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BioXcel Therapeutics, Inc. (BTAI-NASDAQ)

BTAI: Preparations Underway for Commercial Launch of BXCL501; PDUFA Date of Jan. 5, 2022…

Based on our probability adjusted DCF model that takes into account potential future revenues of BXCL501 and BXCL701, BTAI is valued at $110.00/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 (11/30/21)	$22.24
Valuation	**$110.00**

OUTLOOK

On November 10, 2021, BioXcel Therapeutics, Inc. (BTAI) announced financial results for the third quarter of 2021 and provided a business update. The company is preparing for the commercial launch of BXCL501 ahead of the January 5, 2022 PDUFA date, which includes the recent hire of a VP of sales, regional sales directors, and building out the sales team. In addition, the company is deploying an education campaign for healthcare providers to increase awareness of agitation associated with neuropsychiatric disorders. The company remains on track to initiate the Phase 3 program for acute agitation in Alzheimer's patients in the fourth quarter of 2021. In regards to pipeline expansion, the company held a pre-IND meeting with the FDA for the use of BXCL501 in major depressive disorder, with a clinical trial expected to initiate in the first half of 2022, and introduced BXCL502 for the chronic treatment of agitation in patients with dementia.

SUMMARY DATA

52-Week High	**$64.60**
52-Week Low	**$22.24**
One-Year Return (%)	**-49.46**
Beta	**0.98**
Average Daily Volume (sh)	**324,264**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$622**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**47**
Insider Ownership (%)	**9**
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	**-5.1**
P/E using 2020 Estimate	**-6.2**

Risk Level	**Above Avg.**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 A	0 E	0 E
2022					126 E
2023					297 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.79 A	-$1.06 A	-$1.07 A	-$0.87 A	-$3.79 A
2021	-$1.07 A	-$1.11 A	-$0.96 A	-$0.95 E	-$4.08 E
2022					-$1.10 E
2023					$2.81 E

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WHAT'S NEW

Business Update

PDUFA Data of Jan. 5, 2022 for BXCL501; MAA Filing Expected in 1H22

In May 2021, BioXcel Therapeutics, Inc. (BTAI) announced that the New Drug Application (NDA) for BXCL501 for the treatment of schizophrenia and bipolar disorder related agitation was accepted by the FDA with a PDUFA action date of January 5, 2022.

The NDA filing for BXCL501 is based in part on the positive results from the Phase 3 SERENITY I and SERENITY II clinical trials, which the company disclosed in July 2020. The SERENITY I trial was a randomized, double blind, placebo controlled parallel group adaptive trial in patients with schizophrenia or schizoaffective disorder (n=381) that were randomized to receive 120 μg BXCL501, 180 μg BXCL501, or placebo. The SERENITY II trial was a randomized, double blind, placebo controlled parallel group adaptive trial in patients with bipolar disorders (n=378) that were randomized to receive 120 μg BXCL501, 180 μg BXCL501, or placebo. Results showed a robust response in decreasing PEC scores in both trials and a favorable tolerability profile.

In addition to the NDA filing, we anticipate the company filing a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for BXCL501 for the treatment of schizophrenia and bipolar disorder related agitation in the first half of 2022.

In regards to commercialization plans, the company has hired a Vice President of Sales and Regional Sales Directors while continuing to build the sales team, with a plan to hire approximately 75 sales representatives. The medical science liaison and medical managed care teams have begun their engagement with healthcare professional and payers, including participation at a number of scientific conferences.

Phase 3 Program for BXCL501 in Dementia Related Agitation to Initiate 4Q21

In March 2021, BioXcel announced that the FDA had granted Breakthrough Therapy designation to BXCL501 for the treatment of agitation in dementia patients. Breakthrough Therapy designation allows for additional guidance from the FDA on drug development, the involvement of senior FDA managers, and a rolling review of the NDA.

In January 2021, BioXcel announced positive topline results for the Phase 1b/2 TRANQUILITY trial of BXCL501 for the acute treatment of agitation in dementia patients, including those with Alzheimer's disease. Treatment with BXCL501 resulted in a rapid, dose dependent decrease in PEC score from baseline that separated from placebo numerically by 30 minutes post-treatment and was statistically significantly different by 60 minutes. A full recap of the results can be found in our previous report.

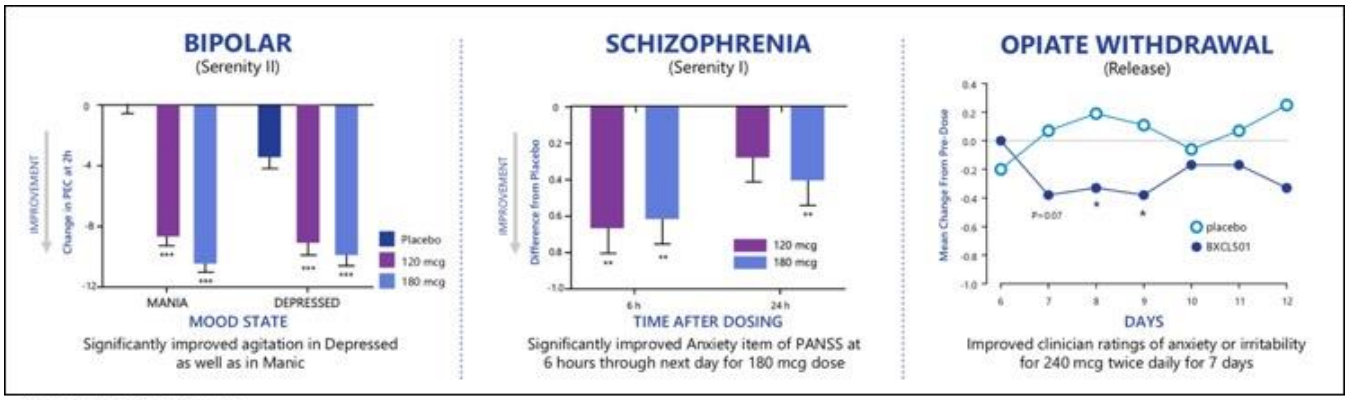
Subsequent to the data announcement, the company initiated a supplemental dosing cohort investigating a 40 μg dose of BXCL501 in 46 patients (randomized 1:1) to help build a comprehensive clinical development strategy with the long-term goal of targeting dementia care from long-term care centers to at-home care.

We anticipate the Phase 3 program in dementia related agitation initiating in the fourth quarter of 2021, with the results of the 40 μg cohort helping to inform what doses the company takes forward into Phase 3 testing.

BXCL501 for Major Depressive Disorder

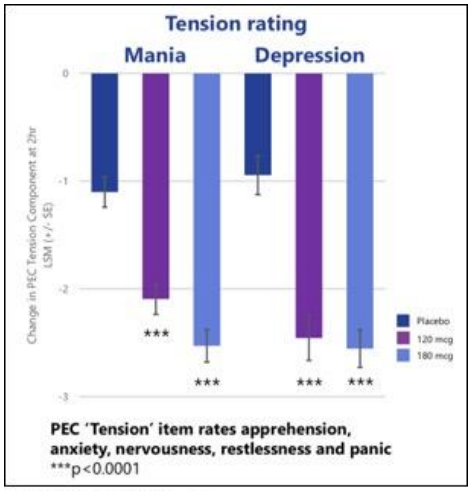
In September 2021, BioXcel held a virtual R&D day and discussed the development of BXCL501 in major depressive disorder (MDD). MDD is characterized by a number of different symptoms, with clinical data showing that BXCL501 can have a direct impact on many of them, including anxiety, restlessness, irritability, panic, and sleep disturbances.

Analyzing data collected from the SERENITY I and II trials and the RELEASE trial showed that BXCL501 reduced agitation consistently in depressed patients (bipolar), schizophrenia, and opioid withdrawal. As the following graphs show, a significant improvement in agitation was seen in bipolar patients in those that were depressed as well as manic. In addition, there was a significant improvement in the anxiety item of the PANSS for schizophrenic patients and a significant improvement in clinician ratings of anxiety or irritability in opioid withdrawal patients.



Source: BioXcel Therapeutics, Inc.

Data from SERENITY II (bipolar) also showed that BXCL501 was effective in reducing Tension in patients with depressed mood. The following graph shows a significant change in PEC 'Tension', which measures apprehension, anxiety, nervousness, restlessness, and panic, in patients with mania and depression treated with BXCL501.



Source: BioXcel Therapeutics, Inc.

BioXcel recently held a pre-IND meeting with the FDA regarding the clinical development of BXCL501 as an adjunctive treatment for MDD with selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). The company is preparing to submit an IND with a plan to initiate a clinical trial in the first half of 2022.

BXCL502 for the Chronic Treatment of Agitation

Using the company's artificial intelligence (AI) drug discovery platform, BioXcel has identified BXCL502 for the chronic treatment of agitation. It is a potent and selective antagonist for a G-protein coupled receptor (GPCR) target that affects serotonergic signaling in the cerebral cortex. Preclinical efficacy was shown in two animal models and the compound was previously tested in patients and shown to be safe and well tolerated for up to 52 weeks of dosing. The company is currently working on the formulation and clinical development plan with the potential for combination therapy with BXCL501.

Financial Update

On November 10, 2021, BioXcel announced financial results for the third quarter of 2021. As expected, the company did not report any revenues in the third quarter of 2021. Net loss in the third quarter of 2021 was $26.8 million, compared to a net loss of $24.8 million in the third quarter of 2020. R&D expenses in the third quarter of 2021 were $11.9 million, compared to $16.3 million for the third quarter of 2020. The decrease was primarily due to decreased clinical trial costs for BXCL501. G&A expenses in the third quarter of 2021 were $14.9 million, compared to $8.5 million for the third quarter of 2020. The increase was primarily due to increased personnel related costs, non-cash stock-based compensation, marketing and commercial expenses, legal and professional fees, and insurance costs.

As of September 30, 2021, BioXcel had approximately $252.9 million in cash and cash equivalents. As of November 5, 2021, the company had approximately 28.0 million shares outstanding and when factoring in stock options a fully diluted share count of approximately 32.0 million.

Conclusion

The PDUFA date of January 5, 2022 for BXCL501 is rapidly approaching and the company is busy preparing for the potential commercial launch of the drug, which includes recently hiring the VP of Sales and Regional Sales Directors with an expected sales force of 75 representatives. In addition to the FDA's decision, in the near term we look forward to the initiation of the Phase 3 program for BXCL501 in Alzheimer's agitation in the fourth quarter of 2021, the initiation of the MDD clinical program for BXCL501 in the first half of 2022, and an update on the development pathway for BXCL502. We continue to remain positive on the prospects for BXCL501 in agitation and our current valuation remains at $110.

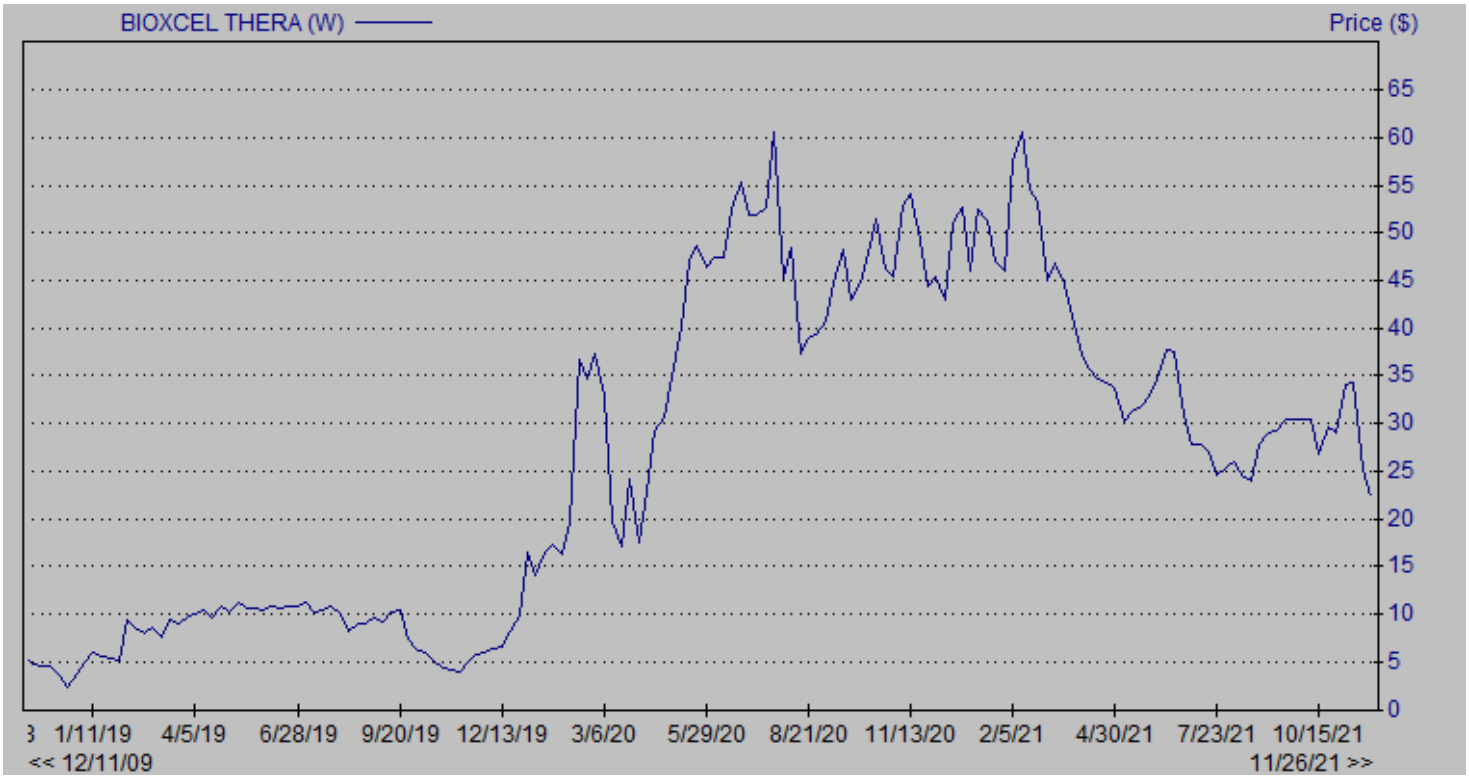
PROJECTED FINANCIALS

BioXcel Therapeutics, Inc.	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 E
BXCL501	$0	$0	$0	$0	$0	$0	$126	$297
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**	**$126**	**$297**
Cost of Sales	$0	$0	$0	$0	$0	$0	$15	$33
Product Gross Margin	-	-	-	-	-	-	*88%*	*89%*
Research & Development	$58.0	$14.7	$13.5	$11.9	$15.0	$55.2	$65.0	$75.0
General & Administrative	$24.3	$11.6	$14.1	$14.9	$11.8	$52.4	$80.0	$100.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($82.3)	($26.3)	($27.6)	($26.8)	($26.8)	($107.6)	($34.0)	$89.0
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	$0.0	($0.0)	$0.0	$0.1	$0.1	$1.0	$1.0
Pre-Tax Income	($82.2)	($26.3)	($27.6)	($26.8)	($26.7)	($107.5)	($33.0)	$90.0
Income Taxes	$0	$0.0	$0.0	$0.0	$0.0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($82.2)**	**($26.3)**	**($27.6)**	**($26.8)**	**($26.7)**	**($107.5)**	**($33.0)**	**$90.0**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.79)**	**($1.07)**	**($1.11)**	**($0.96)**	**($0.95)**	**($4.08)**	**($1.10)**	**$2.81**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	21.7	24.5	25.0	28.0	28.0	26.4	30.0	32.0

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

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Source: Zacks SCR

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