BioXcel Therapeutics Reports Fourth Quarter and Full-Year 2025 Financial Results as Company Prepares for Potential IGALMI® Approval in Outpatient Setting

March 27, 2026

sNDA submitted seeking approval of IGALMI® in the at-home (outpatient) setting for the treatment of acute agitation associated with bipolar disorders or schizophrenia

sNDA submission timeline supports potential approval as early as year-end 2026

Advancing commercial and launch plans based on third-party market assessment

NEW HAVEN, Conn., March 27, 2026 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company built on artificial intelligence ("AI") to develop transformative medicines in neuroscience, today reported financial results for the fourth quarter and full-year 2025 and provided an update on its late-stage pipeline and commercial launch readiness plans. The Company submitted a supplemental New Drug Application (sNDA) in January to the U.S. Food and Drug Administration (FDA) seeking label expansion of IGALMI for the acute treatment of agitation associated with bipolar disorders and schizophrenia in the at-home setting. The Company is also developing commercial strategy and launch plans for IGALMI in the at-home setting, following completion of a comprehensive market assessment.

"2025 was a successful year for our Company, setting the stage for the potential label expansion of IGALMI in the at-home setting and continuing progress with commercial plans for the potential launch of IGALMI," said Vimal Mehta, Ph.D., Chief Executive Officer of BioXcel Therapeutics. "Our confidence in the substantial market opportunity in the at-home setting, where there are no FDA-approved options available, is reiterated by our recent market opportunity assessment. We also remain focused on advancing our Alzheimer's dementia program, which is another large market opportunity."

BXCL501 Late-Stage Clinical Programs

SERENITY Program

- **IGALMI At-Home sNDA Submission:** The Company submitted an sNDA in January to the FDA seeking to expand the IGALMI label for the at-home treatment of acute agitation in bipolar disorder and schizophrenia. The filing is supported by the SERENITY At-Home pivotal Phase 3 trial.
- **Advancing Commercial Preparations:** As part of the commercial preparation efforts, the Company appointed Mark Pavao as Interim Chief Commercial Officer to lead the development and execution of the launch plans for IGALMI in the at-home setting.
- **Market Opportunity Assessment:** BioXcel Therapeutics is progressing commercial preparation efforts, supported by completion of a third-party market assessment and building on insights to guide a launch plan. The third-party commercial assessment shows the large potential total addressable market for IGALMI in the at-home setting. Analysis of market research revealed up to 86 million addressable annual episodes that may require treatment.
- **Growing Awareness for Self-Administered Treatments at Home:** To support commercial preparations through building awareness ahead of potential launch, the Company hosted a virtual roundtable on December 8 featuring leading medical experts discussing advancements in treating acute agitation related to neuropsychiatric conditions, including the potential role of IGALMI outside of the hospital setting.

TRANQUILITY PROGRAM

- **TRANQUILITY In-Care Phase 3 Trial:** designed as a double-blind, placebo-controlled study to evaluate the efficacy and safety of a 60 mcg dose of BXCL501 for acute treatment of agitation associated with Alzheimer's dementia in the care setting.
  - The program remains part of the Company's broader development strategy.
  - FDA has provided feedback on the clinical protocol.
  - The Company has selected a CRO to prepare for trial initiation.

- **Increasing Awareness of Treating Acute Agitation in Alzheimer's Dementia:** The Company sponsored a virtual KOL roundtable on February 27 focused on acute agitation in Alzheimer's dementia and the unmet need for an FDA-approved treatment option. The event featured leading medical experts and included discussions on the latest developments in the treatment of acute agitation in Alzheimer's dementia and the potential role of BXCL501. The event reinforced the significant, differentiated, unmet medical need for an approved treatment in this indication.

Investigator-Sponsored Trial (IST)

- **Positive Phase 2 Topline Results from Columbia University-Led Study of BXCL501 for Treatment of Opioid Withdrawal, Funded by NIDA:** The IST study evaluating BXCL501 for the treatment of opioid withdrawal symptoms in adults with opioid use disorder (OUD) undergoing a methadone taper demonstrated clinical benefits and favorable tolerability profile. These results strengthen the growing body of evidence supporting BXCL501's clinical benefit across multiple potential indications, reinforcing its potential as a pipeline within a product.

Fourth Quarter and Full Year 2025 Financial Results

Net revenue from IGALMI® was $256,000 for the fourth quarter of 2025, compared to $366,000 for the same period in 2024.

Net revenue from IGALMI® was $642,000 for the full year of 2025, compared to $2.3 million for the same period in 2024. The Company is focused on preparing for IGALMI's launch in the at-home setting and maintaining IGALMI's brand awareness with minimal commercial resources.

Cost of Goods Sold for the fourth quarter of 2025 was $32,000, compared to $832,000, and for the full-year was $164,000, compared to $2.1 million, for the same period in 2024, respectively. The decrease in Cost of Goods Sold for the fourth quarter and full-year ended December 31, 2025 is primarily the result of lower charges for reserves for excess or obsolete inventory compared to the same respective periods in 2024.

Research and Development (R&D) expenses were $6.7 million for the fourth quarter of 2025, compared to $5.9 million for the same period in 2024. The increased expenses for the fourth quarter of 2025 were primarily due to the increase in clinical trial expense due to the execution of the SERENITY At-Home pivotal Phase 3 safety trial.

R&D expenses were $30.3 million for the full year of 2025, compared to $30.4 million for the full year of 2024.

Selling, General and Administrative (SG&A) expenses were $3.8 million for the fourth quarter of 2025, compared to $4.1 million for the same period in 2024.

SG&A expenses were $20.5 million for the full year of 2025, compared to $34.5 million for the full year of 2024. The decreased costs for the fourth quarter and the full year 2025 were primarily attributable to a decrease in personnel and related costs, lower legal and professional fees, and lower commercial and marketing costs resulting from the Clinical Reprioritization.

Net Loss: BioXcel Therapeutics reported an operating loss of $10.3 million and a net loss of $12.5 million for the fourth quarter of 2025, compared to an operating loss of $10.5 million and net loss of $10.9 million for the same period in 2024.

For the full year of 2025, BioXcel Therapeutics reported an operating loss of $50.5 million and a net loss of $69.9 million, compared to an operating loss of $67.2 million and a net loss of $59.6 million for the full year of 2024. Total cash used in operating activities for 2025 totaled approximately $57.6 million, down $14.4 million from 2024 cash used in operating activities of approximately $72.0 million.

Cash and cash equivalents and restricted cash totaled $28.8 million as of December 31, 2025.

The Company remains in compliance with the covenants in its Credit Agreement.

About BioXcel Therapeutics, Inc.

BioXcel Therapeutics, Inc. (Nasdaq: BTAI) is a biopharmaceutical company built on artificial intelligence ("AI") to develop transformative medicines in neuroscience. Its wholly owned subsidiary, OnkosXcel Therapeutics, is focused on the development of medicines in immuno-oncology. The Company's drug re-innovation approach leverages existing approved drugs and/or clinically validated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indications. For more information, please visit bioxceltherapeutics.com.

About BXCL501

Outside of its approved indication by the U.S. Food and Drug Administration as IGALMI® (dexmedetomidine) sublingual film, BXCL501 is an investigational proprietary, orally dissolving film formulation of dexmedetomidine, a selective alpha-2 adrenergic receptor agonist. BXCL501 is under investigation by BioXcel Therapeutics for the acute treatment of agitation associated with Alzheimer's dementia and for the acute treatment of agitation associated with bipolar I or II disorder or schizophrenia in the at-home setting. The safety and efficacy of BXCL501 for these investigational uses have not been established. BXCL501 has been granted Breakthrough Therapy designation by the FDA for the acute treatment of agitation associated with dementia and Fast Track designation for the acute treatment of agitation associated with schizophrenia, bipolar disorders, and dementia.

About IGALMI® (dexmedetomidine) sublingual film

IGALMI® (dexmedetomidine) sublingual film is a prescription medicine, administered under the supervision of a health care provider, that is placed under the tongue or behind the lower lip and is used for the acute treatment of agitation associated with schizophrenia and bipolar disorder I or II in adults. The safety and effectiveness of IGALMI has not been studied beyond 24 hours from the first dose. It is not known if IGALMI is safe and effective in children.

IMPORTANT SAFETY INFORMATION

IGALMI can cause serious side effects, including:

- **Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate**, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. IGALMI is taken under the supervision of a healthcare provider who will monitor vital signs (like blood pressure and heart rate) and alertness after IGALMI is administered to help prevent falling or fainting. Patients should be adequately hydrated and sit or lie down after taking IGALMI and instructed to tell their healthcare provider if they feel dizzy, lightheaded, or faint.

- **Heart rhythm changes (QT interval prolongation)**. IGALMI should not be given to patients with an abnormal heart rhythm, a history of an irregular heartbeat, slow heart rate, low potassium, low magnesium, or taking other drugs that could affect heart rhythm. Taking IGALMI with a history of abnormal heart rhythm can increase the risk of torsades de pointes and sudden death. Patients should be instructed to tell their healthcare provider immediately if they feel faint or have heart palpitations.

- **Sleepiness/drowsiness**. Patients should not perform activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours after taking IGALMI.

- **Withdrawal reactions, tolerance, and decreased response/efficacy**. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence, withdrawal symptoms (e.g., nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.

The most common side effects of IGALMI in clinical studies were sleepiness or drowsiness, a prickling or tingling sensation or numbness of the mouth, dizziness, dry mouth, low blood pressure, and low blood pressure upon standing.

These are not all the possible side effects of IGALMI. Patients should speak with their healthcare provider for medical advice about side effects.

Patients should tell their healthcare provider about their medical history, including if they suffer from any known heart problems, low potassium, low magnesium, low blood pressure, low heart rate, diabetes, high blood pressure, history of fainting, or liver impairment. They should also tell their healthcare provider if they are pregnant or breastfeeding or take any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Patients should especially tell their healthcare provider if they take any drugs that lower blood pressure, change heart rate, or take anesthetics, sedatives, hypnotics, and opioids.

Everyone is encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com.

Please see full prescribing information at Igalmi.com.

About the SERENITY At-Home Phase 3 Trial

The SERENITY At-Home Phase 3 trial is a double-blind, placebo-controlled study designed to evaluate the safety of a 120-mcg dose of BXCL501 for the acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting. The trial is designed to evaluate 200 patients with a history of agitation episodes residing at home either alone or with caregivers/informants. Patients are self-administering 120-mcg of BXCL501 or placebo when agitation episodes occur over the 12-week trial period, with safety data (adverse events) collected during the trial. In addition, patients or caregivers/informants will complete a modified global impression of severity (mCGIs) and a clinical global impression of change (mCGI-C) two hours after dosing as an exploratory endpoint to evaluate use in the outpatient setting.

About the TRANQUILITY In-Care Phase 3 Trial

The TRANQUILITY In-Care trial is designed as a double-blind, placebo-controlled study to evaluate the efficacy and safety of a 60-mcg dose of BXCL501 over a 12-week period for agitation associated with Alzheimer's dementia in the care setting. The trial is expected to enroll approximately 150 patients 55 years and older who have mild, moderate, or severe dementia with mini-mental state examination scores of 0 to 25 and who reside in skilled nursing facilities, memory care units, or assisted living facilities. Patients will self-administer 60-mcg of BXCL501 or placebo when episodic agitation episodes occur over the trial period. The primary endpoint is expected to be a change from baseline in the Positive and Negative Syndrome Scale-Excitatory Component (PEC) total score at two hours post-first dose. Additional PEC and Clinical Global Impressions – Improvement Scale measurements will also be obtained during the trial.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including, without limitation, statements related to: acceptance by the FDA of our sNDA, approval by the FDA of the sNDA and expanded label for IGALMI, advancing the clinical evaluation of the broader use of BXCL501 in Alzheimer's dementia, and BXCL501's potential to be a pipeline within a product. When used herein, words including "anticipate," "believe," "can," "continue," "could," "designed," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these 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 are inherently 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; the impact of the reprioritization; its significant indebtedness, ability to comply with covenant obligations and potential payment obligations related to such indebtedness and other contractual obligations; the Company has identified conditions and events that raise substantial doubt about its ability to continue as a going concern; its limited experience in drug discovery and drug development; risks related to the TRANQUILITY program; its dependence on the success and commercialization of IGALMI®, BXCL501, BXCL502, BXCL701 and BXCL702 and other product candidates; the number of episodes of agitation and the size of the Company's total addressable market may be overestimated, and approval that the Company may obtain may be based on a narrower definition of the patient population; its lack of experience in marketing and selling drug products; the risk that IGALMI® or the Company's product candidates may not be accepted by physicians or the medical community in general; the Company still faces extensive and ongoing regulatory requirements and obligations for IGALMI®; 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; the significant influence of and dependence on BioXcel LLC; its exposure to patent infringement lawsuits; its reliance on third parties; its ability to comply with the extensive regulations applicable to it; impacts from data breaches or cyber-attacks, if any; risks associated with the increased scrutiny relating to environmental, social and governance (ESG) matters; risks associated with federal, state or foreign health care "fraud and abuse" laws; and its ability to commercialize its product candidates, as well as the important factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K for the fiscal year ended December 31, 2024, 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 and the Investors section of the Company's website at. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While the Company 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 the Company's views as of any date subsequent to the date of this press release.

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Statements of Operations
(Unaudited, in thousands, except per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2025	2024	2025	2024
Revenues				
Product revenues	$ 256	$ 366	$ 642	$ 2,266
Operating expenses				
Cost of goods sold	32	832	164	2,143
Research and development	6,701	5,901	30,251	30,435
Selling, general and administrative	3,805	4,094	20,494	34,492
Restructuring costs	-	32	194	2,441
Total operating expenses	10,538	10,859	51,103	69,511
Loss from operations	(10,282)	(10,493)	(50,461)	(67,245)
Other (income) expense				
Interest expense, net	4,396	4,032	16,984	15,129
Interest income	(321)	(368)	(1,066)	(2,602)
Other (income) expense, net	(1,812)	(3,298)	3,518	(20,173)
Net loss and comprehensive loss	$ (12,545)	$ (10,859)	$ (69,897)	$ (59,599)
Net loss per share - basic and diluted	$ (0.58)	$ (3.57)	$ (5.73)	$ (23.51)
Weighted average shares outstanding - basic and diluted	21,750	3,039	12,208	2,535

Condensed Balance Sheets
(Unaudited, in thousands)

	December 31, 2025	December 31, 2024
Cash and cash equivalents and restricted cash	$ 28,757	$ 29,854
Total assets	$ 44,916	$ 38,338
Total liabilities	$ 140,379	$ 131,439
Total stockholders' equity (deficit)	$ (95,463)	$ (93,101)