BioXcel Therapeutics (NASDAQ:BTAI)

December 20, 2019

SUMMARY

Success in treating conditions such as schizophrenia and bipolar disorder can arise in measured steps. The neuropsychiatric pathways of each are poorly understood and few biomarkers exist to identify different forms of the diseases.

BioXcel Therapeutics' (NASDAQ:BTAI) lead compound BXCL501, now starting two, phase III confirmatory trials, is following a measured approach. The drug is a sublingual thin film of dexmedetomidine designed to treat acute agitation in patients with schizophrenia and bipolar disorder. *SanaCurrents* **assigns a pivotal sentiment** for topline results for each trial, SERENITY I for schizophrenia patients with agitation and SERENITY II for bipolar patients with agitation. Topline results from each trial of approximately 375 patients are expected in the middle of 2020.

Dexmedetomidine typically is administered intravenously and often requires extended hospitalization. Treating an acutely agitated patient at the hospital may not be an optimal approach in patients with schizophrenia and bipolar disorder. However, a sublingual film that can dissolve in a patient's mouth may provide a more rapid and effective response.

BioXcel expects its modified formulation of dexmedetomidine can help avoid the coercive techniques used in treating agitation episodes, such as physical restraints and seclusion, as well as limit hospitalization.

While now controversial because of the widespread opioid epidemic, BioDelivery Sciences International (NASDAQ: BDSI) introduced Onsolis, an oral transmucosal form of the opioid analgesic, fentanyl citrate, to treat pain in terminal cancer patients. Strong opioids were approved for cancer patients at the time, but many found it difficult to swallow pills and also needed more rapid relief. Onsolis provided a measured step forward.

Dexmedetomidine likewise is approved as a sedative in the hospital setting, albeit administered intravenously. BXCL501 may work better for schizophrenia and bipolar patients outside the hospital, or at least faster within the hospital.

Agitation treatment costs the US healthcare system $40 billion per year, according to BioXcel. An estimated 8.3 million people in the U.S. suffer from each year.

THE EDGE

BXCL501 is a selective alpha-2a receptor agonist that binds to G-Protein-coupled α2-AR, of which there are three subtypes. Each subtype owns unique physiological functions and pharmacological activities. BioXcel claims BXCL501 specifically targets the G-Protein-coupled α2-AR associated with causal agitation mechanisms and works to reduce the activity of brain norepinephrine (the brain hormone that regulates the fight or flight response).

PROBABILITY SENTIMENT

- ☐ SUPERIOR (highest)
- ☑ Pivotal
- ☐ Advantageous

Key Catalyst(s)

- SERENITY I, agitation in schizophrenia
- SERENITY II, agitation in bipolar disorder

Key Catalyst Date(s)

- mid-2020

Insider & Institutional Holdings

61.59% % of Shares Held by All Insider

21.18% % of Shares Held by Institutions

55.15% % of Float Held by Institutions

32 Number of Institutions Holding Shares

Key Executives

Dr. Vimal D. Mehta Ph.D., Founder, CEO, Pres, Sec. & Director

Dr. Frank D. Yocca Ph.D., Chief Scientific Officer

Dr. Vincent J. O'Neill M.D., B.Sc., M.R.C.P., Sr. VP & Chief Medical Officer

Mr. Richard I. Steinhart MBA, Chief Financial Officer

Mr. Chids Mahadevan, VP of Fin. & Chief Accounting Officer

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THE EDGE cont'd

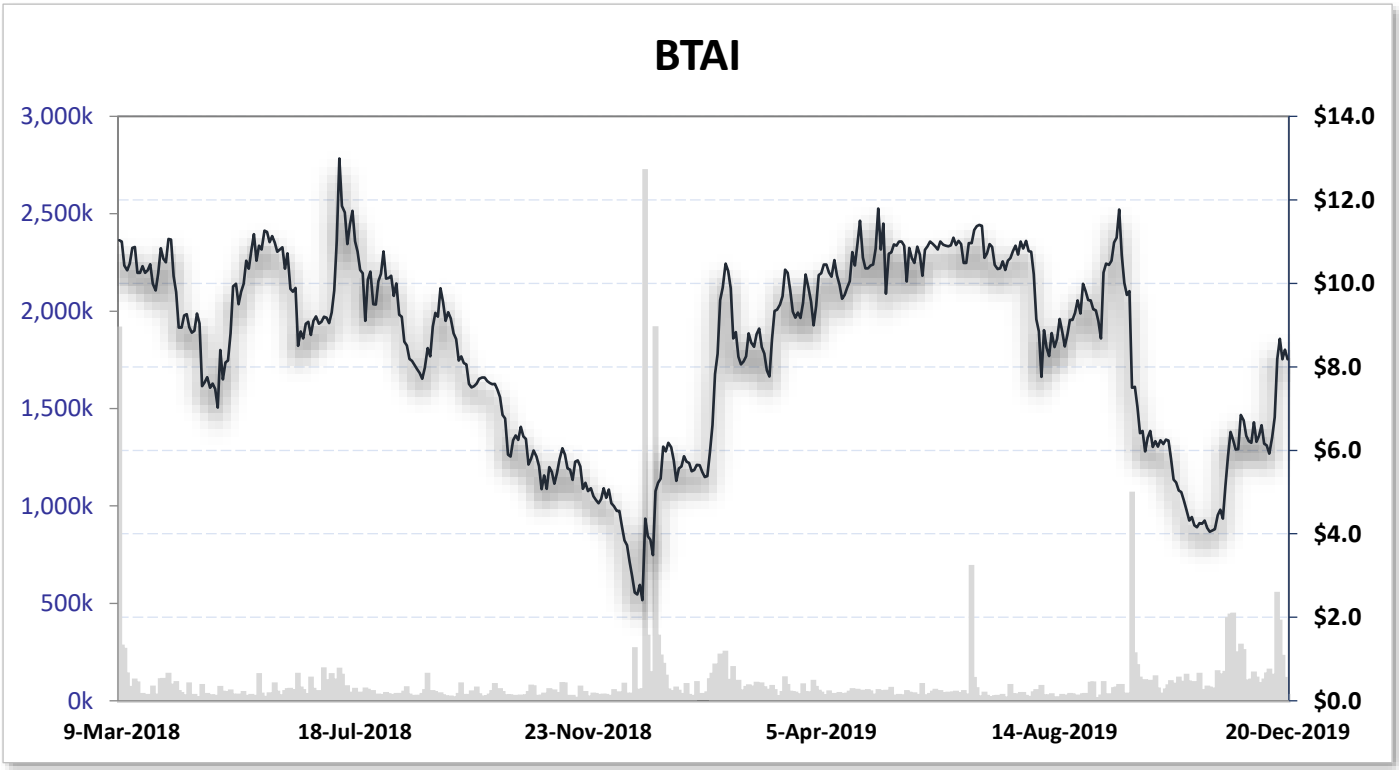
Like most neuropsychiatric therapies, there are no biomarkers to confirm this theory. Instead, BioXcel generally has relied upon the PEC score to test the efficacy of BXCL50; PEC is a validated regulatory endpoint to measure acute agitation in schizophrenia and bipolar patients. The score summarizes five elements associated with agitation: poor impulse control, tension, hostility, uncooperativeness, and excitement; each scored 1 (minimum) to 7 (maximum).

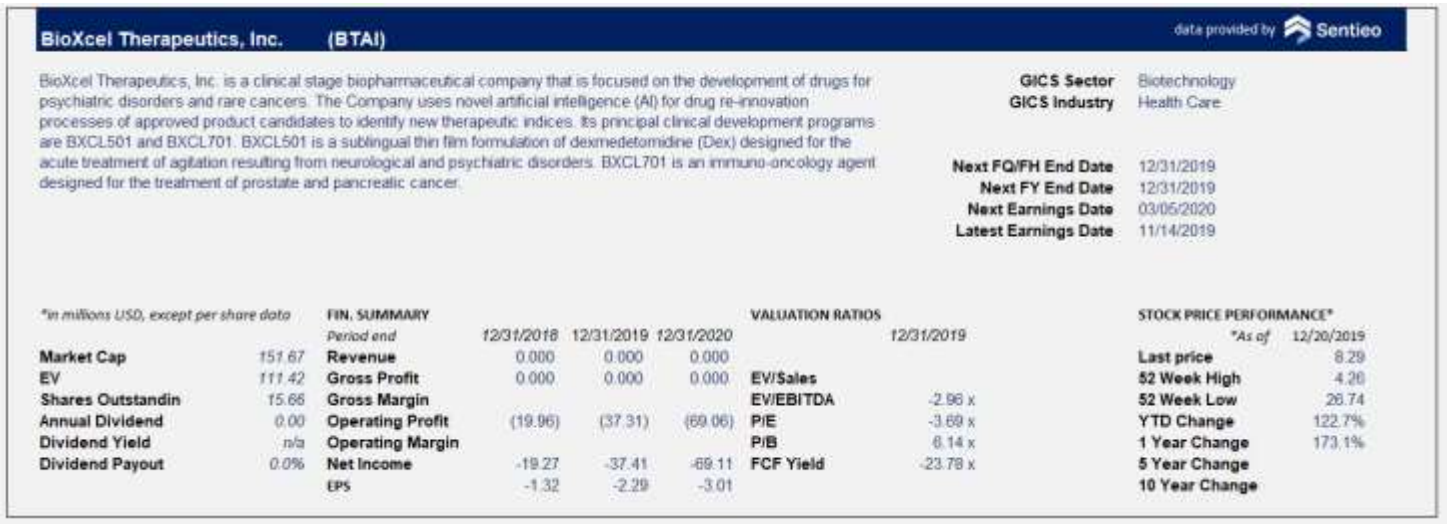
While a qualitative primary endpoint potentially can lead to inconsistent datasets, BioXcel has attempted to avoid this pitfall by testing BXCL50 in larger populations. For example, in a phase Ib trial more than 135 schizophrenia patients were assessed, an impressive total considering most phase I trials rarely include more then 10 patients. Statistical significance in the phase Ib trial in most dosing groups fell well below the 0.01 p-value threshold.

Both primary and secondary endpoints were met in the phase Ib trial. Specifically there was a statistically significant mean reduction in PEC score at two hours compared to placebo following a single dose of 180 mcg ($p<0.0001$), with rapid and durable reductions in PEC score maintained for 4 to 6 hours. In addition, a calming effect (measured by using ACES, Agitation-Calmness Evaluation Scale) was confirmed in all three dosing groups. No serious adverse events were reported, with most side effects limited to just mild somnolence and dry mouth.

The phase III SERENITY studies will closely follow the same guidelines of the phase Ib trial.

Given the strong phase Ib data and the current indication for dexmedetomidine, BioXcel should be able to replicate earlier trial results in the two SERENITY trials.





BioXcel Therapeutics, Inc. (BTAI) — data provided by Sentieo

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company that is focused on the development of drugs for psychiatric disorders and rare cancers. The Company uses novel artificial intelligence (AI) for drug re-innovation processes of approved product candidates to identify new therapeutic indices. Its principal clinical development programs are BXCL501 and BXCL701. BXCL501 is a sublingual thin film formulation of dexmedetomidine (Dex) designed for the acute treatment of agitation resulting from neurological and psychiatric disorders. BXCL701 is an immuno-oncology agent designed for the treatment of prostate and pancreatic cancer.

GICS Sector	Biotechnology
GICS Industry	Health Care
Next FQ/FH End Date	12/31/2019
Next FY End Date	12/31/2019
Next Earnings Date	03/05/2020
Latest Earnings Date	11/14/2019

*In millions USD, except per share data

Market Cap	151.67
EV	111.42
Shares Outstandin	15.66
Annual Dividend	0.00
Dividend Yield	n/a
Dividend Payout	0.0%

FIN. SUMMARY

Period end	12/31/2018	12/31/2019	12/31/2020
Revenue	0.000	0.000	0.000
Gross Profit	0.000	0.000	0.000
Gross Margin			
Operating Profit	(19.96)	(37.31)	(69.06)
Operating Margin			
Net Income	-19.27	-37.41	-69.11
EPS	-1.32	-2.29	-3.01

VALUATION RATIOS

	12/31/2019
EV/Sales	
EV/EBITDA	-2.96 x
P/E	-3.69 x
P/B	6.14 x
FCF Yield	-23.78 x

STOCK PRICE PERFORMANCE*

	*As of 12/20/2019
Last price	8.29
52 Week High	4.26
52 Week Low	26.74
YTD Change	122.7%
1 Year Change	173.1%
5 Year Change	
10 Year Change	

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