UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **September 12, 2022**

BioXcel Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38410**	**82-1386754**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

555 Long Wharf Drive
New Haven, CT 06511
(Address of principal executive offices, including Zip Code)

(475) 238-6837
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001	BTAI	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 8.01 Other Events.

As previously announced, Dr. Vimal Mehta, Founder and Chief Executive Officer of BioXcel Therapeutics, Inc. (the "Company"), will be participating in a fireside chat at the H.C. Wainwright 24th Annual Global Investment Conference (the "Conference") on Monday, September 12, 2022 at 10:30 a.m. Eastern Time. Dr. Mehta will discuss updates for the Company's neuroscience and immuno-oncology programs as well as its artificial intelligence platform used to augment and accelerate the drug candidate discovery and development process. He will also discuss the Company's commercial launch strategy for IGALMI™ (dexmedetomidine) sublingual film as well as the Company's financial condition. The presentation materials that will be used at the Conference as well as a live webcast will be available under "News/Events" within the Investors & Media section of the Company's website at www.bioxceltherapeutics.com. A replay of the webcast will be available on the Company's website following the event. Select slides from the presentation materials are filed as Exhibit 99.1 hereto and incorporated by reference herein.

Forward-Looking Statements

Statements in this Form 8-K regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited, to statements regarding the Company's expected timing of, and data results from, trials and clinical studies involving its product candidates; planned discussions with regulators; its commercial plan and strategy for IGALMI™ and strategic options for OnkosXcel; and its future financial and operational results. Forward-looking statements may be identified by words such as "anticipates," "believe," "continue," "expect," "intend," "may," "plan to," "potential," "projects," "will," and other similar words or expressions, or the negative of these words or similar words or expressions. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon the Company's current expectations and various assumptions. The Company believes there is a reasonable basis for its expectations and beliefs, but they areinherently uncertain. The Company may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation: its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502 and BXCL701 and other product candidates; the Company has no experience in marketing and selling drug products; IGALMI™ or the Company's product candidates may not be accepted by physicians or the medical community in general; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies;its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; undesirable side effects caused by the Company's product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; its ability to commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investors section of our website at www.bioxceltherapeutics.com. All forward-looking statements speak only as of the date of this Form 8-K and, except as required by applicable law, the Company has no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Slides from Investor Fireside Chat, dated September 12, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 12, 2022

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer


bioxcel
therapeutics®
AI-Driven Drug Development in Neuroscience and Immuno-oncology
September 2022
BioXcel Therapeutics | 555 Long Wharf Drive, 12th Floor | New Haven, CT 06511 | www.bioxceltherapeutics.com
NASDAQ: B

Forward-Looking Statements

This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.Forward-looking statements in this presentation include but are not limited to: statements regarding BioXcel Therapeutics' expected timing of, and data results from, trials and clinical studies involving its product candidates; planned discussions with regulators; its commercial plan and strategy for IGALMI™ and strategic options for OnkosXcel; potential market size and opportunity for products and product candidates, and its future financial and operational results. When used herein, words including "anticipate," "being," "will," "plan," "may," "continue," and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon BioXcel Therapeutics' current expectations and various assumptions. BioXcel Therapeutics believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BioXcel Therapeutics may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation: its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502 and BXCL701 and other product candidates; the Company has no experience in marketing and selling drug products; IGALMI™ or the Company's product candidates may not be accepted by physicians or the medical community in general; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; undesirable side effects caused by the Company's product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; its ability to commercialize its product candidates; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at **www.sec.gov** and the Investors section of our website at **www.bioxceltherapeutics.com**.

These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. While BioXcel Therapeutics may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing BioXcel Therapeutics' views as of any date subsequent to the date of this presentation.

Potential Market-Changing Product & Current Pipeline

Compound	Indication/Proposed Indication	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Marke
Neuroscience							
Igalmi (dexmedetomidine) sublingual film - 120 mcg, 180 mcg	Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults	Approved April 5, 2022					
BXCL501	At-home acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults			SERENITY III			
	Acute treatment of agitation associated with Alzheimer's disease*			TRANQUILITY II & III			
	Adjunctive treatment in major depressive disorder						
BXCL502	Chronic agitation in Alzheimer's disease						
Wearable Device (+BXCL501)**	Pre & post-agitation in dementia	Phase 0 device testing					
Immuno-oncology	OnkosXcel Therapeutics						
BXCL701	Metastatic castration-resistant prostate cancer (small cell neuroendocrine and adenocarcinoma)			(Combination with KEYTRUDA®)			

Pipeline as of Sept. 12, 2022

The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established
*Includes intermittent chronic agitation
**Regulatory path to be determined; device + drug combination to be evaluated after further evaluation of predictive algorithm

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Near-Term Catalysts & Key Events

NEUROSCIENCE: BXCL501	Timeframe
IGALMI™ U.S. Commercial Launch	July 2022
Alzheimer's Disease: TRANQUILITY III • Expected study initiation	2H 2022
Bipolar Disorders or Schizophrenia (at-home use): SERENITY III • Expected study initiation	2H 2022
Alzheimer's Disease: TRANQUILITY II • Top-line data readout	1H 2023
Major Depressive Disorder (MDD) • Top-line results from Phase 1 dose-selection trial in healthy volunteers	1H 2023
IMMUNO-ONCOLOGY: BXCL701	OnkosXcel Therapeutics
Aggressive Variant of Metastatic Castration-Resistant Prostate Cancer • Expected enrollment completion of 28-patient SCNC cohort	2H 2022

Anticipated near-term catalysts as of Sept. 12, 2022

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Strong Value Proposition and Long-Term Growth Potential

Transformative Approach With Technology, Business Model, and Medicines

Unprecedented Value Creation*

- Optimize R&D economics
- Shorten development timelines
- Achieve higher probability of success

* all 3 driven by comprehensive AI plan

Clinically Validated AI Platform

- Proprietary EvolverAI™ technology platform
- BXCL501 – **IND acceptance to IGALMI™ approval in 3.5 yrs.**
  - 3 upcoming Phase 3 trials
- BXCL701 – **Human POC established in SCNC**
  - Leader in DPP 8/9 biology (new checkpoint)

Advanced Pipeline

- BXCL501: Alzheimer's-related agitation - **TRANQUILITY II & III** - Pivotal program
- BXCL501: Bipolar & Schizophrenia-related agitation (at-home setting) - **SERENITY III** pivotal trial
- BCXL701: SCNC clinical POC – 800-patient safety database

Large Market Opportunity

- **~39 million*** annual episodes of agitation associated with schizophrenia & bipolar disorders in U.S.[1,2,3,4]
- **~100 million** annual episode of agitation associated with Alzheimer's disease in U.S.[5]
- **300+ million** antidepressant prescriptions filled annually[6]

Strong Financial Position

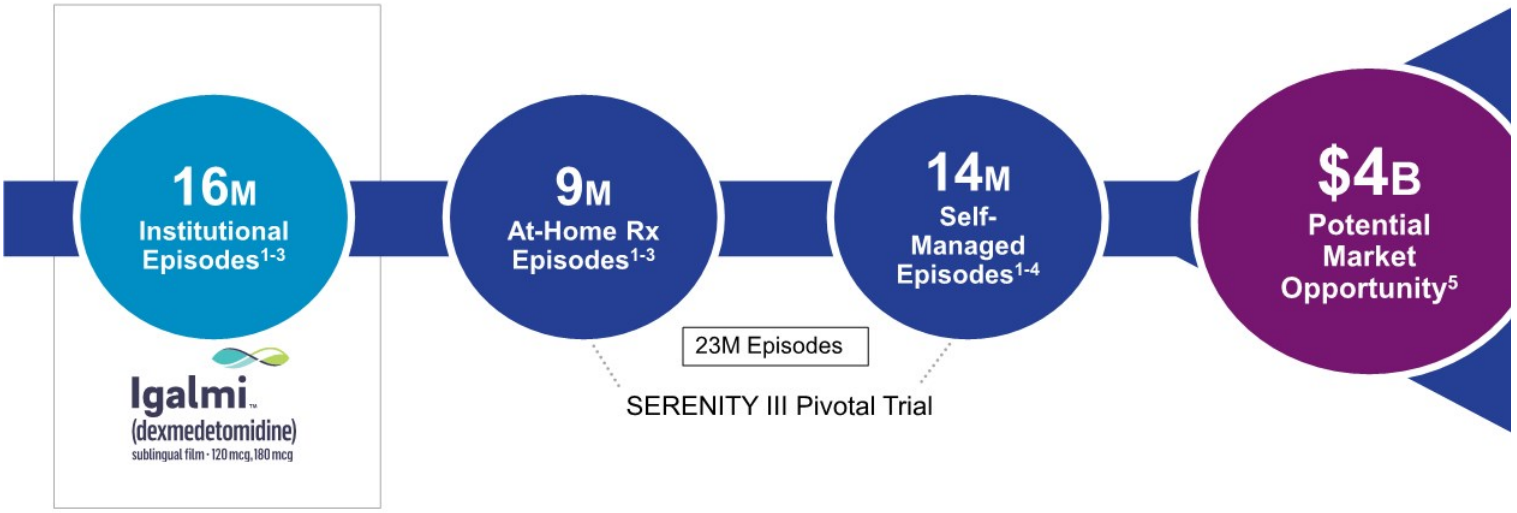
- **Cash runway into 2025****
- Well-funded to drive catalysts & long-term growth

1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on Fil
4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. Estimate based on company market research 6 NIH/WHO, SAMHSA, NIMH Pratt et al, 2017

*Includes 16 million institutional episodes, 9 million at-home Rx episodes, as well as 14 million self-managed episodes
**Assumes full execution of strategic financing agreements announced on April 19, 2022, including funding of remaining tranches subject to regulatory and financial milestones and certain other conditions .

Significant Market Opportunity: Agitation in Bipolar Disorders & Schizophrenia

Institutional Episodes



Igalmi™ (dexmedetomidine) sublingual film · 120 mcg, 180 mcg

1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. 39M episodes @ $105/episode

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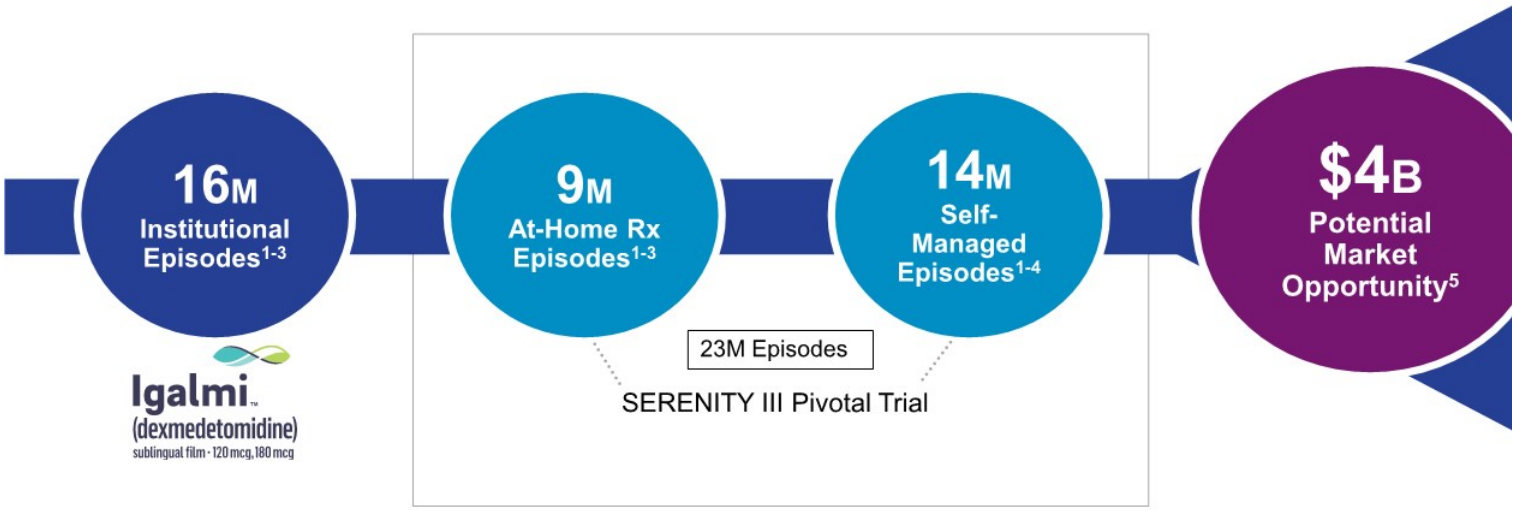
Significant Market Opportunity: Agitation in Bipolar Disorders & Schizophrenia

At-Home & Self-Managed Episodes



1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. 39M episodes @ $105/episode

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