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Antibe Therapeutics Inc.

(V.ATE - TSX)

V.ATE: Topline Data for Phase 2b Efficacy Trial of ATB-346 in 1Q20…

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$1.50 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 (12/04/2019)	CAD$0.41
Valuation	**CAD$1.50**

OUTLOOK

Antibe Therapeutics Inc. (ATE.V) is currently conducting a Phase 2b dose-ranging efficacy study of the company's lead development compound (ATB-346) in patients with osteoarthritis. The study is being performed to determine the optimal dose of ATB-346 to move forward into Phase 3 testing and is a follow up to the successful metabolism study that concluded in 2018. We anticipate topline data in the first quarter of 2020.

In August 2019, the company completed a public offering of approximately 26.8 million Units for gross proceeds of CAD$8.05 million. Each Unit consisted of one share of common stock and one-half of one common share purchase warrant. Antibe is now financed through the release of the topline data from the Phase 2b efficacy trial.

SUMMARY DATA

52-Week High	**$0.54**
52-Week Low	**$0.24**
One-Year Return (%)	**70.83**
Beta	**-1.18**
Average Daily Volume (sh)	**754,640**
Shares Outstanding (mil)	**281**
Market Capitalization ($mil)	**$110**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**19**
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)
2019	2.5 A	2.1 A	2.5 A	2.4 A	9.5 A
2020	2.8 A	2.3 A	2.5 E	2.4 E	9.9 E
2021					10.0 E
2022					11.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2019	-$0.01 A	-$0.01 A	-$0.01 A	-$0.02 A	-$0.06 A
2020	-$0.01 A	-$0.02 A	-$0.01 E	-$0.01 E	-$0.06 E
2021					-$0.04 E
2022					-$0.04 E

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WHAT'S NEW

Business Update

Phase 2b Study Results in 1Q20

In March 2019, Antibe Therapeutics Inc. (ATE.V) announced that the Phase 2b dose-ranging, efficacy study of ATB-346 had commenced. It is a randomized, double blind, placebo controlled trial in approximately 360 patients suffering from osteoarthritis (OA) of the knee. Study subjects will receive once daily doses of placebo or ATB-346 (150 mg, 200 mg, or 250 mg) over a 14-day treatment period. The company increased the number of subjects to 360 (from the original target of 200 patients) in order to power both the 200 mg and 250 mg cohorts for statistical significance. This will also provide a more thorough dataset on the efficacy of ATB-346, which should help facilitate partnering discussions. The study is currently over 70% enrolled and patient recruitment has accelerated recently due to increasing the number of clinical studies to 40. We anticipate topline results in the first quarter of 2020.

The company has undertaken a number of initiatives in preparation for advancing ATB-346 into Phase 3 clinical trials, including:

- Requesting a pre-IND meeting with the FDA, as getting an IND approved by the agency is necessary in order to commence Phase 3 testing in the U.S.
- Preparing for an 'end-of-Phase 2' meeting with the FDA, in order to present the clinical plan for a Phase 3 program and to receive feedback from the FDA
- Initiating several independent market research initiatives, including a health economics study on the impact of NSAID-related adverse events in the U.S., which estimates direct costs associated with NSAIDs totaling $74 billion
- Engaging a life science-focused consulting firm to conduct a comprehensive market opportunity assessment, including a payor study for both the U.S. and E.U.
- Signing an agreement with a global contract manufacturing organization (CMO) for the production of ATB-346 to secure sufficient quantities to meet regulatory timelines.

Each of the aforementioned initiatives is part of the company's overall strategy to get ATB-346 into a position to be licensed to a global pharmaceutical partner. We anticipate partnering discussions to intensify following release of the Phase 2b data.

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).

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®. Follow-up studies have shown celecoxib has similar CV risk as non-selective NSAIDs (Nissen *et al*., 2016), however an analysis of several Phase 4 studies has shown that it's a relatively low-dose of celecoxib administered to low-risk patients that may carry the same CV risk of conventional NSAIDs, but with less effective control of arthritic pain (Antman *et al*., 2017).

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 can be effective at mitigating pain and they cause significantly fewer GI effects, but they come with an increased risk of CV events at therapeutic doses. Thus, what is needed is an effective NSAID that does not increase a patient's risk of serious GI or CV events.

Phase 2b GI Safety Results

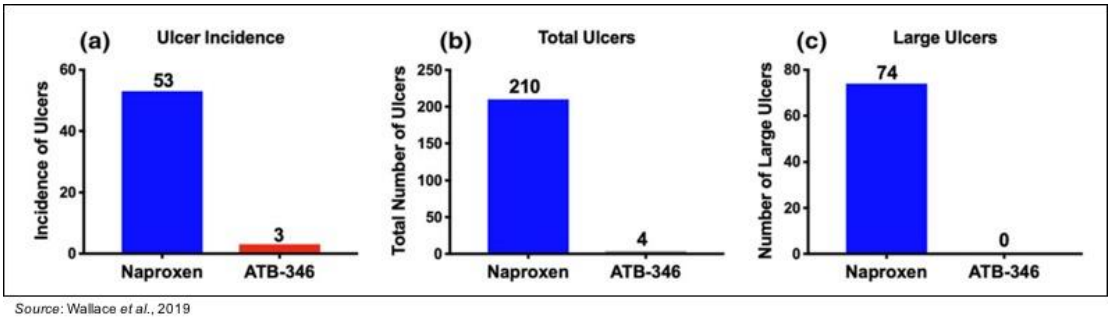
In April 2019, Antibe announced the publication of results from the Phase 2b GI safety study in the *British Journal of Pharmacology* (Wallace *et al*., 2019). The company had previously announced positive topline results from the study showing that 42.1% of naproxen-dosed subjects had GI ulceration compared to only 2.5% of subjects administered ATB-346 following two weeks of dosing in a total of 244 subjects.

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.



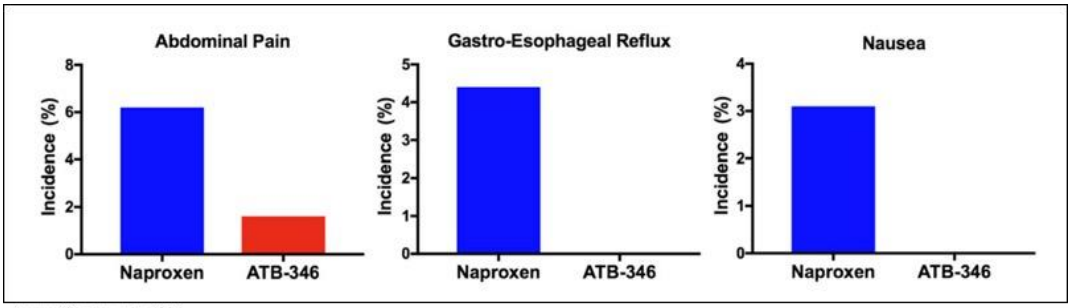
Gastric Ulcer. *Source*: Wallace, 2018

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 participants with ulcers, the total number of ulcers, and the number of large ulcers were all much higher in the naproxen-treated subjects compared to those administered ATB-346.



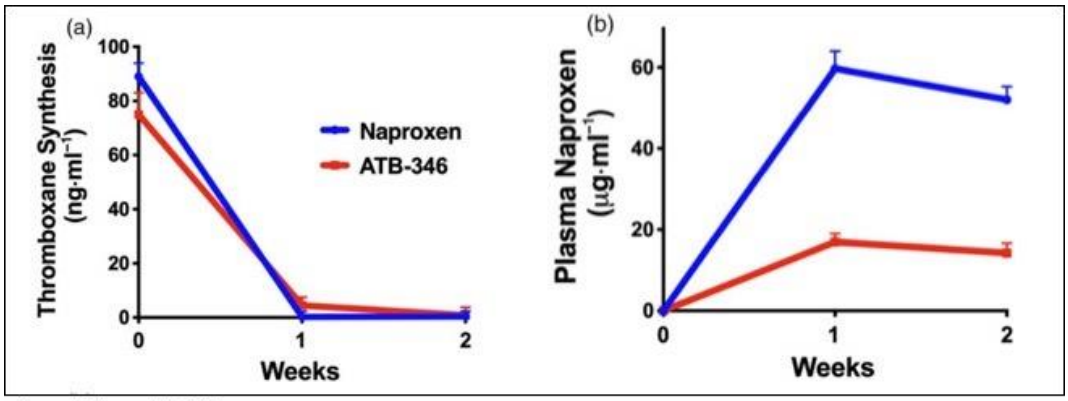
Source: Wallace *et al*., 2019

In addition to significantly decreasing the number of GI ulcers, subjects administered ATB-346 also showed lower rates of GI symptoms such as abdominal pain, gastro-esophageal reflux, and nausea.



Source: Wallace et al., 2019

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 is currently ongoing, 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%), as shown in the following figure on the left. Interestingly, the similar level of COX inhibition was achieved with a much lower level of naproxen in the plasma, as shown in the following figure on the right.



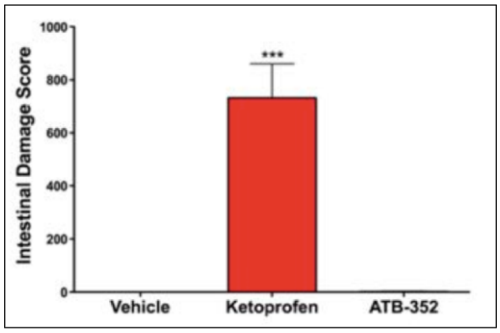
Source: Wallace et al., 2019

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 naproxen (NIH).

ATB-352 for Post-Operative Pain

In June 2019, Antibe announced that the lead indication for ATB-352, a hydrogen-sulfide releasing derivative of ketoprofen, would be post-operative pain. ATB-352 is a potent NSAID that is normally prescribed for acute pain. Opioids such as oxycontin are typically prescribed for pain following surgeries, however they have a very high propensity for abuse due to being highly addictive and the country is currently going through an opioid crisis, thus an effective, non-addictive therapy for post-operative pain is clearly needed.

Antibe has shown that ATB-352 is non-addictive and preclinical data indicates that it results in negligible GI damage compared to ketoprofen, as shown in the following graph. The company will be developing an aqueous formulation of the drug to be utilized for post-operative pain through intravenous administration in the hospital along with a tablet formulation that can then be utilized by patients once they have been discharged from the hospital.



Source: Antibe Therapeutics Inc.

Financial Update

On November 28, 2019, Antibe announced financial results for the second quarter of fiscal year 2020 ending Sep. 30, 2019. The company reported revenues of CAD$2.3 million compared to CAD$2.1 million for the three months ending Sep. 30, 2018.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation expenses totaled CAD$5.8 million for the second quarter of fiscal year 2020 compared to CAD$3.0 million for the second quarter of fiscal year 2019. The increase was primarily due to the following:

- G&A expenses increased from CAD$1.0 million to CAD$1.3 million primarily due to higher professional expenses partially offset by lower salaries and office costs.
- Selling and marketing expenses increased slightly to CAD$0.9 million primarily due to increased salaries, commissions, travel, and entertainment costs.
- R&D expenses increased CAD$1.9 million to CAD$2.4 million primarily due to higher development costs for ATB-346 partially offset by lower salaries and wages.
- Stock-based compensation increased CAD$0.4 million primarily due to expensing of previously granted restricted stock units.
- Amortization and depreciation increased slightly to CAD$0.15 million primarily due to amortization of leases and Citagenix brands and trademarks.

As of September 30, 2019, Antibe had approximately CAD$8.3 million in cash and cash equivalents and subsequent to the end of the quarter the company raised approximately $1.3 million from the exercising of warrants. We estimate that the company has sufficient capital to fund operations beyond the expected release of the ongoing Phase 2b efficacy study. In addition, the company has approximately 41 million warrants that could raise an additional approximately CAD$11.7 million.

We estimate that the company currently has approximately 281 million shares outstanding and when factoring in options, RSUs, and warrants a fully diluted share count of approximately 365 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 first quarter of 2020. 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® (celecoxib) 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 efficacy trial) and we currently model for a 12% royalty with associated milestone payments.

Our current valuation is CAD$1.50, and we believe there remains the potential for considerable upside, particularly with data from the dose-ranging efficacy study due in the first quarter of 2020.

PROJECTED FINANCIALS

Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2019 A	Q1 '20 A	Q2 '20 A	Q3 '20 E	Q4 '20 E	FY 2020 E	FY 2021 E	FY 2022 E
ATB-346 (royalty)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
ATB-352 (royalty)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Citagenix	**$9.5**	**$2.8**	**$2.3**	**$2.5**	**$2.4**	**$9.9**	**$10.0**	**$11.0**
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$9.5	$2.8	$2.3	$2.5	$2.4	$9.9	$10.0	$11.0
YOY Growth	*12.1%*	*8.6%*	*9.7%*	*0.0%*	*-1.2%*	*4.1%*	*4.8%*	*10.0%*
Cost of Goods Sold	$6.0	$1.7	$1.3	$1.6	$1.5	$6.2	$6.3	$6.9
Product Gross Margin	*37.2%*	*37.5%*	*41.4%*	*36.0%*	*37.5%*	*38.0%*	*37.0%*	*37.3%*
SG&A	$8.4	$2.1	$2.2	$2.0	$2.0	$8.3	$9.0	$9.3
% SG&A	*88.0%*	*76.3%*	*96.5%*	*80.0%*	*83.3%*	*83.5%*	*90.0%*	*84.5%*
R&D	$3.9	$0.9	$2.4	$1.2	$1.2	$5.7	$4.7	$4.9
% R&D	*41.3%*	*32.8%*	*104.6%*	*48.0%*	*50.0%*	*57.2%*	*47.0%*	*44.5%*
Stock-based compensation	$3.0	$1.1	$1.1	$1.0	$0.8	$3.9	$3.0	$3.0
% Stock-based	*31.3%*	*38.3%*	*47.4%*	*40.0%*	*33.3%*	*39.6%*	*30.0%*	*27.3%*
Amortization and Depreciation	$0.4	$0.1	$0.2	$0.1	$0.1	$0.5	$0.5	$0.5
% Other	*4.4%*	*5.2%*	*6.6%*	*3.9%*	*5.4%*	*5.2%*	*5.0%*	*4.5%*
Operating Income	($12.2)	($3.2)	($4.8)	($3.4)	($3.2)	($14.7)	($10.5)	($10.6)
Operating Margin	*-127.8%*	*-114.9%*	*-213.7%*	*-136.0%*	*-134.6%*	*-147.5%*	*-105.0%*	*-96.4%*
Interest Income / Net	($0.5)	($0.1)	($0.1)	($0.1)	($0.2)	($0.5)	($0.8)	($0.8)
Pre-Tax Income	($12.7)	($3.3)	($5.0)	($3.5)	($3.4)	($15.2)	($11.3)	($11.4)
Taxes	$0	($0)	$0	$0	$0	($0)	($0)	($0)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($12.8)	($3.3)	($5.0)	($3.5)	($3.4)	($15.1)	($11.3)	($11.4)
Reported EPS	($0.06)	($0.01)	($0.02)	($0.01)	($0.01)	($0.06)	($0.04)	($0.04)
Fully Diluted Shares	214.9	244.5	260.0	274.0	275.0	263.4	300.0	320.0

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

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