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Antibe Therapeutics Inc.

(OTCQX: ATBPF)

ATBPF: Development Plan in Place for Otenaproxesul in Acute Pain…

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 (12/01/2021)	$0.54
Valuation	**$4.00**

OUTLOOK

On November 16, 2021, Antibe Therapeutics Inc. (ATBPF) announced financial results for the second quarter of fiscal year 2022 and provided a business update. The company recently announced that following a comprehensive review of the AME study of otenaproxesul that was paused due to liver transaminase elevations (LTEs) exceeding five times the upper limit of normal in six subjects, the company has determined that otenaproxesul is best suited for use in acute pain management, with an initial indication of post-operative pain. Chronic daily dosing of otenaproxesul is not currently possible, however the company will be evaluating alternative dosing regimens for the potential use of otenaproxesul in chronic pain management. We anticipate the initiation of an acute pain program for otenaproxesul in the first quarter of 2022, which will involve a series of PK/PD studies to identify optimal treatment regimens for post-operative pain.

SUMMARY DATA

52-Week High	**$5.54**
52-Week Low	**$0.54**
One-Year Return (%)	**-82.98**
Beta	**0.29**
Average Daily Volume (sh)	**47,477**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$28**
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	**High**
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 E	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	-$0.12 E	-$0.12 E	-$0.47 E
2023					-$0.44 E
2024					-$0.42 E

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WHAT'S NEW

Business Update

Pivoting to Acute Pain Management for Otenaproxesul

On October 14, 2021, Antibe Therapeutics, Inc. (ATBPF) provided an update on the development of otenaproxesul following a comprehensive review of the absorption, metabolism, and excretion (AME) study that was previously paused due to six patients experiencing liver transaminase elevations (LTEs) exceeding five times the upper limit of normal (ULN). The company has determined that the best path forward for otenaproxesul is in the management of acute pain, with an initial indication of postoperative pain.

The review of the AME study showed that all LTEs occurred following the four-week drug administration period, however all LTEs were transient, self-limiting, and did not require any medical intervention. It was determined that the LTEs were a dose-dependent, drug-related effect, which would make it difficult for daily dosing of otenaproxesul for an extended period of time. Antibe is continuing to investigate the mechanism behind the LTEs, which currently appear to be a function of increased oxidative stress in the liver. This mechanism of action is common to a number of other medications, including nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen.

Now that it has determined it will be very difficult to utilize otenaproxesul for the treatment of chronic pain (at least utilizing the current dosing schedule), Antibe will be pivoting to develop the compound as a treatment for acute pain, with an initial indication of postoperative pain management and potential expansion opportunities in migraine, dysmenorrhea, and dental pain.

The next step for Antibe in the management of acute pain is to conduct a dose-ranging PK/PD study, which should initiate next quarter. Results from that study could be available in the first half of 2022, following which the company anticipates initiating a Phase 2 bunionectomy trial, which could initiate in the fourth quarter of 2022. In contrast to obtaining approval for chronic pain management, which would require multiple long-term clinical trials, the trials necessary for approval in acute pain management are relatively shorter and could lead to a faster time to market than for the original chronic pain indication.

In addition to providing an update on otenaproxesul, Antibe also discussed the company's IP position and the inflammatory bowel disease (IBD) program. The company has filed a patent application covering novel dosing regimens for the acute use of otenaproxesul. In addition, new IP will be filed for ATB-352 in a recently identified specialized indication. We anticipate the company selecting its lead IBD candidate in the next couple of quarters and initiating IND-enabling studies shortly thereafter. The IBD candidate will be developed as a safer and more effective drug for mild to moderate IBD.

Postoperative Pain Market

Postoperative pain represents a large opportunity for Antibe with an estimated global market size of US$13 billion. The most commonly prescribed medications to control postoperative 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 postoperative 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 postoperative 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 postoperative 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 November 16, 2021, Antibe announced financial results for the second quarter of fiscal year 2022 that ended September 30, 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 second quarter of fiscal year 2022.

General and administrative, selling and marketing, research and development, stock-based compensation, and amortization and depreciation totaled CAD$8.4 million for the second quarter of fiscal year 2022 compared to CAD$7.7 million for the second quarter of fiscal year 2021. The increase was primarily related to the following:

- G&A expenses decreased slightly to CAD$1.6 million in 2QFY22 due to decreased professional and consulting fees partially offset by increased salaries and wages, office, and other expenses.
- R&D expenses were CAD$5.2 million in 2QFY22 compared to CAD$4.8 million in 2QFY21. The increase was primarily due to higher development costs for otenaproxesul studies, manufacturing costs, higher salaries, and professional and consulting fees.
- Stock-based compensation in 2QFY22 was CAD$1.5 million compared to CAD$0.8 million in 2QFY21 due to expensing of previously granted RSUs.

As of September 30, 2021, Antibe reported cash and cash equivalents of approximately CAD$60.5 million, which we estimate is enough to fund operations for at least two years. As of September 30, 2020, Antibe had approximately 51.7 million shares outstanding and, when considering stock options and warrants, a fully diluted share count of approximately 64.0 million shares.

Conclusion

While we're disappointed that Antibe's development of otenaproxesul for chronic pain management is under review, the pivot to acute pain management makes sense and potentially provides a faster path to approval in the estimated US$13 billion worldwide postoperative pain market. We have constructed a preliminary model for otenaproxesul in postoperative pain, however this is subject to change as we learn more about the company's plans and the overall market. At this point we are concentrating on postoperative pain in the U.S. and E.U., in which we estimate peak revenues for otenaproxesul of US$500 million and US$400 million, respectively. Our preliminary development timeline forecasts Phase 3 trials initiating in 2023, an NDA filing in 2024, and approval in 2025. With a 50% probability of approval (which we believe is justified by the previously completed successful 14-day clinical trials of otenaproxesul) and a 15% royalty rate the NPV for otenaproxesul in postoperative pain is US$100 million. When factoring in the company's pipeline, current cash position, and potential cash from warrants, the NPV for Antibe is US$258 million. The fully diluted share count currently stands at approximately 64 million shares, which leads to a valuation of $4.00 per share. We understand investors are nervous about the prospects for otenaproxesul, but we do not believe that warrants the company trading at less than cash and risk-tolerant investors could use the current opportunity to build or add to a position prior to the acute pain management program getting into full swing.

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 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	$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	$2.0	$2.1	$6.6	$7.7	$7.9
R&D	$10.6	$2.5	$4.1	$2.8	$3.0	$12.5	$11.1	$11.9
Selling and marketing	$2.1	$0.5	$0.0	$0.5	$0.5	$1.5	$1.9	$1.9
Stock-based compensation	$3.2	$1.4	$1.2	$0.8	$0.8	$4.1	$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	$0.1	$0.1	$0.2	$0.4	$0.4
Operating Income	($19.5)	($5.0)	($6.6)	($6.1)	($6.4)	($24.1)	($24.3)	($25.2)
Operating Margin	-254%	-232%	#DIV/0!	#DIV/0!	#DIV/0!	-1119%	#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)	($6.1)	($6.4)	($24.1)	($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)	($6.1)	($6.4)	($24.1)	($24.2)	($25.2)
Loss from Discontinued Operations	($1.2)	$0.0	($0.2)	$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	($20.8)	($5.0)	($6.9)	($6.1)	($6.4)	($24.1)	($24.2)	($25.2)
Reported EPS	($0.56)	($0.10)	($0.13)	($0.12)	($0.12)	($0.47)	($0.44)	($0.42)
Fully Diluted Shares	37.3	47.5	51.7	52.0	52.0	50.8	55.0	60.0

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

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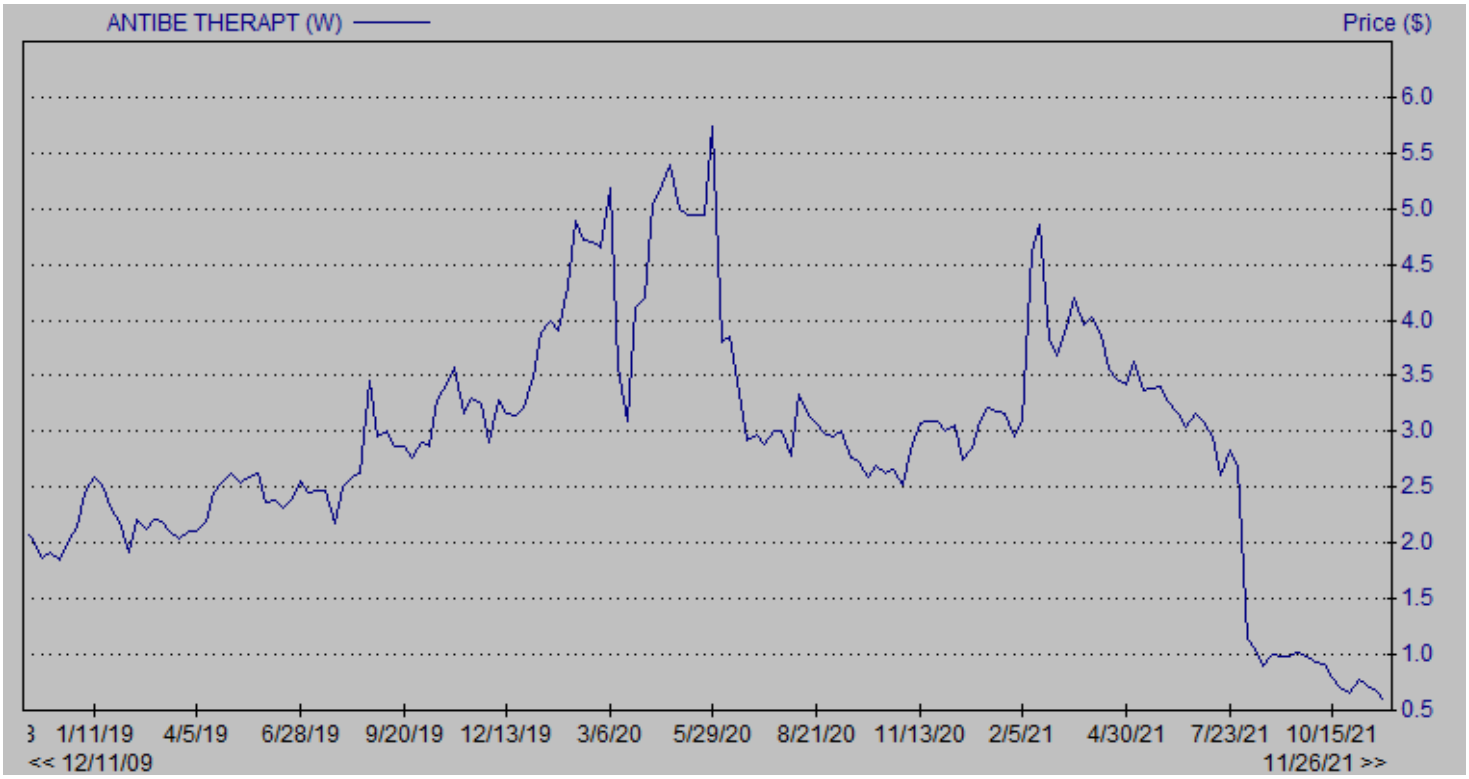

Source: Zacks Small Cap Research

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