

Zacks Small-Cap Research

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BioXcel Therapeutics, Inc.

(BTAI-NASDAQ)

BTAI: Multiple Catalysts Ahead in 2023...

Based on our probability adjusted DCF model that takes into account potential future revenues of BXCL501 and BXCL701, BTAI is valued at \$78.00/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 (01/27/22) \$32.01
Valuation \$78.00

OUTLOOK

Looking ahead to the upcoming year, BioXcel Therapeutics, Inc. (BTAI) has a number of important near-term catalysts. The company recently initiated both the Phase 3 TRANQUILITY III trial of BXCL501 for the treatment of acute agitation in Alzheimer's patients and the Phase 3 SERENITY III trial of BXCL501 for the at-home use of BXCL501 in adults with Bipolar I or II disorder or Schizophrenia. In addition, we will continue to watch the launch of IGALMI™. Following additional analysis, we believe we may have been a bit overly optimistic in regards to anticipated revenues for the first few years post-launch. We have made some adjustments to our model; however, this does not diminish our enthusiasm for the drug or our estimate for peak sales.

SUMMARY DATA

52-Week High \$32.73
52-Week Low \$9.03
One-Year Return (%) 113.40
Beta 1.16
Average Daily Volume (sh) 320,784

Shares Outstanding (mil) 28
Market Capitalization (\$mil) \$897
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 -5.8
P/E using 2020 Estimate -10.8

Risk Level Above Avg.
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)
2021	0 A	0 A	0 A	0 A	0 A
2022	0 A	0 A	0 A	0 E	0 E
2023					11 E
2024					35 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-\$1.07 A	-\$1.11 A	-\$0.96 A	-\$0.93 A	-\$4.05 A
2022	-\$1.12 A	-\$1.35 A	-\$1.49 A	-\$1.42 E	-\$5.09 E
2023					-\$4.82 E
2024					-\$4.09 E

WHAT'S NEW

Business Update

Multiple Catalysts Ahead in 2023

BioXcel Therapeutics, Inc. (BTAI) has a number of important catalysts coming up in 2023 that investors will want to keep on their radar.

- In November 2022, BioXcel [announced](#) the initiation of the Phase 3 SERENITY III trial investigating the at-home use of 60 mg BXCL501 for patients with Bipolar I or II disorder or schizophrenia. This 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 mg 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. Approximately 200 patients will be enrolled in part 1 of the study. Part 2 of the study is designed to assess 60 mg BXCL501 when administered at home. We anticipate topline data in the first half of 2023.
- In December 2022, BioXcel [announced](#) the initiation of the Phase 3 TRANQUILITY III trial of 40 mg or 60 mg BXCL501. 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. We anticipate data from TRANQUILITY II in the first half of 2023.
- We anticipate updates regarding the launch of IGALMI™ during the company's quarterly financial updates. These will be important for investors to monitor to ensure that the launch is continuing on pace. Following further analysis of the formulary process and potential uptake of the drug, we believe we may have been overly optimistic for expected IGALMI™ revenues for the first few years post-launch. We have dialed back our expectations; however, this does not diminish our enthusiasm for the drug or our estimated peak sales. We now believe the uptake will be a bit slower than previously thought and it may take a few extra years to reach peak sales (9-10 years vs. 6-7 years).

BXCL701 Update

OnkosXcel Therapeutics is a subsidiary of BioXcel focused on the company's immuno-oncology programs, including BXCL701. BXCL701 (talabostat) is an oral small molecule immunomodulator designed to activate the innate immune system through inhibition of dipeptidyl peptidase (DPP) 8/9 and fibroblast activation protein (FAP). Its purpose is to initiate inflammation in the tumor microenvironment, thus potentially turning "cold" tumors "hot" and making them more amenable to immunotherapy treatment.

BXCL701 is currently being evaluated in an ongoing Phase 2 trial in combination with Keytruda in metastatic castration-resistant prostate cancer (mCRPC) patients with small cell neuroendocrine (SCNC) or adenocarcinoma phenotype. On January 11, 2023, BioXcel [announced](#) promising topline results in patients with SCNC that included an encouraging response rate. The full data set has been submitted to the 2023 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), which is taking place February 16-18.

Conclusion

BioXcel's stock is up almost 50% in the past month and over 150% over the past three months. Even after this move we believe there remains plenty of additional upside, particularly if the SERENITY III and TRANQUILITY trials have positive readouts. While we've been very encouraged by the early metrics reported for the commercial launch of IGALMI™, we caution investors that it will likely still take some time for sales to ramp up. We've made a few modifications to our model that now estimates a slower uptake for IGALMI™ and a longer time to peak sales. While we remain just as enthusiastic about the drug's long-term prospects, our valuation has been slightly reduced to \$78 per share.

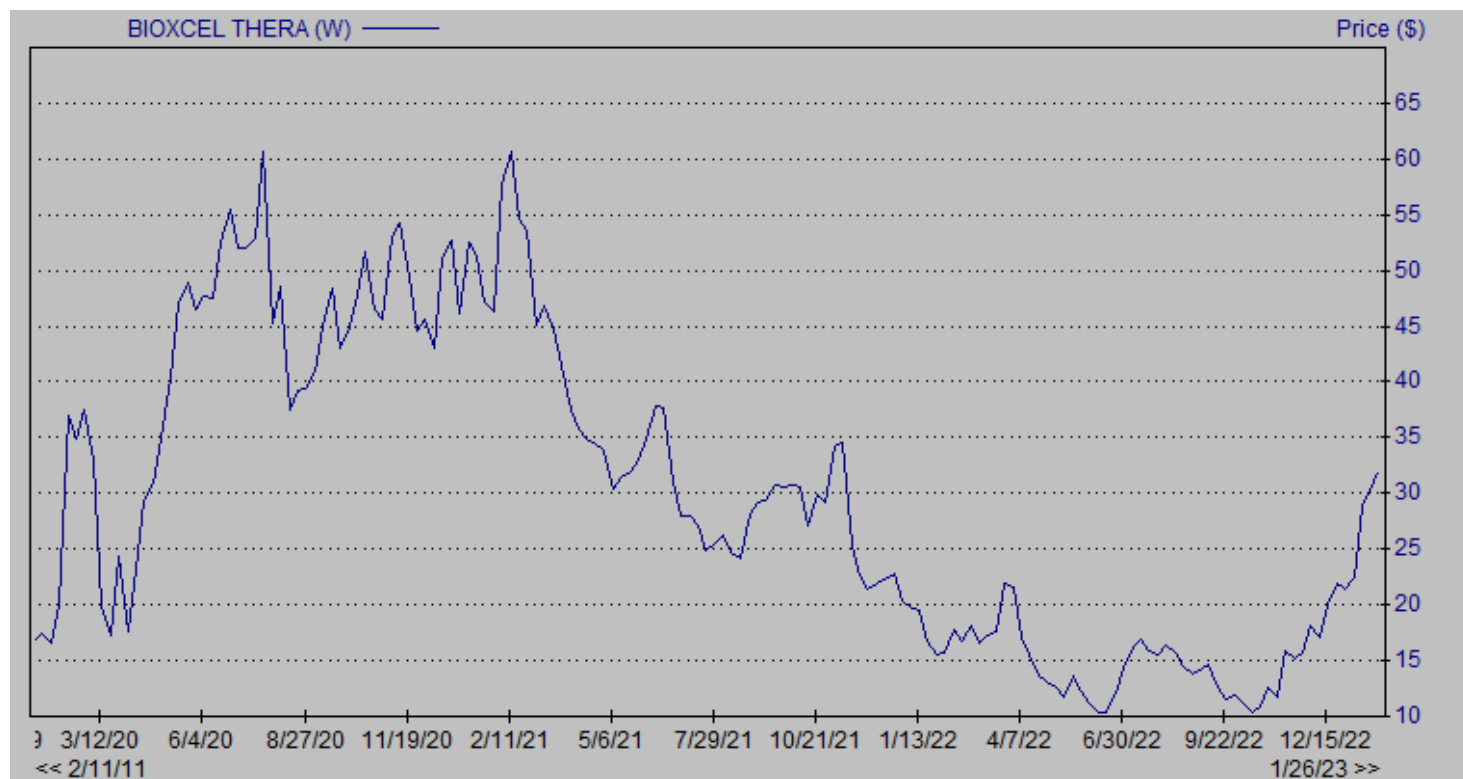
PROJECTED FINANCIALS

BioXcel Therapeutics, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
BXCL501	\$0	\$0	\$0	\$0	\$0	\$0	\$11	\$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	\$0	\$0	\$0	\$11	\$35
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$2	\$5
<i>Product Gross Margin</i>	-	-	-	92%	-	86%	85%	86%
Research & Development	\$52.7	\$18.6	\$17.9	\$22.1	\$22.0	\$80.5	\$85.0	\$90.0
General & Administrative	\$54.2	\$12.9	\$18.4	\$17.1	\$18.0	\$66.4	\$70.0	\$72.0
Other (Income) Expense	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	(\$106.9)	(\$31.4)	(\$36.3)	(\$39.0)	(\$40.0)	(\$146.8)	(\$145.7)	(\$131.8)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.0	\$0.0	\$1.4	\$2.8	\$0.0	\$4.2	\$1.0	\$1.0
Pre-Tax Income	(\$106.9)	(\$31.4)	(\$37.7)	(\$41.8)	(\$40.0)	(\$142.6)	(\$144.7)	(\$130.8)
Income Taxes	\$0	\$0.0	\$0.0	\$0.0	\$0.0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$106.9)	(\$31.4)	(\$37.7)	(\$41.8)	(\$40.0)	(\$142.6)	(\$144.7)	(\$130.8)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$4.05)	(\$1.12)	(\$1.35)	(\$1.49)	(\$1.42)	(\$5.09)	(\$4.82)	(\$4.09)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	26.4	28.0	28.0	28.0	28.1	28.0	30.0	32.0

Source: Zacks Investment Research, Inc.

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HISTORICAL STOCK PRICE



Source: Zacks SCR

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