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Antibe Therapeutics Inc.

(V.ATE - TSX)

V.ATE: Part 1 of Phase 2b Dose-Ranging, Efficacy Study of ATB-346 Complete…

Based on our probability adjusted DCF model that takes into account potential future revenues from ATB-346 along with Citagenix Inc., ATE.V is valued at CAD$1.80 per share. This model is highly dependent upon continued clinical success of ATB-346 along with the global growth strategy for Citagenix and will be adjusted accordingly based upon future clinical results and the company's execution.

Current Price (11/29/2018)	CAD$0.25
Valuation	**CAD$1.80**

OUTLOOK

Antibe Therapeutics Inc. (ATE.V) is developing safer nonsteroidal anti-inflammatory drugs (NSAIDs) based on the company's proprietary hydrogen sulfide releasing technology. The company has completed a Phase 2b gastrointestinal safety study of the lead compound, ATB-346, which showed a significantly reduced rate of ulceration compared to naproxen (2.5% vs. 42.1%). The company recently completed a dose-ranging study in healthy volunteers to better understand the unique metabolic profile of ATB-346. This study will be followed by a Phase 2b dose-ranging efficacy study in patients with osteoarthritis to determine an optimal dose to move forward into Phase 3 testing.

SUMMARY DATA

52-Week High	**$0.79**
52-Week Low	**$0.12**
One-Year Return (%)	**127**
Beta	**-0.28**
Average Daily Volume (sh)	**678,539**
Shares Outstanding (mil)	**212**
Market Capitalization ($mil)	**$53**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**23**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using #Lin Estimate	**N/A**
P/E using #Lin Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of CAD$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2018	2.3 A	1.8 A	2.2 A	2.2 A	8.5 A
2019	2.5 A	2.1 A	2.2 E	2.2 E	9.0 E
2020					10.0 E
2021					12.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2017	-$0.02 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.05 A
2018	-$0.01 A	-$0.01 A	-$0.01 E	-$0.01 E	-$0.04 E
2019					-$0.02 E
2020					-$0.02 E

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WHAT'S NEW

Business Update

Part 1 of Phase 2b Dose-Ranging, Efficacy Study Successfully Completed

On November 27, 2018, Antibe Therapeutics, Inc. (ATE.V) announced that it has successfully completed the first part of the Phase 2b dose-ranging, efficacy study of ATB-346. The first part of the study was a metabolism study in order to better understand the unique metabolic profile of ATB-346. It was conducted in 24 healthy volunteers who were randomized to receive 150 mg, 200 mg, or 250 mg of ATB-346 once daily. As part of the study, data was collected on: 1) cyclo-oxygenase (COX) inhibition to determine the proper doses to use in the dose-ranging, efficacy portion of the study; 2) multiple blood draws to analyze ATB-346 metabolites; and 3) safety and tolerability data of the drug.

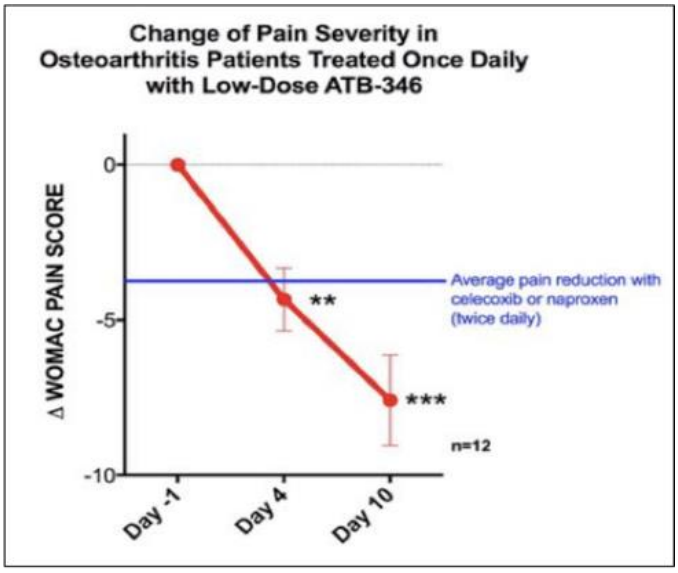
The results showed that COX inhibition of the 250 mg dose was consistent with previous studies and there was also marked inhibition seen with the two lower doses. The company is continuing to evaluate the metabolites of ATB-346 to better understand their properties.

We anticipate the second part of the Phase 2b dose-ranging, efficacy study to initiate in January 2019. It will be a randomized, double blind, placebo controlled efficacy trial in approximately 250 osteoarthritis (OA) patients. The primary endpoint is to evaluate the efficacy of three different doses of ATB-346. We anticipate topline results in the second quarter of 2019.

ATB-346

ATB-346 uses the non-steroidal anti-inflammatory drug (NSAID) naproxen as a base molecule with a hydrogen sulfide releasing moiety covalently attached. Hydrogen sulfide (H_2S) has been identified as an important gasotransmitter, a gas that serves as an important signaling molecule in the body. Other examples of gasotransmitters are nitric oxide (NO) and carbon monoxide (CO).

In 2016, Antibe announced the successful completion of a Phase 2 study of ATB-346 in patients with osteoarthritis of the knee. Twelve patients were treated once daily with 250 mg of ATB-346, which is only 1/6th of the typical daily dose of naproxen for treating osteoarthritis. The patients recorded their pain level one day prior to starting treatment and then again on days 4 and 10 of treatment using the WOMAC pain scale. The graph below shows the change in recorded pain level over the 10 days of the study. Previous studies show typical reductions in WOMAC pain scores for osteoarthritis patients taking celecoxib of approximately 4 units following one week of treatment, with no additional improvement beyond that with continued treatment (Wittenberg *et al*., 2006). Thus, the average reduction of 7.6 units is quite impressive in that study population.



Source: Antibe Therapeutics, Inc.

NSAID Side Effects

Antibe is developing ATB-346 as a solution to the dose-related gastrointestinal (GI) side effects associated with NSAIDs. These effects are a result of the inhibition of the COX-1 enzyme, which is responsible for the normal gastro-protective processes (Roth, 1988). In addition, many NSAIDs are acidic molecules, resulting in irritation to the gastric mucosa. Dyspepsia, abdominal pain, and nausea are all common side effects of oral NSAIDs (Makris *et al*., 2010). While these adverse events are manageable, more serious events are known to occur with oral NSAID use including upper GI bleeding, ulcers, and death (Hernández-Díaz *et al*., 2000). According to The Arthritis, Rheumatism, and Aging Medical Information System, more than 100,000 Americans are hospitalized each year and more than 16,000 die from ulcers and GI bleeding linked to NSAID use.

With the discovery of COX-2, research and development efforts were directed at discovering compounds that inhibited COX-2 selectively in order to overcome the GI side effects. While COX-1 is constitutively expressed throughout the body, COX-2 is typically only expressed in inflammation, with the inhibition of COX-2 resulting in the desired clinical response of NSAIDs.

Selective COX-2 inhibitors, such as rofecoxib (Vioxx®), celecoxib (Celebrex®), and valdecoxib (Bextra®), were initially very popular with both physicians and patients for their ability to relieve pain with a significantly decreased risk of adverse GI events. For example, Vioxx achieved over $1 billion in sales in its first year on the market. However, some clinical trials of the COX-2 inhibitors showed that treatment led to an increased risk of adverse cardiovascular (CV) events (Antman *et al*., 2007; Kearney *et al*., 2006). These results led Merck to voluntarily recall Vioxx® in 2004, with Bextra® withdrawn from the market in 2005. In addition, the FDA required a black box warning on the label for Celebrex®.

While on the one hand non-selective NSAIDs are great at offering pain relief, they are accompanied by the threat of serious GI problems, including the development of intestinal damage and bleeding ulcers. Selective NSAIDs are very effective at mitigating pain and they cause significantly fewer GI effects, but they come with an increased risk of CV events. Thus, what is needed is an effective NSAID that does not increase a patient's risk of serious GI or CV events.

Scientific Report on Phase 2b Trial of ATB-346

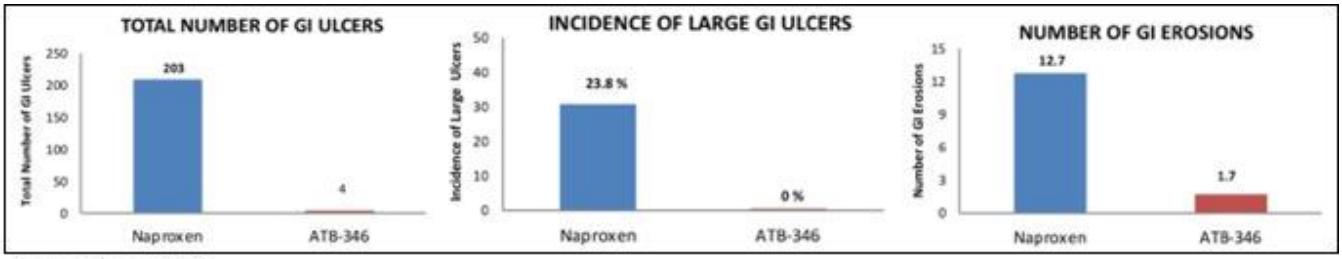
In August 2018, Antibe announced the availability of a comprehensive report summarizing the data from the Phase 2b GI safety trial of ATB-346. The company had previously announced positive topline results from the study showing that 42.1% of naproxen-dosed subjects had GI ulceration compared to only 2.5% of subjects administered ATB-346 following two weeks of dosing. In addition, the report (which can be accessed here) discusses key findings from secondary endpoints.

The Phase 2b study was designed to show superiority of ATB-346 in GI safety compared to naproxen through the quantitation of endoscopically observed gastric and duodenal ulcers that were ≥ 3 mm. The following figure shows what a gastric ulcer looks like.



Gastric Ulcer. *Source*: Wallace, 2018

The primary endpoint of the study was achieved, as 53/126 (42.1%) naproxen-treated subjects had at least one ulcer ≥ 3 mm compared to only 3/118 (2.5%) ATB-346-treated subjects (P<0.0001). In addition, the following figures show that the total number of ulcers, the percentage of subjects with large ulcers (≥ 5 mm), and the number of GI erosions were all much higher in the naproxen-treated subjects compared to those administered ATB-346.



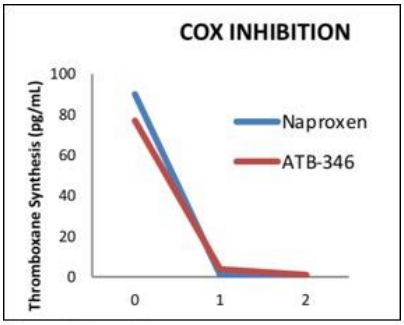
Source: Wallace, 2018

In addition to significantly decreasing the number of GI ulcers, subjects administered ATB-346 also showed fewer dyspepsia events, as shown in the following table.

	Naproxen	ATB-346
Abdominal pain/distension:	6.2%	1.6%
Gastro-esophageal reflux disease:	4.7%	0%
Nausea	3.1%	0%

Source: Wallace, 2018

While the incidence of GI ulcers is a very important outcome, it would not mean much if ATB-346 was not as effective as naproxen. While a full efficacy study will be conducted in the near future, data collected in this study showed that the level of COX activity (as measured by thromboxane, a substance produced mainly via the COX enzyme) was reduced similarly by both ATB-346 and naproxen (>94%).



Source: Wallace, 2018

The report discusses metabolic differences between ATB-346 and naproxen. For the Phase 2b trial, ATB-346 was dosed once daily at 250 mg while naproxen was dosed twice daily at 500 mg each. Following the two weeks of naproxen dosing, the mean plasma concentration of naproxen was 52.1 μg/mL while after two weeks of dosing ATB-346 the mean concentration of naproxen was 14.2 μg/mL. The difference is explained by the daily dose of ATB-346 being approximately 1/4th that of the naproxen dose. ATB-346 has a much longer half-life than naproxen while still maintaining similar COX inhibition data when compared to naproxen. Ultimately, this should allow for once-daily dosing of ATB-346, which is much more favorable from a commercial standpoint.

From a metabolic standpoint, ATB-346 metabolism results in several “naproxen-like” molecules that may have COX inhibitory activity. Subjects administered naproxen either did not have these metabolites or they were at much lower concentration than in ATB-346-treated subjects. Further analysis of these compounds is ongoing and we anticipate the company obtaining additional insight into this phenomenon following the ongoing metabolism study.

From a safety standpoint, there were very few non-GI differences between ATB-346 and naproxen. There was no effect of ATB-346 on blood pressure, a similar low incidence between the two groups in regards to headache and dizziness, and some mild transient elevations of liver transaminases (ALT/AST) that were not clinically important. Specifically, in regards to ALT/AST, non-clinically significant transient elevations were seen in up to 7% of subjects in both treatment groups. Data from all clinical trials conducted with 250 mg ATB-346 once daily show a 4.7% overall incidence of clinically significant, transient elevation in ATL/AST, which is quite similar to the 4% rate seen in those prescribed the NSAID diclofenac (NIH).

Licensing Deal in South Korea

Antibe recently announced an exclusive licensing agreement with Kwang Dong Pharmaceutical Co., Ltd. for ATB-346 in South Korea. The agreement calls for Antibe to receive up to CAD$13 million in development and commercialization milestones, which includes an upfront payment of CAD$1.3 million, and a double-digit royalty on net sales of ATB-346 in South Korea. Perhaps most importantly, the deal provides additional third-party validation of ATB-346's value and its underlying technology.

This is the third regional licensing deal signed for ATB-346. In 2015, Antibe signed a distribution agreement with Knight Therapeutics Inc. that granted exclusive commercial rights to Knight for Antibe's drug candidates in Canada, Israel, Romania, Russia, and sub-Saharan Africa. In 2017, a distribution agreement was signed with Laboratories Acbel SA, a subsidiary of one of Greece's largest pharmaceutical companies, which includes Albania, Algeria, Bulgaria, Greece, Jordan, Romania, and Serbia. The agreement with Acbel included an upfront payment of CAD$1.1 million and a 5% royalty on net sales.

Business Development Advisory Board

In an effort to increase the potential for a transformational deal involving ATB-346 and a multinational pharmaceutical company, Antibe has assembled a business development advisory board, which consists of accomplished pharmaceutical executives with experience in these types of transactions. Included in this board are:

- Mr. Angus Russell, who retired as CEO of Shire in 2013 following a five-year stint. He is currently serving as Chairman of Mallinckrodt and Revance Therapeutics along with serving on the Board at TherapeuticsMD.

- Mr. Dominique Monnet, who recently served as Senior Vice President and Chief Marketing Officer of Alexion and prior to that as a senior business executive at Amgen. Mr. Monnet is currently President of PDL BioPharma.

- Mr. Andrew Powell, who played a key role in a number of biopharmaceutical deals exceeding $6 billion each, including the sale of Medivation to Pfizer, the sale of InterMune to Roche, and the sale of ImClone to Eli Lilly. Mr. Powell currently serves on the Board of Directors at Aclaris Therapeutics and Landec.

- Mr. Rami Batal, who was most recently a senior business development officer for Purdue Canada and is currently the Vice President, Medical Research at Canopy Growth.

We view the formation of the business development board as an important step in the development cycle of ATB-346 and it is nice to see that Antibe will be able to call on a group of knowledgeable business executives as the partnering process gets underway. The fact that Antibe was able to attract a group of that caliber speaks highly of the company's technology and its potential.

Financial Update

On November 23, 2018, Antibe announced financial results for the second quarter of fiscal year 2019 ending September 30, 2018. The company reported CAD$2.1 million in revenue for the three months ending September 30, 2018 compared to CAD$1.8 million for the three months ending September 30, 2017.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation expenses totaled CAD$3.0 million in 2QFY19 compared to CAD$2.4 million in the 2QFY19. The increase was primarily related to the following:

- G&A expenses increased CAD$0.3 million to CAD$1.0 million primarily due to higher salaries, consulting fees, and other expenses.
- Selling and marketing costs were CAD$0.8 million in 2QFY19 compared to CAD$0.7 million in 2QFY18. The increase was primarily due to increased commissions, travel expenses, and advertising.
- R&D increased slightly to CAD$0.5 million in 2QFY19 primarily due to higher salaries and development costs for ATB-346.
- Stock-based compensation increased by $0.5 million in 2QFY19 to CAD$0.7 million.
- Amortization and depreciation decreased slightly to CAD$0.1 million in 2QFY19.

As of September 30, 2018, Antibe had cash and cash equivalents of approximately CAD$3.2 million. We believe this is sufficient to fund part two of the company's ongoing Phase 2b dose-ranging and efficacy study. We remind investors that Antibe still has approximately 29.3 million warrants, including approximately 28 million warrants that are "in-the-money" and could raise an additional CAD$4.5 million.

As of September 30, 2018, Antibe had approximately 212.7 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 259.7 million.

Valuation

We believe the prospects for ATB-346 and the rest of Antibe's pipeline are very good and we are looking forward to data from the dose-ranging efficacy portion of the company's ongoing Phase 2b study in the second quarter of 2019. We model for approval of ATB-346 in OA followed by approval for multiple indications similar to celecoxib. ATB-346 has blockbuster potential and we believe sales in excess of $1 billion are possible in both the U.S. and E.U. with the data from the Phase 2 study lending support to that thesis. In addition, the potential for sales in excess of $1 billion is supported by the fact that Celebrex® (celeoxib) had peak sales of $2.9 billion even with a 'black box' warning regarding an increased risk of cardiovascular events with long-term use. We are confident that Antibe will be able to enter into a partnership with a global pharmaceutical company (most likely following completion of the upcoming metabolism and efficacy trials) and we currently model for a 12% royalty with associated milestone payments.

Our current valuation for Antibe is CAD$1.80. Following an initial rise after release of the Phase 2b GI safety data the stock has pulled back and we believe there remains the potential for considerable upside, particularly with data from the dose-ranging efficacy study due in the second quarter of 2019.

PROJECTED FINANCIALS

Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2018 E	Q1 '19 A	Q2 '19 A	Q3 '19 E	Q4 '19 E	FY 2019 E	FY 2020 E	FY 2021 E
ATB-346 (royalty)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	*#DIV/0!*	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
ATB-352 (royalty)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Citagenix	**$8.5**	**$2.5**	**$2.1**	**$2.2**	**$2.2**	**$9.0**	**$10.0**	**$12.0**
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$8.5	$2.5	$2.1	$2.2	$2.2	$9.0	$10.0	$12.0
YOY Growth	*-6.0%*	*12.0%*	*15.2%*	*0.0%*	*-0.4%*	*6.3%*	*10.5%*	*20.0%*
Cost of Goods Sold	$5.1	$1.6	$1.2	$1.2	$1.3	$5.3	$5.7	$6.9
Product Gross Margin	*39.7%*	*38.7%*	*40.0%*	*46.3%*	*40.9%*	*41.4%*	*43.0%*	*42.5%*
SG&A	$6.2	$2.2	$1.8	$1.6	$1.6	$7.1	$6.7	$7.0
% SG&A	*73.2%*	*86.4%*	*86.0%*	*70.1%*	*72.7%*	*79.0%*	*67.0%*	*58.3%*
R&D	$2.7	$1.0	$0.5	$0.5	$0.5	$2.5	$2.3	$2.5
% R&D	*32.2%*	*40.6%*	*23.4%*	*23.3%*	*22.7%*	*28.0%*	*23.0%*	*20.8%*
Stock-based compensation	$0.7	$0.2	$0.7	$0.1	$0.3	$1.2	$1.0	$1.1
% Stock-based	*8.1%*	*6.0%*	*33.0%*	*4.2%*	*13.6%*	*13.6%*	*10.0%*	*9.2%*
Amortization and Depreciation	$0.4	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.5
% Other	*4.4%*	*3.8%*	*4.7%*	*4.4%*	*5.9%*	*4.7%*	*5.0%*	*4.2%*
Operating Income	($6.7)	($2.5)	($2.2)	($1.2)	($1.6)	($7.6)	($5.2)	($4.9)
Operating Margin	*-78.3%*	*-98.1%*	*-107.1%*	*-55.7%*	*-74.1%*	*-83.8%*	*-52.0%*	*-40.8%*
Interest Income / Net	($1.0)	($0.2)	($0.1)	($0.2)	($0.2)	($0.7)	($0.8)	($0.8)
Pre-Tax Income	($7.7)	($2.7)	($2.3)	($1.5)	($1.8)	($8.3)	($6.0)	($5.7)
Taxes	($0)	($0)	$0	($0)	($0)	($0)	($0)	($0)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($7.4)	($2.7)	($2.5)	($1.5)	($1.7)	($8.3)	($6.0)	($5.7)
Reported EPS	($0.05)	($0.01)	($0.01)	($0.01)	($0.01)	($0.04)	($0.02)	($0.02)
Fully Diluted Shares	151.6	204.8	211.7	220.0	225.0	215.4	250.0	280.0

Source: David Bautz, PhD - Zacks Investment Research, Inc.

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