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BioXcel Therapeutics, Inc. (BTAI-NASDAQ)

BTAI: Three Data Readouts Expected in the Near Term…

Based on our probability adjusted DCF model that takes into account potential future revenues of BXCL501 and BXCL701, BTAI is valued at $75.00/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 (05/11/23)	$28.58
Valuation	**$75.00**

OUTLOOK

On May 8 2023, BioXcel Therapeutics, Inc. (BTAI) announced financial results for the first quarter of 2023 and provided a business update. The company will be reporting data from three studies in the near term: 1) Topline data for Part 1 of the SERENITY III trial of 60 μg BXCL501 in acutely agitated patients with bipolar I or II disorder or schizophrenia in a supervised setting in May 2023; 2) Topline data for the Phase 1b multiple ascending dose (MAD) trial of repeat dosing of BXCL501 for major depressive disorder (MDD) in healthy volunteers in May 2023; 3) Topline data for the TRANQUILITY III trial of BXCL501 for the acute treatment of Alzheimer's agitation in patients in assisted living facilities in June 2023.

SUMMARY DATA

52-Week High	**$33.24**
52-Week Low	**$9.03**
One-Year Return (%)	**195.55**
Beta	**1.12**
Average Daily Volume (sh)	**458,201**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$833**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**42**
Insider Ownership (%)	**37**
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	**-4.3**
P/E using 2020 Estimate	**-5.8**

Risk Level	**High**
Type of Stock	**Mid-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 E	1 E	3 E	5 E
2024					12 E
2025					35 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	-$1.66 E	-$1.74 E	-$1.68 E	-$6.60 E
2024					-$6.07 E
2025					-$5.59 E

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WHAT'S NEW

Business Update

Data Readouts for Three Clinical Trials in Near Future

BioXcel Therapeutics, Inc. (BTAI) lead development compound, BXCL501, is currently being evaluated in multiple clinical trials. We anticipate important data readouts from three trials in the near term:

- Topline data is anticipated in May 2023 from Part 1 of the Phase 3 SERENITY III trial of BXCL501 in patients with bipolar I or II disorder or schizophrenia. SERENITY III is a two-part, double blind, placebo controlled study. The first part of the study is similar to SERENITY I and II and is designed to assess the safety and efficacy of 60 μg BXCL501 in acutely agitated bipolar or schizophrenia patients in a monitored setting. The primary endpoint will be the change from baseline in Positive and Negative Syndrome Scale-Excitatory Component (PEC) score at two hours after dosing compared to placebo. Part 2 of the study is designed to assess 60 μg BXCL501 when administered at home. That trial is anticipated to initiate in the second quarter of 2023.

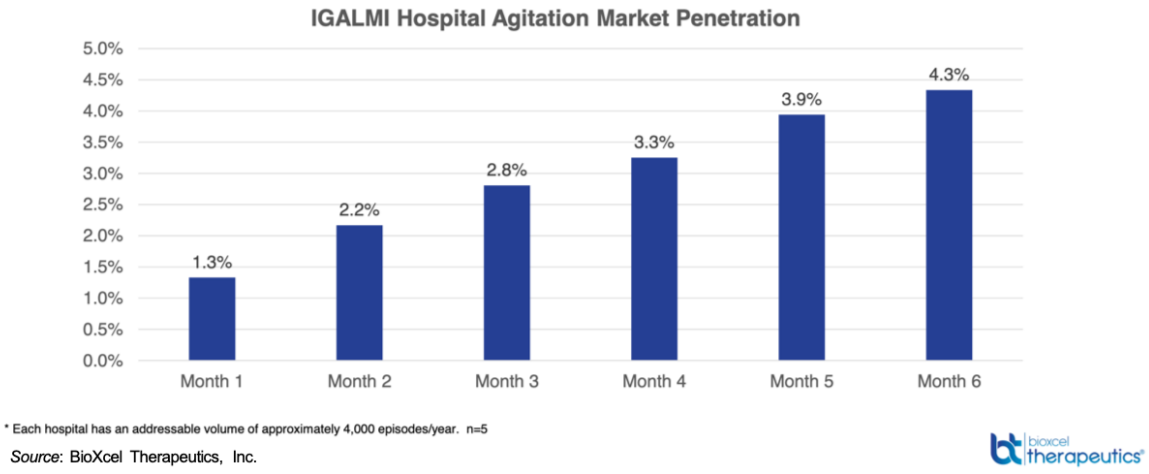
- Topline data is anticipated in May 2023 from repeat dosing of BXCL501 in the Phase 1b multiple ascending dose trial for the major depressive disorder (MDD) program in healthy volunteers. This trial is designed to inform dose selection for the Phase 2 program, which will evaluate BXCL501 in combination with selective serotonin- or serotonin-norepinephrine reuptake inhibitors (SSRIs or SNRIs, respectively) in patients with MDD.

- Topline data is anticipated in June 2023 from the TRANQUILITY II trial of BXCL501 for the acute treatment of Alzheimer's agitation. The TRANQUILITY program includes both TRANQUILITY II and TRANQUILITY III. Each trial will enroll approximately 150 patients with dementia ages 65 and older who will self-administer BXCL501 or placebo under the supervision of a trained research staff member whenever agitation occurs over a three-month period. TRANQUILITY II will assess patients in assisted living or residential care facilities requiring minimal assistance with activities of daily living. TRANQUILITY III will assess patients mainly residing in nursing homes with moderate to severe dementia who require moderate or greater assistance with activities of daily living. The primary endpoint for both trials is the change in PEC total score from baseline measured at two hours after the initial dose and subsequent doses.

Update on IGALMI Launch

BioXcel provided an update on the commercial launch of IGALMI. To date, there have been more than 130 hospital formulary wins (which equates to approximately $55 million of addressable market) and there are approximately 600 votes pending (which equates to approximately $255 million in market opportunity). The sales team has reached >75% of the 1,700 target hospitals. The group purchasing organization (GPO) process is largely complete with nearly 80% of targeted beds under contract.

The company noted that more than half of all ordering hospitals have reordered, which likely demonstrates real world utility. To better quantify this, the company analyzed the top hospital accounts, which manage over 4,000 agitation episodes each per year. The company estimates that each of the early adopting institutions have treated over 160 episodes in the first six months of use. This represents an implied market share of >4% over that time period. The market share growth is shown in the following graph.



Financial Update

On May 8, 2023, BioXcel announced financial results for the first quarter of 2023. Revenue of $206,000 was recorded in the first 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. Net loss in the first quarter of 2023 was $52.8 million, compared to a net loss of $31.5 million in the first quarter of 2022. R&D expenses in the first quarter of 2023 were $27.8 million, compared to $18.6 million for the first quarter of 2022. The increase was primarily due to increased clinical trial costs. SG&A expenses in the first quarter of 2023 were $23.6 million, compared to $12.9 million for the first quarter of 2022. The increase was primarily due to an increase in personnel costs, market access costs, and marketing costs associated with the commercialization of IGALMI in the U.S.

As of March 31, 2023, BioXcel had approximately $165.5 million in cash and cash equivalents. As of May 3, 2023, the company had approximately 29.2 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 34.8 million.

Conclusion

All focus now is on the upcoming data readouts over the next few weeks for the SERENITY III trial, the MDD trial, and the TRANQUILITY II trial. While the pace of sales of IGALMI continue to be slower than we had anticipated, the metrics surrounding formulary wins and upcoming formulary votes are very encouraging and we look for sales to begin ramping up in the second half of 2023. While we await the upcoming clinical trial results, our valuation remains at $75 per share.

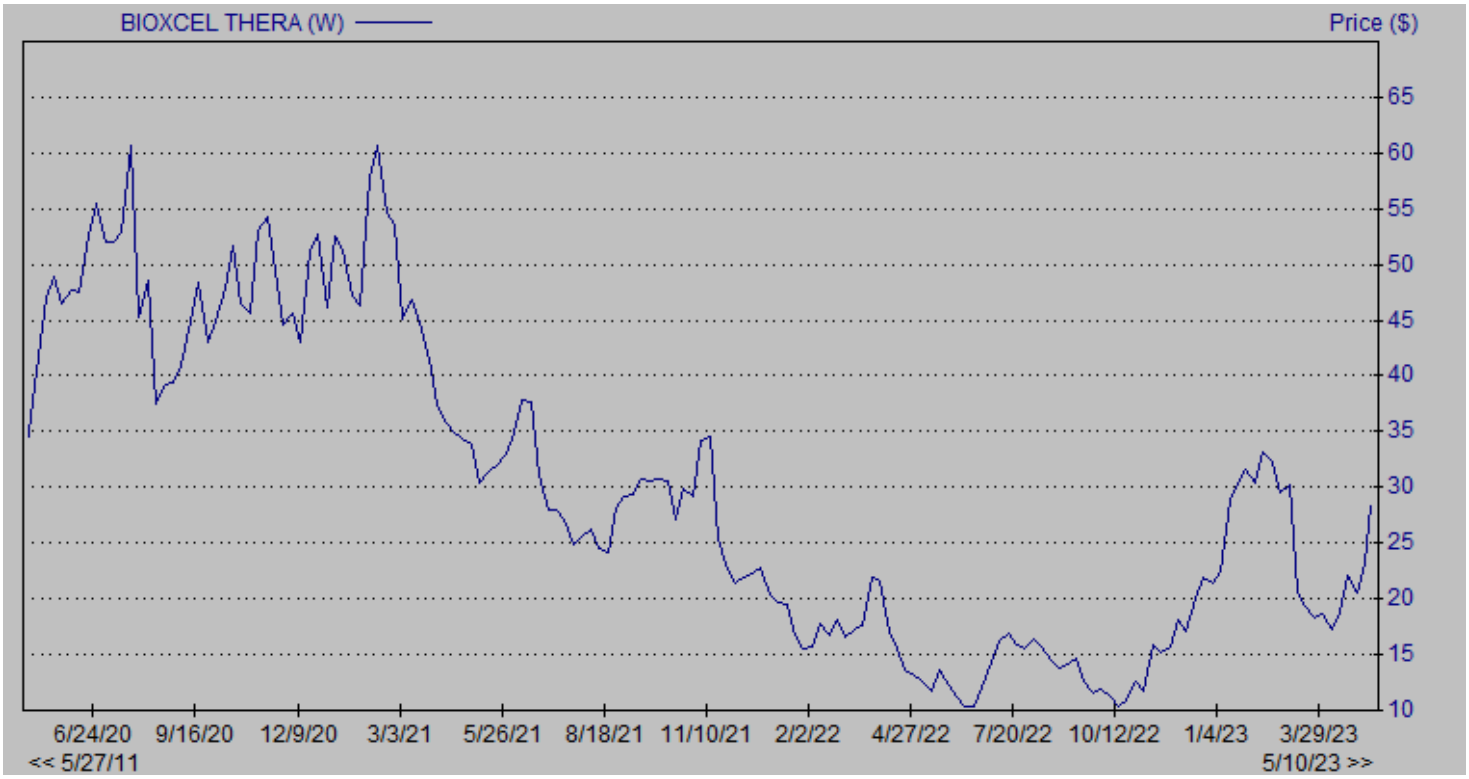
PROJECTED FINANCIALS

BioXcel Therapeutics, Inc.	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
BXCL501	$0	$0	$0	$1	$3	$5	$12	$35
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**	**$3**	**$5**	**$18**	**$35**
Cost of Sales	$0	$0	$0	$0	$0	$0	$1	$2
Product Gross Margin	*95%*	*96%*	*96%*	*96%*	*96%*	*96%*	*94%*	*94%*
Research & Development	$91.2	$27.8	$23.0	$26.0	$29.0	$105.8	$105.0	$110.0
General & Administrative	$68.8	$23.6	$24.0	$24.0	$24.0	$95.6	$100.0	$108.0
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)	($46.6)	($49.0)	($50.1)	($196.9)	($188.0)	($185.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$6.1	$1.6	$1.5	$1.5	$1.5	$6.1	$6.0	$6.0
Pre-Tax Income	($165.8)	($52.7)	($48.1)	($50.5)	($48.6)	($190.8)	($182.0)	($179.0)
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)**	**($48.1)**	**($50.5)**	**($48.6)**	**($190.8)**	**($182.0)**	**($179.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.92)**	**($1.84)**	**($1.66)**	**($1.74)**	**($1.68)**	**($6.60)**	**($6.07)**	**($5.59)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	28.0	28.6	29.0	29.0	29.0	28.9	30.0	32.0

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

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