

**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) **March 15, 2021**

BioXcel Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-38410
(Commission File Number)

82-1386754
(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 4.01. Changes in Registrant’s Certifying Accountant.

On March 15, 2021, the Audit Committee (the “Committee”) of the Board of Directors of BioXcel Therapeutics, Inc. (the “Company”) approved the engagement of Ernst & Young LLP (“E&Y”) as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2021, effective immediately.

On March 15, 2021, the Committee dismissed BDO USA, LLP (“BDO”) as the Company’s independent registered public accounting firm, effective immediately. The reports of BDO on the Company’s financial statements for each of the two fiscal years ended December 31, 2019 and 2020 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles. In the fiscal years ended December 31, 2019 and 2020 and in the subsequent interim period through March 15, 2021, there were there were no “disagreements” (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) between the Company and BDO on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which, if not resolved to the satisfaction of BDO, would have caused BDO to make reference to the matter in its report on the financial statements for such years.

In the fiscal years ended December 31, 2019 and 2020 and in the subsequent interim period through March 15, 2021, there were no “reportable events” (as described in Item 304(a)(1)(v) of Regulation S-K), except that, as reported in Part I, Item 4 of the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 (the “Quarterly Report”), the Company reported a material weakness in its internal control over financial reporting during such period. As disclosed in the Quarterly Report, the Company concluded that a material weakness existed due to its internal controls having not been adequately designed to prevent or timely detect unauthorized cash disbursements made to the sender of electronic communications impersonating one of the Company’s vendors. As reported in Part II, Item 9A of the Company’s Annual Report on 10-K for the fiscal year ended December 31, 2020, management concluded that the material weakness was remediated during the fourth quarter of 2020 and that, as of December 31, 2020, its internal control over financial reporting was effective.

The Company provided BDO with a copy of the disclosures contained in this Form 8-K and requested that BDO furnish the Company with a letter addressed to the Securities and Exchange Commission stating whether it agrees with the statements contained herein. A copy of BDO’s letter, dated March 15, 2021, is filed as Exhibit 16.1 to this Current Report on Form 8-K.

During the fiscal years ended December 31, 2019 and 2020 and the subsequent interim period through March 15, 2021, neither the Company nor anyone on its behalf consulted with E&Y with respect to (a) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company’s consolidated financial statements, and neither a written report nor oral advice was provided to the Company that E&Y concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue, or (b) any matter that was either the subject of a “disagreement” (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a “reportable event” (as described in Item 304(a)(1)(v) of Regulation S-K).

Item 8.01 Other Information.

On March 15, 2021, the Company announced that BXCL501, the Company’s investigational, proprietary, orally dissolving thin film formulation of dexmedetomidine (“Dex”), has been granted Breakthrough Therapy designation from the U.S. Food and Drug Administration (“FDA”) for the acute treatment of agitation associated with dementia. The Breakthrough Therapy designation is intended to expedite the development and review of certain product candidates designed to treat serious or life-threatening diseases or conditions, and the designation includes increased interaction and guidance from the FDA.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
16.1	Letter from BDO USA, LLP, dated March 15, 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 15, 2021

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

March 15, 2021

Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Ladies and Gentlemen:

We have been furnished with a copy of the response to Item 4.01 of Form 8-K for the event that occurred on March 15, 2021, to be filed by our former client, BioXcel Therapeutics, Inc. We agree with the statements made in response to that Item insofar as they relate to our Firm.

Very truly yours,

/s/ BDO USA, LLP
