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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Antibe Therapeutics Inc. (T.ATE - TSX)

T.ATE: Phase 3 Enabling Activities Ongoing; Phase 3 Adaptive Trial to Initiate 1Q22…

Based on our probability adjusted DCF model that takes into account potential future revenues from otenaproxesul, ATE.T is valued at CAD$24.00 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 (07/01/2021)	CAD$3.67
Valuation	**CAD$24.00**

OUTLOOK

On June 28, 2021, Antibe Therapeutics Inc. (ATE.T) announced financial results for fiscal year 2021 that ended March 31, 2021 and provided a business update. The company is currently conducting Phase 3 enabling activities following the clearance of the IND with the U.S. FDA, including a single-dose study that is underway in 24 healthy subjects. The required absorption, metabolism, and excretion (AME) study is set to initiate soon and it will also help guide the company in dose selection for the Phase 3 adaptive trial, which we anticipate initiating in 1Q22. The company has unified the intellectual property base to strengthen its position with potential partners and the partnering process for large markets (U.S., EU4, UK, Japan) is underway.

SUMMARY DATA

52-Week High	**$7.52**
52-Week Low	**$3.05**
One-Year Return (%)	**-8.40**
Beta	**0.05**
Average Daily Volume (sh)	**91,121**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$191**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**13**
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)
2021	1.2 A	2.9 A	2.8 A	2.8 A	9.7 A
2022	2.8 E	2.8 E	2.8 E	2.8 E	11.2 E
2023					11.4 E
2024					11.6 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2021	-$0.16 A	-$0.23 A	-$0.17 A	-$0.02 A	-$0.71 A
2022	-$0.12 E	-$0.12 E	-$0.12 E	-$0.13 E	-$0.48 E
2023					-$0.44 E
2024					-$0.42 E

WHAT'S NEW

Business Update

Phase 3 Enabling Activities Underway; Phase 3 Adaptive Trial to Initiate 1Q22

Antibe Therapeutics, Inc. (ATE.T) 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 as an important signaling molecule in the body. Results from a Phase 2b efficacy trial of otenaproxesul showed a statistically significantly greater decrease in the change in the WOMAC pain subscale score compared to those administered placebo. In addition, a Phase 2 GI safety study 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 (P<0.001). Thus, otenaproxesul can potentially relieve pain without the GI-related side effects of traditional NSAIDs.

The company has undertaken a number of initiatives as it prepares for the Phase 3 program for otenaproxesul following clearance of the Investigational New Drug (IND) application with the U.S. FDA:

- The first study conducted under the IND is a single-dose trial of otenaproxesul in 24 healthy volunteers that is designed to investigate the pharmacokinetics/pharmacodynamics of the drug in the first hours following dosing.

- The company is preparing to initiate the required absorption, metabolism, and excretion (AME) study in 90 healthy volunteers next week. This is a six-week study in which subjects will receive otenaproxesul daily for four weeks with two weeks of follow up. We anticipate results in the fourth quarter of 2021. Results from the AME study will help guide the company's dose selection for the Phase 3 adaptive trial.

- To help strengthen the company's intellectual property base, in June 2021 Antibe announced an amalgamation transaction in which Antibe Holdings Inc. (which owned the intellectual property covering the hydrogen sulfide technology) became a wholly owned subsidiary of Antibe. Previously, Antibe owed royalties to Antibe Holdings on revenues derived from the intellectual property held by Antibe Holdings, however with the new ownership structure that will no longer be the case.

- Initial partnering discussions for the large markets (U.S., U.K., EU4, Japan) are underway with Antibe eliciting the assistance of a leading global transaction firm.

- We continue to anticipate the company uplisting to the Nasdaq, however the timing of that is still uncertain but may coincide with the initiation of the Phase 3 adaptive trial.

The Phase 3 program for otenaproxesul will consist of the following:

- Two 12-week efficacy trials in patients with knee osteoarthritis 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 will 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.

- One or 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.

Following release of the results from the AME trial the company will hold an 'End-of-Phase 2' meeting with the FDA

(and the equivalent meeting with the EMA) to inform the agency of the final Phase 3 trial design and dose selection. Assuming results from the AME trial are released in the fourth quarter of 2021 and a meeting with the FDA can occur early in 2022, we anticipate the Phase 3 adaptive trial initiating in the first quarter of 2022.

Partnership with Dalriada

In June 2021, Antibe announced a collaboration with Dalriada Drug Discovery to identify new H_2S-releasing entities and fortify the company's IP position for its current pipeline candidates. Dalriada will use its extensive medicinal chemistry capabilities to screen, select, and advance drug candidates for IND-enabling studies, with Antibe retaining ownership of all new IP that derives from those activities. Antibe is first screening candidates to address inflammatory bowel disease (IBD), which affects more than three million adults in North America. The company has previously seen encouraging pre-clinical results with compounds that were tested in animal models of IBD.

Licensing Deal in China

In February 2021, Antibe announced a licensing deal for the company's lead development compound, otenaproxesul (the nonproprietary name for ATB-346), with Nuance Pharma that covers China, Taiwan, Hong Kong, and Macau.

Under the terms of the deal, Antibe received a $20 million upfront payment and is eligible to receive up to $80 million in regulatory and sales milestones along with a double-digit royalty on sales. Nuance will be responsible for clinical and regulatory costs for the region and the two companies put a structure in place for collaborating on otenaproxesul's clinical development in the region so that it aligns with Antibe's global regulatory strategy.

Nuance is a Shanghai-based biopharmaceutical company focused on licensing, developing, and commercializing innovative therapies that address critical unmet needs in China and other emerging Asia Pacific markets. It is an excellent partner for Antibe in that region based on the company's understanding of the Chinese market and their expansive commercial, clinical, and regulatory abilities.

Asia represents an exciting opportunity for Antibe. The market for pain management in China has doubled in the past five years, mostly through increased demand for non-steroidal anti-inflammatory drugs (NSAIDs) like otenaproxesul. The countries represented in this licensing deal represent approximately 10% of the global pharmaceutical market.

Financial Update

On June 28, 2021, Antibe announced financial results for fiscal year 2021 that ended March 31, 2021. The company reported revenue of CAD$9.71 million for fiscal year 2021, compared to CAD$9.67 million for fiscal year 2020. Both sales and margins at Citagenix were negatively impacted by the COVID-19 pandemic in the first quarter of fiscal year 2021, but recovered in fiscal Q2 through Q4.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation totaled CAD$28.3 million for fiscal year 2021, compared to CAD$22.3 million for fiscal year 2020. The increase was primarily related to the following:

- G&A expenses were CAD$7.2 million in FY21 compared to CAD$5.2 million in FY20. The increase was primarily due to higher salaries and wages, professional and consulting fees, and office expenses.
- Selling and marketing costs were CAD$2.7 million in FY21 compared to CAD$3.8 million in FY20. The decrease was due to lower salaries and commissions, advertising, travel, and entertainment costs.
- R&D expenses were CAD$13.4 million in FY21 compared to CAD$8.1 million in FY20. The increase was primarily due to higher development costs for otenaproxesul and required non-clinical studies.
- Stock-based compensation was CAD$4.0 million in FY21, an increase of CAD$0.6 million from FY20 due to expensing of previously granted RSUs.
- Amortization and depreciation was CAD$0.5 million in FY21 compared to CAD$0.6 million in FY20.

As of March 31, 2021, Antibe reported cash and cash equivalents of approximately CAD$72 million, which we estimate is enough to fund operations for the next two years along with fully funding the upcoming Phase 3 adaptive trial. We estimate that Antibe currently has approximately 51.6 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 64.4 million.

Conclusion

Antibe is well on its way to getting the Phase 3 program for otenaproxesul underway with the initiation of the AME trial starting very soon. We don't anticipate any issues with the company completing that trial in a timely manner and it should lead to the initiation of the Phase 3 adaptive trial in the first quarter of 2022. While partnering efforts are underway for the large global markets, it will likely be a while before the company is able to share any details as it is a notoriously long process. Upcoming milestones for the second half of 2021 include the data readout for the AME trial and the 'End-of-Phase 2' meeting with the FDA, with the timing of that meeting dictating how quickly the Phase 3 adaptive trial can get underway. After incorporating the financing in February 2021, the IP consolidation (which included issuing approximately 5.8 million shares to the owners of Antibe Holdings Inc.), and the change in the exchange rate our valuation has decreased to CAD$24.00 per share. However, there continues to exist a very large disconnect between our valuation and the share price, which investors could use to build or add to a position ahead of multiple catalysts by the end of 2021.

PROJECTED FINANCIALS

Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2021 A	Q1 '22 E	Q2 '22 E	Q3 '22 E	Q4 '22 E	FY 2022 E	FY 2023 E	FY 2024 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	**$9.7**	**$2.8**	**$2.8**	**$2.8**	**$2.8**	**$11.2**	**$11.4**	**$11.6**
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$9.7	$2.8	$2.8	$2.8	$2.8	$11.2	$11.4	$11.6
YOY Growth	*1.8%*	*127.8%*	*-2.3%*	*0.3%*	*-0.9%*	*15.3%*	*1.8%*	*1.8%*
Cost of Goods Sold	$6.2	$1.8	$1.8	$1.8	$1.8	$7.2	$7.2	$7.2
Product Gross Margin	*36.5%*	*35.7%*	*35.7%*	*35.7%*	*35.7%*	*35.7%*	*36.8%*	*37.9%*
SG&A	$7.2	$2.2	$2.4	$2.5	$2.6	$9.7	$9.8	$10.0
R&D	$13.4	$3.0	$3.3	$3.5	$3.8	$13.6	$14.0	$15.0
Selling and marketing	$2.7	$0.6	$0.6	$0.6	$0.6	$2.4	$2.4	$2.4
Stock-based compensation	$4.0	$1.0	$1.0	$1.0	$1.0	$4.0	$4.0	$4.0
Impairment of goodwill	$0.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Amortization and Depreciation	$0.5	$0.1	$0.1	$0.1	$0.1	$0.5	$0.5	$0.5
Operating Income	($24.7)	($5.3)	($5.8)	($6.1)	($6.5)	($23.8)	($24.1)	($25.1)
Operating Margin	*-254.4%*	*-190.7%*	*-208.5%*	*-217.9%*	*-232.1%*	*-212.3%*	*-211.4%*	*-216.4%*
Interest Income / Net	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($24.7)	($5.3)	($5.8)	($6.1)	($6.5)	($23.8)	($24.1)	($25.1)
Taxes	$0	$0	$0	$0	$0	$0	($0)	($0)
Net Income	($24.7)	($5.3)	($5.8)	($6.1)	($6.5)	($23.8)	($24.1)	($25.1)
Loss from Discontinued Operations	($1.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Exchange differences on translation of foreign operations	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Comprehensive Loss	($26.3)	($5.3)	($5.8)	($6.1)	($6.5)	($23.8)	($24.1)	($25.1)
Reported EPS	($0.71)	($0.12)	($0.12)	($0.12)	($0.13)	($0.48)	($0.44)	($0.42)
Fully Diluted Shares	37.3	46.0	50.0	51.0	52.0	49.8	55.0	60.0

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

HISTORICAL STOCK PRICE

Source: Stockcharts.com

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