

**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 A PLAN OF COMPROMISE OR ARRANGEMENT OF  
ANTIBE THERAPEUTICS INC. (the "Applicant")

**Applicant**

**REPLY RECORD TO CROSS-APPLICATION OF NUANCE**

April 17, 2024

**Paliare Roland Rosenberg Rothstein LLP**  
155 Wellington Street West 35th Floor  
Toronto ON M5V 3H1  
Tel: 416.646.4300

**Kenneth T. Rosenberg** (LSO# 21102H)  
Tel: 416.646.4304  
Email: [ken.rosenberg@paliareroland.com](mailto:ken.rosenberg@paliareroland.com)

**Massimo Starnino** (LSO# 41048G)  
Tel: 416.646.7431  
Email: [Max.Starnino@paliareroland.com](mailto:Max.Starnino@paliareroland.com)

**Kartiga Thavaraj** (LSO# 75291D)  
Tel: 416.646.6317  
Email: [kartiga.thavaraj@paliareroland.com](mailto:kartiga.thavaraj@paliareroland.com)

**Evan Snyder** (LSO# 82007E)  
Tel: 416.646.6320  
Email: [evan.snyder@paliareroland.com](mailto:evan.snyder@paliareroland.com)

Lawyers for the Applicant,  
Antibe Therapeutics Inc.

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THERAPEUTICS INC.

**Applicant**

**SERVICE LIST**

(as at April 16, 2024)

COUNSEL/PARTY	CONTACT
<p><b>PALIARE ROLAND ROSENBERG ROTHSTEIN LLP</b> 155 Wellington Street West 35th Floor Toronto ON M5V 3H1 Tel: 416.646.4300</p> <p><b>Counsel to Antibe Therapeutics Inc.</b></p>	<p><b>Kenneth T. Rosenberg</b> (LSO#21102H) Tel: 416.646.4304 Email: <a href="mailto:ken.rosenberg@paliareroland.com">ken.rosenberg@paliareroland.com</a></p> <p><b>Massimo Starnino</b> (LSO# 41048G) Tel: 416.646.7431 Email: <a href="mailto:max.starnino@paliareroland.com">max.starnino@paliareroland.com</a></p> <p><b>Kartiga Thavaraj</b> (LSO# 75291D) Tel: 416.646.6317 Email: <a href="mailto:kartiga.thavaraj@paliareroland.com">kartiga.thavaraj@paliareroland.com</a></p> <p><b>Evan Snyder</b> (LSO# 82007E) Tel: 416.646.6320 Email: <a href="mailto:evan.snyder@paliareroland.com">evan.snyder@paliareroland.com</a></p>
<p><b>BENNETT JONES LLP</b> 3400 One First Canadian Place P.O. Box 130 Toronto, ON M5X 1A4 Tel: 416.863.1200</p> <p><b>Counsel to Nuance Pharma Ltd.</b></p>	<p>Lincoln Caylor (LSO# 37030L) Tel: 416.777.6121 <a href="mailto:caylorl@bennettjones.com">caylorl@bennettjones.com</a></p> <p><b>Jesse Mighton</b> (LSO# 62291J) Tel: 416.777.6255 <a href="mailto:mightonj@bennettjones.com">mightonj@bennettjones.com</a></p> <p><b>Alexander Payne</b> (LSO# 70712L) Tel: 416.777.5512 <a href="mailto:paynea@bennettjones.com">paynea@bennettjones.com</a></p> <p>Sidney Brejak (LSO# 87177H) Tel: 416.777.7840</p>

COUNSEL/PARTY	CONTACT
<p><b>BLACK SWAN ADVISORS INC.</b> 601 - 70 Port St. East Mississauga, ON L5G 4V8</p> <p><b>Restructuring Advisor</b></p>	<p><a href="mailto:brejaks@bennettjones.com">brejaks@bennettjones.com</a></p> <p><b>Edward Sellers</b> Tel: 647.401.5959 <a href="mailto:esellers@blackswanadvisors.ca">esellers@blackswanadvisors.ca</a></p>
<p><b>Deloitte Restructuring Inc/Restructuration Deloitte Inc.</b> 8 Adelaide St West, Suite 200 Bay Adelaide East Toronto, ON M5H 0A9 Tel: 416.601.6150</p> <p><b>Monitor</b></p>	<p><b>Nigel Meakin</b> Tel: 416.687.1509 <a href="mailto:nmeakin@deloitte.ca">nmeakin@deloitte.ca</a></p> <p><b>Martin Lin</b> Tel: 416.434.9584 <a href="mailto:muslin@deloitte.ca">muslin@deloitte.ca</a></p>
<p><b>Norton Rose Fulbright Canada LLP</b> 222 Bay Street, Suite 3000, P.O. Box 53 Toronto, ON M5K 1E7 Tel: 416.216.4000</p> <p><b>Counsel to the Monitor</b></p>	<p><b>Evan Cobb (LSO # 55787N)</b> Tel: 416.216.1929 <a href="mailto:evan.cobb@nortonrosefulbright.com">evan.cobb@nortonrosefulbright.com</a></p>
SUPPLIERS	
<p><b>Bend Research, Inc., A Lonza Company</b> 1201 NW Wall St. Ste. 200 Bend, OR 97703</p> <p><b>Supplier</b></p>	<p><b>Jason Bertala</b> <b>Mary Heller</b> Tel: 541.382.4100 <a href="mailto:mary.heller@lonza.com">mary.heller@lonza.com</a></p>
<p><b>Lonza Ltd. and Lonza Sales AG</b></p> <p><b>Supplier</b></p>	<p><b>Bart Van Arnhem</b> <a href="mailto:bart.vanaarnhem@lonza.com">bart.vanaarnhem@lonza.com</a></p> <p><b>Marie Leblanc</b> <a href="mailto:marie.leblanc@lonza.com">marie.leblanc@lonza.com</a></p>
<p><b>Lotus Clinical Research, LLC</b> 430 Mountain Avenue, Suite 302, New Providence, NJ 07974</p> <p><b>Supplier</b></p>	<p><b>William Martin</b> <a href="mailto:wmartin@erqclinical.com">wmartin@erqclinical.com</a></p>
<p><b>Pantheon API Services Inc.</b> 101, Technology Place Florence, SC 29501</p> <p><b>Supplier</b></p>	<p><b>Matthew West</b> Tel: 608.504.6871 <a href="mailto:Matthew.west@thermofisher.com">Matthew.west@thermofisher.com</a></p>

COUNSEL/PARTY	CONTACT
<b>LICENSEES</b>	
<p><b>Kwangdong Pharmaceutical Co., Ltd.</b> 85 Seochojungang-ro, Seocho-gu, Seoul, 06650, Korea</p> <p><b>Licensee</b></p>	<p><b>Ki-Lyong Bae</b> <a href="mailto:Kilyong.bae@ekdp.com">Kilyong.bae@ekdp.com</a></p>
<p><b>Laboratoires Acbel SA</b> Rue de la Rotisserie 11 1204 Geneve</p> <p>Tel: +41 022 310 18 22</p> <p><b>Minerva Pharmaceutical s.a.,</b> 132 Kifissou Ave Peristeri, Greece</p> <p><b>Licensee</b></p>	<p><b>Leonardo Zampatti</b></p> <p><b>Dr. George Vassilopoulos</b> <a href="mailto:contact@minervapharm.gr">contact@minervapharm.gr</a></p>
<p><b>Knight Therapeutics</b> 376 Victoria Avenue Suite 220 Westmount, QC H3Z 1C3</p> <p><b>Licensee</b></p>	<p><b>Amal Khouri</b> <a href="mailto:akhouri@knighttx.com">akhouri@knighttx.com</a></p>
<p><b>Davies Ward Phillips &amp; Vineberg LLP</b> 40<sup>th</sup> Floor, 155 Wellington Street West Toronto, ON, M5V 3J7 Tel: 416.863.0900</p> <p><b>Counsel to the Licensee, Knight Therapeutics</b></p>	<p><b>Natalie Renner (LSO# 55954A)</b> Tel: 416.367.7489 <a href="mailto:nrenner@dwpv.com">nrenner@dwpv.com</a></p>
<b>GOVERNMENT</b>	
<p>Canada Revenue Agency 1 Front Street West Toronto, ON M5J 2X6</p>	<p><a href="mailto:aqc-pgc.toronto-tax-fiscal@justice.gc.ca">aqc-pgc.toronto-tax-fiscal@justice.gc.ca</a></p>
<p><b>Attorney General of Canada</b> Department of Justice of Canada Ontario Regional Office, Tax Law Section 120 Adelaide Street West, Suite 400 Toronto, ON M5H 1T1</p> <p><b>Counsel to the Canada Revenue Agency</b></p>	<p><b>Kelly Smith Wayland (LSO# 40290A)</b> <a href="mailto:kelly.smithwayland@justice.gc.ca">kelly.smithwayland@justice.gc.ca</a></p> <p><b>Kevin Dias (LSO # 39035N)</b> <a href="mailto:kdias@justice.gc.ca">kdias@justice.gc.ca</a></p>
<p>Ministry of Finance (Ontario) Insolvency Unit</p>	<p><a href="mailto:Insolvency.Unit@ontario.ca">Insolvency.Unit@ontario.ca</a></p>



COUNSEL/PARTY	CONTACT
6th Floor, 33 King Street West Oshawa, ON L1H 8H5	
Office of the Superintendent of Bankruptcy (Canada) 151 Yonge Street, 4th Floor Toronto, ON M5C 2W7  Tel: 1-877-376-9902	<a href="mailto:ic.osbservice-bsfservice.ic@canada.ca">ic.osbservice-bsfservice.ic@canada.ca</a>

**Email List:**

[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);  
[caylorl@bennettjones.com](mailto:caylorl@bennettjones.com); [mightonj@bennettjones.com](mailto:mightonj@bennettjones.com) ; [paynea@bennettjones.com](mailto:paynea@bennettjones.com) ;  
[brejaks@bennettjones.com](mailto:brejaks@bennettjones.com) ; [esellers@blackswanadvisors.ca](mailto:esellers@blackswanadvisors.ca); [nmeakin@deloitte.ca](mailto:nmeakin@deloitte.ca) ;  
[muslin@deloitte.ca](mailto:muslin@deloitte.ca) ; [evan.cobb@nortonrosefulbright.com](mailto:evan.cobb@nortonrosefulbright.com); [mary.heller@lonza.com](mailto:mary.heller@lonza.com);  
[bart.vanaarnhem@lonza.com](mailto:bart.vanaarnhem@lonza.com) ; [marie.leblanc@lonza.com](mailto:marie.leblanc@lonza.com); [wmartin@ergclinical.com](mailto:wmartin@ergclinical.com);  
[Matthew.west@thermofisher.com](mailto:Matthew.west@thermofisher.com) ; [Kilyong.bae@ekdp.com](mailto:Kilyong.bae@ekdp.com) ; [contact@minervapharm.gr](mailto:contact@minervapharm.gr) ;  
[akhouri@knighttx.com](mailto:akhouri@knighttx.com) ; [nrenner@dwpv.com](mailto:nrenner@dwpv.com); [kelly.smithwayland@justice.gc.ca](mailto:kelly.smithwayland@justice.gc.ca) ;  
[kdias@justice.gc.ca](mailto:kdias@justice.gc.ca); [agc-pgc.toronto-tax-fiscal@justice.gc.ca](mailto:agc-pgc.toronto-tax-fiscal@justice.gc.ca) ; [Insolvency.Unit@ontario.ca](mailto:Insolvency.Unit@ontario.ca) ;  
[ic.osbservice-bsfservice.ic@canada.ca](mailto:ic.osbservice-bsfservice.ic@canada.ca)

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**SECOND AFFIDAVIT OF SCOTT CURTIS**

I, **Scott Curtis**, of the City of Toronto, in the Province of Ontario, **AFFIRM AND SAY:**

1. I am the COO of Antibe. I affirm this affidavit further to my affidavit dated April 8, 2024 (the “**First Curtis Affidavit**”) and to respond to the assertions in the second affidavit of Mark Lotter, contained in Nuance’s Notice of Cross-Application dated April 15, 2024 (the “**Second Lotter Affidavit**”), which appears to have been tendered in

support of Nuance's Enforcement Application. This affidavit should be read in conjunction with the First Curtis Affidavit, and I stand by the statements therein.

2. I have personal knowledge of the matters to which I depose in this affidavit. Where I do not possess personal knowledge, I have stated the source of my knowledge and believe it to be true.

3. Capitalized terms not otherwise defined in this affidavit have the meanings given to them in the First Curtis Affidavit.

4. Antibe brought its application in respect of CCAA proceedings on April 9, 2024. Later that day, Antibe received an order from Justice Black of the Toronto Commercial List staying all other proceedings, including the Enforcement Application, and setting the mandatory 10-day CCAA comeback date for April 18, 2024.

5. On April 9, 2024 (and contrary to the assertions made in the Second Letter Affidavit) the TSX suspended trading of Antibe's common shares.

6. On April 15, 2024, Antibe received Nuance's responding materials and a notice of cross-application, which appear to indicate that Nuance intends to bring its Enforcement Application on the hearing date scheduled for April 18, 2024.

7. Antibe intends to appear before this Court on April 18, 2024, with a request (among other things) that the Court extend the Stay Period (as defined in Antibe's Notice of Motion) to May 24, 2024, to allow Antibe to receive the FDA Hold Letter and to prepare its response, as outlined in the First Curtis Affidavit, with a view to having the FDA hold be released.

8. In this affidavit, having regard to the limited time available to me to respond, I have attempted to address only issues which are particularly noteworthy in the Second Lotter Affidavit, and which I am able to comment on within the short turnaround time. I disagree with many of the remaining statements in the Second Lotter Affidavit and my silence on any issue raised in the Second Lotter Affidavit should not be taken as endorsement.

**A. *The Drug is viable and has significant potential in the marketplace***

9. Below, I have provided some further information regarding the viability of the Drug and Antibe's proprietary platform. The below should be read in conjunction with the information provided in the First Curtis Affidavit, particularly in the Overview, at Part C and at Appendix "A".

10. Contrary to the assertions in the Second Lotter Affidavit, and as outlined in the First Curtis Affidavit, there is a realistic basis upon which Antibe expects that the Drug may be approved for use and, given the time and opportunity to do so, that Antibe can demonstrate to the FDA and this Court that the Drug's performance will match its potential. To do so, Antibe must first have the opportunity to receive the FDA Hold Letter and to respond.

**1. *Antibe's unique Hydrogen Sulfide platform and the Drug's innovation as an NSAID***

11. One of Antibe's unique properties as a biotechnology company is its hydrogen sulfide drug platform. Antibe has designed this platform to enable it to originate, develop and out-license patent-protected new pharmaceuticals that are improved versions of existing drugs.

12. The hydrogen sulfide platform was born from Nobel Prize-winning medical research highlighting the crucial role of gaseous mediators, which are chemical substances produced in the human body to regulate a range of fundamental cellular processes. Since the properties of hydrogen sulfide were elucidated by Dr. John Wallace (Antibe's founder) and his colleagues in the mid-2000s, hydrogen sulfide is now recognized as a gaseous mediator that is made in every cell in the body. It is also now known that hydrogen sulfide plays a crucial protective and repair role at the cellular level, and acts as a key mediator of inflammation.

13. In the Drug, Antibe employs hydrogen sulfide's anti-inflammatory properties to protect the digestive system from the damage induced by NSAIDs. It does this by employing innovative pharmacology that involves chemically linking a base drug to a hydrogen sulfide-releasing moiety.

14. NSAIDs help reduce pain and inflammation by inhibiting the COX (cyclooxygenase) enzymes that control the production of prostaglandins at the site of injury. NSAIDs are indicated for a wide variety of conditions, ranging from acute pain caused by injury or surgery to chronic pain and inflammation caused by diseases such as osteoarthritis. Critically, NSAIDs are non-addictive and constitute the only drug class with analgesic (pain-relieving) effectiveness equivalent to opioids in a range of healthcare settings. As such, safer NSAIDs could help, in a not insignificant way, address the opioid crisis.

15. It is true that NSAIDs are among the most common pain relief medicines in the world. Contrary to Mr. Lotter's assertions, however, this makes the Drug more



potentially valuable, not less—because these drugs are so common, the size of the opportunity in the marketplace is much greater for improved NSAIDs. Further, the entire NSAID class suffers from GI ulceration issues, which the Drug has been shown to solve and the Drug would therefore represent a preferable option to existing NSAIDs (and be regarded as “best-in-class”).

16. Contrary to the assertions in the Second Letter Affidavit, including at paragraphs 6(f), 16, 20 and 27, the Drug does, therefore, meet an unmet patient need. The FDA itself regards the Drug as a novel chemical entity (an ‘NCE’). Further, fast tracking is only applicable to a small subset of novel drugs in development. However, and without getting ahead of myself, Antibe does plan to apply for one of the expedited review designations (including the ‘fast track’ and ‘breakthrough’ designations) at the conclusion of the Phase 2 Trial (as we likely fulfill all of the requirements per the FDA guidance for such designations for acute pain therapies).

17. It is increasingly recognized that inflammation is at the root of a substantial portion of human disease. The unique pharmacology and broad applicability of Antibe’s hydrogen sulfide platform offers a pathway to a new generation of anti-inflammatory drugs that could address a wide range of health conditions.

## **2. Letters of Support from Antibe’s Stakeholders and Creditors**

18. Further to the above, since commencement of its CCAA proceedings, Antibe has received a number of letters of support from its stakeholders and independent members of the scientific community who believe in the viability of the Drug, in Antibe’s

development and management team, and from creditors who further support Antibe's proposed CCAA process, including letters from:

- (a) Simulations Plus Inc., the DILISym contractor, who has an intimate knowledge of the chemical properties of the Drug and of the LTE issues;
  - (b) Lotus Clinical Research, LLC, Antibe's contract research organization who is, in part, assisting with the Phase 2 Trial;
  - (c) Rod Flower, an inflammation research scientist with 40+ years of experience and a particular focus on NSAIDs; a longstanding member of our Board of Directors;
  - (d) Lou Ignarro, a Nobel Laureate for his discovery surrounding nitric oxide (a gaseous mediator like hydrogen sulfide) and who is co-chair of our Scientific Advisory Board; and
  - (e) Harvey Schipper, a respected physician with public policy advisory roles that have included the World Health Organization, who sits on our Scientific Advisory Board.
19. These letters are attached to this affidavit at **Exhibit "A"**.

### **3. Next Steps Following the Lifting of the FDA Hold**

20. I pause here to reiterate that Antibe's primary request before this Court at the hearing scheduled April 18, 2024 is for the Stay Period to be extended to May 24, 2024, in order to provide Antibe time to receive the FDA Hold Letter, and to consider its response, and consult with its stakeholders. As stated in the First Curtis Affidavit, it is

difficult to comment further on Antibe's ability to lift the hold without having received the FDA Hold Letter and the specifics therein.

21. Contrary to the assertions in the Second Lotter Affidavit, including at paragraph 7, however, Antibe does have the germ of a restructuring plan in place. Antibe's plan is to engage with the FDA, have the hold removed from the Phase 2 Trial, and then to successfully complete the Phase 2 trial. Each of these steps is, independently, expected to improve recoveries for the general benefit of creditors. The lifting of the FDA hold is expected to enhance the marketability of Antibe's intellectual property. If Antibe is then allowed to successfully complete the Phase 2 Trial, Antibe expects to be able to use that event as a financial pivot point to fully meet the obligations with respect to Nuance and others and to move forward to the benefit of all stakeholders.

22. Following the successful conclusion of the Phase 2 Trial, Antibe intends to have its end-of-Phase 2 meeting with the FDA and start its first (of two) Phase 3 trials in 2025, followed 6 months later by the second one. To assist the Court, I have developed a timeline of the development of the Drug, which is attached to this affidavit at **Exhibit "B"**, which includes the steps to be followed if the hold is lifted.

23. As noted in the First Curtis Affidavit, since the Arbitration, Antibe has made significant progress in respect of resolving the LTEs, including running a clinical trial in November 2023 where LTEs were not an issue with treatment regimens comparable to the treatment regimen planned for the Phase 2 Trial. Contrary to paragraph 6(d) of the Second Lotter Affidavit, the Drug has not been long-intended for exclusively chronic use, and it has also not been found to present a serious risk to patient safety due to

LTEs. The LTEs that the Drug has experienced are further outlined below in this affidavit, and Antibe's work to overcome this hurdle is further outlined in the First Curtis Affidavit at paragraphs 76-83. The research and development of the Drug was at all material times and currently is intended to be developed for both chronic and acute care. Not one or the other.

24. Further, Antibe expects that information gained from its research into the short-term use of the Drug and the Phase 2 Trial will help identify drug exposure limits in any given time period, whether short or long, that will avoid the triggering of LTEs. Antibe plans to use that data and those insights to provide the necessary platform so it can resume the development of the Drug for long-term use in chronic conditions.

***B. Nuance Has No Direct Claim to Antibe's Monies***

25. I understand from my counsel that in its Cross-Application, Nuance is asking this Court to declare that Antibe's cash is held in trust for Nuance. In these circumstances, I note that contrary to the assertions in paragraph 14 (and elsewhere) of the Second Lotter Affidavit, the funds provided by Nuance were not "earmarked" in any way for Phase 3 testing, were not deposited into a segregated account, and I am not aware of any basis for an expectation that they would be segregated, much less held in trust.

26. The funds were, in fact, a non-refundable non-creditable upfront payment, and were deposited into Antibe's general account, as detailed in the First Curtis Affidavit. In addition, very shortly after completing the Nuance transaction, Antibe raised another \$40 million in the capital markets, and that amount was also deposited to Antibe's general operating account, also as described in the First Curtis Affidavit. At no time,

during the course of the Arbitration did Nuance seek or obtain a declaration of trust in the context, nor did it seek interim relief calling for the segregation or preservation of the funds.

27. To the extent that Nuance is able to assert a trust claim now, I understand that this Court will be called upon to consider the equities of that claim having regard to its impact on the claims of other stakeholders. I believe that the following information, all of which was introduced or obtained in the course of the Arbitration, may inform the grant of the remedy now being sought by Nuance.

28. I wish to be clear that, while Antibe disagrees with the Award, I am not providing the evidence that follows for the purpose of disputing or relitigating the Award. Rather, my intention is to provide context for Nuance's request for further relief in the face of Antibe's insolvency and having regard to the interests of other stakeholders.

#### **1. Nuance Rushed Its Due Diligence**

29. Multiple times in its dealings with Antibe, Nuance indicated that it wanted to close a license agreement with Antibe quickly. On December 30, 2020, Nuance sent Antibe an email in which it indicated that Nuance was "...very keen to move fast and meet [Antibe's] requirements ...". This email is attached as **Exhibit "C"**.

30. On January 6, 2021, Nuance sent Antibe an email confirming Nuance's commitment, as stated in a recent call between Nuance and Antibe, to "concluding the agreement ideally before the Chinese New Year break i.e., end January 2021." This email is attached as **Exhibit "D"**.

31. On January 11, 2021, Mark Lotter sent an email to Dan Legault confirming that Nuance wanted to close the licensing deal by the lunar new year (i.e., by February 12, 2021, less than a month from then):

“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.”

32. This email is attached as **Exhibit “E”**.

33. As detailed in the First Curtis Affidavit, as of January 11, 2023, Nuance still had not requested any documents from Antibe to start Nuance’s due diligence.

34. Normally it would take Antibe many weeks or even months to assemble the documents ordinarily requested by a potential licensee. As it happened, however, Antibe had already assembled its clinical and non-clinical study reports, as well as some corporate and other documents, in connection with certain filings for the FDA, and for the purpose of negotiations with another potential partner. Antibe relied on the data assembled for those other projects to populate a data room with documents that Antibe anticipated would certainly be among the documents that Nuance would request for the potential transaction.

35. As such, as detailed in the First Curtis Affidavit, Antibe was able to set up and populate the Nuance data room with an organized set of documents—approximately 566 documents (consisting of about 23,000 pages) regarding the Drug and Antibe, and including all clinical and non-clinical reports. It did this while expecting to receive

Nuance's full due diligence request list which is a standard element of pharmaceutical licensing transactions.

36. At no time did Antibe ever indicate to anyone at Nuance that the data room contained all relevant and material information, or that it contained all regulatory communications, or that all materials were accurate and up-to-date. Antibe viewed the documents in the Data Room as a "starter package" and that Antibe expected Nuance would request any further documents it needed. Antibe had no way of knowing what Nuance wanted and it was up to Nuance to define the scope of its due diligence and request the documents and information it wanted to review. The transcript of this portion of the arbitration and testimony is attached to this affidavit at **Exhibit "F"**.

37. Nuance was given access to the data room on January 25, 2021.

38. Antibe expected that Nuance would send Antibe a detailed list of all of the documents that they wanted for their due diligence, which is standard practice in pharmaceutical licensing transactions, but Nuance never did. Antibe also expected that after reviewing the documents, Nuance would ask extensive detailed questions, which is also standard practice in pharmaceutical licensing due diligence, but they never did.

39. Instead, Nuance made only two sets of requests:

- (a) On January 28, 2021, Jasmine Lien from Nuance sent Antibe an email indicating that the Nuance clinical team had checked the data room and noted it did not contain any information regarding Phase 3 studies; and

(b) On February 3, 2021, Annie Lee sent Antibe an email with a list of seven items of additional information and documents to be added to the Data Room.

40. These emails are attached as **Exhibit “G”** and **Exhibit “H”**.

41. In fact, Nuance elected to purposefully omit a request that had been discussed internally by the Nuance team for all FDA and EMA (European Medicines Authority) regulatory communications. Emails between Nuance personnel and from Nuance to Antibe are attached as **Exhibit “I”**.

42. Antibe answered Nuance’s questions on February 4, 2021. That email is attached to this affidavit at **Exhibit “J”**.

43. At no time did Nuance request any of Antibe’s communications with Health Canada let alone all of Antibe’s regulatory communications with Health Canada. At no time did Nuance request any of Antibe’s communications with the FDA let alone all of Antibe’s regulatory communications with the FDA. Nuance also never indicated it was interested in seeing regulatory communications or asked whether the Data Room contained all regulatory communications. The transcript of these portions of the Arbitration and testimony are attached to this affidavit at **Exhibit “K”**.

44. To Antibe’s surprise, following commencement of the arbitration, Antibe discovered that representatives from Nuance only looked at approximately 10% of the documents. The ShareVault reports show:



- (a) No one from Nuance, including the CMO read a complete clinical study report. The CMO only reviewed the first few pages (the synopsis) of certain key documents in the Data Room, including the Phase 2B Effectiveness Study Report, which was Antibe's most recent clinical study;
- (b) representatives from Nuance only looked at documents in the Data Room during the period of January 27, 2021-February 7, 2021;
- (c) Nuance representatives only spent 31 hours in the Data Room and looked at approximately 10% of the documents; and
- (d) Jin Li (the Nuance member in charge of regulatory) spent less than 30 minutes reviewing correspondence between Health Canada and Antibe.

45. The ShareVault log is attached to this affidavit at **Exhibit "L"**.

46. Exhibit 1 adduced at the Arbitration identified the regulatory documents involving Health Canada that were in the Data Room, and indicated which of those regulatory documents were reviewed by Nuance (highlighted in blue) and not reviewed by Nuance (highlighted in yellow). This exhibit shows that the Nuance representatives in charge of reviewing regulatory communications failed to open 115 of the regulatory communications with Health Canada. The chart below sets out the communications with Health Canada in the Data Room, the year they were sent or received, and whether they were reviewed by Nuance:

<b>Year</b>	<b>Reviewed</b>	<b>Not Reviewed</b>
2014	3	2
2016	10	9

2017	21	16
2018	1	-
2019	2	88
2020	2	-

47. Exhibit 1 is attached to this affidavit at **Exhibit “M”**.

48. Nuance never asked Antibe a single question about the safety of the Drug or the LTEs that Antibe had described in the Corporate Presentation, disclosed in its public disclosure, or discussed extensively in the most recent clinical study report and other study reports.

49. Nuance did not ask any other questions or ask for any further documents from Antibe prior to signing the License Agreement.

50. During the arbitration, Antibe learned that during this time, Nuance was also reviewing four or five different drug candidates. The transcript of this portion of the arbitration and Mr. Lotter’s testimony is attached to this affidavit at **Exhibit “N”**.

51. The lack of providing a due diligence request and the cursory nature of the document review and the limited questions asked are detached from standard licensing and dealmaking practices in the pharmaceutical industry.

**2. Nuance ought to have known about the LTEs by reviewing the documents in the Data Room**

52. Nuance claimed that had Nuance seen the January 19-22, 2021 Health Canada correspondence between Antibe and Health Canada, it would have known there were safety or regulatory risks associated with the Drug, and would have conducted a full investigation to ensure Antibe could address the regulator’s concerns before proceeding

with the licensing deal. Nuance further claimed that it was particularly concerned with regulators communications.

53. The history of the Health Canada Correspondence and the AME Study is set out at paragraphs 63 to 75 of the First Curtis Affidavit.

54. From reviewing the Second Lotter Affidavit, it appears that Nuance still does not understand the issue of the LTEs in the Drug. Contrary to the assertions in the Second Lotter Affidavit, including at paragraph 17 and 18, LTEs were a particular risk to the Drug and were of a greater nature than the limited class effect of LTEs related to NSAIDs. The work done by Antibe and Antibe's significant advancements in respect of the LTE issue are laid out in the First Curtis Affidavit, at paragraphs 76-83.

55. The history of the Drug's issues with LTEs, which I provide so this Court can better understand how Nuance ought to have understood the LTEs issues, and which is described in Appendix "A" to the First Curtis Affidavit is laid in greater detail in a further **Appendix "A"** to this affidavit.

56. The data room, combined with information readily available in the public domain, provided all of the documents Nuance needed to identify and understand the LTEs and the risk they posed. This ought to have been sufficient information for Nuance to assess the potential risks for the Drug. Meaningful elevations of drug-related liver transaminases, greater than 3 times the upper limit of normal, were observed in four clinical studies, as it outlined further at **Appendix "A"**.

57. At the Arbitration, Nuance agreed that its due diligence team did not identify the LTEs observed in the Drug's clinical studies as a risk. Nuance indicated that the LTEs were not a cause of concern for Nuance as it considered them to be a class effect (which is an incorrect appreciation of the LTE issue with the Drug when used for chronic indications) and Mr. Lotter testified at the Arbitration that he never recognized that the incidence of LTEs of between 8.0% and 12.1% identified in the Phase 2B Efficacy Study were inordinately high, and no one from his team ever told him they were. Similarly, Annie Lee testified that there was no discussion among the due diligence team about the significance of the LTEs seen in Drug's clinical studies because they accepted the LTEs as a class effect, which is also an incorrect appreciation of the LTE issue of the Drug when used for chronic indications. The transcript of this portion of the arbitration and testimony is attached to this affidavit at **Exhibit "O"**.

58. Nuance's expert Ms. Chan, however, agreed that any doctor should be able to recognize the findings were very serious and significant. She testified that the levels of LTEs would raise a red flag for her if she was conducting due diligence and she would identify them as a risk and inquire into their cause to better understand the nature of the Drug. The transcript of this portion of the arbitration and testimony is attached to this affidavit at **Exhibit "P"**.

59. While Nuance claimed, after-the-fact, that regulatory communications themselves were important to Nuance as they would have brought the LTE issue into sharper focus, that is not supported by their actions in never reviewing approximately 75% of the regulatory communications in the data room. In any event, Nuance could have and

should have discerned the information that Health Canada was concerned about—that the LTEs were a risk—by reviewing the documentation provided in the data room.

**3. Nuance Would have Proceeded with the License Agreement once Health Canada approved the AME Study**

60. It was Mr. Lotter's evidence at the Arbitration that Nuance would have proceeded with the licensing deal notwithstanding the January 2021 Health Canada communications, once Health Canada approved the AME Study in June 2021. Mr. Lotter testified that Nuance would have been prepared to proceed with the License Agreement after Health Canada had approved the protocol and the study was allowed to proceed, which is what happened in June 2021. The transcript of this portion of the arbitration and testimony is attached to this affidavit at **Exhibit "Q"**.

**C. Antibe's Good Faith Engagement with Nuance**

61. Contrary to the assertions in the Second Lotter Affidavit at paragraph 20, Antibe did in fact put forward a good faith proposal to restructure and repay the Award, and it was not without prejudice. A copy of Antibe's proposal and related correspondence is appended hereto as at **Exhibit "R"** (the "**Repayment and Restructuring Proposal**").

62. The Repayment and Restructuring Proposal was prepared by Antibe with the guidance of Mr. Sellers, as its restructuring advisor. In summary, Antibe advised that it did not have the ability to make an immediate cash payment, having regard to the preferential nature of such a payment, but that Antibe could provide some immediate value, and further value as soon as possible on a staged basis. Antibe offered to issue common shares equal to 9.9% of the company's capital stock and an additional 6.5

million warrants, all of which could be sold in the public markets in reduction of the Award, and to structure the balance as an 8% term note with prepayment obligations.

63. Nuance did not reject the proposal outright and advised Antibe that it intended to consult its board and respond thereafter.

64. Antibe recognized that additional non-public information might be required by Nuance to assess Antibe's proposal, and it offered to provide that information on execution by Nuance of a non-disclosure agreement. A draft non-disclosure agreement was provided to Nuance by Antibe or about April 4, 2024.

65. Other than by the delivery of Nuance's Notice of Application seeking the appointment of a receiver and triggering these proceedings, Nuance has never responded to either to the Repayment and Restructuring Proposal, and only provided the signed NDA on April 14, 2024. Mr. Lotter's suggestion that the Repayment and Restructuring Proposal was not made in good faith is baseless, particularly when Nuance never bothered to provide Antibe with any comments in respect of the proposal, or to receive additional information in respect of it. To the contrary, I believe that it was a good faith attempt, having regard to applicable securities and insolvency laws, to provide immediate value to Nuance which was otherwise not available as well as a defined pathway to full payment.

66. On April 16, 2024, at 2:29pm, Nuance provided Antibe and the Monitor with a letter containing 46 requests. It appears to me, on a preliminary review, that a number of these requests or questions are already responded to in the record, including in the First Curtis Affidavit. Antibe is working in conjunction with the Monitor to consider and

respond in due course as necessary and appropriate. The request from Nuance is attached as **Exhibit "S"**.

**AFFIRMED** remotely by Scott Curtis at the City of Toronto, in the Province of Ontario, before me on this 17<sup>th</sup> day of April, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely



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Commissioner for Taking Affidavits

Dillon Gohil, a Commissioner, etc.  
Province of Ontario, while a Student at  
Law  
Expires April 17, 2026

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Scott Curtis

**APPENDIX "A"**

67. In the Spring of 2014, after completing all pre-clinical studies, Antibe applied to Health Canada for approval to do a first-in-human study. At this juncture, Antibe had amassed a significant amount of data, all of which pointed to an effective and safe compound. The CTA was approved. By approximately mid-2014, Antibe began the Drug's first in-human (i.e., Phase 1) trial.

68. As with all Phase 1 trials, Antibe began with very low doses delivered for only a single day in a few healthy patients, proceeding to test incrementally higher doses. It then began testing a lower dose in a few healthy patients for a longer duration, and then proceeded to test incrementally higher doses for a longer duration.

69. In the Fall of 2014, Antibe identified transient LTEs in 3 of 6 subjects within the second-highest treatment dose cohort. "Transient" means that the elevated serum aminotransferase levels self-resolved (returned to normal) with no treatment or medical intervention. All of the study patients remained asymptomatic. As noted earlier, LTEs can be caused by many different things. The principal investigator for the initial Phase 1 study, a medical doctor who was not affiliated with Antibe and who was overseeing the study, reviewed the cases and concluded the LTEs in this case were likely due to influenza, which had affected several of the patients in the Phase 1 clinic. As a result, the study continued.

70. Antibe then tested a higher dose of the Drug, which was the anticipated therapeutic dose. This time, 5 of the 6 subjects showed LTEs. In 4 of the patients, the LTEs were only discovered post-treatment; the fifth was thought to likely have been



caused by confounding factors (factors unrelated to the Drug).<sup>1</sup> Nonetheless, the number of study subjects who had exhibited LTEs during or after receiving a trial of the anticipated therapeutic dose was of concern. Antibe made the decision to pause the drug's development until further investigation was carried out as to the cause of the LTEs.

71. By way of a press release, dated January 16, 2015, Antibe announced the suspension of the study. That press release was posted on the Antibe website, where it remains to this day, available for public review. All information regarding the study was included, as required, in subsequent CTAs in Canada and in Antibe's IND submission to the FDA.

72. In mid-March 2015, after two months of intensive review of all safety data collected in and subsequent to the initial Phase 1 study, Antibe concluded its Phase 1 trials. It issued a press release regarding the study and the conclusion of Phase 1 trials the same day along with the company's intention to continue the clinical development of the Drug.

73. In early 2016, Antibe applied to Health Canada for a CTA for a 10-day Phase 2 study of 12 osteoarthritis patients to establish whether a lower 250 mg dose could deliver sufficient analgesia. The CTA contained the results of the previous study ensuring Health Canada was fully informed of the LTEs observed in the previous Phase 1 study, which had happened at far higher doses.

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<sup>1</sup> For the fifth patient, the LTE was identified during the dosing period (day 13). The patient was later found to have hidden key aspects of his health history, particularly a hepatitis A infection, which would have disqualified him from the study. Subsequent examination also found that he had other conditions that might have caused or contributed to the LTEs.

74. Health Canada approved the CTA, and Antibe conducted the trial, which showed patients rated the drug highly in treating their pain. There were no liver issues apart from one patient who exhibited LTEs. That patient was also undergoing intermittent chemotherapy for cancer at the time and the LTE was attributed to a reaction to the chemotherapy.

75. In the Fall of 2017, Antibe submitted a CTA and received approval to conduct a large, 244-subject, 14-day gastrointestinal (“GI”) safety study in healthy volunteers that compared the outcomes of the Drug v. those of prescription-strength naproxen. The Drug had a significant GI safety advantage over naproxen (42% of subjects on naproxen had gastric ulcers compared to 2.5% of those on the Drug). Antibe identified drug-related LTEs in approximately 5% of those taking the Drug, which was in general concordance with the 1-4% range commonly associated with NSAIDs.

76. In early 2019, Antibe conducted another Drug study after receiving approval for a CTA from Health Canada, which again had been provided with the safety results of all prior clinical Drug studies, including LTE incidence. Health Canada requires that an Investigator’s Brochure be provided with each application for a CTA. The Investigator’s Brochure documents the safety findings and conclusions from all previously conducted studies.

77. Also in early 2019, Antibe received CTA approval from Health Canada for a large 14-day placebo-controlled efficacy study involving 384 patients for Drug doses of 150, 200, and 250 mg/day (the “Phase 2B Effectiveness Study”). This is the study referred to in Antibe’s Response to Notice of Arbitration and Nuance’s Statement of Claim.

78. The Phase 2B Effectiveness Study demonstrated impressive statistically significant efficacy for both higher doses, and suggested that the lowest 150 mg/day dose would likely have good efficacy. The drug-related LTE incidence for all study patients, regardless of dose, was in the 9-12% range.

79. As with previous studies, the LTEs were only detected at follow-up appointments. In the Phase 2B Effectiveness Study, it was also apparent that the incidence of LTEs was exacerbated in patients with concomitant liver stressors such as concomitant and post-administration use of Tylenol, which also causes LTEs.

80. A Clinical Study Report (“CSR”) titled “A Double-Blind, Placebo-Controlled, 4-Arm, Phase 2B Study to Assess the Efficacy and Safety of a 14-Day Dosing Regimen of 3 Doses of ATB-346 Versus Placebo, Orally Administered Once Daily to Male and Female Patients Diagnosed with Osteoarthritis of the Knee” dated December 21, 2020 reported on the trial results. The CSR included a 10 page summary of the trial, including a full page in which the LTEs are described and discussed. The entire CSR is 104 pages. Twenty-two of the pages are devoted to an in-depth safety evaluation with LTEs being referenced on most of these pages. Individual patient cases are also discussed. The CSR concludes by recommending that future studies only investigate doses at or less than 150 mg/day because of the LTEs.

This is Exhibit "A" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**



April 15, 2024

Deloitte Restructuring Inc.  
8 Adelaide Street West,  
Toronto, On, M5H 0A9  
[nmeakin@deloitte.ca](mailto:nmeakin@deloitte.ca)

**Attention: Nigel Meakin**

Dear Mr. Meakin,

**Re: Antibe Therapeutics Inc.**

Simulations Plus Inc., (“Simulations”) is a company that conducts modelling for physiologically-based pharmacokinetics (PBPK), pharmacometrics, and quantitative systems pharmacology/toxicology, among other things. In particular, we are a sophisticated liver research organization, focused on understanding and alleviating liver issues in drug development. A main focus is on liver simulation software to perform sophisticated predictions. We have now conducted such simulation projects with greater than 50 drug development organizations, impacting many programs through regulatory submissions. Our software (known as “**DILIsym®**”) is held in high regard by the FDA; in fact, the FDA recently renewed their DILIsym software license for the seventh year in a row.

We have been working with Antibe since 2020, in respect of addressing the liver transaminase elevations that had followed administration of otenaproxesul. We understand otenaproxesul and the liver enzyme elevation issues intimately, and believe that we now understand the cause of the issues. Using DILIsym, we have created sophisticated models, and have validated them with data from three species of animals and Antibe’s human trials. Based on the objective DILIsym analysis and our many years of experience in this field, all indications are that otenaproxesul is safe for acute pain indications, and certainly warrants additional clinical trials to validate its great potential as a new tool against pain.

We have also been assisting Antibe with its current phase 2 trial being undertaken in the United States of America. We understand that the FDA has placed a hold on the trial, and we have been working with Antibe to develop information to be provided to the FDA for having the hold removed.

Antibe’s development team is sophisticated, with a deep familiarity with the drug and a strong commitment to safety. Safety has been at the forefront of Antibe’s development ethos in its work relating to otenaproxesul.

We understand that one creditor may be asking the court to exercise its discretion to impose a trust over all of Antibe’s cash and to appoint a receiver over Antibe. Simulations Plus does not

believe that the imposition of a trust would be fair because we relied on our understanding of Antibe's cash position when we elected to advance credit to Antibe. Simulations Plus is also opposed to the appointment of a receiver, because that would be destabilizing of Antibe's business. We believe it would be in the best interest of Antibe and all related parties for Antibe to successfully have the FDA clinical hold removed, and then conduct their next acute pain (Phase 2) clinical trial successfully.

Respectfully,



Brett A. Howell, Ph.D.  
President, QSP Solutions  
Simulations Plus Inc.  
[Brett.howell@simulations-plus.com](mailto:Brett.howell@simulations-plus.com)  
704-202-1455





# Barts and The London

## School of Medicine and Dentistry

EMERITUS PROF RJ FLOWER FRS  
 CENTRE FOR BIOCHEMICAL PHARMACOLOGY  
 WILLIAM HARVEY RESEARCH INSTITUTE  
 BARTS AND THE LONDON  
 JOHN VANE SCIENCE CENTRE  
 CHARTERHOUSE SQUARE  
 LONDON EC1M 6BQ, UK

TEL: +44 (0)20 7882 8781  
 FAX: +44 (0)20 7882 6076

April 13, 2024

Attention: **Nigel Meakin Esq**  
 Deloitte Restructuring Inc.  
 Deloitte Canada  
 Bay Adelaide East, 8 Adelaide Street West,  
 Toronto, ON, M5H 0A9

**RE: Letter of Support for Antibe Therapeutics Inc.**

Dear Mr. Meakin,

I am a scientist specializing in the mechanism of actions of medicines (pharmacology). For the last 25 years of my career, I worked in St Bartholomews and the Royal London Medical and Dental School in central London where I founded and headed a Department of Biochemical Pharmacology. I now hold an emeritus chair in pharmacology at that medical school. I was also a Principal Fellow of the Wellcome Trust from 1994-2007 and was elected to fellowship of the Academy of Medical Sciences (1999) and the Royal Society (2003).

Throughout my research career (which spans more than four decades) I have worked in both academia and the pharmaceutical industry, publishing over 350 papers during that time. My chief research interest has been the mechanism of action of anti-inflammatory drugs especially that sub-group known as the *non-steroidal anti-inflammatories* (NSAIDs: also called the 'aspirin-like drugs') which comprise a widely used group of drugs including aspirin and acetaminophen. I was a member of the original team who, in the early 1970s, elucidated the mechanism of action of these medicines. We determined that they acted through inhibition of an enzyme in the body (the '*cyclooxygenase*' or simply, '*cox*') which



generates a group of local hormones known as the *prostaglandins*. These have some physiological functions but are also inflammatory messengers which cause pain, fever and inflammation in response to injury or infection. Our proposed mechanism explained why the NSAIDs have analgesic, antipyretic and anti-inflammatory effects and also neatly accounted for several prominent side effects (including gastric intolerance). My mentor was awarded the Nobel Prize in 1982 for this discovery.

Our work is now accepted as providing a comprehensive explanation for the action of these useful medicines. My contributions included the first evidence that aspirin inhibited prostaglandins in normal therapeutic doses in humans; the demonstration that all the NSAIDs shared the same unique mechanism of action and also that there was likely another form of the enzyme with different reactivity to these drugs.

I have been associated with Antibe since its inception (circa 2005). The company was formally constituted in 2010 after which I was invited to become a member of the Board. I did so because I was excited by the work done by my friend and colleague Dr John Wallace, who had pioneered the idea of introducing 'gaseous' anti-inflammatory molecules into standard off-patent NSAIDs.

Since prehistory human beings have sought relief from their aches, pains and fevers in the extracts of certain plants such as meadowsweet, willow, poplar and wintergreen. In 1839 the active substance present in these plants was isolated and found to be salicylic acid. This was synthesised in 1859 and proved to be a popular drug for treating patients with arthritis although it's disagreeable taste, and unpleasant side effects limited its usefulness. In 1899 a simple chemical derivative of salicylic acid was produced by the German Company Bayer and marketed under the name 'Aspirin'. It proved to be an instant success with clinically proven anti-inflammatory/analgesic effects and is still taken in prodigious quantities around the world (some 60 billion tablets each year) over a century later.

Because of aspirin's success, other pharma companies were quick to search for drugs with a similar therapeutic profile. In a recent edition of our textbook, I counted over 25 such 'aspirin-like drugs' including many (e.g., ibuprofen) which are available without prescription from pharmacies. Clinically, the NSAIDs are amongst the most prescribed of all drugs, being used for an entire spectrum of disorders including arthritic conditions, muscle and joint pains, soft tissue injuries, sports injuries, headaches, fevers, period pains, dental pain and post-operative pain. In total, they account for 5-10% of all prescriptions each year here in the UK and our National Health Service spends in excess of £70 million each year on these drugs (and this doesn't include those purchased directly over the counter in pharmacies). At some time in their lives, almost everyone has taken an aspirin,

acetaminophen or other related medicine and several NSAIDs are listed on the WHO 'Essential Drugs' list.

But there is a problem. This group of drugs is well known to cause gastrointestinal damage in susceptible people. The symptoms range from gastric discomfort, heartburn, acid reflux to, more serious issues such as ulcers. Some have estimated that the incidence may be as high as 26-34%. In the UK, some 400-1000 deaths each year result from the side effects of these drugs.

Over the last few decades, strenuous efforts have been made by the pharma industry to solve this problem by producing different types, or different formulations of NSAIDs, but the improvements in gastric tolerance have been marginal. Amongst the most recent new ideas in the area, are the 'coxibs'. These could be regarded as a subset of NSAIDs which are more selective for another form of the cyclooxygenase enzyme (Cox-2; finally identified in 1991). Even though extensive experimental evidence suggested they should be free from gastrointestinal effects, the actual clinical experience was rather disappointing and only 2-3 of these are still used.

It is against this background that you can understand why I think that Otenaproxesul, Antibe's lead drug, is so exciting. In humans it has proven analgesic efficacy and the gastric safety study produced the cleanest data I have seen in my career. High doses given chronically, had undesirable (but reversible) effects on the liver of some patients in an early trial, but the new formulation and dosing schedule we introduced in our last trial has solved this problem too.

The world desperately needs more analgesics. The opioid crisis, which has already claimed well over half a million lives and has left a massive medico-social problem in its wake, has taught us that whilst these drugs are superb analgesics, they have potentially deadly side effects when not properly used. A novel type of analgesic from Boston-based Vertex (*suzetrigine*) has recently concluded late-stage trials but it is too soon to say whether it will ultimately displace opioids or NSAIDs. In addition, it doesn't have any anti-inflammatory or antipyretic actions.

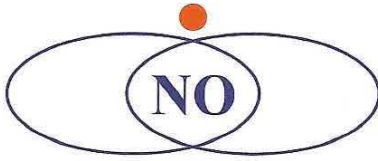
In my opinion, Otenaproxesul is the closest we have seen to a 'clean' NSAID and it would be a tragedy for future patients if this drug was lost from our future therapeutic armamentarium. I feel strongly that this drug could (and should) become a very special medicine and I am committed to working with Antibe to advance this drug through to the next stage of development.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Rod Flower', with a horizontal line underneath.

**Prof. Rod Flower** PhD, DSc, DSc (hon), LLD (hon), FRSB, HonFBPhS, FMedSci, FRS





Lou Ignarro, Inc  
Nitric Oxide for Better Health  
Dr. Louis J. Ignarro  
President, CEO, and CSO

Distinguished Professor Emeritus - UCLA  
National Academies of Science and Medicine

*Nobel Laureate - Physiology or Medicine*

269 South Beverly Drive  
Unit 288  
Beverly Hills, CA 90212  
310-995-3500  
lignarro@gmail.com

April 15, 2024

Nigel Meakin  
Court Monitor  
Deloitte Canada  
[by email]

To whom it may concern,

I am writing this letter in support of the team and science behind otenaproxesul, a promising and novel anti-inflammatory analgesic being developed by Antibe Therapeutics, a Canadian biotech company, where I have co-chaired the Scientific Advisory Board since 2013. Antibe is developing this drug as a non-addictive analgesic that offers the potential to help address the opioid crisis, a worldwide public health emergency.

My background is in academic and industry pharmacology research, specializing in cardiovascular physiology. I started my career at the National Institutes of Health (NIH) and then Ciba-Geigy (now Novartis). At Ciba-Geigy, I headed the company's biochemical and anti-inflammatory program, which led to the development of diclofenac (a widely used pain therapeutic in the same class as otenaproxesul, Antibe's lead drug). Subsequently, I became professor of pharmacology; in 1985, I joined the faculty at UCLA School of Medicine, where I am Professor Emeritus of Molecular and Medical Pharmacology. Since joining academia, my focus has been on nitric oxide's role in human biology. In 1986, I discovered its function as a gaseous mediator, for which I shared the 1998 Nobel Prize in Physiology or Medicine. Further research by myself and others led to many pharmacological and medical advances, including a range of nitric oxide-based medicines and a blockbuster drug (Viagra).

In the mid-1990s, I was contacted by Dr. John Wallace (later the founder of Antibe Therapeutics) to join the scientific advisory board of a company developing nitric oxide releasing anti-inflammatory drugs. John's expertise in anti-inflammatory drugs (known as nonsteroidal anti-inflammatory drugs or "NSAIDs") arose from his post-doctoral research under Sir John Vane, who had first elucidated the mechanism of action of aspirin, the original NSAID. (Sir John received the 1982 Nobel Prize in Physiology or Medicine for this discovery). John Wallace had gone on to discover how NSAIDs damage the gastrointestinal tract -- his expertise in this area was later called upon by the U.S. FDA in reviewing the safety of a new category of NSAIDs in the early 2000s.



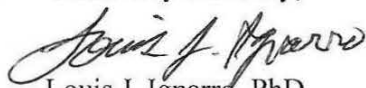
John and I kept in touch after our initial collaboration wrapped up; our professional overlap expanded when he discovered the anti-inflammatory characteristics of hydrogen sulfide, the third gaseous mediator to be identified. When John asked me to co-chair the Antibe Therapeutics' Scientific Advisory Board in 2013, I accepted without hesitation, knowing that its development program was being conducted under his guidance. Even then, the science behind otenaproxesul was extensive and promising, with considerable data (including peer-reviewed work) showing the beneficial effects of hydrogen sulfide in preventing stomach ulcers and bleeding, alleviating a serious and potentially life-threatening side-effect that has dogged this important class of drugs since aspirin was introduced more than 100 years ago.

When I joined Antibe's Scientific Advisory Board, the company was preparing for its first human study of otenaproxesul for treating chronic pain, specifically osteoarthritis. Among other advances, otenaproxesul has since demonstrated a high degree of gastric safety and impressive efficacy data in a pair of large Phase 2 trials together involving more than 600 subjects. Although liver-related considerations have led Antibe to shift otenaproxesul's indication from chronic pain to acute pain, the drug's unique hydrogen sulfide-releasing capability remains central to its therapeutic value proposition. Because acute pain indications require a rapid onset of therapeutic action, the company reformulated the drug -- this new version (along with a unique tapered dose regimen) was shown to be liver-safe in a clinical trial conducted in late 2023.

As reflected in daily news headlines, opioid abuse has killed hundreds of thousands of people in the U.S., wrecking families and communities, and costing our health system more than \$100 billion annually. (I understand that its effect on Canadians is equally grim.) As a novel non-opioid analgesic, otenaproxesul has the potential to help address this vast tragedy. I should add that there have been no novel oral painkillers introduced in the U.S. since the late 1990s, as their development is difficult, time-consuming and requires rare expertise -- it is a credit to the Antibe team to have brought otenaproxesul within striking distance of demonstrating safe and effective treatment of acute pain.

Otenaproxesul represents an important breakthrough in analgesic pharmacology. Given its potency and favorable side-effect profile, the drug could make a worthy difference to doctors, patients and regulators seeking safer, non-addictive pain medicines. While the FDA has delayed the Phase 2 trial to more fully assess the scientific basis for Antibe's confidence in the drug, I strongly believe that otenaproxesul warrants the effort needed to complete its development, with the potential to save many lives and improve the quality of life for many more.

Yours very sincerely,



Louis J. Ignarro, PhD

Professor Emeritus of Molecular and Medical Pharmacology  
University of California, Los Angeles



Nigel Meakin  
Court Monitor  
Deloitte Canada  
**By e-mail**

April 13, 2024

RE:Antibe Therapeutics Inc.  
15 Prince Arthur Ave.  
Toronto, ON M5R 1B2  
Canada

**RE: Letter of Support**

Dear Mr. Meakin,

I am writing this letter from my perspective as Professor of Medicine and Adjunct Professor of Law at the University of Toronto. I was initially trained as an engineer, and have been at the interface of bioscience, clinical medicine and public policy for half a century. I worked with the WHO, shaping pain control and palliative care programs around the world. Our research group developed the quality of life measures that are now the basis of benchmark patient centred care and assessment globally. I am deeply familiar with the challenges inherent in drug development. For the past decade I've taught Biotechnology Law and Policy in the Law School, where these issues are a focus of the course.

I have had both formal and informal roles with Antibe for better than a decade. Dan Legault, the CEO and I met while serving on a Canadian corporate board. I was intrigued by Antibe's potential, and in particular the integrity of Dan's commitment to bringing the benefits of a novel pharmacology to clinical reality. Subsequently we concluded a formal advisory relationship which continued for several years. While that formal relationship is now in abeyance, I'm still informally involved.

The science is fascinating. You take a well known and effective pain killer, naproxen, and attach to it a simple molecule, hydrogen sulfide (H<sub>2</sub>S) and the drug, otenaproxesul, becomes dramatically more potent. More important, the gut toxicity which severely limited its use is abolished. The clinical implications are substantial. First, based on




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clinical trials data in hand, Otenaproxestul, may allow us to replace opioids for the relief of moderate to severe short term pain. That's a major advance, because it alleviates the risk of opioid dependency which we are seeing far too often as a difficult and unintended consequence of pain management. Second, this novel conjugation of H<sub>2</sub>S with other molecules opens a new pathway in drug development with considerable potential. Third, from a Canadian public policy perspective, this is a piece of the new medicine we need to keep alive in Canada.

I've worked in this realm of medicine for a long time. Antibe stands out for me, not only because of the clinical and economic potential of what it is doing, and the novelty of its approach to drug development, but also for the global vision and integrity of its culture. I hope, with your help, it can meet this challenge and go on to make a significant mark in the relief of human suffering.

Sincerely,



H. Schipper, BA Sc (Eng), MD, FRCPC  
Professor of Medicine  
Adjunct Professor of Law  
University of Toronto





*Mailing Address:*  
430 Mountain Avenue, Suite 302  
New Providence, NJ 07974  
P: 908-756-4411 ext. 5

April 16, 2024

Deloitte Restructuring Inc.  
Deloitte Canada  
8 Adelaide Street West,  
Toronto, On, M5H 0A9  
**VIA EMAIL:** [nmeakin@deloitte.ca](mailto:nmeakin@deloitte.ca)

**Attention: Nigel Meakin**

Dear Mr. Meakin:

**Re: Antibe Therapeutics Inc.**

On behalf of Lotus Clinical Research, LLC (“Lotus”), I write further to our meeting of 11 April 2024 with you and Dan Legault of Antibe Therapeutics Inc. (“Antibe”) at which time I was advised of Antibe’s ongoing efforts to restructure its business under the *Companies’ Creditors Arrangement Act* (the “CCAA”). Based on our discussions, Lotus is generally supportive of Antibe’s proposed next steps in its restructuring efforts under the CCAA, which Lotus understands are aimed at providing Antibe with a brief period within which to determine the viability of proceeding with the Phase 2 trial of the drug otenaproxesul.

As you may be aware, Lotus is a clinical research organization based in New Providence, New Jersey (formerly Pasadena, California). Lotus has worked with Antibe since 2018 to support Antibe’s clinical trials in the United States and Canada.

Antibe retained Lotus’ services to support pain trials in Canada for otenaproxesul in 2019-2020 related to the chronic condition, osteoarthritis.

As of December 2023, Lotus was engaged by Antibe to oversee a multi-center randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of otenaproxesul for acute pain following abdominoplasty (known as the Phase 2 trial), with clinical conduct to be conducted at ERG investigative sites in Arkansas and Texas. Lotus has particular experience with such trials, as we are known for developing the surgical model for abdominoplasty which is now used as a soft tissue surgical model for acute pain approval with the Food and Drug Administration (the “FDA”).

Lotus and Antibe have worked extensively since December 2023 in designing and preparing for the Phase 2 trial. Lotus is aware that the FDA placed a hold on the Phase 2 trial and has been advised by Antibe that a letter from the FDA setting out the reasons for the hold is expected before the end of April.



Mailing Address:  
430 Mountain Avenue, Suite 302  
New Providence, NJ 07974  
P: 908-756-4411 ext. 5

Lotus is aware that a separate application has been brought by Nuance Pharma Ltd. seeking, among other things, the appointment of a receiver over Antibe’s property. As a substantial creditor of Antibe, Lotus is concerned that the appointment of a receiver will ultimately destabilize Antibe’s business and is destructive of value, to the serious detriment of Lotus and other stakeholders. As such, Lotus supports the brief extension of the CCAA stay of proceedings to determine whether it is viable to proceed with the Phase 2 trial.

DocuSigned by:  
*William Martin*  
**LOTUS CLINICAL RESEARCH, LLC**  
Signer Name: William Martin  
Signing Reason: I approve this document  
Signing Time: 16-Apr-2024 | 1:45:33 PM PDT  
Per: \_\_\_\_\_  
24A4DB9568974E12B04A688705F1508D


**Certificate Of Completion**

Envelope Id: 4A66ED42295D427DB2FE785EC883A43A	Status: Completed
Subject: Complete with DocuSign: Lotus Clinical Research LLC Letter to Deloitte 16APR2024.docx	
Source Envelope:	
Document Pages: 2	Signatures: 1
Certificate Pages: 4	Initials: 0
AutoNav: Enabled	Envelope Originator:
EnvelopeId Stamping: Enabled	Alicia McLoughlin
Time Zone: (UTC-08:00) Pacific Time (US & Canada)	100 W California Blvd., Unit 25
	Pasadena, CA 91105
	amcloughlin@lotuscro.com
	IP Address: 174.81.22.199

**Record Tracking**

Status: Original	Holder: Alicia McLoughlin	Location: DocuSign
4/16/2024 1:08:46 PM	amcloughlin@lotuscro.com	

**Signer Events**

Signer Events	Signature	Timestamp
William Martin wmartin@ergclinical.com President Security Level: Email, Account Authentication (Required)	  Signature Adoption: Pre-selected Style Signature ID: 24A4DB95-6897-4E12-B04A-688705F1508D Using IP Address: 72.82.15.29  With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 4/16/2024 1:09:28 PM Viewed: 4/16/2024 1:44:45 PM Signed: 4/16/2024 1:45:36 PM

**Electronic Record and Signature Disclosure:**  
Accepted: 9/15/2021 1:17:48 PM  
ID: 870188c0-f921-466a-a26c-bc540b3eaad1

In Person Signer Events	Signature	Timestamp
<b>Editor Delivery Events</b>	<b>Status</b>	<b>Timestamp</b>
<b>Agent Delivery Events</b>	<b>Status</b>	<b>Timestamp</b>
<b>Intermediary Delivery Events</b>	<b>Status</b>	<b>Timestamp</b>
<b>Certified Delivery Events</b>	<b>Status</b>	<b>Timestamp</b>
<b>Carbon Copy Events</b>	<b>Status</b>	<b>Timestamp</b>
<b>Witness Events</b>	<b>Signature</b>	<b>Timestamp</b>
<b>Notary Events</b>	<b>Signature</b>	<b>Timestamp</b>
<b>Envelope Summary Events</b>	<b>Status</b>	<b>Timestamps</b>
Envelope Sent	Hashed/Encrypted	4/16/2024 1:09:28 PM
Certified Delivered	Security Checked	4/16/2024 1:44:45 PM
Signing Complete	Security Checked	4/16/2024 1:45:36 PM
Completed	Security Checked	4/16/2024 1:45:36 PM
<b>Payment Events</b>	<b>Status</b>	<b>Timestamps</b>



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If you decide to receive documents from us electronically, you may at any time change your mind and tell us thereafter that you want to receive documents only in paper format. If you want to withdraw your consent and receive future documents in paper format, please contact your Lotus Lead Project Manager.

**Consequences of changing your mind**

If you elect to receive documents only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the documents to you in paper format, and then wait until we receive back from you and your execution of such paper documents. To indicate to us that you are changing your mind within the DocuSign system, you must withdraw your consent using the DocuSign “Withdraw Consent” form on the signing page of a DocuSign envelope instead of signing it. This will indicate to us that you have withdrawn your consent to receive documents electronically from us and you will no longer be able to use the DocuSign system to receive documents electronically from us or to sign electronically documents from us.

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Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all documents that require your signature during the course of our relationship with you. All documents will be sent to you through your e-mail as recorded in the study-specific Study Contact Sheet. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

**How to contact Lotus Clinical Research, LLC:**

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically:

**To advise Lotus Clinical Research, LLC of your new e-mail address**

To let us know of a change in your e-mail address, you must send an email message to your Lotus Lead Project Manager and in the body of such request you must state: your previous e-mail address, your new e-mail address. We do not require any other information from you to change your email address.

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To request delivery from us of paper copies of the documents previously provided by us to you electronically, you must send an e-mail to your Lotus Lead Project Manager and in the body of such request you must state your e-mail address, full name, US Postal address, and telephone number.

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- ii. send an email to your Lotus Lead Project Manager withdrawing consent, and in the body of such request you must state your e-mail, full name, US Postal Address, and telephone number.

**Required hardware and software**

Operating Systems:	Windows® 2000, Windows® XP, Windows Vista® Mac OS® X
Browsers:	Final release versions of Internet Explorer® 6.0 or above (Windows only); Mozilla Firefox 2.0 or above (Windows and Mac); Safari™ 3.0 or above (Mac only)
PDF Reader:	Acrobat® or similar software may be required to view and print PDF files
Screen Resolution:	800 x 600 minimum
Enabled Security Settings:	Allow per session cookies

\*\* These minimum requirements are subject to change. If these requirements change, you will be asked to re-accept the disclosure. Pre-release (e.g. beta) versions of operating systems and browsers are not supported.

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- You can print on paper the disclosure or save or send the disclosure to a place where you can print it, for future reference and access; and
- Until or unless you notify Lotus Clinical Research, LLC, as described above, you consent to receive through electronic means documents that require your signature



This is Exhibit "B" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

**Antibe Therapeutics Inc.  
Scientific and Business Timeline**

***Key mentions in timeline (in order of first mention):***

**Louis J. Ignarro, PhD – Co-Chair of Antibe’s Scientific Advisory Board; 1998 Nobel Laureate in Medicine; Professor Emeritus, Molecular & Medical Pharmacology, UCLA**

Discoverer of the first gaseous mediator, nitric oxide – two other gaseous mediators have since been identified: carbon monoxide and hydrogen sulfide. (Antibe’s lead drug, otenaproxesul, releases hydrogen sulfide.)

**John L. Wallace, PhD, MBA, FRSC – Founder of Antibe Therapeutics Inc.; Adjunct Professor, University of Calgary and University of Toronto**

Dr. Wallace is the founder and Vice Chair of Antibe Therapeutics and inventor of otenaproxesul, Antibe’s lead drug. Dr. Wallace was the first to elucidate how nonsteroidal anti-inflammatory drugs (“NSAIDs”) damage the stomach. Later, after identifying hydrogen sulfide’s anti-inflammatory properties, he showed that it could prevent NSAID-induced gastrointestinal damage. Scientific research into the biology of hydrogen sulfide has expanded markedly since it was designated a gaseous mediator in 2002 (publishing activity grew five-fold in the 2002-2017 period).

Dr. Wallace is former President of the Canadian Association of Gastroenterology and was Inaugural Director of the Farncombe Institute at McMaster University. In 2009, he received the Premier’s Summit Award in Innovation -- at the time, the Canada’s largest value research award (\$5 million) aimed at supporting the work of an individual scientist. Dr. Wallace is a fellow of the Royal Society of Canada, an honorary member of the British Pharmacological Society, and a member of the Dean’s Special Advisory Board in the Faculty of Science at York University.

Dr. Wallace has published 455 papers in scientific journals that are cited 38,632 times, of which more than 70% are in the top 25% most cited academic papers in the world. He has h-index of 105 (Scopus), placing him in the top 0.5% of scientists publishing in biomedical field worldwide according to a widely cited ranking of scholarly impact, published by Elsevier in 2022. (Dr. Ignarro has published 429 papers that are cited 45,890 times; his h-index is 106.)

**Antibe’s lead drug (“otenaproxesul”)**

Otenaproxesul is an NSAID that releases hydrogen sulfide, protecting the stomach from damage. Otenaproxesul has demonstrated a high degree of gastrointestinal safety and efficacy in chronic pain in large Phase 2 studies. After showing elevated liver enzymes in approximately 10% of subjects taking the drug for more than three weeks, the drug was reformulated for use in short-term acute pain indications, successfully completing its initial clinical study in November 2023.

\* NSAIDs are a large class of drugs used to treat pain and inflammation. The NSAID class includes Advil® (ibuprofen) and Aleve® (naproxen) as well as a wide range of prescription drugs. NSAIDs can replace opioids in a range of acute pain situations but can cause gastrointestinal and other side-effects.

***Historical Timeline:***

Year	Selected Events
1986	<ul style="list-style-type: none"> <li>• <a href="#">Dr. Louis Ignarro</a> identifies first gaseous mediator (awarded Nobel Prize in 1998 for this discovery); Dr. Ignarro is currently co-chair of Antibe Therapeutics’ <a href="#">Scientific Advisory Board</a></li> </ul>
1990	<ul style="list-style-type: none"> <li>• Dr. John Wallace (Antibe Therapeutics’ founder) and colleagues publish <a href="#">peer-reviewed paper</a> that elucidates how aspirin (and other NSAIDs) damages the stomach</li> </ul>

Year	Selected Events
1998	<ul style="list-style-type: none"> <li>• Dr. Ignarro awarded the <a href="#">Nobel Prize in Physiology or Medicine</a> for discovery of the first gaseous mediator, nitric oxide</li> </ul>
2003	<ul style="list-style-type: none"> <li>• Dr. Wallace discovers anti-inflammatory properties of hydrogen sulfide -- this followed the 2002 discovery of hydrogen sulfide's identity as a gaseous mediator (by Canadian researcher, Dr. Rui Wang, now Dean of the Faculty of Science at York University)</li> </ul>
2004	<ul style="list-style-type: none"> <li>• Antibe predecessor company formed by Dr. Wallace while professor of pharmacology at University of Calgary</li> </ul>
2005	<ul style="list-style-type: none"> <li>• Dr. Wallace and colleagues publish seminal <a href="#">peer-reviewed paper</a> showing that hydrogen sulfide can prevent NSAID-induced gastric injury</li> <li>• Development of hydrogen sulfide-releasing NSAIDs begins</li> </ul>
2006	<ul style="list-style-type: none"> <li>• Dr. Wallace and colleagues publish initial <a href="#">peer-reviewed paper</a> on the broader anti-inflammatory properties of hydrogen sulfide</li> </ul>
2007	<ul style="list-style-type: none"> <li>• Initial patent filing in most major markets</li> </ul>
2009	<ul style="list-style-type: none"> <li>• Antibe Therapeutics Inc. formed – based on intellectual property developed by Antibe Therapeutics' predecessor company formed in 2004</li> </ul>
2010	<p>Dr. Wallace and colleagues publish widely cited <a href="#">peer-reviewed paper</a> establishing hydrogen sulfide's role in stomach safety</p>
2012	<ul style="list-style-type: none"> <li>• Dr. Wallace and colleagues publish seminal <a href="#">peer-reviewed paper</a> on otenaproxesul's safety in the stomach and small intestine</li> </ul>
2013	<ul style="list-style-type: none"> <li>• Preclinical studies begun to support application to Health Canada to conduct first human trial of otenaproxesul</li> <li>• Antibe Therapeutics becomes a public company on the Toronto Venture Exchange; <a href="#">Antibe's Board of Directors</a> includes the Vice Chairman of Mastercard (<a href="#">Walt Macnee</a>) and a senior UK medical scientist and Fellow of the Royal Society (<a href="#">Dr. Roderick Flower</a>) – both continue to be Antibe board members</li> <li>• Initial U.S. patent granted</li> <li>• Dr. Ignarro joins Antibe Therapeutics' Scientific Advisory Board</li> </ul>
2014	<ul style="list-style-type: none"> <li>• First clinical trial of otenaproxesul begins in Canada</li> </ul>
2015	<ul style="list-style-type: none"> <li>• During first clinical trial of otenaproxesul, liver enzyme elevations are seen in some patients in the high-dose cohorts; trial halted for two months, analysis shows that dose can be cut by 80%; trial is restarted</li> <li>• Dr. Wallace and colleague publish overview of hydrogen sulfide therapeutic research in a <a href="#">peer-reviewed paper</a> in top-ranked journal, Nature Reviews (Drug Discovery)</li> <li>• <a href="#">Knight Therapeutics</a> (a publicly-traded Canadian drug distributor) licenses otenaproxesul for Canada, Israel and several other countries</li> </ul>
2016	<ul style="list-style-type: none"> <li>• Clinical study confirms effectiveness of lower dose otenaproxesul as identified in its first Phase 2 clinical study in osteoarthritis patients</li> </ul>
2017	<ul style="list-style-type: none"> <li>• Laboratoires Acbel (a European drug distributor with it's subsidiary <a href="#">Galenica</a>) licenses otenaproxesul for several EU markets and other countries</li> </ul>
2018	<ul style="list-style-type: none"> <li>• Large Phase 2 clinical trial (244 subjects) in Canada shows profound gastrointestinal safety of otenaproxesul</li> <li>• <a href="#">Kwang Dong Pharmaceutical Co.</a> (a publicly traded South Korean company) licenses otenaproxesul for South Korean market</li> </ul>

Year	Selected Events
2020	<ul style="list-style-type: none"> <li>• Antibe begins intensive liver modeling with DILIsym to identify root cause of liver enzyme elevations (<a href="#">DILIsym</a> is the leading liver simulation software for drug development)</li> <li>• Phase 2 data from 2018 clinical gastrointestinal safety trial published <a href="#">peer-reviewed paper</a> in the British Journal of Pharmacology</li> </ul>
2020	<ul style="list-style-type: none"> <li>• Large Phase 2 clinical trial (384 patients) in Canada demonstrates pain efficacy in chronic pain but shows transient elevated liver enzymes in approximately 10% of patients at moderate doses</li> <li>• Antibe graduates from the Toronto Venture Exchange to the Toronto Stock Exchange</li> </ul>
2021	<ul style="list-style-type: none"> <li>• Nuance Pharma (privately owned Chinese company) licenses otenaproxesul for the Greater China region</li> <li>• Antibe successfully clears Investigational New Drug application with U.S. FDA; conducts first U.S.-based clinical study</li> <li>• Post-Phase 2 clinical study in Canada (“AME study”) shows liver enzyme elevations in some subjects at lowest doses when treated over longer periods (three weeks or more)</li> <li>• Antibe pivots otenaproxesul to acute pain based on promising chronic pain data and absence of liver issues in shorter term treatment durations (successful use in acute pain is a required waypoint to solving issues in chronic pain dosing)</li> </ul>
2022	<ul style="list-style-type: none"> <li>• Following three years of research, DILIsym modeling indicates that liver enzyme elevations result from downregulation of the liver’s internal hydrogen sulfide production when treated with external hydrogen sulfide over longer periods (as with otenaproxesul)</li> <li>• Successful demonstration of tapered treatment regimen with original formulation of otenaproxesul; predicts excellent liver safety</li> <li>• Patent filed for new formulation of otenaproxesul, a faster absorbing version of the drug that meets rapid onset demands in the acute pain setting; also allows for lower doses, expanding the drug’s safety envelope</li> </ul>
2023	<ul style="list-style-type: none"> <li>• Successful simulation of thousands of doses of new formulation of otenaproxesul; predicts liver safety of intended treatment regimen</li> <li>• Successful clinical study in Canada of otenaproxesul's new formulation and tapered treatment regimen in preparation for Phase 2 trial; demonstrates excellent liver safety</li> </ul>

### ***Anticipated Timeline:***

Projected Dates	Projected Events
May - June 2024	<ul style="list-style-type: none"> <li>• FDA hold lifted following response by Antibe</li> </ul>
June 2024	<ul style="list-style-type: none"> <li>• Phase 2 trial initiated</li> </ul>
Oct. 2024	<ul style="list-style-type: none"> <li>• Phase 2 trial results received</li> </ul>
Jan. - March 2025	<ul style="list-style-type: none"> <li>• FDA meeting to prepare for Phase 3 program</li> </ul>
Mid 2025	<ul style="list-style-type: none"> <li>• Phase 3 program initiated</li> </ul>

This is Exhibit "C" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

R-023

Message

**From:** Annie Lee 李安妮 [annie.lee@cbridgecap.com]  
**Sent:** 12/31/2020 6:01:34 AM  
**To:** mglotter@nuancebiotech.com; Ella Korets-Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daf43ca648534b1eb92e0527fe8aef0f-ella]; 'annie.lee' [annie.lee@nuancepharma.cn]  
**CC:** 'jasmine.lien' [jasmine.lien@nuancepharma.cn]; '张颖' [johnny.zhang@nuancepharma.cn]; Rami Batal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81cdc60d7614985b48d3ac3ee75d829-rami.batal]  
**Subject:** RE: Re:RE: Nuance - Antibe Term Sheet\_Dec 23  
**Attachments:** TW Overview and Lauch Plan - 31Dec 2020.pdf

Dear Ella and Rami,

Attached please find the Taiwan commercialization plan. Speak to you soon.

Best,  
 Annie

---

**From:** mglotter@nuancebiotech.com <mglotter@nuancebiotech.com>  
**Sent:** Thursday, December 31, 2020 1:58 PM  
**To:** 'Ella Korets-Smith' <ella@antibethera.com>; Annie Lee 李安妮 <annie.lee@cbridgecap.com>; 'annie.lee' <annie.lee@nuancepharma.cn>  
**Cc:** 'jasmine.lien' <jasmine.lien@nuancepharma.cn>; '张颖' <johnny.zhang@nuancepharma.cn>; 'Rami Batal' <rami.batal@antibethera.com>  
**Subject:** RE: Re:RE: Nuance - Antibe Term Sheet\_Dec 23

Thanks Ella – chat later today.

Regards  
 Mark

---

**From:** Ella Korets-Smith <ella@antibethera.com>  
**Sent:** Wednesday, December 30, 2020 3:38 PM  
**To:** Annie Lee 李安妮 <annie.lee@cbridgecap.com>; annie.lee <annie.lee@nuancepharma.cn>; mglotter <mglotter@nuancebiotech.com>  
**Cc:** 'jasmine.lien' <jasmine.lien@nuancepharma.cn>; '张颖' <johnny.zhang@nuancepharma.cn>; Rami Batal <rami.batal@antibethera.com>  
**Subject:** Re: Re:RE: Nuance - Antibe Term Sheet\_Dec 23

Dear Annie and Mark,

Please find attached the Nuance/Antibe term sheet with our proposed redline and comments. We look forward to the discussion tomorrow.

Cheers,

Ella

R-023



ELLA KORETS-SMITH MSc, MBA  
 Head Regional Business Development

+1 416-836-1777  
[ella@antibethera.com](mailto:ella@antibethera.com)

15 Prince Arthur Ave.  
 Toronto, ON, Canada, M5R 1B2

[www.antibethera.com](http://www.antibethera.com)

---

**From:** Annie Lee 李安妮 <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>  
**Date:** Wednesday, December 30, 2020 at 7:43 AM  
**To:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>, annie.lee <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>, mglotter <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>  
**Cc:** 'jasmine.lien' <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>, '张颖' <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>, Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Subject:** Re: Re:RE: Nuance - Antibe Term Sheet\_Dec 23

Dear Ella,

If it's ok, 7 am EST is preferred. Look forward to our discussion tomorrow. Thanks.

Best,  
 Annie  
 取得 [iOS 版 Outlook](#)

---

**寄件者:** Annie Lee 李安妮 <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>  
**寄件日期:** Wednesday, December 30, 2020 8:34:08 PM  
**收件者:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>; annie.lee <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>; mglotter <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>  
**副本:** 'jasmine.lien' <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>; '张颖' <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>; Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**主旨:** Re: Re:RE: Nuance - Antibe Term Sheet\_Dec 23

Hi Ella,

Thur 7:30 am EST works for us. Thanks.

Best,  
 Annie

取得 [iOS 版 Outlook](#)

---

**寄件者:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>  
**寄件日期:** Wednesday, December 30, 2020 8:26:21 PM  
**收件者:** annie.lee <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>; mglotter <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>



R-023

**副本:** 'jasmine.lien' <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>; Annie Lee 李安妮 <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>; '张颖' <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>; Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**主旨:** Re: Re:RE: Nuance - Antibe Term Sheet\_Dec 23

Annie, we will send you a version later today. In the meantime let's schedule a follow up call. Would a call on Thursday at 7, 7:30 or 8am EST work for your team?

Please confirm and I will send a calendar hold.

Cheers,

Ella

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---

**From:** annie.lee <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>  
**Sent:** Wednesday, December 30, 2020 3:23:25 AM  
**To:** mglotter <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>; Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>  
**Cc:** 'jasmine.lien' <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>; 'annie.lee' <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>; '张颖' <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>; Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Subject:** Re:RE: Nuance - Antibe Term Sheet\_Dec 23

Dear Ella,

Following-up on Mark's email, we are very keen to move fast and meet your requirements. To do so, please will you send us the redline version of the TS. We've performed some additional analyses re the royalty payment and would like to present these to you. Re Taiwan commercialization, we will send you the plan shortly. If possible, let's schedule a call this week or early next so we can align on the remaining issues and finalise everything. Thanks.

Best,

Annie

----- Original -----

**From:** "mglotter" <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>;  
**Date:** Wed, Dec 30, 2020 01:19 AM  
**To:** "'Ella Korets-Smith'" <[ella@antibethera.com](mailto:ella@antibethera.com)>; "'annie.lee'" <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>;  
**Cc:** "'jasmineliem'" <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>; "'annie.lee'" <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>; "'张颖'" <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>;  
 "'Rami Batal'" <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>;  
**Subject:** RE: Nuance - Antibe Term Sheet\_Dec 23

Dear Ella

Had a relaxing time with the family at home C was actually pleasant just being at home and not having to run from one household to another. Trust that you are having an enjoyable break.



R-023

Really good news - we are excited at the prospect moving forward with Antibe on this initiative. Annie and I will have a call in the morning and we will respond to the considerations points as raised below. Nuance and the team is well prepared to move forward at pace and move quickly to a resolution C fully agree that this is in the interest of both parties.

On the TS C I would suggest that you please send a redline version after which we can have a call to ensure that all are aligned on the issues before replying.

Best Regards

Mark

---

**From:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>  
**Sent:** Tuesday, December 29, 2020 2:57 PM  
**To:** [mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com); 'annie.lee' <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>  
**Cc:** 'jasmine.lien' <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>; 'annie.lee' <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>; '张颖' <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>; Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Subject:** Re: Nuance - Antibe Term Sheet\_Dec 23

Dear Mark and Annie,

Thank you very much for your patience and hope you had some opportunity to relax and celebrate with family.

We have taken the time to discuss internally. Antibe's management team is enthusiastic about the opportunity to partner with Nuance for the China market. As such, 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.

Overall we believe your offer to be fair and reasonable. We would like to offer a number of points for consideration:

1. 50 days for exclusive negotiations instead of the proposed 90.
2. The royalty percentage to move towards a low double digit. This is an important consideration for Antibe in all deals we do for otenaproxesul.
3. Antibe's oversight on the Phase 3 trial, to be conducted by Nuance. We can choose to not have this language in the term sheet, though certainly in the Definitive Agreement.
4. A better understanding of Nuance's commercialization plan in the entire Territory (in particular Taiwan). Once again, perhaps not a change in the term sheet but important to understand.

R-023

With respect to next steps, should we anticipate a more fulsome term sheet from you or shall we work with the version you shared last week? We can propose a redline or have a discussion prior. Please let us know how you would like to proceed.

Looking forward to hearing from you and moving forward.

Cheers,

Ella



ELLA KORETS-  
SMITH MSc, MBA  
Head Regional Business  
Development

+1 416-836-1777  
[ella@antibethera.com](mailto:ella@antibethera.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada,  
M5R 1B2

[www.antibethera.com](http://www.antibethera.com)

---

**From:** [mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com) <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>

**Date:** Wednesday, December 23, 2020 at 2:05 PM

**To:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>, 'annie.lee' <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>

**Cc:** 'jasmine.lien' <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>, 'annie.lee' <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>, '张颖' <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>, Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>

**Subject:** RE: Nuance - Antibe Term Sheet\_Dec 23

Dear Ella & Rami

R-023

Many thanks C best wishes over the holiday period C wishing you and your families all of the very best.

We look forward to your reply.

Best Regards

Mark

---

**From:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>  
**Sent:** Wednesday, December 23, 2020 3:02 PM  
**To:** annie.lee <[annielee@nuancepharma.cn](mailto:annielee@nuancepharma.cn)>  
**Cc:** mglotter <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>; jasmine.lien <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>; annie.lee <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>; 张颖 <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>; Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Subject:** Re: Nuance - Antibe Term Sheet\_Dec 23

Dear Annie and team,

Thank you very much for the prompt follow up. We appreciate your commitment and enthusiasm for the program. Please give us some time to review and discuss, as it is the holidays here and members of our team are taking some well-deserved time off. We will come back to you with comments in as little time as possible.

In the meantime, please find attached the presentations shared by Rami during our last call, for your information. There is a list of questions/discussion points in one of the documents which remain relevant as we consider your proposal. We can review these during our next discussion.

Once again, thank you for the engagement and we look forward to being in touch again shortly. Happy holidays and all the best to you and yours in 2021.

Cheers,

Ella

R-023



ELLA KORETS-  
SMITH MSc, MBA  
Head Regional Business  
Development

+1 416-836-1777  
[ella@antibethera.com](mailto:ella@antibethera.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada,  
M5R 1B2

[www.antibethera.com](http://www.antibethera.com)

---

**From:** annie.lee <[annielee@nuancepharma.cn](mailto:annielee@nuancepharma.cn)>  
**Date:** Wednesday, December 23, 2020 at 8:52 AM  
**To:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>, Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Cc:** mglotter <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>, jasmine.lien <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>, annie.lee <[annie.lee@cbridgecap.com](mailto:annie.lee@cbridgecap.com)>, 张颖 <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>  
**Subject:** Nuance - Antibe Term Sheet\_Dec 23

Dear Rami and Ella,

Thanks again for sharing your insights re ATB346 with us. Consequently, we are very confident that ATB346 has great potential and Nuance has the team, resources and drive to make this a success. As discussed, we are sending you the proposal and TS. Please kindly review and let us know if you have any questions, we are happy to discuss further.

In the meantime, on behalf of the Nuance team, I wish you a Happy Holidays.

Best,

Annie

Error!

Filename

not

specified.

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R-023



NUANCE  
PHARMA

# Taiwan Market Overview

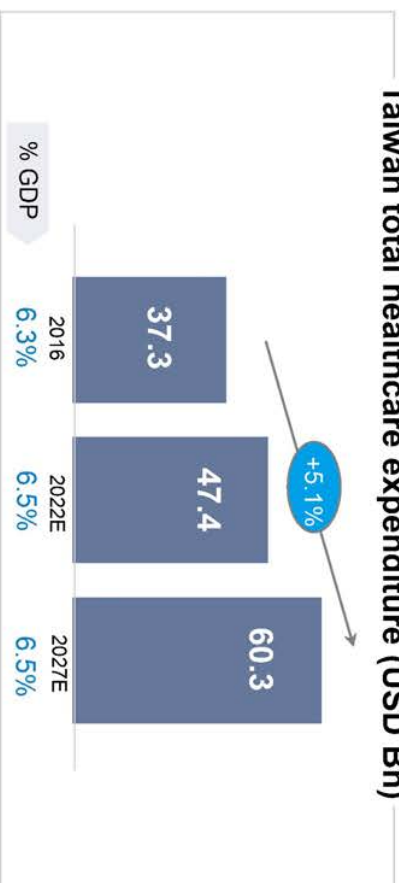


# Taiwan Market Overview

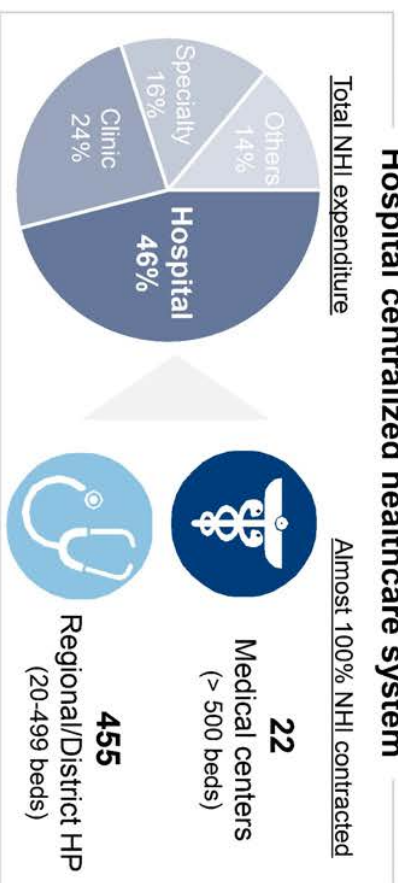
## HP centralized and NHI reimbursement-based market

68

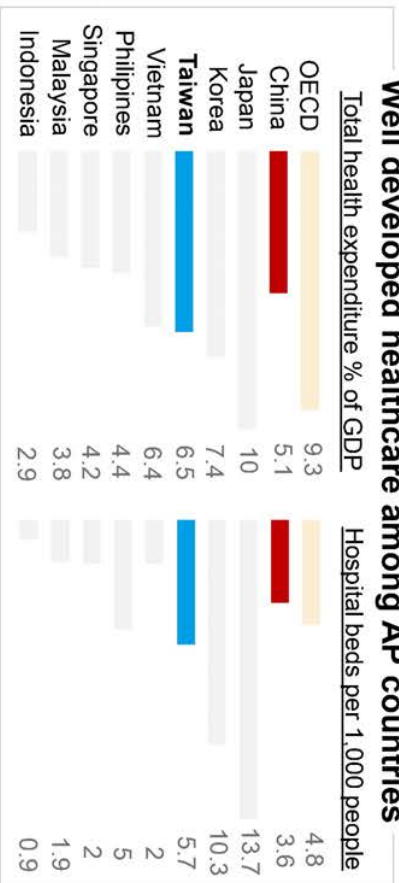
### Taiwan total healthcare expenditure (USD Bn)



### Hospital centralized healthcare system



### Well developed healthcare among AP countries

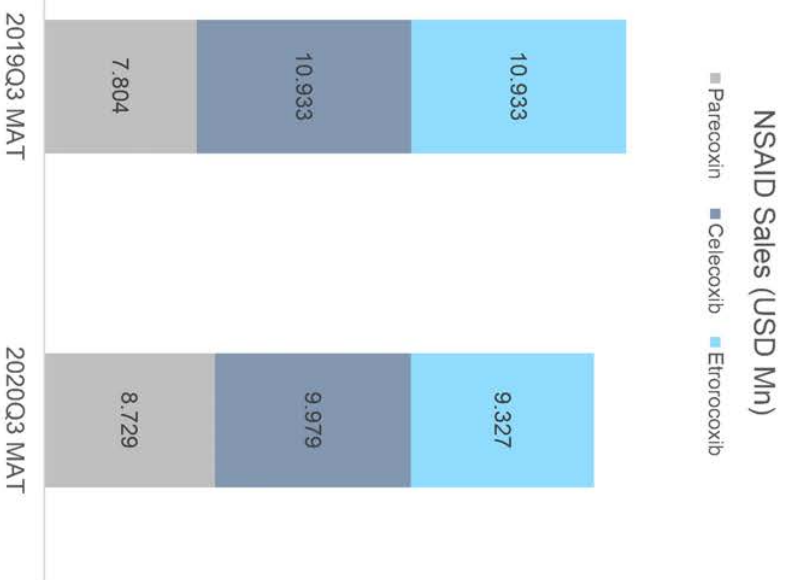


### National Health Insurance (NHI) based market

- NHI reimbursement possess ~95% of new drug total sales. Less than 5% self-pay sales before NHI launch
- Global budget payment system
  - Set for hospitals to cap the total budget
- DRG (diagnosis-related group) system
  - To standardize clinical practice
- DET (drug expenditure target) system
  - To adjust pharmaceutical price on annual basis
  - In 2018 review, total 7,476 drugs received an average price cut of 4.6%



## NSAID market in Taiwan



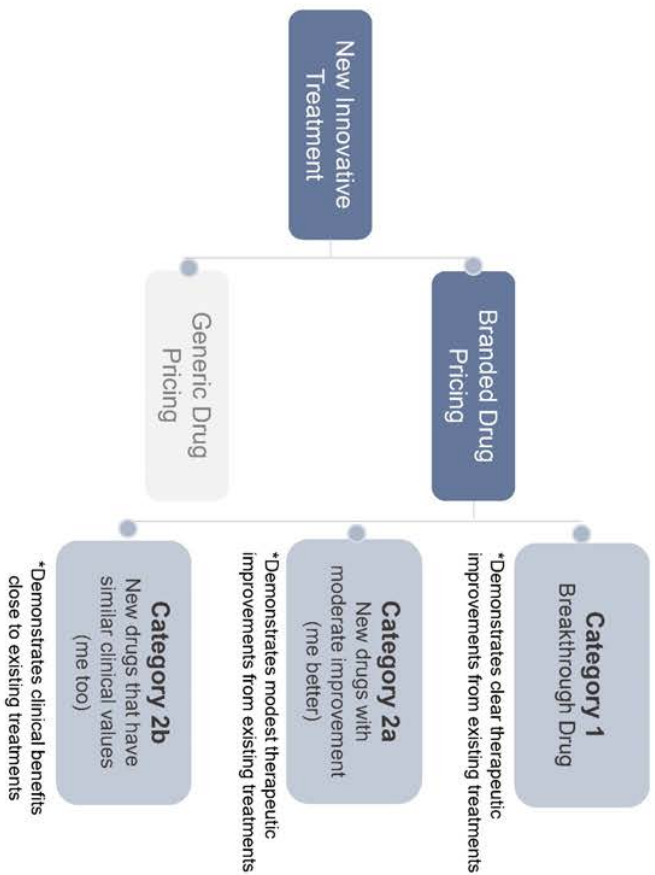
- NSAID market size remains steady. 28mm Q3MAT 2020 v.s 30mm Q3MAT 2019
- Both brand drugs (Dynastat, Celebrex, Acroxia) and generics (12 for celecoxib and 5 etoricoxib) are covered by NHI
- Brand drugs possess 95% of sales (Dynastat 100%, Celebrex 91%, Acroxia 95%)

Brand	Generics	Company	2020Q3MAT Sales (USD)
Dynastat	Parecoxib	Pfizer	8.7 mn
Celebrex	Celecoxib	Pfizer	9.1 mn
Acroxia	Etoricoxib	MSD	8.9 mn

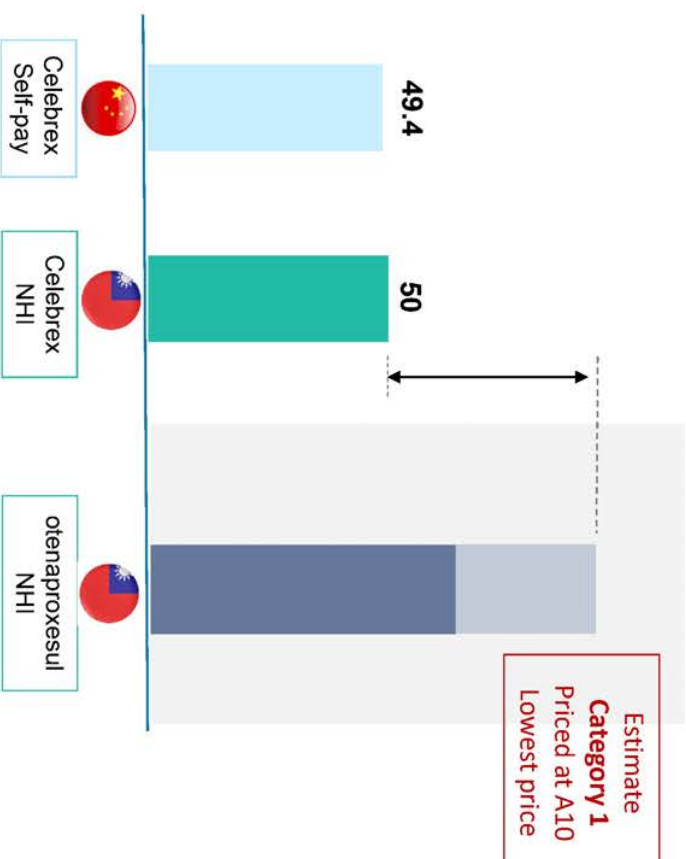
069

# Market access environment Target breakthrough drug status and A10 lowest price for ATB346

**NHIA pricing principles of new drugs**  
(10 price reference countries, 3 HTA reference countries (UK, CA, AU))



Annual cost (USD) **Benchmark**      ATB-346 Proposed Pricing  
Annual cost (USD)





# Taiwan Launch Timeline

## Speed up the launch in Taiwan

### Taiwan NDA submission regulations

	2 CPP	1 CPP	Non-CPP
Full submission package	✓	✓	✓
Taiwanese clinical trial	✓	✓	✓
Post market RMP	✓	✓	✓
GLP/GMP inspection	✓		✓
Review timeline	180 Days	360 Days	360 Days

CPP: Certificate of Pharmaceutical Product  
Approval in US, EU, or Japan with no ethnic difference in clinical studies

### Launch timeline scenarios:

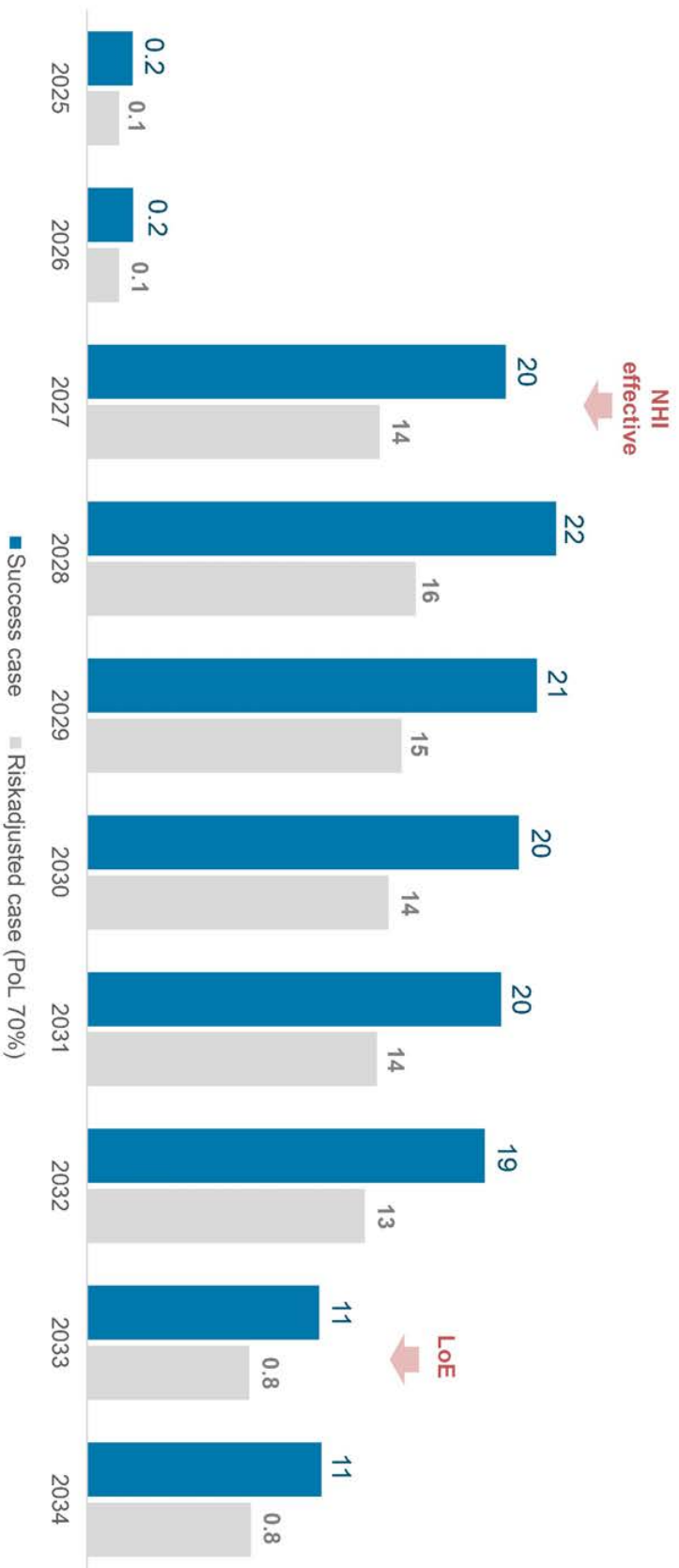
	2021		2022		2023		2024		2025		2026		2027	
	H1	H2	H1	H2	H1	H2	H1	H2	H1	H2	H1	H2	H1	H2
Scenario 1							◇	★	★				■	■
	TW join Global Ph 3 study						US/EU NDA	US/EU Approval	TW Approval				TW NHI Launch	
Scenario 2							◇	◇	★				■	■
	TW join China Ph 3 study						CN/TW NDA	TW Approval					TW NHI Launch	
Nuance Team Set up	Regulatory & Market access consultant				Launch team (Country manager, Medical, Marketing)				HP Sales team		GP*			

\* Leverage partner (DKSH / Zuellig Pharma to expand coverage in GP)

# Sales forecast in Taiwan

DOT 90 days

Annual Non-risk adjusted Sales Projection of ATB-346 (Mn USD)



This is Exhibit "D" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



---

*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

R-025

Message

**From:** mglotter@nuancebiotech.com [mglotter@nuancebiotech.com]  
**Sent:** 1/6/2021 2:30:09 AM  
**To:** Ella Korets-Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daf43ca648534b1eb92e0527fe8aef0f-ella]; 'Annie Lee' [annie.lee@cbridgecap.com]; 'Johnny Zhang' [johnny.zhang@nuancepharma.cn]  
**CC:** Rami Batal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81cdc60d7614985b48d3ac3ee75d829-rami.batal]; Dan Legault [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b620d56edee4feab5085587b4c36576-dan]  
**Subject:** RE: Antibe/Nuance signed Term Sheet and next steps  
**Attachments:** Nuance - Antibe Term Sheet 5jan2021 DLsig ML Sig.pdf

**Importance:** High

Dear Ella

Thanks for quick turnaround and the signed Term Sheet – please see attached for a version with the Nuance signature.

We look forward to the call on Monday to meet with Dan and other members of the team. 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.

Best Regards  
 Mark

---

**From:** Ella Korets-Smith <ella@antibether.com>  
**Sent:** Wednesday, January 6, 2021 2:41 AM  
**To:** Mark Glotter <mglotter@nuancebiotech.com>; Annie Lee <annie.lee@cbridgecap.com>; Johnny Zhang <johnny.zhang@nuancepharma.cn>  
**Cc:** Rami Batal <rami.batal@antibether.com>; Dan Legault <dan@antibether.com>  
**Subject:** Antibe/Nuance signed Term Sheet and next steps

Dear Nuance team,

Please find attached the Term Sheet signed by Antibe Please countersign and return.

For next steps, we have scheduled an introductory meeting with our CEO and other key members of the management team, happening next week (Monday, Jan 11). 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.

Once again, we appreciate your enthusiasm about the product and look forward to working together towards a completion of the transaction in the coming weeks.

Cheers,

Ella



ELLA KORETS-SMITH MSc, MBA  
 Head Regional Business Development



075

R-025

+1 416-836-1777  
[ella@antibethera.com](mailto:ella@antibethera.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada, M5R 1B2

[www.antibethera.com](http://www.antibethera.com)



Virus-free. [www.avg.com](http://www.avg.com)

R-025





<b>Payments</b>	<b>Payment</b>	<b>Event</b>	<b>Amount (US\$)</b>
		<b>Upfront</b>	Payable within 30 business days after signing of the Definitive Agreement
		<b>Upfront Total</b>	<b>20 Million</b>
	<b>Development Milestones</b>	Upon marketing approval of the Products in the first jurisdiction in the Territory	10 Million
		<b>Development Milestone Total</b>	<b>10 Million</b>
	<b>Commercial Milestones</b>	Upon achieving annual aggregate net sales of USD\$100 Million	5 Million
		Upon achieving annual aggregate net sales of USD\$200 Million	12 Million
		Upon achieving annual aggregate net sales of USD\$300 Million	21 Million
		Upon achieving annual aggregate net sales of USD\$400 Million	32 Million
		<b>Sales Milestone Total</b>	<b>70 Million</b>
	<b>Total Upfront, Development, and Sales Milestones</b>		<b>100Million</b>
	<b>Royalty</b>	Payable on the net sales of Products	12.5% <sup>2</sup>
	<p>Note:</p> <ol style="list-style-type: none"> <li>All milestone payments shall be payable within ninety (90) days of the initial achievement of such milestone, and no amounts shall be due hereunder for subsequent or repeated achievement of such milestone in such Field.</li> <li>Upon the loss of market exclusivity during the Term, the Royalty above shall be reduced by 50%. The loss of market exclusivity is defined as market entry of the first generic into the Territory and lead to 50% reduction of market share of the Products in the previous 12 months in the Territory.</li> </ol>		
<b>Costs and Expenses</b>	Nuance shall be responsible for conducting and paying for all costs and expenses for importing, using, offering for sales, and selling the Products in, and obtaining regulatory approval of the Products for the Territory in the Field. To the extent possible under Chinese regulations, Nuance or its affiliates (as the case may be) will be the named applicant for and the holder of the marketing approvals of the Products in the Territory.		
<b>Exclusivity Period</b>	Upon the execution of the Proposed Term Sheet, Antibe will automatically grant Nuance 50 days of Exclusivity Period. Until expiration of this Exclusivity Period, Antibe and its stockholders, directors, officers, employees, affiliates, agents or advisors (including, without limitation, attorneys, accountants, consultants, scientific collaborators, bankers and financial advisors) (collectively, "Antibe Representatives") shall not solicit, enter into, or continue any discussion, negotiations, or agreement with any third party regarding licensing to such third party Antibe's rights to the Products in the Territory.		
<b>Consequences of Expiration or Termination</b>	At the end of the Term (except to be extended by an additional period) with respect to any Product, Nuance would initiate the transfer of the relevant marketing authorization to Antibe or its designee. Nuance would have a sell-off period of 6 months, with the applicable royalty obligations applicable to the resulting net sales.		

R-025

<b>Governing Law</b>	Australia
<b>Other Provisions</b>	The Definitive Agreement will include other standard terms and conditions customary for pharmaceutical-related license and supply agreements.

Agreed and Approved on January 5, 2021

**Antibe Therapeutics**

**Nuance Biotech**

Signature:

  
\_\_\_\_\_

By: Dan Legault, CEO

Signature:

  
\_\_\_\_\_

By: Mark G Lotter, CEO

Signature:

\_\_\_\_\_

By:

Signature:

\_\_\_\_\_

By:

This is Exhibit "E" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



---

*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

R-026

Message

**From:** mglotter@nuancebiotech.com [mglotter@nuancebiotech.com]  
**Sent:** 1/12/2021 3:02:04 AM  
**To:** Dan Legault [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b620d56edee4feab5085587b4c36576-dan]; Ella Korets-Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daf43ca648534b1eb92e0527fe8aef0f-ella]; Rami Batal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81cdc60d7614985b48d3ac3ee75d829-rami.batal]  
**CC:** annie.lee@nuancepharma.cn  
**Subject:** RE: Antibe Nuance Introduction

Thanks Dan

**From:** Dan Legault <dan@antibethera.com>  
**Sent:** Monday, January 11, 2021 9:48 PM  
**To:** Ella Korets-Smith <ella@antibethera.com>; Rami Batal <rami.batal@antibethera.com>; mglotter@nuancebiotech.com  
**Cc:** annie.lee@nuancepharma.cn  
**Subject:** Re: Antibe Nuance Introduction

Hi Mark,

Indeed it was a pleasure meeting the two of you, and I felt the same regarding the fit.

I'll let Rami and Ella take the lead but I'm right there with them; we look forward to sleeves fully rolled up this month.

Best,

Dan



**DAN LEGAULT**  
 CEO

+1 416-473-4095  
[dan@antibethera.com](mailto:dan@antibethera.com)

15 Prince Arthur Avenue  
 Toronto, ON M5R 1B2 Canada

[www.antibethera.com](http://www.antibethera.com)

///save.choice.picture  
[antibe.zoom.us/my/danno1](https://antibe.zoom.us/my/danno1)

[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com) <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>, wrote:

R-026

Dear Dan

Great connecting with you and the broader Antibe team earlier today – I felt call reinforced the strong fit between the companies.

Given the signed TS and planned next steps , we look forward to working with the Ella , Rami and the team over the weeks ahead to get closure. We are excited at the prospect of partnering with Antibe and collectively building a strong presence in the China market.

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.

Best regards

Mark



Virus-free. [www.avg.com](http://www.avg.com)

This is Exhibit "F" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



---

*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

1 09:40 Ms Lin, you may continue.

2 A. Sure. Now I've actually forgotten where I was  
3 going. The general sentiment, though, is we were  
4 looking at the data room as a convenience starter  
5 package, so that was the intention of putting these  
6 documents together. For that reason, I would  
7 anticipate that the starter package was reasonable  
8 to get going and any further information if required  
9 was going to be to be inquired about afterwards.

10 MS LIN: Sure. But as you told the tribunal yesterday,  
11 what you would reasonably expect is that if there  
12 were documents that came later in time and prior to  
13 the data room, it would have been given to you by  
14 the team. Of course, maybe, maybe, there would  
15 still be follow-up questions from your partner. But  
16 at least from within Antibe, that would be the  
17 starting point; correct?

18 MR PALIARE: That wasn't what she said.

19 MS LIN: I have read --

20 ARBITRATOR: I note your objection.

21 Please answer the question. Do you need it  
22 repeated?

23 A. Yes, please.

24 MS LIN: My question is, as you told the tribunal  
25 yesterday -- I can skip the part, because my friend



1 09:41 does not like that.

2 My question is: what you would reasonably  
3 expect is if there were documents that came later in  
4 time and prior to the data room being provided to  
5 your partner, those documents would have been given  
6 to you by the team? Of course, there may still be  
7 follow-up questions from your partner, but at least  
8 from within Antibe that would be the starting point?  
9 That would be your expectation; correct.

10 A. I just want to clarify that. Before the data room  
11 being given to our partner is not the timeline. We  
12 put together a starter package, we put it on  
13 ShareVault. That's what was there. If there was a  
14 lag in time from providing that data room and  
15 providing it to -- excuse me, creating that data  
16 room and then providing it to the partner,  
17 I wouldn't anticipate my team to put their hand up  
18 and say, actually, we should update something in  
19 there right now. That would not be something  
20 I would anticipate.

21 Q. Just as an example here, because you had your  
22 original data room, if I can call it that way,  
23 prepared by more or less 6 January 2021, by the time  
24 you opened up the room to Nuance on 25 January, your  
25 evidence essentially is that if there were documents

This is Exhibit "G" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



---

*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

## Message

**From:** Ella Korets-Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daf43ca648534b1eb92e0527fe8aef0f-ella]  
**Sent:** 2/1/2021 8:44:47 AM  
**To:** Nuance [jasmine.lien@nuancepharma.cn]  
**CC:** jinli@nuancepharma.cn; 李安妮 [annie.lee@nuancepharma.cn]; mglotter [mglotter@nuancebiotech.com]; 刘颖 [edy.liu@nuancepharma.cn]; 张颖 [johnny.zhang@nuancepharma.cn]; Rami Batal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81cdc60d7614985b48d3ac3ee75d829-rami.batal]  
**Subject:** Re: Antibe Due Diligence invitation

Hi Jasmine,

The new user should now have access. Looking forward to receiving your list of questions.

Cheers,

Ella



ELLA KORETS-SMITH MSc, MBA  
Head Regional Business Development

+1 416-836-1777  
[ella@antibetherera.com](mailto:ella@antibetherera.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada, M5R 1B2

[www.antibetherera.com](http://www.antibetherera.com)

---

**From:** Nuance <jasmine.lien@nuancepharma.cn>  
**Date:** Friday, January 29, 2021 at 7:28 PM  
**To:** Ella Korets-Smith <ella@antibetherera.com>  
**Cc:** jinli@nuancepharma.cn <jinli@nuancepharma.cn>, 李安妮 <annie.lee@nuancepharma.cn>, mglotter <mglotter@nuancebiotech.com>, 刘颖 <edy.liu@nuancepharma.cn>, 张颖 <johnny.zhang@nuancepharma.cn>, Rami Batal <rami.batal@antibetherera.com>  
**Subject:** Re: Antibe Due Diligence invitation

Hi Ella,

Thanks for the reply. We will collect all the inquiries to you at one time as talked.

After discussion with Annie, we would need to invite our legal to help the DD regarding corporate part. Please help to grant one more data room access to Cheneye.

Cheneye.ni@katten.com

Thank you,

Ella Korets-Smith <ella@antibethera.com> 於 2021年1月30日 01:52 寫道 :

Hi Jasmine,

Glad to hear that you are now able to access ShareVault.

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.

If helpful, we are happy to schedule a call next week to review the questions you have and take it back to our team for response.

Looking forward to your feedback.

Cheers,

Ella

<image001.jpg>

ELLA KORETS-SMITH MSc, MBA  
Head Regional Business Development

+1 416-836-1777  
[ella@antibethera.com](mailto:ella@antibethera.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada, M5R 1B2

[www.antibethera.com](http://www.antibethera.com)

---

**From:** jasmine.lien <jasmine.lien@nuancepharma.cn>

**Date:** Thursday, January 28, 2021 at 9:39 PM

**To:** Ella Korets-Smith <ella@antibethera.com>

**Cc:** jinli@nuancepharma.cn <jinli@nuancepharma.cn>, 李安妮 <annie.lee@nuancepharma.cn>, mglotter <mglotter@nuancebiotech.com>, 刘颖 <edy.liu@nuancepharma.cn>, 张颖 <johnny.zhang@nuancepharma.cn>, Rami Batal <rami.batal@antibethera.com>

**Subject:** Re: Antibe Due Diligence invitation

Hi Ella,

I'm available to access. Thank you for the support!

R-032

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. Thank you.

Best regards,  
Jasmine

On Jan 27, 2021 08:44, Ella Korets-Smith<ella@antibethera.com> wrote :

Dear Nuance team,

Wanted to make sure that everyone has now gotten access to the ShareVault data room. Please confirm.

Cheers,

Ella

<image002.jpg>

**ELLA KORETS-  
SMITH** MSc, MBA  
Head Regional Business  
Development

+1 416-836-1777  
[ella@antibethera.com](mailto:ella@antibethera.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada, M5R  
1B2

[www.antibethera.com](http://www.antibethera.com)

---

**From:** Nuance <[jasmine.lien@nuancepharma.cn](mailto:jasmine.lien@nuancepharma.cn)>  
**Date:** Monday, January 25, 2021 at 12:05 PM  
**To:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>  
**Cc:** [jinli@nuancepharma.cn](mailto:jinli@nuancepharma.cn) <[jinli@nuancepharma.cn](mailto:jinli@nuancepharma.cn)>, 李安妮 <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>, mglotter <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>, 刘颖 <[edy.liu@nuancepharma.cn](mailto:edy.liu@nuancepharma.cn)>, 张颖 <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>, Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Subject:** Re: Antibe Due Diligence invitation

Hi Ella,

My cellphone number is +86 187 2169 4659.

Thank you.

Best regards,

Jasmine

從我的iPhone傳送

Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)> 於 2021年1月26日 00:11 寫道 :

Dear Nuance team,

We are working through the issue with ShareVault. We need to have a mobile number for you, in order to set up the account. I have numbers for Mark, Johnny and Edy.

Could Annie, Jasmine and Jin please enter their numbers into the system or share with me here?

Thanks so much,

Ella

<image001.jpg>

**ELLA KORETS-**  
**SMITH** MSc, MBA  
Head Regional Business  
Development

+1 416-836-1777  
[ella@antibethera.com](mailto:ella@antibethera.com)



---

**From:** [jinli@nuancepharma.cn](mailto:jinli@nuancepharma.cn) <[jinli@nuancepharma.cn](mailto:jinli@nuancepharma.cn)>  
**Date:** Sunday, January 24, 2021 at 11:49 PM  
**To:** 李安妮 <[annie.lee@nuancepharma.cn](mailto:annie.lee@nuancepharma.cn)>, mglotter <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>, Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>, 刘颖 <[edy.liu@nuancepharma.cn](mailto:edy.liu@nuancepharma.cn)>, 张颖 <[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn)>, 连君洋 <[Jasmine.lien@nuancepharma.cn](mailto:Jasmine.lien@nuancepharma.cn)>  
**Cc:** Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Subject:** Re: RE: Antibe Due Diligence invitation

Dear Ella,

Neither for me about the SV issue.

Thanks and best regards,

Jin

---

[jinli@nuancepharma.cn](mailto:jinli@nuancepharma.cn)

---

**From:** [annie.lee](mailto:annie.lee)

**Date:** 2021-01-25 11:52

**To:** [mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com); 'Ella Korets-Smith'; [edy.liu@nuancepharma.cn](mailto:edy.liu@nuancepharma.cn); [johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn); [Jasmine.lien@nuancepharma.cn](mailto:Jasmine.lien@nuancepharma.cn); [Jinli@nuancepharma.cn](mailto:Jinli@nuancepharma.cn)

**CC:** 'Rami Batal'

**Subject:** RE: Antibe Due Diligence invitation

Hi Ella,

Received the SV invite but had the same issue with verification process.

Best,

Annie

---

**From:** [mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com) <[mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com)>  
**Sent:** Monday, January 25, 2021 11:44 AM  
**To:** 'Ella Korets-Smith' <[ella@antibethera.com](mailto:ella@antibethera.com)>; [edy.liu@nuancepharma.cn](mailto:edy.liu@nuancepharma.cn);  
[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn); [Annie.lee@nuancepharma.cn](mailto:Annie.lee@nuancepharma.cn);  
[Jasmine.lien@nuancepharma.cn](mailto:Jasmine.lien@nuancepharma.cn); [Jinli@nuancepharma.cn](mailto:Jinli@nuancepharma.cn)  
**Cc:** 'Rami Batal' <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Subject:** RE: Antibe Due Diligence invitation

Dear Ella

Many thanks – received the SV invite – had some issues with the 2 step verification – sent you a mail.

The layers will send the draft back by tonight – we will send first thing tomorrow China time.

Regards

Mark

---

**From:** Ella Korets-Smith <[ella@antibethera.com](mailto:ella@antibethera.com)>  
**Sent:** Monday, January 25, 2021 11:08 AM  
**To:** [edy.liu@nuancepharma.cn](mailto:edy.liu@nuancepharma.cn); [mglotter@nuancebiotech.com](mailto:mglotter@nuancebiotech.com);  
[johnny.zhang@nuancepharma.cn](mailto:johnny.zhang@nuancepharma.cn); [Annie.lee@nuancepharma.cn](mailto:Annie.lee@nuancepharma.cn);  
[Jasmine.lien@nuancepharma.cn](mailto:Jasmine.lien@nuancepharma.cn); [Jinli@nuancepharma.cn](mailto:Jinli@nuancepharma.cn)  
**Cc:** Rami Batal <[rami.batal@antibethera.com](mailto:rami.batal@antibethera.com)>  
**Subject:** Antibe Due Diligence invitation

Dear Nuance team,



I hope all is well with you. You should have received invitations to view Antibe's ShareVault due diligence room, prepared for Nuance. Please let me know if you are not able to access the documents or have trouble logging in.

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.

Cheers,

Ella

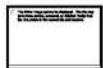
<image002.jpg>

**ELLA KORETS-  
SMITH** MSc, MBA  
Head Regional BU  
Development

+1 416-836-1777  
[ella@antibetherapeutics.com](mailto:ella@antibetherapeutics.com)

15 Prince Arthur  
Toronto, ON, Canada  
M5R 1B2

[www.antibetherapeutics.com](http://www.antibetherapeutics.com)



Virus-free. [www.avg.com](http://www.avg.com)

This is Exhibit "H" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



---

*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

R-034

Message

**From:** annie.lee@nuancepharma.cn [annie.lee@nuancepharma.cn]  
**Sent:** 2/3/2021 7:01:21 AM  
**To:** Ella Korets-Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daf43ca648534b1eb92e0527fe8aef0f-ella]; 'Mark G. Lotter' [mglotter@nuancebiotech.com]  
**CC:** Rami Batal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81cdc60d7614985b48d3ac3ee75d829-rami.batal]  
**Subject:** RE: Antibe diligence questions and comments on List of Issues

Hi Ella,

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**

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

Best,  
Annie

---

**From:** Ella Korets-Smith <ella@antibethera.com>  
**Sent:** Tuesday, February 2, 2021 10:32 AM  
**To:** Mark G. Lotter <mglotter@nuancebiotech.com>; annie.lee <annie.lee@nuancepharma.cn>  
**Cc:** Rami Batal <rami.batal@antibethera.com>  
**Subject:** Antibe diligence questions and comments on List of Issues

Dear Mark and Annie,

Please find attached two important items:

1. A list of questions for our discussion on Wednesday am. We are not anticipating written answers but just wanted to give you a sense of what we would like to discuss with our CFO on the phone.
2. Thank you for sharing the list of issues and Katten's feedback. Please find our response and notes attached. We can take a few minutes to discuss on our call on Wednesday as well.

Looking forward to speaking.

Cheers,

Ella

R-034



ELLA KORETS-SMITH MSc, MBA

Head Regional Business Development

+1 416-836-1777

[ella@antibethera.com](mailto:ella@antibethera.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada, M5R 1B2

[www.antibethera.com](http://www.antibethera.com)

This is Exhibit "1" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



---

*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

**From:** [EL](#)  
**Sent:** February 1, 2021 3:34 AM  
**To:** [连君洋](#)  
**Cc:** [mglotter](#); [李锦](#); [李安妮](#)  
**Subject:** Re: DD plan - Antibe

---

Dear Jasmine,

Based on the discussion today and yesterday via Wechat, please find my comments below after reviewed the available data provided by ATRM.

**Background:**

1. The results of the completed clinical studies: Phase I & II studies.
2. FDA response: Inadequacy of the nonclinical safety data to support the IND-opening clinical study
3. The different naproxen exposure between female and male population from Ph 2B DRF study.
4. The dosage for Ph3 study is not determined.
5. For a new chemical entity, PK study in China is inevitable and could be conducted in healthy volunteers with targeted dose regimen for Ph3 study, so it relates to the dose regimen Antibe established in the planned efficacy study #1.

What we  
require  
from

# MED

# side:

## CDP in US/EU

1. Could you share with us the latest progress about the negotiation results between Antibe and regulatory team from US & EU on the Ph3 registration study plan?
2. Could you share with us the protocols for your proposed 3 efficacy studies (study #1, #2, #3) and 2 GI safety studies (presented in the partnering presentation 2020.9 Page 14)? As well the corresponding timeline?

## Clinical pharmacology

3. We would like to know if any Asian population recruited in the completed studies and whether any plan to recruit in the proposed US or EU local studies which would provide some information to assess the ethnic sensitivity.
4. The protocol and the timeline of the IND-opening Ph1 clinical AME study on metabolites?  
clinical
5. We note from Ph2B DRF study that Naproxen displays different exposure between female and male population after ATB-346 administered, what is the consideration in future clinical trials on this point?
6. We note that for efficacy study #3 Antibe proposes to include patients from Asia Pacific or run a separate Asia-focused development program. We would like to know whether the details are settled based on which to assess whether there is any opportunity for us to join one MRCT which is a favorable strategy for registration in China?

Thanks and Rgs,

Edy

---

**From:** [jasmine.lien](mailto:jasmine.lien)  
**Date:** 2021-01-29 08:44  
**To:** 李锦; Edy; [annie.lee](mailto:annie.lee)  
**CC:** [mjlotter](mailto:mjlotter)  
**Subject:** DD plan - Antibe  
 Hi Jin, Edy and Annie,

Attached is the DD report template for Anibe. Please help to input your comments to relevant parts and send it back to me by EOB next Tuesday. Thank you for the supports!

- 1.1 Non-clinical - [Jin](#) (please verify if it is sufficient to support China registration)
- 1.2 CMC-Product quality - [Jin](#) (please verify if it is sufficient to support China registration)
- 1.3 Regulatory - [Jin](#) (please verify if it is sufficient to support China registration)
- 1.4 Corporate quality - [Annie](#) (Need [CBC legal team](#) to support the verification)

R-057

- 1.5 Clinical - [Edy](#) (Please verify if the clinical design and results applicable to Chinese patients)
- 1.6 Market commercial - [Jasmine](#)
- 1.7 IP - [Annie](#) (Need CBC legal team to support the verification)
- 1.8 Publications - [Jasmine](#)
- 1.9 Corporate - [Annie](#) (Need CBC legal team to support the verification)

If there is any question, please do not hesitate to let me know.

Best regards,  
Jasmine





R-034

Message

**From:** annie.lee@nuancepharma.cn [annie.lee@nuancepharma.cn]  
**Sent:** 2/3/2021 7:01:21 AM  
**To:** Ella Korets-Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daf43ca648534b1eb92e0527fe8aef0f-ella]; 'Mark G. Lotter' [mglotter@nuancebiotech.com]  
**CC:** Rami Batal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81cdc60d7614985b48d3ac3ee75d829-rami.batal]  
**Subject:** RE: Antibe diligence questions and comments on List of Issues

Hi Ella,

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**

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

Best,  
Annie

---

**From:** Ella Korets-Smith <ella@antibethera.com>  
**Sent:** Tuesday, February 2, 2021 10:32 AM  
**To:** Mark G. Lotter <mglotter@nuancebiotech.com>; annie.lee <annie.lee@nuancepharma.cn>  
**Cc:** Rami Batal <rami.batal@antibethera.com>  
**Subject:** Antibe diligence questions and comments on List of Issues

Dear Mark and Annie,

Please find attached two important items:

1. A list of questions for our discussion on Wednesday am. We are not anticipating written answers but just wanted to give you a sense of what we would like to discuss with our CFO on the phone.
2. Thank you for sharing the list of issues and Katten's feedback. Please find our response and notes attached. We can take a few minutes to discuss on our call on Wednesday as well.

Looking forward to speaking.

Cheers,

Ella

R-034



ELLA KORETS-SMITH MSc, MBA  
Head Regional Business Development

+1 416-836-1777  
[ella@antibethera.com](mailto:ella@antibethera.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada, M5R 1B2

[www.antibethera.com](http://www.antibethera.com)

This is Exhibit "J" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



---

*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

R-035

Message

**From:** Ella Korets-Smith [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DAF43CA648534B1EB92E0527FE8AEF0F-ELLA]  
**Sent:** 2/4/2021 9:19:06 AM  
**To:** Mark G. Lotter [mglotter@nuancebiotech.com]; annie.lee [annie.lee@nuancepharma.cn]  
**CC:** Rami Batal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81cdc60d7614985b48d3ac3ee75d829-rami.batal]  
**Subject:** Nuance diligence questions: Antibe responses

Dear Nuance team,

Thank you for the questions you shared. In this note I'm including some answers to the questions and will note where additional materials have been added to ShareVault.

Besides the answers and corresponding documents, we have also received results from an additional non-clinical study in dogs, treated for 28 days. The result of the study has been added to the Non-Clinical/Completed Studies/Toxicology folder in ShareVault.

Please don't hesitate to reach out if you have additional questions/comments.

Cheers,

Ella

\*\*\*\*\*

## 1. Regulatory

### a. Meeting minute of the End-of-phase 2 meeting minute

*We have not yet had an End-of-Phase 2 meeting with the FDA; we anticipate doing so this Fall.*

*We would like to note that our Pre-IND meeting with the FDA in March, 2020 (briefing materials, request, response and minutes in ShareVault) dealt quite extensively with the Phase 3 program — See Questions 8 and 9 in particular. At the time of the meeting, of course, we had already been in ~500 humans, so this was not surprising.*

*During the Pre-IND meeting we proposed a standard, conservative program for which there is abundant FDA precedent (see, for example, the filings for Vimovo). Our view of the discussion, which is supported by the minutes, is that the FDA, also not surprisingly, given the program and precedent, was comfortable with this approach, and provided helpful, collaborative suggestions. Moreover, it is apparent that they would be amenable in an End-of-Phase 2 meeting to a detailed discussion as to whether one GI-safety study versus two might be acceptable, given the profound success of the Phase 2 GI-safety study.*

### b. Risk management plan

*We understand your question to be regarding REMS (Risk Evaluation and Mitigation Strategy) for otenaproxesul. As our drug is a NCE NSAID and not an opioid, we will not be required to have a REMS by the US FDA or other regulatory agencies.*

## 2. Clinical

### a. 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)

Document Shared: Phase 3 RCT study synopsis (ShareVault: Clinical: Planned Studies)



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*Antibe is getting ready to open an IND for otenaproxesul in the coming two months. As we have not yet done so, there are no formalized protocols for any of the studies listed above; however, Antibe's regulatory and medical teams have spent much time consulting on and developing the Phase 3 program. The full program will include three Phase 3 efficacy studies (two for the US FDA and one focused on the EU and Pacific Rim), as well as one or two Phase 3 studies focused on GI safety. Based on our deep knowledge of the space and that of our advisors, Antibe is conceiving a program that looks very much like most NSAID studies and should be well accepted by the regulatory agencies, as we described above.*

*As we are nearly ready to open the IND, we have developed a detailed synopsis for the first Phase3 OA efficacy study, which is now found in ShareVault. As per above, we will conduct a second Phase 3 OA efficacy study, which would be a replicate of the first, with treatment for 12 weeks and a 9-month open-label extension bolted on for FDA/ICH required safety exposures in patients. These two studies only enroll in US and Canada.*

*For the third efficacy study, Antibe will likely replicate the design of the first two, with an additional active comparator arm (celecoxib or naproxen, decision not yet final) for non-inferiority as per expected EU guidance. This study would also include up to 25% Pacific-Rim patients (we are currently planning a mix of Japanese and South Korean sites). In this context, we could consider including sites in China, if timing aligns and the JDC agrees to pursue this option.*

*For the GI-safety study component this will be one or two (as per above) 24-week GI studies (approx. n=400 each) comparing otenaproxesul at max daily dose vs. naproxen at max daily dose in chronic pain patients (LBP, OA, RA, AS, etc.). All patients will have baseline, 3-month and 6-month UGI endoscopy. Primary endpoint will be incidence of 3mm, with 5mm ulcer incidence as one of several secondary endpoints. These are essentially longer versions of the 2-week Phase 2b studies already conducted by Antibe.*

*Assuming all goes accordingly, Antibe will be in the 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.*

**b. Asian population results and ethnic sensitivity in the completed studies**

*Though otenaproxesul has been in over 500 patients to date, we have not had enough Asian patients to be able to assess and comment. We look forward to doing this analysis in the upcoming Phase 3 program.*

**c. Plan number of Asian population to recruit in the proposed US or EU local studies**

*As stated above, we plan to conduct the third Phase 3 efficacy study in 20-25% of Asian sites to meet the requirements of regulatory agencies in Japan and South Korea. We support the current proposal from Nuance to do a separate China study; however, we are open to including sites in China in this third Phase 3 study, if the timing lines up and it is accepted/approved by the JDC.*

**d. Protocol and timeline of the IND-opening Ph1 clinical AME study on metabolites.**

**Document: Draft Phase 1 IND opening study (ShareVault: Clinical: Planned Studies)**

*For clarity, Antibe has plans to conduct at least two Phase 1 studies to satisfy the NDA regulatory requirements. For our US IND-opening study, the objective of this PK/PD design is to gain more insight/understanding into the rapid onset of cyclo-oxygenase inhibition and the relative plasma concentrations of all measurable otenaproxesul metabolites, particularly in the early post-dose time frame (i.e., within two hours). To this end we plan on administering a single 100 mg tablet or a single 150 mg tablet to separate cohorts of healthy younger subjects and take blood samples over a 24-hour period with a noted emphasis on sampling during the first two hours post drug administration. The draft protocol for this study is now in ShareVault.*

*We also intend to conduct a Phase 1 Absorption, Metabolism and Excretion (AME) study to partially satisfy our regulatory requirements and obtain valuable learnings. In this study four different arms of older, healthy subjects will*

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receive 75 mg, 100 mg, 125 mg or 150 mg single daily doses of otenaproxesul for 28 days. During study drug administration, plasma levels of thromboxane B2 will be measured as a surrogate for cyclo-oxygenase inhibition and full 24-hour steady state PK time-concentration curves will be obtained at specified times. The overall objective of these studies, among other required demonstrations, is to identify dose(s) providing robust and sustained cyclo-oxygenase inhibition while generating sufficient steady-state plasma levels of otenaproxesul metabolites considered safe and effective.

The planned timeline for regulatory submission of our IND to the US FDA is March 2021, with the IND-opening study implementation in late Q2 or early Q3. For the Canadian AME study submission is planned for April/May 2021 with study initiation late Q2 2021. Drug product for both studies has been manufactured and is readily available.

**e. Plan to address the different exposure Naproxen displayed between female and male population after ATB-346 administered in Ph2B DRF study**

**Document: DRAFT AME Protocol (ShareVault: Clinical: Planned Studies)**

Plasma otenaproxesul-derived naproxen levels were measured in the DRF study on Day 1 and at steady-state on Day 4 and Day 14. These were single time point measures typically taken 4-hours after the patient's morning dose. The single time point measures from the DRF and other Antibe studies plus more robust PK data from formal pharmacokinetic studies indeed confirm the plasma concentration and plasma exposure differences between male (generally lower) and female (generally higher) populations.

The otenaproxesul plasma exposure differences are going to be fully quantified in the upcoming Canadian AME study. The Draft AME protocol has been added to ShareVault. Formal 24-hour plasma time-concentration curves will be generated from collected plasma samples and full PK outcomes data, such as C<sub>max</sub>, T<sub>max</sub>, half-life and AUC will be tabulated for the range of doses being administered (75 mg to 150 mg). Using concurrent data on thromboxane B2 plasma levels in the AME population, otenaproxesul dosage(s) yielding potent cyclo-oxygenase inhibition will be identified. As mentioned earlier, the objective of the Canadian AME study is to identify all treatment doses affording potent COX inhibition and to select doses that may be gender targeted, e.g., male dose of 150 mg, female dose of 125 mg to generate similar plasma drug concentrations and exposure while improving safety and maintaining efficacy. Through this process, a gender specific, lowest effective dose will be identified.



ELLA KORETS-  
SMITH MSc, MBA  
Head Regional Business  
Development

+1 416-836-1777  
[ella@antibetherapeutics.com](mailto:ella@antibetherapeutics.com)

15 Prince Arthur Ave.  
Toronto, ON, Canada, M5R  
1B2

[www.antibetherapeutics.com](http://www.antibetherapeutics.com)

This is Exhibit "K" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**



1 09:50 of the page. I just need you to agree with me on

2 a number of propositions, Mr Lotter, as we go through

3 this. He says:

4 "Nuance did not request any meetings with key Antibe  
5 personnel during the 15-day due diligence period to ask  
6 questions and obtain further information ..."

7 Now, that statement is true; correct?

8 A. As I recall, yes.

9 Q. Okay. And he says over the page at (c):

10 "On February 3, 2021, Nuance sent a list of  
11 questions to Antibe."

12 We can pull that up if necessary; it's R-034.

13 "This was the only list of questions sent to Antibe  
14 prior to signing the license agreement."

15 I just want to pause there for a moment. You will  
16 recall that there was a list of questions that went  
17 over?

18 A. I do, yes.

19 Q. And that was the only list that went over?

20 A. Correct.

21 Q. Okay. The next sentence says:

22 "There was no request for all of Antibe's  
23 correspondence with Health Canada or with the Food and  
24 Drug Administration ..."

25 And that statement is true?

- 1 09:51 A. Again, let me kind of comment. There was one question,  
2 as I recall, which related to the post-phase 2 study, so  
3 that's technically incorrect. However, as I think our  
4 counsel mentioned yesterday, as part of the data room,  
5 we had assumed, correctly or incorrectly, that all the  
6 information regarding the regulators had been provided.  
7 And so, based on that assumption, we had no further  
8 questions.
- 9 Q. Okay.
- 10 A. And I think that was a reasonable assumption at least  
11 based on our assessment at the time.
- 12 Q. We'll get to that in a moment, but the answer is yes,  
13 I take it, that there was no request for all of Antibe's  
14 correspondence?
- 15 A. I just said that I think there was a request to get  
16 information on the phase 2 regulator feedback.
- 17 Q. You're right, and that was answered by --
- 18 A. Yes, but that's not what the statement is saying. It's  
19 saying there were no questions. That's not correct.
- 20 Q. But the answer was it didn't exist. Isn't that what the  
21 answer is?
- 22 A. No, it's not correct. I don't agree.
- 23 Q. So, with that exception, that was all you asked for?
- 24 A. Correct.
- 25 Q. You didn't ask for all of Antibe's correspondence with

1 09:52 Health Canada?

2 A. Given that we had seen it had been provided in the data  
3 room, as mentioned a few times now.

4 Q. Right. But one of the things you say in your witness  
5 statement, and the other witnesses do as well, is that  
6 the correspondence with the regulators was critical to  
7 the analysis of the drug on the part of Nuance.

8 A. Absolutely.

9 Q. Agreed?

10 A. Correct.

11 Q. And notwithstanding the critical nature of that from  
12 your perspective, that you tell us about now, you didn't  
13 ask for all of the correspondence with the regulators?

14 A. Again, not to repeat myself, we had assumed that the  
15 data that had been provided by a listed company in  
16 an official data room was complete.

17 Q. Okay. So let me ask you to look at (e), at the bottom  
18 of the page. He says:

19 "According to the witness statement of Annie Lee,  
20 the only publicly-available information Nuance reviewed  
21 was obtained from the databases Global Data and  
22 Cortellis."

23 Do you agree with that statement, sir, that that's  
24 true?

25 A. I cannot comment on which databases were accessed. I'm



wanted for their due diligence, but they never did. I also expected they would ask extensive detailed questions, but they never did.

28. At no time did I ever indicate to anyone at Nuance that the data room contained all relevant and material information, or that it contained all regulatory communications, or that all materials were accurate and up-to-date. I would never make such statements. Such statements would not make sense—every potential partner has unique interests and requirements based on, among other things, their resources and interests. It is the potential partner, not me, that defines the scope of their due diligence, and requests documents and information. I have no way of knowing what each potential partner wants, without their requests.

29. No one from Nuance ever told me that Nuance was interested in regulatory correspondence, asked me to include all regulatory correspondence in the data room, or asked me to include all of Antibe's correspondence with Health Canada and with the FDA. Had they asked for such correspondence, I would have provided it, although it would have taken some weeks as most of Antibe's regulatory correspondence was housed with our regulatory consultants in the US, Canada, and Europe. Similarly, no one from Nuance ever asked me to confirm that all regulatory correspondence was in the data room.

30. On January 6, 2021, Mark Lotter sent an email to me confirming the Nuance team was "on standby" for access to the data room as well as to review the first draft of the Definitive Agreement. He also confirmed Nuance's commitment, as stated in a recent call



83. In particular, Nuance never asked me, nor to my knowledge anyone else on the Antibe team, for all of Antibe's regulatory correspondence or even Antibe's regulatory correspondence with the FDA. The only regulatory correspondence Nuance asked for before it signed the License Agreement was a document that did not exist – the minutes of an end-of-phase 2 meeting with the FDA that had not yet taken place.

84. Contrary to Mark Lotter's assertions at paragraph 39 of his witness statement, Nuance never stressed it would require Antibe's communications with the FDA prior to its signing of the License Agreement. Antibe never told Nuance that it had recent communications with the FDA leading up to its submission of its IND application (in fact the IND application was not submitted until after the signing of the License Agreement) or that it was discussing the results of the AME Study with the FDA and with Health Canada - such discussions could not have taken place as the AME Study did not even start until July 2021.

85. Neither I, nor to my knowledge, anyone else from Antibe, told Nuance there was "no further correspondence with Health Canada", that the draft AME Protocol (v1.0) was already more or less finalised, or that Antibe planned to submit the draft AME Protocol (v1.0) to Health Canada in April /May 2021. Mark Lotter is incorrect when he makes these assertions in paragraph 40 of his witness statement.

86. I also disagree with Mark Lotter's characterization in paragraph 44 of his witness statements regarding Antibe's obligations to Nuance during the due diligence period. Health Canada did not reject the AME CTA in January 2021 – Antibe withdrew the CTA. It did so at the suggestion of Health Canada and with the expectation that Health Canada

This is Exhibit "L" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**



R-046

<b>ShareVault:</b>	Amibe Therapeutics
<b>From:</b>	Saturday, October 31, 2020 11:00:00 PM -05:00
<b>To:</b>	Tuesday, February 9, 2021 11:59:59 PM -05:00
<b>Activities:</b>	login, view, download, print, upload, delete, rename, viewed, entry, page
<b>Groups:</b>	Nuance Biotech
<b>Users:</b>	Lin Li, Jasmine Lien, Edy Liu, Mark Lotter, Halin Meng, Chenyue Ni, Johnny Zhang, Annie Lee
<b>Printed:</b>	Thursday, February 3, 2022 9:55:53 AM -05:00
<b>Events:</b>	378

Date/Time	Activity	User	Company	Job Title	File Name	Info	IP address	File ID
Sunday, January 24, 2021 11:05:32 PM -05:00	login	Zhang, Johnny	Nuance	Head	-	Session duration: 0 hour 15 minutes 49 seconds	124.78.9.128(CN, Shanghai, China Mobile)	-
Wednesday, January 27, 2021 12:18:10 AM -05:00	login	Lotter, Mark	Nuance Biotech	CEO	-	Session duration: 0 hour 17 minutes 32 seconds	223.104.66.93(CN, Guangzhou, China Mobile Guangdong)	-
Wednesday, January 27, 2021 12:25:55 AM -05:00	login	Lotter, Mark	Nuance Biotech	CEO	-	Session duration: 0 hour 17 minutes 5 seconds	223.104.66.93(CN, Guangzhou, China Mobile Guangdong)	-
Wednesday, January 27, 2021 2:48:09 AM -05:00	login	Liu, Edy	Nuance	CMO	-	Session duration: 0 hour 21 minutes 12 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	-
Wednesday, January 27, 2021 3:17:23 AM -05:00	view	Liu, Edy	Nuance	CMO	353317 box - (Naproxen plasma protein binding - (Final Report).pdf	14minutes, 15 of 43, range: 1-15	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115921
Wednesday, January 27, 2021 3:19:40 AM -05:00	view	Liu, Edy	Nuance	CMO	353317 box - (Naproxen plasma protein binding - (Final Report).pdf	14minutes, 8 of 43, range: 1-3, 8-12	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115921
Wednesday, January 27, 2021 3:29:45 AM -05:00	view	Liu, Edy	Nuance	CMO	353317 box - (Naproxen plasma protein binding - (Final Report).pdf	Session duration: 1 hour 38 minutes 28 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115921
Wednesday, January 27, 2021 3:32:55 AM -05:00	view	Liu, Edy	Nuance	CMO	353317 box - (Naproxen plasma protein binding - (Final Report).pdf	21minutes, 43 of 43, range: 1-43	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115921
Wednesday, January 27, 2021 3:51:18 AM -05:00	login	Liu, Edy	Nuance	CMO	353317 box - (Naproxen plasma protein binding - (Final Report).pdf	Session duration: 0 hour 48 minutes 10 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115921
Wednesday, January 27, 2021 4:09:11 AM -05:00	view	Liu, Edy	Nuance	CMO	100011978 (Protein binding).pdf	3minute, 1 of 43, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115921
Wednesday, January 27, 2021 4:23:31 AM -05:00	view	Liu, Edy	Nuance	CMO	100011978 (Protein binding).pdf	3minute, 11 of 11, range: 1-11	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115921
Wednesday, January 27, 2021 4:33:12 AM -05:00	view	Liu, Edy	Nuance	CMO	Metabolism-Covance rat radiolabel Final Report v1.0.pdf	3minutes, 1 of 160, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115926
Wednesday, January 27, 2021 4:38:12 AM -05:00	view	Liu, Edy	Nuance	CMO	Metabolism-Covance rat radiolabel Final Report v1.0.pdf	Session duration: 1 hour 53 minutes 10 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115926
Wednesday, January 27, 2021 4:56:57 AM -05:00	login	Liu, Edy	Nuance	CMO	Metabolism-Covance rat radiolabel Final Report v1.0.pdf	36minutes, 160 of 160, range: 1-160	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115926
Wednesday, January 27, 2021 5:00:20 PM -05:00	view	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	10minutes, 1 of 59, range: 1-48	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Wednesday, January 27, 2021 5:03:26 PM -05:00	view	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	Session duration: 0 hour 37 minutes 4 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Wednesday, January 27, 2021 5:29:59 PM -05:00	login	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	3minute, 1 of 58, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Wednesday, January 27, 2021 10:38:27 PM -05:00	view	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	Session duration: 0 hour 22 minutes 4 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Wednesday, January 27, 2021 10:54:35 PM -05:00	view	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	Session duration: 0 hour 17 minutes 16 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Thursday, January 28, 2021 12:08:47 AM -05:00	login	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	Session duration: 0 hour 16 minutes 0 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Thursday, January 28, 2021 12:09:30 AM -05:00	login	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	Session duration: 2 hour 33 minutes 41 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Thursday, January 28, 2021 12:45:56 AM -05:00	view	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	3minute, 1 of 58, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Thursday, January 28, 2021 12:46:02 AM -05:00	view	Liu, Edy	Nuance	CMO	Metabolism-Hepatoocyte profiling Final Report v1.0.pdf	3minute, 12 of 58, range: 1, 48-58	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115922
Thursday, January 28, 2021 12:54:59 AM -05:00	view	Liu, Edy	Nuance	CMO	Pharmacokinetics-dog oral dose Final Report v1.0.pdf	10minute, 19 of 19, range: 1-19	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115927
Thursday, January 28, 2021 12:59:54 AM -05:00	view	Liu, Edy	Nuance	CMO	Pharmacokinetics-rat single dose oral and intravenous Final Report v1.0.pdf	3minute, 1 of 39, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115929
Thursday, January 28, 2021 1:15:01 AM -05:00	view	Liu, Edy	Nuance	CMO	Pharmacokinetics-rat single dose oral and intravenous Final Report v1.0.pdf	10minute, 39 of 39, range: 1-39	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115929
Thursday, January 28, 2021 1:40:56 AM -05:00	view	Liu, Edy	Nuance	CMO	Rat PK Interaction Study (360577) Final report.pdf	3minute, 1 of 58, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115924
Thursday, January 28, 2021 1:46:56 AM -05:00	view	Liu, Edy	Nuance	CMO	Rat PK Interaction Study (360577) Final report.pdf	8minute, 22 of 58, range: 1, 37-57	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115924
Thursday, January 28, 2021 2:03:50 AM -05:00	view	Liu, Edy	Nuance	CMO	Report_100048688_FR095-0011315 copy.pdf	3minute, 1 of 28, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115925
Thursday, January 28, 2021 2:09:39 AM -05:00	view	Liu, Edy	Nuance	CMO	Report_100048688_FR095-0011315 copy.pdf	Session duration: 0 hour 25 minutes 37 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115925
Thursday, January 28, 2021 2:12:17 AM -05:00	login	Liu, Edy	Nuance	CMO	Report_100048688_FR095-0011315 copy.pdf	3minute, 1 of 28, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9115925
Thursday, January 28, 2021 4:18:38 AM -05:00	view	Liu, Edy	Nuance	CMO	Report_100048688_FR095-0011315 copy.pdf	Session duration: 0 hour 51 minutes 11 seconds	150.116.67.11(TW, Taipei, Pecky Digital Cable Television)	9115925
Thursday, January 28, 2021 6:28:15 PM -05:00	login	Lien, Jasmine	Nuance	Head of BD	-	Session duration: 0 hour 30 minutes 4 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	-
Thursday, January 28, 2021 6:20:46 PM -05:00	login	Liu, Edy	Nuance	CMO	ATB-346-PT Clinical Study Report 6Aug2015.pdf	3minute, 1 of 1064, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9116302
Thursday, January 28, 2021 8:24:31 PM -05:00	view	Liu, Edy	Nuance	CMO	ATB-346-P2A Investigators Brochure 4Nov2015.pdf	11minutes, 57 of 57, range: 1-57	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9116083
Thursday, January 28, 2021 8:46:30 PM -05:00	view	Liu, Edy	Nuance	CMO	Meeting Minutes (2).pdf	16minutes, 84 of 84, range: 1-84	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9116001
Thursday, January 28, 2021 9:03:33 PM -05:00	view	Liu, Edy	Nuance	CMO	type-b-meeting-background-materials.pdf	3minute, 1 of 165, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9116002
Thursday, January 28, 2021 9:24:24 PM -05:00	login	Lien, Jasmine	Nuance	Head of BD	-	Session duration: 0 hour 19 minutes 26 seconds	150.116.67.11(TW, Taipei, Pecky Digital Cable Television)	-
Thursday, January 28, 2021 9:24:09 PM -05:00	view	Liu, Edy	Nuance	CMO	type-b-meeting-background-materials.pdf	3minute, 1 of 165, range: 1	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9116002
Thursday, January 28, 2021 10:03:55 PM -05:00	login	Liu, Edy	Nuance	CMO	type-b-meeting-background-materials.pdf	Session duration: 3 hour 55 minutes 34 seconds	120.245.96.25(CN, Beijing, China Mobile Guangdong)	-
Thursday, January 28, 2021 10:05:43 PM -05:00	view	Liu, Edy	Nuance	CMO	type-b-meeting-background-materials.pdf	30minutes, 165 of 165, range: 1-165	120.245.96.25(CN, Beijing, China Mobile Guangdong)	9116002

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Thursday, January 28, 2021 10:32:50 PM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 27 minutes 43 seconds 5minute , 32 of 43 , range: 1-5 , 10-18 , 21-22 , 24-25 , 28-33 , 35-36 , 38-39 , 41-43	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115921
Thursday, January 28, 2021 10:33:46 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	353317 box - (Naproven plasma protein binding - (Final Report)).pdf		120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115953
Thursday, January 28, 2021 10:36:30 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.1.1 Nomenclature_20200924_RED Finished.docx	4minute , 1 of 1 , range: 1	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9116001
Thursday, January 28, 2021 10:38:59 PM -05:00	view	Liu, Eddy	Nuance Pharma	CMO	ATB-34-P2A Clinical Study Report 28(May)2017 .pdf	3minute , 1 of 222 , range: 1	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9116051
Thursday, January 28, 2021 10:49:59 PM -05:00	view	Liu, Eddy	Nuance Pharma	CMO	ATB-34-P2A Clinical Study Report 28(May)2017 .pdf	54minutes , 222 of 222 , range: 1-222	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9116051
Thursday, January 28, 2021 11:15:45 PM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 36 minutes 32 seconds	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	-
Thursday, January 28, 2021 11:19:13 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Opportunity Assessment for ATB-346 - Final Report.pptx	11minutes , 61 of 62 , range: 1-58 , 60-62	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9116343
Thursday, January 28, 2021 11:26:42 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.1.1 Nomenclature_20200924_RED Finished.docx	-	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9115953
Thursday, January 28, 2021 11:28:29 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Metabolism-Covance rat radiolabel Final Report_v1.0 .pdf	3minute , 1 of 160 , range: 1	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9115926
Friday, January 29, 2021 1:02:56 AM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 29 minutes 1 seconds	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	-
Friday, January 29, 2021 1:06:36 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	100011978 (Protein binding).pdf	5minute , 11 of 11 , range: 1-11	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9115923
Friday, January 29, 2021 1:09:51 AM -05:00	view	Liu, Eddy	Nuance Pharma	CMO	type-meeting-background-materials.pdf	-	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9116002
Friday, January 29, 2021 1:09:52 AM -05:00	view	Liu, Eddy	Nuance Pharma	CMO	ATB-346-P1 Clinical Study Report 6Aug2015 .pdf	-	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9116302
Friday, January 29, 2021 1:10:34 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Opportunity Assessment for ATB-346 - Final Report.pptx	-	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9116343
Friday, January 29, 2021 1:12:14 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.1.1 Nomenclature_20200924_RED Finished.docx	3minute , 1 of 1 , range: 1	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9115953
Friday, January 29, 2021 1:14:41 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.2.6 Manufacturing Process Development_20200924_Finished.docx	3minute , 1 of 43 , range: 1	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9115978
Friday, January 29, 2021 1:20:52 AM -05:00	view	Liu, Eddy	Nuance Pharma	CMO	ATB-34-P2A Clinical Study Report 28(May)2017 .pdf	-	120,245,96,25(CN, Beijing, China Mobile Guangdong)	-	9116051
Friday, January 29, 2021 2:09:10 AM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 55 minutes 23 seconds	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	-
Friday, January 29, 2021 2:09:29 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.2.6 Manufacturing Process Development_20200924_Finished.docx	-	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115978
Friday, January 29, 2021 2:09:59 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.1-FG 13Jan2021.docx	2minute , 2 of 2 , range: 1-2	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115981
Friday, January 29, 2021 2:11:48 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.2.Pharmaceutical Development_22JAN2021.docx	3minute , 1 of 50 , range: 1	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115990
Friday, January 29, 2021 2:15:03 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.2.Pharmaceutical Development_22JAN2021.docx	8minute , 31 of 50 , range: 1-11 , 13-14 , 17-25 , 30-31 , 33-34 , 39-40 , 48-50	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115990
Friday, January 29, 2021 2:16:19 AM -05:00	login	Liu, Eddy	Nuance Pharma	CMO	-	Session duration : 0 hour 35 minutes 14 seconds	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	-
Friday, January 29, 2021 2:16:34 AM -05:00	view	Liu, Eddy	Nuance Pharma	CMO	ATB-34-P2A Clinical Study Report 28(May)2017 .pdf	-	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9116051
Friday, January 29, 2021 2:20:14 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.3.1 Manufacturers_04Dec2020.docx	3minute , 1 of 1 , range: 1	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115994
Friday, January 29, 2021 2:21:25 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.4.1 Specifications_FG 14Jan2021.docx	1minute , 1 of 1 , range: 1	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115998
Friday, January 29, 2021 2:22:35 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.4.5 Exipients of Human or Animal Origin_FG 04DEC2020.docx	1minute , 1 of 1 , range: 1	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115996
Friday, January 29, 2021 2:23:55 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.7. Container Closure System_07DEC2020.docx	1minute , 1 of 1 , range: 1	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9115983
Friday, January 29, 2021 2:24:09 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	ATB-P4-484-CMC clarification request (June 05, 2014).pdf	5minute , 2 of 2 , range: 1-2	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9116004
Friday, January 29, 2021 2:26:35 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Meeting Minutes (2).pdf	11minutes , 20 of 84 , range: 1-15 , 19-23	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9116001
Friday, January 29, 2021 2:38:16 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	type-b-meeting-background-materials.pdf	8minute , 9 of 165 , range: 1-8	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	9116002
Friday, January 29, 2021 3:46:56 AM -05:00	login	Liu, Eddy	Nuance Pharma	CMO	-	Session duration : 0 hour 16 minutes 8 seconds	120,245,98,173(CN, Beijing, China Mobile Guangdong)	-	-
Friday, January 29, 2021 6:47:31 PM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 29 minutes 48 seconds	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	-
Friday, January 29, 2021 9:39:51 PM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 1 hour 23 minutes 35 seconds	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	-
Friday, January 29, 2021 10:13:17 PM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 1 hour 8 minutes 17 seconds	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	-
Friday, January 29, 2021 10:15:12 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.1.1 Nomenclature_20200924_RED Finished.docx	1minute , 1 of 1 , range: 1	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	9115953
Friday, January 29, 2021 10:16:55 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.1.2 Structure_20200924_RED Finished.docx	1minute , 1 of 1 , range: 1	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	9115954
Friday, January 29, 2021 10:17:26 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.1.2 Structure_20200924_RED Finished.docx	1minute , 1 of 1 , range: 1	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	9115954
Friday, January 29, 2021 10:18:16 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.1.3 General Properties_20200924_RED Finished.docx	1minute , 1 of 1 , range: 1	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	9115955
Friday, January 29, 2021 10:18:35 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.2.1 Manufacturers_20200924_RED Finished.docx	1minute , 3 of 3 , range: 1-3	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	9115980
Friday, January 29, 2021 10:20:12 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.2.2 Description of Manufacturing Process and Process Controls_20200924_RED_V4_Final.docx	11minutes , 18 of 18 , range: 1-18	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	9115976
Friday, January 29, 2021 10:28:20 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.2.3 Control of Materials_20200924_Finished.docx	4minute , 6 of 59 , range: 1-6	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	9115975
Friday, January 29, 2021 10:32:43 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.2.4 Control of Critical Steps and Intermediates_20200924_Finished Dec102020.docx	3minute , 6 of 14 , range: 1-6	120,245,122,0(CN, Beijing, China Mobile Guangdong)	-	9115979

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Friday, January 29, 2021 10:36:02 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.2.5 Process Validation and-or Evaluation_20200924_Final.docx	3minute , 1 of 1 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9115977
Friday, January 29, 2021 10:36:51 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.3.1 Elucidation of Structure_20200924_Finished_Dec 15 2020.docx	2minute , 6 of 25 , range: 1-6	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9115958
Friday, January 29, 2021 10:40:06 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	BSE TSE statement for ANW-001 batch 2.pdf	1minute , 1 of 1 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9115973
Friday, January 29, 2021 10:41:16 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Clarifax CMC response.docx	1minute , 1 of 1 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116006
Friday, January 29, 2021 10:41:46 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Clarifax CMC response.docx	4minute , 1 of 1 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116006
Friday, January 29, 2021 10:50:55 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Clarification request_Clinic (June 06, 2014).docx	1minute , 3 of 3 , range: 1-3	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116005
Friday, January 29, 2021 10:53:44 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	ATB-346-P1B Investigators Brochure 4 24.Jul2016.pdf	4minute , 1 of 91 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116048
Friday, January 29, 2021 11:03:18 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Anitbe-Phase-2B-Study-Review.pdf	4minute , 2 of 7 , range: 1-2	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116413
Friday, January 29, 2021 11:04:43 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	ATB-346-P2B-DRF Investigators Brochure 28Dec2018.pdf	3minute , 1 of 98 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116301
Saturday, January 30, 2021 2:21:16 AM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 44 minutes 55 seconds	120.245.122.0(CN, Beijing, China Mobile Guangdong)	-
Saturday, January 30, 2021 2:23:29 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	type-b-meeting-background-materials.pdf	17minutes , 30 of 165 , range: 1-30	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116002
Saturday, January 30, 2021 2:23:35 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	ATB-346-P2B-DRF Investigators Brochure 28Dec2018.pdf	-	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116301
Saturday, January 30, 2021 3:53:43 AM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 2 hour 35 minutes 42 seconds	120.245.122.0(CN, Beijing, China Mobile Guangdong)	-
Saturday, January 30, 2021 4:37:12 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Anitbe-Phase-2B-Study-Review.pdf	-	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116413
Saturday, January 30, 2021 4:37:30 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Meeting Minutes (2).pdf	54minutes , 36 of 84 , range: 1-36	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116001
Saturday, January 30, 2021 5:53:17 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	ATB-346-P2B-DRF Investigators Brochure 28Dec2018.pdf	16minutes , 20 of 98 , range: 1-20	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9116301
Saturday, January 30, 2021 6:05:52 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.1.1 Nomenclature_20200924_RED Finished.docx	3minute , 1 of 1 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9115953
Saturday, January 30, 2021 6:09:27 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	a_S.2.1 Manufacturers_20200924_RED Finished.docx	3minute , 1 of 3 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9115980
Saturday, January 30, 2021 6:09:50 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.3.1 Manufacturers_04Dec2020.docx	3minute , 1 of 1 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9115994
Sunday, January 31, 2021 6:11:54 AM -05:00	view	Li, Jin	Nuance Pharma	RA VP	b_P.3.2 Batch Formula_14Jan2021.docx	3minute , 1 of 1 , range: 1	120.245.122.0(CN, Beijing, China Mobile Guangdong)	9115992
Sunday, January 31, 2021 8:33:56 PM -05:00	login	Liu, Eddy	Nuance CMO	CMO	Session duration : 2 hour 51 minutes 42 seconds	-	120.245.98.133(CN, Beijing, China Mobile Guangdong)	-
Sunday, January 31, 2021 8:54:39 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	Safety Pharmacology-Cyp P450 inhibition-Induction Potential_V1.0.pdf	17minutes , 17 of 17 , range: 1-17	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9115935
Sunday, January 31, 2021 9:11:48 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	363319 Validation Final Report (ATB-346 in Dose Formulation).pdf	7minute , 24 of 102 , range: 1-24	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9115918
Sunday, January 31, 2021 9:26:05 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P2A Cover Letter 2Feb2016.pdf	11minutes , 2 of 2 , range: 1-2	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116079
Sunday, January 31, 2021 9:29:12 PM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 55 minutes 51 seconds	120.245.98.133(CN, Beijing, China Mobile Guangdong)	-
Sunday, January 31, 2021 9:30:09 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Metabolism-Hepatoctyle profiling Final Report_V1.0.pdf	6minute , 4 of 59 , range: 1-4	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9115922
Sunday, January 31, 2021 9:35:36 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P1B Investigators Brochure 4 24.Jul2016.pdf	7minute , 4 of 91 , range: 1-4	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116048
Sunday, January 31, 2021 9:43:29 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	Patent Status Report (2021-01-21).xlsx	3minute , 1 of 4 , range: 1	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116361
Sunday, January 31, 2021 9:44:06 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P2B-DRF QOS Attachment 1 28Dec2018.pdf	4minute , 2 of 2 , range: 1-2	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116186
Sunday, January 31, 2021 9:44:59 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P2B-DRF Cover Letter 3Oct2019.pdf	6minute , 2 of 2 , range: 1-2	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116300
Sunday, January 31, 2021 9:45:44 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	ATB-346-P2B-DRF Investigators Brochure 28Dec2018.pdf	3minute , 1 of 98 , range: 1	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116301
Sunday, January 31, 2021 9:50:35 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	ATB-346-P2B-DRF Investigators Brochure 28Dec2018.pdf	14minutes , 14 of 98 , range: 1, 3-7, 9-16	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116301
Sunday, January 31, 2021 9:56:34 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P2B-DRF_Final CSR_21Dec2020.pdf	23minutes , 12 of 104 , range: 1-12	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116194
Sunday, January 31, 2021 10:03:46 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P2B-GIS NOL 26Jun2017.pdf	7minute , 2 of 2 , range: 1-2	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116178
Sunday, January 31, 2021 10:05:11 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	HC Response_Jan 142019.docx	11minutes , 4 of 4 , range: 1-4	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116015
Sunday, January 31, 2021 10:09:59 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P1B Clinical Study Report 24Mar2020.pdf	18minutes , 8 of 535 , range: 1-8	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116019
Sunday, January 31, 2021 10:10:24 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	140708 A1 Cohort Safety Meeting Minutes.doc	11minutes , 3 of 3 , range: 1-3	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116317
Sunday, January 31, 2021 10:52:57 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	Safety Pharmacology-Dog Cardiovascular_Q1c_Final Report_v2.0.pdf	10minute , 18 of 654 , range: 1-8, 15, 17, 30, 32, 148, 151, 648-651	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9115938
Sunday, January 31, 2021 10:52:59 PM -05:00	view	Liu, Eddy	Nuance CMO	CMO	Safety Pharmacology-HERG Final Report_V1.0.pdf	9minute , 10 of 10 , range: 1-10	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9115934
Sunday, January 31, 2021 11:04:05 PM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 25 minutes 4 seconds	120.245.98.133(CN, Beijing, China Mobile Guangdong)	-
Sunday, January 31, 2021 11:37:30 PM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 38 minutes 57 seconds	120.245.98.133(CN, Beijing, China Mobile Guangdong)	-
Sunday, January 31, 2021 11:39:19 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	ATB-346-P2B-DRF Investigators Brochure 28Dec2018.pdf	-	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116301
Sunday, January 31, 2021 11:39:39 PM -05:00	view	Li, Jin	Nuance Pharma	RA VP	Meeting Minutes (2).pdf	12minutes , 28 of 84 , range: 1-9, 14-32	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116001
Monday, February 1, 2021 12:22:59 AM -05:00	login	Liu, Eddy	Nuance CMO	CMO	-	Session duration : 4 hour 50 minutes 54 seconds	120.245.98.219(CN, Beijing, China Mobile Guangdong)	-
Monday, February 1, 2021 12:34:16 AM -05:00	login	Li, Jin	Nuance Pharma	RA VP	-	Session duration : 0 hour 16 minutes 4 seconds	120.245.98.219(CN, Beijing, China Mobile Guangdong)	-
Monday, February 1, 2021 1:33:07 AM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P2A Cover Letter 2Feb2016.pdf	5minute , 2 of 2 , range: 1-2	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116079
Monday, February 1, 2021 1:33:51 AM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P2A Cover Letter 2Feb2016.pdf	3minute , 1 of 2 , range: 1	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116079
Monday, February 1, 2021 1:36:24 AM -05:00	view	Liu, Eddy	Nuance CMO	CMO	ATB-346-P2A Cover Letter 7Apr2016.pdf	4minute , 2 of 2 , range: 1-2	120.245.98.133(CN, Beijing, China Mobile Guangdong)	9116082







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Saturday, February 6, 2021 11:44:40 AM -05:00	view	Liu, Eddy	Nuance	CMO	ATB-346-P2B DRF OOS Attachment 2 28Dec2018.pdf	4minutes, 6 of 6, range: 1-8	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9116188
Saturday, February 6, 2021 11:28:04 PM -05:00	view	Liu, Eddy	Nuance	CMO	DPAT Protocol Canadian AME study.pdf	14minutes, 11 of 69, range: 1-11	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9277913
Saturday, February 6, 2021 11:28:15 PM -05:00	view	Liu, Eddy	Nuance	CMO	DPAT Protocol IND opening Phase 1 study.docx	10minutes, 18 of 49, range: 1-2, 6-11, 14-16, 18-21, 23-25	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9277915
Sunday, February 7, 2021 12:12:38 AM -05:00	login	Liu, Eddy	Nuance	CMO	363319 Validation Final Report (ATB-346 in Dose Formulation).pdf	Session duration: 5 hours, minutes 2, seconds 3	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9115978
Sunday, February 7, 2021 2:38:41 AM -05:00	view	Liu, Eddy	Nuance	CMO	Pharmacokinetics-rat single dose oral and intravenous Final Report_v1.0.pdf	3minutes, 1 of 102, range: 1	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9115978
Sunday, February 7, 2021 2:39:26 AM -05:00	view	Liu, Eddy	Nuance	CMO	Report_v1.0.pdf	35minutes, 18 of 39, range: 1-18	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9115979
Sunday, February 7, 2021 2:42:53 AM -05:00	view	Liu, Eddy	Nuance	CMO	Pharmacokinetics-66g oral dose Final Report_v1.0.pdf	17 of 19, range: 1-6, 9-19	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9115977
Sunday, February 7, 2021 2:42:54 AM -05:00	view	Liu, Eddy	Nuance	CMO	Manufacture Hepatocyte Profiling Final Report_v1.0.pdf	5minutes, 9 of 69, range: 2-10	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9118922
Sunday, February 7, 2021 4:14:33 AM -05:00	view	Liu, Eddy	Nuance	CMO	Phase 1 Final Clinical Study Report.pdf	33minutes, 93 of 1064, range: 1-49, 58-101	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9118354
Sunday, February 7, 2021 4:17:53 AM -05:00	view	Liu, Eddy	Nuance	CMO	ATB-346-P1B Clinical Study Report 24Mar2020.pdf	11 minutes, 19 of 535, range: 1-14, 37-41	120.245.96.156(CN, Beijing, China Mobile Guangdong)	9116079

This is Exhibit "M" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**



1 09:59 Q. I see. And so you're able to identify for us where the  
2 risk was identified by your due diligence team?

3 A. So side effects will always be a key part of any  
4 assessment, and --

5 Q. It should be.

6 A. -- as I mentioned, we had already screened and concluded  
7 another NSAID compound within our portfolio. So one is  
8 we were relatively familiar. I did mention yesterday  
9 that the side effects across different NSAIDs are  
10 varied, ranging from liver to renal to GI to  
11 cardiovascular. So it would absolutely not be true that  
12 side effects were not reviewed. That would be negligent  
13 on our behalf.

14 Q. Right. It would be negligent.

15 Are you able to help us, Mr Lotter, as to where the  
16 documentation is that identified the elevated liver  
17 enzymes?

18 A. I can't specifically go back to which document. I mean,  
19 remembering we were looking at four or five different  
20 transactions at the same time, and that I think has been  
21 communicated with -- there are a number of assets that  
22 were being reviewed. I cannot pinpoint exactly where  
23 every component of a due diligence feedback has been  
24 logged.

25 Q. I understand. Mr Lotter, I'm only interested in one of



1 11:07 of various potential acquisitions, you also oversaw  
2 the due diligence team?

3 A. Correct.

4 Q. You were responsible for ensuring that the level of  
5 due diligence met CBC Group's standards?

6 A. Correct.

7 Q. And that they obviously met Nuance's standards as  
8 well?

9 A. Yes.

10 Q. Do you agree with me that the CBC Group, and Nuance,  
11 did not intend to spend the time or money required  
12 to conduct a full due diligence on any of the  
13 various projects it was undertaking at the time?

14 A. I disagree.

15 Q. How many projects like Antibe's did you have on the  
16 go at that point in time?

17 A. I think we were dedicating most of our time on the  
18 Antibe case at that time, because we had a very  
19 short exclusivity period.

20 Q. That wasn't the question. How many other entities  
21 like Antibe were you doing at the time?  
22 I understood from Mr Lotter that there were --  
23 I forget the precise number -- four or five at the  
24 time that were on the go. Is that right or wrong or  
25 do you agree or disagree?

1 11:08 A. I think we have about three or four in general.

2 Q. On the go doing due diligence at the same time?

3 A. No, no. That's the only project that we have on due  
4 diligence. The others, they are just ongoing  
5 discussion, not on the full due diligence.

6 Q. Ongoing discussions, meaning that you had not yet  
7 signed a deal, or what does ongoing discussions  
8 mean?

9 A. This is a normal BD process. You talk to the  
10 company, you exchange information, you need time to  
11 build business case, and then you negotiate to a  
12 stage where you agree to on the deal economics,  
13 where you sign a non-binding term sheet and then  
14 they give you access to the data room, where you can  
15 see confidential information. Then you will agree  
16 and then go into a contract negotiation. Right? So  
17 at that time Antibe is the only one that we are  
18 doing full due diligence at that time, the only  
19 case.

20 Q. We will see what the evidence reveals on that. But  
21 in addition to full due diligence with respect to  
22 Antibe, you were also engaged in reviewing material  
23 and analysing data and putting together a business  
24 case with respect to some other three or four  
25 entities?

This is Exhibit "N" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**



ShareVault Index									
<b>ShareVault:</b>	Antibe Therapeutics								
<b>Exported On:</b>	4/19/22 1:51 PM UTC								
<b>Exported By:</b>	Scott Curtis, Antibe Therapeutics Inc. <scott.curtis@antibethera.com>								
Tag Index	Tag					File Index	File		
1	Nuance Biotech Due Diligence								
1.1	Non_Clinical								
1.1.1	a_Completed Studies								
1.1.1.1					Pharmacokinetics				
						1.1.1.1.1	<a href="#">353317.tox - (Naproxen plasma protein binding - (Final Report).pdf</a>		
						1.1.1.1.2	<a href="#">100011978 (Protein binding).pdf</a>		
						1.1.1.1.3	<a href="#">Metabolism-Covance rat radiolabel Final Report_v1.0.pdf</a>		
						1.1.1.1.4	<a href="#">Metabolism-Hepatocyte profiling Final Report_v1.0.pdf</a>		
						1.1.1.1.5	<a href="#">Pharmacokinetics-dog oral dose Final Report_v1.0.pdf</a>		
						1.1.1.1.6	<a href="#">Pharmacokinetics-rat single dose oral and intravenous Final Report_v1.0.pdf</a>		
						1.1.1.1.7	<a href="#">Rat PK Interaction Study (360577_Final report).pdf</a>		
						1.1.1.1.8	<a href="#">Report_100048688_FR095-0011315_copy.pdf</a>		
						1.1.1.1.9	<a href="#">VRI55-13108-RP Final Summary Data Report.pdf</a>		
1.1.1.2					Pharmacology				
						1.1.1.2.1	<a href="#">Report_100048688_FR095-0011315.pdf</a>		
						1.1.1.2.2	<a href="#">Safety Pharmacology-Broad Panel Cerep Screen_v1.0.pdf</a>		
						1.1.1.2.3	<a href="#">Safety Pharmacology-Cyp P450 inhibition-Induction Potential_v1.0.pdf</a>		
						1.1.1.2.4	<a href="#">Safety Pharmacology-Dog Cardiovascular_QTc_Final Report_v2.0.pdf</a>		
						1.1.1.2.5	<a href="#">Safety Pharmacology-hERG Final Report_v1.0.pdf</a>		
						1.1.1.2.6	<a href="#">Safety Pharmacology-Rat CNS_Final Report_v1.0.pdf</a>		
						1.1.1.2.7	<a href="#">Wallace 2010 BJP ATB-346.pdf</a>		
1.1.1.3					Phototoxicity				
						1.1.1.3.1	<a href="#">ATB-346 349570 Nucro Technics Analytical Report 9July2019.pdf</a>		
						1.1.1.3.2	<a href="#">Charles River 20214985 draft report.pdf</a>		
						1.1.1.3.3	<a href="#">In vitro phototoxicity test.DOC</a>		
						1.1.1.3.4	<a href="#">Nucro-Technics in vitro phototoxicity test results.msg</a>		
1.1.1.4					Toxicology				
						1.1.1.4.1	<a href="#">8003111_28_day_dog_tox.pdf</a>		
						1.1.1.4.2	<a href="#">Genotoxicology-Ames bacterial reverse mutation Final Report_v1.0.pdf</a>		
						1.1.1.4.3	<a href="#">Genotoxicology-Chromosomal Aberration Final Report_v1.0.pdf</a>		
						1.1.1.4.4	<a href="#">Genotoxicology-Mouse Micronucleus Final Report_v1.0.pdf</a>		
						1.1.1.4.5	<a href="#">Toxicology-7-day_dog_dose_ranging_Final_Report_v2.0.pdf</a>		
						1.1.1.4.6	<a href="#">Toxicology-7-day_rat_dose_ranging_Final_Report_v1.0.pdf</a>		
						1.1.1.4.7	<a href="#">Toxicology-14-day_dog_Final_Report_v1.0.pdf</a>		
						1.1.1.4.8	<a href="#">Toxicology-14-day_rat_Final_Report_v1.0.pdf</a>		
						1.1.1.4.9	<a href="#">Toxicology-28-day_dog_tox_draft_report.pdf</a>		
						1.1.1.4.10	<a href="#">Toxicology-28-day_rat_tox_Final_Report.pdf</a>		
1.1.2	b_Validation reports for bioanalytical methods								
						1.1.2.1	<a href="#">356561.Validation Final Report_(Naproxen in Rabbit Plasma).pdf</a>		
						1.1.2.2	<a href="#">363319 Validation Final_Report(ATB-346 in Dose Formulation).pdf</a>		
						1.1.2.3	<a href="#">365134.Validation Final Report (Naproxen in Rat Plasma).pdf</a>		
						1.1.2.4	<a href="#">365617.Validation Final Report (Naproxen in Dog Plasma).pdf</a>		
1.2	CMC:Product Quality								
1.2.1	a_Drug Substance								
1.2.1.1	a_S.1								
						1.2.1.1.1	<a href="#">a_S.1.1 Nomenclature_20200924_RED Finished.docx</a>		
						1.2.1.1.2	<a href="#">a_S.1.2 Structure_20200924_RED Finished.docx</a>		
						1.2.1.1.3	<a href="#">a_S.1.3 General Properties_20200924_RED Finished.docx</a>		
1.2.1.2	a_S.2								
						1.2.1.2.1	<a href="#">a_S.2.1 Manufacturers_20200924_RED Finished.docx</a>		
						1.2.1.2.2	<a href="#">a_S.2.2 Description of Manufacturing Process and Process Controls_20200924_RED_V4_Final.docx</a>		
						1.2.1.2.3	<a href="#">a_S.2.3 Control of Materials_20200924_finished.docx</a>		
						1.2.1.2.4	<a href="#">a_S.2.4 Control of Critical Steps and Intermediates_20200924_finished Dec102020.docx</a>		
						1.2.1.2.5	<a href="#">a_S.2.5 Process Validation and/or Evaluation_20200924_final.docx</a>		
						1.2.1.2.6	<a href="#">a_S.2.6 Manufacturing Process Development_20200924_Finished.docx</a>		
1.2.1.3	a_S.3								
						1.2.1.3.1	<a href="#">a_S.3.1 Elucidation of Structure_20200924_Finished_Dec15_2020.docx</a>		
						1.2.1.3.2	<a href="#">a_S.3.2 Impurities Non-granular_20200924_finished_Dec15_2020.docx</a>		
1.2.1.4	a_S.4								
						1.2.1.4.1	<a href="#">a_S.4.1 Specification_20200924_Finished_Dec16_2020.docx</a>		
						1.2.1.4.2	<a href="#">a_S.4.2 Analytical Procedures_20200924_Finished_Dec17_2020.docx</a>		
						1.2.1.4.3	<a href="#">a_S.4.3 Validation of Analytical Procedures_20200924_Finished_Dec18_2020.docx</a>		
						1.2.1.4.4	<a href="#">a_S.4.4 Batch Analyses_20200924_Finished_Dec19_2020.docx</a>		
						1.2.1.4.5	<a href="#">a_S.4.5 Justification of Specification_20200924_Finished_Dec16_2020.docx</a>		
						1.2.1.4.6	<a href="#">BSE TSE statement for ANW-001 batch 2.pdf</a>		
						1.2.1.4.7	<a href="#">BSE TSE statement for ANW-001 batch 3.pdf</a>		
						1.2.1.4.8	<a href="#">BSE TSE statement for ANW-001 batch 5.pdf</a>		
						1.2.1.4.9	<a href="#">BSE TSE statement for ANW-001 batch 7.pdf</a>		
						1.2.1.4.10	<a href="#">BSE TSE statement for ANW-001 batch RP1(1).pdf</a>		
						1.2.1.4.11	<a href="#">CoA of ANW-001 batch 2.pdf</a>		
						1.2.1.4.12	<a href="#">CoA of ANW-001 batch 3.pdf</a>		
						1.2.1.4.13	<a href="#">CoA of ANW-001 batch 5.pdf</a>		
						1.2.1.4.14	<a href="#">CoA of ANW-001 batch 7.pdf</a>		
						1.2.1.4.15	<a href="#">CoA of ANW-001 batch RP1.pdf</a>		
1.2.1.5	a_S.5								
						1.2.1.5.1	<a href="#">a_S.5 Reference Standards or Materials_20200924_finished_Dec15_2020.docx</a>		
1.2.1.6	a_S.6								

1.2.1.7			a_5.7		1.2.1.6.1	<a href="#">a_5.6 Container Closure System_20200924_Finished_Dec_15_2020.docx</a>
					1.2.1.7.1	<a href="#">a_5.7.1 Stability Summary and Conclusions Non-granular_20200924_Finished.docx</a>
					1.2.1.7.2	<a href="#">a_5.7.2 Post-approval Stability Protocol and Stability Commitment_20200924_Finished.docx</a>
					1.2.1.7.3	<a href="#">a_5.7.3 Stability Data Non-granular_20200924_Finished_Dec_20_2020.docx</a>
1.2.2			b_Drug Product			
1.2.2.1			b_P.1		1.2.2.1.1	<a href="#">b_P.1-FG_13Jan2021.docx</a>
1.2.2.2			b_P.2		1.2.2.2.1	<a href="#">b_P.2.Pharmaceutical Development_22JAN2021.docx</a>
1.2.2.3			b_P.3		1.2.2.3.1	<a href="#">b_P.3.1 Manufacturers_04Dec2020.docx</a>
					1.2.2.3.2	<a href="#">b_P.3.2 Batch Formula_14Jan2021.docx</a>
					1.2.2.3.3	<a href="#">b_P.3.3 Description of Manufacturing Process and Process Controls_FG_08Dec2020.docx</a>
					1.2.2.3.4	<a href="#">b_P.3.4 Controls of Critical Steps and Intermediates_FG_08Dec2020.docx</a>
1.2.2.4			b_P.4		1.2.2.4.1	<a href="#">b_P.4.1 Specifications_FG_14Jan2021.docx</a>
					1.2.2.4.2	<a href="#">b_P.4.2 Analytical Procedures_FG_14Jan2021.docx</a>
					1.2.2.4.3	<a href="#">b_P.4.3 Validation of Analytical Procedures_FG_14Jan2021.docx</a>
					1.2.2.4.4	<a href="#">b_P.4.4 Justification of Specifications_FG_04Dec2020.docx</a>
					1.2.2.4.5	<a href="#">b_P.4.5 Excipients of Human or Animal Origin_FG_04DEC2020.docx</a>
					1.2.2.4.6	<a href="#">b_P.4.6 Novel Excipients_FG_04DEC2020.docx</a>
1.2.2.5			b_P.5		1.2.2.5.1	<a href="#">b_P.5.1 Specifications_FG_22Jan2021.docx</a>
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					1.2.2.5.3	<a href="#">b_P.5.3 Validation of Analytical Procedures_FG_16JAN2021.docx</a>
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					1.2.2.5.6	<a href="#">b_P.5.6 Justification of Specifications_04Jan2021_FG.docx</a>
1.2.2.6			b_P.6		1.2.2.6.1	<a href="#">b_P.6 Reference Standards or Materials_07DEC2020.docx</a>
1.2.2.7			b_P.7		1.2.2.7.1	<a href="#">b_P.7_Container Closure System_07DEC2020.docx</a>
1.2.2.8			b_P.8 (stability data to follow)			
1.3	Regulatory					
1.3.1		a_Health Canada				
1.3.1.1			Health Canada Communications			
1.3.1.1.1			Phase 1			
					1.3.1.1.1.1	<a href="#">ATB-P4-484-CMC clarification request (June 05, 2014).pdf</a>
					1.3.1.1.1.2	<a href="#">Clarifax CMC response.docx</a>
					1.3.1.1.1.3	<a href="#">Clarification request_Clinic (June 06, 2014).docx</a>
					1.3.1.1.1.4	<a href="#">Clarification response_Clinic.docx</a>
1.3.1.1.2			Phase 2A Pilot OA trial			
					1.3.1.1.2.1	<a href="#">20160224 CMC-clarifax clarification Second Response Feb 24.pdf</a>
					1.3.1.1.2.2	<a href="#">Clinical Claifax Mar 03 Response Mar 03 ICF Clean copy.pdf</a>
					1.3.1.1.2.3	<a href="#">Clinical Clarifax Feb 29 Response Mar 03.pdf</a>
					1.3.1.1.2.4	<a href="#">Clinical Clarifax Mar 03.pdf</a>
					1.3.1.1.2.5	<a href="#">Clinical Clarifax Mar 03 Response Mar 03 ICF showing changes.pdf</a>
					1.3.1.1.2.6	<a href="#">Clinical Clarifax Mar 03 Response Mar 03 Protocol clean copy.pdf</a>
					1.3.1.1.2.7	<a href="#">Clinical Clarifax Mar 03 Response Mar 03 Protocol showing changes.pdf</a>
					1.3.1.1.2.8	<a href="#">CMC Clarifax Feb 17-First Response Feb 22.pdf</a>
1.3.1.1.3			Phase 2B DRF			
					1.3.1.1.3.1	<a href="#">ATB-346 Request for Information 223366 Jan 10 2019.doc</a>
					1.3.1.1.3.2	<a href="#">HC Response_Jan142019.docx</a>
					1.3.1.1.3.3	<a href="#">Laboratory Data.docx</a>
1.3.2			b_FDA			
					1.3.2.1	<a href="#">Meeting Minutes (2).pdf</a>
1.3.2.1			a_PreIND Briefing Package			
					1.3.2.1.1	<a href="#">type-b-meeting-background-materials.pdf</a>
1.3.3			c_EMA			
1.4	Corporate Quality				1.4.1	<a href="#">Standard Operating Procedures - c20Jan2020 - DL v6a DL_sig.pdf</a>
1.5	Clinical					
1.5.1			a_Phase 1			
1.5.1.1			CSR			
					1.5.1.1.1	<a href="#">ATB-346-P1 Clinical Study Report 6Aug2015.pdf</a>
1.5.1.2			Final Protocol_Report			
					1.5.1.2.1	<a href="#">Phase 1_Final Clinical Study Report.pdf</a>
					1.5.1.2.2	<a href="#">Phase 1 Study Protocol.pdf</a>
1.5.1.3			NOL			
					1.5.1.3.1	<a href="#">ATB-346-P1 NOL 18Jun2014.pdf</a>
					1.5.1.3.2	<a href="#">ATB-346-P1 NOL Amendment 3 20Oct2014.pdf</a>
1.5.1.4			Phase 1 Safety Meetings			
					1.5.1.4.1	<a href="#">140708 A1 Cohort Safety Meeting Minutes.doc</a>
					1.5.1.4.2	<a href="#">140708 Dose escalation approval-signed.pdf</a>
					1.5.1.4.3	<a href="#">140721 SAD 75mg Safety and Pk.pdf</a>
					1.5.1.4.4	<a href="#">140723 Dose escalation approval-signed.pdf</a>
					1.5.1.4.5	<a href="#">140805 Dose escalation approval-signed.pdf</a>
					1.5.1.4.6	<a href="#">140902 SAD 500mg Safety and Pk.pdf</a>
					1.5.1.4.7	<a href="#">140915 SAD 1000mg Safety and Pk.pdf</a>
					1.5.1.4.8	<a href="#">140929 SAD 1500mg Safety and Pk 2.pdf</a>
					1.5.1.4.9	<a href="#">140929 SAD 1500mg Safety and Pk.pdf</a>
					1.5.1.4.10	<a href="#">140930 Dose escalation approval-signed.pdf</a>
					1.5.1.4.11	<a href="#">141006 MAD 250mg Safety and Pk.pdf</a>
					1.5.1.4.12	<a href="#">141006 MAD 250mg Safety meeting minutes.doc</a>
					1.5.1.4.13	<a href="#">141015 Food Effect Safety and Pk minutes.doc</a>

						1.5.1.4.14	<a href="#">141015 Food Effect Safety and Pk.pdf</a>
						1.5.1.4.15	<a href="#">141015 Food Effect Safety and Pk unblinded.pdf</a>
						1.5.1.4.16	<a href="#">141111 MAD 750mg Safety and Pk (10 day).pdf</a>
						1.5.1.4.17	<a href="#">141118 MAD 750mg Safety and Pk.pdf</a>
						1.5.1.4.18	<a href="#">141118 MAD 750mg Safety and Pk YYY.pdf</a>
						1.5.1.4.19	<a href="#">141118 Pk data.pdf</a>
						1.5.1.4.20	<a href="#">141125 SAD 2000mg Safety.pdf</a>
						1.5.1.4.21	<a href="#">141216 MAD 1500mg Safety and Pk.pdf</a>
						1.5.1.4.22	<a href="#">141216 MAD 1500mg Safety and Pk YYY.pdf</a>
1.5.1.5			Protocol			1.5.1.5.1	<a href="#">ATB-346-P1 Protocol 0.5 30Apr2014.pdf</a>
1.5.2			b_Phase 2A				
1.5.2.1			Cover Letter			1.5.2.1.1	<a href="#">ATB-346-P2A Cover Letter 2Feb2016.pdf</a>
						1.5.2.1.2	<a href="#">ATB-346-P2A Cover Letter 7Apr2016.pdf</a>
						1.5.2.1.3	<a href="#">ATB-346-P2A Cover Letter 10Mar2016.pdf</a>
						1.5.2.1.4	<a href="#">ATB-346-P2A Cover Letter 29Jul2016.pdf</a>
1.5.2.2			CSR			1.5.2.2.1	<a href="#">ATB-34-P2A Clinical Study Report 26May2017.pdf</a>
1.5.2.3			CTA			1.5.2.3.1	<a href="#">ATB-346-P2A Application Form 2Feb2016.pdf</a>
						1.5.2.3.2	<a href="#">ATB-346-P2A Authorization Sharing NA 2Feb2016.pdf</a>
						1.5.2.3.3	<a href="#">ATB-346-P2A Canadian REB Refusals NA 2Feb2016.pdf</a>
						1.5.2.3.4	<a href="#">ATB-346-P2A Clinical Clarifax Response 3Mar2016.pdf</a>
						1.5.2.3.5	<a href="#">ATB-346-P2A CTA Cover Page 2Feb2016.pdf</a>
						1.5.2.3.6	<a href="#">ATB-346-P2A CTA ICF 1.0 6Jan2016.pdf</a>
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						1.5.2.3.8	<a href="#">ATB-346-P2A ICF 1.2 31Mar2016.pdf</a>
						1.5.2.3.9	<a href="#">ATB-346-P2A ICF 1.2 Redline 31Mar2016.pdf</a>
						1.5.2.3.10	<a href="#">ATB-346-P2A Info Prior-related Applications 2Feb2016.pdf</a>
						1.5.2.3.11	<a href="#">ATB-346-P2A International Info NA 2Feb2016.pdf</a>
						1.5.2.3.12	<a href="#">ATB-346-P2A Letter of Attestation 2Feb2016.pdf</a>
						1.5.2.3.13	<a href="#">ATB-346-P2A Meeting Information NA 2Feb2016.pdf</a>
						1.5.2.3.14	<a href="#">ATB-346-P2A Other Admin Info NA 2Feb2016.pdf</a>
						1.5.2.3.15	<a href="#">ATB-346-P2A pseat 2Feb2016.doc</a>
						1.5.2.3.16	<a href="#">ATB-346-P2A Re Receipt CTA-N 29Jul2016.pdf</a>
						1.5.2.3.17	<a href="#">ATB-346-P2A Table of Contents M1 2Feb2016.pdf</a>
						1.5.2.3.18	<a href="#">ATB-346-P2A Table of Contents 2Feb2016.pdf</a>
1.5.2.4			IB			1.5.2.4.1	<a href="#">ATB-346-P2A Investigators Brochure 4Nov2015.pdf</a>
1.5.2.5			Protocol			1.5.2.5.1	<a href="#">ATB-346-P2A Protocol 1.3 28Jul2016.pdf</a>
1.5.2.5.1			zArchive			1.5.2.5.1.1	<a href="#">ATB-346-P2A Protocol 1.0 12Jan2016.pdf</a>
						1.5.2.5.1.2	<a href="#">ATB-346-P2A Protocol 1.0 12Mar2016.pdf</a>
						1.5.2.5.1.3	<a href="#">ATB-346-P2A Protocol 1.2 31Mar2016.pdf</a>
						1.5.2.5.1.4	<a href="#">ATB-346-P2A Protocol 1.2 Redline 31Mar2016.pdf</a>
						1.5.2.5.1.5	<a href="#">ATB-346-P2A Protocol Redline 12Jan2016.pdf</a>
						1.5.2.5.1.6	<a href="#">ATB-346-P2A RE CTA-N Revised Protocol v1.3 29Jul2016.pdf</a>
1.5.2.6			QOS			1.5.2.6.1	<a href="#">ATB-346-P2A QOS 2Feb2016.doc</a>
						1.5.2.6.2	<a href="#">ATB-346-P2A QOS Intro and Background 2Feb2016.doc</a>
1.5.3			c_Phase2B Safety				
1.5.3.1			Cover Letter			1.5.3.1.1	<a href="#">ATB-346-P2B-GIS Cover Letter 2Aug2017.pdf</a>
						1.5.3.1.2	<a href="#">ATB-346-P2B-GIS Cover Letter 2May2018.pdf</a>
						1.5.3.1.3	<a href="#">ATB-346-P2B-GIS Cover Letter 7Dec2017.pdf</a>
						1.5.3.1.4	<a href="#">ATB-346-P2B-GIS Cover Letter 7Jul2017.pdf</a>
						1.5.3.1.5	<a href="#">ATB-346-P2B-GIS Cover Letter 18Dec2017.pdf</a>
						1.5.3.1.6	<a href="#">ATB-346-P2B-GIS Cover Letter 21Aug2017.pdf</a>
1.5.3.2			CSR			1.5.3.2.1	<a href="#">ATB-346-P2GIS Clinical Study Report 27Aug2018.pdf</a>
1.5.3.3			CTA			1.5.3.3.1	<a href="#">ATB-346-P2B-GIS Application Form 10Jul2017.pdf</a>
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1.6.1.2.2				Shift Health Reports					
					1.6.1.2.2.1				<a href="#">Opportunity Assessment for ATB-346 - Final Report.pptx</a>
					1.6.1.2.2.2				<a href="#">Opportunity Assessment for ATB-346 Final Sales Model June 25.xlsx</a>
					1.6.1.2.2.3				<a href="#">Opportunity Assessment for ATB-346 - Primary Research Findings.pptx</a>
					1.6.1.2.2.4				<a href="#">Opportunity Assessment for ATB-346 - Secondary Research Findings.pptx</a>
					1.6.1.2.2.5				<a href="#">US and Europe5 - SHIFT market assessment summary 10Jan2021 v6.pdf</a>
1.6.2				b_Health-Pharmaco Economics Assessment (US Focus)					
1.6.2.1				Avalon Health economics Report					
1.6.2.1.1				Budget Impact Model					
					1.6.2.1.1.1				<a href="#">Antibe Budget Impact Model (AHE 06-18-2019)-1.xlsx</a>
1.6.2.1.2				Cost Impact Model					
					1.6.2.1.2.1				<a href="#">Antibe Cost Impact Model (AHE 05-14-2019).xlsx</a>
1.6.2.1.3				Literature (Publications)					
					1.6.2.1.3.1				<a href="#">BHIVA Delphi Poster_FINAL_12April12.pdf</a>
					1.6.2.1.3.2				<a href="#">D.Mladi ISPOR-Latin Am. Poster.pdf</a>
					1.6.2.1.3.3				<a href="#">Hoffman_ACR_Poster_2016.pdf</a>
					1.6.2.1.3.4				<a href="#">Literature Review and Conceptual Model - revised (AHE 04-15-19).docx</a>
					1.6.2.1.3.5				<a href="#">Mladi ISPOR Poster 2015.pdf</a>
1.6.2.1.4				Summary					
					1.6.2.1.4.1				<a href="#">Antibe Economic Evaluation ATB-346 (09-03-19).pptx</a>
					1.6.2.1.4.2				<a href="#">Antibe Short Report (AHE 09-03-2019).docx</a>
1.6.3				c_Syndicated Reports - Therapy Areas					
					1.6.3.1				<a href="#">Chronic Pain - Landscape &amp; Forecast - Disease Landscape &amp; Forecast.pdf</a>
					1.6.3.2				<a href="#">Osteoarthritic Pain - Landscape &amp; Forecast - Disease Landscape &amp; Forecast.pdf</a>
1.7	IP			a_ATB-346 patent portfolio					
1.7.1				ATB-346 patents granted					
					1.7.1.1				<a href="#">Patent Status Report (2021-01-21).xlsx</a>
					1.7.1.2				<a href="#">WO2008009127A1.pdf</a>
					1.7.1.1.1				<a href="#">CA2658433C.pdf</a>
					1.7.1.1.2				<a href="#">CN101501018B_granted.pdf</a>
					1.7.1.1.3				<a href="#">EP2057139B1.pdf</a>
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					1.7.1.1.6				<a href="#">MX326091_granted.pdf</a>
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1.7.1.2				ATB-346 patents pending					
					1.7.1.2.1				<a href="#">BR-PI0714466-0 Amended claims - allowed.docx</a>
1.7.2				b_Ownership and Internal License					
					1.7.2.1				<a href="#">change of name.pdf</a>
					1.7.2.2				<a href="#">Intercompany License Agreement.pdf</a>
					1.7.2.3				<a href="#">Ownership documents memo.pdf</a>
1.7.2.1				Antibe Holdings License					
					1.7.2.1.1				<a href="#">091222 Holdings-ATE LIC.pdf</a>
					1.7.2.1.2				<a href="#">130521 Holdings-ATE LIC Amd.pdf</a>
1.7.2.2				Patent Assignments					
					1.7.2.2.1				<a href="#">Executed Assignment - February 25, 2009.pdf</a>
					1.7.2.2.2				<a href="#">Executed Assignment for 11779849.pdf</a>
					1.7.2.2.3				<a href="#">Executed Assignment for 60807639.pdf</a>
					1.7.2.2.4				<a href="#">Executed Assignment for 60887188.pdf</a>
1.7.3				c_Search and reference					
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					1.7.3.3				<a href="#">List of documents identified_updated June 18 2020(1).pdf</a>
					1.7.3.4				<a href="#">WO2008009127-IPRP1-20090120-4170.pdf</a>
1.8				Publications					
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					1.8.1.1				<a href="#">2 OA meta-analysis.pdf</a>
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1.9	Corporate						
1.9.1		a_Corporate Records					
1.9.1.1		a_1				1.9.1.1.1	<a href="#">Antibe Org Chart 11Jun2020.pdf</a>
1.9.1.2		a_2					
1.9.1.2.1			Articles			1.9.1.2.1.1	<a href="#">090505 ART OF INCORP.pdf</a>
						1.9.1.2.1.2	<a href="#">091216 AMEND (name change).pdf</a>
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1.9.1.2.2			By-Laws			1.9.1.2.2.1	<a href="#">090505 By-Law No 1-repealed.pdf</a>
						1.9.1.2.2.2	<a href="#">090505 By-Law No 2-repealed.pdf</a>
						1.9.1.2.2.3	<a href="#">130214 By-Law No 3.pdf</a>
						1.9.1.2.2.4	<a href="#">180625 By-Law No 4 25Jun2018.pdf</a>
						1.9.1.2.2.5	<a href="#">CGX By-laws.pdf</a>
1.9.1.3		a_3				1.9.1.3.1	<a href="#">Antibe Executive Officers.docx</a>
1.9.1.4		a_4				1.9.1.3.2	<a href="#">Citagenix Org Chart - Jan 2020.pdf</a>
						1.9.1.4.1	<a href="#">Summary of Locations.xlsx</a>
1.9.2		b_Financial Information					
1.9.2.1		b_1				1.9.2.1.1	<a href="#">2013 Audit Committee Report.pdf</a>
						1.9.2.1.2	<a href="#">2014 Audit Committee Report.pdf</a>
						1.9.2.1.3	<a href="#">2015 Audit Committee Report.pdf</a>
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						1.9.2.1.5	<a href="#">2017 - ATE - AC Audit Results Package FINAL.pdf</a>
						1.9.2.1.6	<a href="#">2018 - ATE - AC Audit Results Package FINAL.pdf</a>
						1.9.2.1.7	<a href="#">2019 - ATE - AC Audit Results Package.pdf</a>
1.9.2.2		b_2				1.9.2.2.1	<a href="#">170228 EY Letter of Representation-signed AW.pdf</a>
						1.9.2.2.2	<a href="#">170228 EY Letter of Representation-signed DL.pdf</a>
						1.9.2.2.3	<a href="#">170829 E&amp;Y rep letter 29Aug2017-signed DL AW.pdf</a>
						1.9.2.2.4	<a href="#">180226 18 ATE - Q3 - Rep Letter-FINAL-fully executed.pdf</a>
						1.9.2.2.5	<a href="#">180626 18 - ATE - YE Letter of representations-initialled and signed.pdf</a>
						1.9.2.2.6	<a href="#">180828 19 ATE - Q1 - Letter of Representation (616CA)-letterhead-signed.pdf</a>
						1.9.2.2.7	<a href="#">181120 19 - ATE - Q2 - Letter of representation ATE letterhead-signed.pdf</a>
						1.9.2.2.8	<a href="#">190215 - 19 - ATE - Q3 - Representation letter-signed.pdf</a>
						1.9.2.2.9	<a href="#">190716 - 19 - ATE - Letter of Representation-signed.pdf</a>
						1.9.2.2.10	<a href="#">190827 - 20 ATE Q1 Letter of Representation-executed.pdf</a>
						1.9.2.2.11	<a href="#">191127 EY Letter of Representations - Q2 20 - 616CA - signed.pdf</a>
						1.9.2.2.12	<a href="#">200224 - 20 ATE - Q3 - Letter of Representations - 616CA - signed.pdf</a>
1.9.3		c_Officers and Directors				1.9.3.1	<a href="#">Directors &amp; Officers.xlsx</a>
1.9.4		d_Litigation and Audits					
1.9.4.1		d_1				1.9.4.1.1	<a href="#">140718 BJ Legal Confirm - signed by BJ.PDF</a>
						1.9.4.1.2	<a href="#">140724 BJ Confirm Updated Audit Response.pdf</a>
						1.9.4.1.3	<a href="#">140724 NRF Confirm - updated.pdf</a>
						1.9.4.1.4	<a href="#">170726 Norton Rose Fulbright re Response to Inquiry Letter.pdf</a>
						1.9.4.1.5	<a href="#">170727 Bennett Jones Re - Auditors Report.pdf</a>
						1.9.4.1.6	<a href="#">170817 Jolicoeur Lacasse-Response to Inquiry Letter.pdf</a>
						1.9.4.1.7	<a href="#">180620 WeirFoulds LLP Response to Audit Inquiry.pdf</a>
						1.9.4.1.8	<a href="#">180622 Bennett Jones Audit Inquiry Reply.pdf</a>
						1.9.4.1.9	<a href="#">180622 Bereskin &amp; Parr Response to Audit Inquiry.pdf</a>
						1.9.4.1.10	<a href="#">190620 Baker McKenzie Audit Letter Response (June 20, 2019).pdf</a>
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						1.9.4.1.12	<a href="#">190620 WeirFoulds Audit Letter Response (June 20, 2019).pdf</a>
						1.9.4.1.13	<a href="#">190626 Bereskin &amp; Parr Audit Letter Response (June 20, 2019).pdf</a>
						1.9.4.1.14	<a href="#">190711 WeirFoulds - Updated Audit Letter Response (July 11, 2019).pdf</a>
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						1.9.4.1.16	<a href="#">190715 Baker McKenzie - Updated Audit Letter Response (July 15, 2019).pdf</a>

1.9.4.2			d_2				
						1.9.4.2.1	<a href="#">12.4 Antibe Therapeutics Inc Mail - FW - URGENT request - BMT litigation.pdf</a>
1.9.5			e_Insurance				
1.9.5.1			e_1				
						1.9.5.1.1	<a href="#">180630 to 190630 Falvey Marine Policy.pdf</a>
						1.9.5.1.2	<a href="#">180630 to 190630 Lloyds GL-Products Liability-Clinical Trials Policy .pdf</a>
						1.9.5.1.3	<a href="#">180630 to 190630 Northbridge Property Policy-Amended Named Insured.pdf</a>
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						1.9.5.1.5	<a href="#">180630 to 190630 Property Confirmation of Binding Instructions.pdf</a>
						1.9.5.1.6	<a href="#">180701 to 190630 Marine Transparency and Disclosure.pdf</a>
						1.9.5.1.7	<a href="#">190627 to 200630 - Policy - Marine - Falvey - M-20691.pdf</a>
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						1.9.5.2.1	<a href="#">180630 to 190630 Berkley D&amp;O Policy.pdf</a>
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						1.9.5.2.3	<a href="#">190628 Binder - D&amp;O Policy - Encon - DO-532630.pdf</a>
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ShareVault Aribte Therapeutics

	Nuance Biotech	Lotter, Mark	Liu, Edy	Zhang, Johnny	Lee, Annie	Lien, Jasmine	Li, Jjn	Ni, Cheneye	Meng, Haijin
Company	Nuance Biotech	Nuance Biotech	Nuance	Nuance Pharma	Nuance	Nuance Pharma	Nuance Pharma	Kaiten	Nuance Pharma
Job Title	-	CEO	CMO	Head	COO	Head of BD	RA VP	Lawyer	Chief Medical Officer
Logins	55	2	34	1	0	5	13	0	0
Last Login	Sun Feb 07 05:12:38 UTC 2021	Wed Jan 27 05:25:55 UTC 2021	Sun Feb 07 05:12:38 UTC 2021	Mon Jan 25 04:05:32 UTC 2021	-	Sun Feb 07 03:40:16 UTC 2021	Mon Feb 01 05:34:18 UTC 2021	-	-
Accessible Files	566	566	566	566	566	566	566	566	566
Accessible Pages	23315	23315	23315	23315	23315	23315	23315	23315	23315
Files Accessed	126	0	97	0	0	6	31	0	0
Pages Accessed	2372	0	2156	0	0	45	287	0	0
Viewing Time HH:MM	30:41	-	25:49	-	-	0:17	4:35	-	-
By Tag: Pages Accessed	2372 of 23315	0 of 23315	2156 of 23315	0 of 23315	0 of 23315	45 of 23315	287 of 23315	0 of 23315	0 of 23315
Nuance Biotech Due Diligence	2372 of 23315	0 of 23315	2156 of 23315	0 of 23315	0 of 23315	45 of 23315	287 of 23315	0 of 23315	0 of 23315
Untagged	0 of 0	0 of 0	0 of 0	0 of 0	0 of 0	0 of 0	0 of 0	0 of 0	0 of 0

This is Exhibit "O" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**



- 1 14:27 still in the mix for her; agreed?
- 2 A. Potentially, yes.
- 3 Q. Because she goes through this whole step-by-step thing.
- 4 She said this is a dud. She could have said that right
- 5 off the top. She doesn't say that.
- 6 A. Yes. Contingent on many things that were listed, the
- 7 results of why the phase -- the AME phase -- why the AME
- 8 study failed, interactions with Health Canada and
- 9 interactions with the FDA. So yes, but it was highly
- 10 contingent on some important events.
- 11 Q. Sure. And one of the things that you come away with
- 12 when you look at this is that the issue was the LTEs;
- 13 right?
- 14 A. That's correct, yes.
- 15 Q. It wasn't the AME study; rather, it was the LTEs?
- 16 A. Correct.
- 17 Q. And you've known about the LTE issue since virtually
- 18 day 1 --
- 19 A. Yes.
- 20 Q. -- of dealing with Antibe. And so --
- 21 A. Well, even beforehand, it's a class effect.
- 22 Q. I understand, but just on the Antibe side --
- 23 A. Correct, we were aware of it.
- 24 Q. Yes. And you would agree with me that your decision --
- 25 recommendation and ultimately the decision of the board



1 16:36 Q. Okay. But you would have understood that there was work  
2 to be done between the conclusion of phase 2 --

3 A. Absolutely, absolutely, least of which the regulator  
4 approving your protocol.

5 Q. Right. And the third, you would have seen in the second  
6 bullet that they were wanting to use the drug for  
7 various things, including acute and chronic pain  
8 indications?

9 A. Yeah, I mean, I see that clearly on this slide, but  
10 again I specifically recall the discussion with Rami and  
11 Ella at the time. We had a relatively lengthy  
12 discussion on chronic back pain, lower back pain,  
13 because that was one area we had been specifically  
14 looking into. We had no discussion on acute pain during  
15 that call. But, as I say, it would have been in  
16 conflict to the existing agreement.

17 Q. Conflict with ...?

18 A. NewMentum.

19 Q. We learned the drug was efficacious and it caused less  
20 GI effects than other NSAIDs?

21 A. Correct.

22 Q. And you would have learned that Antibe was planning on  
23 conducting a phase 3 efficacy study --

24 A. Correct.

25 Q. -- in the US to establish the dose, because the dose

1 16:38 hadn't yet been established; right?

2 A. No, I can't recall the definition around the phase 3.  
3 I mean, I assumed at the time -- I'm not a scientist,  
4 I'm a clinical development expert, so for me phase 3 is  
5 generally your roll-out to a phase 3 study, which is  
6 your large testing in human subjects.

7 So you can have phase 3 enabling studies -- I mean,  
8 at least my understanding at this stage was "phase 3  
9 ready" as in conducting a large -- your pivotal phase 3  
10 study which would be submitted for your NDA.

11 Q. What about the other steps between the end of phase 2 --

12 A. Well, there's a lot of work that needs to happen, but  
13 I'm saying in terms of definition of phase 3, my  
14 understanding, at this stage of the discussion, was it  
15 was being prepared to go into phase 3 studies, not  
16 phase 3 enabling studies.

17 But that could -- as I said, that was my  
18 understanding at the time of this call.

19 Q. Sure. But one of the phase 3 studies would have been to  
20 determine what the effective dose should be; fair  
21 enough?

22 A. Normally, by phase 3, you are quite clear on what dose  
23 you are going to go with. It's very uncommon, at  
24 phase 3, to still be determining dose. That's not  
25 common practice. By the time you've completed phase 2,

1 16:40 you are pretty clear on the dose you want to go with.

2 Q. Well, you see, if you ...

3 A. Again, as I recall, this was still relatively early  
4 stage, and I think at that stage I hadn't even had  
5 a chance to speak with the CEO. I think that was later  
6 in December.

7 I remember it clearly because I had just gone back  
8 to the UK and I was walking my dogs through a field,  
9 trying to get back to a call in time, in the midst of  
10 a storm, so it was a very clear recollection for me, the  
11 call.

12 Q. I see. But I'm just looking at -- what page is that?

13 So at slide 16, sir, you will see that under  
14 "Multi-arm, placebo-controlled trial in the  
15 United States", do you see that the second bullet says,  
16 "Two treatment arms to establish lowest effective dose"?

17 A. Yes.

18 Q. So I take it, if you've read that, you would have known  
19 that the effective dose had not yet been determined?

20 A. Correct. Right.

21 Q. So --

22 A. And adaptive design would suggest that as well.

23 Q. And it would be established in the phase 3 efficacy  
24 trial; right?

25 A. But again, that's not common. That's my point.

1 16:42 Q. Sorry, it's not?

2 A. It's not common to use a phase 3 study to determine your  
3 dosing.

4 Q. But this is what --

5 A. I understand -- again, this was before I had seen or had  
6 feedback on any data supplied from the phase 2 study.

7 So it would have been a lot clearer after phase 2 in  
8 terms of contextualising adaptive design.

9 Q. Did this raise any flags for you that --

10 A. No. As I said, you know, phase 2 was our starting point  
11 of discussion. So, if there were questions over the  
12 phase 2, that would have absolutely raised a flag. But  
13 net of having to do additional work to get to phase 3,  
14 that's -- you know, it is what it is.

15 Q. And it was going to be done in this case, and they tell  
16 you that in order to establish --

17 A. Yes.

18 Q. -- the effective dose, but that has not been determined  
19 yet?

20 A. Correct.

21 Q. And you were still content to give them a term sheet?

22 A. Because phase 2 is our starting point. As long as  
23 you've got decent phase 2 data, that's where we would  
24 look to partner.

25 Q. So there were, as we've talked about, a number of other

1 16:43 things that needed to happen before Antibe could start  
2 its phase 3 studies that you and I have discussed.

3 So if I could look slide 30 or page 30.

4 So it needed to file an IND with the FDA, the  
5 investigational new drug application; it needed to do  
6 that?

7 A. Yes. I saw your slide earlier. Yes.

8 Q. And the FDA had to approve the IND and to open a file;  
9 right?

10 A. Correct.

11 Q. And Antibe had to complete the phase 3 enabling toxicity  
12 studies; yes?

13 A. Yes.

14 Q. And you knew that Antibe's end-of-phase-2 meeting with  
15 the FDA and the equivalent European Medicines Agency had  
16 not yet happened?

17 A. Correct. That was the one I was most focused on.

18 Q. I'm sorry?

19 A. That was the point I would have been most focused on  
20 because you have completed the phase 2 study, and so the  
21 meeting post-phase 2 with regulators is critical in  
22 determining what happens with phase 3. So, in a sense,  
23 at least the way I would be looking at it, as CEO of the  
24 company, would be understanding: do you have approval to  
25 go to phase 3?

1 16:45 Q. Yes.

2 A. And you only can get that approval through the  
3 post-phase 2 discussion.

4 So that was something we consistently pushed to get  
5 information on: when are you meeting for the phase 2  
6 post-study meeting?

7 Q. Right. What we know is that those end-of-phase-2  
8 meetings did not occur before you transferred the  
9 \$20 million.

10 A. Correct.

11 Q. Okay. And so you did it anyway?

12 A. Correct.

13 Q. Even though you say that those are critical meetings  
14 from your perspective?

15 A. Correct.

16 Q. You knew the FDA meeting was important in order for  
17 Antibe to get feedback from the US regulator about its  
18 proposed phase 3 drug development programme?

19 A. Correct.

20 Q. That's part of these meetings you're talking about; yes?

21 A. Correct.

22 Q. You also knew, I take it, sir, because you had been in  
23 this business for a long time, that Antibe's drug  
24 development plans could change based on FDA feedback?

25 A. Correct.



1 16:46 Q. These things are never static in the drug development  
2 business, I take it?

3 A. Absolutely.

4 Q. High-risk/high-reward as well?

5 A. Correct.

6 Q. And you agree that there is an entire page in this  
7 corporate presentation that Antibe gave you devoted to  
8 adverse effects? We saw those.

9 A. Yes. I mean, I can't recall offhand, in the middle of  
10 December. So I mean, if it's on the deck, I would have  
11 gone through it, correct.

12 Q. Sure. Why don't we put that up, page 35. This is not  
13 a memory test, as I've said. I want to show you --  
14 I trust that where there is a heading that talks about  
15 "Adverse Events" --

16 A. Correct.

17 Q. -- that that's something that you would have turned your  
18 attention to?

19 A. I would have looked at it and then I would have  
20 deflected to my medical and regulatory team to offer  
21 advice on it. Like I would read a financial statement  
22 and then ask my CFO to give an interpretation thereof.

23 Q. I understand. You would have seen, on the second bullet  
24 under the various items there, it says -- forget the one  
25 during the treatment:

1 16:47 "At the post-treatment assessment, patients in the  
2 250mg, 200mg and 150mg treatment arms had LTE incidences  
3 of [ranging from 8 per cent to 12 per cent] ..."

4 A. Correct.

5 Q. I take it you'd agree with me that that's high?

6 A. In context, I wouldn't have been in a position to  
7 determine if that's high or low. I would not have done  
8 any benchmarking or assessments at this stage. And  
9 again, I would have deflected that to our team.

10 Q. Is that the CMO that you would have deferred that to?

11 A. The CMO would have been an intimate part of that.

12 Q. So you would not have recognised those numbers as being  
13 inordinately high?

14 A. No.

15 Q. Did anybody on your team tell you, when they reviewed  
16 this material, that these numbers were inordinately  
17 high?

18 A. No. What was raised to me at the time the data was  
19 looked at was, do we have any guidance in terms of the  
20 phase 3 study, or, in the case of AME, has there been  
21 any guidance provided from the regulator?

22 Again, maybe I can just make a brief commentary  
23 around the importance for a CEO looking at regulatory  
24 data --

25 Q. Why don't you just wait until I ask you a question.



- 1 12:48 about the clinically significant LTEs it had  
2 described to you in the December corporate  
3 presentation?
- 4 A. Correct.
- 5 Q. And you never asked Antibe a single question about  
6 the findings of LTEs in that recent clinical study?
- 7 A. Correct. We didn't have to ask because when they  
8 presented the phase 2 efficacy data, in that call  
9 they made it very clear it was because most higher  
10 LTEs had been in the post-treatment period and a lot  
11 of the patient taking other products and that if  
12 they clean up the data, actually the LTE incidence  
13 is similar to other NSAIDs. They specifically  
14 mentioned it in our call in December.
- 15 Q. There was no discussion among your group, the due  
16 diligence team, about the LTEs and the significance  
17 of them; agreed?
- 18 A. Agreed. We viewed this as a class effect.
- 19 Q. Right. And no one at Nuance compared the level of  
20 LTEs seen with respect to this drug and compared it  
21 to the LTEs in naproxen?
- 22 A. Incorrect. We did. Based on their phase 2B GI  
23 safety study, actually there are two arm, naproxen  
24 and the Antibe's asset. The incidence of LTE is  
25 similar, 5 to 7 per cent.

- 1 12:51 the study, how well is the design, and based on  
2 Antibe's own study, that's a more than 240 patients  
3 controlled randomised study and I would believe that  
4 that's very strong evidence showing that they have  
5 comparable 5 to 7 per cent LTE.
- 6 Q. Ms Lee, there is nothing in the report that  
7 indicates naproxen at the 5 to 7 per cent level.
- 8 A. No, you should refer back to the phase 2 GI safety  
9 study, they have data on that.
- 10 Q. We are happy to do that at the lunch break.
- 11 A. Yes.
- 12 Q. And so your evidence is what with respect to this?  
13 It's that in the GI study it would indicate that the  
14 naproxen level was at the 5 to 7 per cent range?
- 15 A. Correct. And please also provide the evidence of  
16 1 per cent how big is that study.
- 17 Q. I'm dealing with your evidence at the moment. You  
18 say it's 5 to 7?
- 19 A. Yes.
- 20 Q. Because I take it you agree that it is an important  
21 comparator between this drug and naproxen?
- 22 A. Yes.
- 23 Q. From the material I have seen, it appears as though  
24 there are only two documents that indicate the  
25 result of due diligence performed by Nuance and one



human trials) due to study participants experiencing significant liver enzyme elevations. Antibe issued a press release announcing the suspension of the study (the “2015 Press Release”).<sup>3</sup> The Press Release can still be found on Antibe’s website today.

25. In my view, as a result of the study pause in 2015, any Licensee should have been laser focussed on the issue of side effects, and particularly liver enzyme elevations. The 2015 press release alone would be sufficient to put any sophisticated pharma company on a high alert about this side effect.

### **C. *Opinions and Conclusions***

#### **1. Issue 1: Was Nuance’s due diligence adequate?**

26. After reviewing documents in the data room, the witness statements of Nuance, and the pleadings, it is my opinion that the due diligence conducted by Nuance in respect of the Drug was insufficient, based on the following facts:

(a) Antibe opened the data room to Nuance on January 25, 2021.<sup>4</sup> The licensing agreement between Antibe and Nuance was signed on February 9, 2021.<sup>5</sup> This means that Nuance had just over two weeks to review and analyze the information in the data room;

(b) Nuance did not request any meetings with key Antibe personnel during the 15-day due diligence period to ask questions and obtain further information;

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<sup>3</sup> Exhibit R-001: Press Release: Antibe Therapeutics Suspends its Phase I Clinical Trial Due to Safety Concerns

<sup>4</sup> Exhibit R-028: Email from Ella Korets-Smith to Edy Liu et al re: Antibe Due Diligence invitation

<sup>5</sup> Exhibit R-037: License Agreement, Execution Copy

- (c) On February 3, 2021, Nuance sent a list of questions to Antibe.<sup>6</sup> This was the only list of questions sent to Antibe prior to signing the license agreement. There was no request for all of Antibe's correspondence with Health Canada or with the Food and Drug Administration ("FDA"), which Nuance now says were critical to its analysis of the Drug;
- (d) A feature of most data room platforms is the ability to track who has been in the data room, how much time was spent in the data room, and what documents were viewed. During the period between January 25, 2021, and February 9, 2021, only three Nuance team members used the data room provided by Antibe, spending a total of only 31 hours reviewing the available information.<sup>7</sup> The review of documents was done primarily by Jin Li, the VP of Regulatory Affairs, who spent less than 5 hours in the data room and Edy Liu, the Chief Medical Officer, who spent less than 26 hours in the data room. The logs show that the clinical review was largely limited to reading the clinical trial summaries;
- (e) According to the witness statement of Annie Lee, the only publicly-available information Nuance reviewed was obtained from the databases Global Data and Cortellis. Copies of that information do not appear in any of the exhibit bundles I reviewed. It appears from Ms. Lee's witness statement that the information was limited to such matters as whether the

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<sup>6</sup> Exhibit R-034: Email from Annie Lee to Ella Korets-Smith and Mark Lotter RE: Antibe diligence questions and comments on List of Issues

<sup>7</sup> Exhibit R-046: ShareVault Nuance Data Room Activity List, Exhibit R-047: ShareVault Nuance Data Room Activity Summary



mechanism of action and indication were high risk, whether there were any patents in China, and the commercial potential. This kind of general information would not be sufficient to evaluate the benefits and risks of the Drug, and in particular, the side effects;

(f) Nuance did not review the Antibe website or look at any publicly available information other than what was contained in the Global Data and Cortellis databases as described by Ms. Lee;

(g) Nuance did not identify elevated liver enzymes as a risk; and

(h) There is insufficient contemporaneous documentation describing Nuance's due diligence process, findings and analysis.

27. In my view, Nuance failed to identify, obtain, review, and analyze relevant and material information. As noted above, it should have been clear to any relatively sophisticated Licensee that the Drug's side effects, and in particular, the elevated liver enzymes, were of primary concern. Especially in a very compressed due diligence period, such as the two-week period in this case, I would expect to see evidence of a well-organized due diligence plan that focussed on identifying sources of key information and obtaining as much information as possible about the side effects of the Drug, and particularly the elevated liver enzymes, and then having an expert analyse the information. There is no documentation in the exhibits regarding such a plan.

28. I would also expect to see detailed documentation from each reviewer regarding the information they reviewed, their analysis of the information, and the conclusions

This is Exhibit "P" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

- 1 09:35 questions. Before we do that, I know it is in your  
2 material. You are a medical doctor; correct?
- 3 A. Yes.
- 4 Q. And you fully understand and appreciate the  
5 terminology and the kinds of material that one would  
6 find in this type of report; is that fair?
- 7 A. Yes.
- 8 Q. I also need you to confirm with me the raised TEAE  
9 which we find in a number of places in this report  
10 means "treatment emergent adverse events"? Agreed?
- 11 A. Yes.
- 12 Q. And the majority of TEAEs in this report were ALT  
13 and AST liver transaminase elevations; agreed?
- 14 A. Yes.
- 15 Q. You will see where we have highlighted it in yellow,  
16 the very point we just made. And the next line  
17 says:  
18 "In total, 41 liver enzyme TEAEs were reported  
19 in 40 patients."  
20 Do you see that?
- 21 A. Yes.
- 22 Q. That is a significant number; agreed? That is  
23 41 liver enzyme TEAEs in 40 patients, that's a  
24 significant number?
- 25 A. Yes.

1 09:38 Q. And it goes on to say that 32 patients -- let's see  
2 if we can put this together for you -- 32 had liver  
3 LTEs that were greater than 3 times ULN, upper limit  
4 of normal. Do you see that?

5 A. Yes.

6 Q. One patient had an elevation of 3 times ULN and six  
7 patients were reported with abnormal LTEs greater  
8 than 1 and less than 3. Now, what I want to ask you  
9 about was, it says that these -- you have 39  
10 patients, of which 32 had LTEs greater than 3 times  
11 normal, and that's a significant number; correct?

12 A. Yes.

13 Q. And if you find the four female patients -- four  
14 female patients reported treatment-related ALT and  
15 AST elevations of greater than 20 times ULN. Again,  
16 you would agree with me that that's very serious?

17 A. Yes.

18 Q. In fact, it's the kind of thing that if you were a  
19 doctor, you might even prescribe these people going  
20 to a hospital?

21 A. Yes.

22 Q. And patients in all dosing arms had LTEs greater  
23 than 3 times ULN. So it says across the study  
24 treatment group, treatment related 3 times ULN,  
25 et cetera, were noted -- let me just -- when you

- 1 09:41 read that sentence, it says, in essence, "Patients  
2 in all dosing arms had LTEs greater than 3 times  
3 ULN." Agreed?
- 4 A. Yes.
- 5 Q. And the percentage of patients with LTEs greater  
6 than 3 times ULN ranged from 7.2 to 12.9 per cent.  
7 Correct?
- 8 A. Yes.
- 9 Q. And you agree with me, as a doctor, if you saw  
10 patients with LTEs greater than 3 times ULN, you  
11 would be concerned?
- 12 A. Yes.
- 13 Q. And you agree with me, as I said, as a doctor, if  
14 you had one with greater than 20 times ULN, you  
15 would be very concerned? Remember, there was one  
16 with more than 20 times.
- 17 A. 20 times?
- 18 Q. Sorry, more than 20 times ULN, four female patients.  
19 And you would be very concerned about that?
- 20 A. Yes.
- 21 Q. If you were conducting due diligence and you saw  
22 these LTEs, it would raise a red flag for you;  
23 agree?
- 24 A. Yes.
- 25 Q. And you would identify these LTE findings as a risk?

- 1 09:43 A. Yes, a risk at the high dose group.
- 2 Q. Yes. In fact, a serious risk for the high dosage
- 3 group?
- 4 A. Yes.
- 5 Q. And you would make -- if you were doing due
- 6 diligence -- special efforts to get as much
- 7 information as you could about the drug and the
- 8 cause of the LTEs; agree?
- 9 A. Yes. Although you view the whole documentation to
- 10 look at why it's a high dose group, there's a liver
- 11 injury.
- 12 Q. So you would want to inquire into the cause of the
- 13 LTEs and better understand the nature of the drug;
- 14 correct?
- 15 A. Yes.
- 16 Q. And you would expect any doctor, like yourself,
- 17 assessing patients to be able to recognise the
- 18 significance of LTEs greater than 3 times ULN;
- 19 agreed?
- 20 A. Yes, agree. Actually, when I reviewed this
- 21 documentation, I paid much more attention to this
- 22 data, so I reviewed carefully, you know, all the
- 23 assessments in the report. That means that the two
- 24 patients that have liver injury dysfunction, one of
- 25 the patients had liver dysfunction, another one

1 09:45 exactly the patient has combination used with other  
2 NSAIDs, so that's the potential means maybe that  
3 it's not 100 per cent related to the investigational  
4 drug. So I find for this.

5 Q. Sorry, Ms Chan, what happens in this exam, I get to  
6 ask some questions and I need you to answer the  
7 questions. So I was just asking you --

8 A. Okay, sorry. Just that I think you potentially ask  
9 me, you know, for how I will review for this data,  
10 I just it's clear.

11 Q. No, what I asked is: you would expect any doctor,  
12 like yourself, assessing patients to be able to  
13 recognise the significance of LTEs greater than 3  
14 times ULN? I take it the answer to that is yes?

15 A. Yes.

16 Q. And you would anticipate that the Chinese regulator,  
17 if it was reviewing a clinical study where a  
18 significant number of Caucasian patients had LTEs  
19 greater than 3 times ULN, to be very concerned;  
20 agreed?

21 A. Yes. For the high dose group, yes.

22 Q. It's actually not just the high dose group, it was  
23 for all three dosages. That's why I brought that to  
24 your attention, that across all three dosages it was  
25 demonstrated that the LTEs were greater than 3

- 1 09:46 times; correct?
- 2 A. Yes.
- 3 Q. And the reason the Chinese regulator would be  
4 concerned about these kinds of results is because  
5 it's a potential safety issue; agreed?
- 6 A. Yes.
- 7 Q. And that would be especially true in the Chinese  
8 population because all of these results were from  
9 the Caucasian population?
- 10 A. Yes.
- 11 Q. And you agree that the incidence of LTEs of this  
12 drug could indicate that the drug had a greater  
13 liver side effect than naproxen?
- 14 A. No. I think to me I will see more data to support  
15 on this.
- 16 Q. Fine. But that's what you would do in due  
17 diligence. One of the things you would do, when you  
18 know that this drug is made up of a molecule of  
19 naproxen, you would do a comparison?
- 20 A. Yes.
- 21 Q. That is, you would look at what is the LTE  
22 statistics for naproxen and how is this drug in  
23 comparison; agreed?
- 24 A. Yes.
- 25 Q. That's what you would do. Fair enough. And that's



This is Exhibit "Q" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

1 15:42 so, I mean, given that data could have still be included  
2 at the time, I think 19th to 22nd, that data could still  
3 have been included within the data room. That would  
4 have been an important piece of information for the  
5 company. And at least as CEO -- I mean, you know,  
6 I don't generally use the term "showstopper", it's not  
7 a familiar South African term, but that would have  
8 caused pause, at least for myself.

9 ARBITRATOR: Can I take you to paragraph 44 of your  
10 statement, please, and can we keep that timeline up.

11 A. Page 11?

12 ARBITRATOR: Yes, the bottom of page 11. I'm really focused  
13 on the top of page 12. So at the bottom of page 11 you  
14 speak to the point that:

15 "... we would have had to conduct a full  
16 investigation to ensure that Antibe would be able to  
17 address the regulatory authorities' concerns/obtain  
18 positive go-ahead from the regulatory authorities before  
19 proceeding with any licensing deal."

20 A. Correct.

21 ARBITRATOR: So in specific terms tell me what you meant  
22 here by "a positive go-ahead".

23 A. A positive go-ahead would be signing a binding term  
24 sheet.

25 ARBITRATOR: Sorry, here it's a positive go-ahead from the

1 15:43 regulator.

2 A. From the regulator. That would be confirming the AME  
3 study, given that that was the next inflection point for  
4 Antibe to go forward.

5 ARBITRATOR: Confirming in what sense? Approving the study  
6 going forward?

7 A. Approving the protocol. Agreeing to the protocol,  
8 because, I mean, we can only assess against the  
9 protocol, given that the study needs to be conducted.  
10 So for the clinical team, based on the data they have,  
11 they would then review the protocol carefully in  
12 assessing the risk based on the knowledge they have at  
13 that point in time. So those are common links within  
14 drug development is looking at your last phase of data  
15 and looking at what the regulator decides is  
16 a reasonable design to test the next phase. And that  
17 was my kind of reference to the point post getting the  
18 decision. So if the regulator continues to increase the  
19 hurdle, the likelihood for success would be diminished,  
20 so that could be one outcome.

21 Another outcome could be then narrow the focus of  
22 the drug materially which would have an impact on the  
23 commercial assessment of the asset. But in this case,  
24 we weren't even thinking about commercial, it was simply  
25 saying having certainty on the protocol would allow us

1 15:54 Q. -- and so what I'm saying to you is we are going to be  
2 able to demonstrate that wasn't the case. So this would  
3 be another example of them not having looked at a Health  
4 Canada document.

5 A. Okay. So again, I mean, I think when you do that  
6 assessment, I would suggest, in addition to that, look  
7 at the more recent communication between -- so looking  
8 at a document produced by Health Canada in 2020 versus  
9 a document produced in 2014 would at least from our  
10 point of view -- I'm not saying -- you might look at it  
11 differently -- but from our point of view, that would  
12 hold more weight.

13 We also think, since that data was presented, Health  
14 Canada had approved the going ahead of a phase 2 study.  
15 It had been completed. So fundamentally, at least --  
16 and again, this is from a risk perspective -- if Health  
17 Canada were okay for the study to go ahead, and as  
18 importantly Antibe were happy to invest to do the  
19 phase 2 study, and we didn't see any other data to  
20 suggest otherwise, I don't really understand the point.  
21 For me, that's a validation, not the internal validation  
22 but the regulator's validation, to allow you to go ahead  
23 with the phase 2 study. That means they must be  
24 comfortable with the data they've seen.

25 So it would be very strange if we as a company came

1 15:56 and said, "We don't agree with Health Canada; we think  
2 you shouldn't have done a phase 2 study."

3 Q. I'm not sure what you are answering, sir.

4 A. I think it's quite clear what I'm saying.

5 Q. It may be clear what you are saying. I'm not sure it  
6 answers the question. In any event, I think you've  
7 answered my question.

8 A. Sure.

9 Q. And you've already -- it's okay. I don't have any  
10 further questions.

11 ARBITRATOR: Ms Lin, anything else?

12 MS LIN: Nothing from me.

13 ARBITRATOR: Okay. Mr Lotter, thank you very much for your  
14 time. You're excused.

15 (The witness was released)

16 ARBITRATOR: I know we took a ten-minute break but would  
17 people like to take our normal-course 15-minute break?

18 MR PALIARE: Sure.

19 ARBITRATOR: Shall we do that? Okay. And then Ms Chan will  
20 be ready to go.

21 MS LIN: Yes.

22 ARBITRATOR: Thank you very much. So 15 minutes. We'll be  
23 back at 4.15.

24 (3.57 pm)

25 (A short break)

This is Exhibit "R" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**

# Payment Proposal: Key Indicative Terms

MARCH 2024

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PRIVATE & CONFIDENTIAL



## Statement of Intention to Pay

- Antibe respects the outcome of the recent arbitration decision awarded in favour of Nuance
- Antibe intends to pay its obligations to Nuance in full
- Antibe can provide some immediate value and further value as soon as possible on a staged basis
- The Company does not have the ability to make a cash payment at this time
- Successful completion of the Phase 2 trial is necessary to enable Antibe to repay Nuance and other obligations in full

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## Proposal Includes Immediate Value

- We are proposing the following consideration on reaching agreement to satisfy the obligation in full, with details on each item in the slides that follow:
  1. Issuance of 9.9% of the Company's common shares
    - Antibe believes the value of the shares will increase on announcing agreement of payment terms
    - We understand such shares would be freely tradeable if issued to a non-resident
  2. Payment of cash proceeds from the exercise of 6.5 million warrants
    - Antibe can reprice these warrants to encourage exercise by current holders
  3. The remaining amount owed to be structured as an 8% term note with prepayment obligations
    - The note comes with a 'stapled' warrant exercisable at the market price on agreement
    - Prepayment obligations from a portion of Antibe financings or upfront partnering money intended to be pursued after completion of the Phase 2 trial
    - The term would be 18 months to minimize any potential impediment to Antibe's ability to successfully raise financing following the completion of the Phase 2 trial

# 1. Common Shares in Antibe

- Common shares of Antibe
  - Issuance of 9.9% of the Company's common shares (5.8 million shares)
  - Listed on TSX and freely tradeable by a non-resident (no hold)
  - No reporting or filing obligations with the TSX by the holder
  - Initial value of approximately \$2.6M (valued at current share price of \$0.45<sup>1</sup>)
  - The share price is anticipated to increase upon an announced agreement between Antibe and Nuance
    - Prior to the arbitration award the stock was valued at \$1.00<sup>1</sup>
  - Proceeds would reduce the obligation

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1) Market price equivalent to the 5-day volume-weighted average price (VWAP)

## 2. Cash Proceeds from Warrant Exercise

- 100% of cash proceeds from exercise of 6.5 million outstanding warrants will be paid by Antibe to Nuance
  - Current exercise price is \$1.50
  - Antibe can temporarily reduce the exercise price of these warrants following agreement with Nuance
  - Proceeds would reduce the obligation until paid in full

### 3. Term Note

- The balance of the amount owed to Nuance would be structured as a term note
  - 8% interest rate
  - New 'stapled' warrants struck at the market price on an announced agreement between Nuance and Antibe
    - Any net proceeds from exercise of the warrants and the sale of the shares would reduce the obligation
  - 18-month term with prepayment concepts:
    - Prepayment obligations from a portion of Antibe financings or upfront partnering money intended to be pursued after completion of the Phase 2 trial (see next slide)
    - The term is to minimize any potential impediment to Antibe's ability to successfully raise financing following the completion of the Phase 2 trial

### 3. Term Note – Prepayments

- Prepayment obligations provide a mechanism to de-risk Nuance along the way. These would include:
  - Nuance receiving 10% of all net cash proceeds from financings completed by Antibe
  - Nuance receiving 20% of all upfront net cash proceeds from licensing transactions by Antibe
  - Payment in full to Nuance upon on a sale of Antibe
  - Antibe intends to expeditiously pursue financing and partnering initiatives upon completion of the Phase 2 trial
- Proceeds would reduce the obligation until paid in full

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## Next Steps

- Schedule a meeting to discuss:
  - Commercial terms
  - Further information sharing
  - Timing

This is Exhibit "S" referred to in the Second Affidavit of Scott Curtis affirmed by Scott Curtis of the City of Toronto, in the Province of Ontario, before me at the City of Toronto, in the Province of Ontario, on April 17, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely.



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*Commissioner for Taking Affidavits (or as may be)*

**DILLON GOHIL**



Bennett Jones

Bennett Jones LLP

3400 One First Canadian Place, PO Box 130

Toronto, Ontario, Canada M5X 1A4

Tel: 416.863.1200 Fax: 416.863.1716

**Jesse Mighton**

Partner

Direct Line: 416.777.6255

e-mail: mightonj@bennettjones.com

April 16, 2024

Via Email (ken.rosenberg@paliareroland.com; max.starnino@paliareroland.com;  
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

Unit 200

Toronto, Ontario

M5H 0A9

Dear Mr. Rosenberg and Mr. Meakin:

**Re: *Nuance Pharma Ltd. v. Antibe Therapeutics Inc.*, Court File No. CV-24-00717410-00CL**  
**Re: *Antibe Therapeutics Inc.***

As you are aware, we are the lawyers for Nuance Pharma Ltd. Reference is made to the First Report to the Court of Deloitte Restructuring Inc., as monitor, dated April 15, 2024 (the "**First Report**").

We write to request the following information and appreciate your prompt attention to reply:

*Employee Bonus Payments*

1. Paragraph 23 of the First Report discloses that Antibe proposes to pay "an additional US\$200,000 in respect an annual contractual bonus [sic]" during the cash flow forecast period. Please advise which employees or contractors are proposed to receive such bonuses, and in what amounts in each case.
2. Provide details regarding any other bonuses payable.



April 16, 2024

Page 2

3. Provide details regarding the \$40,000 of employee cash advances outstanding as of December 31, 2023, including recipients of the advances, terms for repayment, current balances owing and any additional forecasted advances.

*Black Swan Advisors*

4. Provide a summary of work completed since the start of Black Swan's engagement.
5. Provide details of any restructuring plans and/or cost reduction opportunities identified or developed by Black Swan and implemented by Antibe.

*Administration Charge*

6. Provide the basis for calculation of the requested charge amount, including a break-out by firm.
7. Provide the basis for using approximately 5 weeks of professional fees rather than another time period.

*Directors' Charge*

8. Provide the basis for calculation of the requested charge amount, including a break-out of any components or assumptions used.
9. Provide the basis for using 4 weeks' of vacation (versus 5 weeks for Administration Charge calculation)
10. Provide details regarding a carryforward vacation accrued and any policies regarding the use of accrued vacation.

*U.S. Food & Drug Administration*

11. Provide details concerning the information delivered verbally by FDA on March 28/24 in relation to the Phase 2 Trial clinical hold.
12. Provide details regarding any discussions that have been held between Antibe and FDA representatives since then, including any email support or other available documentation.
13. Provide an estimated timeline for commercialization of the Drug (assuming the FDA issue is resolved).
14. Provide the estimated funding required to achieve commercialization, along with Antibe's commentary on its ability to develop a funding plan that correlates to this timeline.
15. Provide a timeline of development milestones reached since initiation of drug development in 2004.

April 16, 2024  
Page 3

*Cost Reduction Measures*

16. Provide details regarding any cash preservation measures currently being implemented by the Monitor.
17. Provide details regarding any management salary deferrals.

*Current Operations*

18. Confirm the number of current employees and break-out by department.
19. Confirm if all employees are currently active or whether any have been placed on short-term leave or furlough.
20. Confirm number of operating locations and the corresponding details on each office location.
21. Confirm number of leases in effect and corresponding details in respect of each lease.
22. Provide a copy of payroll details from most recent pay period.
23. Provide a bridge outlining the increase in payroll costs between December 2023 and most recent payroll period.
24. Provide a summary of current day-to-day operations in light of FDA clinical hold.

*Cash Flow Forecast (reference to Appendix A to First Report)*

25. Provide employee and contractor cost details.
26. Provide details regarding the forecasted Business travel and Conference fees.
27. Details regarding the forecasted regulatory advisory services provided by Weinberg Group, including details regarding services being provided while the Drug is subject to FDA clinical hold.
28. Provide details regarding the expenses identified as 'Legal expense re Saudi arbitration'.
29. Provide details regarding the expenses identified as 'Accounting assistance – JH'.
30. Provide details regarding forecasted other regulatory fees, public company fees, dues and subscriptions.
31. Provide basis for higher rent payment forecasted in week ending April 19, 2024, compared to subsequent rent payments.

April 16, 2024  
Page 4

*Creditors*

32. Provide the basis upon which the Arbitral Award in favor of Nuance was excluded from Antibe's books and records, as well as the listing of creditors posted to the Monitor's website.

*Tax Matters*

33. Provide current account balances on all tax accounts (including excise taxes, income taxes, payroll taxes).
34. Provide confirmation of most recent filings and details regarding any outstanding returns.
35. Provide details of any tax/regulatory audits in progress, pending review and/or scheduled to be completed.

*Assets*

36. Provide a list of hard assets by office location.
37. Identify assets with realizable value and realization estimates of same.
38. Identify locations (physical and virtual) where data and research are stored.
39. Provide the date the most recent sales tax refund was received and confirmation of what balance, if any, remains outstanding.
40. Provide details regarding any other receivables or other assets and estimated realizable value.
41. Provide copies of any liquidation analysis prepared.

*Payables*

42. Provide details of most recent remittance of source deductions. Confirm if there are any amounts outstanding.
43. Provide details of current accrued vacation payable.
44. Provide details of any severance or terminations obligations that preceded the CCAA.
45. Provide details of any goods/supplies received in the 30 days prior to the CCAA.
46. Provide a complete list of all priority payables with supporting detail that rank in advance of unsecured creditors.

April 16, 2024  
Page 5

We look forward to hearing from you as soon as possible.

Yours truly,



Jesse Mighton  
JM

cc: Lincoln Caylor, Alexander Payne, Sidney Brejak (*Bennett Jones LLP*)  
Evan Cobb (*Norton Rose Fulbright LLP*)

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

Court File No. CV-24-00718083-00CL

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**ONTARIO**  
**SUPERIOR COURT OF JUSTICE**  
**(Commercial List)**

PROCEEDING COMMENCED AT TORONTO

**SECOND AFFIDAVIT OF SCOTT CURTIS**

**Paliare Roland Rosenberg Rothstein LLP**  
155 Wellington Street West 35th Floor  
Toronto ON M5V 3H1  
Tel: 416.646.4300

**Kenneth T. Rosenberg** (LSO#21102H)  
Tel: 416.646.4304  
Email: [ken.rosenberg@paliareroland.com](mailto:ken.rosenberg@paliareroland.com)

**Massimo Starnino** (LSO# 41048G)  
Tel: 416.646.7431  
Email: [Max.Starnino@paliareroland.com](mailto:Max.Starnino@paliareroland.com)

**Kartiga Thavaraj** (LSO# 75291D)  
Tel: 416.646.6317  
Email: [kartiga.thavaraj@paliareroland.com](mailto:kartiga.thavaraj@paliareroland.com)

**Evan Snyder** (LSO# 82007E)  
Tel: 416.646.6320  
Email: [evan.snyder@paliareroland.com](mailto:evan.snyder@paliareroland.com)

Lawyers for the Applicant

Court File No. CV-24-00718083-00CL

**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 A PLAN OF COMPROMISE OR ARRANGEMENT OF  
ANTIBE THERAPEUTICS INC. (the "**Applicant**")

**AFFIDAVIT OF DR. JOSEPH STAUFFER**

I, **JOSEPH STAUFFER**, of the City of Sarasota, in the State of Florida, in the United States of America, **AFFIRM AND SAY**:

1. I am the Chief Medical Officer ("**CMO**") of the Applicant, Antibe Therapeutics Inc. ("**Antibe**"). I have served in this capacity since May 2020. As such, I have personal knowledge of the matters to which I depose in this affidavit. Where I do not possess personal knowledge, I have stated the source of my knowledge and believe it to be true.
2. I am an Anesthesiologist, by training, and have worked in the clinical drug development space, including both public and private drug therapy companies, for over 23 years.
3. Prior to moving to Antibe in 2020, I served in various positions at private companies, including as Global Medical Director at Abbott Laboratories, leading clinical operations, regulatory and medical affairs teams at Alpharma, Inc. and Ikaria, Inc., and

was CMO at Cara Therapeutics (“**Cara**”), a developer of novel chemical entities to treat post-operative pain and chronic itch in Chronic Kidney Disease.

4. Prior to moving to the private world, from 2000 to 2002, I worked for the United States’ Food and Drug Administration (“**FDA**”) as a Medical Review Officer in the Analgesic/Anti-Inflammatory Division for anti-inflammatory and analgesic drugs. I also practiced anesthesiology part-time at Johns Hopkins as a clinical instructor from 2000-2002, while still working full-time at FDA.

5. Prior to that, just following my internship training, I practiced frontline medicine including eight years as a US Navy general practice physician.

6. I earned my medical degree from the Philadelphia College of Osteopathic Medicine and completed my Anesthesiology Residency at Johns Hopkins University Hospital, where I maintained a part-time Assistant Professorship until 2016.

7. I am swearing this affidavit in response to the cross-application brought by Nuance Pharma Limited (“**Nuance**”) dated April 15, 2024 in Antibe’s Application for an Amended and Restated Initial Order pursuant to the *Companies’ Creditors Arrangement Act* (Canada) (the “**CCAA**”). I have reviewed the affidavit of Mark Lotter sworn April 15, 2023 (the “**Second Lotter Affidavit**”), and swear this affidavit in response to Mr. Lotter’s assertions in the Second Lotter Affidavit, including at paragraph 21, that Antibe’s views that it can be successful in having the clinical hold lifted by the FDA are “aspirational”. In the time allotted, I have not been able to adequately review and respond to all of the assertions made by Mr. Lotter, including with respect to the FDA’s process, and the prospects of the Drug, and my silence on these or any other topics outlined in the Second

Lotter Affidavit should not be construed as agreement with the assertions contained therein.

**A. *Role of the FDA and the relationship between the FDA and the sponsor company***

8. In my 23-year career, I have participated in, and been witness to, various trials where clinical and non-clinical holds were placed by the FDA on a drug program or on a particular trial.

9. The FDA's mandate is to protect public health by regulating food, drugs, cosmetics, tobacco, and medical devices that are available to be used by U.S. consumers. In my experience, the FDA considers itself the preeminent regulator, and while it sometimes comes to different conclusions and actions from regulators in other jurisdictions, other regulators hold the FDA in high regard.

10. While the drug development process is filled with both uncertainty and risk making it very difficult to predict regulatory approval at any stage of development, regulator feedback can be an important part of the assessment of the potential for success in a clinical drug development program.

11. The relationship between the FDA and a sponsor company (i.e., the drug developer) is important. If the sponsor company is willing and able, it can often work together with the FDA to manage and get through challenges in development, whether those are dose, duration, or other challenges. In my experience as an FDA Medical Review Officer, I would often work with companies facing similar challenges to Cara, as I describe below, and to Antibe, with its current phase 2 trial (the "**Phase 2 Trial**").



12. While it is certainly the case that in some situations there is no way forward for the sponsor company (for example, when there is a manufacturing issue and the drug load is too low or too high), in many cases, sponsor companies are able to provide explanations that allow for trials to continue. While in some cases, extra data would need to be generated, in my experience that is not always the case.

13. In many of these instances, drug trials have concluded positively, and the drugs have made their way towards Phase 3 and ultimately, approval by the FDA as a new drug. One such example follows.

***B. Clinical Hold Experience with the FDA***

**1. Cara and CR845**

14. An example of a compound being placed on clinical hold where I was involved on the side of the sponsor company was when I worked with Cara. The drug being developed by Cara was a novel intravenous compound, difelakefalin (or “**CR845**”) in development by Cara for acute post-operative pain, starting in the mid-2000’s. I refer to this case because I see similarities to that case and the circumstances of the Drug being developed by Antibe.

15. At the time of its development, CR845 was a novel opioid drug. It was generally devoid of the respiratory side-effects and euphoric side effects of standard opioids (like morphine and oxycodone). The opioid crisis was then, and still is now, raging, with many deaths in America attributed to the misuse and abuse of standard opioid drugs. CR845 was in development so as to bring a novel (non-abusable) potent analgesic to the marketplace.

16. I joined Cara in late 2014 as CMO. Prior to my start at Cara in 2014, the development program for CR845 had been placed on clinical hold by the anesthesia/pain division of the FDA for safety reasons. These reasons, in simple terms, related to serum sodium elevations when being tested at high doses in previous phase 1 and phase 2 bunionectomy trials.

17. In my role as CMO at Cara, I was able to assist in removing the clinical hold that had been placed on the CR845 program. This was done, in part, by working with the FDA to enable them to (a) better understand the chemistry of the drug and the pharmacokinetic (“**PK**”) and pharmacodynamic (“**PD**”) studies that had already taken place, and (b) generating further phase 1 dose-ranging data at a lower level. In agreement with FDA, and following our generation of more Phase 1 safety data, the clinical hold was lifted and a combined Phase 2 and Phase 2 (a “**phase 2/3**”) trial was allowed to proceed.

18. We safely and successfully administered CR845 in a phase 2/3 adaptive design trial in patients undergoing abdominal (hernia and hysterectomy) surgeries. The study was able to demonstrate statistically significant reductions in pain intensity compared to placebo at all pre-specified post-operative periods and statistically significant reductions in the incidence of post-operative nausea and vomiting over the 24-hour period post-surgery. There were no further significant safety issues identified with CR845 during this trial.

19. Afterwards, Cara made a strategic decision to put post-operative pain on the backburner and instead advanced the CR845 compound into further Phase 2 and Phase 3

trials (at similar doses used in post-operative pain) for itching associated with Chronic Kidney Disease patients on dialysis.

20. In 2020, Cara submitted a New Drug Application (“**NDA**”) to the FDA for approval for the indication of pruritis associated with Chronic Kidney Disease. In 2021, the drug obtained approval for this indication from the FDA.

21. Shortly thereafter, Cara began marketing and commercializing CR845 with their partner Vifor Pharma. I am aware that sometime after CR845 was approved, Cara exceeded USD\$1 billion market capitalization.

22. This is one example of a drug and company that ultimately won approval for a drug that had been stalled in development (clinical hold). The sponsor company (and the FDA) worked to get the drug back into the clinic and got it over the finish line. This example proves that a clinical hold, such as that placed by the FDA, is a hurdle, but it is not a brick wall.

23. While I cannot comment on the Antibe Phase 2 Trial without receiving the FDA’s hold letter, I do note that from my experience, the sodium elevations experienced by CR845 were a much more serious problem than the problem currently faced by Antibe in the proposed Phase 2 Trial. As mentioned previously, while in removing the FDA’s hold with respect to CR845, we agreed to do another Phase 1 trial at lower doses so as to establish safety. In Antibe’s case we actually have already generated new Phase 1 safety data in Canada with the new formulation and dosing pattern, as well as robust DILIsym profiling of our new proposed dosing, and it was 100% clean at the doses we are now

recommending for the Antibe Phase 2 trial. Antibe plans to highlight this data to the FDA during our discussions with them.

**AFFIRMED** remotely by Joseph Stauffer at the City of Sarasota, in the State of Florida, before me at the City of Toronto, in the Province of Ontario, on this 16<sup>th</sup> day of April, 2024 in accordance with O. Reg. 431/20, Administering Oath or Declaration Remotely



*Dillon Gohil*

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Dillon Gohil, a Commissioner, etc.  
Province of Ontario, while a Student at  
Law, Expires April 17, 2026

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Joseph Stauffer

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

Court File No. CV-24-00718083-00CL

<b>ONTARIO</b> <b>SUPERIOR COURT OF JUSTICE</b> (Commercial List)
PROCEEDING COMMENCED AT TORONTO
<b>AFFIDAVIT OF DR. JOSEPH STAUFFER</b>
<b>Paliare Roland Rosenberg Rothstein LLP</b> 155 Wellington Street West 35th Floor Toronto ON M5V 3H1 Tel: 416.646.4300  <b>Kenneth T. Rosenberg</b> (LSO#21102H) Tel: 416.646.4304 Email: <a href="mailto:ken.rosenberg@paliareroland.com">ken.rosenberg@paliareroland.com</a>  <b>Massimo Starnino</b> (LSO# 41048G) Tel: 416.646.7431 Email: <a href="mailto:Max.Starnino@paliareroland.com">Max.Starnino@paliareroland.com</a>  <b>Kartiga Thavaraj</b> (LSO# 75291D) Tel: 416.646.6317 Email: <a href="mailto:kartiga.thavaraj@paliareroland.com">kartiga.thavaraj@paliareroland.com</a>  <b>Evan Snyder</b> (LSO# 82007E) Tel: 416.646.6320 Email: <a href="mailto:evan.snyder@paliareroland.com">evan.snyder@paliareroland.com</a>
Lawyers for the Applicant

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

Court File No. CV-24-00718083-00CL

AND IN THE MATTER OF A PLAN OF COMPROMISE OR ARRANGEMENT OF ANTIBE  
THERAPEUTICS INC. (the "Applicant")

**ONTARIO  
SUPERIOR COURT OF JUSTICE  
(COMMERCIAL LIST)**

PROCEEDING COMMENCED AT TORONTO

**REPLY RECORD TO CROSS-APPLICATION OF NUANCE**

**Paliare Roland Rosenberg Rothstein LLP**

155 Wellington Street West 35th Floor  
Toronto ON M5V 3H1

Tel: 416.646.4300

**Kenneth T. Rosenberg** (LSO#21102H)

Tel: 416.646.4304

Email: [ken.rosenberg@paliareroland.com](mailto:ken.rosenberg@paliareroland.com)

**Massimo Starnino** (LSO# 41048G)

Tel: 416.646.7431

Email: [Max.Starnino@paliareroland.com](mailto:Max.Starnino@paliareroland.com)

**Kartiga Thavaraj** (LSO# 75291D)

Tel: 416.646.6317

Email: [kartiga.thavaraj@paliareroland.com](mailto:kartiga.thavaraj@paliareroland.com)

**Evan Snyder** (LSO# 82007E)

Tel: 416.646.6320

Email: [evan.snyder@paliareroland.com](mailto:evan.snyder@paliareroland.com)

Lawyers for the Applicant