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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.

(V.ATE - TSX)

V.ATE: Positive Results for Phase 2b Efficacy Trial of ATB-346; Valuation Increased to CAD$3.00…

Based on our probability adjusted DCF model that takes into account potential future revenues from ATB-346 ATE.V is valued at CAD$3.00 per share. This model is highly dependent upon continued clinical success of ATB-346 and will be adjusted accordingly based upon future clinical results and the company's execution.

Current Price (06/08/2020)	CAD$0.51
Valuation	**CAD$3.00**

OUTLOOK

On June 1, 2020, Antibe Therapeutics Inc. (ATE.V) announced positive topline results for the Phase 2b dose-ranging efficacy study of the company's lead development compound (ATB-346) in patients with osteoarthritis. A total of 385 patients were randomized to once daily placebo or ATB-346 at 250 mg, 200 mg, or 150 mg. Both the 250 mg (*P*=0.01) and 200 mg (*P*=0.007) doses achieved statistical significance compared to placebo for the primary endpoint in the change from baseline in the WOMAC pain subscale at the end of the 14-day treatment period. The company will be meeting with the FDA for an 'End-of-Phase 2' meeting during the fourth quarter of 2020 in the hopes of initiating a pivotal Phase 2/3 adaptive design trial in the first quarter of 2021.

SUMMARY DATA

52-Week High	**$0.89**
52-Week Low	**$0.28**
One-Year Return (%)	**10.64**
Beta	**-0.38**
Average Daily Volume (sh)	**2,130,000**
Shares Outstanding (mil)	**309**
Market Capitalization ($mil)	**$158**
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)
2019	2.5 A	2.1 A	2.5 A	2.4 A	9.5 A
2020	2.8 A	2.3 A	2.6 A	2.4 E	10.0 E
2021					10.0 E
2022					11.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2019	-$0.01 A	-$0.01 A	-$0.01 A	-$0.02 A	-$0.06 A
2020	-$0.01 A	-$0.02 A	-$0.02 A	-$0.01 E	-$0.06 E
2021					-$0.04 E
2022					-$0.04 E

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WHAT'S NEW

Business Update

Positive Topline Results for Phase 2b Efficacy Trial of ATB-346

On June 1, 2020, Antibe Therapeutics Inc. (ATE.V) announced positive topline results from the Phase 2b dose-ranging, efficacy trial of ATB-346. 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 ATB-346: 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 ATB-346 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 following table shows the numerical change from baseline in the WOMAC pain score at both Day 4 and Day 14. The change in the placebo cohort was typical of what is seen in a study such as this, and we anticipate that the decline in the WOMAC pain score in the ATB-346 cohorts would have continued lower had the trial been conducted for longer time period.

	Placebo	ATB-346 (250 mg)	ATB-346 (200 mg)	ATB-346 (150 mg)
WOMAC pain score at baseline (day 0)	325.7	318.5	325.2	325.8
WOMAC pain score at day 4	261.4	229.8	237.4	230.2
Reduction versus baseline at day 4 (%)	*20.3%*	*28.3%*	*27.3%*	*29.3%*
WOMAC pain score at day 14	228.2	183.2	183.8	203.4
Reduction versus baseline at day 14 (%)	*32.7%*	*43.6%*	*43.7%*	*39.3%*
Primary endpoint: p-value versus placebo (day 14)	-	**0.01**	**0.007**	**0.13**

WOMAC scores based on 500-point Likert scale; reduction figures normalized to 100mm WOMAC pain subscale
Study population: 250 mg = 132 patients; 200 mg = 123 patients; 150 mg = 60 patients; placebo = 66 patients

Source: Antibe Therapeutics

The following table shows that ATB-346 treatment also resulted in highly statistically significant reductions in the WOMAC stiffness subscale score (*P*<0.001 for 250 mg and 200 mg cohorts) and the WOMAC DPDA subscale score (*P*=0.004 and *P*=0.001 for 250 mg and 200 mg cohorts, respectively). These results are very impressive and show the wide therapeutic window that ATB-346 has given that the lowest effective dose has yet to be identified. In addition, having a significant effect on clinically relevant endpoints such as the stiffness and DPDA subscales is particularly important.

	Placebo	ATB-346 (250 mg)	ATB-346 (200 mg)	ATB-346 (150 mg)
WOMAC stiffness reduction versus baseline (%)	23.8%	41.7%	40.5%	36.2%
p-value versus placebo (day 14)	-	**< 0.001**	**< 0.001**	**0.03**
WOMAC DPDA reduction versus baseline (%)	24.3%	38.4%	40.1%	32.5%
p-value versus placebo (day 14)	-	**0.004**	**0.001**	**0.106**

Source: Antibe Therapeutics

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). The company reported that there were very few serious adverse events or events leading to withdrawal of treatment. Importantly, only 1 of 318 patients administered any dose of ATB-346 had clinically significant, temporary liver transaminase elevations

(LTEs) during the 14-day treatment period. At follow up (Day 24), the percentage of patients in the 250 mg, 200 mg, and 150 mg cohorts who had clinically significant, temporary LTEs was 12.1%, 8.0%, and 8.2%, respectively. After accounting for factors that typically lead to LTEs (e.g., acetaminophen use, statin use, pre-existing liver injury) the rate of clinically significant, temporary LTEs decreased to 4.5%, 3.2%, and 3.3% for the 250 mg, 200 mg, and 150 mg doses, respectively. These numbers are in line with what is typically seen in clinical trials of NSAIDs (Sriuttha *et al*., 2018) and well below the 39% incidence of LTEs in those taking acetaminophen chronically (NIH).

Patient-reported adverse event (>= 2%)	Placebo	ATB-346 (150 mg)	ATB-346 (200 mg)	ATB-346 (250 mg)
Dyspepsia	1.5%	1.6%	4.8%	4.5%
Constipation	0.0%	4.9%	1.6%	1.5%
Diarrhea	7.6%	1.6%	1.6%	1.5%
Nausea	1.5%	1.6%	1.6%	3.0%
Dizziness	0.0%	0.0%	1.6%	3.8%
Gastroesophageal reflux disease	3.0%	3.3%	0.8%	3.0%
Abdominal pain	0.0%	0.0%	0.8%	2.3%
Abdominal pain upper	1.5%	1.6%	0.8%	2.3%
Faeces soft	3.0%	0.0%	0.0%	0.8%
Pain	3.0%	0.0%	0.8%	2.3%
Headache	3.0%	3.3%	3.2%	7.6%
Nasopharyngitis	4.5%	1.6%	0.8%	3.0%
Urinary tract infection	0.0%	3.3%	3.2%	0.0%

Source: Antibe Therapeutics

Antibe is continuing to analyze the data from the trial and is planning to publish the full results in a peer reviewed journal later this year. Later in the year (likely 4Q20) the company will hold an 'End-of-Phase 2' meeting with the FDA along with meeting with the EMA to discuss the Phase 3 program for ATB-346. While we await word on the specific details of the program, we believe it will involve:

- Two 12-week efficacy trials that will include lower doses of ATB-346 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 ATB-346 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.

Now that the company has the efficacy data in hand, we anticipate partnering discussions with potential global and regional partners to accelerate. Antibe's goal has always been to sign a partnership agreement ahead of initiating the Phase 3 program, however at this point the company is moving timelines along as though it will begin the first Phase 3 trial on its own. 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.

Conclusion and Valuation

The efficacy results from the Phase 2b trial are as good as could have been hoped for and represent a significant inflection point for the company. The fact that the lowest effective dose has yet to be established is a positive, as moving to lower doses may improve an already good safety and tolerability profile. We find very little to be concerned with regarding the data, as even the LTE rate is in line with other NSAID trials after accounting for various confounding factors. With robust efficacy and unparalleled GI safety data in hand the company will be in a strong negotiating position as partnering discussions ramp up. Based on the results, we have increased the probability of approval to 80%, decreased the discount rate to 13%, and increased estimated global peak sales for ATB-346 to $3.0 billion. Based on these changes our valuation has increased to CAD$3.00. We were confused by the sell-off following the data release, which may have been the result of misunderstandings surrounding the data, and would view any continued weakness as a tremendous buying opportunity.

PROJECTED FINANCIALS

Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2019 A	Q1 '20 A	Q2 '20 A	Q3 '20 A	Q4 '20 E	FY 2020 E	FY 2021 E	FY 2022 E
ATB-346 (royalty)	**$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	**$9.5**	**$2.8**	**$2.3**	**$2.6**	**$2.4**	**$10.0**	**$10.0**	**$11.0**
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$9.5	$2.8	$2.3	$2.6	$2.4	$10.0	$10.0	$11.0
YOY Growth	*12.1%*	*8.6%*	*9.7%*	*4.5%*	*-1.2%*	*5.3%*	*4.8%*	*10.0%*
Cost of Goods Sold	$6.0	$1.7	$1.3	$1.7	$1.5	$6.2	$6.3	$6.9
Product Gross Margin	*37.2%*	*37.5%*	*41.4%*	*36.6%*	*37.5%*	*38.2%*	*37.0%*	*37.3%*
SG&A	$8.4	$2.1	$2.2	$2.6	$2.0	$8.9	$9.0	$9.3
% SG&A	*88.0%*	*76.3%*	*96.5%*	*98.8%*	*83.3%*	*88.4%*	*90.0%*	*84.5%*
R&D	$3.9	$0.9	$2.4	$1.6	$1.2	$6.1	$4.7	$4.9
% R&D	*41.3%*	*32.8%*	*104.6%*	*63.0%*	*50.0%*	*61.0%*	*47.0%*	*44.5%*
Stock-based compensation	$3.0	$1.1	$1.1	$0.8	$0.8	$3.7	$3.0	$3.0
% Stock-based	*31.3%*	*38.3%*	*47.4%*	*29.2%*	*33.3%*	*36.8%*	*30.0%*	*27.3%*
Amortization and Depreciation	$0.4	$0.1	$0.2	$0.1	$0.1	$0.6	$0.5	$0.5
% Other	*4.4%*	*5.2%*	*6.6%*	*5.4%*	*5.4%*	*5.6%*	*5.0%*	*4.5%*
Operating Income	($12.2)	($3.2)	($4.8)	($4.2)	($3.2)	($15.4)	($10.5)	($10.6)
Operating Margin	*-127.8%*	*-114.9%*	*-213.7%*	*-159.8%*	*-134.6%*	*-153.6%*	*-105.0%*	*-96.4%*
Interest Income / Net	($0.5)	($0.1)	($0.1)	($0.0)	($0.2)	($0.4)	($0.8)	($0.8)
Pre-Tax Income	($12.7)	($3.3)	($5.0)	($4.2)	($3.4)	($15.9)	($11.3)	($11.4)
Taxes	$0	($0)	$0	$0	$0	($0)	($0)	($0)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($12.8)	($3.3)	($5.0)	($4.2)	($3.4)	($15.8)	($11.3)	($11.4)
Reported EPS	($0.06)	($0.01)	($0.02)	($0.02)	($0.01)	($0.06)	($0.04)	($0.04)
Fully Diluted Shares	214.9	244.5	260.0	278.9	281.0	266.1	300.0	320.0

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

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