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) **April 1, 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 1.01 Entry into a Material Definitive Agreement.

In anticipation of potential FDA approval of IGALMI as described in Item 8.01 below, on April 1, 2022, BioXcel Therapeutics, Inc. (the "Company") entered into a Commercial Supply Agreement (the "Supply Agreement") with ARx, LLC ("ARx"), pursuant to which ARx has agreed to exclusively manufacture and supply the Company with all of the Company's worldwide supply of thin film formulation of dexmedetomidine to be used for the commercial supply of IGALMI and for ongoing clinical trials of the Company's product candidate BXCL501 (collectively, the "Product"), subject to certain alternative supply provisions.

Under the Supply Agreement, ARx, or an approved subcontractor, has agreed to manufacture the Product in the amounts as set forth in purchase orders to be provided by the Company at an agreed upon price per unit, which price may be adjusted annually. The Supply Agreement contemplates specified minimum annual payments, which increase in intervals at specified points in time during the term of the agreement. The initial term of the Supply Agreement extends through April 1, 2032, unless earlier terminated in accordance with the Supply Agreement, and will automatically be extended for successive one year periods, so long as the Product is being marketed or sold, or unless earlier terminated in accordance with the Supply Agreement.

Item 8.01. Other Events.

On April 5, 2022, the U.S. Food and Drug Administration ("FDA") approved the Company's product, IGALMI™ (dexmedetomidine) sublingual film, for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. IGALMI is a sublingual film formulation of dexmedetomidine and can be self-administrated by patients under the supervision of a healthcare provider. The Company is prepared to launch IGALMI in the U.S. in the second quarter of 2022.

Forward-Looking Statements

This Current Report on Form 8-K ("Form 8-K") includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this Form 8-K include but are not limited to the timing of commercial launch of IGALMI. When used herein, words including "anticipate," "will," "plan," "may," "continue," "intend," "designed," "goal" 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 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; 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 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 products and product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; regulatory agencies may not accept or agree with the Company's assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the company in general; the Company has no experience in marketing and selling drug products and has not entered into arrangements for the sale and marketing of IGALMI; IGALMI or the company's other product candidates may not be accepted by physicians or the medical community in general; the Company's exposure to patent infringement lawsuits; the Company's ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; the Company's ability to commercialize its products and product candidates; and the other important factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Form 8-K. 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 Form 8-K.

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: April 7, 2022

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer