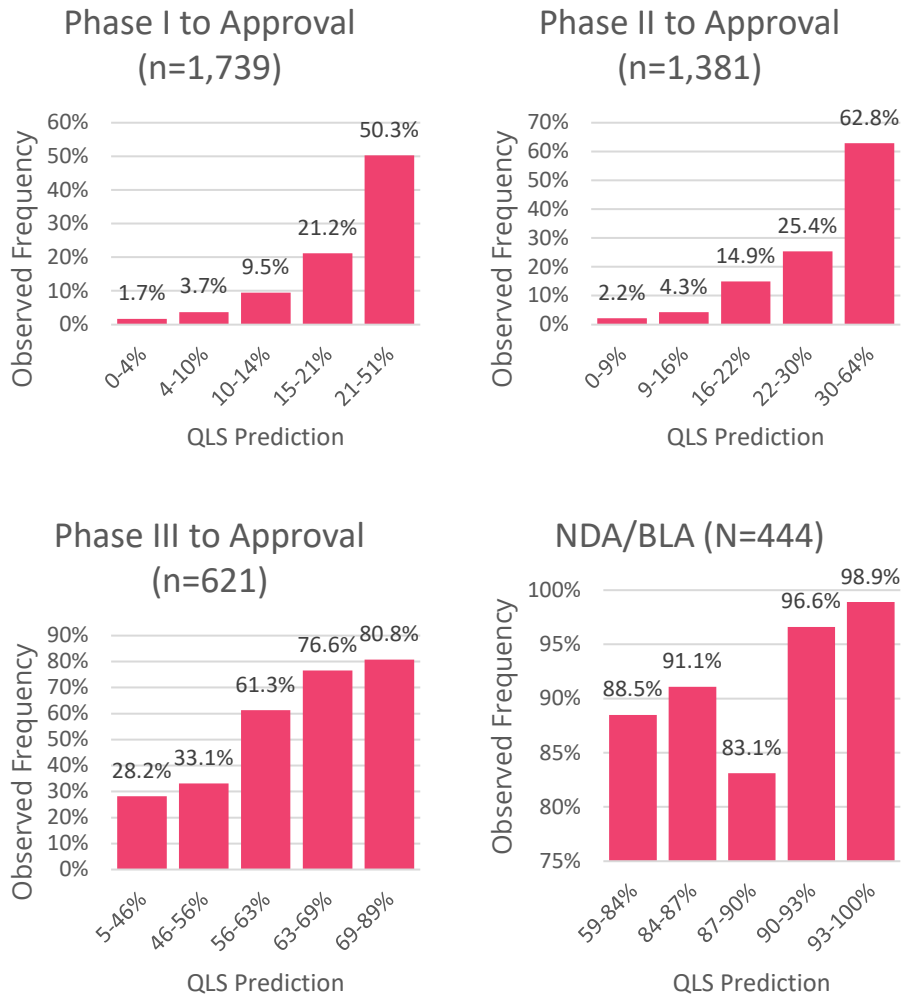
Finally, we find that sponsor track record, quantified by the number of previous successful phase transitions in a given therapeutic area, is also a useful indicator for clinical program predictions. The positive correlation between track record and future success is likely associated with operational experience in conducting clinical trials and navigating the regulatory review process.

## Performance

How well does machine learning predict success? A number of criteria have been proposed to measure machine learning performance, some of them highly complex, but perhaps the most straightforward metric is to see how many correct and incorrect predictions there are on an out-of-sample data set. We analyzed the accuracy of our machine learning predictions by first splitting our dataset into a training set (80%) and an out-of-sample test set that consisted of the most recent 20% of data. **Figure 16** summarizes the results for predictions for drug development programs transitioning through approval. We found that drugs with higher probability estimates were more likely to be approved. Moreover, the predictions were relatively well calibrated; when the model predicted a drug-indication pair had a certain probability of approval, the drug was subsequently approved at approximately the same rate.

<sup>3</sup>Wong CH, Siah KW, Lo A (2019). Estimation of clinical trial success rates and related parameters. *Biostatistics*, 20(2), 273–286. doi: 10.1093/biostatistics/kxx069

### Forecasted vs. actual success rates



**Figure 16:** Histogram of machine-learning forecasts of drug development programs transitioning to approval using the most recent 20% of our dataset. Higher forecasts are associated with higher rates of approval, which indicates positive forecast power. Estimates for each phase are grouped into quintiles.

However, the results also demonstrate that these predictions are by no means perfect. There is considerable noise in these estimates. In certain cases, our model tends to slightly underestimate the approval rates in the most recent out-of-sample period. For example, success rates in oncology have been increasing, concurrently with the emergence of genomic technologies, an improved scientific understanding of cancer biology and ways to disrupt cancer cells, as well as an evolving regulatory environment that includes a higher number of accelerated approvals. As we incorporate more data, more features, and the latest scientific and medical knowledge into the algorithm, these forecasts will improve, which will occur naturally over time as these methods become more popular. The QLS model is trained on the full dataset, which includes the most recent development programs and approvals.

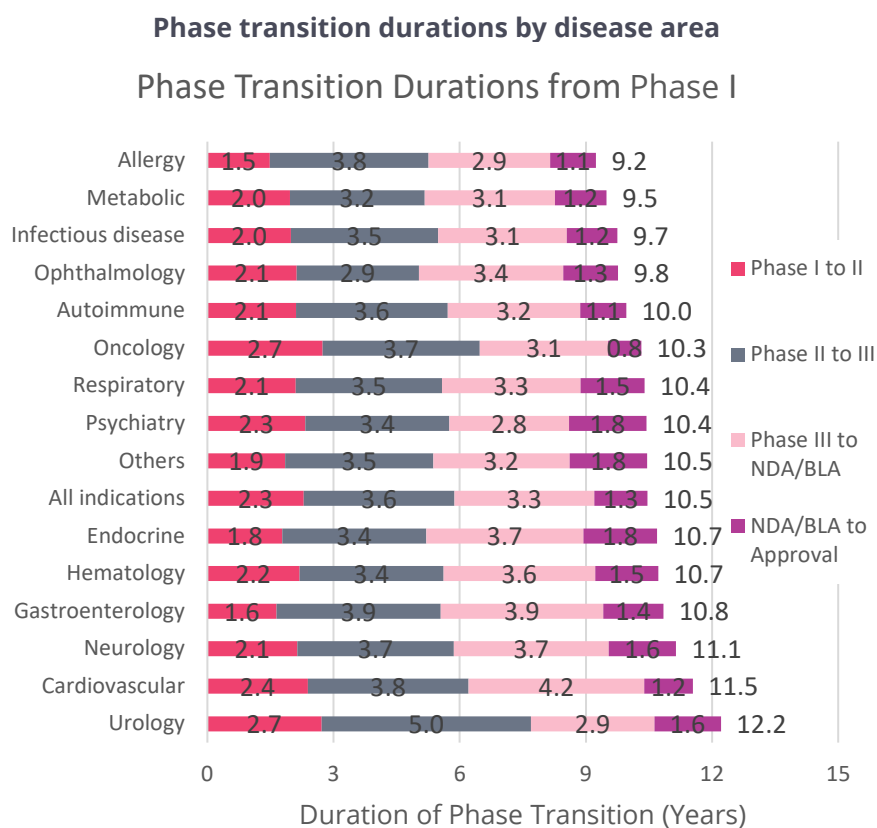
### Part 3. Drug Development Timelines

In addition to determining whether drugs are advanced or suspended at the end of a phase transition, the Biomedtracker and Pharmapremia data can also be analyzed to yield time spent at each clinical stage, and overall drug development timelines. These are valuable metrics as there are considerable opportunity costs associated with investing in an R&D process that may take up to a decade, and a simple analysis of clinical trial durations excludes the contribution of internal decision making and strategic execution from the overall timeline.

Based on 6,151 successful phase transitions over the 2011–2020 period, it took an average of 10.5 years for a drug to successfully progress from Phase I development to regulatory approval. This includes 2.3 years at Phase I, 3.6 years at Phase II, 3.3 years at Phase III, and 1.3 years at the regulatory stage.

Phase duration can vary greatly according to numerous factors, such as disease area and indication, best practices of clinical trial design, and patient availability. Accordingly, **Figure 17** evaluates drug development timelines for the major 14 categorized disease areas.

Disease areas with above-average LOAs tend to be associated with shorter development timelines. Five of the seven best-performing disease areas by LOA fall beneath the 10.5-year average development duration, including all four groups with a duration of less than 10 years (Allergy, Metabolic, Infectious disease, and Ophthalmology). Conversely, the remaining disease areas, with below average LOAs, either have durations that lie very close to the 10.5-year average duration, or in the case of Urology, Cardiovascular and Neurology, notably exceed the average.



**Figure 17a:** Phase transition durations from Phase I by disease area. Chart of phase transition duration from Phase I for all diseases. Source: Biomedtracker® and Pharmapremia®, 2020

Phase Duration	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	Advanced	Duration	Advanced	Duration	Advanced	Duration	Advanced	Duration
Allergy	31	1.5	26	3.8	22	2.9	20	1.1
Metabolic	84	2.0	67	3.2	42	3.1	42	1.2
Infectious disease	233	2.0	159	3.5	126	3.1	145	1.2
Ophthalmology	63	2.1	71	2.9	42	3.4	41	1.3
Autoimmune	228	2.1	148	3.6	143	3.2	190	1.1
Oncology	795	2.7	426	3.7	236	3.1	298	0.8
Respiratory	100	2.1	47	3.5	40	3.3	43	1.5
Psychiatry	79	2.3	44	3.4	40	2.8	52	1.8
Others	98	1.9	88	3.5	54	3.2	61	1.8
All indications	2296	2.3	1424	3.6	1115	3.3	1316	1.3
Endocrine	138	1.8	78	3.4	100	3.7	107	1.8
Hematology	64	2.2	51	3.4	63	3.6	67	1.5
Gastroenterology	21	1.6	25	3.9	20	3.9	30	1.4
Neurology	246	2.1	135	3.7	120	3.7	143	1.6
Cardiovascular	107	2.4	53	3.8	58	4.2	66	1.2
Urology	9	2.7	6	5.0	9	2.9	11	1.6

**Figure 17b:** Table of phase transition duration by disease area with corresponding n values. The n value is the total 'Advanced' transitions within each phase used to calculate duration. The ordering of disease areas is equivalent to the total years overall in clinical development. Source: Biomedtracker® and Pharmapremia®, 2020

Within each individual phase, there are some noteworthy performers. Oncology shares the longest Phase I transition at 2.7 years with Urology, but it is remarkably close to the Phase II and III averages with durations of 3.7 and 3.1 years, respectively. It is also the only disease area to have an average regulatory review of less than 1 year; the 0.8-year duration is almost half as short as the cumulative total for all non-Oncology indications (1.4 years).

Urology drug candidates experience the longest Phase II transition (5.0 years), although this average is calculated from a sample size of just six. Excluding Urology, the remaining disease areas all lie close to the average transition of 3.6 years. Ophthalmology emerges as the fastest disease area for Phase II research (2.9 years).

When looking at Phase III timelines, Cardiovascular drug programs have the longest duration, extending to 4.2 years. The large cardiovascular patient population sizes in trials and the long-term evaluation of cardiovascular outcomes contribute to longer timelines than seen in other highly prevalent diseases, such as Psychiatry (2.8 years), which typically assesses short-term symptomatic improvement using rating-scale questionnaires.



## Discussion

### Comparison with previous reports on attrition rates

In 2016, BIO published a major report on industry attrition rates using Biomedtracker's data from 2006 to 2015 for 9,985 phase transitions, revealing an overall LOA of 9.6% for an asset entering Phase I development. This report analyzed 12,728 transitions from 2011 to 2020 and revealed a lower overall LOA of 7.9%. While the underlying data and analyses are consistent, we caution against direct comparison between the two top-line LOA numbers.

Among the additional ~2,750 phase transitions in this analysis, a sizable portion can be attributed to industry expansion, with more companies (1,779 vs 1,103) and a larger pipeline (9,704 programs vs 7,455) in the dataset. Additionally, increased demand from investors for disclosures on drug pipeline progress has resulted in timelier reporting of suspended programs. Furthermore, the time period examined in this report includes more rigorous scrutiny of the Biomedtracker database. The result is a stronger account of failed transitions in the 2011–2020 analysis vs the 2006–2015 analysis. In particular, this has resulted in a notable correction in the calculation of success rates for the Phase I transition, where drugs can lie dormant or unreported for many years, lowering the success rate from 63.2% during 2006–2015 to 52.0% in 2011–2020. Transition rates at Phase II and III are closer, albeit slightly lower in this update (28.9% vs 30.7%; 57.8% vs 58.1%). Regulatory approval moved in the other direction, increasing from 85.3% to 90.6%

### Comparing current success rates with prior publication

Likelihood of Approval	2016		2021	
	Phase I to Approval	N	Phase I to Approval	N
Hematology	26.1%	283	23.9%	352
Metabolic	15.3%	241	15.5%	399
Infectious disease	19.1%	916	13.2%	1170
Others	16.3%	301	13.0%	541
Ophthalmology	17.1%	267	11.9%	415
Autoimmune	11.1%	837	10.7%	1305
Allergy	14.7%	107	10.3%	201
Gastroenterology	15.1%	156	8.3%	186
All indications	9.6%	9985	7.9%	12728
Respiratory	12.8%	428	7.5%	501
Psychiatry	6.3%	451	7.3%	442
Endocrine	13.2%	791	6.6%	887
Neurology	8.4%	1304	5.9%	1411
Oncology	5.1%	3163	5.3%	4179
Cardiovascular	6.6%	632	4.8%	651
Urology	11.4%	108	3.6%	88

**Figure 18:** Comparing current success rates (2011–2020) with prior publication (2006–2015). Disease areas ranked by the latest LOA results from high to low. See Appendix for a breakdown of individual phase success rates

The observations and takeaways of the 2016 report remains as relevant today as they did in 2016, even accounting for the changes from these improved calculations. The leading factors that correlate with higher success rates remain consistent: clinical validation of a target (e.g., whether a drug with the same mechanism of action has been previously approved), biologic modality (e.g., mAbs), patient population and selection strategy (e.g., rare diseases with detectable gene mutations).



### **Oncology: largest segment of industry, modest success rates**

Oncology continues to possess the largest portion of the 12,728 phase transitions over 2011–2020, even though it has the lowest Phase I LOA (5.3%). Despite our caution against direct comparisons with the 2016 paper, Oncology was one of the few major disease areas to increase its LOA, growing marginally from 5.1% in the previous analysis. In addition to the emergence of IO therapeutics, other drivers of improved success may be due to an increase in biomarker-defined patient populations, and the success of novel drug modalities (CAR-T, ADCs, etc.). That being said, the overall performance of Oncology is still considerably below the industry average (7.9%) and non-oncology indications (9.3%). There is also no substantial benefit to many Oncology indications being classified as rare diseases, as the rare Oncology subset only carries a Phase I LOA of 6.8%. These findings indicate that scientific complexity and the competitive dynamic that characterize this therapy area continue to have an adverse impact on the success rates for oncology therapies. This has not dissuaded investment within Oncology, with nearly half of all venture capital going into cancer companies by the end of the last decade.<sup>4</sup>

### **Challenges for Phase II proof-of-concept drive overall performance**

The Phase II transition is clearly the main translational and limiting step from bench to bedside, as proof-of-concept is only established in 28.9% of drug programs at this stage. Phase II also sees the greatest distribution between major disease areas, with a three-fold difference spanning Urology (15.0%) and Hematology (48.1%) at opposite ends of the spectrum. Within these disease areas, it is the performance of “novel” drug classes – NMEs (New Molecular Entities), biologics, and vaccines – that have the most significant negative contribution to low overall LOA success rates, as the “off-patent” grouping relies on duplication of established science.

Hematology retains a dominant position largely on the strength of hemophilia research, which accounts for the largest number of transitions within the disease area. In the case of hemophilia A, where the underlying biology is extremely well characterized, 32 of 34 of phase transitions have been successful, including all six at Phase II development. The other main hematologic disease, anemia (which includes several different sub-indications), also has notably above-average success rates.

Conversely, Cardiovascular saw a large numbers of failed Phase II transitions for novel drug candidates, with an overall rate of just 21.0%. Compared to the other major disease areas such as Oncology and Autoimmune, there is relatively little penetration of biologics within Cardiovascular, where novel drug discovery is commonly centered on oral small molecules. Of the 507 Cardiovascular development programs in the Biomedtracker dataset, there are just 98 biologics vs 321 NMEs. This approximate 1:3 ratio is far lower than Autoimmune therapies which have a ratio of 1:1 and a LOA of 10.7%. As noted in **Figure 9**, NMEs underperform biologics considerably, including at the critical Phase II transition. For biologics, there is typically a stronger relationship between disease state and drug mechanism, enabling a stronger proof-of-concept.

Neurology is an interesting example where the Phase II transition rate (26.8%) is relatively close to the industry average, with most of the developmental risk realized later in Phase III studies. Clinical development programs for neurodegenerative diseases are often able (or designed) to find adequate justification from biomarker data to progress into late-stage trials, without having a clinical proof-of-concept on clinically validated endpoints. The resulting effect is underperformance in the Phase III and NDA/BLA transitions, dragging down the overall Phase I to LOA success rate for this disease category to 5.9%

### **Characteristics of rare disease R&D not found in highly prevalent chronic disease**

Throughout the last decade, industry investment and drug development have pivoted towards rare, congenital diseases. Specific examples of clinical and commercial successes have encouraged this transition. Drivers of these successes include targeting molecularly defined causes of disease, regulatory incentives, and favorable reimbursement environments. However, as these drivers of success are absent from chronic, highly prevalent diseases, investment for these indications has waned over the same period, with notable

<sup>4</sup>BIO (2020) Emerging Therapeutic Company Investment and Deal Trends. Available [here](#) [Accessed 15 January 2021].

large company exits in psychiatric and cardiovascular medicine. BIO has covered the state of innovation in these areas in a series of industry analysis reports.<sup>6,7,8</sup>

One large difference between this 2011–2020 dataset and the previous 2006–2015 iteration is the intensifying focus on rare diseases. Our latest analysis includes 1,256 phase transitions within rare diseases, a considerable increase over the 521 noted in the previous study. This spans 685 different lead developers (not including those listed solely as partners). This indicates that companies view pivoting to rare disease clinical development as a sound strategy.

While notably more successful than industry averages – and in particular chronic, highly prevalent diseases – the increasing breadth of rare disease R&D is leading to a reduction in overall success. Our calculated Phase I LOA of 17.0%, slightly over double the industry average (7.9%), represents a notable fall from the 25.3% reported in 2016. As the number of programs has grown, so has the number of rare diseases that are being addressed for the first time by therapeutic modalities where less is known about their biology and pathology. In other cases, there are new difficulties in targeting the root cause. Nevertheless, rare disease R&D remains an attractive area for investment, combining a large unmet need with commercial potential, supported by regulatory incentives and above-average clinical success rates.

### Complexity of modality correlates with higher LOA

As an approximate rule, the increasing chemical complexity of the therapeutic being tested is associated with higher rates of phase success, as shown in **Figure 10**. In the past ten years the proportion of complex biologics in the clinical pipeline has steadily expanded from 25% to 40%.<sup>9</sup> However, this trend has not been enough to boost overall industry rates beyond a 10% LOA, as simpler small molecules remain the majority. These account for 57% of the 12,728 phase transitions included in this analysis, with a modest 7.5% Phase I LOA.

Monoclonal antibodies, which entered routine clinical practice three decades ago, have considerably improved LOAs (12.1%) when compared to the drug classes that came before – small molecules (7.5%), peptides (8.0%), and proteins (9.4%). Since then, numerous new classes have emerged that have not yet had a comparable transformational impact, including gene therapies and antibody-drug conjugates. However, recent advances with CAR-T cell therapies and RNA interference are yielding industry-leading LOAs of 17.3% and 13.5%, respectively.

Advanced biologic therapies possess the intrinsic benefit of being precise tools for manipulating human biology and are reserved for indications where there is a clear pathophysiology. Additionally, they are also more likely to benefit indirectly by association with other factors that are highly predictive of success, including regulatory designation, biomarker-enriched patient populations, and reduced competition. On the last point, commercial maturity is one important factor that leads to pipeline attrition. Investment decisions and portfolio prioritization reflect the competitive scenario, so we should realistically expect strategic and clinical suspensions to increase over time. It will be interesting to see whether CAR-T and RNA interference approaches can sustain such remarkable LOAs as fast-followers enter the clinic and attempt to extend the technology into new, unproven treatment settings. Success rates can eventually wane over time as sample sizes increase.

### Contributors of clinical success and predictive analytics

While recent breakthrough therapeutics offer new hope for patients, they have also made biomedical innovation more complex, riskier, and more expensive. In the face of multiple growing uncertainties, the

<sup>5</sup> Thomas D, Wessel C (2019). The State of Innovation in Highly Prevalent Chronic Diseases Volume V: Systemic Hypertension and Heart Failure. Available [here](#) [Accessed 15 January 2021].

<sup>6</sup> Thomas D, Wessel C (2018). The State of Innovation in Highly Prevalent Chronic Diseases Volume II: Pain and Addiction Therapeutics. Available [here](#) [Accessed 15 January 2021].

<sup>7</sup> Thomas D, Wessel C (2017). The State of Innovation in Highly Prevalent Chronic Diseases Volume I: Depression Therapeutics. Available [here](#) [Accessed 15 January 2021].

<sup>8</sup> Lloyd I (2020) Pharma RD Annual Review 2020 Whitepaper. Available [here](#) [Accessed 15 January 2021].

need for greater accuracy in predicting clinical trial outcomes has also grown. More accurate forecasts mean fewer drug failures, faster approval times, a lower cost of capital, and more funding available to bring new and better therapies to patients sooner.

When managing their portfolios of investigational drugs, biopharma companies typically use simple historical averages of regulatory approval rates, based on backward-looking relative frequencies of approval. While these historical averages contain useful insights, they do not take into account the many important predictive features related to therapeutic modality, trial design, sponsor track record, or other characteristics specific to the indication. Drug and device developers need to be able to accurately evaluate the impact of key drivers on the probability of success to efficiently allocate capital to opportunities with the highest potential. In this report, we demonstrate how machine learning techniques can be used to fully exploit all available data.

The relative importance of individual features in our predictive models find that trial outcome, regulatory designation, prior approval for another indication, the use of patient pre-selection biomarkers, drug modality, and sponsor track record are all critical features for predicting success in our set of more than 200 features. Because these classifiers are nonlinear, there is no simple interpretation of the contribution of each predictor to the forecast. However, the intuition behind some of these factors is clear. For example, drug-indication pairs with trials that achieve positive outcomes should have a greater chance of approval; candidates sponsored by companies with strong track records and diverse expertise in drug development should have a higher likelihood of success; and already approved drugs should have higher chances of approval for a second related indication.

When applied to out-of-sample data, the QLS forecasts show that candidates with higher probabilities were indeed more likely to be approved, indicating that our models are able to discriminate between high- and low-probability candidates. These promising results suggest the possibility of even more powerful predictive models with the inclusion of more refined drug development data, including patient-level clinical trial data. Ultimately, such predictive analytics have the potential to facilitate more informed data-driven decisions about the risk assessment and portfolio management of investigational drugs at all clinical stages.

### **Increasing duration in clinical development typically carries an elevated risk**

The average timeline from Phase I to approval over 2011–2020 was 10.5 years. This lengthy timeframe is a significant risk to investors and entrepreneurs, and speaks to the current complexities of today's clinical drug development. This risk is compounded with the correlation of longer timelines in certain disease areas with greater pipeline attrition rates. For example, Urology and Cardiovascular carry both the longest clinical program durations (12.2 years and 11.5 years) and the lowest LOAs from Phase I (3.6% and 4.8%). This may partly be attributed to highly prevalent diseases requiring longer enrollment times and more complex endpoints. The average time to run an Alzheimer's Phase II trial is not going to be as short as a Phase II trial for a Covid-19 antibody. However, for some of the more complex diseases, the failure to terminate R&D programs when the data do not support further progression can add significantly to the duration recorded for a particular phase. There are countless examples of studies yielding inconclusive results, necessitating further clinical investigation and prolonging the duration within a given phase, only for the drug to subsequently fail again.

Oncology timelines were found to have unique characteristics. Although the overall oncology development time is close to the average (10.3 years vs 10.5 years), the length of each constituent phase varies considerably from the average. Its Phase I duration (2.7 years) is the longest of all major disease areas, while its NDA/BLA filing transition is the shortest (0.8 years). Oncology drug developers have broadly adopted the basket trial design at Phase I, whereby multiple different indications are studied in a single trial to evaluate potential efficacy signals, before expansion cohorts are initiated, either within the same trial or in a new Phase II study. At the US FDA, the Office of Oncologic Diseases in particular has led the use of expedited pathways and predictive endpoints, as well as Real Time Oncology Review (RTOR), facilitating the transition of new cancer drugs that address unmet clinical needs.

## Methods

**Drug Development Programs** analyzed in this report track a specific indication for each drug. For example, Rituxan in non-Hodgkin's lymphoma (NHL) qualifies as a different development path than Rituxan in multiple sclerosis (MS). Biomedtracker assigns a unique internal identifier that can be used to isolate all development paths.

In addition to tracking the phase of development, Biomedtracker also assigns "lead" status to certain development paths. This is used to denote the most advanced indication in clinical development for a specific drug. Drugs can only have one lead development program (with some rare exceptions). For example, cancer drugs developed in multiple indications will have the most advanced program assigned as the lead, and the rest as "non-lead". However, in this report we do not differentiate the most advanced programs and analyze the data on a program/development path level, which more accurately reflects company resource utilization.

**Individual Phase Transition Success Rates** were calculated as the number of drugs that moved from one phase to the next phase divided by the sum of the number of drugs that progressed to the next phase and the number of drugs that were suspended. The n value associated with the phase transition success rates represents the number of drugs that have advanced plus the number of drugs that have been suspended, which we label as phase transitions. Phase transition success rates reported in this study were based on transition rates, not necessarily resulting from safety or efficacy data. Transition rates are negatively impacted by early development termination due to commercial and regulatory uncertainty as well as economic and portfolio management decisions.

Biomedtracker further classifies events by phase of development, summarized in the table below:

Biomedtracker phase	Description for purposes of the study
I	Drug is currently in Phase I
I/II, II, IIb	Drug is currently in Phase II
II/III, III	Drug is currently in Phase III
NDA/BLA	Application for approval has been submitted to the FDA and is currently under review
Approved, Withdrawn from Market, Approved (Generic Competition)	Drug has been approved for marketing in the United States
Suspended	Drug is no longer in development
Approved in Europe, Approved in other than U.S./E.U., Development, Development Outside U.S.	The company developing this drug does not plan to market it in the United States

Generic products were not included, but generic manufacturers developing novel investigational drugs were represented. Biosimilars, which require thorough clinical development, were also included.

**Likelihood of Approval (LOA)** denotes the probability of reaching FDA approval from the current phase and is also expressed as a percentage. LOA is calculated as the product of each phase success probability leading to FDA approval. The n value associated with LOA is the sum of the n values for each phase transition included in the LOA calculation.

For example, if a drug is currently in Phase II, and the phase success for Phase II is 50% (n=10), Phase III is 50% (n=10), and FDA approval is 50% (n=10), then the LOA for the Phase II drug would be 12.5% ( $50\% \times 50\% \times 50\% = 12.5\%$ , n=30).

**Data Source for Drug Program Transitions.** Data used for this study were extracted from Biomedtracker



using Pharmapremia, a purpose-built Probability of Technical Success (PTS) tool, which identified all 'Advanced' and 'Suspended' drugs by development phase from January 1, 2011, to November 30, 2020. Biomedtracker and Pharmapremia, subscription-based products of Informa, track the clinical development and regulatory history of investigational drugs to assess their Likelihood of Approval (LOA) by the FDA. Biomedtracker is populated in near real-time with updated information from press releases, corporate earnings calls, investor and medical meetings, and numerous other sources. These data are recorded in Biomedtracker and tagged with a date. Biomedtracker also uses other sources, including regular communication with companies conducting clinical trials, to enhance the accuracy and timeliness of the data.

**Drug Classification Methods.** Biomedtracker records FDA classification (i.e., new molecular entity (NME), non-NME, biologic, or vaccine) as well as the biochemical profile (e.g., small molecule, monoclonal antibody, peptides, natural proteins, antisense, vaccine, etc.). Biologics, as defined by the FDA, can be sugars, proteins, or nucleic acids, or complex combinations of these substances, or may be living entities such as cells and tissues.

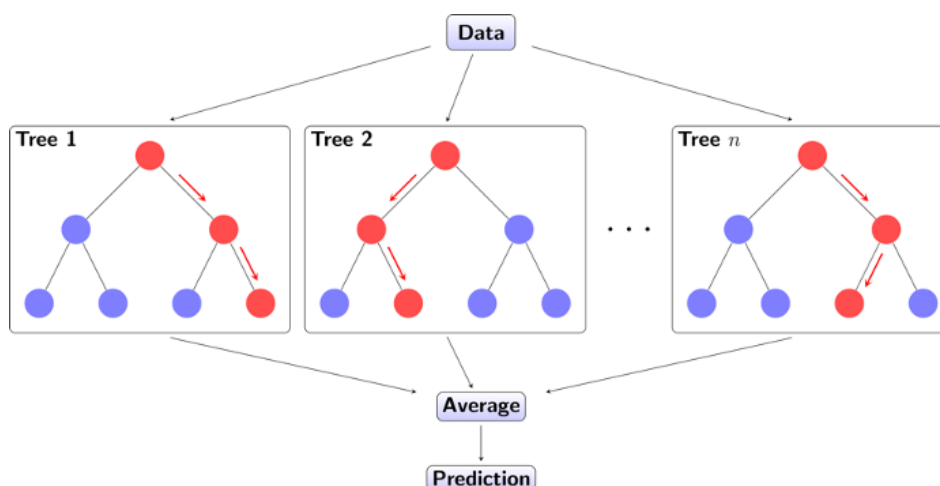
**Patient Preselection Biomarkers.** A subset of the Biomedtracker phase transition data was matched with corresponding entries in Trialrove, an analyst-curated clinical trial database produced by Informa Pharma Intelligence. Where available, NCT numbers (ClinicalTrials.gov) from Biomedtracker for each drug-indication pair was matched according to the corresponding entry in Trialrove, which contains additional information on whether patient preselection biomarkers featured in the trial design. This includes trials incorporating pharmacogenomic and/or pharmacogenetic analysis, including the use of genomic biomarkers (RNA, DNA) for patient selection or stratification. Qualifying trials were also matched by their corresponding phase of clinical development and timing, with completion dates occurring in advance of the subsequent phase transition. Phase transitions for which an associated biomarker-augmented trial could be identified were assigned accordingly, while those that either featured trials without confirmed patient preselection, or for which no information could be identified, were marked as not having patient preselection biomarkers. NDA/BLA transitions were assumed to feature patient preselection biomarker data if the Phase III transitions qualified as such.

**Drug Development Timelines.** In addition to denoting whether a drug was advanced or suspended at the end of a phase, Pharmapremia also calculates the time spent at each clinical or regulatory phase for all successful transitions. Suspended program timelines were not included to assess timelines. This is the duration between public disclosures of the initiation of appropriate stages, and as such does not map exactly to clinical trial timings. Each clinical phase transition may encompass more than one clinical trial, which may or may not run sequentially. Furthermore, there may be an additional delay between planning development strategy, reporting of trial results, the decision to progress or suspend, and the public disclosure of this information.

**QLS Methodology.** As in the case of estimating historical success rates, missing data is a significant challenge when applying machine-learning algorithms to predicting clinical trial outcomes. Gathering and filling in this missing data manually is expensive, time-consuming, susceptible to error, and, in many cases, simply not possible because the missing data no longer exist. A typical solution is to discard any clinical trials or drug-indication pathways with missing features. However, this approach eliminates a great deal of useful information, and can lead to biased inferences in the analysis. A more elegant solution involves replacing it with substituted values obtained through various imputation methods. One approach is a statistical technique called the k-nearest neighbors algorithm, in which the missing data are replaced with the average of the k "most similar" (i.e., closest) examples in the data set. For example, if one were replacing a square of missing bathroom tile, the k-nearest neighbors algorithm using a k of 8 would suggest the replacement tile should have the color average of the eight tiles surrounding the missing piece.

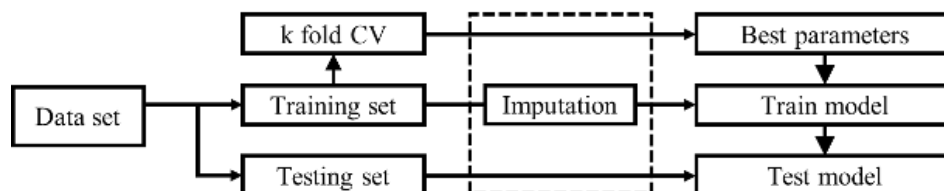
Once the missing information has been imputed, the QLS approach uses a proprietary machine-learning algorithm to analyze the clinical trial data, including its additional features. While the details of the QLS model

are proprietary, an example of a commonly used machine-learning algorithm is a random forest classifier. The motivation for a random forest is to aggregate the predictions of many different decision trees, each of which is trained over a randomized subset of variables (see figure below). While each individual tree is a weak predictor, their collective average forms a strong predictor, similar to the 'wisdom of crowds' that determines the market price of a financial asset. For example, consider a specific dataset of clinical trials in which the successful trials are more frequently associated with big pharma companies having three or more oncology drugs approved over the past five years, all of which were biologics rather than small molecules. The collection of decision trees that form a random forest might recognize this pattern and predict that a small biotech company with no previous drug approvals will have a lower probability of success than a company that more closely fit the profile described in the previous sentence.



A "forest" of decision trees. Each individual tree is a weak predictor, but similar to the wisdom of crowds, their ensemble average forms a strong predictor.

By identifying subtle patterns in a large enough database of historical drug transitions, machine-learning algorithms can often make remarkably accurate predictions. An illustration of the components of the QLS approach is provided below.<sup>9</sup>



Modeling methodology adopted by QLS. Abbreviations: CV=cross-validation.

<sup>9</sup> We use Citeline data provided by Informa Pharma Intelligence, a superset of the most commonly used data sources in the industry. It combines individual clinical trial information from Trialrove and drug approval data from Pharamprojects and Biomedtracker, in addition to incorporating multiple data streams, including nightly feeds from official sources such as ClinicalTrials.gov. We restrict our analysis to drugs being developed for the U.S. market and seeking U.S. FDA approval using Pharamprojects' manually curated Drug Program Landscape data field.

## Appendix

### Comparison of phase success for the 2016 vs. 2021 publications, ranked by 2021 phase success

Phase Success	2016		2021	
	Phase I to Phase II	N	Phase I to Phase II	N
Ophthalmology	84.8%	66	71.6%	88
Hematology	73.3%	86	69.6%	92
Others	66.7%	96	63.6%	154
Metabolic	61.1%	95	61.8%	136
Infectious disease	69.5%	347	57.8%	403
Allergy	67.6%	37	56.4%	55
Respiratory	65.3%	150	55.9%	179
Autoimmune	65.7%	297	55.2%	413
Psychiatry	53.9%	154	52.7%	150
<b>All indications</b>	<b>63.2%</b>	<b>3582</b>	<b>52.0%</b>	<b>4414</b>
Cardiovascular	58.9%	209	50.0%	214
Oncology	62.8%	1222	48.8%	1628
Neurology	59.1%	462	47.7%	516
Gastroenterology	75.6%	41	46.7%	45
Endocrine	58.9%	299	43.3%	319
Urology	57.1%	21	40.9%	22

Phase Success	2016		2021	
	Phase III to NDA/BLA	N	Phase III to NDA/BLA	N
Hematology	75.0%	64	76.8%	82
Urology	71.4%	21	69.2%	13
Endocrine	65.0%	143	66.2%	151
Autoimmune	62.2%	135	65.3%	219
Allergy	71.4%	14	64.7%	34
Respiratory	71.1%	45	64.5%	62
Infectious disease	72.7%	150	64.0%	197
Metabolic	71.4%	35	63.6%	66
Others	69.6%	46	60.0%	90
<b>All indications</b>	<b>58.1%</b>	<b>1491</b>	<b>57.8%</b>	<b>1928</b>
Gastroenterology	60.6%	33	57.1%	35
Psychiatry	55.7%	70	56.3%	71
Cardiovascular	55.5%	110	55.2%	105
Neurology	57.4%	216	53.1%	226
Ophthalmology	58.3%	60	51.2%	82
Oncology	40.1%	349	47.7%	495

Phase Success	2016		2021	
	Phase II to Phase III	N	Phase II to Phase III	N
Hematology	56.6%	83	48.1%	106
Metabolic	45.2%	84	45.0%	149
Others	39.7%	116	38.6%	228
Infectious disease	42.7%	286	38.4%	414
Ophthalmology	44.6%	101	35.5%	200
Gastroenterology	35.7%	56	34.2%	73
Autoimmune	31.7%	319	31.4%	471
<b>All indications</b>	<b>30.7%</b>	<b>3862</b>	<b>28.9%</b>	<b>4933</b>
Allergy	32.5%	40	28.3%	92
Psychiatry	23.7%	169	26.8%	164
Neurology	29.7%	465	26.8%	504
Endocrine	40.1%	242	26.6%	293
Oncology	24.6%	1416	24.6%	1732
Respiratory	29.1%	196	21.9%	215
Cardiovascular	24.1%	237	21.0%	252
Urology	32.7%	52	15.0%	40

Phase Success	2016		2021	
	NDA/BLA to Approval	N	NDA/BLA to Approval	N
Allergy	93.8%	16	100.0%	20
Respiratory	94.6%	37	95.6%	45
Autoimmune	86.0%	86	94.1%	202
Hematology	84.0%	50	93.1%	72
Infectious disease	88.7%	133	92.9%	156
Oncology	82.4%	176	92.0%	324
Psychiatry	87.9%	58	91.2%	57
Ophthalmology	77.5%	40	91.1%	45
Gastroenterology	92.3%	26	90.9%	33
<b>All indications</b>	<b>85.3%</b>	<b>1050</b>	<b>90.6%</b>	<b>1453</b>
Others	88.4%	43	88.4%	69
Metabolic	77.8%	27	87.5%	48
Neurology	83.2%	161	86.7%	165
Endocrine	86.0%	107	86.3%	124
Urology	85.7%	14	84.6%	13
Cardiovascular	84.2%	76	82.5%	80

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**QLS:** Shomesh Chaudhuri, Robert Bowden, Andrew W. Lo





This is Exhibit "G" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

## **Antibe Announces FDA Clinical Hold on Otenaproxesul and Legal Action by Nuance**

TORONTO--(BUSINESS WIRE)--April 1, 2024--Antibe Therapeutics Inc. (“Antibe” or the “Company” TSX: ATE, OTCQX: ATBPF) today announced that it received verbal notice on the afternoon of March 28, 2024 from the U.S. Food and Drug Administration (“FDA”) that otenaproxesul has been placed on clinical hold, postponing the initiation of the planned Phase II trial. Antibe expects to receive a formal Clinical Hold Letter from the FDA within 30 days outlining their rationale and further details.

Separately, the Company announced that Nuance Pharma Limited has commenced legal action in the Ontario Superior Court of Justice to seek recognition of and enforce the arbitration award in Ontario previously announced by Antibe in its press release of March 4, 2024. Nuance Pharma is seeking the appointment of a receiver as part of its relief; a hearing date has not been set.

In light of these developments and to better coordinate operational and governance matters, the Company's Board of Directors is forming an Executive Committee composed of Robert E. Hoffman, Chair of the Board; Dan Legault, CEO; and Yung Wu, Member of the Board.

Antibe will promptly inform the market when any additional material information is available.

### **About Antibe Therapeutics Inc.**

Antibe is a clinical-stage biotechnology company leveraging its proprietary hydrogen sulfide platform to develop next-generation therapies to target pain and inflammation arising from a wide range of medical conditions. The Company's current pipeline includes assets that seek to overcome the gastrointestinal ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”). Antibe's lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids and today's NSAIDs for acute pain. Antibe's second pipeline drug, ATB-352, is being developed for a specialized pain indication. The Company's next target is inflammatory bowel disease (“IBD”), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](https://antibetherapeutics.com).

## **Forward Looking Statements**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, statements concerning the anticipated scope, timing, duration and completion of certain of the Company's pre-clinical and clinical trial programs and studies including the Phase II trial's timeline for initiation and completion and the anticipated timing for seeking market approval for certain of the Company's drugs and therapies for certain additional indications, and Nuance Pharma's seeking recognition of the arbitration award in Ontario. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to timely execute on its business strategy and timely and successfully complete its clinical trials and studies, the Company's inability to obtain the necessary regulatory approvals related to its activities, risks associated with its debt to Nuance Pharma and Nuance Pharma's move to recognize the arbitral award in Ontario, risks associated with drug development generally and those risk factors set forth in the Company's public filings made in Canada and available on [sedarplus.com](http://sedarplus.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

## **Contacts**

Antibe Therapeutics Inc.  
Christina Cameron  
VP Investor Relations  
+1 416-577-1443  
[christina@antibethera.com](mailto:christina@antibethera.com)

This is Exhibit "H" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

*This short form prospectus constitutes a public offering of these securities only in those jurisdictions where they may be lawfully offered for sale and therein only by persons permitted to sell such securities. No securities regulatory authority has expressed an opinion about these securities and it is an offence to claim otherwise. The securities offered hereby have not been and will not be registered under the United States Securities Act of 1933, as amended (the "**U.S. Securities Act**"), or any applicable state securities laws and, therefore, may not be offered or sold within the United States of America, its territories or possessions, any State of the United States or the District of Columbia (collectively, the "**United States**") or to, or for the account or benefit of, persons in the United States or "U.S. persons," as such term is defined in Regulation S promulgated under the U.S. Securities Act ("**U.S. Persons**"), except pursuant to exemptions from the registration requirements of the U.S. Securities Act and applicable state securities laws. This prospectus does not constitute an offer to sell or a solicitation to buy any of such securities within the United States or to, or for the account or benefit of, persons in the United States or U.S. Persons. See "Plan of Distribution".*

*Information has been incorporated by reference in this short form prospectus from documents filed with securities commissions or similar authorities in each of the provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Ontario. Copies of the documents incorporated herein by reference may be obtained on request without charge from the Chief Financial Officer of Antibe Therapeutics Inc., at 15 Prince Arthur Ave., Toronto, ON M5R 1B2, telephone: (416) 473-4095, and are also available electronically at [www.sedar.com](http://www.sedar.com).*

## SHORT FORM PROSPECTUS

New Issue

June 26, 2020



# ANTIBE THERAPEUTICS INC.

**\$25,000,000**  
**62,500,000 Units**

**\$0.40 per Unit**

This short form prospectus (the "**Prospectus**") qualifies the distribution (the "**Offering**") of 62,500,000 units (the "**Units**") of Antibe Therapeutics Inc. ("**Antibe**" or the "**Company**"), at a price of \$0.40 per Unit (the "**Offering Price**") for gross proceeds of \$25,000,000. Each Unit consists of one common share in the capital of the Company (a "**Common Share**", and each Common Share comprising part of a Unit, an "**Offered Share**") and one-third of one Common Share purchase warrant (each whole Common Share purchase warrant, a "**Warrant**"). Each Warrant will entitle the holder thereof to purchase one Common Share (a "**Warrant Share**") at an exercise price of \$0.60 per Warrant Share, subject to adjustment in certain circumstances, at any time prior to 5:00 p.m. (Toronto time) on the date that is 24 months following the Closing Date (as defined below) (the "**Warrant Expiry Date**"). The Units will immediately separate on issuance into Offered Shares and Warrants. This Prospectus qualifies the distribution of Offered Shares and the Warrants comprising the Units and the Broker Warrants (as defined below).

The issued and outstanding Common Shares of the Company are listed on the TSX Venture Exchange (the "**TSXV**") under the symbol "ATE" and are also quoted on the international tier of the OTCQB market in the United States (the "**OTCQB**") under the symbol "ATBPF". On June 8, 2020, the last trading day prior to the public announcement of the Offering, the closing price of the Common Shares on the TSXV and the OTCQB was \$0.475 and US\$0.35 per Common Share, respectively. On June 25, 2020, the last trading day prior to the date of this Prospectus, the closing price of the Common Shares on the TSXV and the OTCQB was \$0.41 and US\$0.307 per Common Share, respectively.

The Units are being offered and sold pursuant to the terms of an underwriting agreement (the "**Underwriting Agreement**") entered into between the Company and Bloom Burton Securities Inc. (the "**Lead Underwriter**"), Echelon Wealth Partners Inc., Paradigm Capital Inc., Raymond James Ltd., Stifel Nicolaus Canada Inc. and Industrial Alliance Securities Inc. (together with the Lead Underwriter, the "**Underwriters**") on June 15, 2020. The terms of the Offering, including the offering price of the Units, were determined by arm's length negotiations between the Company and the Underwriters based upon several factors, including the policies of the TSXV, and may bear no relationship to the price that will prevail in the public marketplace. See "Plan of Distribution".

**An investment in the Units is subject to a number of risks that should be considered by a prospective purchaser. See "Risk Factors".**

	<b>Price to the Public</b>	<b>Underwriters' Fee<sup>(1)(2)</sup></b>	<b>Net Proceeds to the Company<sup>(2)(3)</sup></b>
Per Unit	\$0.40	\$0.028	\$0.372
Total Offering	\$25,000,000	\$1,750,000	\$23,250,000

Notes:

- (1) The Underwriters will receive a cash commission of 7% of the gross proceeds of the Offering including any proceeds received pursuant to the Over-Allotment Option (the "**Underwriters' Fee**"). In addition, the Company will grant to the Underwriters non-transferable broker warrants (the "**Broker Warrants**") to purchase up to that number of Common Shares that is equal to 7% of the aggregate number of Units sold, including the Additional Units (the "**Broker Warrant Shares**"). Each Broker Warrant will entitle the holder to acquire one Broker Warrant Share at a price of \$0.40 per Broker Warrant Share at any time prior to 5:00 p.m. (Toronto time) on the date that is 24 months after the Closing Date. This Prospectus also qualifies the distribution of Broker Warrants. See "Plan of Distribution".
- (2) The Company has agreed to grant to the Underwriters an over-allotment option (the "**Over-Allotment Option**") exercisable, in whole or in part, at the Underwriters' sole discretion, to offer and sell up to an additional number of Units (the "**Additional Units**") and/or Warrants (the "**Additional Warrants**") that is equal to 15% of the number of Units sold hereunder at a price equal to the Offering Price, in respect of the Additional Units, and at \$0.06, in respect of the Additional Warrants, to cover over-allocations, if any, and for market stabilization purposes. The Over-Allotment Option is exercisable, in whole or in part, at any time or times until the date that is 30 days immediately following the Closing Date. The Over-Allotment Option may be exercised by the Underwriters in respect of: (i) Additional Units at the Offering Price; (ii) Additional Warrants at a price of \$0.06 per Additional Warrant; or (iii) any combination of Additional Units and/or Additional Warrants, so long as the aggregate number of Additional Warrants does not exceed 15% of the number of Warrants issued under the Offering (excluding the Over-Allotment Option). Unless the context requires, references to Units herein shall include the Additional Units and references to Warrants herein shall include the Additional Warrants. The Common Shares that are included in the Additional Units are referred to herein as the "Additional Shares" and the Common Shares issuable upon exercise of the Additional Warrants (including Warrants issuable as part of the Additional Units) are referred to herein as the "Additional Warrant Shares". If the Underwriters exercise the Over-Allotment Option in full, the total price to the public, Underwriters' Fee and net proceeds to the Company (before deducting the expenses of the Offering which are estimated to be approximately \$200,000) will be \$28,750,000, \$2,012,500 and \$26,737,500, respectively. This Prospectus also qualifies the grant of the Over-Allotment Option and the distribution of any Additional Shares and Additional Warrants, including Warrants issuable as part of the Additional Units issued or sold pursuant to the exercise of the Over-Allotment Option. A purchaser who acquires Additional Units and/or Additional Warrants forming part of the Underwriters' over-allocation position acquires such Additional Units and/or Additional Warrants under this Prospectus, regardless of whether the over-allocation position is ultimately filled through the exercise of the Over-Allotment Option or secondary market purchases. See "Plan of Distribution".
- (3) Before deducting expenses of the Offering, estimated to be approximately \$200,000, which will, together with the Underwriters' Fee, be paid by the Company from the gross proceeds of the Offering. See "Use of Proceeds".

The following table sets forth the number of securities issuable under the Over-Allotment Option and the Broker Warrants:

Underwriters' Position	Maximum Size or Number of Securities Available <sup>(1)</sup>	Exercise Period	Exercise Price
Over-Allotment Option	Up to 9,375,000 Additional Units	Exercisable until 30 days following the Closing Date	\$0.40 per Additional Unit
Broker Warrants	Up to 5,031,250 Broker Warrants	Exercisable for a period of 24 months following the Closing Date	\$0.40 per Broker Warrant Share

Notes:

(1) Assuming exercise of the Over-Allotment Option in full.

Unless the context otherwise requires, when used in this Prospectus, all references to "Units" includes the Additional Units issuable upon exercise of the Over-Allotment Option and all references to "Offered Shares", "Warrants" and the "Warrant Shares" assumes the exercise of the Over-Allotment Option and includes all securities issuable thereunder.

The Underwriters, as principals, conditionally offer the Units, subject to prior sale, if, as and when issued by the Company and accepted by the Underwriters in accordance with the terms and conditions contained in the Underwriting Agreement and subject to the approval of certain legal matters on the Company's behalf by its counsel, WeirFoulds LLP, and on behalf of the Underwriters by its counsel, Torsys LLP.

In connection with this Offering, the Underwriters may over-allot or effect transactions that stabilize or maintain the price of the Units at levels other than those which otherwise might prevail on the open market. **Such transactions, if commenced may be discontinued at any time. The Underwriters may offer the Units at a price lower than that stated above.** See "Plan of Distribution".

Subscriptions for Units will be received subject to rejection or allotment, in whole or in part, and the right is reserved to close the subscription books at any time without notice. The Units shall be taken up by the Underwriters, if at all, on or before a date not later than 42 days after the date of the receipt for the (final) short form prospectus by the applicable securities commissions. See "Plan of Distribution". The closing of the Offering is expected to take place on or about June 30, 2020 or on such other date as may be agreed to by the Company and the Lead Underwriter, for and on behalf of the Underwriters (the "**Closing Date**").

Except in limited circumstances including, but not limited to, certain securities offered or sold to purchasers in the United States or who are U.S. Persons, no certificates will be issued in respect of the Units, Offered Shares, Warrants or Warrant Shares. The Offering will be conducted under the book-based system in the Canadian jurisdictions where the Units are being sold. A subscriber in a Canadian jurisdiction where the Units are being sold who purchases Units will receive a customer confirmation from the registered dealers through which Units are purchased and who is a CDS Clearing and Depository Services Inc. ("**CDS**") depository-service participant. CDS will record the CDS participants who hold Offered Shares and Warrants on behalf of owners who have purchased them in accordance with the book-based system. See "Plan of Distribution".

The TSXV has conditionally approved listing of the following securities of the Company on the TSXV: (i) the Offered Shares (including any Additional Shares issuable upon exercise of the Over-Allotment Option); (ii) the Warrant Shares (including any Additional Warrant Shares) issuable upon exercise of the Warrants (including any Additional Warrants issuable upon exercise of the Over-Allotment Option); and (iii) the Broker Warrant Shares issuable upon exercise of the Broker Warrants. Listing is subject to the Company fulfilling all of the listing requirements of the TSXV. The Company has not applied and does not intend to apply to list the Warrants on any securities exchange. **There is no market through which the Warrants may be sold and purchasers may not be able to resell the Warrants purchased under this Prospectus. This may affect the pricing of the Warrants in the secondary market, the transparency and availability of trading prices, the liquidity of the securities, and the extent of issuer regulation.** See "Risk Factors".

In this Prospectus, references to "Antibe", the "Company", "we", "us" and "our" refer to Antibe Therapeutics Inc. and/or, as applicable, one or more of its subsidiaries on a consolidated basis.

**An investment in the Units is speculative and involves a high degree of risk that should be considered by potential purchasers. The Company is subject to risks due to the nature of the Company's business and its stage of development. An investment in the Units is suitable only for those purchasers who are willing to risk a loss of some or all of their investment and who can afford to lose some or all of their investment. See "Risk Factors" and "Forward-Looking Information".**

**Prospective purchasers are advised to consult their own tax advisors regarding the application of Canadian federal income tax laws to their particular circumstances, as well as any other provincial, foreign and other tax consequences of acquiring, holding or disposing of Offered Shares and Warrants.**

All dollar amounts in this Prospectus are in Canadian dollars unless otherwise stated.

The registered office and head office of the Company is located at 15 Prince Arthur Ave., Toronto, ON M5R 1B2.

Bloom Burton Securities Inc. is an affiliate of a lender that has provided a credit facility to a subsidiary of the Company. **Consequently, the Company may be considered a "connected issuer" of Bloom Burton Securities Inc. under applicable Canadian securities laws.** See "Plan of Distribution – Relationship Between the Company and Certain of the Underwriters".



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## ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this Prospectus and are not entitled to rely on only certain parts of the information contained or incorporated by reference in this Prospectus to the exclusion of the remainder. The Company and the Underwriters have not authorized anyone to provide investors with different or additional information. If anyone provides you with different or additional information, you should not rely on it. The Company and the Underwriters are not making an offer to sell or seeking an offer to buy the Units in any jurisdiction where the offer or sale is not permitted. Prospective investors should assume that the information contained in this Prospectus is accurate only as of the date on the front of this Prospectus and that information contained in any document incorporated by reference is accurate only as of the date of that document, regardless of the time of delivery of this Prospectus or of any sale of Units pursuant hereto. The Company's business, financial condition, results of operations and prospects may have changed since those dates.

The Company has not done anything that would permit the offering or distribution of our securities under this Prospectus in any jurisdiction in which such offer is not permitted. Investors are required to inform themselves about, and to observe any restrictions relating to, any offering or distribution of our securities under this Prospectus.

This Prospectus contains and incorporates by reference documents that contain market data, scientific data, industry data and forecasts. This information is based on the Company's management estimates or expectations. In arriving to their estimates or expectations, the Company's management relies on third-party market and industry data and forecasts, industry publications and other publicly available information. While these third-party sources are believed to be reliable, neither the Company nor the Underwriters have independently verified the information that they contain, and neither the Company nor the Underwriters make any representation as to the accuracy of such information.

## ELIGIBILITY FOR INVESTMENT

In the opinion of WeirFoulds LLP, counsel to the Company, and Torys LLP, counsel to the Underwriters, based on the provisions of the *Income Tax Act* (Canada) and the regulations thereunder (collectively, the "**Tax Act**"), as of the date hereof, the Offered Shares, Warrants and Warrant Shares, if issued on the date hereof, would be "qualified investments" under the Tax Act for trusts governed by registered retirement savings plans ("**RRSP**"), registered retirement income funds ("**RRIF**"), registered disability savings plans ("**RDSP**"), deferred profit sharing plans, registered education savings plans ("**RESP**") and tax-free savings accounts ("**TFSA**") each as defined in the Tax Act (each, a "**Plan**") at the time of the acquisition of such Offered Shares, Warrants and Warrant Shares by the Plan, provided that, at the time the acquisition by the Plan:

- a) in the case of the Offered Shares and Warrant Shares, such Offered Shares and Warrant Shares are listed on a "designated stock exchange" for purpose of the Tax Act (which currently includes Tiers 1 and 2 of the TSXV) or the Company qualifies as a "public corporation" (as defined in the Tax Act); and
- b) in the case of the Warrants, the Warrant Shares are qualified investments as described in (a) above and neither the Company nor any person with whom the Company does not deal at arm's length is an annuitant, a beneficiary, an employer or a subscriber under, or a holder of, the Plan.

Notwithstanding that the Offered Shares, Warrants and Warrant Shares may be qualified investments for a TFSA, RDSP, RRSP, RRIF or RESP, the holder of a TFSA or RDSP, the annuitant of a RRSP or RRIF or the subscriber of a RESP, as the case may be, will be subject to a penalty tax in respect of the Offered Shares, Warrants and Warrant Shares if such securities are a "prohibited investment" and not "excluded property" for the particular Plan for purposes of the Tax Act. Offered Shares, Warrants and Warrant Shares will generally not be a prohibited investment for a particular TFSA, RDSP, RRSP, RRIF or RESP if the holder of the TFSA or RDSP, the annuitant of the RRSP or RRIF or the subscriber of the RESP, as the case may be, (i) does not have a "significant interest" (as defined for purposes of the prohibited investment rules in the Tax Act) in the Company, and (ii) deals at arm's length with the Company for purposes of the Tax Act. Generally, a holder, annuitant or subscriber, as the case may be, will not have a significant interest in the Company provided the holder, annuitant or subscriber, together with persons or partnerships with whom the holder, annuitant or subscriber does not deal at arm's length, does not own (and is not deemed to own pursuant to the Tax Act), directly or indirectly, 10% or more of the issued shares of any class of the

capital stock of the Company or of any other corporation that is related to the Company (for purposes of the Tax Act). In addition, the Offered Shares and Warrant Shares will not be “prohibited investments” if such securities are “excluded property” (as defined in the Tax Act) for a Plan.

**Prospective purchasers who intend to hold Offered Shares, Warrant Shares or Warrants in trusts governed by Plans should consult their own tax advisors in regard to the application of these rules under the Tax Act in their particular circumstances.**

## FORWARD-LOOKING INFORMATION

This Prospectus, including the documents incorporated herein by reference, contains forward-looking statements and forward-looking information as such terms are defined under applicable Canadian securities laws. These forward-looking statements and forward-looking information include, but are not limited to, statements with respect to management's expectations regarding the future growth, results of operations, performance and business prospects of the Company, and relate to, without limitation:

- the Offering, including the use of proceeds from the Offering;
- the closing of the Offering and the timing thereof, including the approval of the TSXV for the listing of the Offered Shares, Warrant Shares, and Broker Warrant Shares;
- results from the Company's research and development activities;
- the Company's research and development plans, business model, strategic objectives and growth strategy;
- a potential partnering event with a global pharmaceutical company,
- drug regulation in the U.S., Canada and abroad;
- reimbursement and pricing for medical devices and pharmaceutical products generally;
- initial and subsequent therapeutic indications for the Company's products and the prevalence of such indications;
- the Company's pre-clinical and clinical development plans/trials, including the expected timing, location and duration thereof;
- the Company's drug development pipeline, product potential, product market/profile and size;
- sourcing, licensing and launching new products, co-development and partnership plans and objectives;
- the Company's intellectual property;
- the Company's current and future capital requirements and the need for additional financing;
- the benefits and risks of the Company's products as compared to others;
- the Company's future growth plans;
- the Company's estimate of the size of the potential markets for its products;
- the therapeutic benefits, effectiveness and safety of the Company's product candidates;
- the Company's expectations regarding regulatory requirements in certain jurisdictions;

- regulatory developments and the regulatory environments in which the Company operates;
- anticipated trends and challenges in the Company's business and the markets in which it operates;
- the continuation of the Company as a going concern;
- the payment of dividends;
- the Company's use of unallocated proceeds from the Offering;
- the estimated cost of the Offering;
- the Company's expectations regarding net losses and revenue generation;
- the Company's expectations regarding the sufficiency of its cash for funding non-development related expenditures and future cash balances;
- the Company's expectations regarding increases in research and development costs and general and administrative expenses;
- the Company's liability under indemnification provisions; and
- the impact of the recent novel coronavirus ("**COVID-19**") pandemic on our operations.

These forward-looking statements and forward-looking information may also include other statements that are predictive in nature, or that depend upon or refer to future events or conditions. Without limitation, the words "may", "will", "would", "should", "could", "expect", "plan", "intend", "trend", "indication", "assume", "anticipate", "believe", "estimate", "predict", "likely" or "potential", or the negative or other variations of these words or other comparable words or phrases, are intended to identify forward-looking statements. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Forward-looking statements and forward-looking information are not historical facts but instead represent management's expectations, estimates and projections regarding future events.

With respect to forward-looking statements and forward-looking information contained in this Prospectus, assumptions have been made regarding, among other things: future research and development plans for the Company's proceeding substantially as currently envisioned, expected research and development tax credits, future expenditures to be incurred by the Company, research and development and operating costs, the Company's ability to find partners in the pharmaceutical industry, additional sources of funding, including the Company's ability to obtain funding from partners, the impact of competition on the Company and the Company being able to obtain financing on acceptable terms.

Although management believes the expectations reflected in such forward-looking statements and forward-looking information are reasonable, forward-looking statements and forward-looking information are based on the opinions, assumptions and estimates of management at the date the statements are made, and are subject to a variety of risks and uncertainties and other factors that could cause actual events or results to differ materially from those projected in the forward-looking statements and forward-looking information. These factors include, but are not limited to: Antibe's ability to develop, manufacture, and successfully commercialize value-added pharmaceutical products and medical devices, regulatory approvals, pricing and reimbursement, the ability to license its products on acceptable terms and conditions, Antibe's ability to obtain additional capital in the future to conduct operations, research and development activities and develop its products, the successful and timely completion of clinical studies, the availability of tax credits, the ability of Antibe to take advantage of business opportunities in the pharmaceutical and medical device industry, the ability to successfully compete with industry participants that have greater resources, Antibe's reliance on key personnel, collaborative partners, suppliers and third parties, Antibe's ability to attract and retain key personnel, Antibe's ability to secure and maintain adequate protection for its intellectual property, Antibe's ability to find partners in the pharmaceutical industry, Antibe's ability to expand its regenerative medicine

business into additional products and markets, Antibe's history of operating losses, currency fluctuations, the value of our intangible assets, negative operating cash flow, Antibe's ability (or the ability of Antibe's partners) to obtain regulatory approvals for Antibe's products, legal proceedings and other risks related to Antibe's industry. These factors are not intended to represent a complete list of the factors that could affect the Company; however, these factors should be considered carefully by prospective purchasers of Units. More detailed assessment of the risks that could cause actual events or results to materially differ from our current expectations can be found in the AIF (as defined below) under the heading "Risk Factors" filed with the Canadian securities authorities (on Sedar at [www.sedar.com](http://www.sedar.com)) and under the heading "Risk Factors" in this Prospectus.

In addition, if any of the assumptions or estimates made by management prove to be incorrect, actual results and developments are likely to differ, and may differ materially, from those expressed or implied by the forward-looking statements contained in, or incorporated by reference into, this Prospectus. Accordingly, prospective purchasers are cautioned not to place undue reliance on such statements.

All of the forward-looking statements and forward-looking information in this Prospectus, and the documents incorporated herein by reference, is qualified by these cautionary statements. Statements containing forward-looking statements and/or forward-looking information contained herein and in the documents incorporated herein by reference are made only as of the date of such document. The Company and the Underwriters expressly disclaim any obligation to update, revise or alter statements containing any forward-looking statements or forward-looking information, or the factors or assumptions underlying them, whether as a result of new information, future events or otherwise, except as required by law. New factors emerge from time to time, and it is not possible for the Company to predict which factors may arise. In addition, the Company cannot assess the impact of each factor on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements or forward-looking information.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

**Information has been incorporated by reference in this Prospectus from documents filed with securities regulatory authorities in certain of the provinces and territories of Canada. Copies of the documents incorporated herein are available electronically at [www.sedar.com](http://www.sedar.com).**

The following documents of the Company filed with securities commissions or similar regulatory authorities in each of the provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Ontario are incorporated by reference into this Prospectus:

- a) the annual information form of the Company dated July 16, 2019 for the year ended March 31, 2019 (the "AIF");
- b) the audited consolidated financial statements of the Company for the years ended March 31, 2019 and 2018 together with the notes thereto, and the auditors' report thereon dated July 16, 2019;
- c) the management's discussion and analysis of the Company for the year ended March 31, 2019 dated July 16, 2019;
- d) the unaudited condensed interim consolidated financial statements of the Company for the three and nine months ended December 31, 2019 and 2018;
- e) the management's discussion and analysis of the Company for the three and nine months ended December 31, 2019 and 2018;
- f) the material change report dated June 15, 2020 in respect of the Offering; and
- g) the management information circular of the Company dated May 22, 2019 for the annual general and special meeting of shareholders held on July 2, 2019.

Any document of the type referred to in Section 11.1 of Form 44-101 FI – *Short Form Prospectus* filed by the Company with a securities commission or similar regulatory authority Canada after the date of this Prospectus and before the completion or termination of the Offering is deemed to be incorporated by reference into this Prospectus.

**Any statement contained in a document incorporated or deemed to be incorporated by reference is deemed to be modified or superseded, for purposes of this Prospectus, to the extent its content is modified or superseded by a statement contained in this Prospectus or in any other subsequently filed document that is also incorporated by reference in this Prospectus. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any other information contained in the document that it modifies or supersedes. The making of a modifying or superseding statement is not an admission for any purposes that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that is required to be stated or that is necessary to make a statement not misleading in light of the circumstances in which it was made. Any statement so modified or superseded will not, except as so modified or superseded, constitute a part of this Prospectus.**

## MARKETING MATERIALS

Any "template version" of any "marketing materials" (each such term as defined in National Instrument 44-101 – *Short Form Prospectus Distributions*) that is filed under the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com) before termination of the Offering (including any amendments to, or amended version of, any template version of any marketing materials) will be incorporated by reference in this Prospectus. However, such "template version" of "marketing materials" will not form a part of this Prospectus to the extent that the contents of the marketing materials or the template version of the marketing materials, as applicable, have been modified or superseded by a statement contained in the final short form prospectus.

## SUMMARY DESCRIPTION OF THE BUSINESS

Antibe is a biotechnology company that seeks to develop safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug, ATB-346, targets the global need for a safer drug for chronic pain and inflammation. In March 2018, ATB-346 met its primary endpoint in a Phase 2B double-blind clinical trial vs. naproxen, showing a statistically significant difference in the incidence of ulcers, a measure of gastrointestinal ("GI") safety (2.5% versus 42.1% ulceration rate of ulcers of at least 3mm in diameter). ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a safer, non-addictive analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. In addition, Antibe has a commercial subsidiary, Citagenix Inc. ("**Citagenix**"), that is engaged in the sales and marketing of tissue regenerative products for oral and maxillofacial surgery. Citagenix is pursuing a global growth strategy in the dental biologics market.

## RECENT DEVELOPMENTS

On June 1, 2020 the Company announced that ATB-346 met the primary endpoint in the Phase 2B dose-ranging, efficacy study. Both the 250 mg and 200 mg doses of ATB-346 demonstrated superiority to placebo in reducing osteoarthritis ("OA") pain with a high level of statistical significance. The 150 mg dose of ATB-346, although not powered for statistical significance, demonstrated more potency than expected and the lowest effective dose is still to be established. The drug was safe and well tolerated during this study.

A total of 385 patients with osteoarthritis (OA) of the knee were randomized to either placebo or ATB-346 administered once daily: 250 mg, 200 mg or 150 mg. The primary objective in the study was to demonstrate the statistically significant superiority of ATB-346 versus placebo in reducing OA pain as measured by the change from baseline in the WOMAC pain subscale score over a 14-day treatment period. The 250 mg and 200 mg doses were powered for statistical significance and the 150 mg dose was powered to only observe an efficacy response.

ATB-346 demonstrated superiority to placebo at doses of 250 mg (p-value of 0.01) and 200 mg (p-value of 0.007). Similar efficacy was observed between these doses, suggesting that the upper range of the dose-response curve has

been reached. The 150 mg dose demonstrated a robust efficacy response and had it been equivalently powered to the other treatment arms, the Company believes it would have achieved statistical significance. As such, the lower portion of the dose-response curve remains to be established.

In addition, both the 250 mg and 200 mg doses of ATB-346 demonstrated a highly statistically significant reduction in the WOMAC stiffness subscale score (p-value < 0.001 for both doses) and both doses were superior to placebo in the WOMAC difficulty performing daily activities (DPDA) subscale score (p-value of 0.004 and 0.001, respectively). While not statistically powered, the 150 mg dose of ATB-346 nonetheless demonstrated a statistically significant improvement in stiffness compared to placebo (p-value of 0.03) and displayed an efficacy response in DPDA.

Adverse events typically associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”) use, such as dyspepsia, acid reflux and dizziness, were comparable across placebo and all three treatment arms of ATB-346. There were very few serious adverse events or events leading to withdrawal of treatment. Only 1 out of 318 patients administered ATB-346 had clinically significant, temporary liver transaminase elevations (LTEs) during the 14-day treatment period. At the post-treatment assessment (day 24), patients in the 250 mg, 200 mg and 150 mg treatment arms had clinically significant, temporary LTE incidences of 12.1%, 8.0% and 8.2%, respectively. It is standard for pain trials to allow the use of other medications, commonly acetaminophen. Acetaminophen use, especially in the post-treatment assessment period, pre-existing liver conditions and concomitant statin use were associated with a majority of the LTE incidents. Accounting for these factors yields clinically significant, temporary LTE incidence rates of 4.5%, 3.2% and 3.3%, respectively, suggesting a liver safety profile for ATB-346 comparable to commonly prescribed NSAIDs and well below that observed with acetaminophen (39% clinically significant LTE incidence rate; National Institutes of Health). The clinical study was conducted by Veristat, LLC in 39 clinical sites across Canada.

To establish the lowest effective dose of ATB-346, the Company is planning a pivotal Phase 2/3 randomized, controlled trial with an adaptive design. For clarity, although referred to as a “Phase 2/3” trial because it is establishing the lowest effective dose of ATB-346, it is in fact a Phase 3 registration trial. Antibe anticipates that this efficacy trial will compare multiple doses of ATB-346 to placebo in OA patients over a 12-week period. It is the Company’s intention to submit this study to the U.S. FDA as a formal registration trial.

### CONSOLIDATED CAPITALIZATION

The following table sets forth the consolidated capitalization of the Company at December 31, 2019, both before and after giving effect to the Offering.

Description	As at December 31, 2019 (unaudited, \$000’s)	As at December 31, 2019, after giving effect to the Offering (unaudited, \$000’s) <sup>(1)(2)</sup>
<b>Debt</b>		
Loan payable <sup>(3)</sup>	\$2,179	\$2,179
<b>Share Capital</b>		
Common Shares <sup>(4)</sup>	\$44,690 (281,284,125 Common Shares)	\$67,740 (343,784,125 Common Shares)
Common Share purchase warrants <sup>(5)</sup>	40,462,589 Common Share purchase warrants	65,670,922 Common Share purchase warrants
Stock options	18,357,732 stock options	18,357,732 stock options

<b>Total Shareholders' Equity</b>	\$6,934	\$29,984
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Notes:

- (1) After giving effect to the Offering, less the Underwriters' Fee of \$1,750,000 and expenses of the Offering estimated to be \$200,000. All figures on a non-diluted basis.
- (2) Does not include any Additional Shares issuable upon the exercise of the Over-Allotment Option. If the Over-Allotment Option is exercised in full, there will be 353,159,125 Common Shares outstanding upon completion of the Offering and the issue and sale of Additional Shares pursuant to the exercise of the Over-Allotment Option.
- (3) As at the quarter ended June 30, 2020, the Loan Payable will have been repaid in full.
- (4) Excludes Common Shares issuable upon the exercise of the Warrants, Broker Warrants, stock options and other warrants or rights to purchase Common Shares.
- (5) Includes the Broker Warrants and previously issued broker warrants.

### USE OF PROCEEDS

The net proceeds to the Company from the Offering will be approximately \$23,050,000 after deducting the Underwriters' Fee of \$1,750,000 and estimated expenses of the Offering of \$200,000. The foregoing amounts are prior to any exercise of the Over-Allotment Option.

The Company intends to use the net proceeds of the Offering to fund certain activities required to support large market partnering and begin the Phase 3 program for ATB-346. These activities include: (i) completion of reproductive and long-range animal toxicology studies for ATB-346; (ii) U.S. regulatory consulting fees to support a successful Investigational New Drug ("IND") application and end-of-Phase-2 meeting with FDA; (iii) European regulatory consulting fees to support EMA requirements; (iv) market opportunity assessment and partnering studies; (v) IND-opening absorption, metabolism and excretion ("AME") study for ATB-346; (vi) drug supply of ATB-346 for the Phase 3 program; (vii) initiation of the pivotal Phase 2/3 adaptive trial; (viii) completion of IND-enabling studies for ATB-352; and (ix) recruitment of senior business development executive. The remainder of the net proceeds will be used for working capital and general corporate purposes. These activities are expected to benefit future partnering discussions as they aim to materially de-risk ATB-346 from a regulatory and commercialization perspective.

Phase 3-enabling animal toxicity and reproductive toxicity studies have commenced in rats, mini pigs and rabbits. They are being conducted in tranches to enable a timely start of Phase 3 clinical trials. Short range studies are expected to conclude in Q1 2021, enabling the commencement of the 12-week phase 3 efficacy trials. Long range studies are expected to conclude in Q3 2021, enabling the commencement of 24-week Phase 3 GI safety trials. The regulatory consulting fees are to fund the balance of its regulatory consulting effort (initiated in calendar Q1 2019) which include preparation for the Company's IND filing with the FDA and end-of-Phase 2 meetings with the FDA. Both the IND filing and end-of-Phase 2 meeting are expected to occur in the next six months. Upon successful opening of the IND, the Company plans to commence an AME study in calendar Q4 2020 to satisfy its regulatory requirement for such a study. The Company's primary regulatory focus is to obtain FDA approval for ATB-346 given the United States is the largest pharmaceutical market worldwide. The Company has also engaged a European regulatory consulting agency to develop a strategy for EMA approval. Upon the conclusion of this mandate, the Company plans on identifying the optimal path forward for achieving regulatory approval for ATB-346 in Europe.

The Company recently completed a comprehensive market opportunity assessment and payor study for the United State and Europe, and plans to proceed with a partnership study to identify and stratify potential target partners in these markets. The Company will also be conducting similar market opportunity assessment and partnership studies in Japan, the third largest pharmaceutical market worldwide. These studies have already commenced or are commencing shortly, and are expected to conclude in calendar Q3 2020. The Company believes that the findings of these studies should be valuable in future partnering discussions. The Company expects business development activity to increase materially given the recent positive Phase 2B efficacy data for ATB-346. In anticipation of this



increased activity, the Company plans to hire a senior business development executive to lead the negotiation and execution of future licensing deals. The Company also plans to engage an advisory group to support partnering activity in China, the second largest pharmaceutical market worldwide.

In addition, the Company plans on funding all required IND-enabling pre-clinical studies for its second pipeline drug, ATB-352, and anticipates these studies will conclude in calendar Q3 2021. ATB-352 is a hydrogen sulfide-releasing derivative of ketoprofen, one of the more potent NSAIDs commonly prescribed for severe pain. However, ketoprofen is also one of the most damaging NSAIDs to the GI tract. ATB-352 is being developed as a GI-safe and non-addictive alternative to opioids for the treatment of post-surgical pain.

The recent successful outcome of the Phase 2B dose-ranging, efficacy study for ATB-346 represented a major development milestone for the Company and concluded Phase 2 human proof-of-concept development of ATB-346. The Company's overall strategy is to monetize ATB-346 at the optimal time through partnering or M&A activity. In parallel, the Company will continue to advance ATB-346 to maximize both value and negotiating leverage. In the next 12 months, the Company would either complete M&A activity, partner with one or more pharmaceutical companies who would complete Phase 3 development, or raise additional capital and/or secure regional partnerships to further or fully fund Phase 3 development. In any event, the Company estimates that the Phase 3 program for ATB-346 will commence in late calendar Q1 or early calendar Q2 2021 and will take approximately 2 years to complete. Although the Phase 3 design is not finalized, it is expected to replicate the Phase 2B GI safety and Phase 2B dose-ranging, efficacy studies in a larger sample size with a longer treatment duration. The Company is planning for the first registration trial of the Phase 3 program to have an adaptive design which will also establish the lowest effective dose of ATB-346. The Company anticipates that this efficacy trial will compare multiple doses of ATB-346 to placebo in OA patients over a 12-week period. Successful completion of Phase 3 development would allow the Company to file an application with the FDA for regulatory approval.

The Company reported negative cash flow from operating activities of \$8.37 million for the nine-month period ended December 31, 2019, and expects to experience negative cash flow from operating activities for the foreseeable future. The Company's negative cash flow from operating activities is comprised of both development costs and non-development operating and overhead costs. Non-development operating costs are costs to operate the Company and do not include research and development expenditures, which vary across time, based on the specific drug development activities undertaken by the Company. Commitments and contingencies of the Company consist of the following: staff salaries; leases on office space and facilities; public company fees; patent costs; and the ATB-346 toxicology studies.

### ***August 2019 Prospectus***

At the time the Company prepared its short form prospectus dated August 7, 2019 (the "**August 2019 Prospectus**") in connection the offering of the Company which closed on August 13, 2019, the Company prepared a budget based on the cash made available by the August 2019 Prospectus. However, the Company raised substantial additional funds since the August 2019 Prospectus through exercise of warrants and options. This allowed Company management additional flexibility to plan and execute additional valuable expenditures on both development projects and overheads. The budgeted and actual overhead (i.e., non-developmental) expenditures during the period from July 2019 to June 2020 (May 2020 in the case of actual) are as follows:

	At the time of August 2019 Prospectus		Actual Expenditures	
	Budget – June 2019 to June 2020	Budget per month	July 2019 to May 2020	Expenditures per month
Salaries & benefits <sup>(1)</sup>	\$821,462	\$68,455	\$1,123,187	\$102,108
Professional fees – Company Management <sup>(1)</sup>	\$577,224	\$48,102	\$661,840	\$60,167

Professional fees – legal, accounting etc. <sup>(2)</sup>	\$587,920	\$48,993	\$1,317,601	\$119,782
Marketing & promotion <sup>(3)</sup>	\$70,620	\$5,885	\$387,190	\$35,199
Office costs <sup>(4)</sup>	\$141,012	\$11,751	\$191,597	\$17,418
Financial costs	\$35,206	\$2,934	\$36,640	\$3,331
Public company fees	\$121,353	\$10,113	\$86,382	\$7,853
<b>Total</b>	<b>\$2,354,797</b>	<b>\$196,233</b>	<b>\$3,804,438</b>	<b>\$345,858</b>

(1) Salaries & benefits and Professional fees – Company management – The Company hired additional senior executives, namely a Chief Medical Officer and an SVP, Commercial Strategy, during the period following filing of the August 2019 Prospectus. The Company also hired a experienced development professional to manage non-clinical trials and an experienced chemist to assist with managing its production partner.

(2) Professional fees – legal, accounting etc – the Company had higher than budgeted investor relations fees as it expanded its investor reach to both retail and institutional investors, higher legal fees for addressing intellectual property extensions and questions, higher executive search fees to attract and hire new staff, higher business development fees as it reached out to different markets to develop relationships for potential future partnerships and higher communication consultant fees as the Company increased its public relations and marketing activities.

(3) Marketing and promotion – the Company had higher than budgeted marketing and promotion costs as it did extensive outreach to investors in Canada, the US and Europe (prior to the Covid-19 crisis), it expanded its attendance and speaking engagements at conferences and it completely revamped its branding and website.

(4) Office costs rose primarily as the Company took on more office space to accommodate additional staff.

The actual versus anticipated funds used as per the August 2019 Prospectus are as follows, with explanations with respect to the difference between the actual and projected expenditures:

	<b>Projected Amount per August 2019 Prospectus</b>	<b>Actual Amount Spent</b>	<b>Difference</b>	<b>Explanation of Difference</b>
ATB-346 additional FDA regulatory consulting fees	\$300,000	\$432,000	\$(132,000)	Submitting a drug candidate to the FDA requires extensive & rigorous documentation. The Company under budgeted for this expenditure.
ATB-346 European regulatory consulting fees	\$500,000	\$251,000	\$249,000	The Company was able to leverage some of the regulatory work done in the US to lower the anticipated regulatory work in Europe during this period
ATB-346 health economics, payor and market opportunity studies	\$650,000	\$435,000	\$215,000	The Company received lower quotes from consulting firms than anticipated for these studies
ATB-346 reproductive	\$400,000	\$355,000	\$45,000	The initial reproductive

toxicology studies				toxicology study was delayed and is now underway
ATB-346 long-range animal toxicology studies (first tranche)	\$375,000	\$150,000	\$225,000	The start of this work was delayed and only started in calendar Q2 of 2020
ATB-352 IND-enabling toxicology studies	\$300,000	\$150,000	\$150,000	Work with academic labs enabled the Company to lower this cost.
Global branding initiatives	\$100,000	\$50,000	\$50,000	Less was spent than budgeted on this activity, even though the Company was successful in procuring its non-proprietary name.
ATB-346 additional expenditures for Phase 2B dose-ranging, efficacy study	\$250,000 + \$3,827,000* = \$4,077,000	\$6,700,000	\$(2,623,000)	Substantial additional costs were incurred from logistics challenges due to the size and scope of the trial as well as the impact of the Covid-19 at the end of the trial
ATB-346 Metabolite studies	\$0	\$70,000	\$(70,000)	Additional work was done on the metabolites of ATB-346 that had not been budgeted
ATB-346 Drug production	\$0	\$900,000	\$(900,000)	Drug production for additional studies including the Phase 3 trials is a critical requirement with long lead times. The Company chose to pursue this important activity during this period.
Working capital and general corporate purposes	\$3,460,000	\$3,804,000	\$(344,000)	The \$3.8 million is the actual amount of overhead expenditures. Primarily due to option and warrant exercise the Company has \$5.4 in cash and \$5.7 million in working capital as at May 31, 2020.
<b>Total net proceeds</b>	<b>\$6,335,000 + \$4,020,000* =\$10,355,000</b>	<b>\$13,293,000</b>	<b>\$(2,938,000)</b>	

\*from existing cash resources.

## Use of Proceeds

The Company believes that based on management's expected rate of negative cash flow from operating activities, the net proceeds in the Offering of \$23,050,000, plus the Company's cash on hand as at May 31, 2020 of \$5.4 million will be sufficient to cover all the Company's activities (i.e., all of the Company's operating costs and research and development expenditures) during the period ending June 30, 2021 (being the period in which the proceeds of the Offering are expected to be used). This expectation is based on the assumption that Antibe's operating non-development cash burn will be approximately \$539,000 per month going forward. However, this is forward-looking information. Actual results may vary from the forward-looking information and material risk factors could cause actual results to differ materially from the forward-looking information. See "Forward-Looking Information" and "Risk Factors".

The Company does not consolidate accounts on a monthly basis but as at May 31, 2020 had cash balances of \$5.4 million. The Company's working capital balance as at May 31, 2020 was approximately \$5.7 million. The nature of the Company's business is such that the degree of negative cash flow experienced by the Company can vary significantly from period to period as it completes certain phases relating to the advancement of its products. Accordingly, cash flows for a period may not be directly comparable to a future period, and no assurance can be given that such projections will prove to be accurate. Prospective purchasers should carefully review the risk factors entitled "Ability to Continue as a Going Concern" and "Negative Cash Flow from Operating Activities" in the AIF and the other risk factors identified in this Prospectus under "Risk Factors".

The Company's intended use of net proceeds from the Offering are as follows:

	Amount	%
Long-range animal toxicology studies for ATB-346 <sup>(1)</sup>	\$3,000,000	13.02%
Reproductive toxicology studies for ATB-346 <sup>(2)</sup>	\$1,800,000	7.81%
FDA regulatory consulting fees for ATB-346 <sup>(3)</sup>	\$400,000	1.74%
European regulatory consulting fees for ATB-346 <sup>(4)</sup>	\$375,000	1.63%
Market opportunity assessment studies <sup>(5)</sup>	\$1,000,000	4.34%
ATB-346 IND-opening AME study	\$300,000	1.30%
Drug supply of ATB-346 for the Phase 3 program	\$1,400,000	6.07%
Initiation of pivotal Phase 2/3 adaptive trial for ATB-346	\$5,000,000	21.69%
IND-enabling studies for ATB-352 <sup>(6)</sup>	\$1,400,000	6.07%
Recruitment of senior business development executive <sup>(7)</sup>	\$750,000	3.25%
Working capital and general corporate purposes	\$7,625,000	33.08%
<b>Total net proceeds</b>	<b>\$23,050,000</b>	<b>100%</b>

(1) Completion of the current toxicology study and executing 4 additional required studies. All 5 required studies will be completed in the next

year expect for one which extends for 9 months and will be completed in late 2021. See below under the subheading “*Business Objectives and Milestones*”.

(2) Completion of the current reproduction toxicology study and executing 5 additional required studies. All 6 studies will be completed in the next year. See below under the subheading “*Business Objectives and Milestones*”.

(3) For filing IND and subsequent Type-C and end-of-Phase-2 meetings. See below under the subheading “*Business Objectives and Milestones*”.

(4) For initial meeting with European regulators, determining European trial requirements and if appropriate filing required documentation. See below under the subheading “*Business Objectives and Milestones*”.

(5) For partnering and for selected markets including Japan and China. See below under the subheading “*Business Objectives and Milestones*”.

(6) Completion of all required pre-clinical studies to be in a position to file an IND for this drug. See below under the subheading “*Business Objectives and Milestones*”.

(7) Includes expected salary for period ended June 30, 2021

The net proceeds of the Offering will be spent on expenditures incurred following the Offering. If the Over-Allotment Option is exercised in part or in full, the Company intends to use the additional net proceeds of up to \$3,487,500 for working capital and general corporate purposes.

Although the Company intends to expend the net proceeds from the Offering as set forth above, there may be circumstances where, for sound business reasons, a reallocation of funds may be prudent or necessary, and may vary materially from that set forth above. The Company is currently incurring expenditures related to the Company's operations that have generated negative operating cash flows. Operating cash flows may decline in certain circumstances, many of which are beyond the Company's control. There is no assurance that sufficient revenues will be generated in the near future, and the Company may continue to incur negative operating cash flows. The Company may need to deploy a portion of its working capital to fund such negative operating cash flows or seek additional sources of funding. See "Risk Factors".

### **Business Objectives and Milestones**

Antibe’s primary objective is to advance the development of ATB-346 and subsequently monetize this asset for shareholders through partnering activity with pharmaceutical companies. The Company has a pipeline of other drug candidates that it now intends on advancing with net proceeds from the Offering. Specifically, the Company plans to fully fund IND-enabling studies for ATB-352 with net proceeds of the Offering, and will continue to advance academic proof-of-concept work of ATB-340 through academic labs in partnership with Antibe’s Chief Science Officer at minimal or no cost.

#### *August 2019 Prospectus*

The Company achieved all but two of the milestones referred to in the August 2019 Prospectus. Its proposed animal reproductive toxicology studies and the first tranche of its proposed animal toxicology studies have been slightly delayed. A description of the status of various milestones for which proceeds from the August 2019 Prospectus were allocated is as follows, along with the minimum amount of the proceeds from the August 2019 Prospectus which were originally allocated to each such milestone, the projected completion date as at the time of the August 2019 Prospectus, and the current status of each such milestone. See also the table above under the subheading “*August 2019 Prospectus*”.

	<b>Minimum Amount</b>	<b>Projected Completion Date<sup>(1)</sup></b>	<b>Milestone Status and Comments</b>
ATB-346 additional FDA regulatory consulting fees	\$300,000	Q1 2020	Milestone met, Antibe held a pre-IND with the FDA in March 2020. There are many regulatory steps and milestones on the path to getting a drug approved for the market. Additional funds are allocated in this Prospectus for this path

ATB-346 European regulatory consulting fees	\$500,000	Q2 2020	Milestone met. Antibe made substantial progress on initial regulatory European issues. There are many regulatory steps and milestones on the path to getting a drug approved for the market. Additional funds are allocated in this Prospectus for this path
ATB-346 health economics, payor and market opportunity studies	\$650,000	Q4 2019	Milestone met. Health economics and payor studies for the US and Europe were completed. Additional studies are planned for Japan, China and other markets (TBD) as well as a Partner study for the US and Europe.
ATB-346 reproductive toxicology studies	\$400,000	Q2 2020	Delayed slightly. There are 6 different animal reproductive toxicology studies required before a drug is approved. The original plan was to complete one study by Q2 2020. All 6 studies will be completed in the next year.
ATB-346 long-range animal toxicology studies (first tranche)	\$375,000	Q1 2020	Delayed slightly. There are 5 different animal toxicology studies required before a drug is approved. The original plan was to complete one study by Q2 2020. All 5 studies will be completed in the next year except for one which extends for 9 months and which is expected to be completed in late 2021
ATB-352 IND-enabling toxicology studies	\$300,000	Q2 2020	Milestone met. Planned toxicology studies were completed. Full/multiple IND-enabling preclinical studies are planned going forward for ATB-352.
Global branding initiatives	\$100,000	Q4 2019	Milestone met. Antibe received its official non-proprietary name for ATB-346 which was published in the INN list in March.
ATB-346 additional expenditures for Phase 2B dose-ranging, efficacy study	\$250,000	Q3 2019	Milestone met, though delayed. This was one of the largest human trials ever conducted in Canada at over 40 sites across the country. Logistical issues caused initial delays and the Covid-19 crisis caused further delays at the end.
Working capital and general corporate purposes	\$3,460,000		
<b>Total net proceeds</b>	<b>\$6,335,000</b>		

(1) Calendar quarter shown.

*Current Business Objectives and Milestones*

The following is a summary of the Company’s current business objectives and upcoming development milestones for its pipeline, in light of the status of the various milestones disclosed in the table above under the subheading “Business Objectives and Milestones – August 2019 Prospectus”:

<b>Pipeline Asset</b>	<b>Status</b>	<b>Milestone</b>	<b>Timing</b>	<b>Remaining Cost</b>
ATB-346	Phase Complete 2B	FDA regulatory consulting fees <sup>(2)</sup>	To be completed over next 6 months.	\$400,000 <i>(to be funded by proceeds of the Offering)</i>
		European regulatory consulting fees <sup>(3)</sup>	To be completed over next 6 months.	\$375,000 <i>(to be funded by proceeds of the Offering)</i>
		Market opportunity studies <sup>(4)</sup>	The studies are expected to take approximately 6 months to complete.	\$1,000,000 <i>(to be funded by proceeds of the Offering)</i>
		IND-opening AME study	Expected to commence in calendar Q4 2020 and take 3 months to complete.	\$300,000 <i>(to be funded by proceeds of the Offering)</i>
		Reproductive toxicology studies <sup>(1)(5)</sup>	Expected to conclude in calendar Q4 2020.	\$1.8 million <i>(to be funded by proceeds of the Offering)</i>
		Animal toxicology studies <sup>(1)(6)</sup>	First and second tranches expected to conclude in calendar Q1 2021 and calendar Q3 2021, respectively.	\$3.0 million for both phases <i>(to be funded by proceeds of the Offering)</i>
		Carcinogenicity studies	Expected to commence in calendar 2021.	\$2.5 million <i>(when funds become available)</i>
		Phase 3 drug supply	Expected to be available in calendar Q4 2020.	\$1.4 million <i>(to be funded by proceeds of the Offering)</i>
		Completion of Phase 3 studies (comprising four separate studies)	Expected to commence in late calendar Q1 or early calendar Q2 2021 and take 2 years to complete.	Estimated to be \$45-\$50 million in the aggregate <i>(The studies may be commenced and funded in tranches, as funds become available. \$5 million of the funds</i>

				<i>required are to be funded by this Offering and the balance by future partner(s) or when funds become available)</i>
ATB-352	Pre-clinical	Completion of IND-enabling pre-clinical studies (including toxicology studies) <sup>(7)</sup>	IND-enabling studies have commenced and are expected to conclude in calendar Q3 2021.	\$1.4 million <i>(to be funded by proceeds of the Offering)</i>
ATB-340	Pre-clinical	Completion of IND-enabling pre-clinical studies	IND-enabling studies are expected to commence in calendar 2021.	\$1,000,000 <i>(when funds become available)</i>

(1) The Company achieved all but two of the milestones referred to the August 2019 Prospectus. Its proposed animal reproductive toxicology studies and the first tranche of its proposed animal toxicology studies have been slightly delayed. Six different animal reproductive toxicology studies are required before a drug is approved. The Company originally intended to complete a single study by Q2 2020, but now intends to complete all 6 studies within the next twelve months. Similarly, 5 different animal toxicology studies are required before a drug is approved. The Company originally intended to complete one of these studies by Q2 2020, but now intends to complete all 5 studies within the next year, except for one which is expected to commence in autumn of 2020 and be completed in late 2021. See above under the subheading “*Business Objectives and Milestones – August 2019 Prospectus*” and “*Use of Proceeds – August 2019 Prospectus*”.

- (2) For filing IND and subsequent Type-C and end-of-Phase-2 meetings.
- (3) For initial meeting with European regulators, determining European trial requirements and if appropriate filing required documentation.
- (4) For partnering and for selected markets including Japan and China.
- (5) Completion of the current reproduction toxicology study and executing 5 additional required studies. All 6 studies will be completed in the next year.
- (6) Completion of the current toxicology study and executing 4 additional required studies. All 5 required studies will be completed in the next year expect for one which extends for 9 months and will be completed in late 2021.
- (7) Completion of all required pre-clinical studies to be in a position to file an IND for this drug.

Depending on its prevalence at applicable times, COVID-19 could delay the start of the Company’s Phase 2/3 trial for ATB-346 (currently projected to commence in late calendar Q1 2021 or early calendar Q2 2021) and potentially slow down enrolment in the trial. This could also have a negative impact on the cost of the trial in the event the Company needs to take measures to accelerate enrolment in the trial or is required to retain consultants at the Company’s expense for longer time periods than anticipated.

Antibe’s commercial subsidiary, Citagenix, is pursuing a global growth strategy in the dental biologics market. Strategic footprint and portfolio expansion of Citagenix is an on-going process of its normal business activity as it signs up new distributors in the United States and around the world and sources new products for its portfolio of bone grafts and barrier membranes. The Company is exploring strategic transactions for Citagenix with the objective of unlocking value for shareholders. Antibe would consider the successful completion of a merger or sale of Citagenix a significant milestone for the Company.

Although the Company intends to expend the net proceeds from the Offering as set forth above, there may be circumstances where, for sound business reasons, a reallocation of funds may be prudent or necessary, and may vary materially from that set forth above. The Company is currently incurring expenditures related to the Company’s operations that have generated negative operating cash flows. Operating cash flows may decline in certain circumstances, many of which are beyond the Company’s control. There is no assurance that sufficient revenues will be generated in the near future, and the Company may continue to incur negative operating cash flows. The Company may need to deploy a portion of its working capital to fund such negative operating cash flows or seek additional sources of funding. See “Risk Factors”.



## CERTAIN CANADIAN FEDERAL INCOME TAX CONSIDERATIONS

In the opinion of WeirFoulds LLP, counsel to the Company, and Torys LLP, counsel to the Underwriters, the following is, as of the date hereof, a general summary of the principal Canadian federal income tax considerations applicable to a purchaser of Units pursuant to the Offering who, at all relevant times and for purposes of the Tax Act, (i) acquires and holds the Offered Shares and Warrants and will hold the Warrant Shares as capital property, and (ii) deals at arm's length and is not affiliated with the Company, the Underwriters or any subsequent purchaser of such securities (a "**Holder**"). Offered Shares, Warrants and Warrant Shares will generally be considered to be capital property to a Holder unless the Holder holds the Offered Shares, Warrants and Warrant Shares in the course of carrying on a business of trading or dealing in securities or has acquired them in one or more transactions considered to be an adventure or concern in the nature of trade.

This summary is based upon the current provisions of the Tax Act, specific proposals to amend the Tax Act (the "**Proposed Amendments**") which have been announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof, and counsel's understanding of the current published administrative policies and assessing practices of the Canada Revenue Agency (the "**CRA**"). This summary assumes that the Proposed Amendments will be enacted in the form proposed and does not take into account or anticipate any other changes in law, whether by way of judicial, legislative or governmental decision or action, nor does it take into account provincial, territorial or foreign income tax legislation or considerations, which may differ from the Canadian federal income tax considerations discussed herein. No assurances can be given that such Proposed Amendments will be enacted as proposed or at all, or that legislative, judicial or administrative changes will not modify or change the statements expressed herein.

This summary does not apply to a Holder (a) that is a "financial institution" (as defined in the Tax Act) for purposes of the mark-to-market provisions of the Tax Act; (b) that is a "specified financial institution" (as defined in the Tax Act); (c) an interest in which is a "tax shelter investment" for purposes of the Tax Act; (d) that elects or has elected to report its "Canadian tax results" (as defined in the Tax Act) in a currency other than Canadian currency; (e) that has entered into a "derivative forward agreement" (as defined in the Tax Act) with respect to the Offered Shares, Warrants or Warrant Shares; (f) that receives dividends on Offered Shares or Warrant Shares under or as part of a "dividend rental arrangement" (as defined in the Tax Act); or (g) that is a corporation resident in Canada and is, or becomes, or does not deal at arm's length for purposes of the Tax Act with a corporation resident in Canada that is or becomes, as part of a transaction or event or series of transactions or events that includes the acquisition of the Offered Shares or Warrants, controlled by a non-resident corporation (or pursuant to the Proposed Amendments, a non-resident person or a group of persons comprised of any combination of non-resident corporations, non-resident individuals or non-resident trusts that do not deal with each other at arm's length) for purposes of the foreign affiliate dumping rules in section 212.3 of the Tax Act. Such Holders should consult their own tax advisors.

**This summary is not exhaustive of all possible Canadian federal income tax considerations applicable to an investment in Units. The following description of income tax matters is of a general nature only and is not intended to be, nor should it be construed to be, legal or income tax advice to any particular Holder. Holders are urged to consult their own income tax advisors with respect to the tax consequences applicable to them based on their own particular circumstances.**

### **Allocation of Cost**

A Holder who acquires Units will be required to allocate the purchase price of each Unit between the Offered Share and the one-third of one Warrant on a reasonable basis in order to determine their respective costs for purposes of the Tax Act. Holders should consult their own tax advisors in this regard. For its purposes, the Company intends to allocate \$0.38 to the Offered Share and \$0.02 to the one-third Warrant. Although the Company believes that such allocation is reasonable, it is not binding on the CRA or any Holder and the CRA may not agree with such allocation. Counsel expresses no opinion with respect to such allocation.

## **Adjusted Cost Base of Offered Shares**

The adjusted cost base to a Holder of an Offered Share acquired hereunder will be determined by averaging the cost of that Offered Share with the adjusted cost base (determined immediately before the acquisition of the Offered Share) of all other Common Shares held as capital property by the Holder immediately prior to such acquisition.

## **Exercise of Warrants**

The exercise of a Warrant to acquire a Warrant Share will not be considered a disposition of property for purposes of the Tax Act and consequently, a Holder will not realize a gain or loss upon the exercise of a Warrant to acquire a Warrant Share. The Holder's cost of the Warrant Share acquired on the exercise of a Warrant will be equal to the aggregate of the Holder's adjusted cost base of the Warrant exercised, plus the exercise price paid to acquire such Warrant Share. The Holder's adjusted cost base of such Warrant Share will be determined by averaging the cost of the Warrant Share with the adjusted cost base (determined immediately before the acquisition of such Warrant Share) of all other Common Shares held as capital property by the Holder immediately prior to such acquisition.

## **Residents of Canada**

The following portion of the summary applies to a Holder who, for purposes of the Tax Act, is or is deemed to be resident in Canada at all relevant times (a "**Resident Holder**"). Certain Resident Holders to whom Offered Shares and Warrant Shares might not constitute capital property may, in certain circumstances, make the irrevocable election under subsection 39(4) of the Tax Act to deem the Offered Shares, the Warrant Shares, and every other "Canadian security" (as defined in the Tax Act), held by such Resident Holder in the taxation year of the election and all subsequent taxation years to be capital property. This election does not apply to the Warrants. Resident Holders should consult their own tax advisors regarding this election.

## ***Disposition and Expiry of Warrants***

A Resident Holder who disposes or is deemed to dispose of a Warrant (other than upon the exercise thereof, which is discussed above) will generally realize a capital gain (or capital loss) equal to the amount by which the proceeds of disposition, net of any reasonable costs of disposition, are greater (or less) than the adjusted cost base of the Warrant to the Resident Holder. If a Warrant expires unexercised, the Resident Holder will realize a capital loss equal to the adjusted cost base of such Warrant to the Resident Holder. The tax treatment of capital gains and capital losses is discussed under the subheading "Capital Gains and Capital Losses".

## ***Dividends on Offered Shares and Warrant Shares***

Dividends received or deemed to be received on Offered Shares or Warrant Shares by an individual Resident Holder (including certain trusts) will be included in computing the individual's income and will be subject to the gross-up and dividend tax credit rules applicable to taxable dividends received from taxable Canadian corporations including, where applicable, an enhanced gross-up and dividend tax credit for dividends designated as "eligible dividends" by the Company.

Dividends received or deemed to be received on Offered Shares or Warrant Shares by a Resident Holder that is a corporation will be included in computing its income and will generally be deductible in computing its taxable income. In certain circumstances, subsection 55(2) of the Tax Act will treat a taxable dividend received or deemed to be received by a Resident Holder that is a corporation as proceeds of a disposition or a capital gain. Resident Holders that are corporations should consult their own tax advisor having regard to their own particular circumstances.

A Resident Holder that is a "private corporation" or a "subject corporation" (each as defined in the Tax Act) may be liable to pay a refundable tax under Part IV of the Tax Act on dividends received or deemed to be received on the Offered Shares or Warrant Shares, to the extent that such dividends are deductible in computing the Resident Holder's taxable income.

### ***Disposition of Offered Shares and Warrant Shares***

A Resident Holder who disposes or is deemed to dispose of an Offered Share or Warrant Share (other than a disposition to the Company that is not a sale in the open market in the manner in which shares would normally be purchased by any member of the public in an open market) will generally realize a capital gain (or capital loss) equal to the amount by which the proceeds of disposition, net of any reasonable costs of disposition, are greater (or less) than the adjusted cost base of the Offered Share or Warrant Share, as the case may be, to the Resident Holder. The tax treatment of capital gains and capital losses is discussed under the subheading "Capital Gains and Capital Losses".

### ***Capital Gains and Capital Losses***

One-half of any capital gain (a "**taxable capital gain**") realized by a Resident Holder must be included in the Resident Holder's income for the taxation year in which the disposition occurs. Subject to and in accordance with the provisions of the Tax Act, one-half of any capital loss (an "**allowable capital loss**") must be deducted against taxable capital gains realized in the year of disposition. Any unused allowable capital losses may be applied to reduce net taxable capital gains realized in any of the three prior years or in any subsequent year in the circumstances and to the extent provided in the Tax Act.

A capital loss realized on the disposition of an Offered Share or Warrant Share by a Resident Holder that is a corporation may in certain circumstances be reduced by the amount of dividends that have been received or deemed to have been received by the Resident Holder on such share or shares substituted for such share to the extent and in the circumstances described by the Tax Act. Similar rules may apply where a Resident Holder that is a corporation is a member of a partnership or a beneficiary of a trust that owns Offered Shares or Warrant Shares directly or indirectly through a partnership or trust.

A Resident Holder that is throughout the year a "Canadian-controlled private corporation" (as defined in the Tax Act) may be liable to pay a refundable tax on certain investment income, including taxable capital gains. Resident Holders that are "Canadian-controlled private corporations" should consult their own tax advisors regarding their particular circumstances.

### ***Alternative Minimum Tax***

Capital gains realized and taxable dividends received or deemed to be received by a Resident Holder that is an individual or a trust (other than certain trusts) may be liable for alternative minimum tax under the Tax Act. Resident holders should consult their own tax advisors with respect to the application of alternative minimum tax.

### ***Non-Residents of Canada***

The following portion of the summary applies to Holders who, at all relevant times, for the purposes of the Tax Act, (i) are not resident or deemed to be resident in Canada, and (ii) do not use or hold Offered Shares, Warrants or Warrant Shares in the course of a business carried on or deemed to be carried on in Canada (a "**Non-Resident Holder**"). Special rules, which are not discussed in this summary, may apply to a Non-Resident Holder that is an insurer carrying on business in Canada and elsewhere. Such Non-Resident Holders should consult their own tax advisors.

### ***Dividends***

Dividends paid or credited or deemed to be paid or credited on Offered Shares or Warrant Shares to a Non-Resident Holder will generally be subject to Canadian withholding tax at the rate of 25%, subject to reduction under the provisions of an applicable tax treaty or convention. In the case of a Non-Resident Holder that is a resident of the United States and fully entitled to benefits under the *Canada-United States Tax Convention* (1980), as amended, the rate of withholding tax on such dividends beneficially owned by such Non-Resident Holder will generally be reduced to 15%. This rate is reduced to 5% in the case of a Non-Resident Holder that is the beneficial owner of the dividends and that is a corporation that owns beneficially at least 10% of the voting stock of the Company.

### ***Dispositions of Offered Shares, Warrants and Warrant Shares***

A Non-Resident Holder who disposes of or is deemed to have disposed of an Offered Share, a Warrant or a Warrant Share will not be subject to income tax under the Tax Act in respect of any capital gain realized thereon unless, at the time of disposition, the Offered Share, Warrant or Warrant Share, as the case may be, is or is deemed to be "taxable Canadian property" (as defined in the Tax Act) of the Non-Resident Holder, and the gain is not exempt from tax pursuant to the terms of an applicable tax treaty or convention.

Provided the Offered Shares and Warrant Shares are listed on a "designated stock exchange" (which currently includes Tiers 1 and 2 of the TSXV), the Offered Shares, Warrants and Warrant Shares generally will not constitute taxable Canadian property of a Non-Resident Holder at the time of disposition unless at any time during the 60-month period immediately preceding the disposition, the following two conditions are met concurrently: (a) one or any combination of (i) the Non-Resident Holder, (ii) persons with whom the Non-Resident Holder did not deal at arm's length, and (iii) partnerships in which the Non-Resident Holder or a person with whom the Non-Resident Holder did not deal at arm's length holds a membership interest directly or indirectly through one or more partnerships, owned 25% or more of the issued shares of any class or series of the capital stock of the Company, and (b) more than 50% of the fair market value of the Offered Shares or Warrant Shares was derived directly or indirectly from one or any combination of real or immovable property situated in Canada, Canadian resource properties (as defined in the Tax Act), timber resource properties (as defined in the Tax Act) and options in respect of, or interests in, or for civil law rights in, any such property, whether or not such property exists. The Offered Shares, Warrants or Warrant Shares may also be deemed to be taxable Canadian property of a Non-Resident Holder in certain circumstances.

In the event that an Offered Share, Warrant or Warrant Share constitutes taxable Canadian property of a Non-Resident Holder and any capital gain realized on the disposition thereof is not exempt from tax pursuant to the terms of an applicable income tax treaty or convention, the income tax consequences discussed under "Residents of Canada – Capital Gains and Capital Losses" would generally apply to the Non-Resident Holder.

Non-Resident Holders whose Offered Shares, Warrants or Warrant Shares are taxable Canadian property should consult their own tax advisors.

## **DESCRIPTION OF SECURITIES BEING DISTRIBUTED**

### **Authorized Capital**

The Company's authorized share capital currently consists of an unlimited number of Common Shares, of which, as at the date hereof, 281,284,125 Common Shares are issued and outstanding. Assuming the completion of the Offering (and no exercise of the Over-Allotment Option), there will be 343,784,125 Common Shares issued and outstanding (on a non-diluted basis). Assuming the completion of the Offering and the Over-Allotment Option is exercised in full, upon completion of the Offering, there will be 353,159,125 Common Shares issued and outstanding (on a non-diluted basis).

### **Units**

Each Unit consists of one Offered Share and one-third of one Warrant. The following is a summary of the rights, privileges, restrictions and conditions attached to such securities.

### **Common Shares**

Each Offered Share, Warrant Share and Broker Warrant Share is a Common Share. Each holder of a Common Share is entitled to (i) notice of and the right to vote at all meetings of shareholders of the Company, (ii) receive any dividend declared by the board of directors of the Company, and (iii) receive the remaining property of the Company in the event of the voluntary or involuntary liquidation, dissolution or winding up of the Company, or any other distribution of its assets among its shareholders for the purposes of winding up its affairs.

## Warrants

The Warrants will be governed by the terms of a warrant indenture (the "**Warrant Indenture**") to be entered into between the Company and Computershare Trust Company of Canada, as warrant agent thereunder (the "**Warrant Agent**"). The Company will appoint the principal transfer offices of the Warrant Agent in Toronto, Ontario, or such other place designated by the Company with the approval of the Warrant Agent, as the location at which Warrants may be surrendered for exercise or transfer. The following summary of certain provisions of the Warrant Indenture contains all of the material attributes and characteristics of the Warrants but does not purport to be complete and is qualified in its entirety by reference to the provisions of the Warrant Indenture.

Each whole Warrant will entitle the holder to purchase one Warrant Share at an exercise price of \$0.40 per Warrant Share, subject to adjustment in certain circumstances, at any time prior to the Warrant Expiry Time. **WARRANTS NOT EXERCISED PRIOR TO THE WARRANT EXPIRY TIME WILL BE VOID AND OF NO VALUE.**

The exercise price for the Warrants will be payable in Canadian dollars.

The Warrant Indenture will provide for adjustment in the number of Warrant Shares issuable upon the exercise of the Warrants and/or the exercise price per Warrant Share upon the occurrence of certain events, including:

- a) the issuance of Common Shares or securities exchangeable for or convertible into Common Shares to holders of all or substantially all of the Company's Common Shares by way of stock dividend or other distribution (other than a "dividend paid in the ordinary course", as defined in the Warrant Indenture, or a distribution of Common Shares upon the exercise of the Warrants or pursuant to the exercise of director, officer or employee stock options granted under the Company's stock option plan);
- b) the subdivision, redivision or change of the Common Shares into a greater number of shares;
- c) the consolidation, reduction or combination of the Common Shares into a lesser number of shares;
- d) the fixing of a record date for the issue of rights, options or warrants to all or substantially all of the holders of the Common Shares under which such holders are entitled, during a period expiring not more than 45 days after the record date for such issuance, to subscribe for or purchase Common Shares, or securities exchangeable for or convertible into Common Shares, at a price per share to the holder (or having an exchange or conversion price per share) of less than 95% of the "current market price", as defined in the Warrant Indenture, for the Common Shares on such record date; and
- e) the issuance or distribution to all or substantially all of the holders of the securities of the Company including shares, rights, options or warrants to acquire shares of any class or securities exchangeable or convertible into any such shares or cash, property or assets and including evidences of indebtedness, or any cash, property or other assets.

The Warrant Indenture will also provide for adjustment in the class and/or number of securities issuable upon the exercise of the Warrants and/or exercise price per security in the event of the following additional events: (i) reclassifications of the Common Shares; (ii) consolidations, amalgamations, plans of arrangement or mergers of the Company with or into another entity; or (iii) the transfer of the undertaking or assets of the Company as an entirety or substantially as an entirety to another Company or other entity.

No adjustment in the exercise price or the number of Warrant Shares purchasable upon the exercise of the Warrants will be required to be made unless the cumulative effect of such adjustment or adjustments would change the exercise price by at least 1% or the number of Warrant Shares purchasable upon exercise by at least one one-hundredth of a Warrant Share. Further, no adjustment will be made for Common Shares issued: (i) upon exercise of the Warrants; (ii) pursuant to any dividend reinvestment or similar plan adopted by the Company; (iii) pursuant to stock option or purchase plans, as payment of interest on outstanding notes, in connection with strategic license agreements or other partnering arrangements; or (iv) in connection with a strategic merger, consolidation or purchase of substantially all of the securities or assets of a corporation or other entity.

The Company will also covenant in the Warrant Indenture that, during the period in which the Warrants are exercisable, it will give notice to holders of Warrants of certain stated events, including events that would result in an adjustment to the exercise price for the Warrants or the number of Warrant Shares issuable upon exercise of the Warrants, at least 10 business days prior to the record date or effective date, as the case may be, of such event.

If a Warrant holder is entitled to a fraction of a Warrant, the number of Warrants issued to that Warrant holder shall be rounded down to the nearest whole Warrant. No fractional Warrant Shares will be issuable upon the exercise of any Warrants; instead cash will be paid in lieu of fractional shares. Holders of Warrants will not have any voting rights or any other rights which a holder of Common Shares would have.

The Warrants will not be exercisable in the United States or by or on behalf of a person in the United States or a U.S. Person, nor will certificates representing the Common Shares issuable upon exercise of the Warrants be registered or delivered to an address in the United States, unless an exemption from registration under the U.S. Securities Act and any applicable state securities laws is available and the Company has received an opinion of counsel of recognized standing or such other evidence to such effect in form and substance reasonably satisfactory to the Company; provided, however, that a holder who is a Qualified Institutional Buyer (as defined herein) or Accredited Investor (as defined herein) at the time of exercise of the Warrants who purchased Units in the Offering within the United States or to, or for the account or benefit of, persons in the United States or U.S. Persons will not be required to deliver an opinion of counsel or such other evidence in connection with the exercise of Warrants that are a part of those Units.

From time to time, the Company (when properly authorized) and the Warrant Agent, subject to the provisions of the Warrant Indenture, may amend or supplement the Warrant Indenture for certain purposes. Certain amendments or supplements to the Warrant Indenture may only be made by "extraordinary resolution", which is defined in the Warrant Indenture as a resolution either: (i) passed at a meeting of the holders of Warrants at which there are holders of Warrants present in person or represented by proxy representing at least 25% of the aggregate number of the then outstanding Warrants and passed by the affirmative vote of holders of Warrants representing not less than  $66\frac{2}{3}\%$  of the aggregate number of all the then outstanding Warrants represented at the meeting and voted on such resolution; or (ii) adopted by an instrument in writing signed by the holders of Warrants representing not less than  $66\frac{2}{3}\%$  of the aggregate number of all of the then outstanding Warrants.

**The Company has not applied and does not intend to apply to list the Warrants on any securities exchange. There will be no market through which the Warrants may be sold and purchasers may not be able to resell the Warrants purchased in the Offering. This may affect the pricing of the Warrants in the secondary market, the transparency and availability of trading prices, the liquidity of the Warrants, and the extent of issuer regulation. See "Risk Factors".**

## PLAN OF DISTRIBUTION

Pursuant to the Underwriting Agreement, the Company has agreed to sell and the Underwriters have severally and not jointly (and not jointly and severally), agreed to purchase, on the Closing Date, or on such other date as may be agreed upon, but in any event no later than the date that is 42 days after the date of the receipt for the final short form prospectus, an aggregate of 62,500,000 Units at the Offering Price, for an aggregate gross consideration of \$25,000,000 payable in cash to the Company by the Underwriters against delivery of the Units. The obligations of the Underwriters under the Underwriting Agreement may be terminated at their discretion on the basis of "disaster out" and "material adverse change out" provisions and may also be terminated upon the occurrence of certain other stated events. The Underwriters are, however, obligated to take up and pay for all of the Units if any of the Units are purchased under the Underwriting Agreement. The terms of the Offering, including the Offering Price, were determined by negotiations between the Company and the Lead Underwriter, with reference to the market price of the Common Shares.

As partial consideration for their services in connection with the Offering, the Underwriters will receive a cash commission of 7% of the gross proceeds of the Offering including any proceeds received pursuant to the Over-Allotment Option. In addition, the Company will grant to the Underwriters on the Closing Date non-transferable Broker Warrants to purchase up to that number of Common Shares that is equal to 7% of the aggregate number of Units sold on the Closing Date, including the Additional Units. Each Broker Warrant, will enable the holder to

acquire one Broker Warrant Share at a price of \$0.40 per Broker Warrant Share at any time prior to 5:00 p.m. (Toronto time) on the date that is 24 months after the Closing Date. This Prospectus also qualifies the distribution of Broker Warrants.

The Company has agreed to grant to the Underwriters an Over-Allotment Option exercisable, in whole or in part, at the Underwriters' sole discretion, to offer and sell up to a number of Additional Units and/or Additional Warrants that is equal to 15% of the number of Units sold hereunder at a price equal to the Offering Price, in respect of the Additional Units, and at \$0.06, in respect of the Additional Warrants, to cover over-allocations, if any, and for market stabilization purposes. The Over-Allotment Option is exercisable, in whole or in part, at any time or times during the 30-day period immediately following the Closing Date. The Over-Allotment Option may be exercised by the Underwriters in respect of: (i) Additional Units at the Offering Price; (ii) Additional Warrants at a price of \$0.06 per Additional Warrant; or (iii) any combination of Additional Units and/or Additional Warrants, so long as the aggregate number of Additional Warrants does not exceed 15% of the number of Warrants issued under the Offering (excluding the Over-Allotment Option). Unless the context requires, references to Units herein shall include the Additional Units and references to Warrants herein shall include the Additional Warrants. If the Offering is completed and if the Underwriters exercise the Over-Allotment Option in full, the total price to the public, Underwriters' Fee and net proceeds to the Company (before deducting the expenses of the Offering which are estimated to be approximately \$200,000) will be \$28,750,000, \$2,012,500 and \$26,737,500, respectively. This Prospectus also qualifies the grant of the Over-Allotment Option and the distribution of any Additional Shares and Additional Warrants, including Additional Warrants that are part of Additional Units issued or sold pursuant to the exercise of the Over-Allotment Option. A purchaser who acquires Additional Units and/or Additional Warrants forming part of the Underwriters' over-allocation position acquires such Additional Units and/or Additional Warrants under this Prospectus, regardless of whether the over-allocation position is ultimately filled through the exercise of the Over-Allotment Option or secondary market purchases.

Subscriptions for Units will be received subject to rejection or allotment, in whole or in part, and the Underwriters reserve the right to close the subscription books at any time without notice. No certificates will be issued in respect of the Units, Offered Shares, Warrants or Warrant Shares. The Offering will be conducted under the book-based system in the Canadian jurisdictions where the Units are being sold. A subscriber in a Canadian jurisdiction where the Units are being sold who purchases Units will receive a customer confirmation from the registered dealers through which Units are purchased and who is a CDS depository-service participant. CDS will record the CDS participants who hold Offered Shares and Warrants on behalf of owners who have purchased them in accordance with the book-based system.

The Underwriters propose to offer the Units initially at the Offering Price set forth on the cover page of this short form prospectus. After the Underwriters have made reasonable efforts to sell all the Units at the Offering Price, the price at which the Units are sold to purchasers may be decreased. The compensation realized by the Underwriters will be decreased by the amount that the aggregate price paid by the purchasers for the Units is less than the gross proceeds paid by the Underwriters to the Company under the Offering.

The TSXV has conditionally approved listing of the following securities of the Company on the TSXV: (i) the Offered Shares (including any Additional Shares issuable upon exercise of the Over-Allotment Option); (ii) the Warrant Shares (including any Additional Warrant Shares) issuable upon exercise of the Warrants (including any Additional Warrants issuable upon exercise of the Over-Allotment Option); and (iii) the Broker Warrant Shares issuable upon exercise of the Broker Warrants. Listing is subject to the Company fulfilling all of the listing requirements of the TSXV. The Company has not applied and does not intend to apply to list the Warrants on any securities exchange.

Under certain rules of the Canadian securities regulatory authorities and the Universal Market Integrity Rules for Canadian Marketplaces of the Investment Industry Regulatory Organization of Canada (the "UMIR"), the Underwriters may not, throughout the period of distribution, bid for or purchase Common Shares. These rules allow certain exceptions to those prohibitions. The Underwriters may only avail themselves of those exceptions on the condition that the bid or purchase not be for the purpose of creating actual or apparent active trading in, or raising the price, of the Common Shares. These exceptions include a bid or purchase permitted under the UMIRs relating to market stabilization and passive market making activities and a bid or purchase made for and on behalf of a

customer where the order was not solicited during the period of distribution. In connection with the Offering, the Underwriters may over-allot or effect transactions that stabilize or maintain the market price of the Common Shares at levels other than those that may otherwise exist in the open market. These transactions, if commenced, may be discontinued at any time.

The Units, the Offered Shares, the Warrants and the Warrant Shares have not been and will not be registered under the U.S. Securities Act or any applicable state securities laws and, accordingly, the Units may not be offered, sold, or delivered directly or indirectly, within the United States or to, or for the account or benefit of, persons in the United States or U.S. Persons, except in transactions exempt from the registration requirements of the U.S. Securities Act and applicable state securities laws. Accordingly, except to the extent permitted by the Underwriting Agreement, the Units, the Offered Shares and the Warrants may not be offered or sold within the United States or, to or for the account or benefit of, persons in the United States or U.S. Persons. The Underwriters have agreed that they will not offer or sell the Units, the Offered Shares or the Warrants within the United States or to, or for the account or benefit of, persons in the United States or U.S. Persons, except that offers and sales of Units, the Offered Shares and the Warrants may be made in compliance with Rule 15a-6 under the United States Securities Exchange Act of 1934, as amended, or by or through one or more U.S. placement agents, in transactions exempt from the registration requirements of the U.S. Securities Act and applicable state securities laws. The Underwriting Agreement provides that the Units, the Offered Shares and the Warrants may be (i) offered and sold by the Underwriters within the United States or to, for the account or benefit of, persons in the United States or U.S. Persons to “qualified institutional buyers” (as such term is defined in Rule 144A (“**Rule 144A**”) under the U.S. Securities Act) (“**Qualified Institutional Buyers**”) in compliance with Rule 144A and (ii) offered by the Underwriters within the United States or to, for the account or benefit of, persons in the United States or U.S. Persons to substituted purchasers to whom the Company will sell such securities directly to “accredited investors” (as such term is defined in Rule 501(a) of Regulation D (“**Regulation D**”) under the U.S. Securities Act (“**Accredited Investors**”) in compliance with Rule 506(b) of Regulation D, in each case in compliance with applicable state securities laws. The Underwriting Agreement also provides that the Underwriters will offer and sell the Units, the Offered Shares and the Warrants outside the United States to non-U.S. Persons in accordance with Rule 903 of Regulation S promulgated under the U.S. Securities Act.

This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, any of the Units, the Offered Shares or the Warrants within the United States or to, or for the account or benefit of, persons in the United States or U.S. Persons. In addition, until 40 days after the commencement of the Offering, any offer or sale of Units, the Offered Shares or the Warrants offered hereby within the United States or to, or for the account or benefit of, persons in the United States or U.S. Persons by any dealer (whether or not participating in the Offering) may violate the registration requirements of the U.S. Securities Act if such offer or sale is made otherwise than in accordance with an exemption from the registration requirements of the U.S. Securities Act.

The Offered Shares, the Warrants and the Warrant Shares, in each instance issued within the United States or to, or for the account or benefit of, persons in the United States or U.S. Persons, will be “restricted securities” within the meaning of Rule 144(a)(3) under the U.S. Securities Act. Any certificates representing such securities will bear a legend to the effect that the securities represented thereby are not registered under the U.S. Securities Act or any applicable U.S. state securities laws and may only be offered, sold, pledged or otherwise transferred pursuant to certain exemptions from the registration requirements of the U.S. Securities Act and any applicable U.S. state securities laws.

Terms used and not defined in the three preceding paragraphs shall have the meanings ascribed thereto by Regulation S under the U.S. Securities Act.

Certain of the Underwriters and/or their affiliates have performed investment banking and advisory services for the Company and its affiliates from time to time for which they have received customary fees and expenses. The Underwriters and/or their affiliates may, from time to time, engage in transactions with, or perform services for, the Company and its affiliates in the ordinary course of business and receive related fees.

Other than in British Columbia, Alberta, Saskatchewan, Manitoba and Ontario, no action has been taken by the Company or the Underwriters that would permit a public offering of the Units offered by this Prospectus in any jurisdiction where action for that purpose is required. The Units offered by this Prospectus may not be offered or



sold, directly or indirectly, nor may this Prospectus or any other offering material or advertisements in connection with the offer and sale of any Units be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this Prospectus comes are advised to inform themselves about and to observe any restrictions relating to the Offering and the distribution of this Prospectus.

This Prospectus does not constitute an offer to sell or a solicitation of an offer to buy any Units offered by this Prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### Relationship Between the Company and Certain of the Underwriters

Bloom Burton Securities Inc. is an affiliate of an entity with direction or control over a lender that has provided a \$2.25 million senior secured credit facility to Citagenix, a wholly-owned subsidiary of the Company. Consequently, the Company may be considered a “connected issuer” of Bloom Burton Securities Inc. under applicable Canadian securities laws. As of December 31, 2019, Citagenix’s indebtedness under the credit facility owing to the lender of which Bloom Burton Securities Inc. is an affiliate is \$2,250,000. The credit facility is secured by all of the assets of Citagenix and is guaranteed by the Company. The decision to issue the Units and the determination of the terms of the Offering were made through negotiation between the Company and the Underwriters. The entity of which Bloom Burton Securities Inc. is an affiliate did not have any involvement in such decision or determination although such lender may be advised of the Offering and the terms thereof. As a consequence of the Offering, Bloom Burton Securities Inc. will receive its proportionate share of the Underwriters’ Fee. The Company is and has been in compliance with all material terms and conditions of the foregoing credit facility and confirms that no waiver of any default has occurred thereunder. The proceeds of this Offering are not expected to be applied for the benefit of Bloom Burton Securities Inc. or the entity with direction or control over the lender of which Bloom Burton Securities Inc. is an affiliate. See "Use of Proceeds".

### MARKET FOR SECURITIES

The outstanding Common Shares are traded on the TSXV under the trading symbol "ATE" and are also quoted on the OTCQB under the symbol "ATBPF". The following table sets forth the price range and trading volumes for the Common Shares on the TSXV and OTCQB as reported by the TSXV and OTCQB for the periods indicated:

Month	TSX Venture Exchange			OTCQB		
	High (CDNS)	Low (CDNS)	Volume	High (US\$)	Low (US\$)	Volume
June 1 - 25, 2020	<b>0.890</b>	<b>0.395</b>	<b>75,222,361</b>	<b>0.640</b>	<b>0.297</b>	<b>16,282,910</b>
May 2020	0.820	0.570	22,788,144	0.583	0.399	3,294,608
April 2020	0.810	0.540	35,081,412	0.582	0.390	5,470,902
March 2020	0.720	0.395	39,880,142	0.529	0.280	7,091,520
February 2020	0.680	0.560	24,793,019	0.514	0.409	4,514,409
January 2020	0.590	0.440	21,328,532	0.455	0.339	4,453,615
December 2019	0.460	0.370	9,381,503	0.356	0.277	2,027,004
November 2019	0.500	0.365	19,171,735	0.383	0.285	2,553,082
October 2019	0.540	0.370	20,142,271	0.410	0.280	3,399,769
September 2019	0.420	0.365	8,167,488	0.313	0.276	1,237,005
August 2019	0.470	0.280	39,722,631	0.356	0.210	5,312,043
July 2019	0.335	0.280	9,713,831	0.268	0.213	3,135,474
June 2019	0.340	0.300	4,724,602	0.258	0.224	1,995,972

May 2019	0.370	0.325	8,355,590	0.273	0.237	2,437,090
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### PRIOR SALES

During the twelve-month period prior to the date of this Prospectus, the Company issued the following:

Warrants			
Date of Issuance	Number of Common Shares Issuable on Exercise of Warrants	Exercise Price	Expiry Date
June 13, 2019	61,250 <sup>(1)</sup>	\$0.15	June 21, 2020
June 19, 2019	12,500 <sup>(1)</sup>	\$0.15	June 21, 2020
June 20, 2019	2,500 <sup>(1)</sup>	\$0.15	June 21, 2020
August 13, 2019	13,416,666	\$0.40	August 13, 2022
August 13, 2019	1,878,333	\$0.30	August 13, 2021

Restricted Share Units (RSUs) <sup>(2)</sup>	
Date of issuance	Number of RSUs
November 28, 2019	7,630,000
February 25, 2020	390,000

Stock Options <sup>(3)</sup>			
Date of Issuance	Number of Common Shares Issuable on Exercise of Options	Exercise Price	Expiry Date
August 27, 2019	350,000	\$0.30	August 27, 2022

Note:

- (1) Warrants issued pursuant to the exercise of broker warrants granted in connection with the Company's 2017 prospectus financing.
- (2) Granted pursuant to the Company's RSU Plan.
- (3) Granted pursuant to the Company's Stock Option Plan.

### RISK FACTORS

An investment in the Units is speculative and involves a number of risks. Before deciding whether to invest in the Units, prospective purchasers should carefully consider, in light of their own circumstances, the risks described below and the other information contained in this Prospectus including the documents incorporated by reference in this Prospectus. **Prospective purchasers should also carefully review the risks and uncertainties described under the heading "Risk Factors" at pages 30 to 37 of the AIF which include risks related to: Ability to Continue as a Going Concern, Lack of Supporting Clinical Data, Research and Development Risk, Clinical Development Risks, Negative Cash Flow from Operating Activities, Operational Risk, Reliance on Partners and Suppliers, Distributor Risks, Disruptions in Production, Seasonality, Fluctuations in Exchange Rates, Income Taxes, Worsened General Economic Conditions, Acquisitions, Product Liability and Medical**

**Malpractice Claims, Management of Growth, Dependence on Key Personnel, Protection of Intellectual Property, Inability to Implement the Business Strategy, Large Accumulated Deficit, Competitive Market for Antibe's Products, Intellectual Property Litigation, Non-IP Litigation, Regulatory Risk, Regulatory Compliance, International Operations, Financial Instruments, Volatility of Share Price, Influence of Significant Shareholder, Future Sales of Common Shares, Dividends, Internal Controls over Financial Reporting, Prior Losses and Ability to Secure Additional Financing & Dilution of Common Shares.** If any of the events described as risks or uncertainties in the AIF or if any of the following events described as risks or uncertainties actually occurs, the Company's business, prospects, financial condition and operating results would likely suffer, possibly materially. In that event, the market price of the Common Shares could decline and purchasers could lose part or all of their investment. Additional risks and uncertainties presently unknown to the Company, or that the Company believes not to be material at this time, may also impair or have a material adverse effect on the Company's operations.

## **Risks Related to the Company**

### ***COVID-19 pandemic***

In December 2019, COVID-19 emerged in Wuhan, China. Since then, it has spread to most other countries and infections have been reported around the world. Canada confirmed its first case of COVID-19 on January 25, 2020 and its first death related to COVID-19 on March 9, 2020. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. In response to the outbreak, governmental authorities in Canada and internationally have introduced various recommendations and measures to try to limit the pandemic, including travel restrictions, border closures, nonessential business closures, quarantines, self-isolations, shelters-in-place and social distancing. The COVID-19 outbreak and the response of governmental authorities to try to limit it are having a significant impact on the private sector and individuals, including unprecedented business, employment and economic disruptions.

The COVID-19 pandemic has impacted the Company's business to some extent. The Company's Phase 2 trial took an additional six weeks to complete due to factors such as the COVID-19 related closure of medical clinics, doctors becoming ill from COVID-19, and staff working from home, all of which slowed the collation of the trial data. The need to engage the consulting staff responsible for administering the trial for an additional six weeks increased the costs of the trial correspondingly. COVID-19 has also particularly impacted the Company's wholly-owned subsidiary, Citagenix, by causing a significant COVID-19 related decline in sales. The sales decline is solely due to a decline in customer demand, which the Company attributes to COVID-19. COVID-19 could further impact our expected timelines, operations and the operations of our third-party suppliers, manufacturers, and CROs as a result of quarantines, facility closures, travel and logistics restrictions and other limitations in connection with the outbreak. The most significant risk posed by the COVID-19 pandemic is that it could also significantly impact the progress and completion of the pre-clinical trials and other items as noted in the "Use of Proceeds" in this Prospectus.

What further impact, if any, the COVID-19 pandemic may have on the Company is unpredictable. The continued spread of COVID-19 nationally and globally could also lead to a deterioration of general economic conditions including a possible national or global recession. Due to the speed with which the COVID-19 situation is developing and the uncertainty of its magnitude, outcome and duration, it is not possible to estimate its impact on our business, operations or financial results; however, the impact could be material.

### ***The Company's Licensees may not Perform or may Terminate the Licenses***

The Company is party to license agreements for certain of its drug candidates with various counterparties for various geographical jurisdictions. For instance, the Company recently entered into an exclusive license agreement in respect of development and commercialization of ATB-346 in South Korea with Kwang Dong Pharmaceutical Co., Ltd. and the Company may enter into additional license agreements in the future, including with smaller or medium-sized pharmaceutical companies in regions that represent smaller market opportunities (i.e. outside of the United States and Western Europe). Licensees generally have the right to terminate license agreements and/or may not perform as expected or in accordance with the terms and conditions of a license agreement. The actions or inactions of licensees relating to the Company's licenses or otherwise could negatively impact the Company's products,

reputation and results of operations. In addition, disputes may arise between the Company and its licensees that may result in the delay or termination of the research, development or commercialization of drug candidates, as applicable, or that result in costly litigation. While the Company intends to be selective in choosing financially strong and experienced licensees, it will have little or no ability to control the business practices or other actions of its licensees beyond specific matters relating to license set forth in each license agreement.

***Citagenix has Been Advanced Funds Under a Secured Loan Agreement and Failure to Pay All Amounts as and when they Become Due Could Result in a Loss of all of its Assets, Including its Intellectual Property***

On June 29, 2018, Citagenix, a wholly-owned subsidiary of the Company, obtained a \$2.25 million senior secured revolving credit facility from a lender of which Bloom Burton Securities Inc. is an affiliate. The loan bears interest at a rate of 7.0% per annum, compounded monthly and payable quarterly, and has a maturity date of June 29, 2020. The loan is secured by a first priority charge on all of Citagenix's assets, including Citagenix's intellectual property, and contains restrictive and other customary covenants. The loan is guaranteed by the Company. See "Loan Facilities" in the Company's management's discussion and analysis for the three and nine months ended December 31, 2019 and "Plan of Distribution – Relationship Between the Company and Certain of the Underwriters".

There is no assurance that Citagenix or the Company will have sufficient cash available to make interest payments or to repay the principal amount of the loan when it becomes due. If an event of default under the loan occurs, the lender could elect to declare all principal amounts outstanding under the loan at such time, together with accrued interest and applicable fees, to be immediately due and payable. If Citagenix or the Company do not have sufficient capital resources to make quarterly interest payments or payments due at maturity or upon default, Citagenix or the Company may need to seek additional funding through public or private equity or debt financing, or may be required to divert capital that would otherwise have been used for research and development activities, which could adversely affect the Citagenix's and the Company's business, financial condition, prospects and results of operations. If Citagenix or the Company are unable to repay amounts owing under the loan, the lender could proceed to foreclose or otherwise realize upon all of Citagenix's assets, including its intellectual property, that is security for the indebtedness, and/or call upon the Company to repay the indebtedness by virtue of the guarantee.

**Risks Related to the Offering**

***Active Liquid Market for Common Shares***

There may not be an active, liquid market for the Offered Shares and Warrant Shares. There is no guarantee that an active trading market for the Common Shares will be maintained on the TSXV. Investors may not be able to sell their Offered Shares and Warrant Shares quickly or at the latest market price if trading in the Common Shares is not active.

***Future Sales or Issuances of Securities***

The Company may sell additional Common Shares or other securities in subsequent offerings to finance future activities. The Company cannot predict the size of future issuances of securities or the effect, if any, that future issuances and sales of securities will have on the market price of the Common Shares. Sales or issuances of substantial numbers of Common Shares, or the perception that such sales could occur, may adversely affect prevailing market prices of the Common Shares. With any additional sale or issuance of Common Shares, investors will suffer dilution to their voting power and the Company may experience dilution in its earnings per share.

***Forward-Looking Information May Prove Inaccurate***

Investors are cautioned not to place undue reliance on forward-looking statements and forward-looking information. By its nature, forward-looking statements and forward-looking information involve numerous assumptions, known and unknown risks and uncertainties, of both a general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking statements and forward-looking information or contribute to the possibility that predictions, forecasts or projections will prove to be materially inaccurate. Additional

information on the risks, assumptions and uncertainties are found in this Prospectus under the heading "Forward-Looking Information".

### ***Price of the Company's Common Shares May Fluctuate***

Market prices for securities in general, and that of pharmaceutical companies in particular, tend to fluctuate. Factors such as the announcement to the public or in various scientific or industry forums of technological innovations; new commercial products; patents, exclusive rights obtained by the Company or others; disputes or other developments relating to proprietary rights, including patents and data exclusivity, litigation matters and our ability to obtain patent protection and data exclusivity for our technologies; the commencement, enrollment or results of future clinical trials we may conduct, or changes in the development status of our product candidates; results or delays of pre-clinical and clinical studies by the Company or others; any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings; a change of regulations; additions or departures of key scientific or management personnel; overall performance of the equity markets; general political and economic conditions; publications; failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; research reports or positive or negative recommendations or withdrawal of research coverage by securities analysts; actual or anticipated variations in quarterly operating results; announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by the Company or our competitors; public concerns over the risks of pharmaceutical products and dietary supplements; unanticipated serious safety concerns; future sales of securities by the Company or its shareholders; and many other factors, many of which are beyond our control, could have considerable effects on the price of the Company's securities. There can be no assurance that the market price of the Common Shares will not experience significant fluctuations in the future. As a result of any of these factors, the market price of the securities of the Company at any given point in time may not accurately reflect the value of the Company or its securities.

In addition, the stock market in general, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Shares, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Accordingly, investors may not be able to sell their Offered Shares or Warrant Shares at or above the Offering Price.

### ***Dilution to Existing Shareholders, Restrictions on Operations and Relinquishment Rights to Technologies or Product Candidates***

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to the Company.

### ***Decline of Market Price of the Common Shares***

The Company's net losses and expenses may fluctuate significantly and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in the price of the Company's Common Shares. The Company's net losses and expenses have fluctuated in the past and are likely to do so in the future. These

fluctuations could cause the market price of the Common Shares to decline. Some of the factors that could cause the Company's net losses and expenses to fluctuate include the following:

- results of preclinical studies and clinical trials, or the addition or termination of preclinical studies, clinical trials or funding support;
- the timing of the release of results from any preclinical studies and clinical trials;
- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize the Company's products;
- the outcome of any litigation;
- changes in foreign currency fluctuations;
- competition;
- the timing of achievement and the receipt of milestone payments from current or future third parties;
- failure to enter into new or the expiration or termination of current agreements with third parties;
- failure to introduce the Company's products to the market in a manner that generates anticipated revenues;
- our execution of any new collaboration, licensing or similar arrangement, and the timing of payments we may make or receive under such existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by the Company or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, market acceptance and demand for such product candidates;
- regulatory developments or determinations affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If the Company's quarterly operating results fall below the expectations of investors or securities analysts, the market price of the Common Shares could decline substantially. Furthermore, any quarterly fluctuations in the Company's operating results may, in turn, cause the market price of the Common Shares to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

### *Use of Proceeds*

The Company will have broad discretion concerning the use of the proceeds of this Offering as well as the timing of their expenditure. As a result, purchasers will be relying on the judgment of management for the effective use of such proceeds. Management may use such proceeds in ways that purchasers may not consider desirable. The results and the effectiveness of the investment of the proceeds of this Offering are uncertain. If the proceeds are not applied effectively, the results of the Company's operations may suffer.

### ***No Market for the Warrants***

There is no market through which the Warrants may be sold and purchasers of Units may not be able to resell the Warrants purchased under this Prospectus and the Company has not applied and does not intend to apply for the listing of the Warrants on any securities exchange. This may affect the pricing of the Warrants in the secondary market, the transparency and availability of trading prices, the liquidity of the Warrants and the extent of issuer regulation. Even if a market develops for the Warrants, it is not possible to predict the price at which the Warrants will trade in the secondary market or whether such market will be liquid or illiquid. To the extent Warrants are exercised, the number of Warrants outstanding will decrease, resulting in a diminished liquidity for the remaining Warrants. A decrease in the liquidity of the Warrants may cause, in turn, an increase in the volatility associated with the price of the Warrants. To the extent that the Warrants become illiquid, an investor may have to exercise such Warrants to realize value. The Offering Price and the allocation thereof between the Offered Shares and the Warrants comprising the Units have been determined by negotiation between the Company and the Underwriters.

### ***Sale of Common Shares Issued Upon Exercise of the Warrants Could Encourage Short Sales By Third Parties Which Could Further Depress the Price of the Common Shares***

Any downward pressure on the price of Common Shares caused by the sale of Common Shares issued upon the exercise of the Warrants could encourage short sales by third parties. In a short sale, a prospective seller borrows Common Shares from a shareholder or broker and sells the borrowed Common Shares. The prospective seller anticipates that the Common Share price will decline, at which time the seller can purchase Common Shares at a lower price for delivery back to the lender. The seller profits when the Common Share price declines because it is purchasing Common Shares at a price lower than the sale price of the borrowed Common Shares. Such sales could place downward pressure on the price of the Common Shares by increasing the number of Common Shares being sold, which could further contribute to any decline in the market price of the Common Shares.

### ***Immediate Dilution***

The Offering Price will significantly exceed the net tangible book value per share of Common Shares.

### **AGENT FOR SERVICE OF PROCESS**

Roderick Flower, a director of the Company, resides outside of Canada. Mr. Flower has appointed the following agent for service of process:

<b>Name of Person</b>	<b>Name and Address of Agent</b>
<b>Roderick Flower</b>	<b>WeirFoulds LLP 41st Floor 66 Wellington St. W. TD Centre Toronto, ON M5K 1B7</b>

Purchasers are advised that it may not be possible for investors to enforce judgments obtained in Canada against any person that resides outside of Canada, even if the party has appointed an agent for service of process.

### **INTERESTS OF EXPERTS**

Certain legal matters relating to the Offering hereby will be passed upon on behalf of the Company by WeirFoulds LLP, and on behalf of the Underwriters by Torys LLP. As at the date of this Prospectus, the partners and associates of WeirFoulds LLP and Torys LLP beneficially owned, directly or indirectly, less than 1% of the outstanding Common Shares.

Ernst & Young LLP confirms that it is independent with respect to the Company within the meaning of the CPA Code of Professional Conduct of the Chartered Professional Accountants of Ontario.

## **AUDITORS, TRANSFER AGENT AND REGISTRAR**

The Company's auditors are Ernst & Young LLP, Chartered Professional Accountants, Licensed Public Accountants at its office at EY Tower, 100 Adelaide Street West, Toronto, ON M5H 0B3.

Computershare Trust Company of Canada, 100 University Avenue, 9th Floor, North Tower, Toronto, Ontario M5J 2Y1, is the transfer agent and registrar of the Common Shares at its principal offices in Toronto, Ontario.

## **RIGHTS OF WITHDRAWAL AND RESCISSION**

Securities legislation in certain of the provinces of Canada provides purchasers with the right to withdraw from an agreement to purchase securities. This right may be exercised within two business days after receipt or deemed receipt of a prospectus and any amendment. In several of the provinces, the securities legislation further provides a purchaser with remedies for rescission or, in some jurisdictions, revisions of the price or damages if the prospectus and any amendment contains a misrepresentation or is not delivered to the purchaser, provided that the remedies for rescission, revision of the price or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province for the particulars of these rights or consult with a legal adviser.

In an offering of warrants, investors are cautioned that the statutory right of action for damages for a misrepresentation contained in the prospectus is limited, in certain provincial securities legislation, to the price at which the warrants were offered to the public under the prospectus offering. This means that, under the securities legislation of certain provinces, if the purchaser pays additional amounts upon the exercise of the warrants, those amounts may not be recoverable under the statutory right of action for damages that applies in those provinces. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province for the particulars of this right of action for damages or consult with a legal adviser.

## **ADDITIONAL INFORMATION**

Following the completion of the Offering, the Company will be required to file reports and other information with the securities commissions in certain provinces and territories of Canada. These filings will be electronically available from SEDAR at [www.sedar.com](http://www.sedar.com).



**CERTIFICATE OF THE COMPANY**

Dated: June 26, 2020

This short form prospectus, together with the documents incorporated by reference, constitutes full, true and plain disclosure of all material facts relating to the securities offered by this short form prospectus as required by the securities legislation of each of the provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Ontario.

***"Daniel Legault"***

Daniel Legault  
President & Chief Executive Officer

***"Alain Wilson"***

Alain Wilson  
Chief Financial Officer

On behalf of the Board of Directors

***"Walt Macnee"***

Walt Macnee  
Chairman and Director

***"John Wallace"***

John Wallace  
Director

## CERTIFICATE OF THE UNDERWRITERS

Dated: June 26, 2020

To the best of our knowledge, information and belief, this short form prospectus, together with the documents incorporated by reference, constitutes full, true and plain disclosure of all material facts relating to the securities offered by this short form prospectus as required by the securities legislation of each of the provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Ontario.

**BLOOM BURTON SECURITIES INC**

*"Jolyon Burton"*

Jolyon Burton

President, Head of Investment Banking

**ECHELON WEALTH PARTNERS INC.**

*"Michael Lorimer"*

Michael Lorimer

Managing Director

**PARADIGM CAPITAL INC.**

*"Jason Matheson"*

Jason Matheson

Managing Director

**RAYMOND JAMES LTD.**

*"Marwan Kubursi"*

Marwan Kubursi

Managing Director

**STIFEL NICOLAUS CANADA INC.**

*"Matt Gaasenbeek"*

Matt Gaasenbeek

Managing Director, Head of Investment Banking

**INDUSTRIAL ALLIANCE SECURITIES INC.**

*"John Rak"*

John Rak

Managing Director, Investment Banking

This is Exhibit I" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

## **Antibe Therapeutics Announces Closing of Bought Deal Public Offering**

### ***NOT FOR DISTRIBUTION OR DISSEMINATION INTO THE UNITED STATES OR THROUGH U.S. NEWSWIRE SERVICES***

TORONTO--(BUSINESS WIRE)--February 24, 2021--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSX:ATE) today announced that it has closed its previously announced bought deal public offering of 6,727,500 units (the "Offered Securities") in the capital of the Company at a price of C\$6.00 per Offered Security (the "Offering Price") for aggregate gross proceeds to the Company of C\$40,365,000 (the "Offering"), which includes the full exercise of the over-allotment option by the underwriters.

Each Offered Security consisted of one common share (a "Common Share") and one-half of one common share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitles the holder thereof to acquire one Common Share at an exercise price per Common Share of C\$7.50 for a period of 36 months from the closing of the Offering.

The Company intends to use the net proceeds of the Offering to fully fund the adaptive Phase III efficacy trial and remaining non-clinical studies for its lead drug, complete IND-enabling studies for its second and third pipeline drugs, advance new anti-inflammatory drug candidates and for working capital and general corporate purposes, all as more fully described in the prospectus. As of today's date, the Company's cash balance is C\$74 million, including the upfront payment received from Nuance Pharma and the net proceeds of the Offering.

Canaccord Genuity Corp. acted as sole bookrunner and co-lead underwriter with Bloom Burton Securities Inc., on behalf of a syndicate of underwriters including Echelon Wealth Partners Inc., Leede Jones Gable Inc. and Paradigm Capital Inc. (together, the "Underwriters").

The Offered Securities were offered in the provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Ontario, pursuant to a prospectus supplement dated February 19, 2021 to the Company's base shelf prospectus dated January 12, 2021 (the "Prospectus") and elsewhere in compliance with applicable securities laws.

The securities offered have not been, nor will they be, registered under the United States Securities Act of 1933, as amended (the "U.S. Securities Act"), or applicable state securities laws, and may not be offered or sold in the United States or to, or for the account or benefit of, persons in the United States or "U.S. persons" (as such term is defined in Regulation S promulgated under the U.S. Securities Act) absent registration or an applicable exemption from the registration requirements. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. Antibe's

current pipeline includes three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”). Antibe’s lead drug, otenaproxesul (formerly ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. The Company’s next target is inflammatory bowel disease (“IBD”), a condition long in need of safer, more effective therapies. Learn more at [antibethera.com](http://antibethera.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the proposed licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions “will”, “anticipate”, “believe”, “plan”, “estimate”, “expect”, “intend”, “propose” and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company’s inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

*Neither TSX nor its Regulation Services Provider (as that term is defined in the policies of the TSX) accepts responsibility for the adequacy or accuracy of this release.*

## **Contacts**

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This is Exhibit "J" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

## Antibe Therapeutics Reports Q2 2022 Interim Financial and Operating Results

- *Otenaproxesul's acute pain clinical program set to begin early next quarter*
- *Ended quarter with a \$60 million cash position*

TORONTO--(BUSINESS WIRE)--November 16, 2021--Antibe Therapeutics Inc. (TSX:ATE, OTCQX:ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, has filed its financial and operating results for the fiscal quarter ended September 30, 2021.

“With the clinical program for post-operative pain slated to begin early next quarter and third-party commercial studies underway, the scientific and strategic review we initiated during the quarter will soon be yielding results,” commented Dan Legault, Antibe’s CEO. “Our goal is to rapidly deliver a safe and effective alternative for physicians, surgeons and patients who today must choose between GI-damaging NSAIDs and addictive, side effect-prone opioids. With a strong balance sheet and extensive safety and efficacy data on otenaproxesul already in hand, we are well-equipped to target one of the most intractable problems in healthcare.”

### Business Highlights

#### *Launched otenaproxesul's acute pain program*

- Commenced collaboration with world-leading acute pain specialists to optimize treatment regimens for post-operative pain use, clinical program slated to begin in early calendar Q1 2022
- Initiated comprehensive third-party market opportunity and reimbursement study for post-operative pain, results expected in late calendar Q1 2022
- Commenced and completed IND-opening single-dose clinical study and analysis
- Began investigation of alternative treatment regimens as a potential path forward for chronic indications

#### *Other pipeline drugs advancing*

- Identified attractive specialized acute pain indication for ATB-352
- Defined the commercial opportunity and product positioning for the inflammatory bowel disease (“IBD”) program, targeting a market expected to nearly double between 2019 and 2029 to US\$25 billion (GlobalData)

#### *Bolstering intellectual property position*

- Filed new patent application covering uses of otenaproxesul for treatment of acute pain; potential for IP protection to extend into the 2040s
- Identified new IP covering otenaproxesul compositions and methods for treatment of chronic pain
- Identified new indication IP for ATB-352

## Upcoming Milestones

The following summarizes the Company's estimated timeline for its key upcoming milestones:

- PK/PD clinical studies initiated – Q1 2022
- Third-party commercial study results – Q1 2022
- Lead IBD candidate identified – Q2 2022
- Otenaproxesul Phase II bunionectomy trial initiated – Q4 2022

## Financial Results

**Cash Position:** As of September 30, 2021, the Company had an available cash balance totaling \$60.5 million, compared to \$72 million as at March 31, 2021.

**Net Loss:** For the quarter ended September 30, 2021, net loss amounted to \$8.7 million (\$0.17 per share), compared to \$8.9 million (\$0.23 per share) for the same period in fiscal 2021.

**Research and Development Expenses:** Research and development expenses, net of research tax credits, amounted to \$5.2 million for the quarter ended September 30, 2021, compared to \$4.8 million for the same period in fiscal 2021.

**General and Administrative Expenses:** General and administrative expenses totaled \$1.7 million for the quarter ended September 30, 2021, compared to \$2.2 million in fiscal Q2 2021.

The Company's unaudited fiscal Q2 2022 condensed interim financial statements and MD&A are available on SEDAR.

## About Antibe Therapeutics Inc.

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to target inflammation arising from a wide range of medical conditions. The Company's current pipeline includes assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids for post-operative pain. Antibe's second pipeline drug, ATB-352, is being developed for a specialized acute pain indication. The Company's anticipated next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).



### **Forward-Looking Information**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, the anticipated scope, timing, duration and completion of certain of the Company's clinical trial programs and studies and the anticipated timing for seeking market approval for certain of the Company's drugs and therapies for certain additional indications. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to timely execute on its business strategy and timely and successfully complete its clinical trials and studies, the Company's inability to obtain the necessary regulatory approvals related to its activities, risks associated with drug and medical device development generally and those risk factors set forth in the Company's public filings made in Canada and available on [www.sedar.com](http://www.sedar.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

### **Contacts**

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This is Exhibit "K" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

## **Antibe Therapeutics' Lead Drug Shows Promising Effects in Alveolar Bone Loss Study**

### ***These results open up potential uses of Antibe's drug candidates in the fields of regenerative medicine, orthopaedic and craniomaxillofacial surgery***

TORONTO--(BUSINESS WIRE)--October 8, 2015--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQX: ATBPF) is pleased to announce promising results from an independent bone loss study. A study directed by Dr. Marcelo Muscara at the University of Sao Paulo in Brazil provides compelling evidence that ATB-346, Antibe's lead drug candidate for treating chronic inflammatory conditions such as osteoarthritis, has a superior safety profile as compared to conventional non-steroidal anti-inflammatory drugs (NSAIDs) in periodontal disease. NSAIDs, such as naproxen (Aleve), have well characterized adverse effects on bone growth. In the rat study performed by Dr. Muscara's team, induction of periodontitis, an inflammation of the gums, was associated with a marked loss of alveolar bone, which is the thickened ridge of bone that contains the tooth sockets. When the rats were treated with ATB-346 for a week, there was a substantial improvement in the preservation of alveolar bone, while naproxen treatment made the bone loss worse. These results open up potential uses of Antibe's drug candidates in the fields of regenerative medicine, orthopaedic and craniomaxillofacial surgery, where the adverse effects of NSAIDs on bone growth are an increasing concern.

Antibe's CEO, Dan Legault commented, "The discovery by Dr. Muscara's team of significant beneficial effects of ATB-346 in prevention of alveolar bone loss adds to our excitement about the strongly differentiated profile of our drug candidates, including the enhanced safety and tolerability that is imparted by the release of hydrogen sulfide from all of our drug development candidates. This discovery, together with our recent acquisition of Citagenix Inc., has Antibe poised to make significant contributions to the development of medications pertinent to regenerative medicine".

As observed previously, treatment with naproxen also resulted in significant ulceration and bleeding in the stomach of the rats, while no damage was observed in rats treated with ATB-346. Dr. Muscara commented: "The hydrogen sulfide-releasing property of ATB-346 not only prevents tissue injury and bleeding in the stomach, it also markedly improves bone quality, suggesting that it may be a valuable new adjuvant therapy for periodontal disease". The results of this study have been published in the journal *Medical Gas Research* (<http://www.ncbi.nlm.nih.gov/pubmed/25755876>).

#### **About Antibe Therapeutics Inc.**

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer non-steroidal anti-inflammatory drug (NSAID) for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a safer analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin.

Antibe is in the process of acquiring an 85% interest in Citagenix Inc., a Montreal-based sales and distribution company with a focus on regenerative medicine. This will create a diversified healthcare products company with annual revenues of approximately C\$10 million and with commercial infrastructure for additional approved and higher-return, near-approval therapeutic products.

[www.antibethera.com](http://www.antibethera.com)

#### **About Citagenix Inc.**

Citagenix is a leader in the sales and marketing of tissue regenerative products servicing the orthopedic and dental marketplaces. Since its inception in 1997, Citagenix has become the largest source of knowledge and experience in the Canadian medical device industry when it comes to bone regeneration and is known as a valuable reference and resource by clinicians. Operating in Canada through its direct sales teams, and a network of distributor partnerships around the world, Citagenix is active in 15 countries. For more information about the company, please visit <http://www.citagenix.com>.

*Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.*

#### **Forward Looking Information**

This news release includes certain forward-looking statements which may include, but are not limited to, the transition of the Company to a diversified healthcare company, the development of ATB-346 and other drugs, the thrust into regenerative medicine, the acquisition of shares of Citagenix, the completion of non-brokered private placement, opportunities for organic growth, growth of the business and revenue and the addition of products to the company's product line. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, Citagenix financial performance not matching past performance, risks associated with drug development generally, failure to satisfy closing conditions for the Citagenix transaction and the private placement, not obtaining future financing on adequate terms, or at all, anticipated sales not achieving expected volumes and not obtaining TSX Venture Exchange approval for the transactions described herein. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Announces Completion of Validation Studies of ATB-346, Progression to Phase 2 Clinical Trials**

TORONTO--(BUSINESS WIRE)--December 21, 2015--Antibe Therapeutics Inc. ("Antibe") (TSXV: ATE, OTCQX: ATBPF) announced today the completion of the previously announced validation studies being performed on the Company's lead drug, ATB-346. These studies were initiated as a consequence of ATB-346 inducing an elevation of liver enzymes in some subjects taking the higher doses of the drug (750 and 1500 mg/day), and were aimed at gaining a better understanding of the drug's potency, absorption, metabolism and excretion characteristics. The results of these studies support progression to Phase 2 of development of this drug in patients with osteoarthritis.

In the first set of studies, as previously announced, the suppression of the activity of the cyclo-oxygenase (COX) enzyme, which accounts for the anti-inflammatory and pain-killing effects of ATB-346 (and all other NSAIDs), was substantially greater and longer lasting than had been predicted from the monitoring of blood naproxen levels. NSAIDs are well known to cause liver damage in some patients when taken at high doses.

In the second set of studies, rats were administered ATB-346, in which the hydrogen sulfide-releasing portion of the molecule was 'tagged' with a radioactive marker, thereby allowing it to be tracked after it was administered to each rat. This enabled monitoring of the excretion of ATB-346 and of its metabolites, and any accumulation of the drug in particular organs (such as the liver). There was no significant retention or accumulation of the radiolabel in any tissues, with more than 99% being excreted in urine. In rats treated daily with ATB-346 for four days, less than one-tenth of 1% of the radiolabel remained in the liver 8 hours after the final administration of the drug. Additionally, levels of retention of the radiolabel in other organs, including the kidney, stomach, small intestine and lungs, were extremely low. These studies also identified a number of metabolites of ATB-346, all of which were rapidly cleared.

The results of these studies warrant the continuation of development of ATB-346. They suggest that ATB-346 may be effective at lower doses than previously expected - doses that were observed to be safe and well tolerated in the Phase 1 study. The studies also suggest that ATB-346 will produce beneficial effects with only once-daily dosing. Accordingly, Antibe plans to move forward with Phase 2 studies and will submit an application to Health Canada in early 2016.

### **About Antibe Therapeutics Inc.**

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer non-steroidal anti-inflammatory drug (NSAID) for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a safer analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. [www.antibethera.com](http://www.antibethera.com).

Antibe's subsidiary, Citagenix Inc., is a leader in the sales and marketing of tissue regenerative products servicing the orthopedic and dental marketplaces. Since its inception in 1997, Citagenix has become the largest source of knowledge and experience in the Canadian medical device industry when it comes to bone regeneration and is known as a valuable reference and resource by clinicians. Operating in Canada through its direct sales teams, and a network of distributor partnerships around the world, Citagenix Inc. is active in 15 countries. [www.citagenix.com](http://www.citagenix.com).

*Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) and no stock exchange, securities commission or other regulatory authority accepts responsibility for the adequacy or accuracy of this release nor approved or disapproved of the information contained herein.*

### **Forward-Looking Information**

This news release includes certain forward-looking statements which may include, but are not limited to, information on drug development. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, not achieving commercial revenue from Antibe's anti-inflammatory and pain drugs, not achieving the milestone specified in the license agreement, risks associated with drug development generally, not obtaining future financing on adequate terms, or at all, anticipated sales not achieving expected volumes and not obtaining TSX Venture Exchange final approval for any pending transactions. The sections on risks contained in the Company's Prospectus and annual Information Circulars are expressly incorporated herein. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## Antibe Therapeutics Receives Approval to Proceed to Phase 2 Clinical Trial

TORONTO--(BUSINESS WIRE)--March 4, 2016--Antibe Therapeutics Inc. ("Antibe") (TSXV:ATE, OTCQX:ATBPF) is pleased to announce that it has received approval from Health Canada to initiate a Phase 2 trial. Antibe submitted an application to Health Canada to perform a trial in which ATB-346, its lead drug, would be tested for effectiveness in patients with osteoarthritis of the knee. The study is expected to begin in March, and will be performed by Topstone Research, in Toronto. Antibe's CEO, Daniel Legault, commented "We are delighted to move forward into patients. In the past year we have performed a number of non-clinical studies of this drug and these studies suggest that ATB-346 is a much more potent and long-lasting anti-inflammatory drug than we had anticipated."

### About Antibe Therapeutics Inc.

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer non-steroidal anti-inflammatory drug (NSAID) for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a safer analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. [www.antibether.com](http://www.antibether.com).

Antibe's subsidiary, Citagenix Inc. (Citagenix), is a leader in the sales and marketing of tissue regenerative products servicing the orthopedic and dental marketplaces. Since its inception in 1997, Citagenix has become the largest source of knowledge and experience in the Canadian medical device industry. Citagenix Inc. is active in 15 countries, operating in Canada through its direct sales teams, and internationally via a network of distributor partnerships. [www.citagenix.com](http://www.citagenix.com).

### Forward Looking Information

This news release includes certain forward-looking statements which may include, but are not limited to, the development of ATB-346 and other drugs and the addition of products to the company's product line. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, risks associated with drug development generally, and not obtaining future financing on adequate terms, or at all. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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# **Antibe Therapeutics' ATB-346 Receives Approval for Phase 2 Clinical Trial in Osteoarthritis Patients**

TORONTO--(BUSINESS WIRE)--March 7, 2016--Antibe Therapeutics Inc. ("Antibe") (TSXV:ATE, OTCQX:ATBPF) has received approval from Health Canada to conduct a Phase 2 trial of its lead drug, ATB-346, in patients with osteoarthritis of the knee. The primary endpoints of the study will be clinical assessments of pain and inflammation over the course of 10 days of treatment with ATB-346 at 250 mg once daily. Analysis of blood samples from Antibe's Phase 1 clinical study strongly suggested that ATB-346 is considerably more potent and long-lasting than had been predicted from studies in animals. The Phase 2 study is expected to begin in March, and will be performed by Toronto-based Topstone Research. Daniel Legault, Antibe's CEO, remarked: "Receiving Health Canada's approval to move forward in the development of ATB-346 is a significant milestone for Antibe. The study should be started within the next few weeks, with completion expected in mid-summer."

## **About Antibe Therapeutics Inc.**

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## **Forward Looking Information**

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## **Antibe Therapeutics Announces the Appointment of New Board Member and Provides Update on Phase 2 Trial of ATB-346**

TORONTO--(BUSINESS WIRE)--July 19, 2016--Antibe Therapeutics Inc. ("Antibe" or the "Corporation") (TSXV:ATE, OTCQX:ATBPF), a commercial-stage pharmaceutical growth company, is pleased to announce the appointment of Yung Wu to its Board of Directors.

"We're delighted by the addition of Yung to our Board of Directors. We see many growth opportunities ahead for Antibe and we will benefit from Yung's unique insights and perspectives as we work to unlock the full potential of the Company," said Walt Macnee, Antibe's Chair of the Board. "We look forward to continuing a long-term growth trajectory that maximizes shareholder value."

Mr. Wu is Managing Director of private equity firm NFQ Ventures and is a seasoned entrepreneur with a track record of successfully building and growing several businesses throughout his career. As a serial founder and CEO, he has personally built 7 companies and produced multiple successful exits to acquirers such as Upsight and Oracle Financial Services. He also serves as a director on the Board of Green Shield, a multi-billion dollar health benefits insurance and financial services company. Mr. Wu will serve as an independent director of Antibe and is also a shareholder.

In addition, Antibe is pleased to announce recruitment of its final patient to its Phase 2 clinical trial examining the efficacy of ATB-346 in patients with osteoarthritis. Antibe anticipates that final results will be available for release by mid-August. The primary endpoints of the Phase 2 study are clinical assessments of pain and inflammation over the course of 10 days of treatment with ATB-346 at 250 mg once daily.

Finally, the Company has elected to pay in-kind all interest due July 15, 2016 under the Company's 10% senior secured convertible debentures due October 15, 2018 (the "Debentures"). The Debentures provide that Antibe may, at its sole option, elect to pay in-kind certain interest payments.

The aggregate July 15, 2016 interest payment under the Debentures in the amount of \$79,521.56 has been added to the principal amount of the Debentures (the "Added Principal Amount"). The holders of Debentures may convert the principal amount of each Debenture into Antibe common shares at a price of \$0.22 per common share. As a result of the addition of the Added Principal Amount to the principal amount of the Debentures, an additional 361,462 common shares in the capital of Antibe will be issuable on the conversion of the principal amount of the Debentures.

### **About Yung Wu**

Yung is a serial founder and entrepreneur, technology innovator, private equity investor and Corporate Director. He has created, led, financed and directed companies spanning enterprise software, mobile technology, entertainment & media, financial services and oil & gas exploration. Yung has been recognized as one of Canada's "Top 40 under 40" leaders and for leading one of the "50 Best Managed Private Companies" in the nation. He has a bachelor's degree in Computer Science, Economics and Mathematics from the University of Toronto, a graduate of the Entrepreneurial Masters Program at the Massachusetts Institute of Technology, a member of MENSA, the Young Presidents Organization (YPO) and the Institute of Corporate Directors (ICD.D).

### **About Antibe Therapeutics Inc.**

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer, non-addictive drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a safer, non-addictive analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. [www.antibethera.com](http://www.antibethera.com).

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### **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the completion of financing transactions and the licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, failure to raise the full Offering amount, failure to obtain TSX Venture Exchange approval for the transactions described herein, and risks associated with drug and medical device development generally. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

### **CONTACT:**

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## Antibe Therapeutics Announces Successful Phase 2 Trial of ATB-346 in Osteoarthritis

TORONTO--(BUSINESS WIRE)--August 8, 2016--Antibe Therapeutics Inc. ("Antibe") (TSXV:ATE; OTCQX: ATBPF) is pleased to announce the successful completion of its phase 2 clinical trial of ATB-346 in osteoarthritis ("OA"). Twelve patients with OA of the knee were treated once daily for 10 days with ATB-346 at a dose of 250 mg. This dose of ATB-346 contains one-sixth of the typical daily dose of naproxen for treating OA. This lower dose was very effective at reducing pain, and equal to or better than naproxen or celecoxib in comparable studies. The drug was also safe and well-tolerated.

The patients recorded their level of pain one day prior to starting treatment and again on days 4 and 10 of treatment. The "WOMAC pain scale" was used as the measure of beneficial effect, since it is the gold standard in arthritis clinical trials. "There is a large body of evidence showing that market-leading arthritis drugs like celecoxib and naproxen, taken twice daily for a week or more, typically reduce WOMAC pain scores by ~4 units, with no material improvement beyond that level with continued treatment," remarked John Wallace, Antibe's Chief Scientific Officer. "In this trial, a once daily dose of ATB-346 produced a reduction of the WOMAC pain score of 4.3 units on day 4, increasing to 7.6 units on day 10, with a very high level of statistical significance in comparison to baseline pain ( $p < 0.001$ ). The enhanced effectiveness of ATB-346 as compared to the market-leading drugs for osteoarthritis was a pleasant surprise, particularly considering the low dose of ATB-346 that was used." ATB-346 was well-tolerated, with only one "possibly drug-related adverse event", an allergic reaction graded as "mild" by the study's supervising physician. This phase 2 clinical trial was carried out in Toronto, Canada by Topstone Research Ltd.

Antibe's CEO, Dan Legault commented: "We are delighted with these results. Along with ongoing biochemical studies, they suggest that a once daily dose of 250 mg or less will be effective at reducing pain and inflammation in arthritis patients. We plan to expeditiously perform additional clinical trials to confirm the results seen in this phase 2 study, explore the effectiveness of even lower doses of ATB-346, as well as demonstrating increased gastrointestinal safety of this drug in humans."

References reporting the effects of celecoxib and naproxen in reducing osteoarthritis pain, using the same WOMAC pain scale, have been posted at [www.antibethera.com](http://www.antibethera.com).

### About ATB-346

ATB-346, an NSAID (non-steroidal anti-inflammatory drug), is a hydrogen sulfide-releasing derivative of naproxen, the most-prescribed NSAID in North America.

NSAIDs, a \$12 billion/year drug class, are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. Extensive pre-clinical studies demonstrate that ATB-346 does not produce the gastrointestinal damage observed with currently available nonsteroidal NSAIDs.

### About Antibe Therapeutics Inc.

Antibe is a revenue-generating, integrated healthcare company focused on providing solutions for the pain, inflammation and regenerative medicine markets. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug, ATB-346, targets the global need for a safer, non-addictive drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a safer, non-addictive analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. [www.antibethera.com](http://www.antibethera.com)

Antibe's subsidiary, Citagenix Inc. ("Citagenix"), is a leader in the sales and marketing of tissue regenerative products servicing the dental marketplace. Since its inception in 1997, Citagenix has become an important source of knowledge and experience for bone regeneration in the Canadian medical device industry. Citagenix is active in 15 countries, operating in Canada through its direct sales teams, and internationally via a network of distributor partnerships. [www.citagenix.com](http://www.citagenix.com)

### Forward Looking Information

This news release includes certain forward-looking statements which may include, but are not limited to, the development of ATB-346 and other drugs and the addition of products to the company's product line. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, risks associated with drug development generally, and not obtaining future financing on adequate terms, or at all. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

### CONTACT:

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# Antibe Therapeutics Reports Q1 2017 Interim Financial and Operating Results

TORONTO--(BUSINESS WIRE)--August 29, 2016--Antibe Therapeutics Inc. ("Antibe") (TSXV:ATE, OTCQX:ATBPF) filed its financial and operating results on Monday, August 29 for the fiscal quarter ended June 30, 2016. The Corporation's unaudited fiscal Q1 2017 interim consolidated financial statements and MD&A are available on SEDAR.

"We are pleased with the operational progress being made at Citagenix and remain focused on generating growth through new products and international expansion, including in the United States," said Dan Legault, Antibe's CEO. "These strategic initiatives should have a material impact on revenue and profitability over the next 12 months. In addition, we achieved a significant milestone earlier this month with the successful completion of our phase 2 study of ATB-346 in osteoarthritis patients."

Antibe plans to expeditiously perform additional clinical trials to confirm the results of its initial phase 2 study and further explore the effectiveness of ATB-346 at lower doses, as well as demonstrating enhanced gastrointestinal safety of this drug in humans.

## Q1 2017 Highlights

- Completed operational repositioning of Citagenix to focus on dental regenerative medicine and achieved meaningful expense reductions;
- Launched PentOS OI™ Putty, a high-quality bone graft substitute for oral and maxillofacial surgery;
- Successfully completed a non-brokered private placement raising gross proceeds of \$1,455,000; and
- Presented at the 2016 Bloom Burton & Co. Healthcare Conference and the International Hydrogen Sulfide Conference.

## Post Q1 2017 Highlights

- Successfully completed initial phase 2 clinical trial of ATB-346 in osteoarthritis patients with strong efficacy and safety data;
- Appointed Yung Wu, Managing Director of private equity firm NFQ Ventures and a seasoned entrepreneur, to the Board of Directors; and
- Launched Neomem® FlexPlus, a high-performance barrier membrane for regenerative procedures in oral surgery.

## About Antibe Therapeutics Inc.

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer, non-addictive drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a safer analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. [www.antibethera.com](http://www.antibethera.com)

Antibe's subsidiary, Citagenix Inc. ("Citagenix"), is a leader in the sales and marketing of tissue regenerative products servicing the orthopedic and dental marketplaces. Since its inception in 1997, Citagenix has become the largest source of knowledge and experience in the Canadian medical device industry. Citagenix Inc. is active in 15 countries, operating in Canada through its direct sales teams, and internationally via a network of distributor partnerships. [www.citagenix.com](http://www.citagenix.com)

## Forward Looking Information

This news release includes certain forward-looking statements, which may include, but are not limited to, the completion of financing transactions and the licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, failure to satisfy closing conditions for the transactions, not obtaining future financing on adequate terms, or at all, failure to obtain TSX Venture Exchange approval for the transactions described herein, and risks associated with drug and medical device development generally. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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# Antibe Therapeutics Announces CEO Letter to Shareholders

TORONTO--(BUSINESS WIRE)--October 25, 2016--

To my fellow Shareholders,

The recent success of our lead drug, ATB-346, in its initial Phase 2 clinical trial has inspired a sense of renewed vigor as we march closer to a potential monetization event. In addition, October marks the 1-year anniversary of our transformation into a revenue-generating company through the acquisition of Citagenix, our commercial regenerative medicine division. For both of these reasons, we thought it would be a great time to reflect on our achievements over the past year and communicate our strategy for next year and beyond.

The clinical development and strategic planning performed in the 2016 calendar year to-date has been paramount in positioning us to deliver significant value to our shareholders over the next 12-18 months. In 2017, ATB-346 will be initiating two larger Phase 2 clinical studies to support a potential partnering event with a global pharmaceutical company within 18 months. ATB-346 has the potential to safeguard the health of and reduce pain for hundreds of millions of people around the world and, in doing so, deliver significant value to our shareholders. Our commercial division, Citagenix, had 2015 revenues of \$10 million and is poised for global growth as we embark on our market share expansion strategy in the United States and other markets with the support of a senior sales management layer and an innovative e-commerce platform.

We are very proud of the support that our shareholders have given us over the last few years and feel that their patience will be rewarded in the near-term as we work towards our goal of bringing new, safer drugs to market and building a class-leading offering in regenerative medicine.

## **Milestones & Progress Achieved in Past Twelve Months**

### ***Successful Completion of Initial Phase 2 Clinical Trial***

In August 2016, we successfully completed our first Phase 2 clinical trial for ATB-346 in patients with osteoarthritis (“OA”) of the knee. ATB-346 showed pain relief nearly double that of naproxen and celecoxib based on comparable studies, the leading drugs in the market for treating OA. This was a critical study to assess the effectiveness of ATB-346 at a dose of 250 mg, one-sixth of our originally anticipated human dose. The results supported our hypothesis that ATB-346 is much more potent and long-lasting than had been predicted from animal studies. Highlights from the trial include:

- **Efficacy data well beyond expectations:** ATB-346 produced a reduction of the WOMAC pain score of 7.6 units on day 10 compared to the ~4 unit reduction typically seen (and widely published) by market-leading drugs for osteoarthritis.
  - **Once-daily dosing:** ATB-346 was very effective with a once-daily dosing regimen versus typical twice-daily dosing seen with common pain medications for OA; once-daily dosing is a sought-after characteristic due to its convenience and positive impact on patient compliance.
  - **Safety:** The drug was safe and well tolerated.
-

### ***Confirmed Non-Addictive Properties of Second Pipeline Drug, ATB-352***

Antibe recently completed pre-clinical studies that demonstrated ATB-352, unlike opiate drugs, does not bind to opioid receptors and therefore does not pose a risk of addiction. Opiates, such as oxycontin and fentanyl, are among the most widely used drugs to relieve severe pain, with annual sales exceeding US\$7 billion. However, these drugs carry a high risk of addiction and abuse. As earlier announced, Antibe is developing ATB-352, a novel hydrogen sulfide-releasing analgesic, to address the growing need for a powerful but safe and non-addictive acute pain-killer.

### ***Demonstrated Anti-Cancer Potential of Lead Drug, ATB-346***

In experimental studies published this year, ATB-346 was shown to be very effective in reversing colon and intestinal tumour growth in mice, and also delivered promising results in the chemoprevention and treatment of melanoma in mice. Although we remain focused on our ongoing human studies to advance ATB-346 as a treatment for pain and inflammation, we are encouraged by these results and plan to continue this research in support of the potential advancement of ATB-346 into selected cancer indications.

### ***Re-positioned Citagenix onto Global Growth Trajectory***

Antibe's commercial division, Citagenix, has become the market leader in the dental regenerative medicine industry in Canada due to its high-knowledge approach and portfolio of quality products and brands. These strengths are being leveraged to replicate Citagenix's success in Canada on a *global* scale. Over the last 12 months Citagenix has re-positioned its focus on global growth via two main initiatives: strategic footprint expansion and portfolio expansion. We are now beginning to execute this strategy and believe the next few years will see considerable growth in sales and profitability.

- **New product launches.** Products launched this year include Neomem® FlexPlus, a high-performance barrier membrane for oral surgery and the PentOS OI™ family of bone graft substitutes.
- **Launched U.S. growth initiative.** Provided Citagenix with strategic capabilities to ramp up growth in the largest market for dental biologics, estimated to be US\$341 million in 2014 (iData Research).
- **Evaluating internal development opportunities.** We are evaluating two internal development opportunities that have best-in-class potential, low development costs and fast timelines to market (6-12 months).

### ***Strengthened our Board & Governance***

In July of this year, we welcomed the addition of Yung Wu to the Board, who is serving as an independent director. Yung is Managing Director of private equity firm NFQ Ventures and is a seasoned entrepreneur with a track record of successfully building and growing several businesses throughout his career. As a serial founder and CEO, he has personally built 7 companies and produced multiple successful exits to acquirers such as Upsight and Oracle Financial Services. He also serves as a director on the Board of Green Shield, a multi-billion dollar health benefits insurance and financial services company.

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### ***Strengthened our Balance Sheet***

In June 2016, we closed a private placement yielding gross proceeds of \$1.5 million, bringing the total amount raised in the last 12 months to \$4.5 million.

### **Primary Activities for the Next Twelve Months**

#### ***Initiate Two Additional Phase 2 Trials for Lead Drug, ATB-346***

We are gearing up to initiate two larger Phase 2 clinical studies to support our goal of reaching a partnering event with a global pharmaceutical company within 18 months. The first Phase 2 study will be a placebo-controlled dose-ranging trial to determine the lowest effective dose of ATB-346. The second Phase 2 study will validate the GI safety advantage of ATB-346 versus naproxen, one of the most widely used medications for treating osteoarthritis. These clinical studies are important for our global partnering strategy and Antibe intends to judiciously engage large, global pharmaceutical firms in dialogue upon completion of these trials.

#### ***Preclinical Studies for Second Pipeline Drug, ATB-352***

There is an urgent need for a safer, non-addictive pain-killer for severe pain in the wake of a surge in drug overdose deaths related to opioid abuse. Antibe recently confirmed the non-addictive properties of ATB-352, a 'stronger' NSAID, targeting the significant market for severe, acute pain. Antibe is presently evaluating the clinical development strategy for ATB-352 and, due to its short-term use, anticipates its development timeline will be considerably accelerated as compared to that for a chronic-use drug such as ATB-346. We anticipate commencing pre-clinical toxicology studies next year.

#### ***Pursue Partnering Opportunities with Regional Pharma***

Antibe is strategically seeking regional partnering opportunities to provide non-dilutive sources of funding and monetize its drug platform through royalty and milestone revenue. Antibe is presently in active discussions with pharmaceutical companies in regions that represent smaller market opportunities (i.e., outside of the United States and the 'big five' of Western Europe).

#### ***Continue to Execute Citagenix Global Growth Strategy***

Citagenix is now poised to grow its global market share and we are genuinely excited about 2017 and beyond. Earlier this month we launched a U.S. growth initiative that is essential to our footprint expansion strategy; we now have the first set of tools to effectively compete and grow market share in the most important market for dental biologics and expect to see our U.S. sales ramp through 2017. In addition, while we will continue to source and in-license high-quality biologics, we are cultivating a new focus on higher-return proprietary opportunities. We have identified two new product opportunities that have best-in-class potential and could see regulatory clearance in 2017.

#### ***Growing Shareholder Value***

We believe that tremendous value of Antibe resides in our patent-protected, independently-validated hydrogen sulfide-releasing technology and the quality of the science behind our pipeline and drug development platform. We also believe that 2017 will be a pivotal year for our lead drug, ATB-346, as we initiate two more Phase 2 studies to support a potential global partnering event within 18 months. Furthermore, we have augmented the risk-return profile of Antibe through the acquisition of our revenue-generating commercial division in regenerative medicine. Antibe remains unique in the Canadian capital markets as a biotechnology company with blockbuster potential that is de-risked by a commercial platform poised for global growth.

Thank you for your ongoing support.

Sincerely yours,

Daniel Legault, CEO

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## **About Antibe Therapeutics Inc.**

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Antibe's subsidiary, Citagenix Inc. ("Citagenix"), is a leader in the sales and marketing of tissue regenerative products servicing the orthopedic and dental marketplaces. Since its inception in 1997, Citagenix has become an important source of knowledge and experience for bone regeneration in the Canadian medical device industry. Citagenix is active in 15 countries, operating in Canada through its direct sales teams, and internationally via a network of distributor partnerships. [www.citagenix.com](http://www.citagenix.com)

## **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the completion of monetization events, the development of drugs and medical devices, the execution of clinical trials, the conclusion of partnering or other relationships with pharmaceutical companies, the execution of market share and portfolio expansion plans, the existence of internal development opportunities, the adherence to proposed development timelines, and the completion of financing transactions. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's ability to secure additional financing, its ability to execute its business strategy and successfully compete in the market, its ability to conclude partnering or other relationships with pharmaceutical companies, the receptiveness of customers to the Company's products, the capacity of the Company's products to function as anticipated and risks associated with drug and medical device development generally. In making the forward-looking statements in this news release, the Company has assumed that it will be able to secure additional financing, it will be able to execute its business strategy and successfully compete in the market, it will be able to conclude partnering or other relationships with pharmaceutical companies, customers will be receptive to the Company's products, and the Company's products will function as anticipated. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## Antibe Therapeutics Reports Q2 2017 Interim Financial and Operating Results

TORONTO--(BUSINESS WIRE)--November 29, 2016--Antibe Therapeutics Inc. ("Antibe") (TSXV:ATE) (OTCQX:ATBPF) filed its financial and operating results on Tuesday, November 29 for the fiscal quarter ended September 30, 2016. The Corporation's unaudited fiscal Q2 2017 interim consolidated financial statements and MD&A are available on SEDAR.

"The clinical development of ATB-346 continues to be the top priority for our executive team as we prepare to initiate a double-blind, placebo-controlled, phase 2 dose-ranging clinical study for osteoarthritis in the new year," said Dan Legault, Antibe's CEO. "In addition, Citagenix has been executing upon its U.S. expansion strategy and has taken steps to concentrate its focus on dental regenerative medicine. In particular, Citagenix has decided to slowly withdraw from the orthopedic market and has repositioned its surgical instrument line to be more complementary to its dental regenerative business. The launch of its growth initiative in the USA last month is a significant milestone for Citagenix's global expansion strategy and we expect it to deliver a positive contribution to profitability within a few quarters."

### Q2 2017 Highlights

- Successfully completed initial phase 2 clinical trial of ATB-346 in osteoarthritis patients with strong efficacy and safety data;
- Continued promising pre-clinical work for ATB-346 in experimental cancer;
- Launched Neomem® FlexPlus, a high-performance barrier membrane for regenerative procedures in oral surgery;
- Appointed Yung Wu, Managing Director of private equity firm NFQ Ventures and a seasoned entrepreneur, to the Board of Directors; and
- Presented at the 2016 Rodman & Renshaw Global Investment Conference.

### Post Q2 2017 Highlights

- Initiated strategic growth initiative for Citagenix in the United States, the largest global market for dental biologics; and
- Confirmed non-addictive properties for Antibe's second pipeline drug, ATB-352, a potent pain-killer.

### About Antibe Therapeutics Inc.

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a safer, non-addictive analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. [www.antibethera.com](http://www.antibethera.com)

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### Forward Looking Information

This news release includes certain forward-looking statements, which may include, but are not limited to, the growth of product sales, engaging new distributors and independent representatives and the licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's ability to secure additional financing, its ability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Enters into Regional Licensing Deal**

### ***Secures strong regional partner for ATB-346 and further validates Antibe's drug development program***

TORONTO--(BUSINESS WIRE)--February 24, 2017--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQX: ATBPF) is pleased to announce today that it has signed an exclusive licensing and distribution agreement with Laboratories Acbel SA ("Acbel") for ATB-346 in Greece, Romania, Serbia, Bulgaria, Albania, Algeria and Jordan. Acbel is a pharmaceutical company with a strong sales and distribution presence in the Balkan region.

Antibe will receive an upfront, non-dilutive payment of \$1.1 million (€800,000), and is entitled to receive a 5% royalty on net sales of ATB-346 in these countries. The agreement has a 30-year term with contemplated renewals thereafter. Acbel, through its affiliates and partners, is the largest seller of naproxen in this region, which represents approximately 1% of the global market for nonsteroidal anti-inflammatory drugs ("NSAIDs"). The global market for NSAIDs is in excess of US\$12 billion (Evaluate Pharma).

Antibe's CEO, Dan Legault, commented, "We are delighted to have concluded this agreement with Acbel. By delivering on our regional licensing strategy, Antibe has obtained non-dilutive funds that can be immediately deployed for our ongoing clinical trials. Of perhaps greater importance, this agreement represents an important validation of our drug development program, and its market value, by a leading regional pharmaceutical company well versed in the NSAID market."

ATB-346 is a novel anti-inflammatory drug, designed to spare the gastrointestinal tract of the ulcers and bleeding normally associated with NSAIDs. In a recent Phase 2 clinical trial, ATB-346 was found to be highly effective in reducing the pain associated with osteoarthritis of the knee. Antibe will now initiate two larger Phase 2 double-blind trials: a placebo-controlled dose-ranging study to determine the go-to-market dose, and an active comparator trial to demonstrate superior GI safety.

Antibe also has two other therapeutic candidates in development: ATB-352 and ATB-340. ATB-352 is a non-addictive analgesic for treating severe acute pain and ATB-340 is a GI-safe derivative of aspirin. Antibe intends to leverage data across its programs to secure licensing agreements whenever possible.

#### **About Antibe Therapeutics Inc.**

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#### **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the proposed licensing and development of drugs. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar expressions. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its ability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics Inc. assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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# Antibe Therapeutics Provides Update on Clinical Development Program for Its Lead Drug, ATB-346

## *Earlier initiation of key GI safety clinical trial, facilitating earlier strategic exit discussions*

TORONTO--(BUSINESS WIRE)--April 18, 2017--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV:ATE, OTCQX:ATBPF) is pleased to provide an update on its clinical development program for ATB-346, its lead drug that targets the global need for a safer drug for chronic pain and inflammation.

In August of last year, ATB-346 delivered clinical results that were beyond the Company's expectations in its initial Phase 2 clinical study. Using a once-daily dose of 250 mg (one-sixth of the originally anticipated human dose), ATB-346 showed pain relief nearly double that of naproxen and celecoxib based on comparable studies, the leading drugs in the osteoarthritis market.

As a consequence, Antibe has conducted an extensive review of its development strategy for ATB-346 and has concluded that it is now able to advance the start date of its key Phase 2 proof-of-concept study to demonstrate superior GI safety in humans. Accordingly, Antibe plans to commence this study next quarter and, subsequent to its completion, expects to begin strategic exit discussions in parallel with a Phase 2 dose-ranging effectiveness study.

Dan Legault, Antibe's CEO, remarked, "We are very excited to be in a position to soon be launching our key human proof-of-concept study for ATB-346, which cuts to the core of its strategic value. The study is powered to provide best-in-class, unequivocal validation of improved GI safety and the revised timing will allow us to engage in global partnering discussions earlier. This effectively advances the timelines of a potential strategic exit for ATB-346. Moreover, we expect to meet our existing budget and overall development timelines, with the GI study to be completed at approximately year-end and the other Phase 2 study to be concluded by the end of Q2/18."

The first Phase 2, double-blind, upper GI safety study will be an active comparator trial versus naproxen, and will be conducted in 240 healthy volunteers. The primary endpoint will be endoscopically detected upper GI tract ulceration. Subsequently, Antibe plans to launch a Phase 2 placebo-controlled, dose-ranging efficacy study in approximately 200 osteoarthritis patients.

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### **Forward Looking Information**

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### **CONTACT:**

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# Antibe Therapeutics Announces Enrollment of Final Subjects in Phase 2B Gastrointestinal Safety Study of Lead Pain Drug, ATB-346

TORONTO--(BUSINESS WIRE)--January 29, 2018--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a diversified biotechnology company with two best-in-class divisions in pain/inflammation and regenerative medicine, is pleased to announce that the final subjects have been enrolled and are on treatment in the key Phase 2B double-blind clinical trial of ATB-346. The study is being conducted in 240 healthy volunteers and is designed to demonstrate the unequivocal superiority of ATB-346 in gastrointestinal ("GI") safety compared to naproxen, the most prescribed nonsteroidal anti-inflammatory drug ("NSAID") in the USA.

Antibe's Chief Scientific Officer, John Wallace, commented, "We are pleased to provide an update on the progress and timing of our on-going clinical study of ATB-346. The final subjects have commenced dosing and will be on treatment for two weeks, followed by a two-week monitoring period and then standard data analysis for the primary endpoint. As such, we remain on our previously announced schedule and anticipate the release of top-line results within six weeks."

## About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. NSAIDs are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in a number of conditions, including rheumatoid arthritis, ankylosing spondylitis, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

## About Antibe Therapeutics Inc.

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer, non-addictive drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a non-addictive analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin.

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# Antibe Therapeutics Provides Update on Phase 2B Gastrointestinal Safety Study of Lead Pain Drug, ATB-346

TORONTO--(BUSINESS WIRE)--February 26, 2018--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF) would like to confirm the previously announced timing for its Phase 2B double-blind clinical trial of ATB-346. The final subject has now completed treatment and the subsequent two-week monitoring period. The CRO conducting the study, Topstone Research Inc. ("Topstone"), is currently performing data validation and analysis. Antibe remains on its previously announced schedule and anticipates being in a position to report top-line results during the week of March 19<sup>th</sup>, 2018.

The study was conducted in 240 healthy volunteers and is designed to demonstrate the unequivocal superiority of ATB-346 in gastrointestinal ("GI") safety compared to naproxen, the most prescribed nonsteroidal anti-inflammatory drug ("NSAID") in the USA.

## About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. NSAIDs are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in a number of conditions, including rheumatoid arthritis, ankylosing spondylitis, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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## **Antibe Therapeutics Announces Successful Phase 2B Gastrointestinal Safety Study for Lead Pain Drug, ATB-346**

TORONTO--(BUSINESS WIRE)--March 20, 2018--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF) is pleased to announce that its lead drug, ATB-346, met its primary endpoint in the Phase 2B gastrointestinal ("GI") safety study. The double-blind study was conducted in 244 healthy volunteers and was designed to demonstrate the superiority of ATB-346 in GI safety compared to naproxen, the most prescribed nonsteroidal anti-inflammatory drug ("NSAID") in the USA. Subjects on ATB-346 exhibited an ulceration rate of 2.5% versus an ulceration rate of 42.1% for subjects on naproxen at the end of the 2-week treatment period, with a very high degree of statistical significance ( $p < 0.001$ ). ATB-346 was also safe and well tolerated.

Antibe's Chief Scientific Officer, John Wallace, commented, "The successful outcome of this study is the culmination of 15+ years of scientific research, and validates Antibe's hydrogen sulfide-releasing technology. Gastrointestinal safety has been a major global concern with NSAIDs for decades and we now have clinical data unequivocally demonstrating a solution to this unmet and serious medical problem."

Subjects received either 250 mg of ATB-346 once-daily, a dose previously shown to be very effective in reducing osteoarthritis-associated pain, or 500 mg of naproxen twice-daily. The primary endpoint for the study was the incidence of gastric or duodenal ulcers of at least 3 mm diameter with unequivocal depth, considered the gold standard in assessing the GI safety of NSAIDs. "The number of subjects that developed ulcers while on treatment with ATB-346 was 3 (out of 118), compared to 53 (out of 126) for subjects treated with naproxen," remarked John Wallace. "This result was achieved with an impressive level of statistical significance. In addition, the incidence of elevated liver transaminases in the ATB-346 group was consistent with our expectations and the incidence associated with commonly-prescribed NSAIDs." The study was conducted by Topstone Research Ltd. ("Topstone") in Toronto, Canada. A detailed summary of the clinical trial results, including secondary endpoints, will be available for release in Q2 2018.

"This extraordinary result exceeded our expectations for ATB-346," remarked Dan Legault, Antibe's CEO. "With human proof-of-concept GI safety data now in hand, Antibe will continue its regional licensing discussions and will now engage global pharmaceutical firms to support our objective of reaching a partnering event for the major markets. In parallel, we will conduct our placebo-controlled dose ranging and effectiveness study with a data read-out expected in Q4 2018. As well, we will accelerate development of Antibe's other novel NSAIDs, including ATB-352, a non-addictive analgesic for the treatment of severe pain that addresses the global opioid crisis."

### ***Changes to the Board of Directors***

The Company is pleased to announce the appointment of Amal Khouri (B.Sc., MBA) to its Board of Directors, effective immediately. Ms. Khouri brings extensive pharmaceutical business development experience to the Company and succeeded Samira Sakhia as of March 19, 2018.

"On behalf of the entire team at Antibe, I would like to extend our sincere gratitude to Samira for her invaluable contribution to the Company over the past 3 and a half years," commented Walt Macnee, Antibe's Chairman. "We are also delighted to welcome Ms. Khouri to the Antibe Board. Ms. Khouri has extensive experience in global partnering and licensing deals in the pharmaceutical industry. Her expertise will be a tremendous asset to our Board and shareholders as we prepare to commence global partnering discussions for our lead drug, ATB-346."

Ms. Khouri has more than 15 years of business development experience in the pharmaceutical industry and is presently Vice President of Business Development at Knight Therapeutics Inc. ("Knight"). Prior to Knight, Ms. Khouri worked at Novartis Pharma for over 7 years, where she held multiple positions within the global business development and licensing team in Basel, Switzerland. Before joining Novartis, she worked in business development at Paladin Labs in roles with increasing responsibilities. Ms. Khouri holds a B.Sc. in Biochemistry from McGill University and an M.B.A. from the University of Ottawa.

### **About ATB-346**

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. NSAIDs are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in a number of conditions, including rheumatoid arthritis, ankylosing spondylitis, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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## Antibe Therapeutics Announces CEO Letter to Shareholders

TORONTO--(BUSINESS WIRE)--April 26, 2018--Antibe Therapeutics Inc. (TSXV: ATE, OTCQB: ATBPF):

To our stakeholders,

The recent success of our lead drug, ATB-346, in its Phase 2B gastrointestinal ("GI") safety clinical study was a significant milestone for Antibe and represented a major inflection point in our value. Furthermore, we are now one clinical study away from the strategic monetization of our drug platform for the major markets. With such an important and exciting time ahead of us, we thought this would be an ideal opportunity to communicate our strategy for the next year and beyond.

Nearly ten years ago, Antibe was formed to develop safer medicines for pain and inflammation by leveraging our novel hydrogen sulfide ("H<sub>2</sub>S") technology. Over this period, our strategy to maximize value for shareholders has remained consistent: advance our drug candidates to Phase 2 proof-of-concept data and secure high-value partnerships for the large pharmaceutical markets. Fast forward to 2018: we now have unequivocal validation of our H<sub>2</sub>S platform, and are well-positioned to conclude a series of transformational partnerships over the next 12-18 months.

This progress could not have been done without the support of our shareholders, who are now being rewarded for their patience over the years. In the months ahead, our team will be working diligently to ensure that our clinical and business development activities are well aligned with our strategy to maximize shareholder return.

### ***Recent Phase 2B Study Confirms Best-in-Class Status for Drug Platform***

In Antibe's latest Phase 2B study, ATB-346 showed unequivocal superiority to naproxen in GI safety (2.5% versus 42.1% ulceration rate) in 244 healthy volunteers. This human proof-of-concept data replicated the results of our pre-clinical studies, and provides clear validation of the GI-protective properties of our H<sub>2</sub>S technology. The full analysis of this study will be reported this quarter. We are now pushing forward with the planned Phase 2 effectiveness study for ATB-346, and are accelerating development of our other H<sub>2</sub>S platform drugs. Each of Antibe's drugs has blockbuster potential, and would provide physicians and consumers with radically safer alternatives to today's NSAIDs and to the multi-dimensional dangers of corticosteroids and opiates.

### ***Upcoming Phase 2 Effectiveness Study Designed to Validate Efficacy of ATB-346***

With human GI safety for ATB-346 now firmly established, our next clinical objective is to validate its effectiveness at reducing pain in osteoarthritis ("OA") patients. In August 2016, Antibe released top-line data from a Phase 2A study that showed considerable pain relief for ATB-346 at a once-daily dose of 250 mg - the pain relief observed was nearly double that of naproxen and Celebrex based on published data. Although these results were encouraging, the study was conducted in a small number of patients and was not controlled. Our upcoming Phase 2 effectiveness study is designed to validate the pain reduction efficacy of ATB-346 (versus control) and will be conducted in approximately 250 OA patients. In addition, we have biomarker data derived from Phase 1 and Phase 2 blood assays that suggest ATB-346 is effective at lower doses; for this reason, the study will include two additional dosing cohorts with the goal of determining the lowest effective dose. Preparations are well underway for this study and we anticipate commencing it by July with a data read-out in Q4 2018.

### ***Additional Clinical Activities to Support Global Partnering Efforts***

In addition to the Phase 2 effectiveness study, Antibe will also be strategically allocating R&D spend towards activities that we feel will be of the most value to global partners. These activities include: (i) long-range animal toxicology studies (6 months and 9 months) for ATB-346, a standard regulatory requirement for approval of any drug; (ii) additional metabolic studies for ATB-346 to further strengthen our understanding of its pharmacokinetic profile; and (iii) the completion of IND-enabling studies for both ATB-352 and ATB-340, Antibe's two other H<sub>2</sub>S platform drugs. Although ATB-352 and ATB-340 are earlier stage, both individually represent blockbuster drug opportunities and have been considerably de-risked by the latest validation of our H<sub>2</sub>S technology. We remain particularly excited about the potential of ATB-352, a non-addictive, potent analgesic for acute pain that directly addresses the global opioid epidemic, a crisis that the world is struggling to contain.

### ***Partnering Discussions Building Momentum***

In the past, Antibe's partnering efforts were focused on strategically out-licensing the rights for smaller markets (i.e., outside of the United States and Western Europe). We continue to have these discussions and have been successful in concluding two regional deals to-date - this activity remains valuable as it provides non-dilutive funding and further validation of our drug platform. The recent human proof-of-concept GI safety data have undoubtedly benefited these on-going discussions, and more importantly, now allow us to engage multinational pharmaceutical firms to secure strategic partnerships for the large markets. As mentioned earlier, our clinical development activities in the next 12 months are designed to maximize the value of our drug platform and strengthen our position as we engage potential partners.

### ***Commercial Asset in Regenerative Medicine Well-Positioned For Growth***

Our subsidiary, Citagenix Inc. ("Citagenix"), is nearly done assembling the building blocks for its growth strategy in the dental regenerative medicine market. Citagenix's sales team in the United States is working hard at expanding its distribution network, and recently signed Benco Dental, the 3<sup>rd</sup> largest dental distributor in the US by market share. Antibe's relationship with Citagenix has been a symbiotic one: Antibe provided the resources to position Citagenix on a growth trajectory while Citagenix provided valuable diversification. With Citagenix now on a path to growth and Antibe's drug development activities de-risked considerably by the recent GI safety data, our team will now begin exploring strategic alternatives for Citagenix in an effort to unlock value for shareholders.

### ***Strong Balance Sheet and Maturing Capital Markets Strategy***

Antibe's balance sheet is well-funded with approximately \$5 million of cash, and recently benefited from the entire conversion of its debentures. The upcoming Phase 2 effectiveness trial for ATB-346 will be funded entirely with cash-on-hand. In addition, given our stage of development, we are now exploring a listing on the NASDAQ exchange to grow our institutional investor base in the United States.

We look forward to the year ahead as we drive closer towards our goal of bringing safer medicines to market for pain and inflammation.

Sincerely,

Dan Legault  
Chief Executive Officer

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## **Antibe Therapeutics Releases Secondary Endpoint Data from Recent Phase 2B Gastrointestinal Safety Study for Lead Drug, ATB-346**

TORONTO--(BUSINESS WIRE)--July 3, 2018--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce the secondary endpoint data from the recent Phase 2B gastrointestinal ("GI") safety study for its lead drug, ATB-346. The double-blind study was conducted in 244 healthy volunteers and was designed to demonstrate the superiority of ATB-346 in GI safety compared to naproxen, the most prescribed nonsteroidal anti-inflammatory drug ("NSAID") in the United States.

Antibe announced the successful completion of this study on March 20, 2018 with strong primary endpoint data. The primary endpoint for the study was the incidence of gastric or duodenal ulcers of at least 3 mm diameter with unequivocal depth, considered the gold standard in assessing the GI safety of NSAIDs. As previously reported, subjects on ATB-346 exhibited an ulceration rate of 2.5% versus an ulceration rate of 42.1% for subjects on naproxen at the end of the 2-week treatment period. These results exhibited a very high degree of statistical significance ( $p < 0.0001$ ). ATB-346 was also safe and well tolerated.

### **Secondary Endpoint Data**

The secondary endpoints in the study were:

- Incidence of gastric or duodenal ulcers of at least 5 mm diameter with unequivocal depth
- Number of gastric and/or duodenal erosions and/or ulcers
- Incidence of dyspepsia leading to discontinuation of study treatment
- Changes from baseline in hematocrit levels
- Changes from baseline in ex vivo whole blood thromboxane B2 (TXB2) synthesis

#### ***Incidence of gastric or duodenal ulcers of at least 5 mm diameter with unequivocal depth***

No subjects treated with ATB-346 exhibited ulcers of more than 5 mm diameter (0% ulcer incidence) versus 30 subjects treated with naproxen (24% ulcer incidence), with an average of 2.5 ulcers per subject.

#### ***Number of gastric and/or duodenal erosions and/or ulcers***

There were a total of 4 gastric ulcers and 0 duodenal ulcers in the ATB-346 group, versus a total of 203 gastric and duodenal ulcers in the naproxen group.

The average number of gastric and duodenal erosions (which are much less significant than ulcers) in the ATB-346 group was 1.7 per subject, versus 12.7 per subject in the naproxen group.

#### ***Incidence of dyspepsia leading to discontinuation of study treatment***

There were no cases of dyspepsia (i.e., indigestion) leading to study discontinuation in either treatment group.

#### ***Change from baseline in hematocrit levels***

There was no difference in change from baseline in hematocrit between the two treatment arms at the end of the two-week dosing period. A significant decrease in hematocrit is a potential indicator of intestinal bleeding.

#### ***Changes from baseline in whole blood thromboxane B2 (TXB2) synthesis***

NSAIDs exert analgesic and anti-inflammatory effects through inhibition of cyclo-oxygenase (COX) enzyme activity. COX activity can be assessed by measuring a biomarker in the blood known as TXB2.

The average baseline TXB2 values were 86 ng/mL in the ATB-346 treatment group versus 88 ng/mL in the naproxen group (no significant difference). Both naproxen and ATB-346 inhibited TXB2 synthesis by more than 94%.

John Wallace, Antibe's Chief Scientific Officer, remarked, "The secondary GI safety endpoint data for ATB-346 are consistent with the primary endpoint data, showing unequivocal superiority over naproxen. Moreover, the thromboxane data demonstrate that profound COX inhibition was achieved with ATB-346 at 250 mg once daily, fully consistent with the Phase 2A study completed in 2016 that showed excellent pain relief compared with published data for naproxen and celecoxib. We look to fully validate the effectiveness of ATB-346 in our upcoming Phase 2 dose-ranging, efficacy study."

A comprehensive review of the study will be posted on the Company's website in the coming weeks.

### **About ATB-346**

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. NSAIDs are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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## Antibe Therapeutics Provides Clinical Development Update on Its Lead Drug

TORONTO--(BUSINESS WIRE)--July 31, 2018--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to provide an update on its clinical development activities for its lead drug, ATB-346.

The Phase 2 dose-ranging, efficacy study remains on track to commence this quarter. Furthermore, as per the recent CEO letter to shareholders, Antibe has been pursuing additional development activities that are required for regulatory approval and of strategic value to future partners. In that regard, the Company recently completed a series of animal metabolism studies that have provided key insights on the pharmacokinetic ("PK") profile of ATB-346. Importantly, these insights can now be leveraged to better determine the doses and dosing regimens to be used in the upcoming Phase 2 study.

"Based on the recently reported COX inhibition data and metabolism insights, we have augmented our Phase 2 dose-ranging, efficacy study for ATB-346 to include two protocols," remarked Dan Legault, Antibe's CEO. "The first protocol will expand upon the metabolism findings which should enable us to better select the optimal doses for the subsequent protocol. Although this modestly extends the timelines of the overall study, it provides a faster path to obtaining the comprehensive package of efficacy and metabolism data that is required for regulatory bodies such as the FDA, and valued by global partners."

### *Upcoming Phase 2 Study De-Risked by Inclusion of Metabolism Protocol*

The upcoming Phase 2 study will now include a metabolism protocol that will directly inform the dosing cohorts (i.e., the doses and dosing regimens) to be used in the subsequent dose-ranging, efficacy protocol. Thus, the augmented development plan will include two parts:

- **Part 1: Characterization of Metabolites.** The primary objective of the metabolism study is to determine the principle metabolites of ATB-346 in humans and characterize their activity and PK profile. The study will be conducted in approximately 25 healthy volunteers and is anticipated to commence this quarter and should take 8-10 weeks to complete.
- **Part 2: Validation of Effectiveness.** The dose-ranging, efficacy study will be conducted in approximately 200 osteoarthritis patients. The primary objective of the study is to evaluate the efficacy of ATB-346 in reducing pain at three doses (versus control) and establish the lowest effective dose. The profile of each ATB-346 dosing cohort will be finalized based on the findings of the above-mentioned metabolism protocol. A top-line data read-out from this study is anticipated in Q2 2019.

Antibe estimates that the full Phase 2 study (including the metabolism protocol) will cost approximately \$3 million and will be funded with cash-on-hand. The Company will provide regular updates on the progress and timing of the study.

### *Recently Completed Metabolism Studies Show Promising Results*

Antibe recently concluded a series of animal studies with an objective of further characterizing the metabolic profile of ATB-346. Clinical studies conducted to-date indicate that ATB-346 is far more potent than naproxen and suggests one or more active metabolites are contributing to the mechanism of action. The recently obtained data on several metabolites of ATB-346 provide significant insights to understanding the increased potency and duration-of-activity of the drug. A defined understanding of a drug's mechanism of action and metabolism is a key requirement for regulatory approval and will also support partnering discussions. These metabolism studies were conducted by a leading clinical research organization ("CRO") in the United States.

### **About ATB-346**

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. NSAIDs are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

### **About Antibe Therapeutics Inc.**

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer, non-addictive drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a non-addictive analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. [www.antibethera.com](http://www.antibethera.com).

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### **Forward Looking Information**

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### **CONTACT:**

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## **Antibe Provides Scientific Report on Its Recently Completed Phase 2B Study Showing Unequivocal Gastrointestinal Safety of ATB-346**

TORONTO, Ontario--(BUSINESS WIRE)--August 29, 2018--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV:ATE, OTCQB:ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce that it has prepared a comprehensive report of the recently-completed Phase 2B study for its lead drug, ATB-346. The study was completed in March 2018 and demonstrated unequivocal superiority in gastrointestinal ("GI") safety compared to naproxen, the most prescribed NSAID in the United States.

The report provides a discussion of the study objectives and design, an analysis of the primary and secondary outcomes and additional effectiveness and safety parameters, and a brief discussion of the possible mechanisms related to the metabolism of ATB-346 responsible for the favourable pharmacokinetics and enhanced cyclo-oxygenase (COX) inhibition. The review article is available for download on Antibe's website at: <http://www.antibethera.com/news-media/scientific-publications/>.

### **About ATB-346**

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. NSAIDs are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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# Antibe Therapeutics Receives Approval to Initiate Part One of Phase 2B Dose-Ranging, Efficacy Study for ATB-346

TORONTO--(BUSINESS WIRE)--October 10, 2018--Antibe Therapeutics Inc. ("Antibe") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce that it has received approval from Health Canada to initiate the first part of its Phase 2B dose-ranging, efficacy study for its lead drug, ATB-346. The first part of the study is a metabolism protocol that will be conducted in 24 healthy volunteers over a 7 day treatment period. The primary objective of the protocol is to determine the principle metabolites of ATB-346 in humans and characterize their activity and pharmacokinetic profile.

Antibe's CEO, Daniel Legault, commented, "We are pleased with the approval and excited to begin the first part of this Phase 2B dose-ranging, efficacy study for ATB-346. The results will directly inform the dosing cohorts to be used in the subsequent, larger efficacy protocol. Moreover, this study will further elucidate ATB-346's unique metabolic profile and will strengthen our data package as we engage regulatory bodies for Phase 3 development and advance strategic partnering activities."

The metabolism study will commence immediately and is expected to conclude in December 2018. The study will be performed in Toronto, Canada by Boston-based Veristat. The timing of the second part of the dose-ranging, efficacy study remains on track for completion in Q2 2019.

## About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. NSAIDs are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346. In March 2018, ATB-346 showed unequivocal superiority to naproxen in GI safety (2.5% versus 42.1% ulceration rate) in a Phase 2B double-blind clinical trial.

## About Antibe Therapeutics Inc.

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## Forward Looking Information

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## CONTACT:

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## **Antibe Therapeutics Announces Successful Completion of Part One of Phase 2B Dose-Ranging, Efficacy Study for ATB-346**

TORONTO--(BUSINESS WIRE)--November 27, 2018--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce the successful completion of part one of the Phase 2B dose-ranging, efficacy study for its lead drug, ATB-346. The study was conducted in 24 healthy volunteers who were randomized to once daily doses of ATB-346 at 250 mg, 200 mg or 150 mg.

The primary objectives of the study were to: (i) evaluate cyclo-oxygenase (COX) inhibition to inform the doses of ATB-346 to be used in part two, the upcoming dose-ranging, efficacy study; (ii) obtain a series of blood samples at distinct time intervals to facilitate analysis of the principal metabolites of ATB-346; and (iii) further assess the overall safety and tolerability of the drug.

The blood samples were successfully collected over the 7-day treatment period. COX enzyme activity was assessed through the measurement of thromboxane (TXB2) synthesis, a known biomarker that can be measured in the blood. NSAIDs exert analgesic and anti-inflammatory effects through inhibition of COX activity. The COX inhibition data of the 250 mg dose was consistent with the Phase 2A and Phase 2B studies, and marked inhibition was also observed with the two lower doses. This provides management with confidence in the initial selection of the doses to be used in the upcoming dose-ranging, efficacy study. Additionally, comprehensive analysis is underway to characterize the pharmacokinetic profile of each principal metabolite of ATB-346. The drug was also safe and well tolerated.

Part two of the Phase 2B dose-ranging, efficacy study remains on track to commence in January 2019 with a top-line data read-out anticipated in Q2 2019. This will be a double-blind, placebo-controlled study and will be conducted in approximately 250 osteoarthritis patients. The primary objective is to evaluate the efficacy of three doses of ATB-346 in reducing pain.

### **About ATB-346**

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs ("NSAIDs") are the most commonly used therapy for osteoarthritis, yet their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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# Antibe Therapeutics Receives Approval to Initiate Part Two of Phase 2B Dose-Ranging, Efficacy Study for ATB-346

TORONTO--(BUSINESS WIRE)--January 21, 2019--Antibe Therapeutics Inc. ("Antibe") (TSXV:ATE, OTCQB:ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce that it has received approval from Health Canada to initiate the second part of its Phase 2B dose-ranging, efficacy study for its lead drug, ATB-346. The primary objective of the study is to evaluate the efficacy of ATB-346 in reducing osteoarthritis ("OA") pain over a 14-day treatment period. The study will involve a total of 360 patients with OA of the knee, who will be randomized to placebo or one of three doses of ATB-346 administered once daily: 150 mg, 200 mg or 250 mg.

Antibe's CEO, Dan Legault, commented, "This is an exciting time for Antibe as a significant number of patients will be receiving ATB-346 for the first time to assess efficacy in a controlled setting. A positive outcome in this Phase 2B study will validate the effectiveness of ATB-346 in reducing pain, and will be a breakthrough for patients and physicians. Furthermore, it will unlock significant value for Antibe as we advance global partnering discussions and deepen our understanding of the ideal development path for ATB-346 and our other pipeline drug candidates."

The study will be conducted by Veristat, Inc. ("Veristat") in approximately 35 clinical sites across Canada and is expected to commence enrollment shortly. Antibe will update the timing for the trial completion as Veristat informs us of enrollment progress during the coming months.

## About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs ("NSAIDs") are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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## Antibe Therapeutics Announces \$5 Million Bought Deal Offering

### NOT FOR DISTRIBUTION OR DISSEMINATION INTO THE UNITED STATES OR THROUGH U.S. NEWSWIRE SERVICES

TORONTO--(BUSINESS WIRE)--February 4, 2019--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, today announced that it has entered into an agreement with Bloom Burton Securities Inc., on behalf of a syndicate of underwriters including Echelon Wealth Partners Inc. and Dominick Capital Corporation (collectively, the "Underwriters"), pursuant to which the Underwriters have agreed to purchase, on a bought deal basis, 20,000,000 units of the Company (the "Units") at a price of \$0.25 per Unit (the "Offering Price"), for aggregate gross proceeds of \$5,000,000 (the "Offering"). Each Unit will be comprised of one common share of the Company (a "Common Share") and one-half of one common share purchase warrant (each full warrant, a "Warrant"). Each Warrant will entitle the holder thereof to purchase one Common Share at an exercise price of \$0.35 for a period 36 months.

"This strategic financing will allow us to fund additional development activities for ATB-346 that set the stage for Phase 3 development and fulfill key requirements for regulatory progression and approval," commented Dan Legault, CEO of Antibe. "This should strengthen our position as we advance global partnering discussions later this year in an effort to fully monetize ATB-346 for shareholders."

The net proceeds of the Offering will be used to fund research and development activities, including but not limited to, ATB-346's clinical development, regulatory consulting fees, working capital needs and other general corporate purposes.

The Company has granted the Underwriters an over-allotment option (the "Over-Allotment Option"), at the Underwriters' sole discretion, to purchase up to 3,000,000 Units at the Offering Price, exercisable in whole or in part up to 30 days following closing of the Offering.

The Units will be offered by way of a short form prospectus to be filed in British Columbia, Alberta, Saskatchewan, Manitoba and Ontario. The Units may be sold in such other jurisdictions as the Company and the Underwriters may agree.

Closing of the Offering is expected to occur on or about February 26, 2019, subject to customary closing conditions, including, without limitation, receipt of applicable regulatory approvals, including the approval of the TSX Venture Exchange.

A preliminary short form prospectus containing important information relating to the securities described in this document has not yet been filed with the securities regulatory authorities in each of Ontario, Alberta, Saskatchewan, Manitoba and British Columbia. Copies of the preliminary short form prospectus may be obtained from Bloom Burton Securities Inc., 65 Front Street East, Suite 300, Toronto, Ontario, M5E 1B5, Email: [ecm@bloomburton.com](mailto:ecm@bloomburton.com). There will not be any sale or any acceptance of an offer to buy the securities until a receipt for the final short form prospectus has been issued. This news release does not provide full disclosure of all material facts relating to the securities offered. Investors should read the preliminary short form prospectus, final short form prospectus and any amendment, for disclosure of those facts, especially risk factors relating to the securities offered, before making an investment decision.

This press release does not constitute an offer to sell or a solicitation of an offer to buy the Units in any jurisdiction, nor will there be any offer or sale of the Units in any jurisdiction in which such offer, solicitation or sale would be unlawful. The Units have not and will not be registered under the United States Securities Act of 1933, as amended (the "U.S. Securities Act"), or any U.S. state securities laws and, therefore, may not be offered or sold to, or for the benefit or account of, persons within the United States or "U.S. persons" (as such term is defined in Regulation S under the U.S. Securities Act) except pursuant to exemptions from the registration requirements of the U.S. Securities Act and applicable state securities laws.

#### About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs ("NSAIDs") are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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#### Forward Looking Information

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uncertainties and other factors that may cause the actual results of the Company to differ materially from those discussed in the forward-looking information, and even if such actual results are realized or substantially realized, there can be no assurance that they will have the expected consequences to, or effects on the Company. Factors that could cause actual results or events to differ materially from current expectations include, but are not limited to, the failure of the Company to obtain the approval of the TSX Venture Exchange for the Offering; the inability of the Company to satisfy all conditions to the completion of the Offering and the risk of unforeseen delays in the completion of the Offering, if at all, whether as a result of market conditions or otherwise. Reference is also made to the risk factors disclosed under the heading "Risk factors" in the Company's AIF for the year ended March 31, 2018 which has been filed on SEDAR and is available under the Company's profile at [www.sedar.com](http://www.sedar.com).

***The TSX Venture Exchange has in no way passed upon the merits of the proposed Offering and has neither approved nor disapproved the contents of this press release. Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.***

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## Antibe Therapeutics Recognized as a 2019 TSX Venture 50 Company

TORONTO--(BUSINESS WIRE)--February 22, 2019--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce that it has been named a 2019 TSX Venture 50™ company, an award that recognizes the top performing companies on the TSX Venture Exchange over the past year. Antibe was ranked second in the Clean Technology and Life Sciences sector.

The TSX Venture 50™ is a ranking of the top ten performers on TSX Venture Exchange from each of five industry sectors: Clean Technology and Life Sciences, Diversified Industries, Energy, Mining, and Technology. The 2019 Venture 50™ winners were selected based on market capitalization growth, share price appreciation and trading volume for the 2018 calendar year.

"We are honoured to be recognized as a top performer on the TSX Venture Exchange, which reflects the best-in-class potential of our pipeline of novel hydrogen sulfide-releasing NSAIDs," commented Dan Legault, Antibe's CEO. "We hope to continue this success for our shareholders in 2019 as we look to fully validate the effectiveness of our lead drug, ATB-346, in the recently commenced Phase 2B dose-ranging, efficacy study."

For more information on the TSX Venture 50™, including the ranking and list of this year's winners, please visit: [www.tsxventure50.com](http://www.tsxventure50.com).

### About ATB-346

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# Antibe Therapeutics Inc. Announces Closing of \$5.75 Million Bought Deal Offering

## Underwriters Exercise Over-Allotment Option in Full

TORONTO--(BUSINESS WIRE)--February 27, 2019--Antibe Therapeutics Inc. ("**Antibe**" or the "**Company**") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce that it has closed its previously announced bought deal public offering of 23,000,000 units of the Company (the "**Units**") at a price of \$0.25 per Unit (the "**Offering Price**") for aggregate gross proceeds of \$5,750,000 (the "**Offering**"), including the exercise in full of the Underwriters' over-allotment option. The Offering was made pursuant to an underwriting agreement dated February 8, 2019 with a syndicate of underwriters led by Bloom Burton Securities Inc., together with Echelon Wealth Partners Inc. and Dominick Capital Corporation (collectively, the "**Underwriters**").

Each Unit was comprised of one common share of the Company (a "**Common Share**") and one-half of one common share purchase warrant. Each full warrant is exercisable to purchase one Common Share at any time prior to February 27, 2022 at a price of \$0.35 per Common Share.

The units were offered and sold by way of a short form prospectus filed in each of the provinces of Alberta, British Columbia, Manitoba, Ontario, and Saskatchewan. The net proceeds of the Offering will be used to fund research and development activities, including but not limited to, ATB-346's clinical development, regulatory consulting fees, working capital needs and other general corporate purposes.

As consideration for the services rendered by the Underwriters in connection with the Offering, the Company has paid the Underwriters a cash commission equal to 7% of the gross proceeds raised under the Offering and has granted the Underwriters non-transferable broker warrants equal to 7% of the number of Units sold under the Offering exercisable at any time prior to February 27, 2021 at an exercise price equal to the Offering Price.

This press release does not constitute an offer to sell or a solicitation of an offer to buy the Units in any jurisdiction, nor will there be any offer or sale of the Units in any jurisdiction in which such offer, solicitation or sale would be unlawful. The Units have not and will not be registered under the United States Securities Act of 1933, as amended (the "**U.S. Securities Act**"), or any U.S. state securities laws and, therefore, may not be offered or sold to, or for the benefit or account of, persons within the United States or "U.S. persons" (as such term is defined in Regulation S under the U.S. Securities Act) except pursuant to exemptions from the registration requirements of the U.S. Securities Act and applicable state securities laws.

### About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs ("**NSAIDs**") are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

### About Antibe Therapeutics Inc.

Antibe develops safer medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer, non-addictive drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a non-addictive analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. [www.antibetherapeutics.com](http://www.antibetherapeutics.com).

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*The TSX Venture Exchange has in no way passed upon the merits of the proposed Offering and has neither approved nor disapproved the contents of this press release. Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.*

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# Antibe Therapeutics Announces Commencement of Phase 2B Dose-Ranging, Efficacy Study for Lead Drug, ATB-346

TORONTO--(BUSINESS WIRE)--March 29, 2019--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV:ATE, OTCQB:ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce that its Phase 2B dose-ranging, efficacy study for ATB-346 has formally commenced. Enrollment is open, clinical sites have been activated and patients will now begin screening.

The study is designed to validate the efficacy of ATB-346 in reducing osteoarthritis ("OA") pain and establish the dose for Phase 3 development. The study will involve a total of 360 patients with OA of the knee, who will be randomized to placebo or one of three doses of ATB-346 administered once daily: 150 mg, 200 mg or 250 mg.

"We are excited to officially commence the final Phase 2 study for ATB-346," commented Dan Legault, Antibe's CEO. "A successful outcome in this large clinical trial will further validate the best-in-class potential of ATB-346, and will represent a major inflection point as we position ourselves for Phase 3 development and global partnering discussions."

The study is being conducted by Veristat, Inc. ("Veristat") in approximately 35 clinical sites across Canada and is expected to have a top-line data read-out this summer.

## About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs ("NSAIDs") are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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## Phase 2B GI Safety Results For ATB-346 Published in British Journal of Pharmacology

TORONTO--(BUSINESS WIRE)--April 16, 2019--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, today highlights that a research article has been published in the British Journal of Pharmacology ("BJP") on the successful Phase 2B GI safety trial for its lead drug, ATB-346. BJP is considered one of the world's pre-eminent scientific journals in pharmacology.

"We are pleased that the results of our Phase 2B GI safety study for ATB-346 have been published in BJP," remarked John Wallace, Antibe's Chief Scientific Officer. "The results provide unequivocal evidence for a dramatic reduction of GI toxicity of ATB-346 as compared to naproxen, with equivalent suppression of the enzyme (cyclooxygenase; COX) that produces substances that cause pain. The equivalent suppression of COX is suggestive of comparable analgesic effects in the clinic, a finding demonstrated in our previous Phase 2A study. Additional validation of the effectiveness of ATB-346 is the major endpoint in the recently commenced Phase 2B dose-ranging, efficacy study. Results of that study are anticipated this summer."

The research article is available for download on Antibe's website at: <http://www.antibethera.com/news-media/scientific-publications/>

### About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs ("NSAIDs") are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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## Antibe Therapeutics Announces Upcoming Conference Schedule

TORONTO--(BUSINESS WIRE)--May 30, 2019--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, is pleased to announce its conference schedule for the upcoming months.

### **2019 BIO International Convention (June 3 – 6, 2019) – Philadelphia, United States**

Antibe will be engaging in several days of one-on-one meetings with pharmaceutical companies to discuss licensing and partnering opportunities for Antibe's lead drug, ATB-346. BIO International is the largest biopharma partnering event of the year, attracting over 16,000 leaders and business development executives from 5,000 companies across the globe.

### **9<sup>th</sup> Annual LD Micro Invitational (June 4 – 5, 2019) – Los Angeles, United States**

Antibe's CEO, Dan Legault, has been invited to present at the LD Micro investor conference on Tuesday, June 4<sup>th</sup>, 2019 at 9:40 am (Pacific Time) at the Luxe Hotel in Los Angeles, California. The LD Micro Invitational will feature 250 companies and will be attended by over 1,000 individuals.

### **European Congress of Rheumatology 2019 (June 12 – 15, 2019) – Madrid, Spain**

Antibe's Chief Scientific Officer, John Wallace, will be representing Antibe at Europe's major conference for osteoarthritis organized by the European League Against Rheumatism (EULAR). EULAR promotes the translation of research advances into daily care and fights for the recognition of the needs of people with musculoskeletal diseases by the governing bodies in Europe.

### **TSX Venture 50 Capital Conference (July 11 – 13, 2019) – Kelowna, Canada**

Antibe will be participating in the TSX Venture 50 Capital Conference, an investor networking event that includes one-on-one meetings exclusively for this year's TSX Venture 50 winners. Antibe was ranked second in the Clean Technology and Life Sciences sector on the TSX Venture Exchange based on its performance last year.

In addition, the Company has amended its agreement with MKR Group, Inc. ("MKR"), a California-based investor relations firm, reflecting a monthly retainer of US\$7,000 (per a revised agreement in 2018). MKR will continue to broaden awareness of Antibe amongst institutional investors and sell-side analysts in the United States. The engagement can be terminated by either party upon 30 days notice.

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## **Antibe Therapeutics Announces CEO Letter to Shareholders**

TORONTO--(BUSINESS WIRE)--June 25, 2019--Antibe Therapeutics Inc. (TSXV: ATE, OTCQB: ATBPF):

To our shareholders,

As we approach the end of Phase 2 development for ATB-346 and launch into global partnering discussions, we thought this would be an ideal time to reflect on recent developments and reiterate our strategy to maximize value for shareholders.

Last year was pivotal for Antibe as we delivered dramatic gastrointestinal (“GI”) safety data for our lead drug, ATB-346, in a head-to-head Phase 2B study versus naproxen, the most prescribed NSAID in the United States. This was an important result as it strongly suggests we have solved one of the most pervasive medical problems of our time: the GI safety issue with NSAIDs. Our Phase 2A efficacy study and recent dose-ranging metabolism study in humans provided encouraging effectiveness and COX inhibition data. Collectively, this gave us the confidence to march forward with a Phase 2B efficacy study of impressive scale – a total of 360 patients across 35 clinical sites in what is considered one of the largest clinical studies ever undertaken in Canada. A successful data read-out in this trial will fully validate the best-in-class status of ATB-346 in a US\$11 billion drug category, and will set the stage for global partnering activity.

Our overarching objective for shareholders remains the same: monetize our drug pipeline through high-value partnerships for the large pharmaceutical markets. Given the strength of our existing data package and the successful conclusion of Phase 2 within our reach, we feel we are well positioned to deliver upon that goal.

### ***Phase 2B Dose-Ranging, Efficacy Study Remains on Track***

Our Phase 2B dose-ranging, efficacy study for ATB-346 remains on track for a top-line data read-out this summer; the study is well underway with all 35 clinical sites actively enrolling patients. The study is designed to validate the effectiveness of ATB-346 in reducing osteoarthritis (“OA”) pain and establish the lowest effective dose. Specifically, the study includes three doses of ATB-346 that will be individually assessed for superiority versus placebo. With a total of 360 patients, the study powers both the high dose (250 mg) and middle dose (200 mg) for statistical significance which will provide more robust efficacy data that can be leveraged as we engage global partners. Importantly, this is the final Phase 2 study for ATB-346 and represents a major development milestone and inflection point for Antibe if one of the doses meets the primary endpoint.

### ***Gearing Up for Successful End-of-Phase 2 Meeting with FDA***

In parallel with our development activities for ATB-346, we have been busy readying the drug for a successful IND application and positive end-of-Phase-2 meeting with the FDA. This preparation is non-trivial and require comprehensive data packages encompassing pharmacokinetics, metabolism, toxicology, chemistry and manufacturing, among other factors.

We have assembled a team of regulatory experts to support this initiative, including several former heads of FDA directorates and a leading regulatory agency based out of Washington, DC. Our efforts to fully elucidate the metabolic pathways of ATB-346 over the past year are nearly complete and will be very valuable in regulatory discussions. A successful end-of-Phase-2 meeting strengthens our position with future partners as it surmounts a major regulatory hurdle in the United States and we will pursue that as expeditiously as possible, once the Phase 2B results are in hand.

### ***Partnering Discussions Await Key Phase 2B Efficacy Data***

We have seen mounting interest in ATB-346 since the dramatic Phase 2B GI safety data last year. At the moment we are in discussions with numerous pharmaceutical companies across the globe, and our data room has never been more active. Due to risk management, the vast majority of pharmaceutical companies require complete Phase 2 human proof-of-concept data before licensing a drug – we are on the verge of surpassing this requirement. Furthermore, our partnering advisory team has been a superb resource and is adding invaluable depth to our business development efforts. Assuming the Phase 2B efficacy results are favourable, we anticipate being in a position of strength to execute a series of regional and global licensing deals.

### ***Non-Opioid Acute Painkiller, ATB-352, Poised to Deliver Value in Partnership Deals***

With the clinical advancement of our lead drug, ATB-346, we continue to validate our hydrogen sulfide (H<sub>2</sub>S) technology platform. We are now leveraging this platform to unlock further value for shareholders and potential partners. In support of this initiative, we recently announcing the lead indication for the next drug in our pipeline, ATB-352, a non-addictive, potent analgesic for treating acute pain. Post-operative pain is a US\$9 billion market opportunity that is in desperate need of safer treatment alternatives without abuse potential. Furthermore, the recent characterization of our strategy for ATB-352 affirms to potential partners that Antibe is building a best-in-class platform of drug candidates that address several blockbuster markets.

### ***Commercial Asset in Regenerative Medicine Delivering Impressive Growth***

Citagenix Inc. (“Citagenix”), our commercial asset in regenerative medicine is now delivering impressive growth driven by the successful roll-out of its US expansion strategy. Sales in the United States were up 62% year-over-year in the fiscal 2019 period, and we’re seeing that growth rate accelerate in the current fiscal period. We expect its recent performance to benefit strategic discussions that are geared to unlock additional value for shareholders.

The time has never been more exciting for Antibe with another pivotal inflection point on the horizon. We look forward to the next 12 months as we complete our final Phase 2 clinical trial for ATB-346 and work on executing significant partnerships to maximize shareholder value.

Sincerely,

Dan Legault  
*Chief Executive Officer*

### **About Antibe Therapeutics Inc.**

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## Antibe Therapeutics Provides Update on Phase 2B Dose-Ranging, Efficacy Study for ATB-346

TORONTO--(BUSINESS WIRE)--August 27, 2019--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer therapeutics for pain and inflammation, today provides an update on the Phase 2B dose-ranging, efficacy study for its lead drug, ATB-346. The clinical study commenced in March 2019 and is designed to validate the efficacy of ATB-346 in reducing pain and establish the dose for Phase 3 development. A total of 360 patients with osteoarthritis of the knee are being randomized to either placebo or one of three doses of ATB-346 administered once daily: 150 mg, 200 mg or 250 mg.

The clinical trial is proceeding well and the Company is pleased with the execution and quality of patient screening, which determines admittance into the study across the 35 clinical sites. Previous guidance for enrollment of the last patient had been late calendar Q3 2019, but this will now occur in calendar Q4 2019. The delay is largely the result of the rigorous screening discipline and a temporary slowdown in patient recruitment due to the summer holiday period.

Dan Legault commented, "We have designed our clinical trial in a rigorous way and have been successful to-date in recruiting suitable patients to ensure a robust set of data. Although this has mildly delayed our timelines, we view data quality as paramount for this trial. With the recent successful financing, we're adequately capitalized to complete the trial while funding continued development of our other programs, and anticipate being in a strong position to negotiate potential partnerships upon a successful study outcome."

Antibe will issue another press release upon final enrollment of the last patient in the study.

### About ATB-346

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs ("NSAIDs") are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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## **Antibe Therapeutics Provides Corporate Update and Reports Q2 2020 Interim Financial and Operating Results**

TORONTO--(BUSINESS WIRE)--November 28, 2019--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer, non-addictive therapeutics for pain and inflammation, is pleased to provide a corporate update in conjunction with the filing of its financial and operating results for the fiscal quarter ended September 30, 2019.

### ***Phase 2B Dose-Ranging, Efficacy Study Nearing Completion***

The Company's on-going Phase 2B dose-ranging, efficacy study is evaluating the effectiveness of its lead drug, ATB-346, in reducing osteoarthritis pain compared to placebo in 360 patients. Total enrollment has surpassed 70% and patient recruitment has accelerated due to several initiatives, including the activation of an additional five clinical sites. This brings the total number of clinical sites to 40, the largest number of sites for any clinical trial ever conducted in Canada.

Dan Legault, Antibe's CEO, remarked, "We're pleased with the conduct of the study, although enrollment has been slower than originally anticipated. We've taken extra measures to expedite the completion of enrollment, but with the inevitable slowdown during the holiday season, we are pushing our guidance for top-line data to calendar Q1 2020."

The Company will issue a press release upon enrollment of the last patient.

### ***Balance Sheet Remains Strong; Recent Benefit from Warrant Activity***

Antibe reported a cash balance at September 30, 2019, of \$8 million, which reflects the successful prospectus offering that was concluded in August. Subsequently, the Company has raised \$1.3 million from the exercising of warrants. The Company's unaudited fiscal Q2 2020 condensed interim consolidated financial statements and MD&A will be available on SEDAR today.

### ***Continued Progress with FDA Regulatory Requirements***

The Company recently requested a Pre-Investigational New Drug ("IND") meeting to support its IND filing with the FDA and, in parallel, is preparing for an end-of-Phase-2 FDA meeting. A successful IND filing will allow for Phase 3 testing of ATB-346 in the United States. In combination with a successful end-of-Phase-2 FDA meeting, Antibe will have achieved a valuable regulatory milestone for potential partners seeking a Phase 3-ready asset. In addition, the Company is pursuing the equivalent regulatory pathway with the EMA to prepare ATB-346 for approval in Europe.

### ***Preparing for Global Pharma Partnerships***



The Company has advanced several independent market research initiatives aimed at global partners, who will be focusing on commercialization strategy as ATB-346 nears approval. This includes a recently completed health economics study on the overall cost of NSAID-related adverse events in the United States. The study estimates that direct costs associated with NSAIDs, including the treatment of adverse events, total approximately \$74 billion annually in the United States. It also estimates that the introduction of ATB-346 could deliver significant savings to the US healthcare system.

In addition, Antibe recently completed a commercial positioning study for ATB-346, and has now engaged a leading life science-focused consulting firm to conduct a comprehensive market opportunity assessment and payor study for both the United States and Europe. Collectively, these initiatives will complement the scientific and clinical data that Antibe shares with potential partners.

### ***Global Supply Secured for ATB-346***

Antibe is pleased to announce that it recently engaged a leading global contract manufacturing organization (“CMO”) for ATB-346. This contract supports the interests of Antibe and its potential global partners by securing a reliable supply of ATB-346 to meet regulatory approval timelines.

### ***New Corporate Website Reflects Maturing Stage of Company***

The Company has launched its new corporate website reflecting its refreshed brand and identity. The new website contains in-depth information on Antibe’s science, drug pipeline and market opportunity, making it a valuable resource for investors and future partners.

### ***Issuance of Restricted Share Units***

It is the Company’s standard practice to grant equity compensation awards on an annual basis. A total of 7,630,000 restricted share units (“RSUs”) were granted to directors, officers, employees and consultants pursuant to the Company’s RSU plan. The vesting of 50% of the RSUs granted to key executives will be subject to the achievement of specific performance goals that reflect the successful execution of the Company’s business plan and strategy. In addition, all RSUs are subject to time-based vesting; one third (1/3) of the RSUs granted will vest on each of the first, second and third anniversaries of today’s date.

### ***About ATB-346***

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs (“NSAIDs”) are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

## **About Antibe Therapeutics Inc.**

Antibe develops safer, non-addictive medicines for pain and inflammation. Antibe's technology involves linking a hydrogen sulfide-releasing molecule to an existing drug to produce a patented, improved medicine. Antibe's lead drug ATB-346 targets the global need for a safer, non-addictive drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a non-addictive analgesic for treating severe acute pain, while ATB-340 is a GI-safe derivative of aspirin. Citagenix Inc., an Antibe subsidiary, is a market leader and worldwide distributor of regenerative medicine products for the dental marketplace. [www.antibethera.com](http://www.antibethera.com).

## **Forward Looking Information**

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## **Antibe Therapeutics Provides Corporate Update and Reports Q3 2020 Interim Financial and Operating Results**

TORONTO--(BUSINESS WIRE)--February 25, 2020--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer, non-addictive therapeutics for pain and inflammation, is pleased to provide a corporate update in conjunction with the filing of its financial and operating results for the fiscal quarter ended December 31, 2019.

### ***Enrollment of Phase 2B Dose-Ranging, Efficacy Study Nearly Complete***

The Company's ongoing Phase 2B dose-ranging, efficacy study is evaluating the effectiveness of its lead drug, ATB-346, in reducing osteoarthritis pain compared to placebo in 360 patients. Total enrollment has reached 98% and there are a sufficient number of patients in screening to satisfy the enrollment target. Antibe will issue a press release upon enrollment of the last patient, which is now expected within the next two weeks.

### ***Balance Sheet Continues to Benefit from Warrant Activity***

Antibe reported a cash balance of \$6.6 million at December 31, 2019. Subsequently, the Company has raised \$2.6 million from the exercising of warrants. The Company's unaudited fiscal Q3 2020 condensed interim consolidated financial statements and MD&A are available on SEDAR.

### ***Pre-IND Meeting with FDA Scheduled for Next Month***

The Company is scheduled to meet the FDA for a Pre-Investigational New Drug ("IND") meeting for ATB-346 in four weeks. This meeting will inform the IND filing with the FDA, which will ultimately allow for Phase 3 testing of ATB-346 in the USA. A successful IND filing in combination with a positive end-of-Phase-2 FDA meeting would strengthen Antibe's position as it prepares to engage global partners seeking a Phase 3-ready asset.

### ***Issuance of Restricted Share Units***

The Company granted a total of 390,000 restricted share units ("RSUs") to employees and a consultant. All RSUs are subject to time-based vesting; one third (1/3) of the RSUs granted will vest on each of the first, second and third anniversaries of today's date.

## **About ATB-346**

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## **Antibe Therapeutics Announces Enrollment of Last Patient in Phase 2B Dose-ranging, Efficacy Study of Lead Drug, ATB-346**

TORONTO--(BUSINESS WIRE)--February 28, 2020--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSXV: ATE, OTCQB: ATBPF), a leader in developing safer, non-addictive therapeutics for pain and inflammation, is pleased to announce that the last patient has been enrolled and is on treatment in the Phase 2B dose-ranging, efficacy study of Antibe's lead drug, ATB-346. The study is evaluating the effectiveness of ATB-346 in reducing osteoarthritis (OA) pain compared to placebo in 360 patients.

The final patients will be on treatment for two weeks, followed by a two-week monitoring period and analysis of the primary endpoint data. The primary endpoint in the study is the change in OA knee pain of ATB-346 versus placebo as measured by the WOMAC subscale pain score, considered the gold standard in pain assessment for arthritis trials. Patients have been randomized to placebo or one of three doses of ATB-346 administered once daily: 150 mg, 200 mg or 250 mg.

The Company anticipates the release of top-line results within six weeks.

### **About ATB-346**

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs ("NSAIDs") are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

### **About Antibe Therapeutics Inc.**

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## **Antibe Therapeutics Updates Timing for Top-Line Results From Completed Phase 2B Dose-Ranging, Efficacy Study**

*- Top-line data expected within six weeks -*

TORONTO--(BUSINESS WIRE)--May 4, 2020--Antibe Therapeutics Inc. (TSXV: ATE, OTCQB: ATBPF) today provides an update on the timing of top-line results for the Phase 2B dose-ranging, efficacy study for its lead drug, ATB-346. Involving 360 patients across 40 clinical sites, this study is one of the largest ever undertaken in Canada. The Company is pleased to report that its clinical research organization (“CRO”), Veristat, was able to complete the trial and capture all patient data without compromising the size and integrity of the study. However, ongoing hospital restrictions, clinic closures and complexities arising from remote working constraints have slowed Veristat’s data collection, validation and analysis beyond the timeframe envisioned last month. As a result of these new updates from its CRO, the Company anticipates the release of top-line results within six weeks. Antibe confirms that it will remain blinded until Veristat releases these results to the Company.

Dan Legault, Antibe’s CEO, remarked, “Although the world is facing singular challenges in light of the COVID-19 health crisis, we are fortunate to have successfully completed the collection of data for every patient enrolled in the study. Validating and processing these data is a non-trivial task in the current environment, especially given the study’s large number of sites. Although later than anticipated, we look forward to delivering robust and complete top-line data as soon as possible.”

The Company has benefited from recent warrant exercise activity and had a cash balance of \$6 million as of May 1, 2020. Accordingly, Antibe confirms that it is funded beyond the upcoming data readout.

### **About ATB-346**

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs (“NSAIDs”) are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346. The current Phase 2 dose-ranging, efficacy study is designed to validate ATB-346’s effectiveness compared to placebo in reducing osteoarthritis pain.

## **About Antibe Therapeutics Inc.**

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## **Antibe Therapeutics Announces Positive Top-Line Data From Phase 2B Dose-Ranging, Efficacy Study For ATB-346**

TORONTO--(BUSINESS WIRE)--June 1, 2020--

*- ATB-346 demonstrates superiority to placebo in reducing osteoarthritis pain -*

*- ATB-346 is more potent than expected; lowest effective dose still to be established -*

*- Antibe plans pivotal Phase 2/3 adaptive registration trial -*

Antibe Therapeutics Inc. (TSXV: ATE, OTCQB: ATBPF) is pleased to announce that its lead drug, ATB-346, met the primary endpoint in the Phase 2B dose-ranging, efficacy study. Both the 250 mg and 200 mg doses of ATB-346 demonstrated superiority to placebo in reducing osteoarthritis (“OA”) pain with a high level of statistical significance. The 150 mg dose of ATB-346, although not powered for statistical significance, demonstrated more potency than expected and the lowest effective dose is still to be established. The drug was safe and well tolerated during this study. The Company is planning a pivotal Phase 2/3 randomized, controlled trial with an adaptive design that will define the lower end of the dose-response curve.

“We are pleased that our drug provided excellent pain relief to the patients in the study,” remarked Dan Legault, Antibe’s CEO. “The success of this study is a worthy complement to the GI safety results already in hand. With the extensive learning that these Phase 2 studies have provided, we have a clear path forward including an opportunity to lower the dose further. Through an adaptive registration trial we can maintain our clinical and commercial timelines, and focus on large market partnering.”

A total of 385 patients with osteoarthritis (OA) of the knee were randomized to either placebo or ATB-346 administered once daily: 250 mg, 200 mg or 150 mg. The primary endpoint in the study was the change from baseline in the WOMAC pain subscale score as measured at the end of the 14-day treatment period. The 250 mg and 200 mg doses were powered for statistical significance and the 150 mg dose was powered to only observe an efficacy response.

ATB-346 demonstrated superiority to placebo at doses of 250 mg (p-value of 0.01) and 200 mg (p-value of 0.007). Similar efficacy was observed between these doses, suggesting that the upper range of the dose-response curve has been reached. The 150 mg dose demonstrated a robust efficacy response and had it been equivalently powered to the other treatment arms, the Company believes it would have achieved statistical significance. As such, the lower portion of the dose-response curve remains to be established.

In addition, both the 250 mg and 200 mg doses of ATB-346 demonstrated a highly statistically significant reduction in the WOMAC stiffness subscale score (p-value < 0.001 for both doses) and both doses were superior to placebo in the WOMAC difficulty performing daily activities (DPDA) subscale score (p-value of 0.004 and 0.001, respectively). While not statistically powered, the 150 mg dose of ATB-346 nonetheless demonstrated a statistically significant improvement in stiffness compared to placebo (p-value of 0.03) and displayed an efficacy response in DPDA.

Adverse events typically associated with NSAID use, such as dyspepsia, acid reflux and dizziness, were comparable across placebo and all three treatment arms of ATB-346. There were very few serious adverse events or events leading to withdrawal of treatment. Only 1 out of 318 patients administered ATB-346 had clinically significant, temporary liver transaminase elevations (LTEs) during the 14-day treatment period. At the post-treatment assessment (day 24), patients in the 250 mg, 200 mg and 150 mg treatment arms had clinically significant, temporary LTE incidences of 12.1%, 8.0% and 8.2%, respectively. It is standard for pain trials to allow the use of other medications, commonly acetaminophen. Acetaminophen use, especially in the post-treatment assessment period, pre-existing liver conditions and concomitant statin use were associated with a majority of the LTE incidents. Accounting for these factors yields clinically significant, temporary LTE incidence rates of 4.5%, 3.2% and 3.3%, respectively, suggesting a liver safety profile for ATB-346 comparable to commonly prescribed NSAIDs and well below that observed with acetaminophen (39% clinically significant LTE incidence rate; National Institutes of Health).

Joe Stauffer, Antibe's Chief Medical Officer, commented, "I joined Antibe to help set a new standard of safety and effectiveness in the treatment of pain and inflammation. The results of this study, in conjunction with the profound GI safety results already demonstrated, indicate that we are on track to this new standard in patient care. The LTEs will need to be considered moving forward, but are manageable from a clinical perspective. Given the robust upper portion of the dose-response curve, we anticipate lower doses will be effective and further optimize the safety profile of ATB-346."

To establish the lowest effective dose of ATB-346, the Company is planning a pivotal Phase 2/3 randomized, controlled trial with an adaptive design. Antibe anticipates that this efficacy trial will compare multiple doses of ATB-346 to placebo in OA patients over a 12-week period. It is the Company's intention to submit this study to the U.S. FDA as a formal registration trial.

The clinical study was conducted by Veristat, LLC in 39 clinical sites across Canada. David Vaughan, Antibe's Chief Development Officer, commented, "We would like to express our gratitude to the Veristat team and the clinicians across the country for their commitment and contribution to this well-run and successful clinical trial."

## **About ATB-346**

ATB-346 is a hydrogen sulfide-releasing derivative of naproxen. Nonsteroidal anti-inflammatory drugs (“NSAIDs”) are the most commonly used therapy for osteoarthritis, but their use is associated with a high incidence of gastrointestinal ulceration and bleeding. NSAIDs are also widely used in conditions such as rheumatoid arthritis, ankylosing spondylitis, gout, and general pain reduction, with a similarly high rate of gastrointestinal ulceration and bleeding. It is well-accepted that patients with these conditions would benefit greatly from an effective, non-addictive, GI-sparing anti-inflammatory/analgesic agent such as ATB-346.

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## Antibe Therapeutics Provides Corporate Update

TORONTO--(BUSINESS WIRE)--August 4, 2020--Antibe Therapeutics Inc.:

*- Phase II secondary data confirmed remarkable potency of ATB-346 -*

*- 3rd party commercial studies project peak annual sales of \$5.3 billion across seven key countries -*

*- Large market partnering efforts to accelerate in parallel with Phase III program -*

*- Non-opioid painkiller advancing towards the clinic; pipeline expansion initiatives underway*

To our shareholders,

As we transition into a Phase III company, we want to take the opportunity to highlight recent progress and to outline our strategy as we pursue monetization of our promising drug candidates and hydrogen sulfide platform.

### RECENT DEVELOPMENTS

#### *Analysis of Phase II Dose-Ranging, Efficacy Data Now Complete*

Having completed the analysis of primary and secondary data from ATB-346's recent placebo-controlled efficacy trial, we can confidently report strong results across all key measures.

The WOMAC pain scores constituting the study's primary endpoint showed 44% improvement from baseline at day 14 for the 200 and 250 mg once-daily doses, and 39% for the 150 mg once-daily dose. NSAIDs typically reach their maximum effectiveness after 6-8 weeks of administration and remain at that level while treatment continues. ATB-346 produced significant decreases in pain within 2 weeks of treatment. All three doses of ATB-346 reflect well in light of results from a recent peer-reviewed meta-analysis of historical NSAID osteoarthritis pain trials from Harvard researchers<sup>1</sup>. (For further information, please see our website and updated Corporate Presentation).

Beyond the impressive pain relief, ATB-346 also delivered significant improvements in the two secondary endpoints that address therapeutic benefit for patients: the WOMAC scores for *stiffness* and for *difficulty in performing daily activities*. These results are important, 'real-world' measures for patients with osteoarthritis ("OA") and provide additional support for the drug's best-in-class positioning.

Supplementing the WOMAC results are the secondary data of cyclo-oxygenase (“COX”) enzyme inhibition. NSAIDs reduce pain and inflammation by inhibiting the activity of COX enzymes. ATB-346 exhibited profound inhibition of COX (all doses yielding >90% inhibition) with a very high degree of statistical significance, and with negligible difference observed across the three doses. This is exceptionally strong data that is consistent with self-assessment of pain by the patients.

Adverse events across the three doses of ATB-346 were similar to placebo, with very few serious adverse events or events leading to withdrawal of treatment. Adjudicating for patient-specific factors reflected a liver safety profile for ATB-346 that was comparable to commonly prescribed NSAIDs, and substantially improved over that of acetaminophen.

Trial participants treated with ATB-346 experienced neither an increase nor decrease in blood pressure in contrast with other NSAIDs, which often increase blood pressure. Blood pressure increases are viewed by medical practitioners globally as being an important proxy for the cardiovascular risk of NSAIDs. The absence of an increase in blood pressure has been a consistent finding in all of ATB-346’s clinical trials to-date and suggests a favourable cardiovascular safety profile for the drug.

### ***Human Proof-of-Concept Now Firmly Established for ATB-346***

The strong Phase II efficacy results from this trial are a worthy complement to Antibe’s Phase II gastrointestinal (“GI”) safety trial, published last year in the *British Journal of Pharmacology*<sup>2</sup>. That study demonstrated unequivocal GI safety superiority of ATB-346 over naproxen, one of the most prescribed NSAIDs in the US. This combined evidence for GI safety and efficacy firmly validates ATB-346 as a potential best-in-class therapy, indicating that we are on the verge of solving one of the most pervasive medical problems of our time, namely the ulcers and bleeding caused by NSAIDs.

### ***Third Party Commercial Studies Validate Blockbuster Potential of ATB-346***

In addition to completing strong GI safety and efficacy studies over the past two years, we have conducted an extensive series of market and commercial studies in key pharmaceutical markets — a total of four studies were completed, framing an impressive commercial opportunity for ATB-346 and preparing us well for late-stage partner engagement and monetization.

This effort began with a thorough health economics study led by US-based Avalon Health, quantifying the major economic impact to society arising from the damage caused by today’s NSAIDs. A subsequent commercial positioning study executed by an ex-Amgen strategy consulting team validated ATB-346’s target product profile and best-in-class positioning.

The results of these two initial studies served as the foundation for two comprehensive commercial studies for the large markets (namely, the US, the five largest European countries, and Japan), led by Shift Health and LEK, two well-respected strategy consultancies. These studies involved extensive primary and secondary research, including 62 interviews with country-specific clinicians, payors and pharmacy benefit managers – whose preferences and policies together determine the adoption of new drugs. This was followed by an in-depth survey of 80 clinicians, including primary care physicians, rheumatologists and orthopedic surgeons that prescribe NSAIDs on a daily basis. Finally, the studies developed detailed revenue models, utilizing the uptake and pricing information obtained from the research and interview phases of the project.

For the OA market alone, Antibe's initial focus, peak annual sales of \$5.3 billion are projected for ATB-346 in these seven countries, and cumulative revenues in excess of \$28 billion by the early 2030s. These projections conservatively assume peak adoption of 21% and only represent 65% of the global market. Pricing and reimbursement, which drive a drug's adoption and ability to gain market share, were favourable, with limited system resistance and few reimbursement hurdles expected. The forecasts assumed a price of US\$6 per day in the US, in line with today's branded prescription NSAIDs, with corresponding pricing in the other markets. The revenue projections combined with a high anticipated gross margin imply an impressive net present value of ATB-346, which is how potential partners determine a drug's expected value. (For further information, please see our website and updated Corporate Presentation).

## **STRATEGY AND NEXT STEPS**

With human proof-of-concept development and key commercial studies complete, we now have a clear line-of-sight to the significant revenue and margin potential of ATB-346. Our strategic objective is now to monetize this asset through partnering activity, while at the same time expeditiously moving forward with Phase III development. This parallel strategy is important, as partnering outreach and execution is an extensive, involved process, and the continued advancement of the drug's development program is expected to increase market value and negotiating leverage.

### ***Executive Team Evolving to Support Late Stage Development and Partnering***

We continue to deepen the capabilities of our senior team, including the recent hiring of Dr. Rami Batal to guide our commercial strategy, and Dr. Joseph Stauffer as the Company's Chief Medical Officer. Dr. Stauffer's experience as an FDA reviewer, along with more than fifteen years of guiding regulatory strategy for other pain therapeutics, has already been invaluable as we pursue our regulatory, development and commercial strategies in the US and other markets. We are also hiring a US-based senior business development officer to execute the large market partnering, who will be armed with fully validated human proof-of concept data and a robust package of third-party commercial assessments.

Strategic out-licensing and monetization discussions are underway and have benefited from the strength of the recent efficacy data, while partnering discussions in the major markets are expected to accelerate following specific regulatory engagement with both the Food and Drug Administration (“FDA”) in the US and the European Medicines Agency (“EMA”) in Europe. We are encouraged by the preliminary feedback and hope to report on the progress on this front over the coming months.

### ***Phase III Preparation and Regulatory Strategy Well Underway***

With the successful conclusion of ATB-346’s Phase II studies and acceleration of partnering activities, preparation for Phase III trials is well underway. The Phase III program will replicate the Phase IIB GI safety and dose-ranging, efficacy studies with larger sample sizes and longer treatment durations. The first registration trial of the Phase III program will use a multi-arm design to establish the lowest effective dose and is anticipated to begin next spring, with the follow-on trials starting in a staggered fashion every several months thereafter. The strategy is global in nature, with the first trials focusing on the US and the last trial expected to address the unique regulatory requirements for Europe and the key Asian markets. The go-to-market indication will be OA, although we intend to rapidly expand this to encompass ankylosing spondylitis, rheumatoid arthritis and other chronic pain conditions. It is worth noting that successful completion of Phase III development would enable the Company to file a New Drug Application (“NDA”) with the FDA and other regulatory agencies for marketing approval. This approval would deliver the first truly novel NSAID in over 20 years, and a major breakthrough in the safe and non-addictive treatment of pain and inflammation.

As part of Phase III preparation, we completed our Pre-IND (“Investigational New Drug”) meeting for ATB-346 with members of the US FDA Division of Anesthesiology, Addiction Medicine, and Pain Medicine. Based on the valuable guidance received, we are moving expeditiously to complete and submit an IND application to the FDA for ATB-346. Prior to the start of the first Phase III trial, we anticipate an End-of-Phase II Meeting with the FDA and the equivalent meeting with the EMA, which will strengthen Antibe’s position with potential large market partners.

We are pleased to have recently received approval for ATB-346’s International Nonproprietary Name: otenaproxesul. (The non-proprietary name is equivalent to, for example, the “ibuprofen” of *Advil*®). We will be using otenaproxesul going forward, and our Corporate Presentation and website have been amended as such. In addition, we have now engaged a healthcare branding agency to help us select a proprietary (brand) name (the equivalent to “Advil®”).

### ***ATB-352 Advancing Towards Clinical Development Next Year***

Expanding beyond our lead drug, we have commenced IND-enabling preclinical studies for our second pipeline drug, ATB-352. This drug is being developed as a GI-safe and non-addictive alternative to opioids for the treatment of post-surgical pain, a US\$11 billion market<sup>3</sup>. Many physicians find themselves in a quandary regarding opioids, which have been the drug-of-choice for post-surgical pain. The natural alternative would be the stronger NSAIDs, already shown to equal the pain relief of opioids in such settings. However, such NSAIDs are also the most harmful to the digestive tract. ATB-352, a hydrogen sulfide-releasing version of ketoprofen (a particularly strong NSAID), is being developed as a solution to this longstanding problem. In animal experiments, ATB-352 has delivered greater pain effectiveness than ketoprofen yet demonstrated robust GI safety. We anticipate that preclinical studies of ATB-352 will conclude in calendar Q3 2021, following which we will seek regulatory approval to initiate human trials. We plan to pursue a Fast Track designation with the FDA to expedite the development and regulatory approval process.

Our third pipeline drug, ATB-340, a hydrogen-sulfide releasing version of low-dose aspirin, has been shown to cause negligible GI damage in preclinical studies. Low-dose aspirin is generally regarded as a wonder drug for cardiovascular and cancer protection for people over 50, but its prevalence of GI-damage precludes its broad prescription by clinicians. We are presently evaluating the clinical development strategy for ATB-340 and anticipate commencing IND-enabling preclinical studies in calendar 2021.

### ***Pipeline Expansion Initiatives Launched***

The strength of the recent clinical data has also encouraged us to commit to unlocking additional value from our hydrogen sulfide platform. To this end, Antibe recently signed a contract with a leading academic institution in the US known for the quality of its hydrogen sulfide science. The objective of this mandate is to identify promising new hydrogen sulfide-releasing compounds for the treatment of chronic pain, acute pain and other indications, including inflammatory bowel disease. Antibe will retain ownership rights to any new intellectual property arising from this work.

In addition, we are exploring collaborations for additional indications for otenaproxesul, including familial adenomatous polyposis (FAP), a pre-cancerous and often-fatal orphan disease.



## *Capital Markets Strategy Taking Institutional Focus*

The success of otenaproxesul over the past few years has increased our valuation and de-risked our story considerably – this could not have been done without the long-term support of our existing shareholders. The last several months culminated in significant achievements, including a \$29 million bought deal financing, that position us well to crystalize the value of our efforts. While we believe the issue price did not reflect the opportunities before us, the financing was essential for executing our plans in the coming 15 months at full speed with a fully funded balance sheet. We will now be pursuing a capital markets strategy to support our next stage of growth, while enabling our share price to reach an inherent value that is more comparable to our Phase III peers.

The completion of human proof-of-concept development for otenaproxesul with such strong results has put us on the radar screens of institutional investors that will be instrumental in supporting this growth. Preparations are largely complete to list on a senior exchange at the optimal time, such as NASDAQ. In addition, we will shortly engage a premier life science-focused investor relations firm in the US to implement and lead a strategic outreach program towards institutional investors, sell-side analysts and bankers.

We are in the process of evaluating a potential sale of Citagenix, our commercial asset that is no longer a strategic fit. This will simplify our story into a “pure play” late-stage biotech company with a clear focus and growth trajectory. And as we attract more institutions and mature as an organization, we will correspondingly require more active and deepened governance to guide our decision-making. We have retained a specialized recruitment firm to help us find a new, US-based Board member, whom we expect to have in place by year end.

We are excited by the opportunities ahead, as we strive to unlock shareholder value and execute our strategy over the course of the coming year.

Sincerely,

Dan Legault

*Chief Executive Officer*

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<sup>1</sup> *Comparative Pain Reduction of Oral Non-steroidal Anti-inflammatory Drugs and Opioids for Knee Osteoarthritis: Systematic Analytic Review.* Osteoarthritis and Cartilage. S.R. Smith et al., 2016.

<sup>2</sup> *A proof-of-concept, Phase 2 clinical trial of the gastrointestinal safety of a hydrogen sulfide-releasing anti-inflammatory drug.* British Journal of Pharmacology. Wallace et al., 2019.

<sup>3</sup> Transparency Market Research, 2018.

## **About Antibe Therapeutics Inc.**

Antibe develops safer, non-addictive medicines for pain and inflammation. Antibe's technology involves the linking of a hydrogen sulfide-releasing molecule to an existing drug to produce an improved medicine. Antibe's lead drug, ATB-346, targets the global need for a safer, non-addictive drug for chronic pain and inflammation. ATB-352, the second drug in Antibe's pipeline, targets the urgent global need for a non-addictive analgesic for treating post-surgical pain, while ATB-340 is a GI-safe derivative of aspirin. Citagenix Inc., an Antibe subsidiary, is a market leader and worldwide distributor of regenerative medicine products for the dental marketplace. [www.antibetherera.com](http://www.antibetherera.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the proposed licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

***Neither TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.***

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## **Antibe Therapeutics to Present at the Oppenheimer Fall Healthcare Life Sciences & MedTech Summit**

TORONTO--(BUSINESS WIRE)--September 15, 2020--Antibe Therapeutics Inc. (TSXV: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today announced that Dan Legault, Antibe's Chief Executive Officer, will present a corporate overview at the upcoming virtual Oppenheimer Fall Healthcare Life Sciences & MedTech Summit on Wednesday, September 22, 2020 at 9:10 am (Eastern Time).

A live webcast of the presentation will be available on the Company's website at [www.antibethera.com/events](http://www.antibethera.com/events). Following the presentation, a replay of the webcast will be available on the website for 90 days.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation, safer nonsteroidal anti-inflammatory drugs ("NSAIDs") for pain and inflammation arising from a wide range of medical conditions. Antibe is developing three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with NSAIDs. Antibe's lead drug, otenaproxesul (ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. Learn more at [antibethera.com](http://antibethera.com).

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## **Antibe Therapeutics Receives Conditional Approval to Graduate to the Toronto Stock Exchange**

TORONTO--(BUSINESS WIRE)--October 30, 2020--Antibe Therapeutics Inc. (TSXV: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, is pleased to announce that it has received conditional approval from the Toronto Stock Exchange (“TSX”) to graduate from the TSX Venture Exchange (“TSXV”) and list its common shares on the TSX.

“Graduating to the TSX is an important milestone for Antibe, reflecting both our progress and potential,” remarked Dan Legault, Antibe’s CEO. “With partnering activities expanding and preparations for our first Phase III study fully underway, this is the right time to broaden our investor base and raise the Company’s profile in the investment community. We appreciate the support of our shareholders and the efforts of the TSXV and TSX as we implement the next phase of our corporate strategy.”

Final approval of the listing is subject to the Company meeting certain standard and customary conditions required by the TSX. Once these conditions are satisfied, Antibe’s shares will begin trading on the TSX under its existing ticker symbol “ATE” and will be delisted from the TSXV. Shareholders will not be required to take any action in connection with the graduation. The Company will make a further announcement once the TSX confirms the date on which its shares will commence trading.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation, safer nonsteroidal anti-inflammatory drugs (“NSAIDs”) for pain and inflammation arising from a wide range of medical conditions. Antibe is developing three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with NSAIDs. Antibe’s lead drug, otenaproxesul (ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

### **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, statements about the proposed graduation to TSX, the broadening of Antibe’s investor audience and raising of the Company’s profile in the investment community. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company’s inability to satisfy the standard TSX listing conditions or to broaden its investor audience and increase its profile, inability to secure

additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Receives Final Approval to Graduate to the Toronto Stock Exchange**

TORONTO--(BUSINESS WIRE)--November 10, 2020--Antibe Therapeutics Inc. (TSXV: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today announced that it has received final approval from the Toronto Stock Exchange (“TSX”) to list its common shares on the TSX.

“We are excited to graduate to the TSX, as it represents a further step in reaching the broader investment community while increasing liquidity for our shareholders,” remarked Dan Legault, Antibe’s CEO. “We look forward to continued progress as we advance our partnering discussions and prepare for Phase III trials of otenaproxesul, our lead drug.”

Antibe’s shares will commence trading on the TSX under its existing ticker symbol “ATE” at the market open on Thursday, November 12, 2020. Shareholders will not be required to take any action in connection with the graduation and listing on the TSX.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation, safer nonsteroidal anti-inflammatory drugs (“NSAIDs”) for pain and inflammation arising from a wide range of medical conditions. Antibe is developing three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with NSAIDs. Antibe’s lead drug, otenaproxesul (ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. Learn more at [antibethera.com](http://antibethera.com).

### **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, statements about the graduation to the TSX, reaching the broader investment community and increasing liquidity for shareholders. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose", “look forward” and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company’s inability to satisfy the standard TSX listing conditions or to broaden its investor audience and increase its profile, inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Reports Q2 2021 Interim Financial and Operating Results**

TORONTO--(BUSINESS WIRE)--November 13, 2020--Antibe Therapeutics Inc. (TSX: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today announced the filing of its financial and operating results for the fiscal quarter ended September 30, 2020. The Company's unaudited fiscal Q2 2021 condensed interim consolidated financial statements and MD&A are available on SEDAR.

“We’ve made tremendous progress this quarter in preparing our lead drug for Phase III trials and partnering,” commented Dan Legault, Antibe’s CEO. “We are getting closer to the start of our Phase III program, with a total of eight Phase III-enabling studies now running in parallel. Additionally, the recent commercial data strengthens our position as we engage partners for the large markets. Finally, we are executing our capital markets strategy to increase institutional awareness and liquidity, highlighted by the recent graduation to the TSX. We look forward to providing a comprehensive corporate update in the coming weeks.”

### **Q2 2021 Highlights**

- Announced robust secondary data from otenaproxesul’s Phase IIB dose-ranging, efficacy study, confirming the drug’s remarkable potency shown in earlier top-line results;
- Completed third party studies for the seven largest markets, framing an impressive commercial opportunity for otenaproxesul;
- Initiated two animal toxicology studies required for all companies by the US Food and Drug Administration to begin Phase III trials (six additional such studies have commenced in the current quarter);
- Launched pipeline expansion initiatives aimed at developing new intellectual property based on the Company’s hydrogen sulfide platform;
- Commenced a proprietary naming initiative for otenaproxesul with a leading global branding agency to determine the commercial brand/trademark;
- Engaged Stern IR, a premier investor relations agency for healthcare and biotechnology companies worldwide, to support Antibe’s institutional outreach in the US; and
- Completed the quarter with a cash balance of \$22.5 million.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation, safer nonsteroidal anti-inflammatory drugs (“NSAIDs”) for pain and inflammation arising from a wide range of medical conditions. Antibe is developing three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with NSAIDs. Antibe’s lead drug, otenaproxesul (ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).



## **Forward Looking Information**

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## **Antibe Therapeutics to Complete Share Consolidation in Preparation for Potential NASDAQ Listing**

TORONTO--(BUSINESS WIRE)--November 17, 2020--Antibe Therapeutics Inc (TSX: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today announced that it intends to complete a consolidation of its issued and outstanding common shares (“Common Shares”) on the basis of one (1) new Common Share for every ten (10) Common Shares presently issued and outstanding (“Consolidation”). Completion of the Consolidation remains subject to the approval of the Toronto Stock Exchange (“TSX”) and is expected take effect on or about December 1, 2020.

At the Annual and Special Meeting of Shareholders held on August 20, 2020, Antibe’s shareholders re-approved a special resolution authorizing the Board of Directors of the Company to effect the Consolidation to better prepare it for a possible future listing on the NASDAQ or other senior US stock exchange. The Company believes the Consolidation and such a listing would enable Antibe to further broaden its investor base and increase liquidity.

Upon receipt of TSX approval of the Consolidation, Antibe will provide additional details regarding a new CUSIP number for its Common Shares to distinguish between the pre- and post-consolidated Common Shares. The Company’s name and trading symbol will remain unchanged. If, as a result of the Consolidation, a shareholder becomes entitled to a fractional share, each fractional Common Share that is at least 0.5 of a Common Share will be rounded up to the nearest whole Common Share and each fractional Common Share that is less than 0.5 of a Common Share will be rounded down to the nearest whole Common Share, provided that each shareholder shall receive at least one (1) Common Share post Consolidation. Following the completion of the Consolidation, the Company will have approximately 38,678,280 Common Shares issued and outstanding.

Warrants issued by Antibe will also be adjusted proportionately in response to the Consolidation. On the effective date of the Consolidation, the exercise of ten (10) Warrants will be required to purchase one (1) post-Consolidation Common Share. The exercise price of the Warrants will be adjusted as of the effective date of the Consolidation as set out in the warrant indentures governing the terms of the Warrants.

Antibe’s transfer agent, Computershare Investor Services (“Computershare”), will act as the exchange agent for the Consolidation. On the effective date of the Consolidation, Computershare will send instructions (i.e. a Letter of Transmittal) to shareholders who hold the Company’s stock certificates regarding the exchange of old certificates for new certificates, should they wish to do so. Until surrendered, each stock certificate representing pre-Consolidation Common Shares will be deemed for all purposes to represent the number of whole post-Consolidation Common Shares to which the shareholder is entitled as a result of the Consolidation.

Shareholders who hold their Common Shares in brokerage accounts or “street name” are not required to take any action to effect the exchange of their Common Shares.

## **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation, safer nonsteroidal anti-inflammatory drugs (“NSAIDs”) for pain and inflammation arising from a wide range of medical conditions. Antibe is developing three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with NSAIDs. Antibe’s lead drug, otenaproxesul (ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. Learn more at [antibethera.com](http://antibethera.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements under applicable securities laws, which include, but are not limited to, statements about the potential for the US listing, the consolidation of the Company’s shares, and the potential to further broaden the Company’s investor base and gain increased liquidity with respect to the Common Shares with a US listing. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose", “look forward” and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company’s ability to meet all of the quantitative and qualitative listing criteria to list the Common Shares on a US securities exchange; the Company’s ability to satisfy the conditions for a share consolidation; the Company’s ability to broaden its investor base and increase the liquidity of the Common Shares with the US listing; the Company’s ability to execute its business strategy and successfully compete in the market, and the other risks identified in the Company’s public filings made in Canada. The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Announces Intent to Unify Intellectual Property Ownership**

***- Supports U.S. capital markets strategy, large market partnering and pipeline expansion initiatives -***

TORONTO--(BUSINESS WIRE)--December 18, 2020--Antibe Therapeutics Inc. (TSX: ATE, OTCQB: ATBPF) (the “Company”), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today announced that it has commenced preliminary discussions to amalgamate Antibe Holdings Inc. (“Holdings”) with the Company in order to unify the intellectual property (“IP”) ownership of the Company’s drugs and platform. The Company believes that such an initiative would unlock value for potential partners and investors while simplifying IP protection for pipeline expansion efforts now underway.

“As described in our ongoing disclosures, the Company was founded with an exclusive license from Holdings,” commented Dan Legault, Antibe’s CEO. “Based on this IP, we have achieved human proof-of-concept for otenaproxesul and developed compelling preclinical data for our other pipeline drugs. As we map out strategic initiatives with prospective partners and healthcare-specialized investors, we expect full ownership of the underlying IP to strengthen our corporate position. It also represents another step in our growth strategy, complementing our recent graduation to the TSX, share consolidation and the appointment of U.S.-based directors.”

The Company will update the market upon further material developments as they are achieved.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation, safer nonsteroidal anti-inflammatory drugs (“NSAIDs”) for pain and inflammation arising from a wide range of medical conditions. Antibe is developing three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with NSAIDs. Antibe’s lead drug, otenaproxesul (ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the proposed licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions “will”, “anticipate”, “believe”, “plan”, “estimate”, “expect”, “intend”, “propose” and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company’s inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Strengthens Governance and U.S. Capital Markets Expertise With Appointment of Two Independent Directors**

TORONTO--(BUSINESS WIRE)--November 24, 2020--Antibe Therapeutics Inc (TSX: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today announced the appointment of Robert E. Hoffman and Jennifer McNealey to its Board of Directors.

“We are delighted to welcome Jennifer and Robert to our team,” said Walt Macnee, Chair of Antibe’s Board of Directors. “Both are highly accomplished biotechnology executives, with significant experience in U.S. capital markets, public company governance and financial operations – all of which will be invaluable to Antibe as we move toward a potential listing on a senior U.S. exchange in parallel with large market partnering efforts.”

Until his retirement last month, Mr. Hoffman was Chief Financial Officer of San Diego-based Heron Pharmaceuticals, a NASDAQ-listed commercial stage drug developer with a pipeline of acute pain therapeutics. During his tenure at Heron, the company raised more than \$650 million and launched its second commercial drug product. His career in the sector began in 1997 at Arena Pharmaceuticals, where he rose to become CFO, holding that position for ten years. While at Arena, he was involved with its IPO and financings raising more than \$1.5 billion. Mr. Hoffman is currently a member of the boards of three NASDAQ-listed pharmaceutical companies: Kura Oncology, Kintara Therapeutics (as Chairman) and ASLAN Pharmaceuticals; he previously served as a board member for three other publicly listed biotechnology companies. Trained as a Certified Public Accountant, he is a longstanding member of the Small Business Advisory Committee of the Financial Accounting Standards Board (FASB). Mr. Hoffman is also a founding board member of Day for Change, which has funded charities serving underprivileged and abused children in the San Diego area for 20 years.

Mr. Hoffman commented, “I’m excited to join Antibe’s board. The market opportunity for safer, non-opioid pain therapeutics has never been greater. And with otenaproxesul moving into its Phase III program, the company’s strategic opportunities are also expanding. It’s a great time to work with Antibe’s impressive team to capture the full potential of a uniquely promising drug pipeline and platform.”

Ms. McNealey is a senior financial and strategy executive with a considerable breadth of experience in the biotechnology sector, as an analyst, portfolio manager, information provider and expert in corporate communications and investor relations. She is currently Vice President, Investor Relations and Strategy for South San Francisco-based Calithera Biosciences, a clinical stage developer of small molecule oral therapies targeting a range of cancers and other life-threatening diseases. Ms. McNealey began her career as a healthcare equity analyst, transitioning to management of biopharmaceutical-focused investment funds for Morgan Stanley Dean Witter Advisors, Amerindo Investment Advisors and latterly at Franklin Templeton, where she co-managed the Franklin Biotechnology Discovery Fund. She subsequently founded Laurient LLC, an independent equity research and competitive intelligence platform analyzing publicly traded biopharmaceutical companies. Since 2013, Ms. McNealey has served on the board of Enzon Pharmaceuticals. She earned her B.A. and Master of Health Administration degrees from Cornell University.

Ms. McNealey remarked, “The severe shortcomings of today’s pain medications constitute one of the world’s most pressing medical needs. Patients deserve better. Antibe’s novel drug platform is a promising way forward – I am delighted to be a part of it.”

#### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation, safer nonsteroidal anti-inflammatory drugs (“NSAIDs”) for pain and inflammation arising from a wide range of medical conditions. Antibe is developing three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with NSAIDs. Antibe’s lead drug, otenaproxesul (ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. Learn more at [antibethera.com](http://antibethera.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements under applicable securities laws, which include, but are not limited to, statements about listing on a senior U.S. exchange, large market partnering and the expansion of strategic opportunities. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose", "promises", "move toward", "look forward" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's ability to meet all of the quantitative and qualitative listing criteria to list on a US securities exchange; the Company's ability to successfully arrange large market partnerships; the Company's ability to capitalize on strategic opportunities; the Company's ability to capture the full potential of its drug pipeline and platform, and the other risks identified in the Company's public filings made in Canada. The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Announces TSX Approval and Effective Date of Share Consolidation**

TORONTO--(BUSINESS WIRE)--November 30, 2020--Antibe Therapeutics Inc. (TSX: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today announced that, further to a press release issued on November 17, 2020, the consolidation (“Consolidation”) of the Company’s issued and outstanding common shares (“Common Shares”) on the basis of ten (10) pre-consolidation Common Shares for one (1) post-Consolidation Common Share has been approved by the Toronto Stock Exchange (“TSX”). The Consolidation will be effective as of market open tomorrow, December 1, 2020.

Following the Consolidation, approximately 38,754,063 Common Shares will be issued and outstanding. As a result of the Consolidation, the Company’s outstanding warrants will be proportionately adjusted such that ten (10) warrants are now exercisable for one (1) post-Consolidation Common Share. The Company’s outstanding restricted share units and options will also be adjusted accordingly. The Company’s name and trading symbol will remain unchanged. The CUSIP number for the post-Consolidation Common Shares is 037025509.

### **About Antibe Therapeutics Inc.**

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## **Antibe Therapeutics Strengthens Partnering Advisory Team With Appointment of Don Haut**

***- Dr. Haut spearheaded AskBio's recent \$4 billion acquisition by Bayer AG -***

TORONTO--(BUSINESS WIRE)--January 7, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today announced the appointment of Dr. Don Haut to its Partnering Advisory Team.

“I am delighted to welcome another superstar to our Partnering Advisory Team,” remarked Dan Legault, Antibe’s CEO. “Don’s broad background and tremendous recent success will add new depth to our business development capability as our partnering activities accelerate in 2021.”

Most recently, Dr. Haut was Chief Business Officer of AskBio, a leading clinical stage developer of gene therapies and technologies. He led the firm’s business development activities, completing four transactions in 2020 before taking a leading role in AskBio’s \$4 billion acquisition by Bayer AG. In a career spanning academic science, consulting, sales management, and business development, he has completed transactions exceeding \$8 billion and been instrumental in multiple product launches. He has also served on the boards of several healthcare companies, including firms involved in joint replacement and repair.

Originally trained as a molecular biologist before joining McKinsey, Dr. Haut has since held senior business roles at 3M Company, Smith & Nephew, and The Medicines Company. More recently, he was Chief Business Officer of Histogenics and Sherlock Biosciences. He earned his PhD in Molecular Biology from the Medical School at the University of Missouri-Columbia and an MBA from Washington University’s Olin School of Business.

Dr. Haut commented, “Antibe’s platform promises a major advance in the treatment of pain and inflammation-based disease. This area is overdue for disruption and represents a massive commercial opportunity. I’m excited to put my shoulder to the wheel to help Antibe fully capture the value of its pipeline as it enters late-stage development.”

### **About Antibe Therapeutics Inc.**

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## **Antibe Therapeutics Provides 2021 Corporate Update**

*- Large market partnering program now underway -*

*- Limited COVID-19 impact: Phase III program slated to start in second half of 2021 -*

*- U.S. institutional outreach expanding -*

TORONTO--(BUSINESS WIRE)--January 11, 2021--Antibe Therapeutics Inc.:

To our shareholders,

As we build on last year's significant clinical and capital markets achievements and enter the homestretch in the strategic monetization of otenaproxesul, we want to update you on our progress and plans. We are particularly gratified by the recent uptick in interest by both global and regional potential partners, supporting otenaproxesul's compelling value proposition and revenue opportunity. We are also encouraged by the response to our U.S. institutional outreach, further validating our strategy for unlocking the value of our assets as we move toward a potential listing on a senior U.S. exchange.

### **Clinical and Scientific Programs Advance**

Otenaproxesul's Phase III preparations remain on schedule. With eight Phase III-enabling animal studies finished and a further two to complete, we have already discharged the bulk of registration trial preparations begun last summer. We also remain on track with CMC (chemistry, manufacturing and controls), an extensive set of activities crucial to late-stage clinical development and commercialization. Our manufacturing partner is in the final stages of tablet production.

As planned, we will be submitting otenaproxesul's IND ("Investigational New Drug") application to the U.S. FDA within weeks. In ordinary circumstances, we would then expect to proceed with the adaptive Phase III trial in the upcoming quarter. However, the ongoing rise in COVID-19 infections is increasingly compromising the ability of clinics and hospitals to accommodate large clinical trials, particularly in the U.S. where this trial must take place. With this situation expected to ease later in the year as vaccines take hold, guidance for trial initiation is being adjusted to the second half of 2021. In the interim, and supported by our strong balance sheet, we are taking the opportunity to perform an enhanced version of the previously planned absorption, metabolism and excretion ("AME") study which is set to begin in Canada this quarter. In addition to providing valuable information for potential partners, this 6-week study (which includes 2 weeks of follow-up monitoring) will further de-risk dose selection for our Phase III program, while also supplying pharmacokinetic data required for drug marketing approval.

Our pipeline's value and depth continue to grow. Last quarter, we commissioned a market opportunity assessment to guide the detailed development of our second drug, ATB-352, an opioid replacement aimed at the post-operative pain market. The study provided important input

for trial design and confirmed the large unmet medical need for a gastrointestinal-safe NSAID for acute pain, projecting peak year sales exceeding US\$800 million in the U.S. alone. While stronger nonsteroidal anti-inflammatory drugs (“NSAIDs”) have demonstrated analgesic efficacy comparable to opioids in many settings, they are correspondingly more damaging to the gastrointestinal tract, limiting their use and leaving physicians, payors and policymakers with few options as they address a resurgent opioid crisis.

Leveraging our hydrogen sulfide platform beyond its current focus on NSAIDs, our pipeline expansion initiatives are now generating promising new molecules and fresh intellectual property. Our first candidate for in vivo testing targets inflammatory bowel disease (“IBD”). More than three million U.S. adults suffer from this condition, long in need of safe and more effective first-line treatments. Previous work with hydrogen sulfide-releasing substances has shown encouraging results in animal models of IBD. The development of new molecules is an ongoing process and we hope to announce further progress in the coming months.

### **Corporate Developments to Drive Value for Partnering and Capital Markets**

As anticipated, the attainment of human proof-of-concept for otenaproxesul and promising third party commercial projections are driving new interest by potential partners. Correspondingly, we are intensifying our focus on increasing the value of our assets and improving negotiating leverage. Our efforts include this month’s launch of our large market partnering program, spearheaded by Dr. Rami Batal, our Chief Commercial Officer, and Ella Korets-Smith, our Head of Regional Business Development. As recently announced, we also strengthened our capabilities with the addition of Dr. Don Haut to our Partnering Advisory Team. His 20-year record of healthcare-related business development, including a leading role in AskBio’s recent \$4 billion acquisition by Bayer AG offers us rich insight into the dynamics and key players in today’s pharma partnering landscape.

To support our accelerating business development efforts, we have also retained a premier global life science transaction firm. Their first task was an in-depth partner targeting study, identifying and characterizing the most promising 70 global and regional pharma firms with an interest in pain and inflammation. The formal outreach process has commenced and we will report material developments as they occur.

Further supporting our partnering activities and in preparation for a potential listing on a senior U.S. exchange, Antibe recently initiated efforts to unify the intellectual property (“IP”) ownership of our drugs and platform. We believe that full control of the underlying IP would unlock value for potential partners and investors while simplifying IP protection for our pipeline expansion efforts. In addition, we will soon upgrade our current U.S. OTC listing to the “QX” level from its current “QB” designation. These initiatives complement our recent graduation to the TSX, share consolidation and the appointment of U.S.-based directors.

### **Board of Directors Recognizes Significant Progress with RSU Grants**

In view of the achievement of human proof-of-concept for otenaproxesul and commercial validation, the Board of Directors is awarding 2,092,000 restricted share units (“RSUs”) to

directors, officers, employees and consultants pursuant to Antibe's RSU plan. The vesting of 50% of the RSUs granted to key executives will be subject to specific performance goals that reflect the successful execution of Antibe's business plan, including our monetization strategy. All RSUs are subject to time-based vesting; one third (1/3) of the RSUs granted will vest on each of the first, second and third anniversaries of today's date. In addition, we have granted BND Projects Inc. 66,000 options for investor relations services. Each option has an exercise price of \$4.00, vests quarterly starting on the date of the grant, and will expire January 11, 2024.

We are excited to hit the ground running in 2021, as we embark on the next steps in developing and commercializing a new generation of anti-inflammatory drugs to meet the pressing needs of doctors and patients around the world.

Sincerely,

Dan Legault  
*Chief Executive Officer*

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation, safer nonsteroidal anti-inflammatory drugs ("NSAIDs") for pain and inflammation arising from a wide range of medical conditions. Antibe is developing three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with NSAIDs. Antibe's lead drug, otenaproxesul (ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

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## **Antibe Therapeutics Announces Strategic Licensing Deal in China With Nuance Pharma**

***- US\$100 million in milestone payments including US\$20 million upfront, as well as a double-digit royalty***

***- Nuance's business model, commercial acumen and collaborative approach considered an ideal fit for Antibe***

TORONTO--(BUSINESS WIRE)--February 9, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQB: ATBPF) today announced that it has licensed otenaproxesul to Nuance Pharma for commercialization in the Greater China region. Nuance is a biopharmaceutical company focused on licensing, developing and commercializing globally innovative therapies to address critical unmet medical needs in China and other Asia Pacific markets. Founded by Mark Lotter, who built the AstraZeneca commercial franchise in China, and led by executives with extensive multinational pharma experience, Nuance focuses on identifying and in-licensing therapies that have achieved best-in-class, human proof-of-concept status.

The license provides Nuance with exclusive rights to commercialize otenaproxesul in China, Hong Kong, Macau, and Taiwan, representing approximately 10% of the worldwide pharma market.<sup>1</sup> Under the terms of the agreement, Antibe is entitled to US\$100 million in milestone payments, including US\$20 million upfront and US\$80 million in development and sales milestones, in addition to a double-digit royalty on sales. Clinical development and regulatory costs for the region will be borne by Nuance. Antibe and Nuance have established a structure for collaborating on otenaproxesul's clinical development in the region, ensuring a fit with Antibe's global regulatory strategy.

"We are very impressed with Nuance's strategic grasp of the dynamics and opportunities in China's pharma marketplace," commented Dan Legault, Antibe's CEO. "Their globalized business practices and business model, combined with deep commercial, clinical and regulatory capabilities, make them an ideal partner to address this increasingly sophisticated market. Mark has built an exceptional team, providing us with confidence that Nuance can realize otenaproxesul's full potential."

China's extensive economic progress, combined with significant advances in drug regulation, intellectual property protection and health insurance coverage, has stimulated demand for leading-edge therapies. This trend has been particularly evident in pain management, a market that has doubled in the past five years, driven principally by demand for nonsteroidal anti-inflammatory drugs ("NSAIDs") like otenaproxesul.

"Our team is thrilled to partner with Antibe to commercialize otenaproxesul," commented Mark Lotter, CEO of Nuance. "This deal is a key part of our strategy to bring the next generation of best-in-class pain therapies to the region. As doctors and patients seek safer, non-addictive therapies for chronic pain, we see a great opportunity for otenaproxesul."

## **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. Antibe's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul (formerly ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

## **About Nuance Pharma**

Nuance is a Shanghai-based late clinical-stage biopharmaceutical company focused on licensing, developing and commercializing globally innovative therapies with the mission of addressing critical unmet medical needs in China and other emerging Asia Pacific markets. Its world-class clinical and regulatory teams, visionary approach to business development and integrated commercial platforms enable Nuance to continuously accelerate the access of innovative treatments to patients. Since its inception in 2014, Nuance has assembled a portfolio of promising clinical-stage drug candidates for respiratory, pain and iron deficiency anemia. The company has targeted these therapeutic areas based on the severity of the unmet medical needs, the size of the at-risk patient population, and the emergence of innovative products worldwide.

## **Forward Looking Information**

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<sup>1</sup> *IQVIA, The Global Use of Medicine in 2019 and Outlook to 2023.*

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## Antibe Therapeutics Reports Q3 2021 Interim Financial and Operating Results

TORONTO--(BUSINESS WIRE)--February 12, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQB: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today filed its financial and operating results for the fiscal quarter ended December 31, 2020.

“We had a busy quarter and made excellent progress on a number of fronts,” commented Dan Legault, Antibe’s CEO. “With our Phase III preparations on track, we intensified our focus on the strategic monetization of otenaproxesul, culminating in an exclusive license with Nuance Pharma in China earlier this week. We’ve also strengthened our capital markets positioning by graduating to the TSX, completing the consolidation of our shares, expanding our institutional outreach, and appointing two senior U.S. directors.”

### Business Highlights

*Otenaproxesul, lead product candidate entering Phase III trials for osteoarthritis pain*

- Initiated six Phase III-enabling animal toxicology studies
- Commissioned and completed an in-depth partner targeting study by recently retained global life science transaction firm
- Completed a strategic licensing deal with Nuance Pharma for the commercialization of otenaproxesul in the Greater China region, with milestone payments totaling US\$100 million and a double-digit royalty

*Broader pipeline including ATB-352 for peri-operative pain and ATB-340, a GI-safe alternative to aspirin*

- Completed third party market study of peri-operative pain drug opportunity, projecting a peak annual sales potential of US\$800 million
- Identified the first candidate drug molecule (targeting inflammatory bowel disease) originating from the Company’s pipeline expansion initiatives

*Corporate*

- Appointed Robert Hoffman and Jennifer McNealey to the Company’s Board of Directors
- Recruited Dr. Don Haut to the Company’s Partnering Advisory Team
- Graduated to the Toronto Stock Exchange and completed a share consolidation
- Initiated efforts to unify the intellectual property ownership of the Company’s drugs and platform

### Financial Results

**Cash Position:** As of December 31, 2020, the Company had an available cash balance totaling \$15.4 million, compared to \$6.2 million at March 31, 2020. Subsequent to the end of the quarter,

Antibe announced a license for otenaproxesul to Nuance Pharma that provides for a US\$20 million upfront payment.

**Revenue:** For the quarter ended December 31, 2020, revenue totaled \$2.8 million, compared to \$2.6 million for the same period in fiscal 2020. All revenue was due to the Company's subsidiary, Citagenix and the increase was driven by higher sales in the United States.

**Net Loss:** For the quarter ended December 31, 2020, net loss amounted to \$6.5 million (\$0.17 per share), compared to \$4.2 million (\$0.15 per share) for the same period in fiscal 2020.

**Research and Development Expenses:** Research and development expenses, net of research tax credits, amounted to \$3.4 million for the quarter ended December 31, 2020, compared to \$1.6 million for the same period in fiscal 2020. The increase was primarily due to higher development costs and professional and consulting fees for non-clinical development studies for otenaproxesul.

**General and Administrative Expenses:** General and administrative expenses amounted to \$2.0 million for the quarter ended December 31, 2020, compared to \$1.5 million for the same period in fiscal 2020. The increase was primarily due to higher salaries, professional and consulting fees and office costs partly offset by lower other costs.

**Sales and Marketing Expenses:** Sales and marketing expenses amounted to \$0.9 million for the quarter ended December 31, 2020, compared to \$1.0 million for the same period in fiscal 2020. The decrease consisted of lower salaries and commissions, travel and entertainment costs and advertising and promotions costs.

With the divestiture of a Citagenix subsidiary (BMT Medizintechnik GmbH) during the quarter, the above-stated financial results reflect continuing operations. The Company's unaudited fiscal Q3 2021 condensed interim consolidated financial statements and MD&A will be available shortly on SEDAR.

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## **Antibe Therapeutics Announces C\$35 Million Bought Deal Public Offering**

### ***NOT FOR DISTRIBUTION OR DISSEMINATION INTO THE UNITED STATES OR THROUGH U.S. NEWSWIRE SERVICES***

**TORONTO – (BUSINESS WIRE) – February 17, 2021** – Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSX:ATE) today announced that it has entered into an agreement with Canaccord Genuity Corp. on behalf of a syndicate of underwriters (together, the "Underwriters") and pursuant to which the Underwriters have agreed to purchase, on a bought deal basis, 5,850,000 units (the "Offered Securities") in the capital of the Company at a price of C\$6.00 per Offered Security (the "Offering Price") for aggregate gross proceeds to the Company of C\$35,100,000 (the "Offering").

Each Offered Security shall consist of one common share (a "Common Share") and one-half of one common share purchase warrant (each whole warrant, a "Warrant"). Each Warrant shall entitle the holder thereof to acquire one Common Share at an exercise price per Common Share of C\$7.50 for a period of 36 months from the closing of the Offering.

The Company intends to use the net proceeds of the Offering to fully fund the adaptive Phase III efficacy trial and remaining non-clinical studies for its lead drug, complete IND-enabling studies for its second and third pipeline drugs, advance new anti-inflammatory drug candidates and for working capital and general corporate purposes, all as more fully described in the prospectus.

The Offered Securities will be offered in the provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Ontario, pursuant to a prospectus supplement to be dated on or about February 19, 2021 to the Company's base shelf prospectus dated January 12, 2021 (the "Prospectus") and elsewhere in compliance with applicable securities laws.

The closing of the Offering is expected to occur on or about February 24, 2021 and is subject to the completion of formal documentation and receipt of all regulatory approvals, including the approval of the Toronto Stock Exchange.

In addition, the Company intends to grant the Underwriters a 30-day option to purchase up to an additional 15% of the Offered Securities pursuant to the proposed Offering on the same terms and conditions.

Copies of the Prospectus, following filing thereof, may be obtained on SEDAR at [www.sedar.com](http://www.sedar.com) and from Canaccord Genuity Corp., 161 Bay Street, Suite 3000, Toronto, ON M5J 2S1. The Prospectus contains important detailed information about the Company and the proposed Offering. Prospective investors should read the Prospectus and the other documents the Company has filed on SEDAR at [www.sedar.com](http://www.sedar.com) before making an investment decision.

The securities being offered have not been, nor will they be, registered under the United States Securities Act of 1933, as amended (the "U.S. Securities Act"), or applicable state securities laws, and may not be offered or sold in the United States or to, or for the account or benefit of, persons in the United States or "U.S. persons" (as such term is defined in Regulation S promulgated under the U.S. Securities Act) absent registration or an applicable exemption from the registration requirements. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

#### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. Antibe's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul (formerly ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibethera.com](http://antibethera.com).

**Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the possible exercise of the Over-Allotment Option, the proposed licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions “will”, “anticipate”, “believe”, “plan”, “estimate”, “expect”, “intend”, “propose” and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company’s inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

***Neither TSX nor its Regulation Services Provider (as that term is defined in the policies of the TSX) accepts responsibility for the adequacy or accuracy of this release.***

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## **Antibe Therapeutics Announces Closing of Bought Deal Public Offering**

### ***NOT FOR DISTRIBUTION OR DISSEMINATION INTO THE UNITED STATES OR THROUGH U.S. NEWSWIRE SERVICES***

TORONTO--(BUSINESS WIRE)--February 24, 2021--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSX:ATE) today announced that it has closed its previously announced bought deal public offering of 6,727,500 units (the "Offered Securities") in the capital of the Company at a price of C\$6.00 per Offered Security (the "Offering Price") for aggregate gross proceeds to the Company of C\$40,365,000 (the "Offering"), which includes the full exercise of the over-allotment option by the underwriters.

Each Offered Security consisted of one common share (a "Common Share") and one-half of one common share purchase warrant (each whole warrant, a "Warrant"). Each Warrant entitles the holder thereof to acquire one Common Share at an exercise price per Common Share of C\$7.50 for a period of 36 months from the closing of the Offering.

The Company intends to use the net proceeds of the Offering to fully fund the adaptive Phase III efficacy trial and remaining non-clinical studies for its lead drug, complete IND-enabling studies for its second and third pipeline drugs, advance new anti-inflammatory drug candidates and for working capital and general corporate purposes, all as more fully described in the prospectus. As of today's date, the Company's cash balance is C\$74 million, including the upfront payment received from Nuance Pharma and the net proceeds of the Offering.

Canaccord Genuity Corp. acted as sole bookrunner and co-lead underwriter with Bloom Burton Securities Inc., on behalf of a syndicate of underwriters including Echelon Wealth Partners Inc., Leede Jones Gable Inc. and Paradigm Capital Inc. (together, the "Underwriters").

The Offered Securities were offered in the provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Ontario, pursuant to a prospectus supplement dated February 19, 2021 to the Company's base shelf prospectus dated January 12, 2021 (the "Prospectus") and elsewhere in compliance with applicable securities laws.

The securities offered have not been, nor will they be, registered under the United States Securities Act of 1933, as amended (the "U.S. Securities Act"), or applicable state securities laws, and may not be offered or sold in the United States or to, or for the account or benefit of, persons in the United States or "U.S. persons" (as such term is defined in Regulation S promulgated under the U.S. Securities Act) absent registration or an applicable exemption from the registration requirements. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. Antibe's

current pipeline includes three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”). Antibe’s lead drug, otenaproxesul (formerly ATB-346), is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. The Company’s next target is inflammatory bowel disease (“IBD”), a condition long in need of safer, more effective therapies. Learn more at [antibethera.com](http://antibethera.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the proposed licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions “will”, “anticipate”, “believe”, “plan”, “estimate”, “expect”, “intend”, “propose” and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company’s inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics to Present at Upcoming Virtual Investor Conferences**

TORONTO--(BUSINESS WIRE)--March 3, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions, today announced its participation in the following investor conferences in March:

**H.C. Wainwright Global Life Sciences Conference** on Tuesday, March 9, 2021 at 7:00 am (Eastern Time) a pre-recorded company presentation will become available for on-demand viewing.

**Roth Capital Partners Annual Conference**, Live fireside chat on Monday, March 15, 2021, at 9:00 am (Eastern Time).

**Oppenheimer & Co. 31<sup>st</sup> Annual Healthcare Conference**, Company presentation on Tuesday, March 16, 2021 at 9:20 am (Eastern Time).

**Maxim Group Emerging Growth Virtual Conference** on Wednesday, March 17, 2021 at 10:00 am (Eastern Time) a pre-recorded company presentation will become available for on-demand viewing.

A link to the webcast of each event will be available on the News and Events section of the Company's website at [antibethera.com](http://antibethera.com). Following the events, a replay of the webcasts will be available on the website for 90 days.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. Antibe's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is entering Phase III for osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-safe alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibethera.com](http://antibethera.com).

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## **Antibe Therapeutics Receives FDA Clearance of IND Application for Otenaproxesul for Osteoarthritis Pain**

*- Enables expansion to U.S.-based clinical trials, advances preparation for Phase III program*

TORONTO--(BUSINESS WIRE)--March 29, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for inflammation arising from a wide range of medical conditions, today announced that the U.S. Food and Drug Administration (“FDA”) has cleared the Company’s Investigational New Drug (“IND”) application for otenaproxesul, in development for the treatment of osteoarthritis pain. This enables Antibe to undertake human clinical trials in the U.S.; as previously announced, Antibe anticipates initiating its Phase III program later this year.

“We are pleased to have been authorized to proceed with our clinical program for otenaproxesul,” commented Dr. Joseph Stauffer, Antibe’s Chief Medical Officer. “Because we completed Phase II trials prior to the IND application, we were able to provide a comprehensive package of preclinical and clinical data in a submission comprising more than 55,000 pages. We look forward to working with the FDA as we pursue development of a gastrointestinal-protective, non-addictive analgesic for the many millions of patients seeking better medicines for osteoarthritis.”

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company’s current pipeline includes three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”). Antibe’s lead drug, otenaproxesul, is entering Phase III for the treatment of osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-protective alternative to low-dose aspirin. The Company’s next target is inflammatory bowel disease (“IBD”), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

## **Forward Looking Information**

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## **Antibe Therapeutics to Present at 2021 Bloom Burton & Co. Healthcare Investor Conference**

TORONTO--(BUSINESS WIRE)--April 14, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for inflammation arising from a wide range of medical conditions, is pleased to announce its participation in the Bloom Burton & Co. Healthcare Investor Conference being held virtually on Tuesday, April 20 and Wednesday, April 21. Dan Legault, Antibe's CEO, will deliver the Company's presentation and will discuss recent business highlights and its growth strategy:

**Date:** Wednesday, April 21, 2021

**Time:** 11:00 am (Eastern Time)

A link to the webcast of the presentation will be available on the News and Events section of the Company's website at [antibethera.com](http://antibethera.com). Following the presentation, a replay of the webcast will be available for 90 days.

The Bloom Burton & Co. Healthcare Investor Conference brings together U.S., Canadian and international investors who are interested in the latest developments in the Canadian healthcare sector. Attendees will have an opportunity to obtain corporate updates from Canada's premier publicly traded and private companies through presentations and private meetings.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is preparing to enter Phase III for the treatment of osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-protective alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibethera.com](http://antibethera.com).

### **About Bloom Burton & Co.**

Bloom Burton & Co. (Bloom Burton Securities Inc.) is a firm dedicated to accelerating returns in the healthcare sector for both investors and companies. Bloom Burton has an experienced team of medical, scientific, pharmaceutical, legal and capital markets professionals who perform a deep level of diligence, which combined with a creative and entrepreneurial approach, assists clients in achieving the right monetization events. Bloom Burton and its affiliates provide capital raising, M&A advisory, equity research, business strategy and scientific consulting, advisory on direct investing and company creation and incubation services. Bloom Burton Securities Inc. is a member of the Investment Industry Regulatory Organization of Canada (IIROC) and is also a member of the Canadian Investor Protection Fund (CIPF).

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## **Antibe Therapeutics Announces Agreement to Unify Intellectual Property Ownership**

**- Amalgamation secures 100% ownership of IP underlying Antibe's pipeline**

**- Strengthens position in large-market partnering discussions**

TORONTO--(BUSINESS WIRE)--May 7, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF) ("Antibe" or the "Company"), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for a wide range of inflammatory conditions, today announced that the boards of directors of Antibe and Antibe Holdings Inc. ("Holdings") have agreed to combine the companies in an amalgamation transaction pursuant to which shareholders of Holdings will receive common shares of the Company in exchange for their shares of Holdings. This agreement follows negotiations originally announced in December 2020.

"This is a desirable outcome for all parties," commented Dan Legault, Antibe's CEO. "With this agreement, we've unlocked value by providing potential partners and institutional investors with a straightforward, unified IP base for our drugs and platform. We've also extinguished a significant royalty commitment, amounting to 15% of licensing revenues from our pipeline drugs. As we accelerate our partnering efforts for the large markets, we expect this agreement to strengthen our position and expand our options for monetization."

The Company was founded with an exclusive IP license from Holdings to develop and commercialize the Company's pipeline drugs. The license obligated the Company to pay royalties to Holdings on future revenues derived from this IP. Under the terms of the agreement announced today, the Company will acquire full ownership of Holdings' patent portfolio, eliminating the royalty liability on future revenues. The companies will be combined in a three-cornered amalgamation transaction pursuant to which Holdings will amalgamate with a newly-incorporated subsidiary of the Company.

In consideration, the Company will issue an aggregate of approximately 5,872,000 common shares to acquire all of the issued and outstanding shares of Holdings, following which Holdings will cease to exist. These new shares will account for approximately 11.4% of the ownership of Antibe Therapeutics on a post-transaction basis. Shares issued to Company insiders, who collectively own approximately 37.5% of the outstanding shares of Holdings, will be subject to lockup agreements with half of them to be released 120 days after closing and the balance to be released 240 days after closing.

The Company and Holdings have received opinions from independent financial advisory firms that the terms of the amalgamation are fair, from a financial point of view, to the shareholders of the respective companies. The transaction is expected to close on or about May 31, 2021 and is subject to approval by Holdings shareholders. The Toronto Stock Exchange has conditionally approved the issuance of shares by the Company pursuant to the amalgamation, subject to receipt of standard documentation.



## **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is entering Phase III for the treatment of osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-protective alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements, which include, but are not limited to, statements with respect to the proposed amalgamation of a subsidiary of the company with Holdings and the proposed licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the risk that the proposed amalgamation may not be completed, the Company's inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Announces Close of Amalgamation Transaction to Unify Intellectual Property Ownership**

*Not for Distribution or Dissemination Into the United States or Through U.S. Newswire Services*

TORONTO--(BUSINESS WIRE)--June 3, 2021--Antibe Therapeutics Inc. ("Antibe" or the "Company") (TSX:ATE) is pleased to announce that, further to its press release dated May 7, 2021, the Company has completed its previously announced amalgamation transaction (the "Transaction") to combine Antibe with Antibe Holdings Inc. ("Holdings"). Antibe was founded with an exclusive intellectual property license from Holdings to develop and commercialize the Company's pipeline drugs. The license obligated the Company to pay royalties to Holdings on revenues derived from this intellectual property. Pursuant to the Transaction, the Company has acquired full ownership of Holdings' patent portfolio, eliminating the royalty liability on future revenues.

The Transaction was completed by way of three-cornered amalgamation pursuant to which Holdings amalgamated with a newly incorporated subsidiary of the Company, resulting in Holdings becoming a wholly owned subsidiary of Antibe. In consideration, Antibe issued an aggregate of 5,873,092 common shares in the capital of the Company ("Common Shares") to acquire all of the issued and outstanding shares of Holdings. The shares issued pursuant to the Transaction account for approximately 11.4% of the ownership of the Company on a post-Transaction basis. Common Shares issued to the Company's insiders, who collectively held approximately 37.5% of the outstanding shares of Holdings, are subject to lock up agreements with half of the Common Shares received in connection with Transaction to be released on September 30, 2021 and the balance to be released on January 28, 2022.

As part of the Transaction, Antibe intends to complete a vertical short-form amalgamation to amalgamate itself with Holdings and carry on as one entity under the existing corporate name "Antibe Therapeutics Inc." The Transaction was conditionally approved by the Toronto Stock Exchange and remains subject to receipt of standard closing documentation.

The securities issued pursuant to the Transaction have not been, nor will they be, registered under the United States Securities Act of 1933, as amended (the "U.S. Securities Act"), or applicable state securities laws, and may not be offered or sold in the United States or to, or for the account or benefit of, persons in the United States or "U.S. persons" (as such term is defined in Regulation S promulgated under the U.S. Securities Act) absent registration or an applicable exemption from the registration requirements. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the securities in any jurisdiction in which such offer, solicitation or sale would be unlawful.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs").

Antibe's lead drug, otenaproxesul, is entering Phase III for the treatment of osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-protective alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibether.com](http://antibether.com).

### **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, receipt of final acceptance by the Toronto Stock Exchange and the proposed licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

*The Toronto Stock Exchange has neither approved nor disapproved the information contained therein.*

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## **Antibe Therapeutics to Present at Upcoming Virtual Investor Conferences**

TORONTO--(BUSINESS WIRE)--June 7, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for a wide range of inflammatory conditions, today announced its participation in the following U.S.-based virtual investor conferences in June:

**2021 LD Micro Invitational XI**, Live company presentation by Scott Curtis, Executive VP, and Dr. Joseph Stauffer, Chief Medical Officer, on Wednesday, June 9, 2021 at 12:30 pm (Eastern Time).

**Raymond James Human Health Innovation Conference**, Live company presentation by Dan Legault, CEO, and Dr. Joseph Stauffer on Wednesday, June 23, 2021 at 8:40 am (Eastern Time).

A link to the webcast of each event will be available on the News and Events section of the Company's website at [antibethera.com](http://antibethera.com). Following the presentations, a replay of the webcasts will be available on the website for 90 days.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is entering Phase III for the treatment of osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-protective alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibethera.com](http://antibethera.com).

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## **Antibe Therapeutics Collaborates With Dalriada Drug Discovery to Accelerate Pipeline Expansion**

**- Enables rapid advancement of multiple drug discovery programs to exploit hydrogen sulfide platform in new disease areas**

TORONTO--(BUSINESS WIRE)--June 25, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical-stage company leveraging its unique hydrogen sulfide platform to develop next-generation safer therapies to target inflammation in a wide range of health conditions, today announced a strategic collaboration with Dalriada Drug Discovery to develop new drug candidates and fortify Antibe's intellectual property ("IP") position for its current pipeline.

"The robust data from otenaproxesul's extensive animal studies and human trials have highlighted the broad therapeutic and commercial potential of our drug platform," commented Dan Legault, Antibe's CEO. "As we prepare for otenaproxesul's Phase III program, our strong balance sheet also enables us to tap Dalriada's scientific expertise and throughput capacity to further our pipeline expansion strategy and IP position – efficiently and cost-effectively. This collaboration also leverages the projects already underway with our U.S. university-based chemistry group."

Dalriada is a contract research organization ("CRO") specializing in the development of small-molecule drugs (such as those based on Antibe's platform) from initial discovery to development candidate nomination and management of IND-enabling studies. Its team comprises more than 50 scientists, including world-class experts in medicinal chemistry, bioanalytical chemistry, pharmacology, biochemistry and computational chemistry. Dalriada has supported integrated programs of public and venture capital-backed companies, including Janpix, Canopy Growth and Dunad Therapeutics.

Dalriada's efforts will extend medicinal chemistry capabilities and accelerate screening, selection and advancement of drug candidates for IND-enabling studies. As previously announced, Antibe's first candidates for screening address inflammatory bowel disease ("IBD"), a condition affecting more than three million North American adults. Dalriada's efforts are also being directed towards the development of fresh IP for existing pipeline drugs to lengthen the duration of patent and market protection. Antibe will retain ownership rights to any new IP.

Diana Kraskouskaya, CEO of Dalriada, noted, "With the increasing recognition of inflammation's central role in many diseases, we see the profound potential of Antibe's revolutionary anti-inflammatory platform. Dalriada's Turn-Key model is specifically designed to enable rapid expansion of therapeutic pipelines and accelerate value creation for our partners' programs. We are excited to commit our resources to this undertaking in collaboration with Antibe's world-renowned scientists and expert commercial team."

In support of these efforts, Antibe is pleased to appoint Harvey Schipper, MD, FRCPC, to its Scientific Advisory Board. A practicing physician, Dr. Schipper is also a professor of medicine and law at the University of Toronto. His efforts have shifted medical practice, scientific investigation and health policy around the world. In particular, Dr. Schipper's pioneering work with the World Health Organization helped establish 'Quality of Life' as a substantive indicator of patient well-being. With a background also encompassing venture capital and business governance, he will spearhead efforts to uncover business opportunities by mapping unmet medical needs to scientific feasibility and commercial potential.

### **About Antibe Therapeutics Inc.**

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## **Antibe Therapeutics Reports 2021 Year-End Financial Results and Business Highlights**

***- Phase III-enabling activities for otenaproxesul proceeding well; AME study begins next week***

***- Ended year with a strong \$72 million cash position, providing over two years of runway and fully funding Phase III adaptive trial***

TORONTO--(BUSINESS WIRE)--June 28, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, today filed its financial and operating results for the fiscal year ended March 31, 2021.

“Since the beginning of the year we’ve made significant progress,” commented Dan Legault, Antibe’s CEO. “Our Phase III preparations for otenaproxesul achieved several milestones, including the clearance of its IND application with the FDA in the United States. While we continue to navigate COVID-19 restrictions, we’re pleased to launch our required AME study next week which will also inform the dose selection for the Phase III adaptive trial. The successful amalgamation with Antibe Holdings provides a unified intellectual property base and strengthens our position with potential partners. On that front, our ability to execute deals was highlighted by the US\$100 million partnership with Nuance Pharma in China, and we’re now entering confidential discussions for the large markets.”

### **Business Highlights**

*Otenaproxesul, lead product candidate entering Phase III trials for osteoarthritis pain*

- Completed all Phase III-enabling animal long-range and reproductive toxicology studies required to commence the Phase III adaptive trial (10 studies in total)
- Cleared Investigational New Drug (“IND”) filing with U.S. FDA to allow human clinical trials in the United States – IND-opening single-dose study underway in 24 subjects
- Received approval to commence the required absorption, metabolism and excretion (“AME”) study in 90 subjects
- Retained senior clinical operations director, Dr. Ana Stegic, to support clinical trial management and execution
- Completed a strategic licensing deal with Nuance Pharma for the commercialization of otenaproxesul in the Greater China region, with milestone payments totaling US\$100 million and a double-digit royalty
- Commenced partnering process for the large markets (United States, EU4, UK and Japan) led by a leading global transaction firm

*New chemistry initiatives targeting candidates to expand and bolster pipeline*

- Announced collaboration with Dalriada Drug Discovery to exploit hydrogen sulfide platform in new disease areas including inflammatory bowel disease

- Fortifying intellectual property position for existing pipeline

*Fully funded for over two years with 100% ownership of underlying intellectual property*

- Successfully raised \$40 million in a bought deal public offering, providing over two years of cash runway and fully funding otenaproxesul's Phase III adaptive efficacy trial
- Completed amalgamation with Antibe Holdings to unify the intellectual property ownership of the Company's drugs and platform – eliminates significant royalty liability on future revenues

### **Upcoming Milestones**

- Completion of single-dose IND-opening study – Q3 2021
- Completion of AME study – Q4 2021
- Request FDA meeting prior to start of Phase III program – Q4 2021
- Initiation of Phase III adaptive trial – Q1 2022

### **Financial Results**

**Cash Position:** As of March 31, 2021, the Company had an available cash balance totaling \$72 million, compared to \$6.2 million at March 31, 2020.

**Revenue:** For the year ended March 31, 2021, revenue totaled \$9.7 million, a negligible increase compared to the fiscal 2020 period. All revenue was due to the Company's subsidiary, Citagenix; sales were adversely affected by the COVID-19 crisis in fiscal Q1 but recovered strongly in fiscal Q2 through Q4.

**Net Loss:** For the year ended March 31, 2021, net loss amounted to \$26.3 million (\$0.70 per share), compared to \$19.3 million (\$0.71 per share) for fiscal 2020.

**Research and Development Expenses:** Research and development expenses for the year increased to \$13.4 million compared to \$8.1 million in fiscal 2020. The increase was primarily due to higher development costs for the Phase IIB dose-ranging, efficacy study for otenaproxesul as well as required non-clinical studies.

**General and Administrative Expenses:** General and administrative expenses amounted to \$7.2 million for the year compared to \$5.2 million for fiscal 2020. The increase was primarily due to higher overall payroll, professional and consulting fees, office expenses and other costs.

**Sales and Marketing Expenses:** Selling and marketing expenses totaled \$2.7 million for the year compared to \$3.8 million in fiscal 2020. The decrease consisted of lower salaries and commissions, advertising and promotions costs and travel and entertainment costs.

With the divestiture of a Citagenix subsidiary (BMT Medizintechnik GmbH) during the year, the above-stated financial results reflect continuing operations. The Company's audited fiscal 2021 consolidated financial statements, MD&A and AIF will be available shortly on SEDAR.



## **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is entering Phase III for the treatment of osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-sparing alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibether.com](http://antibether.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the proposed licensing and development of drugs and medical devices. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Provides July 2021 Corporate Update**

*- Phase III preparations proceeding well; AME study underway*

*- New IP in development to expand indications and bolster existing pipeline*

*- Potential listing on senior U.S. exchange synchronized with first Phase III trial*

TORONTO--(BUSINESS WIRE)--July 27, 2021--Antibe Therapeutics Inc.:

To our shareholders,

Our achievements in the last twelve months have set the stage for a promising year ahead. With a cash position that provides more than two years of runway and fully funds the initial Phase III trial, we are adding value through comprehensive clinical development, ongoing partnering engagement and multi-pronged intellectual property (“IP”) advancement.

### **Otenaproxesul’s Clinical Development on Track**

With the U.S. FDA’s recent clearance of otenaproxesul’s Investigational New Drug (“IND”) application and the requisite animal toxicology studies now complete, the receding COVID-19 pandemic is enabling us to solidify plans for our first Phase III trial. Involving approximately 750 patients, this efficacy trial is planned for approximately 50 sites in the U.S. and Canada, with enrollment set to commence in Q1 2022. The associated CMC (chemistry, manufacturing and controls) activities are on schedule, with drug tablet and placebo production well in hand by our global manufacturing partner.

Antibe is taking a comprehensive approach to maximizing the likelihood of a successful Phase III program outcome. We are currently evaluating proposals from leading global contract research organizations (“CROs”) with extensive osteoarthritis clinical trial experience; we expect to finalize our choice within weeks. The program also combines several state-of-the-art aspects, including the hiring of leading providers of bioanalytic, quality control and data management services. The latter will enable us to track and manage screening and enrollment in real-time, ensuring that the subject population matches trial criteria. To mitigate the risks that arise in the conduct of every placebo-controlled pain trial, we have contracted with one of the world’s foremost providers of clinic staff and patient education to ensure accurate and consistent reporting of pain scores and other measures. This firm will also provide us with real-time data during the trials, enabling us to make timely interventions if data quality issues arise – all without unblinding the trials. We have also retained a former chair of the U.S. FDA’s Advisory Committee on Anesthesia, Critical Care and Addiction Products for ongoing advice to ensure that our process meets FDA expectations for approving a novel chronic pain therapeutic.

We are also in the process of selecting three physicians to constitute the Independent Data Monitoring Committee (“IDMC”), a key de-risking aspect of the initial trial’s adaptive design. Favorably viewed by the FDA, adaptive design increases trial control and flexibility while maintaining statistical integrity. Once 50% of the patients in the trial have completed treatment, the IDMC will review the data, allowing for sample size increases to preserve statistical powering if needed. Achieving statistically significant superiority to placebo in this trial would be a major clinical milestone for our company. The balance of the Phase III program involves a second efficacy trial and a gastrointestinal (“GI”) safety trial. An additional efficacy trial will be required to provide data specifically for European and Asian regulators.

The Phase III program will be overseen by Dr. Joseph Stauffer, our Chief Medical Officer. Dr. Stauffer is a former analgesic and anti-inflammatory drug reviewer at the FDA as well as a pioneer in the design and conduct of adaptive analgesic trials, with experience as chair and member of several IDMCs. To support the expansion of our development activities, we continue to strengthen our team, including the recent hiring of Dr. Ana Stegic as our Director of Clinical Operations. Dr. Stegic is a medical doctor with more than fifteen years of experience in managing global clinical trials for large U.S.-based CROs.

In the lead-up to Phase III program initiation, we are taking the opportunity to conduct two smaller clinical studies to support our commercial, regulatory and drug development priorities. To be completed this quarter, we are conducting an IND-opening single-dose detailed pharmacokinetics/ pharmacodynamics study in 24 healthy volunteers at a U.S. site. Subjects have received the drug and post-administration monitoring is complete, with data analysis now underway.

Earlier this month, we initiated an absorption, metabolism and excretion (“AME”) study involving a total of 90 healthy volunteers being randomized to lower doses of otenaproxesul. The drug will be administered to each dose cohort for four weeks, followed by two weeks of post-drug monitoring. In addition to providing valuable information for potential partners, this study will further de-risk dose selection for the Phase III program, while also supplying pharmacokinetic data required for drug marketing approval. Following the anticipated completion of this study in the upcoming quarter, we will request a meeting with the FDA; that meeting will be the last key milestone before Phase III initiation.

### **Recent Validation Driving Partnering Activity**

As we focus our partnering efforts on the large markets of the U.S., U.K., the four largest E.U. countries and Japan, we are benefiting from the validation inherent in our licensing deal earlier this year with Nuance Pharma in China. Supported by the unification of our IP ownership and the hiring of a premier pharma transaction firm to manage a formal outreach process, we are now interacting with pharmaceutical companies around the globe, with several conversations having reached the confidential stage. Recognizing that we are on the cusp of solving a problem that has challenged medical practice for 50 years, our strong corporate position provides us with the opportunity to select partners that can fully exploit otenaproxesul’s potential.

## **IP Development Creating New Value**

In parallel with our Phase III preparations, we are working to realize the potential of our hydrogen sulfide platform through a cost-effective, early-stage research and development program. As recently announced, we have entered into a strategic collaboration with Dalriada Drug Discovery to aid us in identifying new drug candidates and to fortify the IP position of our current pipeline. Dalriada is presently screening molecules to select our go-forward candidate for inflammatory bowel disease (“IBD”), a process expected to be completed within months. With inflammation increasingly understood to underlie a wide range of health conditions, we look forward to broadening our pipeline to address this pervasive medical issue. We are also pursuing the development of fresh IP to lengthen the duration of patent and market protection available to our peri-operative pain and aspirin-based drug candidates.

## **Potential Listing on Senior U.S. Exchange Synchronized with Phase III Initiation**

Our preparations for a potential listing on a senior U.S. exchange are largely complete. To capture the momentum of our upcoming Phase III program initiation, we are synchronizing a potential U.S. uplisting with our first Phase III trial. We also recognize that the completion of a strategic transaction for Citagenix would simplify Antibe’s story for new investors, and we are actively engaged in pursuing such an arrangement.

With a state-of-the-art Phase III design, enhanced bench strength and the support of a team of world-class service providers, we are poised to embark on the final phase of development of a best-in-class solution for millions of osteoarthritis patients and their doctors. Enabled by a strong balance sheet and heightened industry visibility, we also are well-positioned to partner with companies that can capture otenaproxesul’s potential. Our efforts to target inflammation more broadly are underway, addressing unmet medical needs across a spectrum of indications.

We look forward to updating you on our progress.

Sincerely,

Dan Legault  
*Chief Executive Officer*

## **About Antibe Therapeutics Inc.**

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## **Forward Looking Information**

This news release includes certain forward-looking statements, which may include, but are not limited to, the proposed licensing and development of drugs and medical devices, and the potential of a US listing. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to secure additional financing and licensing arrangements on reasonable terms, or at all, its inability to execute its business strategy and successfully compete in the market, and risks associated with drug and medical device development generally. Antibe Therapeutics assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

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## **Antibe Therapeutics Provides Clinical Update for Otenaproxesul**

### **- Current AME study paused in adherence to safety protocol**

TORONTO--(BUSINESS WIRE)--August 3, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, has placed its absorption, metabolism and excretion (“AME”) study of otenaproxesul on a required pause because a pre-specified safety threshold was exceeded. The study is one of several nonclinical and clinical studies being conducted in advance of otenaproxesul’s planned Phase III program.

The AME study had enrolled a total of 42 subjects on either a 75 mg or 100 mg daily dose of otenaproxesul, of whom 35 had completed the 28-day drug administration period, with seven subjects having been administered the drug for 21 days. Three subjects in the 100 mg cohort, who had completed the full drug administration period, exhibited liver transaminase elevations exceeding five times the upper limit of normal, triggering the required pause. Other indicators of liver function for these subjects were normal. The study incorporates an in-clinic post-administration observation period of 14 days, which is continuing. Although the treatment duration was longer than in previous Antibe studies, these observations were unexpected given the results of efficacy, safety and pharmacokinetic studies conducted to date. The Company will continue to collect and analyze additional data over the next several weeks to understand the cause and implications of these events and to determine the optimal plan for the continued development of otenaproxesul. In parallel, Antibe will discuss the status of the AME study and the development path going forward with Health Canada. The Company will update its shareholders once this work is complete.

Patient safety is paramount to Antibe in developing clinically relevant and novel medicines to control pain and inflammation. As the AME study was designed in part to identify doses for the initial Phase III trial, these findings indicate that further research is warranted with respect to both the optimal dose range and potential improvements to the formulation. These efforts will impact the plan for the Phase III program.

Supported by a strong team and a \$66 million cash position, Antibe is also continuing to advance the development of its pipeline of other novel drug candidates for pain and inflammation.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company’s current pipeline includes three assets that seek to overcome the gastrointestinal (“GI”) ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”). Antibe’s lead drug, otenaproxesul, is entering Phase III for the treatment of osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-sparing alternative to low-dose aspirin. The Company’s next target is inflammatory bowel disease (“IBD”), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

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## **Antibe Therapeutics to Present at Canaccord Genuity 41st Annual Growth Conference**

TORONTO--(BUSINESS WIRE)--August 9, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for a wide range of inflammatory conditions, today announced its participation in the Canaccord Genuity 41st Annual Growth Conference being held virtually on August 10 - 12. Dan Legault, Antibe's CEO, and Dr. Joseph Stauffer, Chief Medical Officer, will deliver the Company's presentation:

**Date:** Thursday, August 12, 2021

**Time:** 9:00 am (Eastern Time)

A link to the webcast of the presentation will be available on the News and Events section of the Company's website at [antibethera.com](http://antibethera.com). Following the presentation, a replay of the webcast will be available on the website for 90 days.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development for the treatment of osteoarthritis pain. Additional assets include a safer alternative to opioids for peri-operative pain, and a GI-sparing alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibethera.com](http://antibethera.com).

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## Antibe Therapeutics Reports Q1 2022 Interim Financial and Operating Results

- *Ended quarter with a strong \$67 million cash position*
- *AME study on required pause; data expected in October*

TORONTO--(BUSINESS WIRE)--August 17, 2021--Antibe Therapeutics Inc. (TSX:ATE, OTCQX:ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, has filed its financial and operating results for the fiscal quarter ended June 30, 2021.

“We made progress across all activities during the quarter,” commented Dan Legault, Antibe’s CEO. “However, subsequent to the quarter, we placed otenaproxesul’s AME study on a required pause because a pre-specified safety threshold was exceeded. As announced earlier this month, we are collecting and analyzing additional data to understand the cause and implications of the events, and to determine the optimal plan for otenaproxesul’s continued development. We will update our shareholders in October when we expect this work to be complete. In parallel, development of fresh IP continues for the rest of our pipeline, including our pursuit of a novel candidate for inflammatory bowel disease. While there is much to be done to address recent events, our dedicated team and cash position put us in a strong position to move forward.”

During the course of the absorption, metabolism and excretion (“AME”) study, the Company conducted twice-weekly blood draws and collected other specimens to measure key biomarker and pharmacokinetic data. More than 6,200 samples will be analyzed at five specialized labs in Canada and internationally, providing insight on the drug’s behavior and the potential for effectiveness at lower doses.

### Business Highlights

*Otenaproxesul, lead product candidate in clinical development for osteoarthritis pain*

- Cleared Investigational New Drug (“IND”) filing with U.S. FDA to allow human clinical trials in the United States – IND-opening single-dose study completed with analysis underway
- Completed Phase III-enabling animal long-range and reproductive toxicology studies (10 studies in total), one further study to conclude in calendar Q4
- Received approval to commence the absorption, metabolism and excretion (“AME”) study in 90 subjects; subsequent to the quarter, the AME study was placed on a required pause (*see August 3, 2021 press release*)
- Retained senior clinical operations director, Dr. Ana Stegic, to support clinical trial management and execution

*New chemistry initiatives targeting candidates to expand and bolster pipeline*

- Initiated collaboration with Dalriada Drug Discovery to exploit hydrogen sulfide platform in new disease areas including inflammatory bowel disease (“IBD”)

- Stepped up pace of new chemistry initiatives to fortify intellectual property position for existing pipeline, including peri-operative pain and aspirin-based drug candidates

*Fully funded for over two years with 100% ownership of underlying intellectual property*

- Successfully raised \$40 million in a bought deal public offering, providing over two years of cash runway
- Completed amalgamation with Antibe Holdings to unify the intellectual property ownership of the Company's drugs and platform – eliminates significant royalty liability on future revenues

## **Financial Results**

**Cash Position:** As of June 30, 2021, the Company had an available cash balance totaling \$66.8 million, compared to \$72 million as at March 31, 2021.

**Revenue:** For the quarter ended June 30, 2021, revenue totaled \$2.7 million, compared to \$1.1 million for the same period in fiscal 2021. All revenue was due to the Company's subsidiary, Citagenix; sales were higher as the impact of COVID-19 caused dental clinics to close for a significant part of the prior year's quarter.

**Net Loss:** For the quarter ended June 30, 2021, net loss amounted to \$6.3 million (\$0.13 per share), compared to \$4.9 million (\$0.16 per share) for the same period in fiscal 2021.

**Research and Development Expenses:** Research and development expenses, net of research tax credits, amounted to \$3.2 million for the quarter ended June 30, 2021, compared to \$2.1 million for the same period in fiscal 2021. The increase was primarily due to higher salaries and wages, professional and consulting fees costs, research and clinical trial costs partly offset by SR&ED rebates.

**General and Administrative Expenses:** General and administrative expenses totaled \$1.6 million for the quarter ended June 30, 2021, a negligible decrease compared to the same period in fiscal 2021. The difference was primarily due to decreased professional and consulting fees partly offset by higher overall payroll, office expenses and other costs.

**Sales and Marketing Expenses:** Selling and marketing expenses amounted to \$0.7 million for fiscal Q1 2022 compared to \$0.4 million for the same period in fiscal 2021. The increase consisted of increased salaries and wages, commissions, advertising and promotion, and travel and entertainment costs.

With the divestiture of Citagenix's subsidiary (BMT Medizintechnik GmbH) during the 2021 fiscal year, the above-stated financial results reflect continuing operations. The Company's unaudited fiscal Q1 2022 condensed interim financial statements and MD&A are available on SEDAR.

## **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development for the treatment of osteoarthritis pain. Additional assets under development include a safer alternative to opioids for peri-operative pain, and a GI-sparing alternative to low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibether.com](http://antibether.com).

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## Antibe Therapeutics Announces Results of 2021 Annual Meeting

TORONTO--(BUSINESS WIRE)--August 19, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its unique hydrogen sulfide platform to develop safer medicines for pain and inflammation, is pleased to announce the results of its annual meeting of shareholders (the “Meeting”) held earlier today. All resolutions outlined in the management information circular were approved. Detailed results for the election of directors are provided below:

Director Nominee	Outcome	% For	% Withheld
Walt Macnee	Elected	86.88%	13.12%
Roderick Flower	Elected	86.15%	13.85%
Robert Hoffman	Elected	87.49%	12.51%
Amal Khouri	Elected	86.91%	13.09%
Dan Legault	Elected	71.86%	28.14%
Jennifer McNealey	Elected	77.66%	22.34%
John L. Wallace	Elected	73.35%	26.65%
Yung Wu	Elected	86.73%	13.27%

Voting results on all matters voted on at the Meeting have been filed on SEDAR.

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## **Antibe Therapeutics to Present at the H.C. Wainwright 23<sup>rd</sup> Annual Global Investment Conference**

TORONTO--(BUSINESS WIRE)--September 8, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for a wide range of inflammatory conditions, today announced its participation in the H.C. Wainwright 23<sup>rd</sup> Annual Global Investment Conference being held virtually on September 13 - 15. Dan Legault, Antibe's CEO, and Dr. Joseph Stauffer, Chief Medical Officer, will deliver the Company's pre-recorded presentation:

**Date:** Monday, Sept 13, 2021

**Time:** Available for on-demand viewing from 7:00 am (Eastern Time) onwards

A link to the webcast of the presentation will be available on the News & Events section of the Company's website at [antibethera.com](http://antibethera.com). The webcast will be available on the website for 90 days.

### **About Antibe Therapeutics Inc.**

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## **Antibe Therapeutics Provides Update on Otenaproxesul and Expanded Drug Pipeline**

*- Acute pain program launched for otenaproxesul*

*- New patent application aimed at extending otenaproxesul's IP protection into the 2040s*

*- Dosing regimen for osteoarthritis indication requires additional investigation*

*- Company fully funded into 2024*

TORONTO--(BUSINESS WIRE)--October 14, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for a wide range of inflammatory conditions, is pleased to provide an update following a full scientific and strategic review involving external experts and key opinion leaders. The key findings are:

- Lead drug, otenaproxesul, ideally suited for US\$13 billion post-operative pain market
- Targets urgent need to reduce opioid prescriptions, with shorter path to market envisaged
- Label expansion strategy potentially includes migraine, dysmenorrhea and dental pain
- Enlarged pipeline addresses significant unmet medical needs, additional IP protection expected
- Chronic pain program investigating alternative treatment regimens
- Strong balance sheet fully funds multiple parallel clinical development programs

“In our comprehensive review, it became apparent that otenaproxesul’s remarkable potency, GI protection and overall safety profile should be leveraged for acute pain use,” commented Dan Legault, Antibe’s CEO. “Short-term pain management has its own considerable challenges, not the least being a continued reliance on opioids, for which otenaproxesul is an ideal fit. Building on commercial research already in hand, we are initially targeting post-operative pain, with a plan to add further acute pain indications over time. Importantly, given the relatively short trials required, we foresee a faster path to market than originally envisaged with our chronic pain program. We are also pursuing a new indication with high unmet need for ATB-352, harmonizing its development with otenaproxesul’s new acute pain program.”

### **Otenaproxesul’s Osteoarthritis Program to Explore Alternative Dosing Regimens**

In collaboration with outside experts and key opinion leaders, the Company has completed a comprehensive assessment of the AME study data. In addition to the three subjects described in the August 3rd press release, a further three subjects exhibited liver transaminase elevations (“LTEs”) exceeding five times the upper limit of normal, which occurred following the four-week drug administration period. All six subjects, including five in the 100 mg cohort and one in the 75 mg cohort, completed their in-clinic observation period without any additional safety findings. Notably, all LTEs were transient, self-limiting and required no clinical intervention.

The review confirms that the observed LTEs are a dose-dependent, drug-related effect and present a challenge for daily drug administration over longer treatment durations. The mechanism underlying the LTEs is being intensively researched in collaboration with recognized liver scientists. To date, the evidence suggests that daily doses administered for longer treatment durations leads to increased hepatocellular oxidative stress, triggering LTEs in a subset of individuals. Increased oxidative stress is a common finding associated with widely used medications, including nonsteroidal anti-inflammatory drugs (“NSAIDs”) and acetaminophen. The Company is investigating alternative dosing regimens as a potential path forward for chronic indications.

### **Acute Pain Program Launched for Otenaproxesul**

The Company has commenced an acute pain program for otenaproxesul to harness its demonstrated potency, profound gastrointestinal (“GI”) protection and a safety profile that remains suitable for short-term treatment regimens. Initially targeting the post-operative pain market, the Company intends to expand to indications such as migraine, dysmenorrhea and dental pain – all large markets with few safe and effective therapies.

The global market for post-operative pain is estimated to be US\$13 billion, with opioids and NSAIDs accounting for the majority share (Transparency Research). In the U.S., there are 50 million surgical procedures annually that require post-operative pain medication and more than two million Americans may become persistent opioid users each year (Brummett et al.).

“The resurgent opioid crisis is pressuring prescribers, payors and policymakers to reduce the use of opioids across medical practice,” commented Dr. Joseph Stauffer, Antibe’s Chief Medical Officer. “In particular, the treatment of post-operative pain continues to rely on opioids, with little innovation addressing the period beyond two to three days following surgery, when the transition to home care generally occurs. With extensive human clinical data on otenaproxesul already in hand, we are well-equipped to pursue a solution to this long-intractable problem.”

In a commercial study of acute pain conducted by leading life science strategy consultancy, Shift Health, GI safety was cited as the top concern amongst surgeons and clinicians prescribing NSAIDs in a hospital setting. Antibe's Phase IIB GI safety trial showed that patients administered prescription naproxen for fourteen days exhibited a 42% incidence of 3 mm ulcers, compared to 2.5% in those taking otenaproxesul.

Research is underway to identify optimal dosing regimens for otenaproxesul in acute pain indications, with initial clinical studies expected to begin in the upcoming quarter. Because acute pain is inherently a short-term indication, the Phase II and III clinical trials required to establish safety and efficacy are also relatively short, enabling a more rapid time to market than was envisaged for the original chronic pain development program.

## **New Patent Applications Potentially Extend IP Protection**

The Company has filed a patent application that covers the novel dosing regimens envisaged for acute use of otenaproxesul. In addition, Antibe also recently identified an attractive specialized indication for ATB-352 for which new IP is being sought. If granted, both drugs will benefit from new IP protection in major markets into the 2040s.

## **IBD Program Progressing Toward Candidate Selection**

The Company's Inflammatory Bowel Disease ("IBD") candidate is expected to be selected in the coming quarters, with IND-enabling studies to begin immediately thereafter. Intended to address the need for a safe and more effective drug for mild to moderate IBD, its product strategy aims to delay or avoid the requirement for expensive and side effect-prone steroids and biologics. The new IBD candidate is being designed using the architecture of ATB-429, a hydrogen sulfide-releasing IBD drug acquired via the recent amalgamation with Antibe Holdings that has extensive and promising animal data but diminishing patent life. Covering treatments for Crohn's disease and ulcerative colitis, the IBD market is expected to nearly double between 2019 and 2029 to US\$25 billion (Global Data).

## **Strong Balance Sheet to Drive Development Programs**

The Company's cash position as of September 30, 2021 was \$60 million, which fully funds all development activities into calendar 2024.

## **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids for acute pain and the treatment of osteoarthritis. Additional assets include GI-sparing alternatives to ketoprofen and low-dose aspirin. The Company's next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).



## **Forward Looking Information**

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## **Contacts**

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[christina@antibethera.com](mailto:christina@antibethera.com)

## **Antibe Therapeutics Outlines Plan for Otenaproxesul's Acute Pain Program**

*- Leverages existing extensive clinical data to shorten development path*

*- Acute pain clinical program initiating early next quarter*

*- Third-party commercial studies underway*

TORONTO--(BUSINESS WIRE)--November 1, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for a wide range of inflammatory conditions, is pleased to provide further detail on otenaproxesul's development plan for acute pain indications. Further to its October 14<sup>th</sup> press release, Antibe has now identified timing for the program's key regulatory and development milestones for post-operative pain, the Company's initial acute indication for otenaproxesul.

“With otenaproxesul's impressive 14-day efficacy and GI safety profile, which is ideally suited for acute pain, we are well-positioned to rapidly bring to market a novel and safe non-opioid analgesic,” commented Dan Legault, Antibe's CEO. “From a commercial standpoint, we see the \$13 billion post-operative pain segment as an ideal springboard to the much broader acute pain market. Combined with the lack of innovation in oral analgesics and the urgent global need for non-addictive alternatives, we expect otenaproxesul to be especially attractive to potential partners. And with the option of funding the entire Phase III program with our current cash position, Antibe has a unique opportunity to shift the treatment paradigm of acute pain.”

Leveraging otenaproxesul's existing comprehensive clinical data package, Antibe anticipates launching its clinical program for acute pain in early calendar Q1 2022. To this end, the Company has begun collaborating with world-leading acute pain specialists to optimize treatment regimens for post-operative pain use. This includes a series of brief pharmacokinetic (“PK”) and pharmacodynamic (“PD”) studies to determine the go-forward treatment regimens for the Phase II program, including the use of loading doses to ensure rapid analgesic onset.

In parallel, Antibe is undertaking a comprehensive third-party market opportunity and reimbursement study, including revenue projections for the large markets, with results expected in late calendar Q1 2022. This will involve both primary and secondary research, including interviews with surgeons, anesthesiologists and pain specialists. Subsequently, the Company plans to initiate a partner targeting study to support strategic outreach as the drug's therapeutic and commercial potential is fully validated.

With the optimal treatment regimens and commercial data in hand, the Company will prepare for otenaproxesul's Phase II program, slated to commence in calendar Q4 2022. Involving only a single efficacy trial with a treatment period of up to 10 days, it is expected to deliver top-line data in six months. This trial will employ a surgical bunionectomy model, recognized as one of the most reliable methods for evaluating analgesic efficacy in post-operative pain. Given the extensive animal data already available for otenaproxesul, the Company does not anticipate the need for additional animal studies for its acute pain program.

Upon success of this Phase II trial, the Company will request an end of Phase 2 meeting with the U.S. FDA to discuss the Phase III program. Given the short treatment durations employed in acute pain trials, it is anticipated that the full Phase III program can be completed within 12 months. This includes two concurrent, pivotal efficacy trials to assess post-operative pain relief for the following surgical procedures: (i) the hard tissue model of bunionectomy, replicating the Phase II trial with a larger sample size; and (ii) abdominoplasty, a widely accepted soft tissue surgical model. The Company intends to apply for marketing approval for a broad acute pain indication.

### **Anticipated Milestones**

The following summarizes the Company's estimated development timeline for otenaproxesul's post-operative pain indication:

- PK/PD clinical studies initiated – Q1 2022
- Third-party commercial study results – Q1 2022
- Optimal treatment regimens determined – Q3 2022
- Phase II bunionectomy trial initiated – Q4 2022
- End of Phase 2 meeting and initiation of 12-month Phase III program – H2 2023

Upon marketing approval, Antibe plans to initiate a series of studies to further investigate the effectiveness of otenaproxesul in other acute pain indications such as migraine, dysmenorrhea, blunt trauma and gout, all large markets with few safe and effective therapies.

### **About Antibe Therapeutics Inc.**

Antibe is leveraging its proprietary hydrogen sulfide platform to develop next-generation safer therapies to address inflammation arising from a wide range of medical conditions. The Company's current pipeline includes three assets that seek to overcome the gastrointestinal ("GI") ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"). Antibe's lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids for acute pain and the treatment of osteoarthritis. Additional assets include GI-sparing alternatives to ketoprofen and low-dose aspirin. The Company's anticipated next target is inflammatory bowel disease ("IBD"), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](http://antibetherapeutics.com).

## **Forward Looking Information**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, the anticipated scope, timing, duration and completion of certain of the Company's clinical trial programs and studies and the anticipated timing for seeking market approval for certain of the Company's drugs and therapies for certain additional indications. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to timely execute on its business strategy and timely and successfully compete its clinical trials and studies, the Company's inability to obtain the necessary regulatory approvals related to its activities, risks associated with drug and medical device development generally and those risk factors set forth in the Company's public filings made in Canada and available on [www.sedar.com](http://www.sedar.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

## **Contacts**

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VP Investor Relations  
+1 416-577-1443  
[christina@antibethera.com](mailto:christina@antibethera.com)

This is Exhibit "L" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

## **Antibe Therapeutics Provides Update on Otenaproxesul and Expanded Drug Pipeline**

*- Acute pain program launched for otenaproxesul*

*- New patent application aimed at extending otenaproxesul's IP protection into the 2040s*

*- Dosing regimen for osteoarthritis indication requires additional investigation*

*- Company fully funded into 2024*

TORONTO--(BUSINESS WIRE)--October 14, 2021--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical stage company leveraging its hydrogen sulfide platform to develop next-generation safer therapies for a wide range of inflammatory conditions, is pleased to provide an update following a full scientific and strategic review involving external experts and key opinion leaders. The key findings are:

- Lead drug, otenaproxesul, ideally suited for US\$13 billion post-operative pain market
- Targets urgent need to reduce opioid prescriptions, with shorter path to market envisaged
- Label expansion strategy potentially includes migraine, dysmenorrhea and dental pain
- Enlarged pipeline addresses significant unmet medical needs, additional IP protection expected
- Chronic pain program investigating alternative treatment regimens
- Strong balance sheet fully funds multiple parallel clinical development programs

“In our comprehensive review, it became apparent that otenaproxesul’s remarkable potency, GI protection and overall safety profile should be leveraged for acute pain use,” commented Dan Legault, Antibe’s CEO. “Short-term pain management has its own considerable challenges, not the least being a continued reliance on opioids, for which otenaproxesul is an ideal fit. Building on commercial research already in hand, we are initially targeting post-operative pain, with a plan to add further acute pain indications over time. Importantly, given the relatively short trials required, we foresee a faster path to market than originally envisaged with our chronic pain program. We are also pursuing a new indication with high unmet need for ATB-352, harmonizing its development with otenaproxesul’s new acute pain program.”

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“The resurgent opioid crisis is pressuring prescribers, payors and policymakers to reduce the use of opioids across medical practice,” commented Dr. Joseph Stauffer, Antibe’s Chief Medical Officer. “In particular, the treatment of post-operative pain continues to rely on opioids, with little innovation addressing the period beyond two to three days following surgery, when the transition to home care generally occurs. With extensive human clinical data on otenaproxesul already in hand, we are well-equipped to pursue a solution to this long-intractable problem.”

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## **Contacts**

Antibe Therapeutics Inc.  
Christina Cameron  
VP Investor Relations  
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[christina@antibethera.com](mailto:christina@antibethera.com)

This is Exhibit "M" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

## **Antibe Announces Unfavorable Decision in Arbitration With Nuance Pharma**

TORONTO--(BUSINESS WIRE)--March 4, 2024--Antibe Therapeutics Inc. (TSX: ATE, OTCQX: ATBPF), a clinical-stage biotechnology company leveraging its hydrogen sulfide platform to target pain and inflammation, today announced that the arbitrator has found in favor of Nuance Pharma in the dispute regarding the license agreement for the commercialization of otenaproxesul in the Greater China region. The confidential ruling from the Singapore International Arbitration Centre rescinds the license agreement and requires Antibe to refund the US\$20 million upfront payment and pay interest and costs of approximately US\$4 million. The decision is not subject to appeal. Antibe views this unexpected result as highly unusual based on best practices for licensing deals in the biotech industry.

“We strongly disagree with this decision,” commented Dan Legault, Antibe’s CEO. “Nonetheless, we acknowledge the fact that we agreed to binding arbitration in a foreign jurisdiction. Antibe respects the confidentiality and final nature of the arbitration proceedings and will accept the decision in good faith. We continue to believe that the comprehensive data package shared with Nuance for the previous chronic pain formulation fully reflected the drug’s safety and efficacy characteristics. Although this ruling presents a significant short-term challenge, we remain committed to developing otenaproxesul -- particularly due to the strength of recent clinical results for acute pain that have significantly de-risked its final trials.”

In light of the arbitral ruling, the Company is evaluating its development and milestone plans for the balance of 2024, which may include adjusting timelines as circumstances require. The strong data from the recent PK/PD study highlight otenaproxesul’s potential and the priority remains conducting the Phase II trial as soon as possible. More information will be shared as the Company determines the best path forward for all stakeholders.

### **About Antibe Therapeutics Inc.**

Antibe is a clinical-stage biotechnology company leveraging its proprietary hydrogen sulfide platform to develop next-generation therapies to target pain and inflammation arising from a wide range of medical conditions. The Company’s current pipeline includes assets that seek to overcome the gastrointestinal ulcers and bleeding associated with nonsteroidal anti-inflammatory drugs (“NSAIDs”). Antibe’s lead drug, otenaproxesul, is in clinical development as a safer alternative to opioids and today’s NSAIDs for acute pain. Antibe’s second pipeline drug, ATB-352, is being developed for a specialized pain indication. The Company’s next target is inflammatory bowel disease (“IBD”), a condition long in need of safer, more effective therapies. Learn more at [antibetherapeutics.com](https://antibetherapeutics.com).

## **Forward Looking Statements**

This news release includes certain forward-looking statements under applicable securities laws, which may include, but are not limited to, statements concerning the payment of amounts due to Nuance under the arbitral award, the anticipated scope, timing, duration and completion of certain of the Company's pre-clinical and clinical trial programs and studies and the anticipated timing for seeking market approval for certain of the Company's drugs and therapies for certain additional indications. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking, including those identified by the expressions "will", "anticipate", "believe", "plan", "estimate", "expect", "intend", "propose" and similar wording. Forward-looking statements involve known and unknown risks and uncertainties that could cause actual results, performance, or achievements to differ materially from those expressed or implied in this news release. Factors that could cause actual results to differ materially from those anticipated in this news release include, but are not limited to, the Company's inability to timely execute on its business strategy and timely and successfully complete its clinical trials and studies, the Company's inability to obtain the necessary regulatory approvals related to its activities, risks associated with drug development generally and those risk factors set forth in the Company's public filings made in Canada and available on [sedarplus.com](http://sedarplus.com). The Company assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements except as required by applicable law.

## **Contacts**

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This is Exhibit "N" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK



Court File No.

**ONTARIO  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST**

B E T W E E N:

(Court Seal)

**NUANCE PHARMA LTD.**

Applicant

- and -

**ANTIBE THERAPEUTICS INC.**

Respondent

**NOTICE OF APPLICATION**

APPLICATION UNDER Article III of the *Convention on the Recognition and Enforcement of Foreign Arbitral Award*, in Schedule 1 to the *International Commercial Arbitration Act*, S.O. 2017, c. 2, Sched. 5, and Rule 14.05(2)(3)(g)(h) of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194

TO THE RESPONDENTS

A LEGAL PROCEEDING HAS BEEN COMMENCED by the applicant. The claim made by the applicant appears on the following page.

THIS APPLICATION will come on for a hearing (*choose one of the following*)

- In person
- By telephone conference
- By video conference

at the following location

330 University Avenue, Toronto, Ontario M5G 1R8

on .....(day), ..... (date), at .....(time) (or on a day to be set by the registrar).

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application you or an Ontario lawyer acting for you must forthwith prepare a notice of appearance in Form 38A prescribed by the *Rules of Civil Procedure*, serve it on the applicant's lawyer or, where the applicant does not have a lawyer, serve it on the applicant, and file it, with proof of service, in this court office, and you or your lawyer must appear at the hearing.

IF YOU WISH TO PRESENT AFFIDAVIT OR OTHER DOCUMENTARY EVIDENCE TO THE COURT OR TO EXAMINE OR CROSS-EXAMINE WITNESSES ON THE APPLICATION, you or your lawyer must, in addition to serving your notice of appearance, serve a copy of the evidence on the applicant's lawyer or, where the applicant does not have a lawyer, serve it on the applicant, and file it, with proof of service, in the court office where the application is to be heard as soon as possible, but at least four days before the hearing.

IF YOU FAIL TO APPEAR AT THE HEARING, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO OPPOSE THIS APPLICATION BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date \_\_\_\_\_ Issued by \_\_\_\_\_  
Local Registrar

Address of court office: Superior Court of Justice  
330 University Avenue  
Toronto ON M5G 1R8

TO: **ANTIBE THERAPEUTICS INC.**  
15 Prince Arthur Avenue,  
Toronto, Ontario,  
M5R 1B2

## APPLICATION

### A. RELIEF SOUGHT IN THE APPLICATION

1. The applicant, Nuance Pharma Ltd. ("**Nuance**"), makes an application against the respondent, Antibe Therapeutics Inc. ("**Antibe**"), for:

- (a) an order recognizing and making enforceable as a judgment of this Court the arbitral award rendered in the arbitration proceedings, SIAC Arbitration No. 021 of 2022 (the "**Arbitral Award**"), under the auspices of the Singapore International Arbitration Centre ("**SIAC**") by the arbitral tribunal (Ms. Catherine Amirfar, the "**Tribunal**") seated in the Republic of Singapore, dated February 27, 2024, which ordered Antibe to pay to Nuance:
  - (i) US\$ 20 million representing the sum that Nuance had paid to Antibe as upfront payment under the License Agreement ("**License Agreement**") dated February 9, 2021 entered into between the parties;
  - (ii) costs in the sums of SG\$ 153,716.31 and US\$ 1,084,403.74;
  - (iii) pre-award simple interest on the sum at (i) above at the rate of 5.33% per annum, from February 19, 2021 to the date of the Arbitral Award (*i.e.*, February 27, 2024): and
  - (iv) post-award simple interest on any outstanding amounts at the rate of 5.33% per annum, from the date of the Arbitral Award (*i.e.*, February 27, 2024) to the date of full and complete payment.



- (b) An order restraining the Antibe from selling, removing, dissipating, alienating, transferring, assigning, encumbering, or similarly dealing with any of its assets, including, but not limited to, real property, bank accounts, insurance policies, annuities and other assets held by it or any other person or entity on its behalf.
- (c) An order appointing a receiver of all the assets, undertakings and properties of Antibe pursuant to section 101 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;
- (d) the costs of this proceeding, plus all applicable taxes; and
- (e) such further and other relief as to this Honourable Court may seem just.

**B. THE GROUNDS FOR THE APPLICATION ARE:**

**The Parties**

2. Nuance is a Hong-Kong incorporated biopharmaceutical company focused on licensing, developing and commercializing medical therapies in the Greater China region, with its registered address at Unit 417 4/F, Lippo Centre Tower Two, No. 89 Queensway, Admiralty, Hong Kong. Nuance is the 100% subsidiary of Nuance Biotech and the 100% shareholder of Nuance Pharma (Shanghai) Co. Ltd. It is a subsidiary of CBC Group, Asia's largest healthcare-dedicated investment firm.

3. Antibe is a biotech company registered under Ontario's *Business Corporations Act*, R.S.O. 1990, c. B.16, with its registered office located at 15 Prince Arthur Avenue, Toronto, Ontario, M5R 1B2, Canada.

## The License Agreement and the Arbitration Agreement

4. The arbitration arose out of a License Agreement between Nuance and Antibe. Under the License Agreement, Nuance would provide Antibe an upfront payment of US\$ 20 million for an exclusive license to develop and commercialize the drug Otenaproxesul (the "**Drug**") in China, Hong Kong, Macau, and Taiwan.

5. Sometimes referred to as ATB-346, Otenaproxesul is a "hydrogen sulfide releasing version of naproxen," and a kind of nonsteroidal anti-inflammatory drug ("**NSAID**"). A major issue associated with the use of NSAIDs is that they can put stress on the liver, indicated by an elevation of certain enzymes – this is commonly called "liver transaminase elevations" ("**LTEs**"). Moreover, NSAIDs can cause side effects such as gastrointestinal ulcers as well as kidney and liver symptoms.

6. Importantly for Nuance, the development of the Drug was to specifically address primarily and firstly chronic, not acute, pain. NSAIDs related to acute pain are common and the market is saturated; whereas NSAIDs which treat chronic pain are more complex to develop and are lucrative. The Drug's supposed novelty (and commercial potential) lies with its (alleged) enhanced efficacy and safety for long-term (chronic) use as compared to other NSAIDs in the market.

7. The License Agreement also contains an arbitration agreement which requires the parties to submit any dispute arising from the License Agreement to binding arbitration using the arbitration procedures set forth under the international arbitration rules of the SIAC. The Arbitration Agreement permits the parties to disclose the Arbitral Award to the extent required to have it enforced.

8. The License Agreement contained a governing law clause which provided that the agreement would be governed and construed in accordance with the laws of the State of New York.

### **The Underlying Dispute**

9. The facts giving rise to the arbitration are not in dispute and were settled by the Tribunal in the Arbitral Award.

### ***The Parties' Introduction and Due Diligence***

10. The CBC Group connected Nuance and Antibe in September 2020. At the time, Nuance did not have any chronic-use NSAIDs in its portfolio and was looking for opportunities in the chronic pain field. The parties conducted extensive negotiations and due diligence leading to the conclusion of the License Agreement.

11. At the time of parties' initial meetings in the fall of 2020, Antibe had completed Phase 1 and Phase 2 clinical studies of the Drug focused on chronic pain conditions (specifically, its lead indication, osteoarthritis) in Canada. However, because of the COVID-19 pandemic, Antibe believed it was unlikely to be able to start its first planned Phase 3 trial. As a result, Antibe decided to conduct an absorption, metabolism and excretion study ("**AME Study**") in Canada. The AME Study would be a "precursor" to the absorption, distribution, metabolism and excretion study ("**ADME**") which, in addition to Phase 3 trials, was also required for approval.

12. As part of the due diligence leading up to the License Agreement, on January 25, 2021, Antibe opened a Data Room using ShareVault to Nuance. Among other things, the Data Room had a Regulatory category with 15 documents relating to Health Canada. In February 2021, Nuance sent Antibe a list of requests for further information and documents. In response, in

particular, on the AME Study, Antibe stated: "For the Canadian AME study submission is planned for April/May 2021 with study initiation late Q2 2021" and "The Draft AME protocol has been added to ShareVault." As to the timeline for Phase 3, Antibe stated: "Assuming all goes accordingly, Antibe will be in a position to start the initial Phase 3 OA efficacy trial in Q2 2021 and will be on an ambitious timeline to have the NDA submitted in Q4 2024."

13. On February 9, 2021, the parties entered into the License Agreement, and on February 19, 2021, Nuance paid to Antibe the upfront payment of US\$ 20 million.

*Antibe's Communications with Health Canada and the Termination of the License Agreement*

14. In relation to the AME Study, on January 19, 2021, Health Canada wrote to Antibe, seeking additional information and expressing "serious concerns regarding the potential risk of liver related AEs [adverse events]/SAEs [serious adverse events]" in Antibe's Phase 1 study.

15. On January 22, 2021, Antibe met with Health Canada to discuss the AME Study. At the meeting, Health Canada indicated to Antibe that it could not issue a favourable decision for Antibe's application, and offered to allow Antibe to withdraw its application and resubmit or a rejection would be issued. On the same day, Antibe sent a withdrawal letter.

16. After some further communication with Health Canada, Antibe submitted a revised AME Study application with study design changes, which included, among other things, lowering the age limit of the subjects, removal of a higher strength / dose, and formal stopping criteria. The revised AME Study application was approved on June 2, 2021 and began in July 2021. On July 21, 2021, Antibe shared with Nuance the final protocol for the AME study.

17. All such communication and correspondence with Health Canada were not disclosed to Nuance, and (save for the final protocol for the AME study which was provided to Nuance only on July 21, 2021) such information was only produced for the first time through document production in the arbitration.

18. On July 30, 2021, the AME Study hit the stopping criteria, and Antibe paused the AME Study. On August 3, 2021, Antibe issued a press release and emailed Nuance that the AME Study was placed on pause because a pre-specified safety threshold was exceeded.

19. A few months after the AME Study was paused, without consulting Nuance, Antibe decided to "pivot" the use of the Drug to treat acute pain.

20. On September 5, 2021, Nuance informed Antibe that it was terminating the License Agreement and demanded an immediate refund of the US\$ 20 million as well as demanding US\$ 10 million in damages.

21. Following Nuance's demand for repayment, Nuance filed its Notice of Arbitration in January 2022. Nuance alleged, among other things, fraudulent misrepresentation.<sup>1</sup>

### **Findings in the Arbitration**

22. The Tribunal found Antibe made material misrepresentations and/or omissions leading up to the License Agreement. Specifically, it found that Health Canada's "serious concerns" expressed

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<sup>1</sup> Nuance also alleged fraudulent concealment, breach of the License Agreement, unilateral mistake, and fraudulent concealment/fraudulent or negligent misrepresentations post-License Agreement. However, the Tribunal did not address these claims after it found for Nuance on its claim for fraudulent misrepresentation.

in January 2021 in the context of the AME Study were material and significant and were intentionally not disclosed to Nuance until the arbitration proceeding commenced.

23. Moreover, the Tribunal also found that the parties contemplated that Nuance would in-license the Drug in China by building on the Drug's development process in the United States and Canada, and thus complete and up-to-date regulatory information was a material consideration in entering into the Licensing Agreement.

24. The Tribunal found that Antibe also acted with the requisite fraudulent intent with respect to the above misrepresentations and omissions involving the correspondence and discussions with Health Canada.

25. Specifically, in responding to questions from Nuance leading up to the License Agreement, the Tribunal found that Antibe omitted its correspondence with Health Canada with respect to the AME Study and deliberately chose to show Nuance the version of the AME Study that had already been withdrawn. The Tribunal found that Antibe's responses "can only be characterized as being so incomplete as to be affirmatively and deliberately misleading, evincing conscious misbehavior and recklessness, rather than an intent to be truthful or honest."

26. Notably, the Tribunal found that Antibe's Chief Executive Officer, Mr. Daniel Legault ("**Mr. Legault**"), was one of the senior executives who attended the meeting with Health Canada and throughout had "direct knowledge of the events that resulted in Antibe withdrawing the AME Protocol to prevent receiving an official rejection from Health Canada." At the same time, Mr. Legault played a key role in the due diligence process and specifically reviewed the response Antibe sent to Nuance with respect to the AME Study.

27. The Tribunal also found that on July 30, 2021, the AME Study hit the stopping criteria and Antibe paused the AME Study and “fundamentally pivoted the development of the Drug towards an indication for acute (vs. chronic) pain”.

28. As for Antibe’s motive, the Tribunal determined that Antibe had deceived Nuance to enter into the License Agreement in order to secure the necessary funding for the Drug’s continued development, considering Antibe’s admission that the development of the Drug could not go forward without Nuance’s US\$ 20 million upfront payment. The Tribunal also recognised the significance to Nuance of the Drug’s potential indication for chronic (vs. acute) pain and the Drug’s development timeline in that regard as understood by Nuance when it signed the License Agreement.

### **The Arbitral Award**

29. On February 27, 2024, the Tribunal rendered the Arbitral Award in favour of Nuance.

30. In the Arbitral Award, the Tribunal, having canvassed the facts and analyzed the parties' legal arguments, concluded that Antibe fraudulently misrepresented and concealed material facts to induce Nuance to enter into the Licence Agreement.

31. As a result, the Tribunal declared that Nuance had validly rescinded the License Agreement on the basis of Antibe's fraudulent inducement.

32. The Tribunal ordered Antibe to:

- (a) pay Nuance US\$ 20 million, representing the sum that Nuance had paid to Antibe as upfront payment under the License Agreement, plus pre-award simple interest

on this sum at the rate of 5.33% per annum, from February 19, 2021 to the date of the Arbitral Award;

- (b) pay Nuance SG\$ 153,716.31 as reimbursement for the costs of the arbitration;
- (c) pay Nuance US\$ 1,025,374.12 as the legal fees of Nuance in the arbitration; US\$ 43,745.02 as the disbursements of Nuance in the arbitration; US\$ 6,885.21 in transcription charges paid for by Nuance; as well as US\$ 8,399.39 in charges for hearing rooms at Maxwell Chambers, paid for by Nuance;
- (d) pay Nuance, if Antibe fails to pay full within 7 business days the amounts in paragraphs (a), (b), and (c), simple post-award interest on any outstanding amounts at the rate of 5.33% per annum, from the date of the Arbitral Award to the date of full and complete payment.

### **Recognition and Enforcement of the Arbitral Award**

33. The Arbitral Award is final and binding.

34. Article 32.11 of the SIAC Rules provides:

Subject to Rule 33 and Schedule 1, by agreeing to arbitration under these Rules, the parties agree that any Award shall be final and binding on the parties from the date it is made, and undertake to carry out the Award immediately and without delay. The parties also irrevocably waive their rights to any form of appeal, review or recourse to any State court or other judicial authority with respect to such Award insofar as such waiver may be validly made.

35. In an announcement on March 4, 2024, Antibe confirmed that it will not be challenging the Arbitral Award.



36. However, notwithstanding its obligation to pay the Arbitral Award, Antibe has failed to pay the amounts awarded to Nuance.

37. Nuance seeks the recognition and enforcement of the Arbitral Award by this Court as against Antibe.

38. Section 2(1) of the *International Commercial Arbitration Act, 2017*, S.O. 2017, c. 2, Sched. 5 provides that the *Convention on the Recognition and Enforcement of Foreign Arbitral Award* (the “**Convention**”) has force of law in Ontario.

39. Article V of the Convention enumerates the limited circumstances where recognition and enforcement of an international arbitral award such as the Arbitral Award may be refused. None of those limited circumstances apply in this case.

40. There is no basis on which Antibe could credibly resist recognition and enforcement of the Arbitral Award. Under the Convention, the Arbitral Award must therefore be recognized and made enforceable as a judgment of this Court.

### **Asset Preservation**

41. Nuance has established a strong *prima facie* case against Antibe. Absent the limited circumstances which an international arbitral award may be refused (of which there are none in this case), the Arbitral Award must be recognized and enforced.

42. As the Tribunal had found, Nuance was fraudulently induced by Antibe to invest US\$ 20 million to develop the Drug to treat chronic pain, without which, as Mr. Legault confirmed, Antibe would "not be able to develop and commercialize the Drug." However, following the pause of the

AME Study, Antibe decided to "pivot" the use of the Drug to treat acute pain. This was done without notice to or consultation with Nuance, and was likely done to circumvent the negative findings of Health Canada, which were fraudulently misrepresented to and withheld from Nuance.

43. The Arbitral Award confirms that the License Agreement was validly rescinded by Nuance in September 2021 and the sum of at least US\$ 20 million representing Nuance's upfront payment paid thereunder have since then been Nuance's (not Antibe's) monies. Accordingly, Antibe should not be permitted to (continue to) spend Nuance's monies for Antibe's expenses / *own* purposes of funding the Drug's development in acute (vs. chronic) pain, much less for an indication which (as the Tribunal found) Nuance never agreed to as a primary and foremost indication.

44. To compound matters, based on a number of public disclosures, Antibe is in a deteriorating financial position and the current assets held by Antibe (including Nuance's investment) are already insufficient to pay Nuance's entitlement under the Arbitral Award. Added to this, it has stated its intention to continue to diminish Nuance's invested funds and at an even faster rate. Specifically:

- (a) In its March 4, 2024 public announcement, Antibe confirmed that it plans to move forward with conducting the Drug's Phase 2 trial for acute pain as soon as possible. This will cause Antibe to ramp up spending.
- (b) Antibe now proposes to use Nuance's remaining investment to test a speculative version of the Drug that can no longer be used to address chronic pain, only acute pain. This is not the type of drug Nuance agreed to finance under the License Agreement, as the Tribunal found.

- (c) The above was confirmed by Antibe to Nuance even more recently. In response to Nuance's demands for payment pursuant to the Arbitral Award made on March 1<sup>st</sup> and 13<sup>th</sup>, 2024, Antibe's representatives informed Nuance's founder and CEO, Mr. Mark Lotter, during a call on March 18, 2024 that Antibe does not have sufficient cash to satisfy the Arbitral Award in full and instead proposed that parties explore alternative options. Yet, and notwithstanding its precarious financial position and non-compliance with the Arbitral Award, Antibe was determined to go ahead with the Drug's Phase 2 study in acute pain and have in fact started recruiting subjects for the study which will accelerate its unjustified use of Nuance's monies.

45. Unless Nuance obtains urgent injunctive relief, there is a real risk that its monies/investment or in any case any remaining assets held by Antibe will be dissipated in this speculative venture that is no longer focused on what was represented to Nuance and what Nuance agreed to invest in (which the Tribunal has thus determined to be rescinded). The only way for Nuance to prevent the dissipation of Nuance's (or in any case Antibe's remaining) funds is to restrain Antibe from selling, assigning, transferring or encumbering assets held by Antibe.

46. Nuance will suffer irreparable harm unless injunctive relief is obtained. Antibe continues to dissipate Nuance's investment, and, if the assets held by Antibe (including Nuance's remaining investment) are not preserved for the purposes of execution, there will be no way for Nuance to collect on the Arbitral Award.

47. The balance of convenience favours Nuance. Antibe's fraudulent conduct coupled with Nuance's right to recover its monies / investment (or in any case the Arbitral Award) being in

serious jeopardy supports the need for the preservation of assets held by Antibe. Therefore, in all of the circumstances, it is just and equitable for this Honourable Court to grant the order requested.

48. Nuance has provided an undertaking regarding damages.

49. Despite Nuance's repeated demands for payment and Antibe confirming that it will not challenge the Arbitral Award and will accept it "in good faith," Antibe has not complied with the Arbitral Award and intends to continue to deplete the funds it fraudulently obtained from Nuance to develop the Drug for a purpose Nuance did not agree to.

50. The Applicant therefore asks this Honourable Court to grant the order requested.

#### **Other Grounds**

51. There are unlikely to be any material facts in dispute.

52. Rules 1.04, 14.05(2), 14.05(3)(h), 38, 39, 40, 41, and 57 of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 194.

53. Sections 2-3 of the *International Commercial Arbitration Act*, S.O. 2017, c. 2, Sched. 5.

54. Article III of the *Convention on the Recognition and Enforcement of Foreign Arbitral Award*, in Schedule 1 to the *International Commercial Arbitration Act*, S.O. 2017, c. 2, Sched. 5.

55. Sections 101, 121 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43.

56. Such further and other grounds as counsel may advise.

**THE FOLLOWING DOCUMENTARY EVIDENCE** will be used at the hearing of the application:

57. The Affidavit of Mark Lotter, to be sworn.
  
58. Such further and other evidence as counsel may advise and this Court may permit.

March 25, 2024

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Lawyers for the Applicant

Applicant

-and-

ANIBSE THERAPEUTICS INC.

Respondent

Court File No.

*ONTARIO*  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST

PROCEEDING COMMENCED AT  
TORONTO

**NOTICE OF APPLICATION**

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Toronto ON M5X 1A4

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Telephone: 416.777.6121

Lawyers for the Applicant

This is Exhibit "O" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

**From:** [kartiga.thavaraj@paliareroland.com](mailto:kartiga.thavaraj@paliareroland.com)  
**To:** [Lincoln Caylor](#); [Jesse Mighton](#); [Alexander Payne](#); [Sidney Brejak](#)  
**Cc:** [Ken.Rosenberg@paliareroland.com](mailto:Ken.Rosenberg@paliareroland.com); [Max.Starnino@paliareroland.com](mailto:Max.Starnino@paliareroland.com); [kartiga.thavaraj@paliareroland.com](mailto:kartiga.thavaraj@paliareroland.com); [Evan.Snyder@paliareroland.com](mailto:Evan.Snyder@paliareroland.com); [esellers@blackswanadvisors.ca](mailto:esellers@blackswanadvisors.ca); [nmeakin@deloitte.ca](mailto:nmeakin@deloitte.ca); [evan.cobb@nortonrosefulbright.com](mailto:evan.cobb@nortonrosefulbright.com); [mmuslin@deloitte.ca](mailto:mmuslin@deloitte.ca)  
**Subject:** Antibe v Nuance - CCAA Proceedings [IWOV-PRiManage.FID411465]  
**Date:** Tuesday, April 9, 2024 2:13:21 AM  
**Attachments:** [image001.png](#)  
[APPLICATION RECORD - APPLICANT - ANTIBE - 08-APR-2024.pdf.pdf](#)

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Counsel,

Please find attached the Application Record of Antibe Therapeutics Inc.

We will be uploading this record shortly to the bundle in Caselines for the case conference scheduled for tomorrow morning in court file number No. CV-24-00717410-00CL.

The issued Notice of Application will follow tomorrow morning.

Kind regards,  
Kartiga



**Roland**

**Paliare**

**Kartiga Thavaraj (she)**  
Associate  
**Phone:** (647) 327-4550  
**Email:** [kartiga.thavaraj@paliareroland.com](mailto:kartiga.thavaraj@paliareroland.com)  
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This is Exhibit "P" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

---

Commissioner for Taking Affidavits  
SIDNEY BREJAK



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April 9, 2024

Via Email ([ken.rosenberg@paliareroland.com](mailto:ken.rosenberg@paliareroland.com); [nmeakin@deloitte.ca](mailto:nmeakin@deloitte.ca))

**Paliare Roland Rosenberg Rothstein LLP**  
155 Wellington Street West  
35th Floor  
Toronto, Ontario  
M5V 3H1

**Deloitte Restructuring Inc.**  
8 Adelaide Street West  
Suite 200  
Toronto, Ontario  
M5H 0A9

Dear Messrs. Rosenberg and Meakin:

**Re: *Nuance Pharma Ltd. v. Antibe Therapeutics Inc.*, Court File No. CV-24-00717410-00CL**  
***Re: Antibe Therapeutics Inc. (Unissued)***

As you are aware, we are the lawyers for Nuance Pharma Ltd. We write to request the following information. Given the developments this morning, we request that it be provided on an urgent basis.

- (a) Black Swan's qualifications as CRO and its relevant experience in pharmaceutical industry turnarounds;
- (b) account information for all Antibe accounts from the time of receipt of the Nuance US\$20 million payment to present;
- (c) a soft copy of Antibe's cash flow forecast model with backup relating to all underlying assumptions;
- (d) the particulars of any cost reduction measures that have been implemented to-date or are intended to be implemented during the *CCAA* period; and
- (e) details of all ordinary business expenses anticipated to be incurred by Antibe from today's date until April 18, 2024.

We look forward to hearing from you as soon as possible.

Yours truly,

Jesse Mighton

cc: Lincoln Caylor, Alexander Payne & Sidney Brejak, Bennett Jones LLP; Evan Cobb, Norton Rose Fulbright LLP

This is Exhibit "Q" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

# Canadian Investment Regulatory Organization Trading Halt - ATE Français

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NEWS PROVIDED BY

**Canadian Investment Regulatory Organization (CIRO) - Halts/Resumptions →**

Apr 09, 2024, 09:42 ET

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TORONTO, April 9, 2024 /CNW/ - The following issues have been halted by CIRO:

Company: Antibe Therapeutics Inc.

TSX Symbol: ATE

All Issues: Yes

Reason: Dissemination

Halt Time (ET): 9:15 AM

CIRO can make a decision to impose a temporary suspension (halt) of trading in a security of a publicly-listed company. Trading halts are implemented to ensure a fair and orderly market. CIRO is the national self-regulatory organization which oversees all investment dealers and trading activity on debt and equity marketplaces in Canada.

SOURCE Canadian Investment Regulatory Organization (CIRO) - Halts/Resumptions



For further information: For further information about CISO's trading halt policy, please see Trading Halts & Timely Disclosure at [www.iiroc.ca](http://www.iiroc.ca) under the Markets tab. Please note that CISO staff cannot provide any information about a specific halt beyond what is contained in this halt notice. For general information about CISO, contact CISO's Complaints & Inquiries team by submitting a Secure Form located on our contact page at [www.iiroc.ca](http://www.iiroc.ca) or dialing 1-877-442-4322 (Option 1). For company-related enquiries, please contact the company directly.

This is Exhibit "R" referred to in the Affidavit of Mark Lotter sworn before me on April 15, 2024 in accordance with *O. Reg. 431/20*, Administering Oath or Declaration Remotely.

*Sidney Brejak*

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Commissioner for Taking Affidavits  
SIDNEY BREJAK

**IN THE MATTER OF THE COMPANIES' CREDITORS  
ARRANGEMENT ACT, R.S.C. 1985, c.C-36 AS AMENDED  
AND IN THE MATTER OF A PROPOSED PLAN OF  
COMPROMISE OR ARRANGEMENT OF ANTIBE THERAPEUTICS INC.**

**List of Creditors**

1. The attached list of creditors with claims greater than \$1,000 was prepared based on information available from the books and records of Antibe Therapeutics Inc. as at April 9, 2024.
2. This list is provided pursuant to section 23(1)(a) of the CCAA and the regulations made thereunder. This list of creditors has been prepared without admission as to the liability for, or the quantum of, any of the amounts shown.
3. Creditors are not required to submit a proof of claim at this time.
4. Amounts in US Dollars have been converted into Canadian Dollar at an exchange rate of US\$1.00:CAD1.35.
5. Amounts due certain creditors are not known at this time. Accordingly, a \$1 placeholder amount is reported herein.

<b>Creditor Name</b>	<b>Address</b>	<b>City</b>	<b>Province/Region</b>	<b>Postal Code</b>	<b>Country</b>	<b>Amount (SCAD)</b>
<b>Unsecured Creditors</b>						
14130855 Canada (Wallace, John)	Private	Toronto	ON	M5S 2W7	Canada	\$ 22,600
Allele Capital Partners	275 Commercial Blvd, Suite 333	Lauderdale by the Sea	FL	33308	USA	\$ 3,396
Allele Communications	275 Commercial Blvd, Suite 333	Lauderdale by the Sea	FL	33308	USA	\$ 6,791
Axiom Real-Time Metrics	5205 Satellite Drive	Mississauga	ON	L4W 5P9	Canada	\$ 50,973
BCS Statistical Solutions	Private	Delray Beach	FL	33483	USA	\$ 19,791
Bell Canada	1 Carrefour Alexander-Graham-Bell Building A, 4th Floor	Verdun	QC	H3E 3B3	Canada	\$ 1,157
Bhito Integrated Solutions	Private	Toronto	ON	M4S 1G7	Canada	\$ 1,752
Bloom Burton Securities Inc.	181 Bay St. Suite 3410	Toronto	ON	M5J 2T3	Canada	\$ 33,900
BND Projects	Private	Unionville	ON	L3R 6M2	Canada	\$ 21,656
Business Wire	144 Front Street West, STE 340	Toronto	ON	M5J 2L7	Canada	\$ 5,933
Caligor Opco LLC (CalCog)	1500 Business Park Drive, Unit B	Bastrop	TX	78602	USA	\$ 4,755
CDM Canada Ltd.	Private	Innisfil	ON	L9S 4X3	Canada	\$ 11,300
Charles River CANADA	22022 Transcanadienne	Senneville	QC	H9X 3R3	Canada	\$ 10,399
Computershare	100 University Ave, 11th Floor, South Tower	Toronto	ON	M5J 2Y1	Canada	\$ 8,426
Corealis Pharma	200 Armand-Frappier Blvd.	Laval	QC	H7V 4A6	Canada	\$ 1
CSC	251 Little Falls Drive	Wilmington	DE	19808-1674	USA	\$ 1
Deloitte Restructuring	8 Adelaide Street West, Suite 200	Toronto	ON	M5H 0A9	Canada	\$ 1
Digby, Thomas J.	Private	Vancouver	BC	V6R 2P7	Canada	\$ 2,958
DILisym Services	6 David Drive, P.O. Box 12317	Research Triangle Park	NC	27709-2137	USA	\$ 49,705
Directors	-	-	-	-	USA	\$ 1
DLA Piper	One Liberty Place 1650 Market Street, Suite 5000	Philadelphia	PA	19103-7301	USA	\$ 20,325
EKS Business Development	Private	Toronto	ON	M5N 2K5	Canada	\$ 10,819
Elegen Group	Private	Toronto	ON	M5M 1T1	Canada	\$ 14,634
Employees	-	-	-	-	USA	\$ 1
Ernst & Young	P.O. Box 57104, Postal Station A	Toronto	ON	M5W 5M5	Canada	\$ 171,280
FG Pharma	Private	Boucherville	QC	J4B 0C1	Canada	\$ 13,560
Fifteen Prince Arthur	15 Prince Arthur Ave	Toronto	ON	M5R 1B2	Canada	\$ 19,026
Florida Division of Taxation	-	-	-	-	USA	\$ 1
Forney, Mark	Private	Torrance	CA	90505	USA	\$ 2,716
Garland, Anthony	Private	Porto	-	4000-212	Portugal	\$ 16,097
Gowling WLG	160 Elgin Street, Suite 2600	Ottawa	ON	K1P 1C3	Canada	\$ 1
Haut, Donald	Private	Concord	MA	01742	USA	\$ 2,500
Independent Trading Group	33 Yonge St. Suite 420	Toronto	ON	M5E 1G4	Canada	\$ 10,000
Innomar Strategies	3470 Superior Court	Oakville	ON	L6L 0C4	Canada	\$ 13,673
IRS	-	-	-	-	USA	\$ 1
Klick Health	175 Bloor Street East North Tower, Suite 301	Toronto	ON	M4W 3R8	Canada	\$ 15,255
Lonza Bend	1201 NW Wall Street, Suite 200	Bend	OR	97703	USA	\$ 544,246
Lonza Nansha	Muncheinsteinerstrasse 38	Basel	-	CH-4002	Switzerland	\$ 53,575
Lonza Tampa	4910 Savarese Cir	Tampa	FL	33634	USA	\$ 20,555
Lotus Clinical Research	430 Mountain Avenue, Suite 302	New Providence	NJ	07974	USA	\$ 3,737,737
Minister of Finance - ON	-	-	-	-	USA	\$ 1
Monnet, Dominique P.	Private	Incline Village	NV	89451	USA	\$ 6,000
National Institute of Oncology (Budapest)	1122 Budapest Rath Gyorgy u. 7-9	Budapest	-	-	Hungary	\$ 28,515
Nucro-Techmics	2000 Ellesmere Road, Unit 16	Scarborough	ON	M1H 2W4	Canada	\$ 50,937
Oklohoma Division of Taxation	-	-	-	-	USA	\$ 1
Paliare Roland	155 Wellington Street West, 35th Floor	Toronto	ON	M5V 3H1	Canada	\$ 63,020
Passageways	8 N 3rd St., Suite 101	Lafayette	IN	47901	USA	\$ 7,950
Patheon (Thermo Fisher)	6173 E Old Marion Highway	Florence	SC	29506-9330	USA	\$ 1,181,567
Pharma Medica	6100 Belgrave Rd	Mississauga	ON	L5R 0B7	Canada	\$ 80,726
PharmaWrite	152 Wall Street	Princeton	NJ	08540	USA	\$ 1
Powell, Andrew	Private	San Francisco	CA	94109	USA	\$ 2,500
ProPharma Group	1129 Twentieth St, NW, Suite 600	Washington	DC	20036	USA	\$ 146,277
R. P. Chiaochierini Consulting	Private	Gaithersburg	MD	20878	USA	\$ 1,664
Receiver General (CRA)	-	-	-	-	USA	\$ 1
Russell, Angus	Private	Ormond Beach	FL	32176	USA	\$ 2,500
Scendea	Ground Floor, 20 The Causeway	Bishop's Stortford	Hertfordshire	CM23 2EJ	UK	\$ 2,698
Stern, Charlotte	Private	Toronto	ON	M8Y 3N9	Canada	\$ 1
Stonehedge Pharma	Private	Mount Airy	MD	21771	USA	\$ 8,037
Summit Analytical	8354 E Northfield Blvd	Denver	CO	80238	USA	\$ 23,683
Taylor, Jared	Private	Toronto	ON	M6P 3A6	Canada	\$ 1
Toronto Stock Exchange (TSX)	300 - 100 Adelaide St. West	Toronto	ON	M5H 1S3	Canada	\$ 20,755
Troutman Pepper	222 Central Park Avenue, Suite 2000	Virginia Beach	VA	23462	USA	\$ 15,641
Uppsala Monitoring Centre	Box 1051	Uppsala	-	75140	Sweden	\$ 14,738
Vaughan, David	Private	Pickering	ON	L1V 1E5	Canada	\$ 33,123
WeirFoulds	4100 - 66 Wellington Street West PO Box 35 Toronto-Dominion	Toronto	ON	M5K 1B7	Canada	\$ 72,564
Wu, Christopher	Private	New York	NY	10021	USA	\$ 12,228
<b>Total</b>						<b>\$ 6,696,626</b>

# TAB 3



**ONTARIO  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST**

IN THE MATTER OF THE *COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985,  
c. C-36, AS AMENDED

AND IN THE MATTER OF THE COMPROMISE OR ARRANGEMENT OF  
ANTIBE THERAPEUTICS INC.

**CONSENT TO ACT AS RECEIVER**

**FTI CONSULTING CANADA INC.** hereby consents to act as the receiver and manager, without security, of the present and after-acquired assets, undertakings, and properties of Antibe Therapeutics Inc. pursuant to the terms of the proposed order substantially in the form requested in the Respondent's Application Record and section 101 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended.

Dated at Toronto, Ontario this 15<sup>th</sup> day of April, 2024

**FTI CONSULTING CANADA INC.**

Per: 

Name: Jim Robinson

Title: Senior Managing Director

# TAB 4

Court File No.

ONTARIO  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST

THE HONOURABLE ) ~~WEEKDAY~~THURSDAY, THE #18th  
JUSTICE — OSBORNE ) DAY OF ~~MONTH~~APRIL, ~~20YR~~2024

~~PLAINTIFF~~<sup>†</sup>

~~Plaintiff~~

NUANCE PHARMA LTD.

Applicant

- and -

~~DEFENDANT~~

~~Defendant~~

ANTIBE THERAPEUTICS INC.

Respondent

**ORDER**  
(appointing Receiver)

~~†—The Model Order Subcommittee notes that a receivership proceeding may be commenced by action or by application. This model order is drafted on the basis that the receivership proceeding is commenced by way of an action.~~

THIS MOTION made by the ~~Plaintiff~~<sup>2</sup> Applicant for an Order pursuant to ~~section 243(1) of the Bankruptcy and Insolvency Act, R.S.C. 1985, c. B-3, as amended (the "BIA") and~~ section 101 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended (the "CJA") appointing ~~[RECEIVER'S NAME]~~ FTI Consulting Inc. ("FTI") as receiver ~~{and manager}~~ (in such capacities, the "Receiver") without security, of all of the assets, undertakings and properties of ~~[DEBTOR'S NAME]~~ Antibe Therapeutics Inc. (the "Debtor") acquired for, or used in relation to a business carried on by the Debtor, was heard this day at 330 University Avenue, Toronto, Ontario.

ON READING the affidavits of ~~[NAME]~~ Mark Lotter sworn ~~[DATE]~~ March 28 and April [●], 2024 (collectively, the "Lotter Affidavits") and the Exhibits thereto, ~~[●]~~, and on hearing the submissions of counsel for ~~[NAMES]~~ the Applicant, the Respondent, the Receiver and Deloitte Restructuring Inc. in its capacity as court-appointed monitor of the Respondent, no one appearing ~~for [NAME]~~ although duly served as appears from the affidavit of service of ~~[NAME ●]~~ sworn ~~[DATE ●]~~ and on reading the consent of ~~[RECEIVER'S NAME]~~ FTI to act as the Receiver,

## SERVICE AND DEFINITIONS

1. THIS COURT ORDERS that the time for service of the Notice of ~~Motion~~ Cross-Application and the ~~Motion~~ Cross-Application is hereby abridged and validated<sup>3</sup> so that this ~~motion~~ Cross-Application is properly returnable today and hereby dispenses with further service thereof.

2. THIS COURT ORDERS that capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Lotter Affidavits.

## APPOINTMENT

<sup>2</sup> ~~Section 243(1) of the BIA provides that the Court may appoint a receiver "on application by a secured creditor".~~

<sup>3</sup> ~~If service is effected in a manner other than as authorized by the Ontario Rules of Civil Procedure, an order validating irregular service is required pursuant to Rule 16.08 of the Rules of Civil Procedure and may be granted in appropriate circumstances.~~

3. ~~2.~~ **THIS COURT ORDERS** that pursuant to section ~~243(1) of the BIA and section~~ 101 of the CJA, ~~[RECEIVER'S NAME]~~FTI is hereby appointed Receiver, without security, of all of the assets, undertakings and properties of the Debtor acquired for, or used in relation to a business carried on by the Debtor, including all proceeds thereof (the "**Property**").

**DECLARATION OF TRUST, RECOGNITION OF ARBITRAL AWARD**

4. **THIS COURT ORDERS AND DECLARES that the arbitral award dated February 27, 2024 rendered in the arbitration proceedings SIAC Arbitration No. 021 of 2022 under the auspices of the Singapore International Arbitration Centre by the arbitral tribunal seated in the Republic of Singapore (the "Arbitral Award") be and is hereby recognized as a judgment of this Court.**

5. **THIS COURT DECLARES that as of September 5, 2021, the Debtor held US\$20,000,000 (the "Investment Payment Amount") in funds in trust for Nuance Therapeutics Ltd. ("Nuance").**

6. **THIS COURT DELCARES that the Debtor held approximately CAD\$19,600,000 in funds in trust for Nuance as of April 8, 2024.**

7. **THIS COURT DELCARES that Nuance be and is hereby authorized and entitled to trace or follow any proceeds of the Investment Payment Amount and other amounts Nuance is entitled to be paid pursuant to the Arbitral Award into any assets, funds, effects and property currently held by the Debtor or to which the Debtor main come into possession to in the future.**

**RECEIVER'S POWERS**

8. ~~3.~~ **THIS COURT ORDERS** that the Receiver is hereby empowered and authorized, but not obligated, to act at once in respect of the Property and, without in any way limiting the generality of the foregoing, the Receiver is hereby expressly empowered and authorized to do any of the following where the Receiver considers it necessary or desirable:

- (a) to take possession of and exercise control over the Property and any and all proceeds, receipts and disbursements arising out of or from the Property;
- (b) to receive, preserve, and protect the Property, or any part or parts thereof, including, but not limited to, the changing of locks and security codes, the relocating of Property to safeguard it, the engaging of independent security personnel, the taking of physical inventories and the placement of such insurance coverage as may be necessary or desirable;
- (c) to manage, operate, and carry on the business of the Debtor, including the powers to enter into any agreements, incur any obligations in the ordinary course of business, cease to carry on all or any part of the business, or cease to perform any contracts of the Debtor;
- (d) to engage consultants, appraisers, agents, experts, auditors, accountants, managers, counsel and such other persons from time to time and on whatever basis, including on a temporary basis, to assist with the exercise of the Receiver's powers and duties, including without limitation those conferred by this Order;
- (e) to purchase or lease such machinery, equipment, inventories, supplies, premises or other assets to continue the business of the Debtor or any part or parts thereof;
- (f) to receive and collect all monies and accounts now owed or hereafter owing to the Debtor and to exercise all remedies of the Debtor in collecting such monies, including, without limitation, to enforce any security held by the Debtor;
- (g) to settle, extend or compromise any indebtedness owing to the Debtor;

- (h) to execute, assign, issue and endorse documents of whatever nature in respect of any of the Property, whether in the Receiver's name or in the name and on behalf of the Debtor, for any purpose pursuant to this Order;
- (i) to initiate, prosecute and continue the prosecution of any and all proceedings and to defend all proceedings now pending or hereafter instituted with respect to the Debtor, the Property or the Receiver, and to settle or compromise any such proceedings.<sup>4</sup> The authority hereby conveyed shall extend to such appeals or applications for judicial review in respect of any order or judgment pronounced in any such proceeding;
- (j) to market any or all of the Property, including advertising and soliciting offers in respect of the Property or any part or parts thereof and negotiating such terms and conditions of sale as the Receiver in its discretion may deem appropriate;
- (k) to sell, convey, transfer, lease or assign the Property or any part or parts thereof out of the ordinary course of business,
  - (i) without the approval of this Court in respect of any transaction not exceeding \$~~\_\_\_\_\_~~[250,000], provided that the aggregate consideration for all such transactions does not exceed \$~~\_\_\_\_\_~~[1,000,000]; and
  - (ii) with the approval of this Court in respect of any transaction in which the purchase price or the aggregate purchase price exceeds the applicable amount set out in the preceding clause;

~~<sup>4</sup> This model order does not include specific authority permitting the Receiver to either file an assignment in bankruptcy on behalf of the Debtor, or to consent to the making of a bankruptcy order against the Debtor. A bankruptcy may have the effect of altering the priorities among creditors, and therefore the specific authority of the Court should be sought if the Receiver wishes to take one of these steps.~~

and in each such case notice under subsection 63(4) of the Ontario *Personal Property Security Act*, ~~[for section 31 of the Ontario *Mortgages Act*, as the case may be,]<sup>5</sup> shall not be required, and in each case the *Ontario Bulk Sales Act* shall not apply.~~

- (l) to apply for any vesting order or other orders necessary to convey the Property or any part or parts thereof to a purchaser or purchasers thereof, free and clear of any liens or encumbrances affecting such Property;
- (m) to report to, meet with and discuss with such affected Persons (as defined below) as the Receiver deems appropriate on all matters relating to the Property and the receivership, and to share information, subject to such terms as to confidentiality as the Receiver deems advisable;
- (n) to register a copy of this Order and any other Orders in respect of the Property against title to any of the Property;
- (o) to apply for any permits, licences, approvals or permissions as may be required by any governmental authority and any renewals thereof for and on behalf of and, if thought desirable by the Receiver, in the name of the Debtor;
- (p) to enter into agreements with any trustee in bankruptcy appointed in respect of the Debtor, including, without limiting the generality of the foregoing, the ability to enter into occupation agreements for any property owned or leased by the Debtor;
- (q) to exercise any shareholder, partnership, joint venture or other rights which the Debtor may have; and

~~<sup>5</sup> If the Receiver will be dealing with assets in other provinces, consider adding references to applicable statutes in other provinces. If this is done, those statutes must be reviewed to ensure that the Receiver is exempt from or can be exempted from such notice periods, and further that the Ontario Court has the jurisdiction to grant such an exemption.~~



- (r) to take any steps reasonably incidental to the exercise of these powers or the performance of any statutory obligations.

and in each case where the Receiver takes any such actions or steps, it shall be exclusively authorized and empowered to do so, to the exclusion of all other Persons (as defined below), including the Debtor, and without interference from any other Person.

#### **DUTY TO PROVIDE ACCESS AND CO-OPERATION TO THE RECEIVER**

9. ~~4.~~ **THIS COURT ORDERS** that (i) the Debtor, (ii) all of its current and former directors, officers, employees, agents, accountants, legal counsel and shareholders, and all other persons acting on its instructions or behalf, and (iii) all other individuals, firms, corporations, governmental bodies or agencies, or other entities having notice of this Order (all of the foregoing, collectively, being "**Persons**" and each being a "**Person**") shall forthwith advise the Receiver of the existence of any Property in such Person's possession or control, shall grant immediate and continued access to the Property to the Receiver, and shall deliver all such Property to the Receiver upon the Receiver's request.

10. ~~5.~~ **THIS COURT ORDERS** that all Persons shall forthwith advise the Receiver of the existence of any books, documents, securities, contracts, orders, corporate and accounting records, and any other papers, records and information of any kind related to the business or affairs of the Debtor, and any computer programs, computer tapes, computer disks, or other data storage media containing any such information (the foregoing, collectively, the "**Records**") in that Person's possession or control, and shall provide to the Receiver or permit the Receiver to make, retain and take away copies thereof and grant to the Receiver unfettered access to and use of accounting, computer, software and physical facilities relating thereto, provided however that nothing in this paragraph 5 or in paragraph 6 of this Order shall require the delivery of Records, or the granting of access to Records, which may not be disclosed or provided to the Receiver due to the privilege attaching to solicitor-client communication or due to statutory provisions prohibiting such disclosure.

11. ~~6.~~ **THIS COURT ORDERS** that if any Records are stored or otherwise contained on a computer or other electronic system of information storage, whether by independent service

provider or otherwise, all Persons in possession or control of such Records shall forthwith give unfettered access to the Receiver for the purpose of allowing the Receiver to recover and fully copy all of the information contained therein whether by way of printing the information onto paper or making copies of computer disks or such other manner of retrieving and copying the information as the Receiver in its discretion deems expedient, and shall not alter, erase or destroy any Records without the prior written consent of the Receiver. Further, for the purposes of this paragraph, all Persons shall provide the Receiver with all such assistance in gaining immediate access to the information in the Records as the Receiver may in its discretion require including providing the Receiver with instructions on the use of any computer or other system and providing the Receiver with any and all access codes, account names and account numbers that may be required to gain access to the information.

**12.** ~~7.~~ **THIS COURT ORDERS** that the Receiver shall provide each of the relevant landlords with notice of the Receiver's intention to remove any fixtures from any leased premises at least seven (7) days prior to the date of the intended removal. The relevant landlord shall be entitled to have a representative present in the leased premises to observe such removal and, if the landlord disputes the Receiver's entitlement to remove any such fixture under the provisions of the lease, such fixture shall remain on the premises and shall be dealt with as agreed between any applicable secured creditors, such landlord and the Receiver, or by further Order of this Court upon application by the Receiver on at least two (2) days notice to such landlord and any such secured creditors.

**NO PROCEEDINGS AGAINST THE RECEIVER**

**13.** ~~8.~~ **THIS COURT ORDERS** that no proceeding or enforcement process in any court or tribunal (each, a "**Proceeding**"), shall be commenced or continued against the Receiver except with the written consent of the Receiver or with leave of this Court.

**NO PROCEEDINGS AGAINST THE DEBTOR OR THE PROPERTY**

**14.** ~~9.~~ **THIS COURT ORDERS** that no Proceeding against or in respect of the Debtor or the Property shall be commenced or continued except with the written consent of the Receiver or

with leave of this Court and any and all Proceedings currently under way against or in respect of the Debtor or the Property are hereby stayed and suspended pending further Order of this Court.

**NO EXERCISE OF RIGHTS OR REMEDIES**

15. ~~10.~~ **THIS COURT ORDERS** that all rights and remedies against the Debtor, the Receiver, or affecting the Property, are hereby stayed and suspended except with the written consent of the Receiver or leave of this Court, provided however that this stay and suspension does not apply in respect of any "eligible financial contract" as defined in the BIA, and further provided that nothing in this paragraph shall (i) empower the Receiver or the Debtor to carry on any business which the Debtor is not lawfully entitled to carry on, (ii) exempt the Receiver or the Debtor from compliance with statutory or regulatory provisions relating to health, safety or the environment, (iii) prevent the filing of any registration to preserve or perfect a security interest, or (iv) prevent the registration of a claim for lien.

**NO INTERFERENCE WITH THE RECEIVER**

16. ~~11.~~ **THIS COURT ORDERS** that no Person shall discontinue, fail to honour, alter, interfere with, repudiate, terminate or cease to perform any right, renewal right, contract, agreement, licence or permit in favour of or held by the Debtor, without written consent of the Receiver or leave of this Court.

**CONTINUATION OF SERVICES**

17. ~~12.~~ **THIS COURT ORDERS** that all Persons having oral or written agreements with the Debtor or statutory or regulatory mandates for the supply of goods and/or services, including without limitation, all computer software, communication and other data services, centralized banking services, payroll services, insurance, transportation services, utility or other services to the Debtor are hereby restrained until further Order of this Court from discontinuing, altering, interfering with or terminating the supply of such goods or services as may be required by the Receiver, and that the Receiver shall be entitled to the continued use of the Debtor's current telephone numbers, facsimile numbers, internet addresses and domain names, provided in each case that the normal prices or charges for all such goods or services received after the date of this Order are paid by the Receiver in accordance with normal payment practices of the Debtor or

such other practices as may be agreed upon by the supplier or service provider and the Receiver, or as may be ordered by this Court.

### RECEIVER TO HOLD FUNDS

18. ~~13.~~ **THIS COURT ORDERS** that all funds, monies, cheques, instruments, and other forms of payments received or collected by the Receiver from and after the making of this Order from any source whatsoever, including without limitation the sale of all or any of the Property and the collection of any accounts receivable in whole or in part, whether in existence on the date of this Order or hereafter coming into existence, shall be deposited into one or more new accounts to be opened by the Receiver (the "Post Receivership Accounts") and the monies standing to the credit of such Post Receivership Accounts from time to time, net of any disbursements provided for herein, shall be held by the Receiver to be paid in accordance with the terms of this Order or any further Order of this Court.

### EMPLOYEES

19. ~~14.~~ **THIS COURT ORDERS** that all employees of the Debtor shall remain the employees of the Debtor until such time as the Receiver, on the Debtor's behalf, may terminate the employment of such employees. The Receiver shall not be liable for any employee-related liabilities, including any successor employer liabilities as provided for in section 14.06(1.2) of the BIA, other than such amounts as the Receiver may specifically agree in writing to pay, or in respect of its obligations under sections 81.4(5) or 81.6(3) of the BIA or under the *Wage Earner Protection Program Act*.

### PIPEDA

20. ~~15.~~ **THIS COURT ORDERS** that, pursuant to clause 7(3)(c) of the Canada *Personal Information Protection and Electronic Documents Act*, the Receiver shall disclose personal information of identifiable individuals to prospective purchasers or bidders for the Property and to their advisors, but only to the extent desirable or required to negotiate and attempt to complete one or more sales of the Property (each, a "Sale"). Each prospective purchaser or bidder to whom such personal information is disclosed shall maintain and protect the privacy of such information and limit the use of such information to its evaluation of the Sale, and if it does not

complete a Sale, shall return all such information to the Receiver, or in the alternative destroy all such information. The purchaser of any Property shall be entitled to continue to use the personal information provided to it, and related to the Property purchased, in a manner which is in all material respects identical to the prior use of such information by the Debtor, and shall return all other personal information to the Receiver, or ensure that all other personal information is destroyed.

#### **LIMITATION ON ENVIRONMENTAL LIABILITIES**

**21.** ~~16.~~ **THIS COURT ORDERS** that nothing herein contained shall require the Receiver to occupy or to take control, care, charge, possession or management (separately and/or collectively, "**Possession**") of any of the Property that might be environmentally contaminated, might be a pollutant or a contaminant, or might cause or contribute to a spill, discharge, release or deposit of a substance contrary to any federal, provincial or other law respecting the protection, conservation, enhancement, remediation or rehabilitation of the environment or relating to the disposal of waste or other contamination including, without limitation, the *Canadian Environmental Protection Act*, the *Ontario Environmental Protection Act*, the *Ontario Water Resources Act*, or the *Ontario Occupational Health and Safety Act* and regulations thereunder (the "Environmental Legislation"), provided however that nothing herein shall exempt the Receiver from any duty to report or make disclosure imposed by applicable Environmental Legislation. The Receiver shall not, as a result of this Order or anything done in pursuance of the Receiver's duties and powers under this Order, be deemed to be in Possession of any of the Property within the meaning of any Environmental Legislation, unless it is actually in possession.

#### **LIMITATION ON THE RECEIVER'S LIABILITY**

**22.** ~~17.~~ **THIS COURT ORDERS** that the Receiver shall incur no liability or obligation as a result of its appointment or the carrying out the provisions of this Order, save and except for any gross negligence or wilful misconduct on its part, or in respect of its obligations under sections 81.4(5) or 81.6(3) of the BIA or under the *Wage Earner Protection Program Act*. Nothing in

this Order shall derogate from the protections afforded the Receiver by section 14.06 of the BIA or by any other applicable legislation.

## RECEIVER'S ACCOUNTS

23. ~~18.~~ **THIS COURT ORDERS** that the Receiver and counsel to the Receiver shall be paid their reasonable fees and disbursements, in each case at their standard rates and charges unless otherwise ordered by the Court on the passing of accounts, and that the Receiver and counsel to the Receiver shall be entitled to and are hereby granted a charge (the "**Receiver's Charge**") on the Property, as security for such fees and disbursements, both before and after the making of this Order in respect of these proceedings, and that the Receiver's Charge shall form a first charge on the Property in priority to all security interests, trusts, liens, charges and encumbrances, statutory or otherwise, in favour of any Person, but subject to sections 14.06(7), 81.4(4), and 81.6(2) of the BIA.<sup>6</sup>

24. ~~19.~~ **THIS COURT ORDERS** that the Receiver and its legal counsel shall pass its accounts from time to time, and for this purpose the accounts of the Receiver and its legal counsel are hereby referred to a judge of the Commercial List of the Ontario Superior Court of Justice.

25. ~~20.~~ **THIS COURT ORDERS** that prior to the passing of its accounts, the Receiver shall be at liberty from time to time to apply reasonable amounts, out of the monies in its hands, against its fees and disbursements, including legal fees and disbursements, incurred at the standard rates and charges of the Receiver or its counsel, and such amounts shall constitute advances against its remuneration and disbursements when and as approved by this Court.

## FUNDING OF THE RECEIVERSHIP

26. ~~21.~~ **THIS COURT ORDERS** that the Receiver be at liberty and it is hereby empowered to borrow by way of a revolving credit or otherwise, such monies from time to time as it may

<sup>6</sup> ~~Note that subsection 243(6) of the BIA provides that the Court may not make such an order "unless it is satisfied that the secured creditors who would be materially affected by the order were given reasonable notice and an opportunity to make representations".~~

consider necessary or desirable, provided that the outstanding principal amount does not exceed \$ ~~\_\_\_\_\_~~ [2,000,000] (or such greater amount as this Court may by further Order authorize) at any time, at such rate or rates of interest as it deems advisable for such period or periods of time as it may arrange, for the purpose of funding the exercise of the powers and duties conferred upon the Receiver by this Order, including interim expenditures. The whole of the Property shall be and is hereby charged by way of a fixed and specific charge (the "Receiver's Borrowings Charge") as security for the payment of the monies borrowed, together with interest and charges thereon, in priority to all security interests, trusts, liens, charges and encumbrances, statutory or otherwise, in favour of any Person, but subordinate in priority to the Receiver's Charge and the charges as set out in sections 14.06(7), 81.4(4), and 81.6(2) of the BIA.

27. ~~22.~~ **THIS COURT ORDERS** that neither the Receiver's Borrowings Charge nor any other security granted by the Receiver in connection with its borrowings under this Order shall be enforced without leave of this Court.

28. ~~23.~~ **THIS COURT ORDERS** that the Receiver is at liberty and authorized to issue certificates substantially in the form annexed as Schedule "A" hereto (the "Receiver's Certificates") for any amount borrowed by it pursuant to this Order.

29. ~~24.~~ **THIS COURT ORDERS** that the monies from time to time borrowed by the Receiver pursuant to this Order or any further order of this Court and any and all Receiver's Certificates evidencing the same or any part thereof shall rank on a *pari passu* basis, unless otherwise agreed to by the holders of any prior issued Receiver's Certificates.

#### **SERVICE AND NOTICE**

30. ~~25.~~ **THIS COURT ORDERS** that the E-Service Protocol of the Commercial List (the "**Protocol**") is approved and adopted by reference herein and, in this proceeding, the service of documents made in accordance with the Protocol (which can be found on the Commercial List website at <http://www.ontariocourts.ca/scj/practice/practice-directions/toronto/e-service-protocol/>) shall be valid and effective service. Subject to Rule 17.05 this Order shall constitute an order for substituted service pursuant to Rule 16.04 of the Rules of Civil Procedure. Subject to Rule

3.01(d) of the Rules of Civil Procedure and paragraph 21 of the Protocol, service of documents in accordance with the Protocol will be effective on transmission. This Court further orders that a Case Website shall be established in accordance with the Protocol with the following URL

 .

**31.** ~~26.~~ **THIS COURT ORDERS** that if the service or distribution of documents in accordance with the Protocol is not practicable, the Receiver is at liberty to serve or distribute this Order, any other materials and orders in these proceedings, any notices or other correspondence, by forwarding true copies thereof by prepaid ordinary mail, courier, personal delivery or facsimile transmission to the Debtor's creditors or other interested parties at their respective addresses as last shown on the records of the Debtor and that any such service or distribution by courier, personal delivery or facsimile transmission shall be deemed to be received on the next business day following the date of forwarding thereof, or if sent by ordinary mail, on the third business day after mailing.

#### **GENERAL**

**32.** ~~27.~~ **THIS COURT ORDERS** that the Receiver may from time to time apply to this Court for advice and directions in the discharge of its powers and duties hereunder.

**33.** ~~28.~~ **THIS COURT ORDERS** that nothing in this Order shall prevent the Receiver from acting as a trustee in bankruptcy of the Debtor.

**34.** ~~29.~~ **THIS COURT HEREBY REQUESTS** the aid and recognition of any court, tribunal, regulatory or administrative body having jurisdiction in Canada or in the United States to give effect to this Order and to assist the Receiver and its agents in carrying out the terms of this Order. All courts, tribunals, regulatory and administrative bodies are hereby respectfully requested to make such orders and to provide such assistance to the Receiver, as an officer of this Court, as may be necessary or desirable to give effect to this Order or to assist the Receiver and its agents in carrying out the terms of this Order.

**35.** ~~30.~~ **THIS COURT ORDERS** that the Receiver be at liberty and is hereby authorized and empowered to apply to any court, tribunal, regulatory or administrative body, wherever located, for the recognition of this Order and for assistance in carrying out the terms of this Order, and



that the Receiver is authorized and empowered to act as a representative in respect of the within proceedings for the purpose of having these proceedings recognized in a jurisdiction outside Canada.

36. ~~31.~~ **THIS COURT ORDERS** that the Plaintiff shall have its costs of this motion, up to and including entry and service of this Order, provided for by the terms of the Plaintiff's security or, if not so provided by the Plaintiff's security, then on a substantial indemnity basis to be paid by the Receiver from the Debtor's estate with such priority and at such time as this Court may determine.

37. ~~32.~~ **THIS COURT ORDERS** that any interested party may apply to this Court to vary or amend this Order on not less than seven (7) days' notice to the Receiver and to any other party likely to be affected by the order sought or upon such other notice, if any, as this Court may order.

**SCHEDULE "A"**  
**RECEIVER CERTIFICATE**

CERTIFICATE NO. \_\_\_\_\_

AMOUNT \$ \_\_\_\_\_

1. THIS IS TO CERTIFY that ~~[RECEIVER'S NAME]~~FTI Consulting Inc., the receiver (the "Receiver") of the assets, undertakings and properties ~~[DEBTOR'S NAME]~~Antibe Therapeutics Inc. acquired for, or used in relation to a business carried on by the Debtor, including all proceeds thereof (collectively, the "Property") appointed by Order of the Ontario Superior Court of Justice (Commercial List) (the "Court") dated the \_\_\_ day of ~~\_\_\_\_\_~~April, 2020~~20~~24 (the "Order") made in an action having Court file number \_\_\_-CL-\_\_\_\_\_, has received as such Receiver from the holder of this certificate (the "Lender") the principal sum of \$ \_\_\_\_\_, being part of the total principal sum of \$ \_\_\_\_\_ which the Receiver is authorized to borrow under and pursuant to the Order.

2. The principal sum evidenced by this certificate is payable on demand by the Lender with interest thereon calculated and compounded [daily][monthly not in advance on the \_\_\_\_\_ day of each month] after the date hereof at a notional rate per annum equal to the rate of \_\_\_\_\_ per cent above the prime commercial lending rate of Bank of \_\_\_\_\_ from time to time.

3. Such principal sum with interest thereon is, by the terms of the Order, together with the principal sums and interest thereon of all other certificates issued by the Receiver pursuant to the Order or to any further order of the Court, a charge upon the whole of the Property, in priority to the security interests of any other person, but subject to the priority of the charges set out in the Order and in the *Bankruptcy and Insolvency Act*, and the right of the Receiver to indemnify itself out of such Property in respect of its remuneration and expenses.

4. All sums payable in respect of principal and interest under this certificate are payable at the main office of the Lender at Toronto, Ontario.

5. Until all liability in respect of this certificate has been terminated, no certificates creating charges ranking or purporting to rank in priority to this certificate shall be issued by the Receiver

to any person other than the holder of this certificate without the prior written consent of the holder of this certificate.

6. The charge securing this certificate shall operate so as to permit the Receiver to deal with the Property as authorized by the Order and as authorized by any further or other order of the Court.

7. The Receiver does not undertake, and it is not under any personal liability, to pay any sum in respect of which it may issue certificates under the terms of the Order.

DATED the \_\_\_\_ day of \_\_\_\_\_, ~~20~~2024.

~~[RECEIVER'S NAME]~~ FTI Consulting Inc.,  
solely in its capacity  
as Receiver of the Property, and not in its  
personal capacity

Per: \_\_\_\_\_

Name:

Title:

Document comparison by Workshare 10.0 on Monday, April 15, 2024 3:05:11 PM

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Description	#37523247v1<WSLegal> - Receivership Order
Rendering set	Standard

Legend:	
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Statistics:	
	Count
Insertions	83
Deletions	87
Moved from	0
Moved to	0
Style changes	0
Format changes	0
Total changes	170

# TAB 5

**ONTARIO**  
**SUPERIOR COURT OF JUSTICE**  
**COMMERCIAL LIST**

THE HONOURABLE ) THURSDAY, THE 18th  
 )  
JUSTICE OSBORNE ) DAY OF APRIL, 2024

**NUANCE PHARMA LTD.**

Applicant

- and -

**ANTIBE THERAPEUTICS INC.**

Respondent

**ORDER**  
**(appointing Receiver)**

**THIS MOTION** made by the Applicant for an Order pursuant to section 101 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended (the "**CJA**") appointing FTI Consulting Canada Inc. ("**FTI**") as receiver and manager (in such capacities, the "**Receiver**") without security, of all of the assets, undertakings and properties of Antibe Therapeutics Inc. (the "**Debtor**") acquired for, or used in relation to a business carried on by the Debtor, was heard this day at 330 University Avenue, Toronto, Ontario.

**ON READING** the affidavits of Mark Lotter sworn March 28 and April 15, 2024 (collectively, the "**Lotter Affidavits**") and the Exhibits thereto, [●], and on hearing the submissions of counsel for the Applicant, the Respondent, the Receiver and Deloitte Restructuring Inc. in its capacity as court-appointed monitor of the Respondent, no one

appearing although duly served as appears from the affidavit of service of [●] sworn [●] and on reading the consent of FTI to act as the Receiver,

### **SERVICE AND DEFINITIONS**

1. **THIS COURT ORDERS** that the time for service of the Notice of Cross-Application and the Cross-Application is hereby abridged and validated so that this Cross-Application is properly returnable today and hereby dispenses with further service thereof.

2. **THIS COURT ORDERS** that capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Lotter Affidavits.

### **APPOINTMENT**

3. **THIS COURT ORDERS** that pursuant to section 101 of the CJA, FTI is hereby appointed Receiver, without security, of all of the assets, undertakings and properties of the Debtor acquired for, or used in relation to a business carried on by the Debtor, including all proceeds thereof (the "**Property**").

### **DECLARATION OF TRUST, RECOGNITION OF ARBITRAL AWARD**

4. **THIS COURT ORDERS AND DECLARES** that the arbitral award dated February 27, 2024 rendered in the arbitration proceedings SIAC Arbitration No. 021 of 2022 under the auspices of the Singapore International Arbitration Centre by the arbitral tribunal seated in the Republic of Singapore (the "**Arbitral Award**") be and is hereby recognized as a judgment of this Court.

5. **THIS COURT DECLARES** that as of September 5, 2021, the Debtor held US\$20,000,000 (the "**Investment Payment Amount**") in funds in trust for Nuance Therapeutics Ltd. ("**Nuance**").

6. **THIS COURT DELCARES** that the Debtor held approximately CAD\$19,600,000 in funds in trust for Nuance as of April 8, 2024.

7. **THIS COURT DELCARES** that Nuance be and is hereby authorized and entitled to trace or follow any proceeds of the Investment Payment Amount and other amounts Nuance is entitled to be paid pursuant to the Arbitral Award into any assets, funds, effects and property currently held by the Debtor or to which the Debtor main come into possession to in the future.

#### **RECEIVER'S POWERS**

8. **THIS COURT ORDERS** that the Receiver is hereby empowered and authorized, but not obligated, to act at once in respect of the Property and, without in any way limiting the generality of the foregoing, the Receiver is hereby expressly empowered and authorized to do any of the following where the Receiver considers it necessary or desirable:

- (a) to take possession of and exercise control over the Property and any and all proceeds, receipts and disbursements arising out of or from the Property;
- (b) to receive, preserve, and protect the Property, or any part or parts thereof, including, but not limited to, the changing of locks and security codes, the relocating of Property to safeguard it, the engaging of independent security personnel, the taking of physical inventories and the placement of such insurance coverage as may be necessary or desirable;
- (c) to manage, operate, and carry on the business of the Debtor, including the powers to enter into any agreements, incur any obligations in the ordinary course of business, cease to carry on all or any part of the business, or cease to perform any contracts of the Debtor;
- (d) to engage consultants, appraisers, agents, experts, auditors, accountants, managers, counsel and such other persons from time to time and on whatever basis, including on a temporary basis, to assist with the exercise of the Receiver's powers and duties, including without limitation those conferred by this Order;



- (e) to purchase or lease such machinery, equipment, inventories, supplies, premises or other assets to continue the business of the Debtor or any part or parts thereof;
- (f) to receive and collect all monies and accounts now owed or hereafter owing to the Debtor and to exercise all remedies of the Debtor in collecting such monies, including, without limitation, to enforce any security held by the Debtor;
- (g) to settle, extend or compromise any indebtedness owing to the Debtor;
- (h) to execute, assign, issue and endorse documents of whatever nature in respect of any of the Property, whether in the Receiver's name or in the name and on behalf of the Debtor, for any purpose pursuant to this Order;
- (i) to initiate, prosecute and continue the prosecution of any and all proceedings and to defend all proceedings now pending or hereafter instituted with respect to the Debtor, the Property or the Receiver, and to settle or compromise any such proceedings. The authority hereby conveyed shall extend to such appeals or applications for judicial review in respect of any order or judgment pronounced in any such proceeding;
- (j) to market any or all of the Property, including advertising and soliciting offers in respect of the Property or any part or parts thereof and negotiating such terms and conditions of sale as the Receiver in its discretion may deem appropriate;
- (k) to sell, convey, transfer, lease or assign the Property or any part or parts thereof out of the ordinary course of business,
  - (i) without the approval of this Court in respect of any transaction not exceeding \$[250,000], provided that the aggregate consideration for all such transactions does not exceed \$[1,000,000]; and

(ii) with the approval of this Court in respect of any transaction in which the purchase price or the aggregate purchase price exceeds the applicable amount set out in the preceding clause;

and in each such case notice under subsection 63(4) of the Ontario *Personal Property Security Act*, shall not be required.

- (l) to apply for any vesting order or other orders necessary to convey the Property or any part or parts thereof to a purchaser or purchasers thereof, free and clear of any liens or encumbrances affecting such Property;
- (m) to report to, meet with and discuss with such affected Persons (as defined below) as the Receiver deems appropriate on all matters relating to the Property and the receivership, and to share information, subject to such terms as to confidentiality as the Receiver deems advisable;
- (n) to register a copy of this Order and any other Orders in respect of the Property against title to any of the Property;
- (o) to apply for any permits, licences, approvals or permissions as may be required by any governmental authority and any renewals thereof for and on behalf of and, if thought desirable by the Receiver, in the name of the Debtor;
- (p) to enter into agreements with any trustee in bankruptcy appointed in respect of the Debtor, including, without limiting the generality of the foregoing, the ability to enter into occupation agreements for any property owned or leased by the Debtor;
- (q) to exercise any shareholder, partnership, joint venture or other rights which the Debtor may have; and
- (r) to take any steps reasonably incidental to the exercise of these powers or the performance of any statutory obligations,

and in each case where the Receiver takes any such actions or steps, it shall be exclusively authorized and empowered to do so, to the exclusion of all other Persons (as defined below), including the Debtor, and without interference from any other Person.

#### **DUTY TO PROVIDE ACCESS AND CO-OPERATION TO THE RECEIVER**

9. **THIS COURT ORDERS** that (i) the Debtor, (ii) all of its current and former directors, officers, employees, agents, accountants, legal counsel and shareholders, and all other persons acting on its instructions or behalf, and (iii) all other individuals, firms, corporations, governmental bodies or agencies, or other entities having notice of this Order (all of the foregoing, collectively, being "**Persons**" and each being a "**Person**") shall forthwith advise the Receiver of the existence of any Property in such Person's possession or control, shall grant immediate and continued access to the Property to the Receiver, and shall deliver all such Property to the Receiver upon the Receiver's request.

10. **THIS COURT ORDERS** that all Persons shall forthwith advise the Receiver of the existence of any books, documents, securities, contracts, orders, corporate and accounting records, and any other papers, records and information of any kind related to the business or affairs of the Debtor, and any computer programs, computer tapes, computer disks, or other data storage media containing any such information (the foregoing, collectively, the "**Records**") in that Person's possession or control, and shall provide to the Receiver or permit the Receiver to make, retain and take away copies thereof and grant to the Receiver unfettered access to and use of accounting, computer, software and physical facilities relating thereto, provided however that nothing in this paragraph 5 or in paragraph 6 of this Order shall require the delivery of Records, or the granting of access to Records, which may not be disclosed or provided to the Receiver due to the privilege attaching to solicitor-client communication or due to statutory provisions prohibiting such disclosure.

11. **THIS COURT ORDERS** that if any Records are stored or otherwise contained on a computer or other electronic system of information storage, whether by independent service provider or otherwise, all Persons in possession or control of such Records shall forthwith give unfettered access to the Receiver for the purpose of allowing the Receiver to recover and fully copy all of the information contained therein whether by way of printing the information onto

paper or making copies of computer disks or such other manner of retrieving and copying the information as the Receiver in its discretion deems expedient, and shall not alter, erase or destroy any Records without the prior written consent of the Receiver. Further, for the purposes of this paragraph, all Persons shall provide the Receiver with all such assistance in gaining immediate access to the information in the Records as the Receiver may in its discretion require including providing the Receiver with instructions on the use of any computer or other system and providing the Receiver with any and all access codes, account names and account numbers that may be required to gain access to the information.

12. **THIS COURT ORDERS** that the Receiver shall provide each of the relevant landlords with notice of the Receiver's intention to remove any fixtures from any leased premises at least seven (7) days prior to the date of the intended removal. The relevant landlord shall be entitled to have a representative present in the leased premises to observe such removal and, if the landlord disputes the Receiver's entitlement to remove any such fixture under the provisions of the lease, such fixture shall remain on the premises and shall be dealt with as agreed between any applicable secured creditors, such landlord and the Receiver, or by further Order of this Court upon application by the Receiver on at least two (2) days notice to such landlord and any such secured creditors.

#### NO PROCEEDINGS AGAINST THE RECEIVER

13. **THIS COURT ORDERS** that no proceeding or enforcement process in any court or tribunal (each, a "**Proceeding**"), shall be commenced or continued against the Receiver except with the written consent of the Receiver or with leave of this Court.

#### NO PROCEEDINGS AGAINST THE DEBTOR OR THE PROPERTY

14. **THIS COURT ORDERS** that no Proceeding against or in respect of the Debtor or the Property shall be commenced or continued except with the written consent of the Receiver or with leave of this Court and any and all Proceedings currently under way against or in respect of the Debtor or the Property are hereby stayed and suspended pending further Order of this Court.

### **NO EXERCISE OF RIGHTS OR REMEDIES**

15. **THIS COURT ORDERS** that all rights and remedies against the Debtor, the Receiver, or affecting the Property, are hereby stayed and suspended except with the written consent of the Receiver or leave of this Court, provided however that this stay and suspension does not apply in respect of any "eligible financial contract" as defined in the BIA, and further provided that nothing in this paragraph shall (i) empower the Receiver or the Debtor to carry on any business which the Debtor is not lawfully entitled to carry on, (ii) exempt the Receiver or the Debtor from compliance with statutory or regulatory provisions relating to health, safety or the environment, (iii) prevent the filing of any registration to preserve or perfect a security interest, or (iv) prevent the registration of a claim for lien.

### **NO INTERFERENCE WITH THE RECEIVER**

16. **THIS COURT ORDERS** that no Person shall discontinue, fail to honour, alter, interfere with, repudiate, terminate or cease to perform any right, renewal right, contract, agreement, licence or permit in favour of or held by the Debtor, without written consent of the Receiver or leave of this Court.

### **CONTINUATION OF SERVICES**

17. **THIS COURT ORDERS** that all Persons having oral or written agreements with the Debtor or statutory or regulatory mandates for the supply of goods and/or services, including without limitation, all computer software, communication and other data services, centralized banking services, payroll services, insurance, transportation services, utility or other services to the Debtor are hereby restrained until further Order of this Court from discontinuing, altering, interfering with or terminating the supply of such goods or services as may be required by the Receiver, and that the Receiver shall be entitled to the continued use of the Debtor's current telephone numbers, facsimile numbers, internet addresses and domain names, provided in each case that the normal prices or charges for all such goods or services received after the date of this Order are paid by the Receiver in accordance with normal payment practices of the Debtor or such other practices as may be agreed upon by the supplier or service provider and the Receiver, or as may be ordered by this Court.

## **RECEIVER TO HOLD FUNDS**

18. **THIS COURT ORDERS** that all funds, monies, cheques, instruments, and other forms of payments received or collected by the Receiver from and after the making of this Order from any source whatsoever, including without limitation the sale of all or any of the Property and the collection of any accounts receivable in whole or in part, whether in existence on the date of this Order or hereafter coming into existence, shall be deposited into one or more new accounts to be opened by the Receiver (the "Post Receivership Accounts") and the monies standing to the credit of such Post Receivership Accounts from time to time, net of any disbursements provided for herein, shall be held by the Receiver to be paid in accordance with the terms of this Order or any further Order of this Court.

## **EMPLOYEES**

19. **THIS COURT ORDERS** that all employees of the Debtor shall remain the employees of the Debtor until such time as the Receiver, on the Debtor's behalf, may terminate the employment of such employees. The Receiver shall not be liable for any employee-related liabilities, including any successor employer liabilities as provided for in section 14.06(1.2) of the BIA, other than such amounts as the Receiver may specifically agree in writing to pay, or in respect of its obligations under sections 81.4(5) or 81.6(3) of the BIA or under the *Wage Earner Protection Program Act*.

## **PIPEDA**

20. **THIS COURT ORDERS** that, pursuant to clause 7(3)(c) of the Canada *Personal Information Protection and Electronic Documents Act*, the Receiver shall disclose personal information of identifiable individuals to prospective purchasers or bidders for the Property and to their advisors, but only to the extent desirable or required to negotiate and attempt to complete one or more sales of the Property (each, a "Sale"). Each prospective purchaser or bidder to whom such personal information is disclosed shall maintain and protect the privacy of such information and limit the use of such information to its evaluation of the Sale, and if it does not complete a Sale, shall return all such information to the Receiver, or in the alternative destroy all such information. The purchaser of any Property shall be entitled to continue to use the personal information provided to it, and related to the Property purchased, in a manner which is in all

material respects identical to the prior use of such information by the Debtor, and shall return all other personal information to the Receiver, or ensure that all other personal information is destroyed.

### **LIMITATION ON ENVIRONMENTAL LIABILITIES**

21. **THIS COURT ORDERS** that nothing herein contained shall require the Receiver to occupy or to take control, care, charge, possession or management (separately and/or collectively, "**Possession**") of any of the Property that might be environmentally contaminated, might be a pollutant or a contaminant, or might cause or contribute to a spill, discharge, release or deposit of a substance contrary to any federal, provincial or other law respecting the protection, conservation, enhancement, remediation or rehabilitation of the environment or relating to the disposal of waste or other contamination including, without limitation, the *Canadian Environmental Protection Act*, the *Ontario Environmental Protection Act*, the *Ontario Water Resources Act*, or the *Ontario Occupational Health and Safety Act* and regulations thereunder (the "Environmental Legislation"), provided however that nothing herein shall exempt the Receiver from any duty to report or make disclosure imposed by applicable Environmental Legislation. The Receiver shall not, as a result of this Order or anything done in pursuance of the Receiver's duties and powers under this Order, be deemed to be in Possession of any of the Property within the meaning of any Environmental Legislation, unless it is actually in possession.

### **LIMITATION ON THE RECEIVER'S LIABILITY**

22. **THIS COURT ORDERS** that the Receiver shall incur no liability or obligation as a result of its appointment or the carrying out the provisions of this Order, save and except for any gross negligence or wilful misconduct on its part, or in respect of its obligations under sections 81.4(5) or 81.6(3) of the BIA or under the *Wage Earner Protection Program Act*. Nothing in this Order shall derogate from the protections afforded the Receiver by section 14.06 of the BIA or by any other applicable legislation.

### **RECEIVER'S ACCOUNTS**

23. **THIS COURT ORDERS** that the Receiver and counsel to the Receiver shall be paid their reasonable fees and disbursements, in each case at their standard rates and charges unless

otherwise ordered by the Court on the passing of accounts, and that the Receiver and counsel to the Receiver shall be entitled to and are hereby granted a charge (the "**Receiver's Charge**") on the Property, as security for such fees and disbursements, both before and after the making of this Order in respect of these proceedings, and that the Receiver's Charge shall form a first charge on the Property in priority to all security interests, trusts, liens, charges and encumbrances, statutory or otherwise, in favour of any Person, but subject to sections 14.06(7), 81.4(4), and 81.6(2) of the BIA.

24. **THIS COURT ORDERS** that the Receiver and its legal counsel shall pass its accounts from time to time, and for this purpose the accounts of the Receiver and its legal counsel are hereby referred to a judge of the Commercial List of the Ontario Superior Court of Justice.

25. **THIS COURT ORDERS** that prior to the passing of its accounts, the Receiver shall be at liberty from time to time to apply reasonable amounts, out of the monies in its hands, against its fees and disbursements, including legal fees and disbursements, incurred at the standard rates and charges of the Receiver or its counsel, and such amounts shall constitute advances against its remuneration and disbursements when and as approved by this Court.

#### **FUNDING OF THE RECEIVERSHIP**

26. **THIS COURT ORDERS** that the Receiver be at liberty and it is hereby empowered to borrow by way of a revolving credit or otherwise, such monies from time to time as it may consider necessary or desirable, provided that the outstanding principal amount does not exceed **[\$2,000,000]** (or such greater amount as this Court may by further Order authorize) at any time, at such rate or rates of interest as it deems advisable for such period or periods of time as it may arrange, for the purpose of funding the exercise of the powers and duties conferred upon the Receiver by this Order, including interim expenditures. The whole of the Property shall be and is hereby charged by way of a fixed and specific charge (the "**Receiver's Borrowings Charge**") as security for the payment of the monies borrowed, together with interest and charges thereon, in priority to all security interests, trusts, liens, charges and encumbrances, statutory or otherwise, in favour of any Person, but subordinate in priority to the Receiver's Charge and the charges as set out in sections 14.06(7), 81.4(4), and 81.6(2) of the BIA.



27. **THIS COURT ORDERS** that neither the Receiver's Borrowings Charge nor any other security granted by the Receiver in connection with its borrowings under this Order shall be enforced without leave of this Court.

28. **THIS COURT ORDERS** that the Receiver is at liberty and authorized to issue certificates substantially in the form annexed as Schedule "A" hereto (the "Receiver's Certificates") for any amount borrowed by it pursuant to this Order.

29. **THIS COURT ORDERS** that the monies from time to time borrowed by the Receiver pursuant to this Order or any further order of this Court and any and all Receiver's Certificates evidencing the same or any part thereof shall rank on a *pari passu* basis, unless otherwise agreed to by the holders of any prior issued Receiver's Certificates.

#### **SERVICE AND NOTICE**

30. **THIS COURT ORDERS** that the E-Service Protocol of the Commercial List (the "**Protocol**") is approved and adopted by reference herein and, in this proceeding, the service of documents made in accordance with the Protocol (which can be found on the Commercial List website at <http://www.ontariocourts.ca/scj/practice/practice-directions/toronto/e-service-protocol/>) shall be valid and effective service. Subject to Rule 17.05 this Order shall constitute an order for substituted service pursuant to Rule 16.04 of the Rules of Civil Procedure. Subject to Rule 3.01(d) of the Rules of Civil Procedure and paragraph 21 of the Protocol, service of documents in accordance with the Protocol will be effective on transmission. This Court further orders that a Case Website shall be established in accordance with the Protocol with the following URL [●].

31. **THIS COURT ORDERS** that if the service or distribution of documents in accordance with the Protocol is not practicable, the Receiver is at liberty to serve or distribute this Order, any other materials and orders in these proceedings, any notices or other correspondence, by forwarding true copies thereof by prepaid ordinary mail, courier, personal delivery or facsimile transmission to the Debtor's creditors or other interested parties at their respective addresses as last shown on the records of the Debtor and that any such service or distribution by courier, personal delivery or facsimile transmission shall be deemed to be received on the next business

day following the date of forwarding thereof, or if sent by ordinary mail, on the third business day after mailing.

## **GENERAL**

32. **THIS COURT ORDERS** that the Receiver may from time to time apply to this Court for advice and directions in the discharge of its powers and duties hereunder.

33. **THIS COURT ORDERS** that nothing in this Order shall prevent the Receiver from acting as a trustee in bankruptcy of the Debtor.

34. **THIS COURT HEREBY REQUESTS** the aid and recognition of any court, tribunal, regulatory or administrative body having jurisdiction in Canada or in the United States to give effect to this Order and to assist the Receiver and its agents in carrying out the terms of this Order. All courts, tribunals, regulatory and administrative bodies are hereby respectfully requested to make such orders and to provide such assistance to the Receiver, as an officer of this Court, as may be necessary or desirable to give effect to this Order or to assist the Receiver and its agents in carrying out the terms of this Order.

35. **THIS COURT ORDERS** that the Receiver be at liberty and is hereby authorized and empowered to apply to any court, tribunal, regulatory or administrative body, wherever located, for the recognition of this Order and for assistance in carrying out the terms of this Order, and that the Receiver is authorized and empowered to act as a representative in respect of the within proceedings for the purpose of having these proceedings recognized in a jurisdiction outside Canada.

36. **THIS COURT ORDERS** that the Plaintiff shall have its costs of this motion, up to and including entry and service of this Order, provided for by the terms of the Plaintiff's security or, if not so provided by the Plaintiff's security, then on a substantial indemnity basis to be paid by the Receiver from the Debtor's estate with such priority and at such time as this Court may determine.

37. **THIS COURT ORDERS** that any interested party may apply to this Court to vary or amend this Order on not less than seven (7) days' notice to the Receiver and to any other party

likely to be affected by the order sought or upon such other notice, if any, as this Court may order.

---

**SCHEDULE "A"**  
**RECEIVER CERTIFICATE**

CERTIFICATE NO. \_\_\_\_\_

AMOUNT \$ \_\_\_\_\_

1. THIS IS TO CERTIFY that FTI Consulting Canada Inc., the receiver (the "**Receiver**") of the assets, undertakings and properties Antibe Therapeutics Inc. acquired for, or used in relation to a business carried on by the Debtor, including all proceeds thereof (collectively, the "**Property**") appointed by Order of the Ontario Superior Court of Justice (Commercial List) (the "**Court**") dated the \_\_\_ day of April, 2024 (the "**Order**") made in an action having Court file number \_\_-CL-\_\_\_\_\_, has received as such Receiver from the holder of this certificate (the "Lender") the principal sum of \$\_\_\_\_\_, being part of the total principal sum of \$\_\_\_\_\_ which the Receiver is authorized to borrow under and pursuant to the Order.

2. The principal sum evidenced by this certificate is payable on demand by the Lender with interest thereon calculated and compounded [daily][monthly not in advance on the \_\_\_\_\_ day of each month] after the date hereof at a notional rate per annum equal to the rate of \_\_\_\_\_ per cent above the prime commercial lending rate of Bank of \_\_\_\_\_ from time to time.

3. Such principal sum with interest thereon is, by the terms of the Order, together with the principal sums and interest thereon of all other certificates issued by the Receiver pursuant to the Order or to any further order of the Court, a charge upon the whole of the Property, in priority to the security interests of any other person, but subject to the priority of the charges set out in the Order and in the *Bankruptcy and Insolvency Act*, and the right of the Receiver to indemnify itself out of such Property in respect of its remuneration and expenses.

4. All sums payable in respect of principal and interest under this certificate are payable at the main office of the Lender at Toronto, Ontario.

5. Until all liability in respect of this certificate has been terminated, no certificates creating charges ranking or purporting to rank in priority to this certificate shall be issued by the Receiver to any person other than the holder of this certificate without the prior written consent of the holder of this certificate.

6. The charge securing this certificate shall operate so as to permit the Receiver to deal with the Property as authorized by the Order and as authorized by any further or other order of the Court.

7. The Receiver does not undertake, and it is not under any personal liability, to pay any sum in respect of which it may issue certificates under the terms of the Order.

DATED the \_\_\_\_ day of \_\_\_\_\_, 2024.

FTI Consulting Canada Inc., solely in its  
capacity  
as Receiver of the Property, and not in its  
personal capacity

Per: \_\_\_\_\_

Name:

Title:

IN THE MATTER OF *THE COMPANIES' CREDITORS ARRANGEMENT ACT*, R.S.C. 1985, C. C-36, AS AMENDED  
AND IN THE MATTER OF THE COMPROMISE OR ARRANGEMENT OF ANTIBE THERAPEUTICS INC. (the "Applicant")

Court File No. CV-23-00693758-00CL

*ONTARIO*  
SUPERIOR COURT OF JUSTICE  
COMMERCIAL LIST

PROCEEDING COMMENCED AT  
TORONTO

**RESPONDING AND CROSS-APPLICATION RECORD  
OF THE CROSS-APPLICANT, NUANCE PHARMA LTD.**

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