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Antibe Therapeutics Inc.

(V.ATE - TSX)

V.ATE: Results from Phase 2b Efficacy Trial in 3Q19…

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 (07/23/2019)	CAD$0.31
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 results from the Phase 2b study in 3Q19.

The company also recently announced the lead indication for its second pipeline drug, ATB-352, will be post-operative pain, which is a $9 billion market opportunity. Approximately 80% of patients who undergo surgery are prescribed opioids, and with the country currently in the midst of an opioid epidemic there is an urgent need for potent, safe pain medications that do not have the potential for abuse.

SUMMARY DATA

52-Week High	**$0.39**
52-Week Low	**$0.24**
One-Year Return (%)	**-1.5**
Beta	**-0.63**
Average Daily Volume (sh)	**344,280**
Shares Outstanding (mil)	**243**
Market Capitalization ($mil)	**$75**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**20**
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	2.4 E	2.3 E	2.5 E	2.4 E	9.6 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 E	-$0.01 E	-$0.01 E	-$0.01 E	-$0.06 E
2021					-$0.04 E
2022					-$0.04 E

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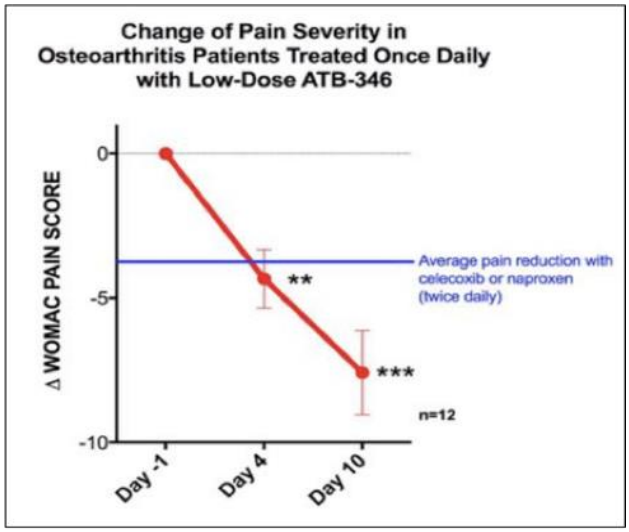
WHAT'S NEW

Business Update

Phase 2b Study Results in 3Q19

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. We anticipate topline results in the third quarter of 2019.

In 2016, Antibe announced the successful completion of a Phase 2 study of ATB-346 in patients with OA 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.

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 its 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 Published

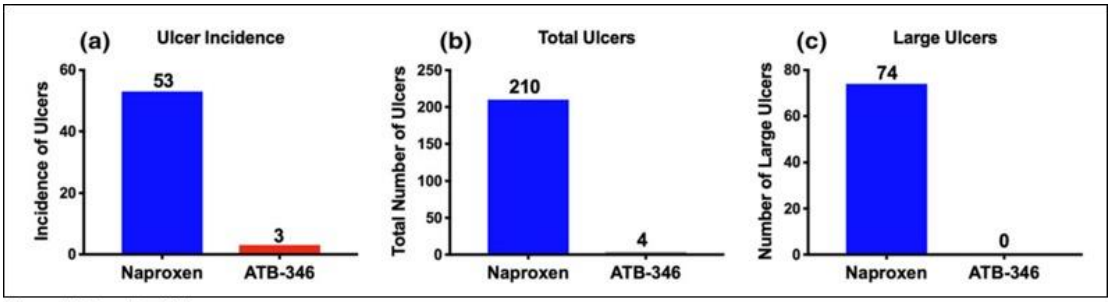
In April 2019, Antibe announced the publication of results from the Phase 2b GI safety study in the *British Journal of Pharmacology* (Wallace *et al*., 2019). The company had previously announced positive topline results from the study showing that 42.1% of naproxen-dosed subjects had GI ulceration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

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.



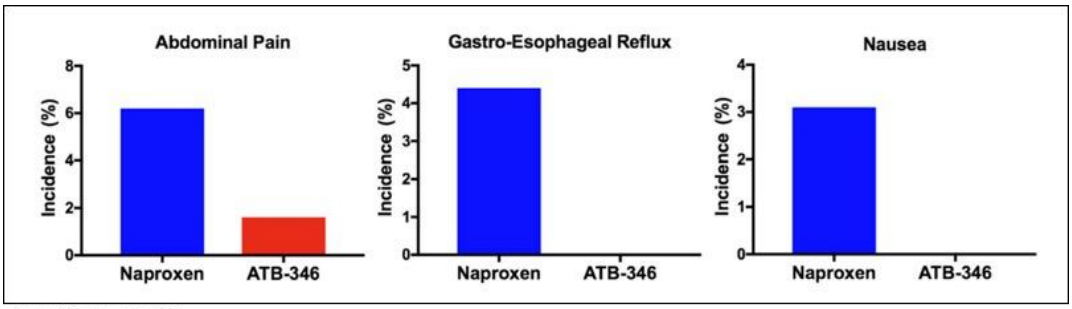
Gastric Ulcer. *Source*: Wallace, 2018

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.



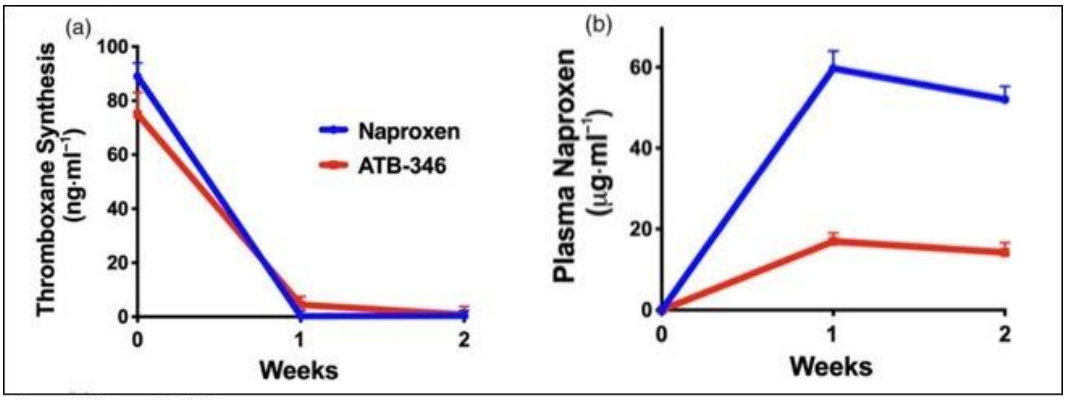
Source: Wallace *et al*., 2019

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.



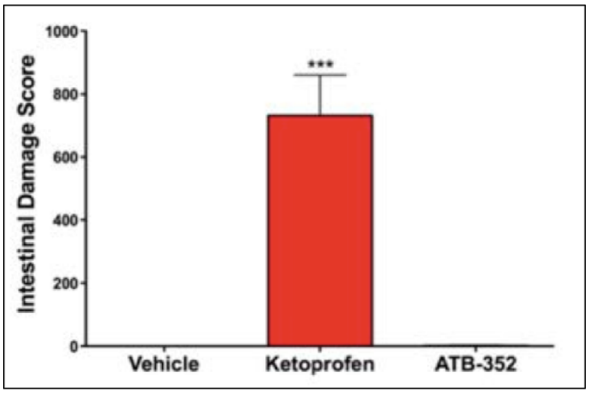
Source: Wallace *et al.*, 2019

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 July 16, 2019, Antibe announced financial results for the fourth quarter and full fiscal year 2019 ending Mar. 31, 2019. The company reported CAD$9.5 million for FY19 compared to CAD$8.5 million for FY18. The increase in revenue was primarily due to increased sales in the U.S., which grew at 62% over the previous year.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation expenses totaled CAD$15.7 million for FY19 compared to CAD$10.0 million for FY18. The increase was primarily related to the following:

- G&A expenses increased CAD$2.0 million to CAD$4.9 million primarily due to increased salaries, professional and consulting fees, and office costs.
- Selling and marketing expenses increased CAD$0.1 million to CAD$3.5 million primarily due to increased salaries and commissions and travel and entertainment costs.
- R&D expenses increased CAD$1.2 million to CAD$3.9 million primarily due to higher salaries and development costs for the Phase 2 trials partially offset by a higher rebate of Scientific Research and Experimental Development (SR&ED).
- Stock-based compensation increased CAD$2.3 million primarily due to a one-time catch up expensing of performance options.
- Amortization and depreciation increased slightly to CAD$0.4 million primarily due to increased depreciation of certain Citagenix assets.

As of March 31, 2019, Antibe had cash and cash equivalents of approximately CAD$6.0 million. We believe this is sufficient to fund operations beyond the expected release of the ongoing Phase 2b efficacy study, with those results expected in the 3Q of calendar 2019. In addition, the company has approximately 33.8 million warrants that could raise an additional approximately CAD$7.5 million.

As of March 31, 2019, Antibe had approximately 243.4 million shares outstanding and when factoring in options, RSUs, and warrants a fully diluted share count of approximately 312.5 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 third 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® (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 third quarter of 2019.

PROJECTED FINANCIALS

Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2019 A	Q1 '20 E	Q2 '20 E	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**	**$2.4**	**$2.3**	**$2.5**	**$2.4**	**$9.6**	**$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	$2.4	$2.3	$2.5	$2.4	$9.6	$10.0	$11.0
YOY Growth	*12.1%*	*-5.6%*	*11.2%*	*0.0%*	*-1.2%*	*0.6%*	*4.8%*	*10.0%*
Cost of Goods Sold	$6.0	$1.6	$1.4	$1.6	$1.5	$6.1	$6.3	$6.9
Product Gross Margin	*37.2%*	*35.1%*	*39.1%*	*36.0%*	*37.5%*	*36.9%*	*37.0%*	*37.3%*
SG&A	$8.4	$2.5	$2.2	$2.0	$2.0	$8.7	$9.0	$9.3
% SG&A	*88.0%*	*104.2%*	*95.7%*	*80.0%*	*83.3%*	*90.6%*	*90.0%*	*84.5%*
R&D	$3.9	$1.0	$1.1	$1.2	$1.2	$4.5	$4.7	$4.9
% R&D	*41.3%*	*43.0%*	*47.8%*	*48.0%*	*50.0%*	*47.2%*	*47.0%*	*44.5%*
Stock-based compensation	$3.0	$0.5	$0.7	$1.0	$0.8	$3.0	$3.0	$3.0
% Stock-based	*31.3%*	*20.8%*	*30.4%*	*40.0%*	*33.3%*	*31.3%*	*30.0%*	*27.3%*
Amortization and Depreciation	$0.4	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.5
% Other	*4.4%*	*4.0%*	*4.2%*	*3.9%*	*5.4%*	*4.4%*	*5.0%*	*4.5%*
Operating Income	($12.2)	($3.3)	($3.2)	($3.4)	($3.2)	($13.1)	($10.5)	($10.6)
Operating Margin	*-127.8%*	*-137.0%*	*-139.0%*	*-136.0%*	*-134.6%*	*-136.6%*	*-105.0%*	*-96.4%*
Interest Income / Net	($0.5)	($0.2)	($0.1)	($0.1)	($0.2)	($0.6)	($0.8)	($0.8)
Pre-Tax Income	($12.7)	($3.5)	($3.3)	($3.5)	($3.4)	($13.7)	($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)	($3.4)	($3.4)	($3.5)	($3.3)	($13.7)	($11.3)	($11.4)
Reported EPS	($0.06)	($0.01)	($0.01)	($0.01)	($0.01)	($0.06)	($0.04)	($0.04)
Fully Diluted Shares	214.9	243.4	245.0	247.0	249.0	246.1	260.0	280.0

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

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