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Antibe Therapeutics Inc.

(V.ATE - TSX)

V.ATE: Final Subject Enrolled in Phase 2b Trial of ATB-346; Data Expected in March 2018…

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$0.85 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 (01/30/2018)	CAD$0.21
Valuation	**CAD$0.85**

OUTLOOK

On January 29, 2018, Antibe Therapeutics Inc. announced that the final subject has been enrolled in the phase 2b study of its lead drug, ATB-346. The study is enrolling 240 healthy volunteers with the goal of demonstrating unequivocal superiority in gastrointestinal safety for ATB-346 compared to naproxen. With a two week dosing period, a two week follow-up period, and approximately two weeks for data analysis we anticipate topline results being reported in mid-March 2018.

SUMMARY DATA

52-Week High	**$0.28**
52-Week Low	**$0.08**
One-Year Return (%)	**5.0**
Beta	**-0.56**
Average Daily Volume (sh)	**513,580**
Shares Outstanding (mil)	**163**
Market Capitalization ($mil)	**$37**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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	**N/A**
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)
2017	2.6 A	2.2 A	2.0 A	2.3 A	9.1 A
2018	2.3 A	1.8 A	2.5 E	2.6 E	9.2 E
2019					12.0 E
2020					15.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2017	-$0.01 A	-$0.01 A	-$0.02 A	-$0.01 A	-$0.06 A
2018	-$0.02 A	-$0.01 A	-$0.02 E	-$0.01 E	-$0.05 E
2019					-$0.04 E
2020					-$0.04 E

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WHAT'S NEW

Antibe Therapeutics Inc. (ATE.V) is a Canadian biotechnology company developing treatments for pain, inflammation, and regenerative medicine. The company's lead compound, ATB-346, is an improved non-steroidal anti-inflammatory drug (NSAID) that attempts to overcome the well-known and serious side effects of that class of compounds, including ulcers and bleeding in the gastrointestinal (GI) tract. Antibe has successfully completed a series of Phase 1 and 2 clinical trials for ATB-346. Recently, the company initiated a Phase 2b trial designed to show superiority in gastrointestinal (GI) safety, with a second Phase 2 dose-ranging effectiveness study set to commence in 2018. The results of these trials will support a potential partnering opportunity with a larger pharmaceutical company in order to advance ATB-346 into a Phase 3 program.

The company is complementing the high-risk nature of the drug development process with its subsidiary Citagenix, a low-risk, revenue generating entity that is the leader in Canada in the sales and marketing of tissue regenerative products for primarily the dental market.

Business Update

Final Subjects Enrolled in Phase 2b Study of ATB-346

On January 29, 2018, Antibe announced that the final subjects have been enrolled in the Phase 2b study of ATB-346. The double-blind, GI safety study enrolled 240 healthy volunteers, in which participants are being given either ATB-346 once daily or naproxen twice-daily for two weeks. All subjects will have an endoscopic examination of the upper GI tract prior to drug treatment and at the end of the 14-day study period. The primary endpoint of the study is the percentage of subjects with a GI ulcer ≥3 mm in diameter. This study is necessary as the FDA considers endoscopically examining upper GI ulceration the 'gold standard' in assessing NSAID-associated toxicity. Positive results from this study would allow Antibe to pursue a GI safety claim of superiority to naproxen. With the final subjects starting the two-week dosing period and two-week follow up, along with approximately two weeks for data analysis, we anticipate results in March 2018.

Antibe is currently planning on targeting ATB-346 for patients with osteoarthritis, for whom NSAIDs are the most commonly used therapy. Given the risks associated with NSAID use, these patients could benefit greatly from an effective anti-inflammatory/analgesic medication that does not carry the same GI risk. Additional indications for which ATB-346 could be approved include all traditional markets for NSAIDs, including rheumatoid arthritis, ankylosing spondylitis, etc.

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.

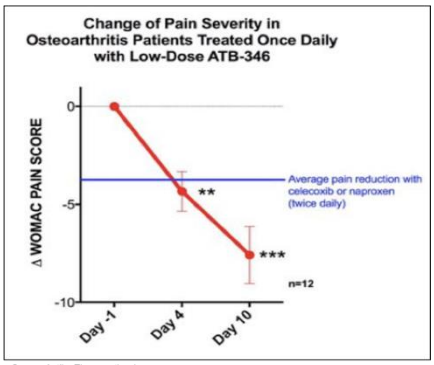
Selective COX-2 inhibitors, such as rofecoxib (Vioxx®), celecoxib (Celebrex®), and valdecoxib (Bextra®), were initially very popular with both physicians and patients for their ability to relieve pain with a significantly decreased risk of adverse GI events. For example, Vioxx achieved over $1 billion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

Valuation

We value Antibe using a probability adjusted discounted cash flow model that takes into account potential future revenues for ATB-346 and Citagenix. For ATB-346, we anticipate that the company will enter into a collaboration with a larger pharmaceutical company before Phase 3 studies commence. For modeling purposes, we are estimating that Phase 3 studies for ATB-346 will begin in 2019, with an NDA filing in 2020 and approval in 2021. We model for approval in the E.U. a year later.

ATB-346 is the main value driver for Antibe as the NSAID market is valued at $8 billion total. We model for approval in OA, however we believe that if the drug is approved it will likely go on to be approved for multiple indications similar to celecoxib. There are approximately 27 million individuals in the U.S. with OA (NIAMS). Of those, we estimate approximately 50% are taking or are open to taking oral NSAIDs. With a conservatively estimated 6% of the market, ATB-346 would have peak sales of $1.0 billion. In the E.U., where there are approximately 40 million patients with OA (WHO), a similar market share could generate close to $1 billion in revenue. Using a 12% royalty rate, an 18% discount rate, and a 50% chance of approval, we estimate the net present value of ATB-346 to be $171 million. When taking into account estimated capital requirements, the current conversion to Canadian Dollars (USD$1 = CAD$1.23), and dividing by the fully diluted share count of 259.5 million shares leads to a valuation of approximately CAD$0.85. We believe investors would be wise to take a close look at Antibe ahead of the Phase 2b results in March 2018.

PROJECTED FINANCIALS

Antibe Therapeutics, Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2017 A	Q1 '18 A	Q2 '18 A	Q3 '18 E	Q4 '18 E	FY 2018 E	FY 2019 E	FY 2020 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!*
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!*
Citagenix	**$9.1**	**$2.3**	**$1.8**	**$2.5**	**$2.6**	**$9.2**	**$12.0**	**$15.0**
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$9.1	$2.3	$1.8	$2.5	$2.6	$9.2	$12.0	$15.0
YOY Growth	*104.1%*	*#REF!*	*#REF!*	*#REF!*	*#REF!*	*1.2%*	*30.9%*	*25.0%*
Cost of Goods Sold	$5.1	$1.3	$1.1	$1.9	$2.0	$6.3	$8.3	$9.9
Product Gross Margin	*43.4%*	*42.7%*	*36.7%*	*24.0%*	*23.1%*	*30.9%*	*30.8%*	*34.0%*
SG&A	$6.9	$1.6	$1.6	$2.1	$2.2	$7.6	$9.0	$11.0
% SG&A	*76.6%*	*72.0%*	*91.2%*	*84.0%*	*84.6%*	*82.6%*	*75.0%*	*73.3%*
R&D	$0.7	$0.6	$0.5	$0.4	$0.5	$2.0	$1.8	$2.0
% R&D	*7.7%*	*27.5%*	*25.9%*	*16.0%*	*19.2%*	*21.7%*	*15.0%*	*13.3%*
Stock-based compensation	$1.2	$0.3	$0.2	$0.3	$0.4	$1.2	$1.8	$1.8
% Stock-based	*12.8%*	*12.2%*	*11.3%*	*12.0%*	*15.4%*	*12.9%*	*15.0%*	*12.0%*
Amortization and Depreciation	$0.4	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.6
% Other	*3.9%*	*4.0%*	*5.1%*	*5.2%*	*5.0%*	*4.8%*	*4.2%*	*4.0%*
Operating Income	($5.2)	($1.7)	($1.7)	($2.3)	($2.6)	($7.2)	($7.6)	($8.5)
Operating Margin	*-57.5%*	*-73.0%*	*-96.7%*	*-93.2%*	*-101.2%*	*-78.3%*	*-63.3%*	*-56.7%*
Interest Income / Net	($0.9)	($0.2)	($0.1)	$0.0	$0.0	($0.3)	$0.0	$0.0
Pre-Tax Income	($6.1)	($1.8)	($1.9)	($2.3)	($2.6)	($7.5)	($7.6)	($8.5)
Taxes	($0)	($0)	($0)	$0	($0)	($0)	($0)	($0)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($5.7)	($1.7)	($1.7)	($2.5)	($2.5)	($7.2)	($7.6)	($8.5)
YOY Growth	*71.1%*	-	-	-	-	*25.7%*	*5.0%*	*11.9%*
Net Margin	*-63.5%*	-	*-94.0%*	*-99.6%*	*-95.7%*	*-78.8%*	*-63.2%*	*-56.5%*
Reported EPS	($0.06)	($0.02)	($0.01)	($0.02)	($0.01)	($0.05)	($0.04)	($0.04)
Fully Diluted Shares	95.7	116.7	157.9	162.0	180.0	154.1	200.0	220.0

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

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