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BioXcel Therapeutics, Inc. (BTAI-NASDAQ)

BTAI: Strategic Reprioritization Underway…

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 (08/17/23)	$4.17
Valuation	**$12.00**

OUTLOOK

On August 14, 2023, BioXcel Therapeutics, Inc. (BTAI) announced financial results for the second quarter of 2023 and provided a business update. The company has commenced a strategic reprioritization to shift resources away from the institutional setting to focus on retail pharmacy and the outpatient setting for IGALMI. This change was undertaken because the hospital setting proved to be more difficult for the company to penetrate than originally anticipated. Contracting with large hospitals, health care systems, and integrated delivery networks will continue. In addition, BioXcel will be reducing its workforce from 190 to 80 employees, mostly through reductions in the commercial organization. The company will keep a core 12-member team for market access, commercial operations, sales, and trade functions. BioXcel will be meeting with the FDA to discuss the TRANQUILITY program, including the results of the TRANQUILITY II trial. The TRANQUILITY III trial has been paused due to a much higher background frequency of agitation episodes than originally expected.

SUMMARY DATA

52-Week High	**$33.24**
52-Week Low	**$4.14**
One-Year Return (%)	**-71.34**
Beta	**0.89**
Average Daily Volume (sh)	**1,718,063**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$122**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**42**
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	**-0.6**
P/E using 2020 Estimate	**-0.8**

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	1 E	1 E	3 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	-$1.45 E	-$1.04 E	-$5.87 E
2024					-$2.36 E
2025					-$2.08 E

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WHAT'S NEW

Business Update

Strategic Reprioritization Underway

On August 14, 2023, BioXcel Therapeutics, Inc. (BTAI) announced a strategic reprioritization that will impact a number of the areas of the business, including:

- The commercial strategy for IGALMI will shift to focus more on the retail pharmacy and at-home setting and away from the institutional setting. The company has indicated that the hospital setting proved to be more difficult to penetrate than originally anticipated, particularly in a post-COVID environment. However, a contracting effort with large hospitals, health care systems, and integrated delivery networks is ongoing. These actions were undertaken prior to the reprioritization and have yielded some initial success, as exemplified by a doubling of 2Q23 revenues compared to 1Q23. The company has had over 185 formulary wins with a win rate of approximately 65%. There are still approximately 650 hospitals that are scheduled to have formulary votes. Assuming that additional positive votes are achieved, the company will continue to reach out to them through medical affairs activities, market access activities, contracting, and distribution to ensure that IGALMI is available to them.

- The company will be reducing its workforce from 190 to 80 individuals. Most of the reductions will be in the commercial organization, however a core team of 12 members will be maintained for market access, commercial operations, sales, and trade functions.

- The focus for BXCL501 will now turn toward high potential agitation market opportunities in bipolar disorders, schizophrenia, and Alzheimer's dementia in the at-home and retail setting. For example, there are approximately 23 million episodes of bipolar or schizophrenia-related agitation occurring annually in the U.S. in the at-home setting. Of the 100 million Alzheimer's-related agitation episodes that occur each year in the U.S., approximately 50% of them are in the at-home or assisted living facility (ALF) setting.

- While the company reported positive results for the Phase 1b multiple ascending dose trial of BXCL501 in the major depressive disorder program, that program will be paused to focus efforts on BXCL501 in agitation.

- The company will prioritize AI-driven innovation, including the next-generation AI platform capabilities. An R&D day is planned for later in 2023 that will highlight BXCL502 and introduce BXCL503 and BXL504, which are two reinnovated late-stage drug candidates.

Update on TRANQUILITY Program

The company will be requesting a meeting with the FDA to discuss the TRANQUILITY program, including the results of the TRANQUILITY II trial. As disclosed last month, the company announced positive topline results for the TRANQUILITY II trial as the 60 μg dose of BXCL501 showed a 39% greater reduction in PEC score from baseline compared to placebo at 2 hours (P=0.0112). However, the company also disclosed that following an FDA inspection of one of the clinical trial sites in December 2022, the FDA issued a Form 483 identifying three inspectional observations. This site enrolled approximately 40% of the patients in the TRANQUILITY II trial. There were also potential issues of investigator misconduct by the principal investigator at that site. In addition to the FDA investigation, BioXcel is conducting an investigation into protocol adherence and data integrity at that clinical trial site through an independent third-party audit of data collected at that site. The company is hopeful that its independent investigation will be concluded before the end of 2023. Lastly, enrollment has been paused in the TRANQUILITY III trial after early data showed a much higher background frequency of agitation episodes than originally anticipated. That patient population may require chronic

treatment of agitation, while the company is focused on the acute treatment of Alzheimer's agitation. The FDA granted Breakthrough Therapy Designation to BXCL501 for the acute treatment of agitation associated with dementia.

Update on SERENITY III Trial

For the SERENITY III trial, BioXcel previously announced results for Part 1 of that study in which patients were administered a 60 μg dose of BXCL501 in a monitored medical setting as a surrogate for the at-home setting. The primary endpoint of the mean change in PEC score at two hours was not met. However, the 60 μg dose was well tolerated and demonstrated favorable safety results, which included proportionally fewer adverse events compared to those observed in the SERENITY I and II trials, which evaluate the 120 μg and 180 μg doses. Part 2 of the SERENITY III trial is currently ongoing. It is a 12-week study to evaluate the safety of a 60 μg dose of BXCL501, with an optional second 60 μg dose. The company performed PK and PD modeling to identify a dose that would provide an optimal balance between safety and efficacy, and that modeling suggested the use of an 80 μg dose. Thus, BioXcel is planning to meet with the FDA to discuss the 80 μg dose and a protocol amendment to the SERENITY III Part 2 study. The primary outcome of Part 2 of the study is a comparison of serious adverse events and treatment emergent adverse events between BXCL501- and placebo-treated patients. There are also a number of efficacy assessments that are serving as secondary endpoints.

Financial Update

On August 14, 2023, BioXcel announced financial results for the second quarter of 2023. Net loss in the second quarter of 2023 was $53.5 million, compared to a net loss of $37.7 million in the second quarter of 2022. Revenue of $457,000 was recorded in the second quarter of 2023 compared to no revenue in the first quarter of 2022. The revenue reflects limited market access since the launch of IGALMI in July 2022. R&D expenses in the second quarter of 2023 were $27.0 million, compared to $17.9 million for the second quarter of 2022. The increase was primarily due to increased clinical trial costs. SG&A expenses in the second quarter of 2023 were $25.9 million, compared to $18.4 million for the second 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 June 30, 2023, BioXcel had approximately $127.5 million in cash and cash equivalents. As part of the reprioritization, the company's goal is to get the annual burn rate to approximately $80 million per year. We estimate that the company has sufficient capital to fund operations into 2024. The previous cash projections into 2025 were based on the company's ability to draw additional tranches from the $260 million financing agreement entered into with Oaktree and Qatar Investment Authority. The agreement includes satisfaction of certain conditions (regulatory milestone, patent milestones, and specified minimum net sales of BXCL501) to make additional drawdowns, however the conditions to enable additional drawdowns are not likely to be met.

In addition, a Revenue Covenant Measurement Test begins on December 31, 2023, in which a minimum revenue amount needs to be met for the prior six-month period in order for the company to remain in compliance with the terms of the funding agreement. If the minimum revenue amount is not met, the company must make payments in an amount equal to the difference between the minimum required revenue and the company's actual revenues. For the testing dates ending December 31, 2023, March 31, 2024, and June 30, 2024, the shortfalls in revenue could result in payments of $7.657 million, $10.636 million, and $14.313 million, respectively, along with aggregate prepayment fees of up to $1.5 million. The company is currently in active discussion with its lenders to restructure the financing agreement and/or waive the Revenue Covenant.

As of August 10, 2023, the company had approximately 29.3 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 34.9 million.

Conclusion

While difficult, we believe the decisions made by BioXcel as part of the reprioritization are necessary and will hopefully set the company back on the right track. Focusing on the at-home and retail market for BXCL501 in agitation appears to be the best path forward, however the company still needs to meet with the FDA to

discuss the 80 μg dose of BXCL501 for Part 2 of the SERENITY III trial as well as the TRANQUILITY program to determine the registration path forward in Alzheimer's agitation. We have made a number of changes to our model based on the company's reprioritization, which includes increasing the discount rate given the increased financing risk, decreasing the estimated peak sales for BXCL501 in schizophrenia and bipolar agitation to $200 million, and increasing potential future dilution. Our valuation is now $12 per share.

PROJECTED FINANCIALS

BioXcel Therapeutics, Inc.	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
BXCL501	$0	$0	$0	$1	$1	$3	$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**	**$1**	**$1**	**$3**	**$5**	**$10**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$1
Product Gross Margin	*95%*	*96%*	*94%*	*96%*	*87%*	*92%*	*94%*	*94%*
Research & Development	$91.2	$27.8	$27.0	$22.0	$18.0	$94.8	$55.0	$57.0
General & Administrative	$68.8	$23.6	$25.9	$20.0	$15.0	$84.5	$50.0	$52.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($159.6)	($51.1)	($52.4)	($41.0)	($32.1)	($176.7)	($100.3)	($99.6)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$6.1	$1.6	$1.1	$1.5	$1.5	$5.7	$6.0	$6.0
Pre-Tax Income	($165.8)	($52.7)	($53.5)	($42.5)	($30.6)	($171.0)	($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)**	**($42.5)**	**($30.6)**	**($171.0)**	**($94.3)**	**($93.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.92)**	**($1.84)**	**($1.83)**	**($1.45)**	**($1.04)**	**($5.87)**	**($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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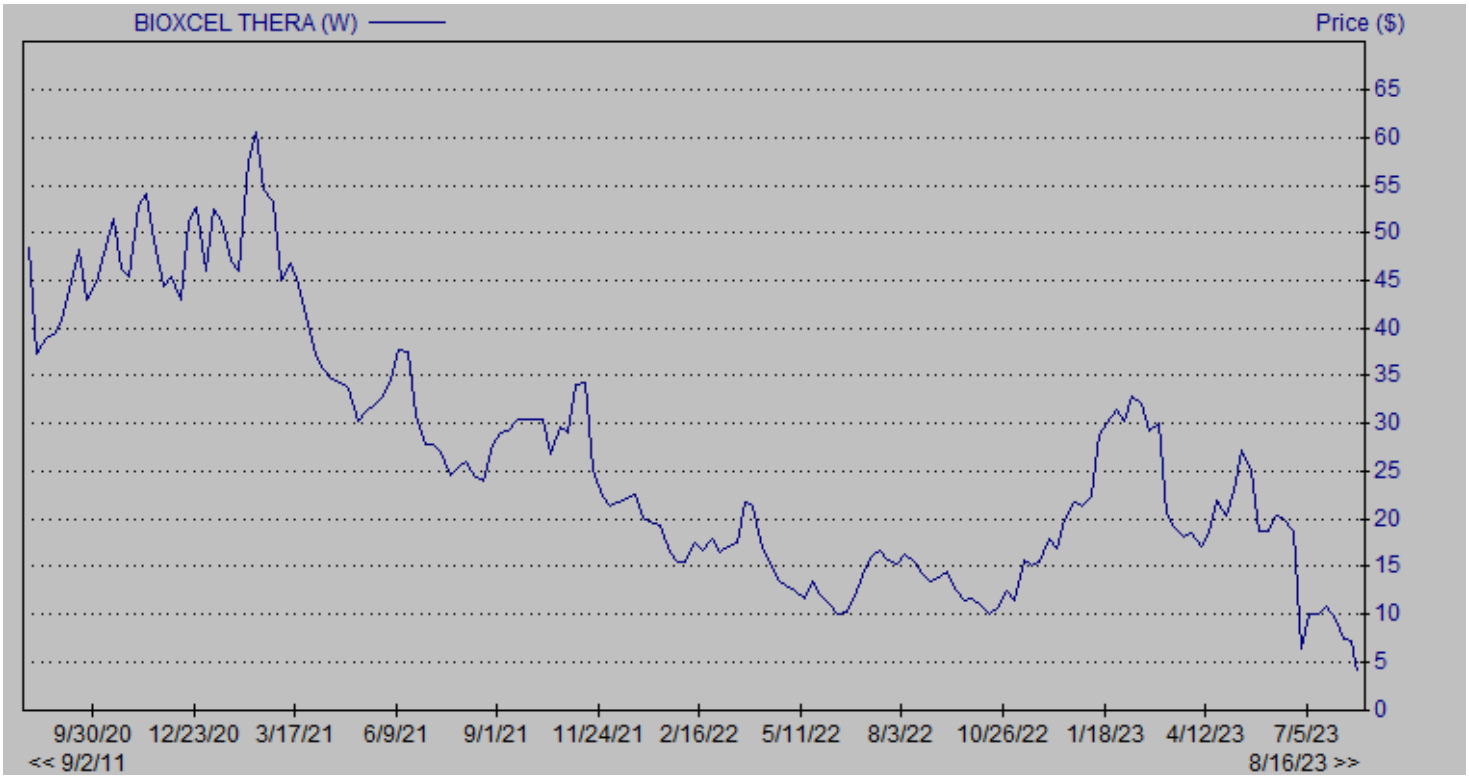

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