

## BioXcel Therapeutics

TRANQUILITY focus brings label expansion  
top of mind: Thoughts post the 4Q23 call

Reiterate Rating: BUY | PO: 7.00 USD | Price: 2.90 USD

## Looking for FDA meeting minutes to finalize path forward

BioXcel announced a 4Q23 update as the company continues to [finalize the clinical programs \(see report\)](#) designed to expand the Igalmi label into AAD and at-home use in S/BP. With plans to focus on the institutional AAD population through the TRANQUILITY program, we look for clinical trial initiation and clinical data, with PEC as the primary endpoint, to support label expansion into the larger population. While we note that the commercial Igalmi program has been deprioritized, we now model 2024 revenue of \$2M (from \$3M previously) and note that BioXcel reported revenues of \$1.4M for FY23 (versus \$1.4M consensus). We look for additional clarity about trial design and phase 3 timing after the minutes from the recent FDA meeting are released. With a cash runway into mid-2024, we note that financing continues to be a risk and focus for investors, and we look for updates from management regarding future financing. Given the potential for label expansion for the '501 programs into large populations with unmet medical need, we reiterate our Buy rating, with a new PO of \$7 (from \$8 previously).

## Clinical development on deck to expand Igalmi label

With [recent patent allowance bringing use in Alzheimer's out to 2037 \(see report\)](#), we look for successful label expansion and launch in this indication and model PoS 25% for TRANQUILITY. We also model 80% PoS for SERENITY at-home. While we look for finalized trial design data from both TRANQUILITY and SERENITY programs after the company receives FDA meeting minutes, we model a SERENITY at-home launch in 2026 and TRANQUILITY launch in the institutional setting in 2026 and at-home in 2027. With the company noting FDA requests for long-term safety data for TRANQUILITY, we look for future FDA interactions to finalize the details of this requirement.

## Model Updates

We update our model for 4Q23 reporting and update our '501 revenue builds, resulting in a new PO of \$7 (from \$8). We include an institutional AAD launch in 2026 and move the AAD at-home modeled launch to 2027 and move our SERENITY at-home modeled launch to 2026. We now model 2024 and 2025 EPS of -\$2.60 (from -\$2.86) and -\$1.85 (from -\$1.41), respectively. BioXcel has \$65.2M in cash and cash equivalents and a cash runway into mid-2024.

## See our catalyst calendar below (Exhibit 1).

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026
EPS	(5.92)	(6.15)	(2.60)	(1.85)	NA
EPS Change (YoY)	-46.2%	-3.9%	57.7%	28.8%	NA
Consensus EPS (Bloomberg)			(2.49)	(1.67)	(1.11)
DPS	0	0	0	0	NA
<b>Valuation (Dec)</b>					
Free Cash Flow Yield*	-135.6%	-160.6%	-82.6%	-61.4%	NA

\* For full definitions of *IQmethod*<sup>SM</sup> measures, see page 5.

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12 March 2024

## Equity

## Key Changes

(US\$)	Previous	Current
Price Obj.	8.00	7.00
2024E Rev (m)	3.0	2.0
2025E Rev (m)	55.3	10.9
2024E EPS	-2.86	-2.60
2025E EPS	-1.41	-1.85

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## Stock Data

Price	2.90 USD
Price Objective	7.00 USD
Date Established	12-Mar-2024
Investment Opinion	C-1-9
52-Week Range	1.91 USD - 29.56 USD
Mkt Val (mn) / Shares Out (mn)	100 USD / 34.5
Free Float	69.8%
Average Daily Value (mn)	7.58 USD
BofA Ticker / Exchange	BTAI / NAS
Bloomberg / Reuters	BTAI US / BTAIOQ
ROE (2024E)	NA
Net Dbt to Eqty (Dec-2023A)	NA
ESGMeter™	Low

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to ["BofA ESGMeter Methodology"](#).

AAD: agitation associated with Alzheimer's dementia  
S/BP: schizophrenia and bipolar disorder  
PEC: Positive and Negative Syndrome Scale-Excitatory Component  
PO: price objective

PoS: probability of success

# iQprofile<sup>SM</sup> BioXcel Therapeutics

## iQmethod<sup>SM</sup> – Bus Performance\*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Return on Capital Employed	-72.6%	-146.6%	-146.4%	-77.5%	NA
Return on Equity	-111.1%	-1,933.4%	NM	-3,809.6%	NA
Operating Margin	-42,573.9%	-12,146.4%	-4,688.1%	-845.6%	NA
Free Cash Flow	(135)	(160)	(83)	(61)	NA

## iQmethod<sup>SM</sup> – Quality of Earnings\*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Cash Realization Ratio	NM	NM	NM	NM	NA
Asset Replacement Ratio	0.1x	1.1x	1.1x	1.1x	NA
Tax Rate	NM	NM	NM	16.9%	NA
Net Debt-to-Equity Ratio	-128.1%	NM	NM	-206.6%	NA
Interest Cover	NA	NA	NA	NA	NA

## Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Sales	0	1	2	11	NA
% Change	NA	268.0%	47.2%	435.2%	NA
Gross Profit	0	0	2	10	NA
% Change	NA	-66.5%	NM	436.7%	NA
EBITDA	(158)	(171)	(95)	(92)	NA
% Change	-48.6%	-8.2%	44.6%	3.5%	NA
Net Interest & Other Income	0	0	0	0	NA
<b>Net Income (Adjusted)</b>	<b>(166)</b>	<b>(179)</b>	<b>(105)</b>	<b>(85)</b>	<b>NA</b>
<b>% Change</b>	<b>-55.0%</b>	<b>-8.0%</b>	<b>41.3%</b>	<b>19.5%</b>	<b>NA</b>

## Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Net Income from Cont Operations (GAAP)	(166)	(179)	(105)	(85)	NA
Depreciation & Amortization	1	0	0	0	NA
Change in Working Capital	11	0	2	0	NA
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	19	19	21	23	NA
Capital Expenditure	0	0	0	0	NA
<b>Free Cash Flow</b>	<b>-135</b>	<b>-160</b>	<b>-83</b>	<b>-61</b>	<b>NA</b>
<b>% Change</b>	<b>-64.0%</b>	<b>-18.4%</b>	<b>48.5%</b>	<b>25.7%</b>	<b>NA</b>
Share / Issue Repurchase	0	25	125	100	NA
Cost of Dividends Paid	0	0	0	0	NA
Change in Debt	0	0	0	0	NA

## Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Cash & Equivalents	194	58	101	140	NA
Trade Receivables	0	0	0	1	NA
Other Current Assets	9	8	9	10	NA
Property, Plant & Equipment	1	1	1	1	NA
Other Non-Current Assets	2	2	2	3	NA
<b>Total Assets</b>	<b>206</b>	<b>69</b>	<b>113</b>	<b>155</b>	<b>NA</b>
Short-Term Debt	0	0	0	0	NA
Other Current Liabilities	33	31	34	37	NA
Long-Term Debt	95	95	95	95	NA
Other Non-Current Liabilities	NA	NA	NA	NA	NA
<b>Total Liabilities</b>	<b>129</b>	<b>128</b>	<b>130</b>	<b>133</b>	<b>NA</b>
<b>Total Equity</b>	<b>77</b>	<b>(58)</b>	<b>(17)</b>	<b>22</b>	<b>NA</b>
<b>Total Equity &amp; Liabilities</b>	<b>206</b>	<b>69</b>	<b>113</b>	<b>155</b>	<b>NA</b>

\* For full definitions of iQmethod<sup>SM</sup> measures, see page 5.

## Company Sector

Biotechnology

## Company Description

BioXcel is a commercial-stage biopharmaceutical company looking to leverage the capabilities of artificial intelligence to discover and target therapies that can be repurposed for new therapies or methods of delivery. The company's commercial product, Igalmi, is approved to treat agitation associated with schizophrenia and bipolar disorder.

## Investment Rationale

BioXcel is approaching launch of its de-risked lead asset BXCL501 in schizophrenia and bipolar disorder and has the potential to continue to add on additional indications in acute agitation over time.

## Stock Data

Average Daily Volume

2,615,170

## Quarterly Earnings Estimates

	2023	2024
Q1	-1.84A	-0.67E
Q2	-1.83A	-0.75E
Q3	-1.72A	-0.73E
Q4	-0.76A	-0.71E

**Exhibit 1: BioXcel Catalyst Calendar**

We look for the FDA meeting minutes to finalize the clinical development plans for TRANQUILITY and SERENITY programs.

Company Asset		Indication	Event	Timing	Importance
BioXcel	Igalmi	Alzheimer's disease	Phase 3 trial initiation	2024	Low
BioXcel	Igalmi	Schizophrenia/ Bipolar disorder	Phase 3 trial initiation	2024	Low

**Source:** BofA Global Research, company reports

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## Price objective basis & risk

### BioXcel Therapeutics (BTAI)

Our \$7 PO is based on a sum-of-the-parts valuation. We assume a 13% discount rate for each of the programs and a probability of success (PoS) of 100% for BXCL501 for both of the schizophrenia (approved) and bipolar disorder (approved) indications in the institutional setting and 80% PoS for the at-home setting (phase 3), and 25% for dementia (phase 3). Given this, we ascribe \$5/share for BXCL501 and net cash of \$2/share.

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

## Analyst Certification

I, Greg Harrison, CFA, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

### US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
<b>BUY</b>				
	89bio, Inc	ETNB	ETNB US	Geoff Meacham
	Acumen Pharma	ABOS	ABOS US	Geoff Meacham
	Agiros Pharmaceuticals	AGIO	AGIO US	Greg Harrison, CFA
	BioMarin	BMRN	BMRN US	Geoff Meacham
	BioXcel Therapeutics	BTAI	BTAI US	Greg Harrison, CFA
	BridgeBio Pharma	BBIO	BBIO US	Greg Harrison, CFA
	Caribou	CRBU	CRBU US	Geoff Meacham
	CRISPR Therapeutics	CRSP	CRSP US	Geoff Meacham
	Eli Lilly and Company	LLY	LLY US	Geoff Meacham
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham
	HUTCHMED	HCM	HCM US	Alec W. Stranahan
	Immatics	IMTX	IMTX US	Alec W. Stranahan
	Insmid Incorporated	INSM	INSM US	Jason Zemansky
	Intellia Therapeutics	NTLA	NTLA US	Greg Harrison, CFA
	Janux Therapeutics	JANX	JANX US	Alec W. Stranahan
	Keros	KROS	KROS US	Greg Harrison, CFA
	Kiniksa Pharmaceuticals, Ltd.	KNSA	KNSA US	Geoff Meacham
	Krystal Biotech	KRYS	KRYS US	Alec W. Stranahan
	Kura Oncology	KURA	KURA US	Jason Zemansky
	Liquidia Corporation	LQDA	LQDA US	Greg Harrison, CFA
	Lyell Immunopharma	LYEL	LYEL US	Geoff Meacham
	MeiraGTx	MGTX	MGTX US	Alec W. Stranahan
	Merck & Co.	MRK	MRK US	Geoff Meacham
	Mineralys Therapeutics	MLYS	MLYS US	Greg Harrison, CFA
	Neumora Therapeutics	NMRA	NMRA US	Geoff Meacham
	Rani Therapeutics	RANI	RANI US	Geoff Meacham
	Regenxbio, Inc.	RGNX	RGNX US	Alec W. Stranahan
	Revolution Medicines	RVMD	RVMD US	Alec W. Stranahan
	Rocket Pharmaceuticals, Inc.	RCKT	RCKT US	Greg Harrison, CFA
	Royalty Pharma	RPRX	RPRX US	Geoff Meacham
	Sana Biotechnology	SANA	SANA US	Geoff Meacham
	SpringWorks	SWTX	SWTX US	Alec W. Stranahan
	Syndax Pharmaceuticals	SNDX	SNDX US	Jason Zemansky
	Traverse Therapeutics Inc	TVTX	TVTX US	Greg Harrison, CFA
	Turnstone Biologics	TSBX	TSBX US	Geoff Meacham
	Vertex Pharmaceuticals Inc.	VRTX	VRTX US	Geoff Meacham
	Werewolf Therapeutics	HOWL	HOWL US	Jason Zemansky
	Xencor	XNCR	XNCR US	Alec W. Stranahan

## US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
<b>NEUTRAL</b>				
	AbbVie	ABBV	ABBV US	Geoff Meacham
	Alector, Inc	ALEC	ALEC US	Greg Harrison, CFA
	Amgen Inc.	AMGN	AMGN US	Geoff Meacham
	Amylyx Pharmaceuticals	AMLX	AMLX US	Geoff Meacham
	Arcus Biosciences	RCUS	RCUS US	Jason Zemansky
	Beam Therapeutics	BEAM	BEAM US	Greg Harrison, CFA
	Biogen Inc.	BIIB	BIIB US	Geoff Meacham
	Bristol-Myers Squibb	BMJ	BMJ US	Geoff Meacham
	Cytokinetics, Incorporated	CYTK	CYTK US	Jason Zemansky
	Editas Medicine	EDIT	EDIT US	Greg Harrison, CFA
	Erasca	ERAS	ERAS US	Alec W. Stranahan
	Esperion	ESPR	ESPR US	Jason Zemansky
	Exscientia	EXAI	EXAI US	Alec W. Stranahan
	IGM Biosciences	IGMS	IGMS US	Greg Harrison, CFA
	Johnson & Johnson	JNJ	JNJ US	Geoff Meacham
	Kymira Therapeutics	KYMR	KYMR US	Geoff Meacham
	Moderna	MRNA	MRNA US	Geoff Meacham
	Pfizer	PFE	PFE US	Geoff Meacham
	Recursion Pharmaceuticals, Inc.	RXR	RXR US	Alec W. Stranahan
	Tyra Biosciences	TYRA	TYRA US	Greg Harrison, CFA
	Vir	VIR	VIR US	Alec W. Stranahan
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
<b>UNDERPERFORM</b>				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky
	CureVac	CVAC	CVAC US	Geoff Meacham
	Day One Biopharmaceuticals	DAWN	DAWN US	Alec W. Stranahan
	Novavax	NVAX	NVAX US	Alec W. Stranahan
	Regeneron Pharmaceuticals Inc.	REGN	REGN US	Geoff Meacham
	Reneo Pharmaceuticals	RPHM	RPHM US	Jason Zemansky
	TG Therapeutics	TGTX	TGTX US	Alec W. Stranahan
	United Therapeutics Corporation	UTHR	UTHR US	Greg Harrison, CFA

**IQmethod<sup>SM</sup> Measures Definitions****Business Performance**

Return On Capital Employed

Return On Equity

Operating Margin

Earnings Growth

Free Cash Flow

**Quality of Earnings**

Cash Realization Ratio

Asset Replacement Ratio

Tax Rate

Net Debt-To-Equity Ratio

Interest Cover

**Valuation Toolkit**

Price / Earnings Ratio

Price / Book Value

Dividend Yield

Free Cash Flow Yield

Enterprise Value / Sales

EV / EBITDA

**Numerator**

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization

Net Income

Operating Profit

Expected 5 Year CAGR From Latest Actual

Cash Flow From Operations – Total Capex

**Numerator**

Cash Flow From Operations

Capex

Tax Charge

Net Debt = Total Debt – Cash &amp; Equivalents

EBIT

**Numerator**

Current Share Price

Current Share Price

Annualised Declared Cash Dividend

Cash Flow From Operations – Total Capex

EV = Current Share Price × Current Shares + Minority Equity + Net Debt +

Other LT Liabilities

Enterprise Value

**Denominator**

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill Amortization

Shareholders' Equity

Sales

N/A

N/A

**Denominator**

Net Income

Depreciation

Pre-Tax Income

Total Equity

Interest Expense

**Denominator**

Diluted Earnings Per Share (Basis As Specified)

Shareholders' Equity / Current Basic Shares

Current Share Price

Market Cap = Current Share Price × Current Basic Shares

Sales

Basic EBIT + Depreciation + Amortization

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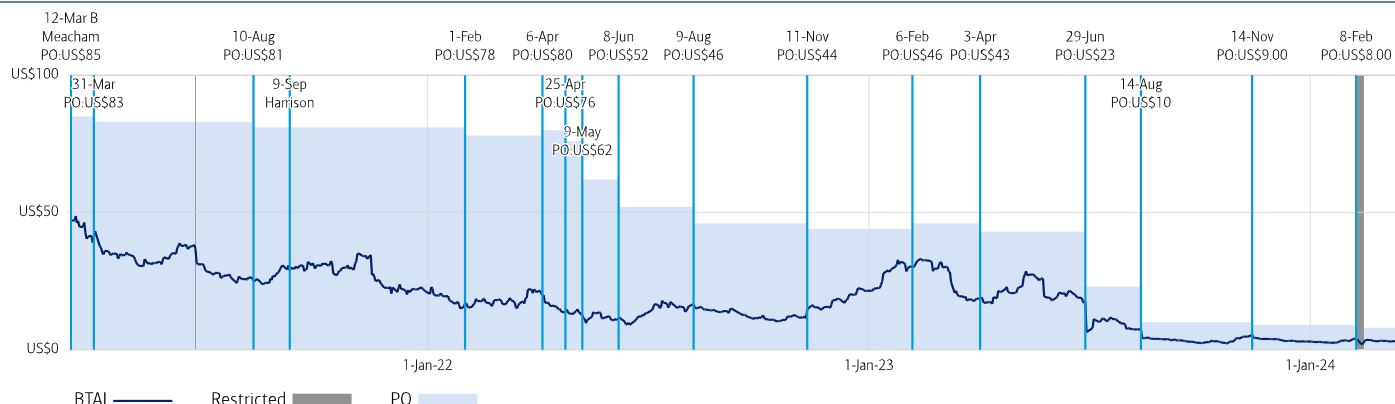
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B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

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Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	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 <sup>R1</sup>	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

<sup>R1</sup> Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster <sup>R2</sup>
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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