

Antibe Therapeutics Inc.

(V.ATE - TSX)

V.ATE: Additional Secondary Endpoint Data 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 (07/09/2018) CAD\$0.38
Valuation CAD\$1.80

OUTLOOK

On July 3, 2018, Antibe Therapeutics, Inc. (ATE.V) announced key secondary endpoint data from the company's Phase 2b gastrointestinal (GI) safety study of its lead drug ATB-346. The company had previously reported an ulceration rate of only 2.5% in healthy volunteers administered ATB-346 for two weeks compared to 42.1% of those administered naproxen. The secondary endpoints included data showing 1) no ATB-346 treated subjects developed ulcers \geq 5 mm compared to 24% administered naproxen; and 2) the total number of ulcers in the ATB-346 group was only 4 compared to 203 in the naproxen group. These data support the conclusion based on the primary data that ATB-346 is superior to naproxen in regards to GI safety. The company is planning on conducting a Phase 2 dose-ranging efficacy study beginning in the 3Q18 with data available in 1Q19.

SUMMARY DATA

52-Week High \$0.79
52-Week Low \$0.08
One-Year Return (%) 327
Beta -2.19
Average Daily Volume (sh) 774,470

Shares Outstanding (mil) 199
Market Capitalization (\$mil) \$76
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	2.3 E	2.0 E	2.2 E	2.2 E	8.7 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	-\$0.02 E	-\$0.01 E	-\$0.01 E	-\$0.01 E	-\$0.03 E
2019					-\$0.02 E
2020					-\$0.02 E

WHAT'S NEW

Business Update

Secondary Endpoint Data from Phase 2b Trial of ATB-346

On July 3, 2018, Antibe Therapeutics, Inc. (ATE.V) [announced](#) key secondary endpoint data from the company's Phase 2b gastrointestinal (GI) safety study. 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 (see below). The secondary endpoint data included the following:

- 1) **Incidence of gastric or duodenal ulcers \geq 5 mm in diameter.** The data showed that none (0%) of the subjects administered ATB-346 developed ulcers \geq 5 mm in diameter compared to 30 subjects (24%) treated with naproxen, with an average of 2.5 ulcers per subject.
- 2) **Number of gastric and/or duodenal ulcers and/or erosions.** There were a total of 4 gastric ulcers and 0 duodenal ulcers among the 3 subjects that developed ulcers in the ATB-346 group. In contrast, there were a total of 204 gastric and duodenal ulcers among the 53 subjects that developed ulcers in the naproxen group. In addition, there were an average of 1.7 gastric and duodenal erosions (which are less significant than ulcers) per subject in the ATB-346 group compared to an average of 12.7 erosions per subject in the naproxen group.
- 3) **Discontinuation due to dyspepsia.** No subjects discontinued from the study due to dyspepsia in either the ATB-346 or naproxen group.
- 4) **Change in hematocrit.** A change in hematocrit, or the volume of red blood cells in the blood, can be an indication of GI bleeding. There were no significant differences in hematocrit from baseline to the end of dosing in either treatment arm.
- 5) **Thromboxane B2 (TXB2) Synthesis.** NSAIDs analgesic and anti-inflammatory effects are caused by an inhibition of cyclo-oxygenase (COX) enzyme activity, which can be measured through the blood biomarker TXB2. The average baseline values for TXB2 in the ATB-346 and naproxen groups were 86 ng/mL and 88 ng/mL, respectively (not significantly different). ATB-346 and naproxen both inhibited TXB2 synthesis by $>$ 94%. This is particularly encouraging given that the company will be testing ATB-346 in an upcoming efficacy study, since it appears that ATB-346 is just as effective at inhibiting COX as naproxen.

These secondary data support the conclusion based on the initial topline data that ATB-346 has superior GI safety compared to naproxen.

Topline Data from Phase 2b Trial of ATB-346

On March 20, 2018, Antibe [announced](#) positive topline results for the Phase 2 GI safety study of its lead drug, ATB-346. The double-blind GI safety study enrolled 244 healthy volunteers, in which participants were administered either 250 mg ATB-346 once daily or 500 mg naproxen twice daily. All subjects had an endoscopic examination of the upper GI tract prior to drug treatment and at the end of the 14-day study period.

The results showed that 42.1% (53/126) of naproxen-dosed subjects had GI ulceration compared to only 2.5% (3/118) of subjects treated with ATB-346, which was a statistically significant difference ($P < 0.001$). Importantly, there were no safety signals and transient increases in liver enzymes were seen at levels comparable to what is seen with the most commonly prescribed NSAIDs.

Dose-Ranging Efficacy Study

Now that the company has positive GI safety data the next step is to conduct a Phase 2 dose-ranging efficacy study. This will be a randomized, double blind, placebo controlled trial with osteoarthritis (OA) patients that we anticipate initiating in the third quarter of 2018 with topline results available in the first quarter of 2019. We anticipate learning more about this study once the company finalizes details about the study and gets closer to initiating it.

NSAID Side Effects

Antibe is developing ATB-346 as a solution to the dose-related 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.

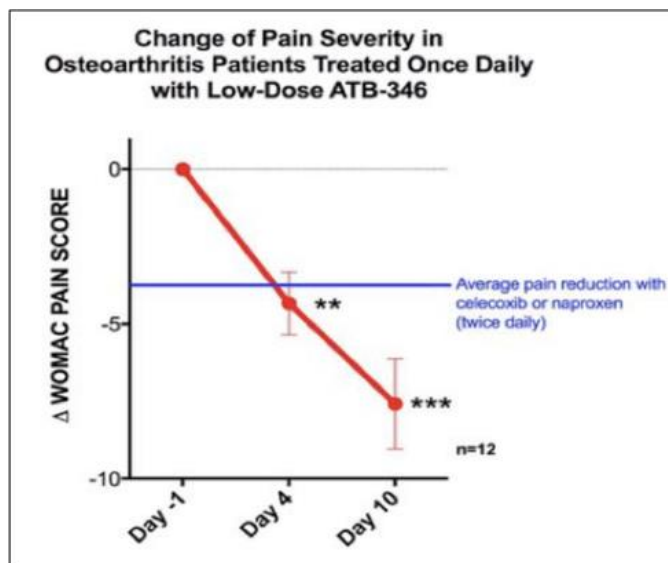
Selective COX-2 inhibitors, such as rofecoxib (Vioxx®), celecoxib (Celebrex®), and valdecoxib (Bextra®), were initially very popular with both physicians and patients for their ability to relieve pain with a significantly decreased risk of adverse GI events. For example, Vioxx achieved over \$1 billion 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®.

So 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.

ATB-346

ATB-346 uses naproxen as a base molecule with a hydrogen sulfide releasing moiety covalently attached. Hydrogen sulfide (H₂S) 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.

Financial Update

On June 29, 2018, Antibe announce financial results for the fourth quarter and full fiscal year 2018 ending Mar. 31, 2018. The company reported CAD\$8.5 million for FY18 compared to CAD\$9.1 million for FY17. The decrease in revenue was mostly due to increased competition in Canada.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation expenses totaled CAD\$10.0 million in FY18 compared to CAD\$9.1 million in FY17. The increase in expenses was due to the following:

- G&A expenses decreased CAD\$1.1 million in FY18 to CAD\$2.8 million due to decreased salaries and wages, professional and consulting fees, licensing fees, and other expenses partially offset by increased office expenses.
- Selling and marketing expenses were CAD\$3.4 million in FY18 compared to CAD\$3.0 million in FY17. The increase was primarily due increased salaries and wages, commissions, travel and entertainment expenses, and advertising and promotion costs.
- R&D expenses increased CAD\$2.0 million to CAD\$2.7 million in FY18 compared to CAD\$0.7 million in FY17. The increase was primarily due to higher salaries and wages and development costs for the Phase 2 clinical trials partially offset by lower professional and consulting fees and a rebate of past tax credits.
- Stock based compensation decreased CAD\$0.5 million to CAD\$0.7 million in FY18.
- Amortization and depreciation expenses decreased slightly to CAD\$0.4 million.

As of Mar. 31, 2018, Antibe had cash and cash equivalents of CAD\$3.7. 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 approximately CAD\$5 million, thus the company's upcoming Phase 2b dose-ranging efficacy study of ATB-346 is fully funded.

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 Mar. 31, 2018, Antibe had approximately 198.6 million shares outstanding and when factoring in the remaining warrants and stock options a fully diluted share count of approximately 259.6 million.

Valuation

Based on the positive results of the Phase 2 GI safety study we have made adjustments to our model. We continue to 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 and we currently model for a 12% royalty with associated milestone payments.

In terms of cash, we estimate the company now has approximately CAD\$5 million in cash and cash equivalents with the potential to raise an additional approximately CAD\$6 million from warrant exercises. Most importantly, the Phase 2b dose-ranging efficacy study is fully funded.

Based on increasing the chance for approval and the price for ATB-346 our new valuation 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 study still to come in the next 6-9 months.

PROJECTED FINANCIALS

Antibe Therapeutics Inc. Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2018 E	Q1 '19 E	Q2 '19 E	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
<i>YOY Growth</i>	<i>#DIV/0!</i>	-	-	-	-	<i>#DIV/0!</i>	<i>#DIV/0!</i>	<i>#DIV/0!</i>
ATB-352 (royalty)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>YOY Growth</i>	-	-	-	-	-	<i>#DIV/0!</i>	<i>#DIV/0!</i>	<i>#DIV/0!</i>
Citagenix	\$8.5	\$2.3	\$2.0	\$2.2	\$2.2	\$8.7	\$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	\$2.3	\$2.0	\$2.2	\$2.2	\$8.7	\$10.0	\$12.0
<i>YOY Growth</i>	-6.0%	1.3%	11.4%	0.0%	-0.4%	2.6%	14.5%	20.0%
Cost of Goods Sold	\$5.1	\$1.3	\$1.1	\$1.2	\$1.3	\$4.9	\$5.7	\$6.9
<i>Product Gross Margin</i>	39.7%	43.4%	43.2%	46.3%	40.9%	43.5%	43.0%	42.5%
SG&A	\$6.2	\$1.6	\$1.6	\$1.6	\$1.6	\$6.4	\$6.7	\$7.0
<i>% SG&A</i>	73.2%	71.1%	81.8%	70.1%	72.7%	73.7%	67.0%	58.3%
R&D	\$2.7	\$0.6	\$0.5	\$0.5	\$0.5	\$2.1	\$2.3	\$2.5
<i>% R&D</i>	32.2%	27.1%	23.2%	23.3%	22.7%	24.2%	23.0%	20.8%
Stock-based compensation	\$0.7	\$0.3	\$0.2	\$0.1	\$0.3	\$0.9	\$1.0	\$1.1
<i>% Stock-based</i>	8.1%	12.1%	10.1%	4.2%	13.6%	10.0%	10.0%	9.2%
Amortization and Depreciation	\$0.4	\$0.1	\$0.1	\$0.1	\$0.1	\$0.4	\$0.5	\$0.5
<i>% Other</i>	4.4%	4.0%	4.6%	4.4%	5.9%	4.7%	5.0%	4.2%
Operating Income	(\$6.7)	(\$1.63)	(\$1.5)	(\$1.2)	(\$1.6)	(\$6.0)	(\$5.2)	(\$4.9)
<i>Operating Margin</i>	-78.3%	-70.8%	-76.6%	-55.7%	-74.1%	-69.1%	-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)	(\$1.8)	(\$1.7)	(\$1.5)	(\$1.8)	(\$6.8)	(\$6.0)	(\$5.7)
Taxes	(\$0)	(\$0)	(\$0)	(\$0)	(\$0)	(\$0)	(\$0)	(\$0)
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$7.4)	(\$1.7)	(\$1.5)	(\$1.5)	(\$1.7)	(\$6.8)	(\$6.0)	(\$5.7)
Reported EPS	(\$0.05)	(\$0.02)	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.03)	(\$0.02)	(\$0.02)
Fully Diluted Shares	151.6	200.0	205.0	220.0	225.0	212.5	250.0	280.0

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

HISTORICAL STOCK PRICE



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