

## Antibe Therapeutics Inc.

(V.ATE - TSX)

### V.ATE: Full Data Set Released for Phase 2b GI Safety Study of ATB-346...

Based on our probability adjusted DCF model that takes into account potential future revenues from ATB-346 along with Citigenix 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 Citigenix and will be adjusted accordingly based upon future clinical results and the company's execution.

Current Price (09/04/2018) CAD\$0.28  
Valuation CAD\$1.80

## OUTLOOK

On August 29, 2018, Antibe Therapeutics Inc. (ATE.V) announced the availability of a comprehensive report on the results of the recently completed Phase 2b study of ATB-346. The company previously announced topline results 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 full report provides additional information on secondary outcomes as well as data on safety and tolerability.

The company will be performing a metabolism study to better understand the unique metabolic profile of ATB-346. This study will be followed by a Phase 2 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 \$0.08  
One-Year Return (%) 229  
Beta -2.45  
Average Daily Volume (sh) 523,740

Shares Outstanding (mil) 212  
Market Capitalization (\$mil) \$59  
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)
2018	2.3 A	1.8 A	2.2 A	2.2 A	8.5 A
2019	2.5 A	2.0 E	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 E	-\$0.01 E	-\$0.01 E	-\$0.04 E
2019					-\$0.02 E
2020					-\$0.02 E

## WHAT'S NEW

### Business Update

#### *Scientific Report on Phase 2b Trial of ATB-346*

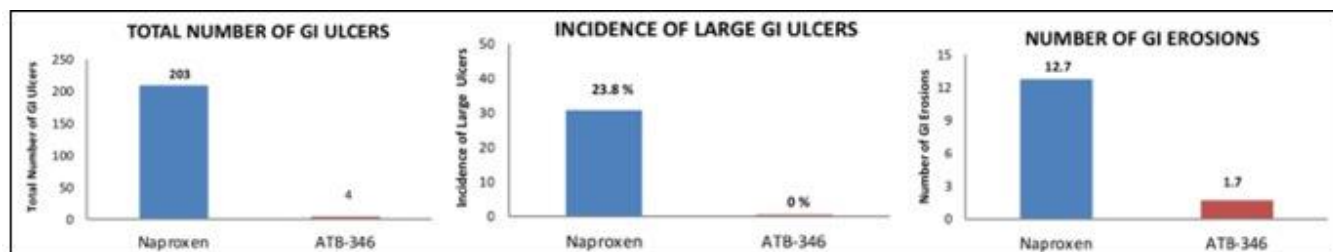
On August 29, 2018, Antibe Therapeutics, Inc. (ATE.V) [announced](#) the availability of a comprehensive report summarizing the data from the Phase 2b trial of ATB-346. ATB-346 is a hydrogen sulfide (H<sub>2</sub>S) releasing form of naproxen, a non-steroidal anti-inflammatory drug (NSAID), with the goal being to reduce the known gastrointestinal (GI) side effects of NSAIDs without altering the drugs ability to reduce inflammation and pain. 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  $\geq 3$  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  $\geq 3$  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 ( $\geq 5$  mm), and the number of GI erosions were all much higher in the naproxen-treated subjects compared to those administered ATB-346.



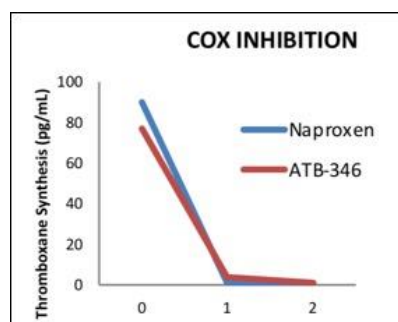
Source: Wallace, 2018

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  $\mu\text{g/mL}$  while after two weeks of dosing ATB-346 the mean concentration of naproxen was 14.2  $\mu\text{g/mL}$ . The difference is explained by the daily dose of ATB-346 being approximately 1/4<sup>th</sup> 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 upcoming metabolism study (see below).

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).

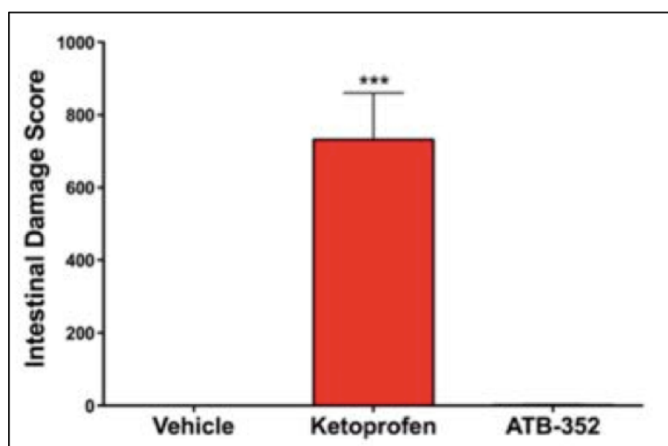
#### *Upcoming Clinical Trials of ATB-346*

Now that the company has positive GI safety data the next step is to conduct a metabolism study, to better understand the unique metabolic profile of ATB-346, and a Phase 2 dose-ranging efficacy study. The metabolism study will study the principle metabolites of ATB-346 in approximately 25 healthy volunteers. We anticipate this study commencing in the third quarter of 2018 and taking approximately 8-10 weeks to finish. Based on the results of that study, the company will perform a randomized, double blind, placebo controlled efficacy trial with osteoarthritis (OA) patients. Three different doses (to be determined based on the findings of the metabolism study) of ATB-346 will be evaluated to determine the lowest effective dose. Topline results from this study should be available in the second quarter of 2019.

#### *Advancing ATB-352 Development*

Last year, Antibe [announced](#) that it has formally begun Investigational New Drug (IND) enabling studies for ATB-352, a hydrogen sulfide-releasing derivative of ketoprofen, a potent NSAID that is normally prescribed for acute pain. Opioids such as oxycontin have a very high propensity for abuse due to being highly addictive, however they are still prescribed at a very high rate as 227 million prescriptions for opioid medications were dispensed in 2015 (IMS Health). In 2016, there were almost 17,000 overdose deaths resulting from the use of prescription opioid medications, a 300% increase since 1999 (CDC). Thus, there is an urgent need for a non-addictive acute pain reliever.

Antibe has confirmed that ATB-352 is non-addictive and preclinical data indicates that it results in negligible GI damage compared to ketoprofen. The following graph shows the results from a study in rats in which ketoprofen treatment resulted in significant GI damage, however no damage was seen in rats treated with ATB-352.



Source: Antibe Therapeutics Inc.

## **Financial Update**

On August 29, 2018, Antibe announced financial results for the first quarter of fiscal year 2019 ending June 30, 2018. The company reported CAD\$2.5 million in revenue for the three months ending June 30, 2018 compared to CAD\$2.3 million for the three months ending June 30, 2017. The increase in revenue was due to increased sales in the U.S. from the company's focused efforts in that country.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation expenses totaled CAD\$3.5 million in 1QFY19 compared to CAD\$2.6 million in 1QFY18. The increase in expenses was due to the following:

- G&A expenses increased CAD\$0.5 million in 1QFY19 to CAD\$1.3 million due to increased salaries and wages, professional and consulting fees, licensing fees, and other expenses.
- Selling and marketing expenses were CAD\$0.9 million in 1QFY19 compared to CAD\$0.7 million in 1QFY18. The increase was primarily due to increased commissions, travel and entertainment expenses, and advertising partially offset by decreased salaries and wages.
- R&D expenses increased CAD\$0.4 million to CAD\$1.0 million in 1QFY19 compared to CAD\$0.6 million in 1QFY18. The increase was primarily due to higher salaries and wages and development costs.
- Stock based compensation decreased CAD\$0.1 million to CAD\$0.2 million in 1QFY19.
- Amortization and depreciation expenses decreased slightly to CAD\$0.1 million.

As of June 30, 2018, Antibe had cash and cash equivalents of CAD\$4.2 million. On April 3, 2018, Antibe [announced](#) that following the successful completion of the Phase 2b gastrointestinal safety study and release of positive topline results, the company has raised approximately CAD\$4 million from the exercise of outstanding warrants and that there is the potential to raise an additional approximately CAD\$6 million from the exercise of outstanding warrants that are significantly in-the-money. We estimate the company's current cash total is enough to fund the upcoming metabolism study and Phase 2b dose-ranging efficacy study of ATB-346.

In addition to the capital raised through warrant exercises, the company has also eliminated almost all of its debt from the balance sheet through conversions of approximately \$3 million of convertible debentures, which bore interest at 10% per year and were convertible at CAD\$0.22 per share. The only remaining debt on the balance sheet is a standard operating line of credit for Antibe's subsidiary Citagenix, Inc.

As of August 28, 2018, Antibe had approximately 211.9 million shares outstanding and when factoring in the remaining warrants and stock options a fully diluted share count of approximately 260.2 million.

## **Valuation**

We believe the prospects for ATB-346 and the rest of Antibe's pipeline are very good. 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. 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 some and we believe there remains the potential for considerable upside, particularly with data from the dose-ranging efficacy and metabolism studies still to come in the next 12 months.

## PROJECTED FINANCIALS

### Antibe Therapeutics Inc. Income Statement

<b>Antibe Therapeutics, Inc.</b> Fiscal Year Ends Mar. 31 / in Canadian dollars	<b>FY 2018 E</b>	<b>Q1 '19 A</b>	<b>Q2 '19 E</b>	<b>Q3 '19 E</b>	<b>Q4 '19 E</b>	<b>FY 2019 E</b>	<b>FY 2020 E</b>	<b>FY 2021 E</b>
<b>ATB-346 (royalty)</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>YOY Growth</i>	#DIV/0!	-	-	-	-	#DIV/0!	#DIV/0!	#DIV/0!
<b>ATB-352 (royalty)</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>YOY Growth</i>	-	-	-	-	-	#DIV/0!	#DIV/0!	#DIV/0!
<b>Citagenix</b>	\$8.5	\$2.5	\$2.0	\$2.2	\$2.2	\$9.0	\$10.0	\$12.0
<b>Licensing / Development</b>	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Total Revenues</b>	\$8.5	\$2.5	\$2.0	\$2.2	\$2.2	\$9.0	\$10.0	\$12.0
<i>YOY Growth</i>	-6.0%	12.0%	11.4%	0.0%	-0.4%	5.5%	11.4%	20.0%
<b>Cost of Goods Sold</b>	\$5.1	\$1.6	\$1.1	\$1.2	\$1.3	\$5.2	\$5.7	\$6.9
<i>Product Gross Margin</i>	39.7%	38.7%	43.2%	46.3%	40.9%	42.1%	43.0%	42.5%
<b>SG&amp;A</b>	\$6.2	\$2.2	\$1.6	\$1.6	\$1.6	\$7.0	\$6.7	\$7.0
<i>% SG&amp;A</i>	73.2%	86.4%	81.8%	70.1%	72.7%	78.0%	67.0%	58.3%
<b>R&amp;D</b>	\$2.7	\$1.0	\$0.5	\$0.5	\$0.5	\$2.5	\$2.3	\$2.5
<i>% R&amp;D</i>	32.2%	40.6%	23.2%	23.3%	22.7%	28.0%	23.0%	20.8%
<b>Stock-based compensation</b>	\$0.7	\$0.2	\$0.2	\$0.1	\$0.3	\$0.8	\$1.0	\$1.1
<i>% Stock-based</i>	8.1%	6.0%	10.1%	4.2%	13.6%	8.4%	10.0%	9.2%
<b>Amortization and Depreciation</b>	\$0.4	\$0.1	\$0.1	\$0.1	\$0.1	\$0.4	\$0.5	\$0.5
<i>% Other</i>	4.4%	3.8%	4.6%	4.4%	5.9%	4.6%	5.0%	4.2%
<b>Operating Income</b>	(\$6.7)	(\$2.5)	(\$1.5)	(\$1.2)	(\$1.6)	(\$6.9)	(\$5.2)	(\$4.9)
<i>Operating Margin</i>	-78.3%	-98.1%	-76.6%	-55.7%	-74.1%	-76.9%	-52.0%	-40.8%
<b>Interest Income / Net</b>	(\$1.0)	(\$0.2)	(\$0.1)	(\$0.2)	(\$0.2)	(\$0.7)	(\$0.8)	(\$0.8)
<b>Pre-Tax Income</b>	(\$7.7)	(\$2.7)	(\$1.7)	(\$1.5)	(\$1.8)	(\$7.6)	(\$6.0)	(\$5.7)
<b>Taxes</b>	(\$0)	(\$0)	(\$0)	(\$0)	(\$0)	(\$0)	(\$0)	(\$0)
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
<b>Net Income</b>	(\$7.4)	(\$2.7)	(\$1.5)	(\$1.5)	(\$1.7)	(\$7.6)	(\$6.0)	(\$5.7)
<b>Reported EPS</b>	(\$0.05)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.04)	(\$0.02)	(\$0.02)
<b>Fully Diluted Shares</b>	151.6	204.8	212.0	220.0	225.0	215.5	250.0	280.0

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

# HISTORICAL STOCK PRICE

**ATE.V** Antibe Therapeutics Inc. TSXV

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30-Aug-2018 10:40am

Open 0.28 High 0.29 Low 0.28 Last 0.28 Volume 290.4K Chg -0.00 (-1.72%)

▲ RSI(14) 41.94



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