

BioXcel Therapeutics

Patent allowance extends Igalmi usage in Alzheimer's out to 2037

Maintain Rating: BUY | PO: 9.00 USD | Price: 3.33 USD

Focus remains on the planned phase 3 trials

BioXcel announced the United States Patent and Trademark Office (USPTO) has allowed the '740 US patent application which when issued is expected to have an expiration date of December 29, 2037. While we note investor focus surrounds the initiation and execution of the 2 planned phase 3 trials for the TRANQUILITY program in Alzheimer's disease and the SERENITY program for the at-home use of Igalmi in schizophrenia and bipolar disorder, we think the patent allowance adds strength to the company's market exclusivity for the potential usage of Igalmi in Alzheimer's patients. We look for future updates to announce the initiation of the phase 3 trials, noting the company believes the trials will be relatively inexpensive and quick to enroll and run. We anticipate data from the TRANQUILITY at-home trial in 1Q25 and we look for data supportive of a label expansion of Igalmi into the Alzheimer's at-home treatment setting. Given the planned phase 3 trial initiations designed to allow for the label expansion of Igalmi into Alzheimer's disease and at-home usage in schizophrenia and bipolar disorder, we maintain Buy, PO \$9.

Patent addition strengthens market exclusivity

With the addition of the '470 patent when issued, BioXcel will have 8 total US patents for Igalmi, including 4 method of use patents. The '740 patent specifically includes claims pertaining to the method of treating agitation in AD using oromucosal administration of 60mcg of dexmedetomidine. The patent when issued is expected to have an expiration date of December 29, 2037, and could have patent term adjustment, patent term extension, and terminal disclaimers.

Exhibit 1: BioXcel Catalyst Calendar

We focus on the anticipated initiation of 2 phase 3 trials evaluating '501 at home.

Company	Asset	Indication	Event	Timing	Importance
BioXcel	Igalmi	Alzheimer's disease	Phase 3 trial initiation	2024	Low
		Schizophrenia/			
BioXcel	Igalmi	Bipolar disorder	Phase 3 trial initiation	2024	Low
BioXcel	Igalmi	Alzheimer's disease	TRANQUILITY At-Home readout	1Q25	High

Source: BofA Global Research, company reports

BofA GLOBAL RESEARCH

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Stock Data

Price	3.33 USD
Price Objective	9.00 USD
Date Established	14-Nov-2023
Investment Opinion	C-1-9
52-Week Range	2.23 USD - 34.13 USD
Mrkt Val (mn) / Shares Out (mn)	114 USD / 34.3
Free Float	69.1%
Average Daily Value (mn)	1.77 USD
BofA Ticker / Exchange	BTAI / NAS
Bloomberg / Reuters	BTAI US / BTAIOQ
ROE (2023E)	NA
Net Dbt to Eqty (Dec-2022A)	-128.1%
ESGMeter™	Low

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Timestamp: 05 February 2024 11:02AM EST

Price objective basis & risk

BioXcel Therapeutics (BTAI)

Our \$9 PO is based on a sum-of-the-parts valuation. We assume a 13% discount rate for each of the programs and a likelihood of success (PoS) of 100% for BXCL501 for both of the schizophrenia (approved) and bipolar disorder (approved) indications, and 25% for dementia (phase 3). Given this, we ascribe \$6/share for BXCL501 and net cash of \$3/share.

Downside risks: 1) failure of clinical trials, 2) limited commercial uptake, 3) limited formulary access due to pricing.

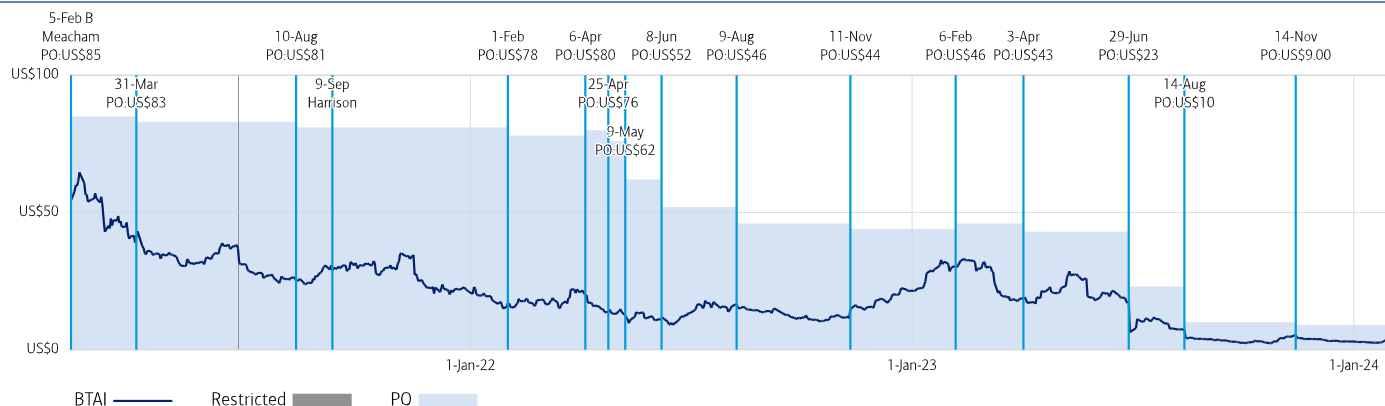
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Disclosures

Important Disclosures

BioXcel (BTAI) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
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Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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