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BioXcel Therapeutics, Inc. (BTAI-NASDAQ)

BTAI: Alignment with FDA on At-Home Study of BXCL501 in Alzheimer's Agitation…

Based on our probability adjusted DCF model that takes into account potential future revenues of BXCL501 and BXCL701, BTAI is valued at $12.00/share. This model is highly dependent upon continued clinical success of the company's pipeline and will be adjusted accordingly based on future clinical results.

Current Price (11/16/23)	$4.40
Valuation	**$12.00**

OUTLOOK

On November 14, 2023, BioXcel Therapeutics, Inc. (BTAI) announced financial results for the third quarter of 2023 and provided a business update. The company has aligned with the FDA on the plans for a Phase 3 trial of BXCL501 in the at-home setting for the treatment of Alzheimer's agitation. The company is planning to enroll 100 patients who will self-administer 60 μg of BXCL501 or placebo whenever agitation episodes occur over a four-week period. The company also met with the FDA regarding designs for a Phase 3 study of 120 μg of IGALMI for the treatment of agitation associated with bipolar disorders or schizophrenia. Final plans for that study will be shared following receipt of the meeting minutes.

SUMMARY DATA

52-Week High	**$33.24**
52-Week Low	**$2.32**
One-Year Return (%)	**-71.34**
Beta	**0.86**
Average Daily Volume (sh)	**7,349,879**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$129**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**91**
Insider Ownership (%)	**36**
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 2019 Estimate	**-0.7**
P/E using 2020 Estimate	**-1.6**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 A	1 E	2 E
2024					5 E
2025					10 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$1.12 A	-$1.35 A	-$1.49 A	-$1.95 A	-$5.92 A
2023	-$1.84 A	-$1.83 A	-$1.72 A	-$1.04 E	-$6.10 E
2024					-$2.36 E
2025					-$2.08 E

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WHAT'S NEW

Business Update

Alignment with FDA on Path Forward for TRANQUILITY and SERENITY At-Home Studies

BioXcel Therapeutics, Inc. (BTAI) recently conducted a meeting with the FDA regarding the development pathway for BXCL501 for the treatment of agitation associated with Alzheimer's disease (AD). Following receipt of the meeting minutes, the company announced that it was aligned with the FDA's recommendation to conduct an additional Phase 3 trial of BXCL501 to evaluate its safety and collect additional efficacy data in the at-home setting. The planned study will enroll approximately 100 patients 65 years of age and older with mild, moderate, or severe dementia who will self-administer 60 μg of BXCL501 or placebo whenever agitation episodes occur over a four-week period. The long-term safety requirement will be discussed with the FDA and will be based on the frequency of agitation episodes. The TRANQUILITY III trial is no longer required for an sNDA application. The company had previously paused enrollment in that trial after early data showed a much higher background frequency of agitation episodes than originally anticipated (i.e., the patients had chronic agitation, not acute episodes). The company will explore the possibility of a separate clinical development program for chronic agitation.

BioXcel also conducted a meeting with the FDA in early November regarding changes to Part 2 of the SERENITY III trial, which is evaluating the at-home use of IGALMI for agitation associated with bipolar disorders and schizophrenia. The company had previously reported results from Part 1 of the study, which was evaluating a 60 μg dose of IGALMI. Results from Part 1 of the study did not meet the primary efficacy endpoint, which was the change in PEC score from baseline at two hours post-dose. While the company will wait until it receives the meeting minutes before making any final decisions, based on feedback received from the FDA during the meeting the current plan is to conduct Part 2 of the SERENITY III trial with 120 μg IGALMI.

Positive Findings from Third Party Independent Audit of Data Integrity at TRANQUILITY II Site

On October 25, 2023, BioXcel announced the results of a third-party, independent audit of the data from a single site in the TRANQUILITY II Phase 3 trial. The company had previously disclosed that following an FDA inspection of this site in December 2022, the FDA issued a Form 483 identifying three inspectional observations. There were also potential issues of investigator misconduct by the principal investigator at that site. This site enrolled approximately 40% of the patients in the TRANQUILITY II trial. Following an extensive review, the team of auditors did not identify any findings that they believe impact the data reliability or integrity, and there was no evidence of additional misconduct or fraud. Thus, we are confident that the data from the TRANQUILITY II trial can be used to support an sNDA for BXCL501 for the acute treatment of agitation associated with dementia.

Positive Overall Survival Results Seen in Phase 2 Trial of BXCL701 in Adenocarcinoma Phenotype

On November 8, 2023, BioXcel announced positive overall survival (OS) results from the single-arm, open-label Phase 2 clinical trial of BXCL701 in combination with Keytruda® in patients with metastatic castration-resistant prostate cancer (mCRPC) of adenocarcinoma phenotype. As of the September 6, 2023 cutoff date, the median OS was 15.5 months (95% CI 9.6 – NR) with a 12-month survival rate of 59%. While difficult to make cross-trial comparisons, the KEYNOTE-199 study of Keytruda in patients with mCRPC showed an OS of 9.6 months (Antonarakis *et al*., 2020). In addition, BXCL701 + Keytruda showed a median progression free survival of 4.2 months compared to 2.1 months seen in the KEYNOTE-199 study.

Financial Update

On November 14, 2023, BioXcel announced financial results for the third quarter of 2023. Net loss in the third quarter of 2023 was $50.5 million, compared to a net loss of $41.8 million in the third quarter of 2022. Revenue of $341,000 was recorded in the third quarter of 2023 compared to $137,000 in the third quarter of

2022. The revenue reflects limited market access since the launch of IGALMI in July 2022. Cost of goods sold in the third quarter of 2023 were $512,000 compared to $11,000 in the third quarter of 2022. The increase is primarily due to an increase in the reserve for excess and obsolete inventory. R&D expenses in the third quarter of 2023 were $19.6 million, compared to $22.1 million for the third quarter of 2022. The decrease was primarily due to decreased clinical trial costs and CMC costs partially offset by an increase in professional fees and stock-based compensation. SG&A expenses in the third quarter of 2023 were $24.3 million, compared to $17.1 million for the third quarter of 2022. The increase was primarily due to an increase in personnel and related costs associated with the commercialization of IGALMI in the U.S.

As of September 30, 2023, BioXcel had approximately $90.0 million in cash and cash equivalents. The company has entered into a binding term sheet to restructure key financial terms of its agreements with Oaktree Capital Management and Qatar Investment Authority, which includes the potential to access additional tranches of capital. We currently estimate that the company has sufficient capital to fund operations into mid-2024.

As of November 10, 2023, the company had approximately 29.3 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 34.8 million.

Conclusion

We're glad to see the company has aligned with the FDA on advancing the TRANQUILITY and SERENITY Phase 3 at-home trials, as the use of BXCL501 in the at-home setting represents the largest growth opportunity for the company. In the near term, we anticipate further details on the restructuring of the financial agreements with Oaktree Capital Management and Qatar Investment Authority, including the potential for additional tranches of capital. With no changes to our model, our valuation remains at $12 per share.

PROJECTED FINANCIALS

BioXcel Therapeutics, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
BXCL501	$0	$0	$0	$0	$1	$2	$5	$10
BXCL701	$0	$0	$0	$0	$0	$0	$0	$0
Other Income	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$1**	**$2**	**$5**	**$10**
Cost of Sales	$0	$0	$0	$1	$0	$1	$0	$1
Product Gross Margin	*95%*	*96%*	*94%*	*-50%*	*87%*	*67%*	*94%*	*94%*
Research & Development	$91.2	$27.8	$27.0	$19.6	$18.0	$92.4	$55.0	$57.0
General & Administrative	$68.8	$23.6	$25.9	$24.3	$15.0	$88.8	$50.0	$52.0
Other (Income) Expense	$0.0	$0.0	$0.0	$4.2	$0.0	$4.2	$0.0	$0.0
Operating Income	($159.6)	($51.1)	($52.4)	($48.3)	($32.1)	($184.0)	($100.3)	($99.6)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$6.1	$1.6	$1.1	$2.2	$1.5	$6.4	$6.0	$6.0
Pre-Tax Income	($165.8)	($52.7)	($53.5)	($50.5)	($30.6)	($177.6)	($94.3)	($93.6)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($165.8)**	**($52.7)**	**($53.5)**	**($50.5)**	**($30.6)**	**($177.6)**	**($94.3)**	**($93.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.92)**	**($1.84)**	**($1.83)**	**($1.72)**	**($1.04)**	**($6.10)**	**($2.36)**	**($2.08)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	28.0	28.6	29.2	29.3	29.4	29.1	40.0	45.0

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

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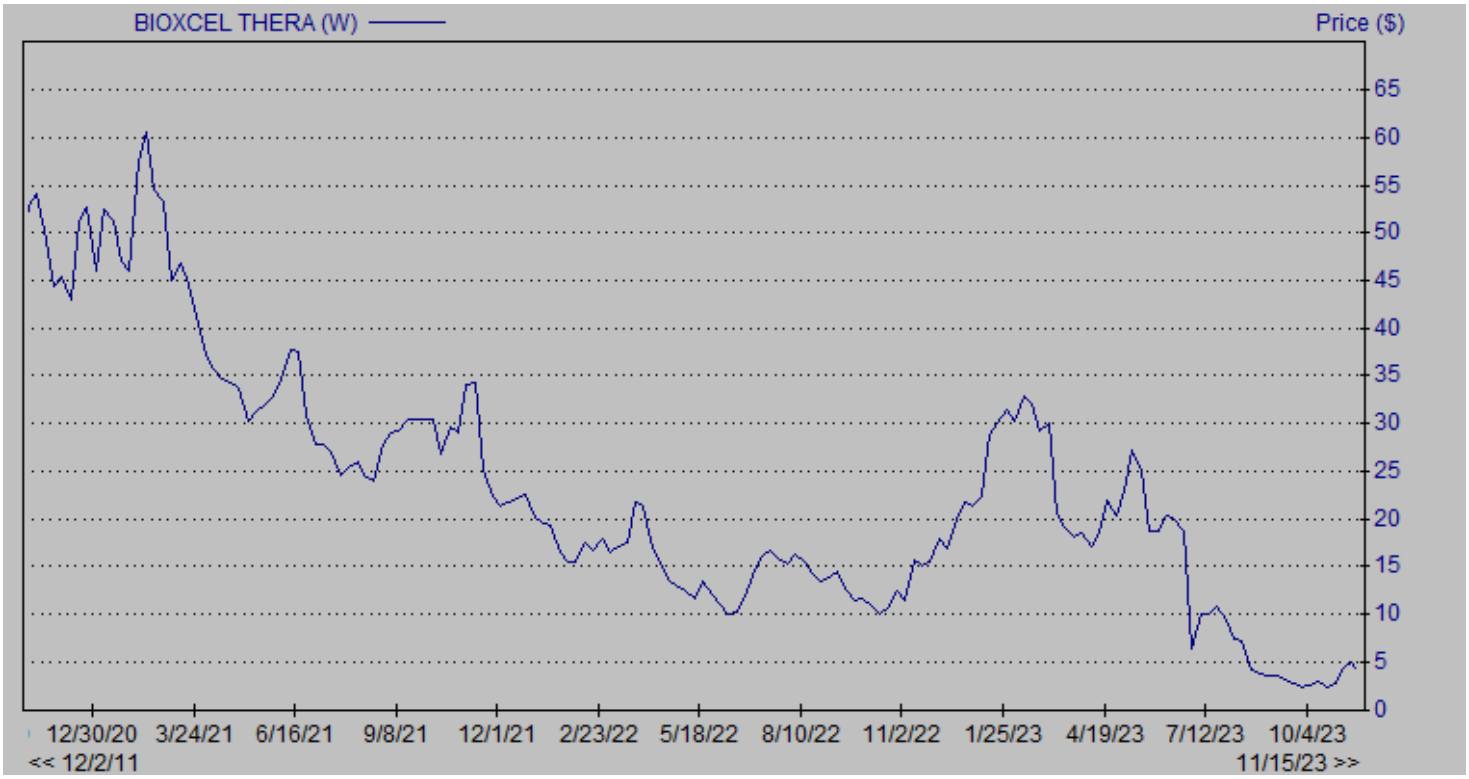

Source: Zacks SCR

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