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Antibe Therapeutics Inc.

(OTCQX: ATBPF)

ATBPF: First Human PK/PD Studies Underway in Otenaproxesul's Post-Operative Pain Program…

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 (02/16/2022)	$0.56
Valuation	**$4.00**

OUTLOOK

On February 14, 2022, Antibe Therapeutics, Inc. (ATBPF) announced financial results for the third quarter of fiscal year 2022 and provided a business update. The company announced that the first human pharmacokinetic/pharmacodynamic (PK/PD) study is underway in otenaproxesul's post-operative pain program. There are a series of PK/PD studies planned over the next 6-9 months that are focused on determining the optimum dosing regimen for post-operative pain. Assuming the PK/PD studies go as planned, the company should be in a position to initiate a Phase 2 bunionectomy trial in the fourth quarter of 2022.

SUMMARY DATA

52-Week High	**$5.54**
52-Week Low	**$0.50**
One-Year Return (%)	**-89.56**
Beta	**0.25**
Average Daily Volume (sh)	**14,046**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$29**
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	**Above Avg.**
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)
2021	0.9 A	2.2 A	2.2 A	2.2 A	7.7 A
2022	2.2 A	0.0 A	0.0 A	0.0 E	2.2 E
2023					0.0 E
2024					0.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2021	-$0.12 A	-$0.16 A	-$0.13 A	-$0.02 A	-$0.56 A
2022	-$0.10 A	-$0.13 A	-$0.07 A	-$0.12 E	-$0.43 E
2023					-$0.44 E
2024					-$0.42 E

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WHAT'S NEW

Business Update

First Human PK/PD Studies Underway in Post-Operative Pain Program

Antibe Therapeutics, Inc. (ATBPF) 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 gasotrasmitter, which is a gas that serves as an important signaling molecule in the body.

The company had previously been developing otenaproxesul as a treatment for chronic pain. However, results obtained during an absorption, metabolism, and excretion (AME) study, which showed six patients experienced liver transaminase elevations (LTEs) exceeding five times the upper limit of normal (ULN), led the company to transition otenaproxesul to the management of acute pain, with an initial indication of post-operative pain.

Prior to initiating a clinical trial in post-operative pain, the company first needs to establish the optimal dose and dosing regimen for that indication. This will be determined through a series of short pharmacokinetic/pharmacodynamic (PK/PD) studies in healthy volunteers including:

- A comparator study between naproxen and celecoxib in which subjects will be administered standard daily doses of each drug in order to get accurate readings on the PK/PD of each drug as well as information on COX-1/COX-2 inhibition. This study is currently underway and we anticipate it should be completed by the end of April 2022.

- Two studies to determine the optimal loading dose of otenaproxesul that can deliver pain relief quickly.

- A final study to examine multiple combinations of a loading dose, maintenance dose, and potentially a tapering dose that will help guide which dosing regimens to use in the Phase 2 bunionectomy trial.

Assuming that these studies go as planned, we anticipate the company initiating a Phase 2 bunionectomy trial in the fourth quarter of 2022. 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 has also completed a preliminary commercial analysis of the post-operative pain market, and is currently conducting a comprehensive, third-party market opportunity and reimbursement study that is anticipated to be completed in the second quarter of 2022.

FDA Releases Draft Guidance for Development of Non-Opioid Analgesics

In February 2022, the FDA released draft guidance for the development of non-opioid analgesics for acute pain (FDA). The guidance was written in response to statutory requirement of section 3001(b) of the SUPPORT for Patients and Communities Act. This bill was passed in response the country's ongoing opioid epidemic. Encouragingly, Antibe's post-operative pain program aligns with much of the guidance that the FDA provides, but perhaps most importantly, the guidance document shows that the FDA recognizes the need for non-opioid pain management and is ready to work with drug developers to bring new products to market.

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 $471 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.

Financial Update

On February 14, 2022, Antibe announced financial results for the third quarter of fiscal year 2022 that ended December 31, 2021. During the quarter ending September 30, 2021, Antibe met the requirements to record Citagenix as Held for Sale and a Discontinued Operation as the company is in active discussions with a potential purchaser of Citagenix. Thus, there were no revenues recorded for the third quarter of fiscal year 2022.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation totaled CAD$5.2 million for the third quarter of fiscal year 2022 compared to CAD$5.9 million for the third quarter of fiscal year 2021. The decrease was primarily related to the following:

- G&A expenses decreased slightly to CAD$1.3 million in 3QFY22 due to decreased professional and consulting fees partially offset by increased salaries and office expenses.
- R&D expenses were CAD$2.5 million in 3QFY22 compared to CAD$3.4 million in 3QFY21. The decrease was primarily due to lower development costs and consulting fees partially offset by higher salaries.
- Stock-based compensation in 3QFY22 was CAD$1.4 million compared to CAD$0.8 million in 3QFY21 due to expensing of RSUs.

As of December 31, 2021, Antibe reported cash and cash equivalents of approximately CAD$58.6 million, which we estimate is enough to fund operations for at least two years. As of December 31, 2021, Antibe had approximately 51.9 million shares outstanding and, when considering stock options and warrants, a fully diluted share count of approximately 64.8 million shares.

Conclusion

We are glad to see that the post-operative pain program for otenaproxesul is underway and we look forward to updates from the company regarding the PK/PD studies as the year progresses. Assuming everything runs smoothly with the PK/PD studies and the Phase 2 bunionectomy trial, we currently forecast Phase 3 trials initiating in 2023, an NDA filing in 2024, and approval in 2025. With no changes to our model, our valuation remains at $4.00 per share.

PROJECTED FINANCIALS

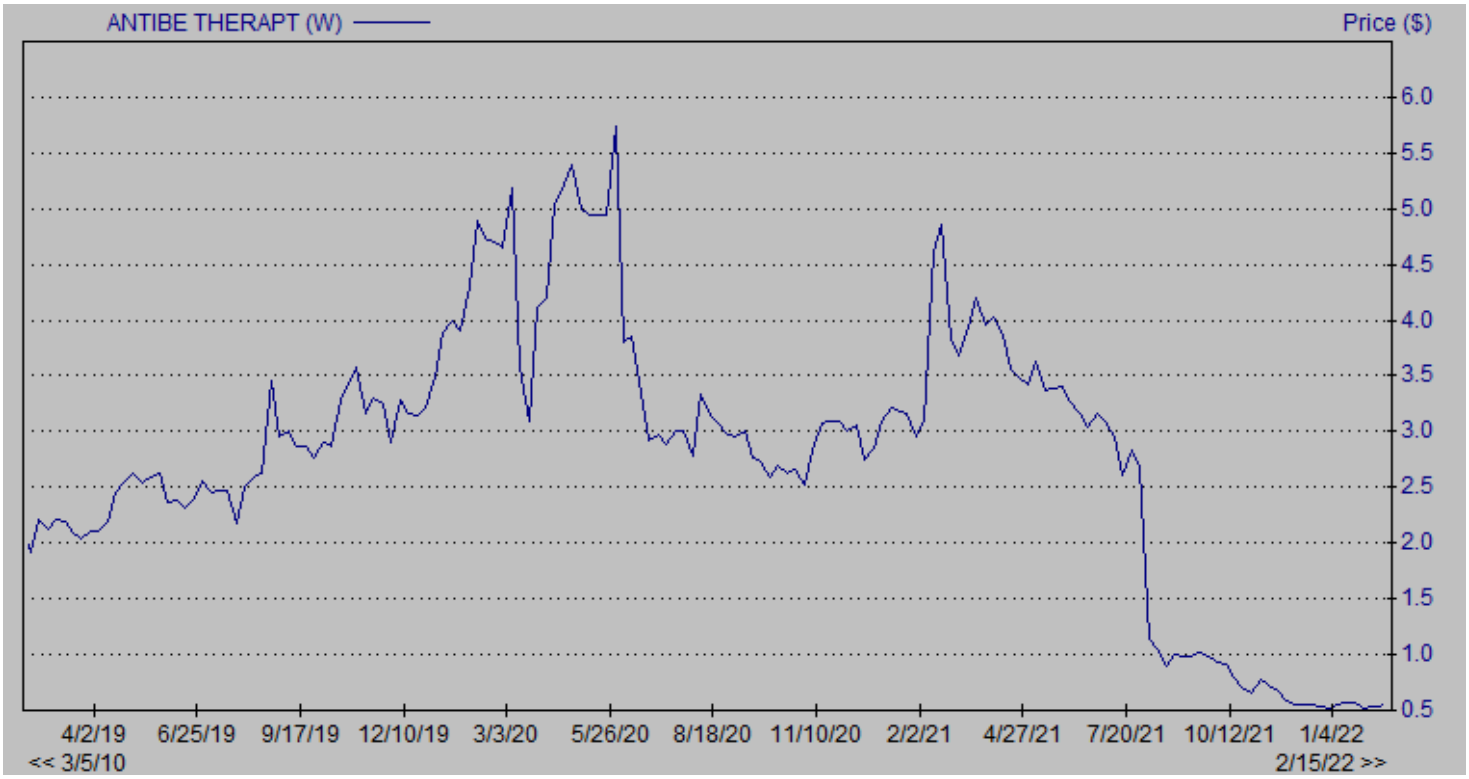
Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Year Ends Mar. 31 / in US Dollars	FY 2021 A	Q1 '22 A	Q2 '22 A	Q3 '22 A	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	$7.7	$2.2	$0.0	$0.0	$0.0	$2.2	$0.0	$0.0
Licensing / Development	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	$7.7	$2.2	$0.0	$0.0	$0.0	$2.2	$0.0	$0.0
YOY Growth	*2.4%*	*130.6%*	*-100.0%*	*-100.0%*	*-100.0%*	*-71.9%*	*-100.0%*	*#DIV/0!*
Cost of Goods Sold	$4.9	$1.3	$0.0	$0.0	$0.0	$1.3	$0.0	$0.0
Product Gross Margin	*36.5%*	*39.7%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*39.7%*	*#DIV/0!*	*#DIV/0!*
SG&A	$5.7	$1.3	$1.3	$1.0	$2.1	$5.7	$7.7	$7.9
R&D	$10.6	$2.5	$4.1	$2.0	$3.0	$11.7	$11.1	$11.9
Selling and marketing	$2.1	$0.5	$0.0	$0.0	$0.0	$0.6	$1.9	$1.9
Stock-based compensation	$3.2	$1.4	$1.2	$1.1	$1.2	$4.9	$3.2	$3.2
Impairment of goodwill	$0.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Amortization and Depreciation	$0.4	$0.1	$0.0	$0.0	$0.0	$0.1	$0.4	$0.4
Operating Income	($19.5)	($5.0)	($6.6)	($4.1)	($6.3)	($22.0)	($24.3)	($25.2)
Operating Margin	-254%	-232%	#DIV/0!	#DIV/0!	#DIV/0!	-1022%	#DIV/0!	#DIV/0!
Interest Income / Net	($0.0)	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($19.5)	($5.0)	($6.6)	($4.1)	($6.3)	($22.0)	($24.3)	($25.2)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	($0.0)	($0.0)
Net Income	($19.5)	($5.0)	($6.6)	($4.1)	($6.3)	($22.0)	($24.2)	($25.2)
Loss from Discontinued Operations	($1.2)	$0.0	($0.2)	$0.3	$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	($20.8)	($5.0)	($6.9)	($3.8)	($6.3)	($22.0)	($24.2)	($25.2)
Reported EPS	($0.56)	($0.10)	($0.13)	($0.07)	($0.12)	($0.43)	($0.44)	($0.42)
Fully Diluted Shares	37.3	47.5	51.7	51.8	52.0	50.8	55.0	60.0

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

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