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Antibe Therapeutics Inc. (OTCQX: ATBPF)

ATBPF: Plans on Track for Acute Pain Program for Otenaproxesul…

Based on our probability adjusted DCF model that takes into account potential future revenues from otenaproxesul, ATBPF is valued at $4.00 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 (09/07/2022)	$0.49
Valuation	**$4.00**

OUTLOOK

On August 15, 2022, Antibe Therapeutics Inc. (ATBPF) announced financial results for the first quarter of fiscal year 2023 that ended June 30, 2022 and provided a business update. Antibe will be conducting a Phase 2 molar (wisdom tooth) extraction study in order to obtain PK/PD data and other exploratory pain endpoints in post-operative patients. We anticipate that study initiating this quarter and completing by the end of 2022. Results should be available in January 2023. Assuming everything goes as planned, this would lead to the previously planned bunionectomy study initiating in the first half of 2023. Antibe will also be testing three additional candidates for the inflammatory bowel disease program and we anticipate a lead candidate being chosen before the end of calendar 2022.

SUMMARY DATA

52-Week High	**$1.02**
52-Week Low	**$0.45**
One-Year Return (%)	**-50.96**
Beta	**0.28**
Average Daily Volume (sh)	**6,480**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$26**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**0**
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	**Average**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	2.2 A	0.0 A	0.0 A	0.0 A	2.2 A
2023	0.0 A	0.0 E	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	-$0.12 A	-$0.13 A	-$0.07 A	-$0.07 A	-$0.38 A
2023	-$0.09 E	-$0.09 E	-$0.09 E	-$0.09 E	-$0.35 E
2024					-$0.36 E
2025					-$0.35 E

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WHAT'S NEW

Business Update

Phase 2 Post-Operative Pain Program to Initiate in Calendar 4Q22

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.

The company is developing otenaproxesul for the management of acute pain, with an initial indication of post-operative pain. The most recent pharmacokinetic/pharmacodynamic (PK/PD) study conducted by Antibe examined various loading doses of otenaproxesul. The results from this study suggests that the drug has a potentially rapid onset of action that would be necessary for an acute pain treatment.

While two other PK/PD studies had been planned in healthy volunteers, the company has decided to instead focus on a Phase 2 study molar (wisdom teeth) extraction study to obtain additional data in post-operative patients. Approximately 80 patients will be randomized to one of two dosing groups; half of the study subjects will be evaluated through PK/PD measurements as a primary outcome while the other half of patients will be evaluated using exploratory pain scores. We believe this study could be performed rather quickly and it should be completed by the end of calendar 2022 with results likely in January 2023.

Results from the molar study will help guide dose selection for the previously planned Phase 2 bunionectomy study. 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.

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 May 2022, Antibe announced the signing of a binding agreement to sell 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 occurring at closing. The remaining $3 million will be subject to Citagenix achieving sales milestones over the three-year period following closing.

Changes to Board of Directors

In May 2022, Antibe announced the appointment of Robert E. Hoffman, a Director of the company, as the new Chair of its Board of Directors. Mr. Hoffman is the current President, CEO, and Chairman of Kintara Therapeutics. He is the former CFO of Heron Pharmaceuticals, a commercial stage company with a recently approved acute pain drug. During his time at Heron, the company raised $650 million and launched its second commercial therapeutic. Mr. Hoffman's career began at Arena Pharmaceuticals where he eventually rose to the role of CFO. During his time at Arena, he was involved in its IPO and financings that raised more than $1.5 billion.

Antibe also created two corporate Vice Chair positions to recognize the contributions of Walt Macnee, the outgoing Chair, and Dr. John Wallace, Chief Scientific Officer and Director since he founded the company. Both individuals will continue to serve on the Board of Directors. Dr. Wallace will also be returning to work as a research scientist, with a focus on contributions to the company's pipeline.

Financial Update

On August 15, 2022, Antibe announced financial results for the first quarter of fiscal year 2023 that ended June 30, 2022. General and administrative, selling and marketing, research and development, and stock-based compensation totaled CAD$5.8 million for the three months ending June 30, 2022 compared to CAD$6.5 million for the first quarter of fiscal year 2022. The increase was primarily related to the following:

- G&A expenses were CAD$1.1 million in 1QFY23 compared to CAD$1.3 million in 1QFY22. The decrease was primarily due to decreased salaries and wages along with professional and consulting fees partially offset by higher office expenses.
- Selling and marketing costs were CAD$0.09 million in 1QFY23 compared to CAD$0.11 million in 1QFY22. The decrease was due to lower advertising and promotion costs partially offset by increased travel and entertainment costs.
- R&D expenses were CAD$3.8 million in 1QFY23 compared to CAD$3.2 million in 1QFY22. The increase was primarily due to higher salaries and wages and professional and consulting fees partially offset by decreased research and clinical trial costs.
- Stock-based compensation was CAD$0.7 million in 1QFY23 compared to CAD$1.8 million in 1QFY22 due to expensing of previously grants RSUs.

As of June 30, 2022, Antibe reported cash, cash equivalents, and term deposits of approximately CAD$50.2 million, which we estimate is enough to fund operations for at least the next two years. We estimate that Antibe currently has approximately 52.1 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 62.7 million.

Conclusion

We look forward to the company initiating the Phase 2 post-operative pain program for otenaproxesul, with results from the molar study likely January 2023. This would lead to the Phase 2 bunionectomy study initiating in the first half of 2023. With over two years of cash, the company is well financed to complete these studies. We have made no changes to our model and our valuation remains at $4.00 per share.

PROJECTED FINANCIALS

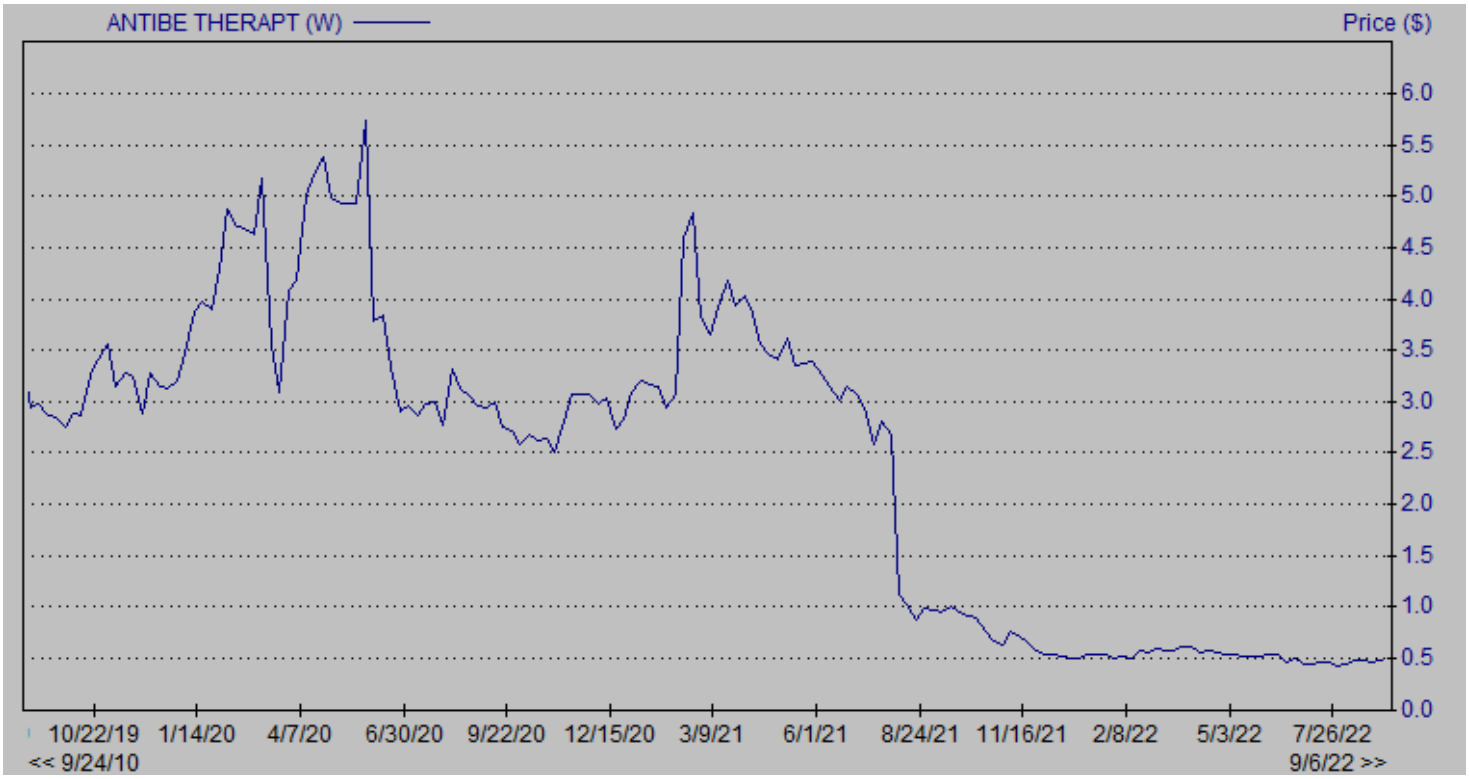
Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Fiscal Year Ends Mar. 31 / in US Dollars	FY 2022 E	Q1 '23 A	Q2 '23 E	Q3 '23 E	Q4 '22 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
SG&A	$4.2	$0.9	$1.0	$1.1	$1.1	$4.1	$4.4	$4.6
R&D	$11.1	$2.9	$2.4	$2.5	$2.7	$10.5	$10.6	$11.4
Selling and marketing	$0.2	$0.1	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Stock-based compensation	$4.3	$0.6	$1.1	$1.1	$1.1	$4.0	$4.7	$4.9
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	($19.7)	($4.4)	($4.6)	($4.7)	($4.9)	($18.6)	($19.8)	($20.8)
Interest Income / Net	$0.2	$0.1	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($19.4)	($4.3)	($4.6)	($4.7)	($4.9)	($18.5)	($19.8)	($20.8)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($19.4)	($4.3)	($4.6)	($4.7)	($4.9)	($18.5)	($19.8)	($20.8)
Loss from Discontinued Operations	$0.1	$0.1	$0.0	$0.0	$0.0	$0.1	$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	($19.3)	($4.2)	($4.6)	($4.7)	($4.9)	($18.4)	($19.8)	($20.8)
Reported EPS	($0.38)	($0.08)	($0.09)	($0.09)	($0.09)	($0.35)	($0.36)	($0.35)
Fully Diluted Shares	50.8	52.1	53.0	53.5	54.0	53.2	55.0	60.0

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

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HISTORICAL STOCK PRICE



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