# 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) **February 23, 2021**

# 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On February 23, 2021, the Board of Directors (the "Board") of BioXcel Therapeutics, Inc. (the "Company") appointed June Bray to the Board, effective March 1, 2021. Ms. Bray will serve as a Class I director for a term expiring at the Company's annual meeting of stockholders to be held in 2022 and until her successor is duly elected and qualified or her earlier death, disqualification, resignation or removal. In connection with her appointment, Ms. Bray was also appointed to the Nominating and Corporate Governance Committee (the "Nominating Committee), effective with her commencement, and will serve in lieu of Vimal Mehta who stepped down from the Nominating Committee on February 12, 2021.

Ms. Bray, 69, has served as Senior Vice President, Global Regulatory Affairs and Medical Writing of Allergan, Inc. since 2008, where she is in charge of global regulatory strategies for development projects and lifecycle management for all therapeutic areas. From 2006 to 2008, Ms. Bray was Vice President, Regulatory Affairs at Organon & Co. (prior to its merger with Merck & Co.), where she led departments responsible for regulatory activities for development and marketed products and, from 1980 to 2006, Ms. Bray served in various capacities at Berlex Laboratories, Inc., most recently as Vice President, Global Regulatory Affairs for Specialized Therapeutics/Oncology, a position she held from 2003 to 2006. Ms. Bray holds an M.B.A. from Fairleigh Dickinson University and a B.S. from the University of Rhode Island.

Ms. Bray is eligible to participate in the Company's Non-Employee Director Compensation Program, as previously disclosed, which provides for annual compensation in the form of cash and equity-based awards. In addition, the Board granted Ms. Bray, effective with her commencement of service on March 1, 2021 (the "initial award grant date"), an option to purchase 4,167 shares of the Company's common stock, representing a prorated amount for the period she serves on the Board until the annual equity award granted to eligible non-employee directors, which prorated award will vest and become exercisable on the earlier of the first anniversary of the initial award grant date or the day immediately prior to the date of the next annual meeting of the Company's stockholders occurring after the initial award grant date, in either case, subject to Ms. Bray's continued service as a non-employee director through such vesting date.

Ms. Bray is expected to enter into the Company's standard indemnification agreement for directors and officers.

**Item 7.01 Regulation FD Disclosure.**

On March 1, 2021, the Company issued a press release announcing Ms. Bray's appointment.

The press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Press release, dated March 1, 2021. |

**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: March 1, 2021

**BIOXCEL THERAPEUTICS, INC.**

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

**Exhibit 99.1**

# BioXcel Therapeutics Appoints June Bray to Board of Directors

*Former Allergan executive brings extensive global regulatory experience across multiple therapeutic areas*

**NEW HAVEN, Conn., March 1, 2021** -- BioXcel Therapeutics, Inc. ("BioXcel" or the "Company") (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced the appointment of June Bray to its Board of Directors. Ms. Bray brings over forty years of extensive U.S. and global regulatory experience in the healthcare industry and most recently served as Senior Vice President, Global Regulatory Affairs and Medical Writing at Allergan.

“June is a pharmaceutical industry veteran with a proven track record in leading successful regulatory activities for both investigational and marketed products in various therapeutic areas,” commented Vimal Mehta, Chief Executive Officer of BioXcel. “Her demonstrated achievements, which include 32 New Drug Approvals (“NDAs”) in the U.S., will provide invaluable insight as we look to submit our first NDA later this month and transition to becoming a commercial neuroscience-focused organization. We are pleased to welcome June to our Board and look forward to her expertise and guidance as we work toward delivering transformative medicines to neuropsychiatric patients struggling with agitation and other stress-related symptoms.”

“I am excited to join BioXcel’s Board as the Company prepares to transition to a commercial-stage organization,” said June Bray. “I truly believe BioXcel’s strong neuroscience program has the potential to change the way patients struggling with agitation are treated across various settings, ranging from hospitals to at-home care. Based on my extensive experience developing strategies for countless global product approvals, I look forward to working with management and the members of the Board, sharing my extensive regulatory knowledge to help BioXcel potentially bring innovative treatments to patients.”

In her role at Allergan (formerly Actavis/Forest Research Institute), Ms. Bray was responsible for regulatory strategies on development projects and lifecycle management in all therapeutic areas, including psychiatry and neurology, overseeing more than 400 employees globally. During her tenure, she led numerous NDA approvals, including Namenda XR®, Namzaric®, Vraylar®, and Ubrelvy®. Previously, Ms. Bray served as Vice President, Regulatory Affairs at Organon (now Merck), where she led regulatory activities for development and marketed products, including the NDA for Saprhis® (asenapine) for the treatment of schizophrenia and bipolar disorder. Earlier in her career, Ms. Bray held numerous roles of increasing responsibility over a 25-year period at Berlex Laboratories, Inc. (now Bayer HealthCare Pharmaceuticals). She began her pharmaceutical career in sterile manufacturing at Hoechst-Roussel Pharmaceuticals (now Sanofi-Aventis). Ms. Bray holds a B.S. in Pharmacy from the University of Rhode Island and an M.B.A in Pharmaceutical Marketing from Fairleigh Dickinson University.

**BioXcel Therapeutics, Inc.**

BioXcel Therapeutics, Inc. is a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology. BioXcel'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 indices. BioXcel's two most advanced clinical development programs are BXCL501, an investigational, proprietary, orally dissolving thin film formulation of dexmedetomidine for the treatment of agitation and opioid withdrawal symptoms, and BXCL701, an investigational, orally administered, systemic innate immunity activator in development for the treatment of aggressive forms of prostate cancer and advanced solid tumors that are refractory or treatment naïve to checkpoint inhibitors. For more information, please visit www.bioxceltherapeutics.com.

**Forward-Looking Statements**

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include but are not limited to the timing of the Company's NDA submission, the Company's intended commercialization plans and the value of BXCL501 as a potential treatment option. 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's current expectations and various assumptions. BioXcel believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BioXcel 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 BXCL501 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 BioXcel's product candidates; its approach to the discovery and development of product candidates based on EvolverAI is novel and unproven; 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 September 30, 2020, as such factors may be updated from time to time in its other filings with the SEC, 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 press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While BioXcel 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's views as of any date subsequent to the date of this press release.

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