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BioXcel Therapeutics, Inc. (BTAI-NASDAQ)

BTAI: Pivotal Phase 3 Trials for BXCL501 to Initiate by End of 2019…

Based on our probability adjusted DCF model that takes into account potential future revenues of BXCL501 and BXCL701, BTAI is valued at $21.00/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 (12/06/19)	$6.35
Valuation	**$21.00**

OUTLOOK

On December 3, 2019, BioXcel Therapeutics, Inc. (BTAI) announced that following a successful 'end-of-Phase 2' meeting with the FDA, the company is now prepared to initiate two pivotal Phase 3 clinical trials for BXCL501 for the acute treatment of agitation in patients with schizophrenia and bipolar disorder. The SERENITY trials will enroll up to 750 patients 18 to 75 years of age, with the SERENITY I trial enrolling patients with agitation associated with schizophrenia and the SERENITY II trial enrolling patients with agitation associated with bipolar disorder. Each trial will enroll up to 375 patients randomized 1:1:1 between 120 μg BXCL501, 180 μg BXCL501, or placebo. The trials are expected to commence prior to the end of 2019 and we anticipate topline results in mid-2020.

SUMMARY DATA

52-Week High	**$11.79**
52-Week Low	**$2.41**
One-Year Return (%)	**25.49**
Beta	**3.11**
Average Daily Volume (sh)	**170,758**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$115**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**23**
Insider Ownership (%)	**65**
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	**-2.6**

Risk Level	**High**
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)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 A	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.37 A	-$0.19 A	-$0.31 A	-$0.47 A	-$1.32 A
2019	-$0.46 A	-$0.54 E	-$0.57 A	-$0.50 E	-$2.12 E
2020					-$2.00 E
2021					-$2.10 E

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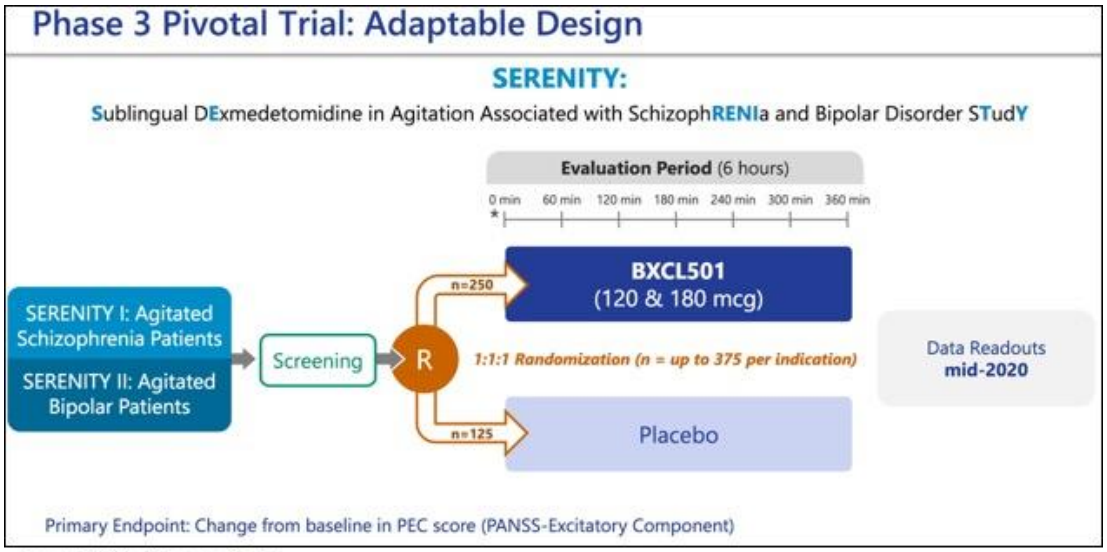
Business Update

Phase 3 Program for BXCL501 in Schizophrenia and Bipolar Disorder to Initiate Before End of 2019

On December 3, 2019, BioXcel Therapeutics, Inc. (BTAI) announced that following a successful 'end-of-Phase 2' meeting with the FDA, the company will be initiating the Phase 3 SERENITY (Sub-Lingual DExmedetomidine in Agitation Associated With SchizophRENIa and Bipolar Disorder STudY) program before the end of 2019.

The SERENITY I trial will be a randomized, double blind, placebo controlled, adaptive trial involving up to 375 patients age 18 to 75 with agitation associated with schizophrenia who will be randomized 1:1:1 to receive either 120 μg BXCL501, 180 μg BXCL501, or placebo. The SERENITY II trial is designed similarly to the SERENITY I trial, but will enroll patients with agitation associated with bipolar disorder.

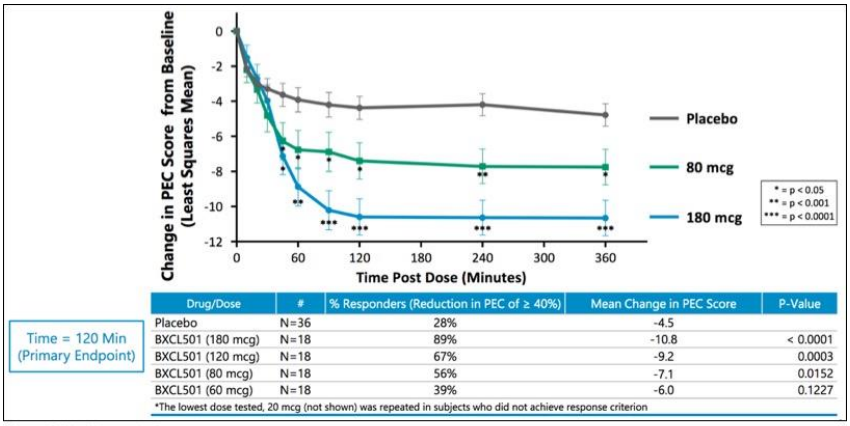
The primary endpoint of both trials will be a reduction of symptoms of acute agitation using the Positive and Negative Syndrome Scale – Excitatory Component (PEC), a validated regulatory endpoint for quantifying agitation comprised of five elements associated with agitation scored from 1 (minimum) to 7 (maximum) (Montoya *et al*., 2011), as measured from baseline compared to placebo. A key secondary endpoint will be determining the earliest time where an effect on agitation is apparent by measuring the change in PEC score from baseline. We anticipate topline results in mid-2020. An outline of the SERENITY program is shown below.



Source: BioXcel Therapeutics, Inc.

Data from Phase 1b Trial in Schizophrenia Patients

In July 2019, BioXcel announced positive top line results from a Phase 1b, randomized, double blind, placebo controlled, multi-center U.S. trial evaluating multiple doses of BXCL501 for the treatment of agitation in 135 schizophrenia patients (NCT04010305). The primary endpoint was the reduction in PEC score from baseline at 120 minutes. Results showed rapid calming without excessive sedation at two hours, with the 80 μg, 120 μg, and 180 μg doses showing reductions in PEC scores of -7.1, -9.2, and -10.8, respectively, compared to -4.5 for placebo. These results were all statistically significant. The following slide shows a rapid and durable response with statistically significant separation from placebo <60 minutes following dosing. The reduction in PEC scores attained by BXCL501 was comparable to levels achieved by IM antipsychotics in other trials (Breier *et al*., 2002).



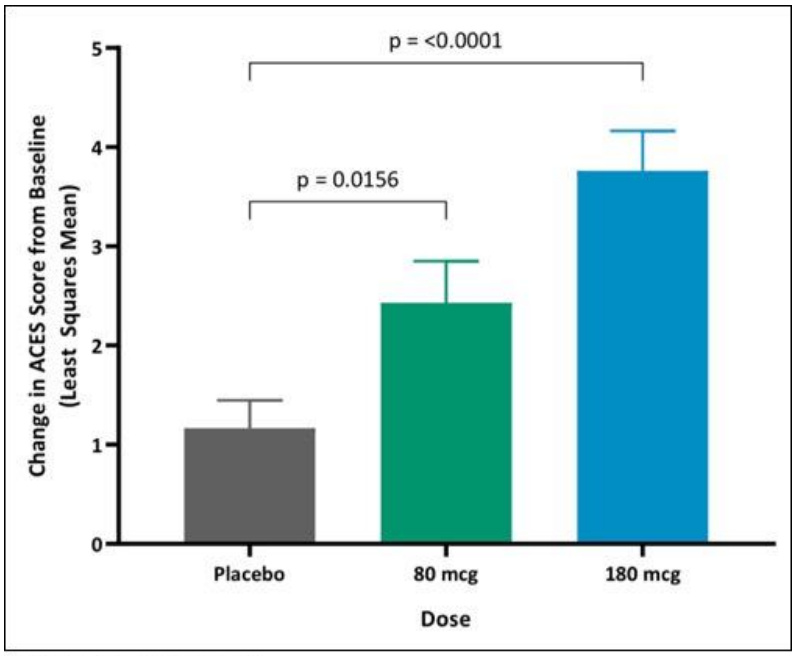
Time = 120 Min (Primary Endpoint)

Drug/Dose	#	% Responders (Reduction in PEC of ≥ 40%)	Mean Change in PEC Score	P-Value
Placebo	N=36	28%	-4.5	
BXCL501 (180 mcg)	N=18	89%	-10.8	< 0.0001
BXCL501 (120 mcg)	N=18	67%	-9.2	0.0003
BXCL501 (80 mcg)	N=18	56%	-7.1	0.0152
BXCL501 (60 mcg)	N=18	39%	-6.0	0.1227

*The lowest dose tested, 20 mcg (not shown) was repeated in subjects who did not achieve response criterion

Source: BioXcel Therapeutics, Inc.

A secondary endpoint in the trial included assessment using the Agitation-Calmness Evaluation Scale (ACES), which is a single item that rates the overall agitation and sedation at the time of evaluation, ranging from 1-marked agitation, 2-moderate agitation, 3-mild agitation, 4-normal behavior, 5-mild calmness, 6-moderate calmness, 7-marked calmness, 8-deep sleep, and 9-unarousable. The following graph shows a statistically significant change in ACES from baseline at both 180 μg and 80 μg BXCL501 compared to placebo, consistent with what was seen in the primary endpoint.



Source: BioXcel Therapeutics, Inc.

BXCL501 was well tolerated with no serious adverse events reported across the entire dose range tested. The most common treatment emergent adverse event was mild somnolence and dry mouth. In addition, all study subjects were able to self-administer the film and complete the study.

Conclusion

We look forward to the results of the upcoming Phase 3 clinical trials of BXCL501 for agitation associated with schizophrenia and bipolar disorder, which we anticipate will be reported in mid-2020. Based upon the Phase 1b results we believe there is a high probability of success in both those trials. Our current valuation is $21.00 per share.

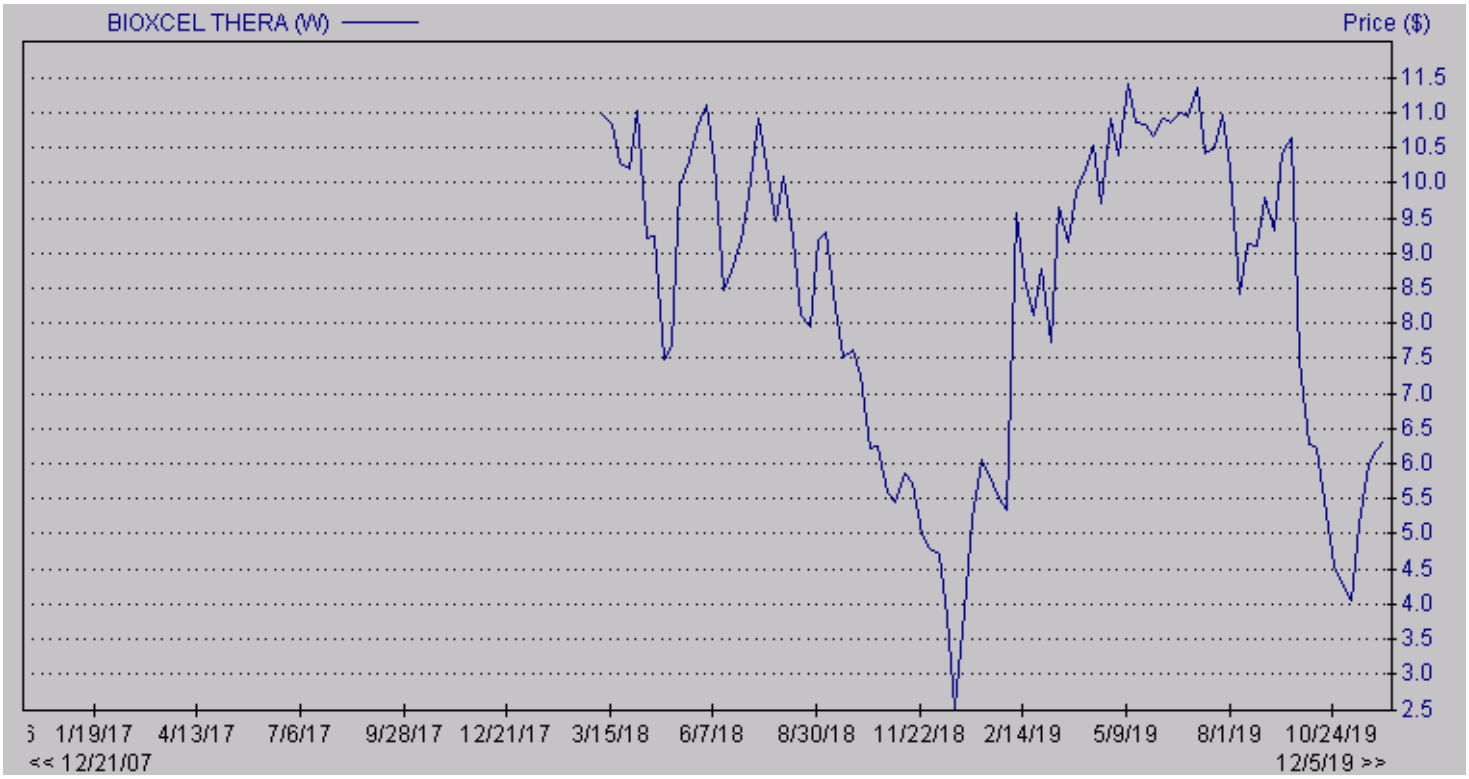
PROJECTED FINANCIALS

BioXcel Therapeutics, Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
BXCL501	$0	$0	$0	$0	$0	$0	$0	$0
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**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$14.6	$5.7	$6.5	$7.1	$6.7	$26.0	$27.0	$30.0
General & Administrative	$5.4	$1.7	$2.1	$2.0	$2.3	$8.2	$10.0	$12.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($19.9)	($7.4)	($8.6)	($9.1)	($9.0)	($34.2)	($37.0)	($42.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.7	($0.2)	($0.2)	$0.1	($0.1)	($0.4)	$0.0	$0.0
Pre-Tax Income	($19.2)	($7.2)	($8.5)	($9.0)	($9.1)	($34.6)	($37.0)	($42.0)
Income Taxes	$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	**($19.2)**	**($7.2)**	**($8.5)**	**($9.0)**	**($9.1)**	**($34.6)**	**($37.0)**	**($42.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.32)**	**($0.46)**	**($0.54)**	**($0.57)**	**($0.50)**	**($2.12)**	**($2.00)**	**($2.10)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	14.6	15.7	15.7	15.8	18.1	16.3	18.5	20.0

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

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Source: Zacks SCR

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