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Antibe Therapeutics Inc.

(T.ATE - TSX)

T.ATE: On Track to Initiate Phase 2 Trial for Otenaproxesul in 1H23…

Based on our probability adjusted DCF model that takes into account potential future revenues from otenaproxesul, ATE.T is valued at CAD$5.00 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 (11/22/2022)	CAD$0.48
Valuation	**CAD$5.00**

OUTLOOK

On November 15, 2022, Antibe Therapeutics Inc. (ATE.T) announced financial results for the second quarter of fiscal year 2023 that ended September 30, 2022 and provided a business update. In October 2022, the company announced a faster-dissolving formulation for otenaproxesul that includes filing a patent application to strengthen the drug's IP protection to 2042. The company has decided to forego the planned molar extraction study and will instead focus on the Phase 2 bunionectomy trial, which we anticipate starting up in the first half of 2023. We also anticipate the company selecting a lead candidate for the inflammatory bowel disease program before the end of 2022.

SUMMARY DATA

52-Week High	**$0.84**
52-Week Low	**$0.47**
One-Year Return (%)	**-40.00**
Beta	**-0.05**
Average Daily Volume (sh)	**19,230**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$25**
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	**Average**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of CAD$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	2.7 A	0.0 A	0.0 A	0.0 A	2.7 A
2023	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2024					0.0 E
2025					0.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	-$0.16 A	-$0.17 A	-$0.09 A	-$0.09 A	-$0.50 A
2023	-$0.11 A	-$0.12 A	-$0.12 E	-$0.12 E	-$0.46 E
2024					-$0.47 E
2025					-$0.46 E

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WHAT'S NEW

Business Update

Update on Otenaproxesul

Antibe Therapeutics, Inc. (ATE.T) is developing otenaproxesul as a solution to the dose-related gastrointestinal (GI) side effects associated with non-steroidal 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, which is a gas that serves as an important signaling molecule in the body.

In October 2022, the company announced a new faster-dissolving formulation for otenaproxesul that has some important advantages: 1) its rapid dissolution mechanics should help to accelerate the drug's onset of action, which will be crucial in an acute pain setting; 2) enhanced bioavailability should lead to a reduction in dose compared to the prior formulation; and 3) the company has filed a patent application based on the new formulation that should extend IP protection to 2042.

The company had previously planned to initiate a Phase 2 molar extraction study, however it has decided to forego that trial and to instead focus on initiating the previously planned Phase 2 bunionectomy trial with the new formulation in the first half of 2023. Details regarding that trial will likely be announced by the company as it gets closer to starting. If successful, Antibe will request an 'End-of-Phase 2' meeting with the FDA to discuss the Phase 3 program. The FDA requires two pivotal trials for an approval in post-operative pain. The bunionectomy trial is typically used as a "hard tissue model" while an abdominoplasty can serve as a "soft tissue model". Positive results in both those trials should allow Antibe to apply for marketing approval for a broad acute pain indication.

Antibe recently completed a comprehensive third-party assessment on the acute pain market that included focus groups and an in-depth survey of medical specialists who treat acute pain on a daily basis. The assessment considered the potential use of otenaproxesul in post-operative pain, acute musculoskeletal pain, dysmenorrhea, migraine, and gout. For the U.S. market, the assessment projects peak annual sales for otenaproxesul of US$1 billion. Physician response indicated a potential 50% adoption rate for post-operative pain and 30% for all other cases. Doctors who prescribe NSAIDs and opioids showed the highest interest in otenaproxesul and cited gastrointestinal safety as the principal safety concern for NSAID use. The assessment was conducted by Shift Health, a life science strategy consultancy.

In September 2022, an academic collaborator presented a poster at the PAINWeek National Conference that detailed otenaproxesul's ability to reduce pain and inflammation (Glanville *et al*., 2022). Compared to untreated controls, otenaproxesul significantly inhibited neutrophil infiltration at the site of inflammation at four hours. In addition, HLA-DR-T/NK cells were significantly lower in the otenaproxesul group compared to untreated controls. This data serves as excellent proof-of-concept for otenaproxesul's acute pain management.

Post-operative Pain Market

Post-operative pain represents a large opportunity for Antibe with an estimated global market size of US$13 billion. The most commonly prescribed medications to control post-operative pain are opioids and NSAIDs. Newer prescription therapies include the following, and while indicated for only certain surgical procedures they are forecast to derive substantial future revenues:

Zynrelef®: This is a combination of bupivacaine and meloxicam that is approved for postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty. It is a single use application into the surgical site following final irrigation and suction but prior to suturing. While treatment with Zynrelef resulted in a significant reduction in pain intensity compared to those treated with bupivacaine or placebo for up to 72 hours, it is only indicated for specific surgical procedures. The drug launched in July 2021 and is forecast to generate revenues of $474 million by 2026 (EvaluatePharma).

Dextenza®: This is an ophthalmic insert that releases dexamethasone for up to 30 days. It is intended for the treatment of ocular inflammation and pain following ophthalmic surgery. In three clinical trials, treatment with Dextenza resulted in a higher proportion of patients who were pain free on post-operative Day 8 when compared to those treated with placebo. The drug launched in July 2019 and is forecast to generate revenues of $133 million by

2026 (EvaluatePharma).

In addition to likely being utilized as a general therapy for post-operative pain, as opposed to be restricted to only certain surgical procedures like the aforementioned therapies, otenaproxesul has a number of positive characteristics that sets it apart from the two most commonly prescribed drug classes for post-operative pain (NSAIDs and opioids):

- The U.S. is currently experiencing an ever-growing opioid epidemic, thus a drug that could provide similar pain relief to opioids without the fear of addiction is desperately needed. Otenaproxesul has no addiction-related issues.

- While able to provide effective pain relief, NSAIDs are known to have GI safety issues. Antibe has previously shown in a Phase 2b GI safety study that following 14 days of dosing, those administered naproxen had a 42% incidence of ≥3 mm ulcers compared to 2.5% for those administered otenaproxesul.

Sale of Citagenix Inc.

In November 2022, Antibe announced the closing of the previously announced sale of its Citagenix Inc. subsidiary to HANSAmed Limited for CAD$6.5 million. HANSAmed Limited is a Canadian full-service distributor of pharmaceuticals and medical devices to dental professionals. The CAD$6.5 million transaction includes a guaranteed $3.5 million divided into four equal payments over three years, with the first payment having occurred at closing. The remaining $3 million will be subject to Citagenix achieving sales milestones over the three-year period following closing.

Financial Update

On November 15, 2022, Antibe announced financial results for the second quarter of fiscal year 2023 that ended September 30, 2022. General and administrative, selling and marketing, research and development, and stock-based compensation totaled CAD$6.5 million for the three months ending September 30, 2022 compared to CAD$8.4 million for the second quarter of fiscal year 2022. The decrease was primarily related to the following:

- G&A expenses were CAD$1.7 million in 2QFY23 compared to CAD$1.6 million in 2QFY22. The increase was primarily due to higher salaries and wages along with professional and consulting fees partially offset by lower office expenses.
- Selling and marketing costs were CAD$0.1 million in 2QFY23 compared to CAD$0.09 million in 2QFY22. The increase was due to higher advertising and promotion costs along with increased travel and entertainment costs.
- R&D expenses were CAD$3.8 million in 2QFY23 compared to CAD$5.2 million in 2QFY22. The decrease was primarily due to lower development costs for otenaproxesul studies and pill manufacturing partly offset by higher professional and consulting fees.
- Stock-based compensation was CAD$0.8 million in 2QFY23 compared to CAD$1.5 million in 2QFY22 due to expensing of previously grants RSUs.

As of September 30, 2022, Antibe reported cash, cash equivalents, and term deposits of approximately CAD$45.4 million, which we estimate is enough to fund operations for at least the next two years. Antibe currently has approximately 52.1 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 62.6 million.

Conclusion

The new formulation for otenaproxesul is an exciting development for the company as it not only should lead to lower dosing but also extends the IP protection out to 2042. We look forward to the initiation of the Phase 2 bunionectomy trial in the first half of 2023. Investors should be aware that with the short duration of acute pain trials, the development pathway for otenaproxesul could potentially be completed in 12-18 months. Lastly, the company is expected to select a lead development candidate for the inflammatory bowel disease program before the end of 2022, which offers upside to the story. We have made no changes to our model and our valuation remains at CAD$5.00 per share.

PROJECTED FINANCIALS

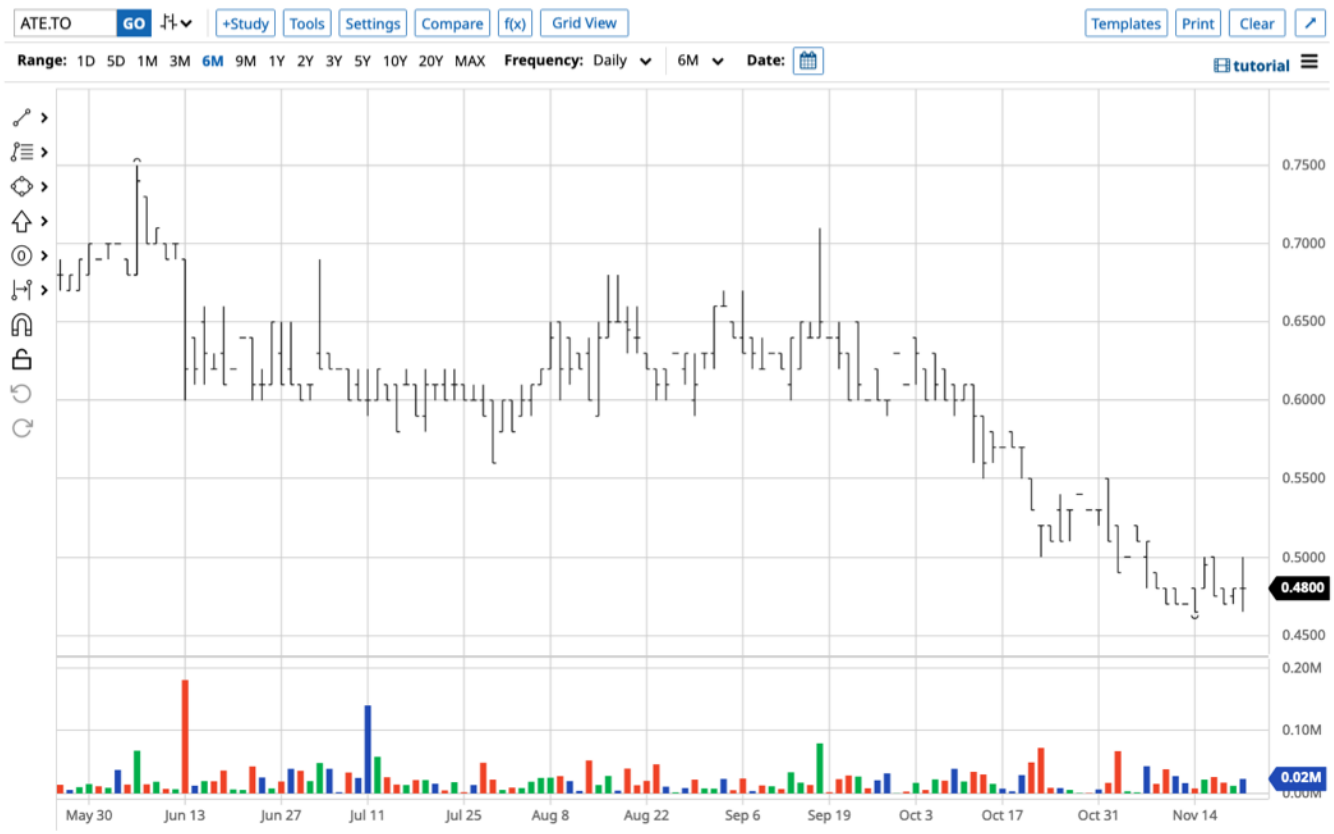
Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY 2022 A	Q1 '23 A	Q2 '23 A	Q3 '23 E	Q4 '23 E	FY 2023 E	FY 2024 E	FY 2025 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**
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
SG&A	$5.4	$1.1	$1.7	$1.4	$1.5	$5.8	$5.8	$6.0
R&D	$14.4	$3.8	$3.9	$3.3	$3.5	$14.5	$14.0	$15.0
Selling and marketing	$0.2	$0.1	$0.1	$0.0	$0.0	$0.2	$0.0	$0.0
Stock-based compensation	$5.5	$0.7	$0.8	$1.5	$1.5	$4.5	$6.2	$6.4
Impairment of goodwill	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Amortization and Depreciation	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($25.5)	($5.8)	($6.5)	($6.2)	($6.5)	($25.0)	($26.0)	($27.4)
Interest Income / Net	$0.3	$0.2	$0.3	$0.0	$0.0	$0.5	$0.0	$0.0
Pre-Tax Income	($25.3)	($5.6)	($6.2)	($6.2)	($6.5)	($24.5)	($26.0)	($27.4)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($25.3)	($5.6)	($6.2)	($6.2)	($6.5)	($24.5)	($26.0)	($27.4)
Loss from Discontinued Operations	$0.2	$0.1	$0.2	$0.0	$0.0	$0.2	$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	($25.1)	($5.5)	($6.1)	($6.2)	($6.5)	($24.3)	($26.0)	($27.4)
Reported EPS	($0.50)	($0.11)	($0.12)	($0.12)	($0.12)	($0.46)	($0.47)	($0.46)
Fully Diluted Shares	50.8	52.1	52.1	53.5	54.0	52.9	55.0	60.0

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

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