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Antibe Therapeutics Inc.

(V.ATE - TSX)

V.ATE: Phase 3 Program for Otenaproxesul to Initiate in 2021…

Based on our probability adjusted DCF model that takes into account potential future revenues from otenaproxesul, ATE.V is valued at CAD$3.00 per share. This model is highly dependent upon continued clinical success of otenaproxesul and will be adjusted accordingly based upon future clinical results and the company's execution.

Current Price (08/28/2020)	CAD$0.40
Valuation	**CAD$3.00**

OUTLOOK

Antibe Therapeutics Inc. (ATE.V) is developing safer medicines for pain and inflammation utilizing the company's proprietary hydrogen-sulfide releasing technology. Antibe recently announced positive topline results for the Phase 2b dose-ranging efficacy study of the company's lead development compound, ATB-346 (otenaproxesul) in patients with osteoarthritis. Near-term milestones include filing an IND for otenaproxesul before the end of 2020, meeting with the FDA for an 'End-of-Phase 2' within the next six months, and initiating a pivotal Phase 2/3 adaptive design trial late in the first quarter or early in the second quarter of 2021.

SUMMARY DATA

52-Week High	**$0.89**
52-Week Low	**$0.32**
One-Year Return (%)	**17.65**
Beta	**N/A**
Average Daily Volume (sh)	**2,020,000**
Shares Outstanding (mil)	**385**
Market Capitalization ($mil)	**$154**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**14**
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	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of CAD$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	2.8 A	2.3 A	2.6 A	2.3 A	10.0 A
2021	1.2 A	2.0 E	2.5 E	2.5 E	8.2 E
2022					11.0 E
2023					11.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	-$0.01 A	-$0.02 A	-$0.02 A	-$0.02 A	-$0.07 A
2021	-$0.02 A	-$0.01 E	-$0.01 E	-$0.01 E	-$0.05 E
2022					-$0.04 E
2023					-$0.04 E

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WHAT'S NEW

Business Update

Advancing Toward Phase 3 Program for ATB-346 (Otenaproxesul)

Antibe Therapeutics, Inc. (ATE.V) is preparing to move its lead development compound, otenaproxesul (the nonproprietary name for ATB-346), into a Phase 3 program. Otenaproxesul is being developed as a solution to the dose-related gastrointestinal (GI) side effects associated with nonsteroidal anti-inflammatory drugs (NSAIDs). It uses naproxen as a base molecule with a hydrogen sulfide moiety covalently attached. Hydrogen sulfide (H_2S) is an important gasotransmitter, a gas that serves an important signaling molecule in the body.

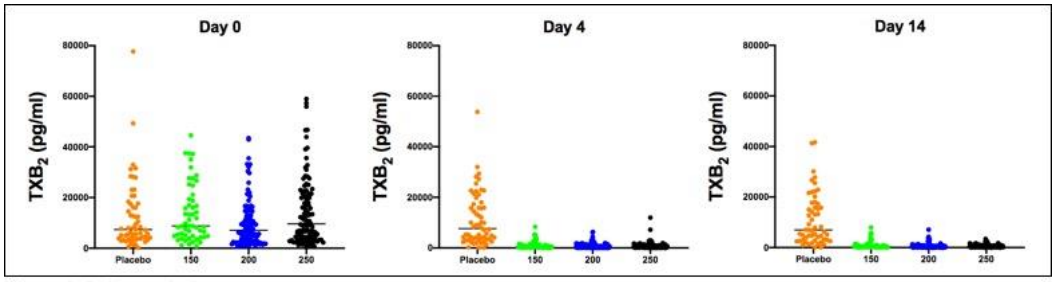
In 2018, Antibe announced positive topline results for the Phase 2 GI safety study of otenaproxesul. The double-blind, study enrolled 244 healthy volunteers, in which participants were administered either 250 mg otenaproxesul once daily or 500 mg naproxen twice daily. All subjects had an endoscopic examination 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 otenaproxesul, 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.

In June 2020, Antibe announced positive topline results from the Phase 2b dose-ranging, efficacy trial of otenaproxesul. The randomized, double blind, placebo controlled trial enrolled 385 patients with osteoarthritis (OA) of the knee to once daily placebo or one of the three doses of otenaproxesul: 250 mg, 200 mg, and 150 mg. The primary endpoint of the trial was the change from baseline in the WOMAC pain subscale score following 14 days of treatment. Secondary efficacy endpoints included the WOMAC stiffness subscale score and the WOMAC difficulty performing daily activities (DPDA) subscale score.

Patients administered otenaproxesul showed a statistically significantly greater decrease in the change in the WOMAC pain subscale score compared to those administered placebo at both 250 mg (P=0.01) and 200 mg (P=0.007). The 150 mg cohort was not powered for statistical significance, however that dose showed robust efficacy in the primary endpoint and likely would have been statistically significant if it had been adequately powered like the other treatment arms. The full results are discussed in detail in our previous report. The adverse event profile was similar between placebo and all three doses of ATB-346, and consisted of events typically seen with the use of NSAIDs (e.g., dyspepsia, acid reflux, and dizziness).

In addition to the WOMAC results, the company also recently reported that otenaproxesul treatment resulted in a marked inhibition of cyclo-oxygenase enzymes (TXB_2 is a product of COX enzyme activity). The following figure shows that all three doses of otenaproxesul resulted in a profound inhibition by Day 4 and this continued through Day 14. In addition, there was little difference between the three doses, and likely indicates that the company will be able to decrease the dose before seeing any decrease in efficacy.



Source: Antibe Therapeutics, Inc.

Now that the efficacy and GI safety data for otenaproxesul is in hand, the company has begun planning the Phase 3 development program. We anticipate an IND being filed before the end of 2020 and an 'End-of-Phase 2' meeting occurring with the FDA (and the equivalent meeting with the EMA) within the next six months. While we await word on the specific details of the Phase 3 program, we believe it will involve:

- Two 12-week efficacy trials that will include lower doses of otenaproxesul than were seen in the Phase 2b dose-ranging efficacy trial (tested against placebo) such that the lowest effective dose can be determined. The first of those trials is likely to be a Phase 2/3 adaptive design trial, whereby an interim analysis is conducted following 50% enrollment to ensure that an adequate number of patients are enrolled to achieve statistical significance. The second efficacy trial will likely commence following the interim analysis of the first trial.

- Two six-month GI-safety trials will be conducted so that the company can obtain a label for otenaproxesul that does not include the 'black box' warning regarding GI toxicity that is found on the labels for all NSAIDs.

- Safety data out to one year that will likely be collected from an open-label extension trial of the efficacy studies.

Additional development activities will include an absorption, metabolism, and excretion (ADME) study in the fourth quarter of 2020. The company has also initiated Phase 3-enabling animal toxicity and reproductive toxicity studies in rats, pigs, and rabbits. The short range studies are expected to be completed by the first quarter of calendar 2021 such that the 12-week dosing portion of the Phase 3 trial can initiate while the long-range studies are expected to conclude in the third quarter of calendar 2021 such that the 24-week Phase 3 GI safety studies can commence.

We anticipate partnering discussions with potential global and regional partners to accelerate now that the Phase 2 trials are completed. Antibe will be actively advancing toward initiation of a Phase 3 trial while simultaneously engaging with potential partners. While we continue to believe a partnership with a major, global pharmaceutical company is likely, we are unsure of the timing for such an agreement knowing that these arrangements can take a considerable amount of time to pull together.

Financial Update

On August 24, 2020, Antibe announced financial results for the first quarter of fiscal year 2021 that ended June 30, 2020. The company reported revenues of CAD$1.2 million for the three months ending June 30, 2020 compared to revenues of CAD$2.8 million for the three months ending June 30, 2019. Sales were lower due to the impact of COVID-19 as many dental clinics closed for much of the quarter.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation totaled CAD$5.4 million for the first quarter of fiscal year 2021 compared to CAD$4.2 million for the first quarter of fiscal year 2020. The increase was primarily related to the following:

- G&A expenses were CAD$1.8 million in 1QFY21 compared to CAD$1.2 million in 1QFY20. The increase was primarily due to higher professional and consulting fees.
- Selling and marketing costs were CAD$0.4 million in 1QFY21 compared to CAD$1.0 million in 1QFY20. The decrease was due to lower salaries, commissions, travel, and entertainment costs.
- R&D expenses were CAD$2.1 million in 1QFY21 compared to CAD$0.9 million in 1QFY20. The increase was primarily due to higher salaries, professional and consulting fees, and research and clinical trial costs.
- Stock-based compensation in 1QFY21 was CAD$1.0 million compared to CAD$1.1 million in 1QFY20 due to expensing of previously granted RSUs.
- Amortization and depreciation was CAD$0.1 million in both 1QFY21 and 1QFY20.

As of June 30, 2020, Antibe reported cash and cash equivalents of approximately CAD$30.8 million, due in part to: 1) from April 1, 2020 through July 24, 2020, the company raised approximately CAD$1.2 million from exercised stock options and CAD$3.3 million from exercised warrants; and 2) the company completed a public financing in June 2020 for gross proceeds of CAD$28 million.

As of June 30, 2020, Antibe had approximately 385.5 million shares outstanding and, when considering stock options and warrants, a fully diluted share count of approximately 461.9 million shares. Antibe is preparing for the optimal time to uplist the company's shares to a senior exchange, most likely either the Nasdaq and/or the Toronto Stock Exchange. In addition, the company will be expanding its investor outreach in the coming months to include institutional investors in an effort to expand its shareholder base.

Conclusion

Antibe has a plan in place to get otenaproxesul into a global Phase 3 program, with the first Phase 3 clinical trial likely to start in the Spring of 2021, and subsequent trials initiating over the subsequent months. We are looking forward to continued updates as the company meets with regulatory authorities in the second half of 2020 in preparation for the Phase 3 program. With no changes to our model the valuation remains at CAD$3.00 per share.

PROJECTED FINANCIALS

Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2020 A	Q1 '21 A	Q2 '21 E	Q3 '21 E	Q4 '21 E	FY 2021 E	FY 2022 E	FY 2023 E
Otenaproxesul	**$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	**$10.0**	**$1.2**	**$2.0**	**$2.5**	**$2.5**	**$8.2**	**$11.0**	**$11.0**
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$10.0	$1.2	$2.0	$2.5	$2.5	$8.2	$11.0	$11.0
YOY Growth	*4.7%*	*-55.5%*	*-11.8%*	*-4.2%*	*6.6%*	*-13.7%*	*33.7%*	*0.0%*
Cost of Goods Sold	$6.1	$0.7	$1.3	$1.6	$1.6	$5.2	$6.9	$6.9
Product Gross Margin	*38.9%*	*41.7%*	*35.0%*	*36.0%*	*36.0%*	*36.6%*	*37.3%*	*37.3%*
SG&A	$9.5	$2.2	$2.2	$2.4	$2.6	$9.4	$9.3	$9.5
R&D	$8.1	$2.1	$2.0	$2.2	$2.4	$8.7	$9.0	$10.0
Stock-based compensation	$3.4	$1.0	$1.1	$0.8	$0.8	$3.0	$3.0	$3.0
Impairment of goodwill	$1.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Amortization and Depreciation	$0.6	$0.1	$0.2	$0.1	$0.1	$0.5	$0.5	$0.5
% Other	*5.7%*	*11.2%*	*7.5%*	*5.6%*	*2.9%*	*6.1%*	*4.5%*	*4.5%*
Operating Income	($18.9)	($4.9)	($4.7)	($4.6)	($5.0)	($18.6)	($17.7)	($18.9)
Operating Margin	*-189.4%*	*-400.2%*	*-236.3%*	*-184.1%*	*-198.9%*	*-225.7%*	*-160.9%*	*-171.8%*
Interest Income / Net	($0.4)	($0.0)	($0.1)	($0.0)	($0.2)	($0.8)	($0.8)	($0.8)
Pre-Tax Income	($19.3)	($4.9)	($4.8)	($4.6)	($5.2)	($19.4)	($18.5)	($19.7)
Taxes	($0)	$0	$0	$0	$0	$0	($0)	($0)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($19.3)	($4.9)	($4.8)	($4.6)	($5.2)	($19.4)	($18.5)	($19.7)
Reported EPS	($0.07)	($0.02)	($0.01)	($0.01)	($0.01)	($0.05)	($0.04)	($0.04)
Fully Diluted Shares	272.7	302.9	360.0	385.5	390.0	359.6	450.0	500.0

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

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