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BioXcel Therapeutics, Inc. (BTAI-NASDAQ)

BTAI: Important Data Readouts in 2Q23…

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 (03/22/23)	$19.36
Valuation	**$75.00**

OUTLOOK

On March 9 2023, BioXcel Therapeutics, Inc. (BTAI) announced financial results for the fourth quarter and full year 2022 and provided a business update. We are anticipating multiple data readouts for BXCL501 in the second quarter of 2023: 1) Topline data for the TRANQUILITY II trial of BXCL501 for the acute treatment of Alzheimer's agitation in patients in assisted living facilities; 2) 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; and 3) Topline data for the Phase 1b multiple ascending dose (MAD) trial of BXCL501 in combination with SSRIs or SNRIs in patients with major depressive disorder (MDD).

SUMMARY DATA

52-Week High	**$33.24**
52-Week Low	**$9.03**
One-Year Return (%)	**3.14**
Beta	**1.21**
Average Daily Volume (sh)	**668,245**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$562**
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	**-3.0**
P/E using 2020 Estimate	**-5.3**

Risk Level	**Above Avg.**
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 E	1 E	2 E	4 E	7 E
2024					18 E
2025					35 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$1.12 A	-$1.35 A	-$1.49 A	-$1.95 A	-$5.92 A
2022	-$1.35 A	-$1.44 A	-$1.52 A	-$1.44 E	-$5.43 E
2023					-$5.23 E
2024					-$4.66 E

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WHAT'S NEW

Business Update

Multiple Data Readouts in 2Q23

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 second quarter of 2023:

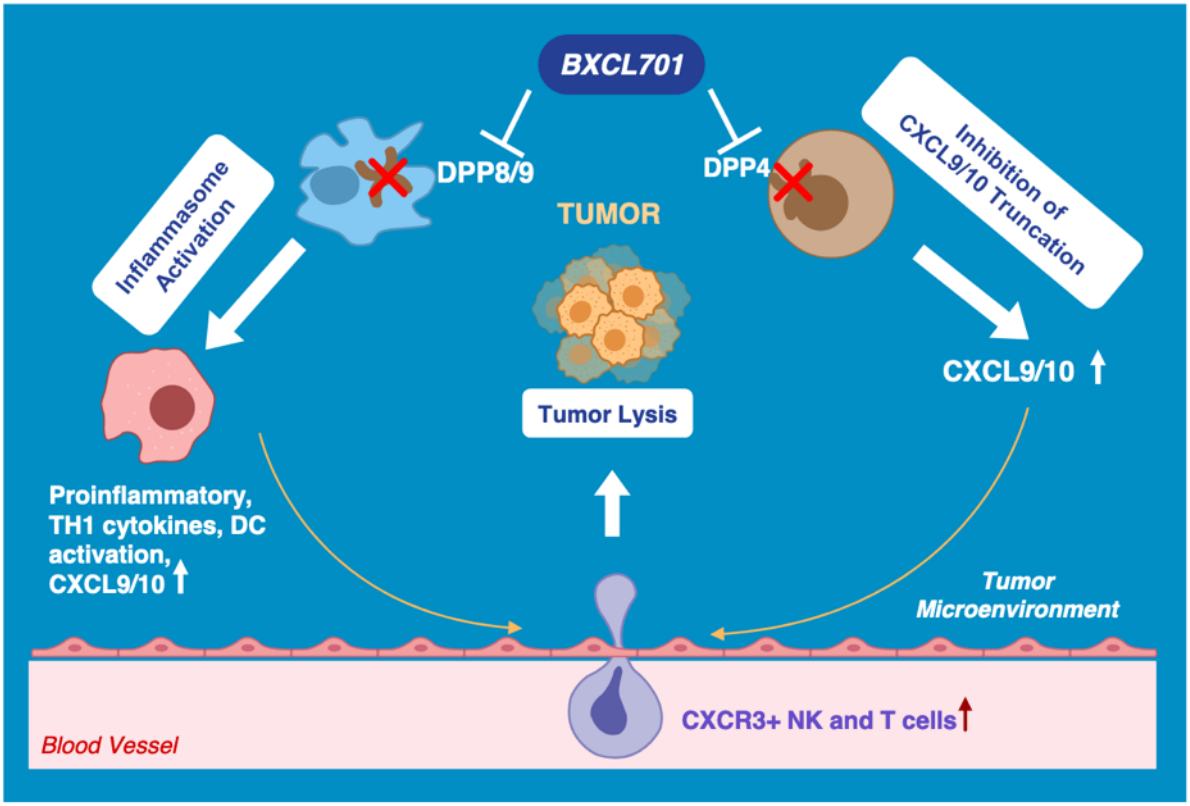
- Topline data is anticipated from the TRANQUILITY II trial of BXCL501 for the acute treatment of Alzheimer's agitation. The TRANQUILITY program includes both TRANQUILITY II and TRANQUILITY III. Each trial will enroll approximately 150 patients with dementia ages 65 and older who will self-administer 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. In December 2022, BioXcel announced the initiation of the Phase 3 TRANQUILITY III trial of 40 mg or 60 mg BXCL501. Enrollment is ongoing for that trial.

- Topline data is anticipated 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 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. Part 2 of the study is designed to assess 60 mg BXCL501 when administered at home. That trial is anticipated to initiate in the second quarter of 2023.

- Topline data is anticipated from the Phase 1b multiple ascending dose trial of BXCL501 in combination with selective serotonin- or serotonin-norepinephrine reuptake inhibitors (SSRIs or SNRIs, respectively) in patients with major depressive disorder. Enrollment has completed in the trial with cohorts receiving either daily or twice-daily dosing regimens for seven days. Data cleaning and verification are in progress before the data can be released.

BXCL701 Potentially Pivotal Phase 2b Trial in 2H23

In February 2023, BioXcel held a key opinion leader (KOL) day for BXCL701, the company's oral innate immune activator that inhibits DPP8/9. The following slide gives an overview of the proposed mechanism of action of BXCL701, in which inhibition of DPP8/9 leads to inflammasome activation, release of proinflammatory cytokines, and enhancement of natural killer (NK) and CD8+ T cell infiltration. BXCL701 is designed to make "cold" tumors "hot" and enhance the activity of checkpoint inhibition.



Source: BioXcel Therapeutics, Inc.

The KOL event included multiple presentations regarding prostate cancer, BXCL701, data from the Phase 2a trial, and the plans for the Phase 2b trial. Below are highlights from each of the presentations.

Daniel P. Petrylak, MD: Dr. Petrylak is a Professor of Medicine and Urology at Yale School of Medicine. He provided a comprehensive overview of the therapeutic landscape for prostate cancer along with the challenges of using checkpoint inhibitor therapy (CPI).

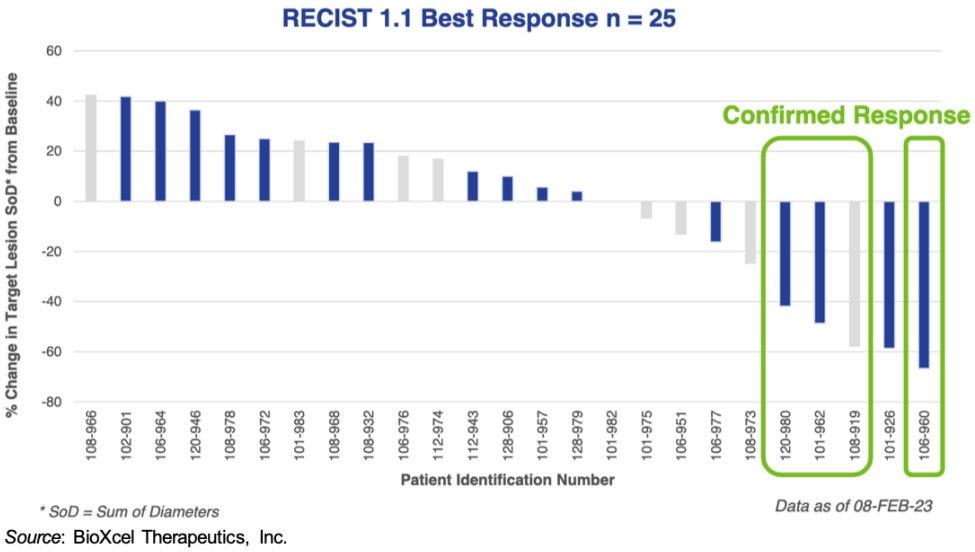
- KEYNOTE-921 data presented at ASCO GU 2023 showed that Keytruda in combination with docetaxel did not significantly improve the efficacy compared to docetaxel alone
- KEYNOTE-199 data of Keytruda in metastatic castration resistant prostate cancer (mCRPC) patients with adenocarcinoma phenotype showed minimal activity
- CPI's are only effective in prostate cancer's with microsatellite instability (MSI), which is phenotype of deficient DNA mismatch repair
- These results point to the fact that there is a need for therapeutic agents that can inflame the prostate cancer tumor microenvironment (TME) and turn cold tumors to hot

Louis M. Weiner, MD: Dr. Weiner is the Director of Georgetown Lombardi Comprehensive Cancer Center and Professor of Oncology at Georgetown University Medical Center. He discussed evidence of preclinical activity of BXCL701 in combination with pembrolizumab in multiple animal models.

- BXCL701 reduced tumor growth and extended survival time in a murine model of pancreatic ductal adenocarcinoma
- BXCL701 both alone and in combination with anti-PD1 therapy reduced fibrosis in the TME
- The combination of BXCL701 and anti-PD1 therapy resulted in both NK and T cell recruitment into the TME
- The combination of BXCL701 and anti-PD1 therapy induced memory response against tumor re-challenge
- In addition to anti-PD1 therapy, BXCL701 also synergizes with anti-CTLA-4 and anti-OX40
- DPP9 copy number correlates with BXCL701 cytotoxicity in leukemic cell lines and may also be a predictive biomarker in leukemias

Dr. Rahul Aggarwal, MD: Dr. Aggarwal is the Associate Director for Clinical Sciences of Helen Diller Family Comprehensive Cancer Center and Associate Professor of Medicine at UCSF. He discussed the results of the Phase 2a trial of BXCL701 in mCRPC patients with small cell neuroendocrine (SCNC) phenotype.

- Its estimated that 288,300 men will be diagnosed with prostate cancer in the U.S. in 2023 (American Cancer Society). Approximately 20% of those will progress to mCRPC and 20% of those mCRPC will develop SCNC phenotype, which is characterized by poor prognosis and low survival rate
- The objective response rate in the Phase 2a trial was 20%, which included 4 confirmed partial responses (PR) and 1 unconfirmed partial response. The disease control rate (PR + stable disease) was 48%. The median duration of response was 6+ months



Source: BioXcel Therapeutics, Inc.

- BXCL701 was generally well tolerated with the most common treatment-related adverse events being fatigue, hypotension, pruritis, dizziness, and nausea
- BXCL701 in combination with pembrolizumab in adenocarcinoma patients showed response rate, duration of efficacy, and safety data that were consistent with SCNC

Vincent J. O'Neill, MD: Dr. O'Neill is the Chief R&D Officer of OnkosXcel Therapeutics, a subsidiary of BioXcel Therapeutics with a mission of developing therapies for difficult-to-treat cancers with high unmet need. Dr. O'Neill discussed future directions for BXCL701, including its potential in other cancers with frequent DPP alterations.

- The planned Phase 2b study of BXCL701 in SCNC is a potentially registrational trial expected to initiate in 2H23
- It will enroll approximately 60 patients randomized 2:1 between BXCL701 + pembrolizumab compared to BXCL701 monotherapy
- The primary endpoint is objective response by RECIST 1.1
- With an expected readout in the first half of 2025, the company could be in a position to file an NDA in the second half of 2025 under accelerated approval pathway
- In addition to prostate cancer, BXCL701 will be evaluated in a Phase 1b/2 trial in patients with extensive stage small cell lung cancer (SCLC) in combination with atezolizumab, which is approved for the treatment of SCLC
- The Phase 1b (determining recommended Phase 2 dose) portion of the trial is expected to initiate in the second half of 2023 and the SCLC Phase 2 proof-of-concept trial is expected to initiate in the first half of 2024
- BXCL701 will also be tested in two investigator sponsored trials in acute myeloid leukemia (AML) and metastatic pancreatic ductal adenocarcinoma

Financial Update

On March 9, 2023, BioXcel announced financial results for the fourth quarter and full year 2022. Revenue of $238,000 was recorded in the fourth quarter of 2022 compared to no revenue in the fourth quarter of 2021. The revenue reflects limited market access since the launch of IGALMI in July 2022. Net loss in the fourth quarter of 2022 was $54.8 million, compared to a net loss of $26.1 million in the fourth quarter of 2021. R&D expenses in the fourth quarter of 20212 were $32.5 million, compared to $12.5 million for the fourth quarter of 2021. The increase was primarily due to increased clinical trial costs. G&A expenses in the fourth quarter of 2022 were $20.7 million, compared to $13.6 million for the fourth quarter of 2021. The increase was primarily due to an increase in personnel costs related to the launch of IGALMI.

For 2022, BioXcel reported product revenues of $375,000 since the launch of IGALMI in July 2022. Sales thus far have resulted from early product trials and are indicative of limited market access. There were no sales in 2021. Net loss for 2022 was $165.8 million, compared to a net loss of $54.8 million in 2021. R&D expenses in 2022 were $91.2 million, compared to $52.7 million in 2021. The increase was primarily due to increased clinical trial costs for BXCL501. G&A expenses in 2022 were $68.8 million, compared to $54.2 million in 2021. The increase was primarily due to increased personnel costs related to the launch of IGALMI.

As of December 31, 2022, BioXcel had approximately $193.7 million in cash and cash equivalents. As of March 13, 2023, the company had approximately 29.0 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 33.9 million.

Conclusion

The pace of sales for IGALMI continues to be below our expectations, although we believe that the company has all the pieces in place to make the drug a commercial success: the expanded sales force of 70 representatives covers more than 1,700 target hospitals, more than 600 hospital Pharmacy and Therapeutics Committee decisions are scheduled (65 positive formulary decisions thus far), and the company has launched a new promotional campaign. While we will keep an eye on how IGALMI sales continue to evolve, the most important upcoming catalysts for the company are the data readouts in the second quarter of 2023. Based on the sales data thus far, we have slightly reduced our sales projections for IGALMI for the next couple of years, which has slightly decreased our valuation to $75 per share.

PROJECTED FINANCIALS

BioXcel Therapeutics, Inc.	2022 A	Q1 E	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
BXCL501	$0	$0	$1	$2	$4	$7	$18	$35
BXCL701	$0	$0	$0	$0	$0	$0	$0	$0
Other Income	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$1**	**$2**	**$4**	**$7**	**$18**	**$35**
Cost of Sales	$0	$0	$0	$0	$0	$0	$1	$2
Product Gross Margin	*95%*	*95%*	*95%*	*95%*	*95%*	*95%*	*94%*	*94%*
Research & Development	$91.2	$20.0	$23.0	$26.0	$29.0	$98.0	$105.0	$110.0
General & Administrative	$68.8	$18.0	$18.0	$18.0	$18.0	$72.0	$75.0	$78.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($159.6)	($37.6)	($40.2)	($42.6)	($43.2)	($163.6)	($163.0)	($155.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$6.1	$1.5	$1.5	$1.5	$1.5	$6.0	$6.0	$6.0
Pre-Tax Income	($165.8)	($39.1)	($41.7)	($44.1)	($41.7)	($157.6)	($157.0)	($149.0)
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)**	**($39.1)**	**($41.7)**	**($44.1)**	**($41.7)**	**($157.6)**	**($157.0)**	**($149.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.92)**	**($1.35)**	**($1.44)**	**($1.52)**	**($1.44)**	**($5.43)**	**($5.23)**	**($4.66)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	28.0	29.0	29.0	29.0	29.0	29.0	30.0	32.0

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

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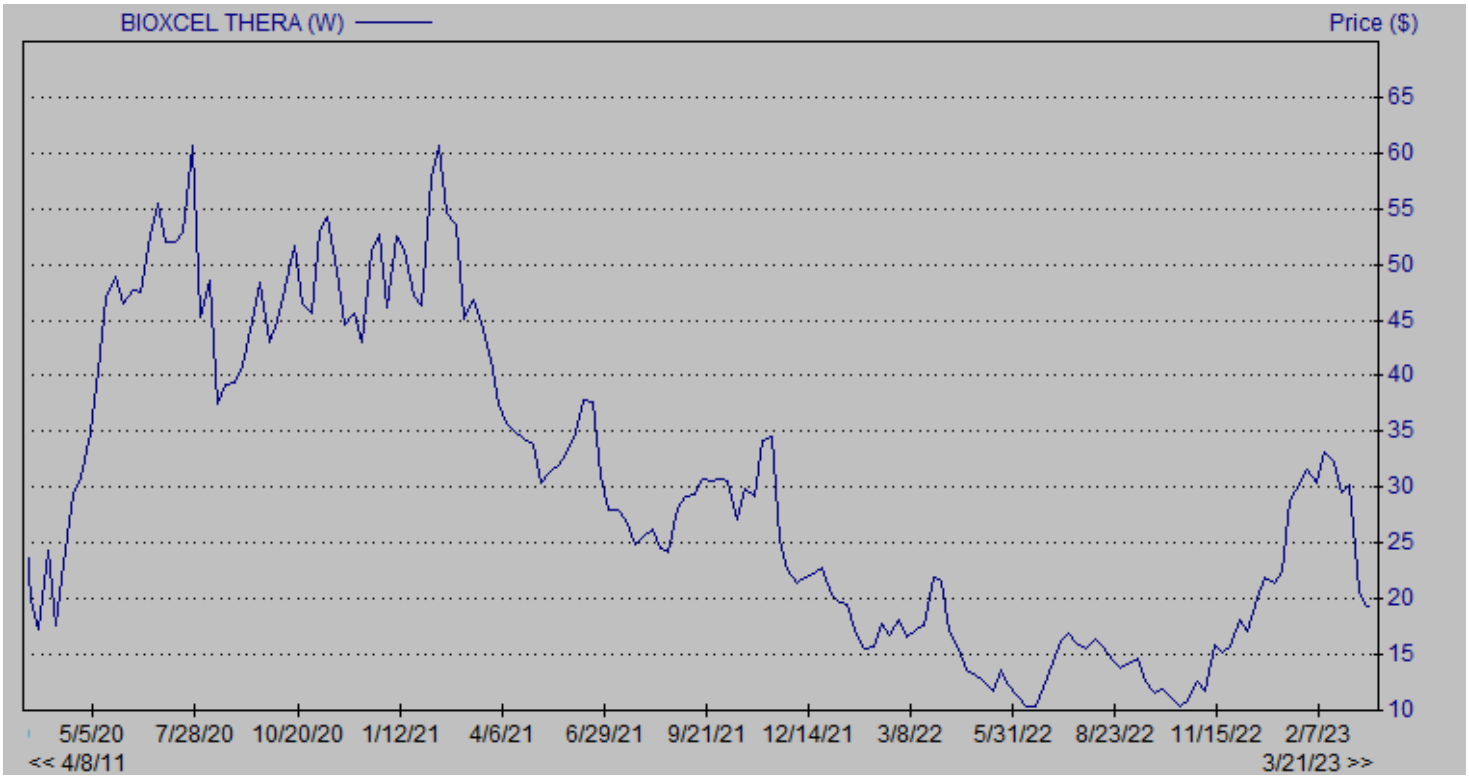
HISTORICAL STOCK PRICE



Source: Zacks SCR

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