



BioXcel Therapeutics Completes Market Opportunity Assessment and Advances Commercialization Plans for IGALMI® in the At-Home Setting

February 12, 2026

Third party commercial assessment shows larger than expected potential total addressable market for IGALMI® in the at-home setting

Strong prescriber interest, patient demand, and positive payer feedback on formulary coverage

NEW HAVEN, Conn., Feb. 12, 2026 (GLOBE NEWSWIRE) -- BioXcel Therapeutics, Inc. (Nasdaq: BTAI), a biopharmaceutical company built on artificial intelligence ("AI") to develop transformative medicines in neuroscience, today announced the completion of an updated market opportunity assessment for IGALMI® for acute agitation associated with bipolar disorders or schizophrenia in the at-home (outpatient) setting, informed by results from the SERENITY At-Home clinical study. The assessment represents a key milestone in the Company's commercial preparation initiatives for IGALMI, with findings intended to inform launch planning activities. A comprehensive launch plan for IGALMI in the at-home setting is in development. The Company submitted a supplemental New Drug Application (sNDA) last month seeking the FDA's approval of IGALMI for at-home use in the acute treatment of agitation associated with bipolar disorders or schizophrenia.

Overview of Market Opportunity Assessment

The commercial opportunity assessment was based on recently completed market research leveraging an updated Target Product Profile based on results from the SERENITY At-Home clinical study. The assessment incorporated interviews with 15 prescribers and 5 payers with leadership responsibility at large health plans as well as survey responses from 180 prescribers with extensive relevant experience. In addition, patient-level claims analyses were used to estimate the number of diagnosed and treated patients who may be candidates for IGALMI.

Current agitation landscape insights:

- Prescribers reported a moderate to high unmet need, noting that current treatment options are not indicated for at-home use, may be sedating, are slow to take effect, and/or are controlled substances with the potential to cause dependence.
- Analyses of market research and claims data identified approximately 2.3 million treated bipolar disorder and schizophrenia patients experiencing frequent episodes of acute agitation in the at-home setting in the United States, of whom up to 1.8 million may be eligible for IGALMI treatment. This represents up to 86 million addressable annual episodes that may require treatment. This updated estimate is generally consistent with prior estimates of approximately 57-77 million addressable annual episodes,¹⁻⁴ with further refinement based on the additional insights from market research.

IGALMI opportunity in the at-home setting:

- Prescribers reported moderate to high interest in IGALMI for the treatment of acute agitation in the at-home setting, projecting use in approximately 70% of their schizophrenia and bipolar disorder patients, regardless of agitation severity.
- Prescribers anticipated that IGALMI would be used either alone or in combination with existing off-label treatments for acute agitation, and that IGALMI would most frequently replace benzodiazepines, which may cause dependence.
- Payers indicated expectations for broad formulary coverage with standard adjudication controls.
- Previously reported patient and caregiver research (N=80) indicated that patients with schizophrenia and bipolar disorder would expect to use IGALMI in approximately 80% of their acute agitation episodes.

"This assessment further validates IGALMI's commercial opportunity in the at-home setting," said Mark Pavao, Interim Chief Commercial Officer of BioXcel Therapeutics. "The strong prescriber and patient interest, as well as positive payer feedback on potential formulary coverage, reinforce our confidence in launch planning and represent a critical step as we advance our commercial strategy. We will build on these insights as we develop and finalize a comprehensive launch plan."

To view the updated market opportunity assessment, visit the Investors page on the BioXcel Therapeutics corporate website at www.ir.bioxccltherapeutics.com.

Additional Insights from Patient Interview and KOLs

As part of increasing awareness around agitation, the Company conducted an interview with [Gabe Howard](#), a patient advocate who struggles with acute agitation episodes due to underlying bipolar disorder and shared his experience about the high unmet need for a therapy in the at-home setting. As observed in the patient interview and in the market assessment, there is an urgent need for an effective at-home treatment option for this condition.

The video interview is available below.

[A Media Snippet accompanying this announcement is available by clicking on this link.](#)

The updated market opportunity assessment is further augmented by a series of prior Company-sponsored Key Opinion Leader (KOL) initiatives designed to increase awareness and advance dialogue around acute agitation, including:

- **December 8, 2025:** A virtual expert roundtable discussing emerging approaches and the potential role of self-administered at-home treatments for acute agitation. It featured Leslie Citrome, M.D., M.P.H., Clinical Professor of Psychiatry and Behavioral Sciences at New York Medical College, Marc A. Milano, M.D., FACEP, Chair of Emergency Medicine at Newark Beth Israel Medical Center and Children's Hospital of New Jersey, and Leon Ravin, M.D., Statewide Psychiatric Medical Director for the Division of Public and Behavioral Health, State of Nevada. A replay is available at this [link](#).
- **September 10, 2025:** A live webcast and Q&A session focused on clinical data from the SERENITY At-Home trial, featuring Leslie Citrome, M.D., M.P.H., Clinical Professor of Psychiatry and Behavioral Sciences at New York Medical College. A replay is available at this [link](#).

About IGALMI® (dexmedetomidine) sublingual film

INDICATION

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 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 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.

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: the approval of IGALMI for use in the at-home setting; bringing IGALMI® directly to patients in the at-home setting; the approval of IGALMI for use in the at-home setting; bringing IGALMI® directly to patients in the at-home setting; use of IGALMI in approximately 70% of schizophrenia and bipolar disorder patients, regardless of agitation severity; prescribers using IGALMI either alone or in combination with existing off-label treatments for acute agitation; IGALMI replacing benzodiazepines, which may cause dependence; broad formulary coverage of IGALMI with standard adjudication controls; patients with schizophrenia and bipolar disorder using IGALMI in approximately 80% of their acute agitation episodes; evaluating go-to-market options; reimagining existing medicines and accelerating the development of innovative therapies; transforming the standard of care in neuropsychiatry and improve lives around the world. 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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