# 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)
**September 21, 2018**

# 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) | (I. R. S. Employer Identification No.) |

**555 Long Wharf Drive**
**New Haven, CT 06511**
(Address of principal executive offices, including ZIP code)

**(203) 643-8060**
(Registrant's telephone number, including area code)

**780 East Main Street**
**Branford, CT 06405**
(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 x

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. x

**Item 1.01 Entry into a Material Definitive Agreement.**

On September 21, 2018, BioXcel Therapeutics, Inc., a Delaware corporation (the "Company"), entered into a Clinical Trial Collaboration Agreement (the "Collaboration Agreement") with Nektar Therapeutics, a Delaware corporation ("Nektar"). Pursuant to the Collaboration Agreement, the Company and Nektar will jointly collaborate to conduct a Phase 1/2 clinical trial evaluating a combination therapy using BXCL701, the Company's small molecule immune-modulator, DPP 8/9 and FAP inhibitor ("BXCL701"), NKTR-214, a CD122-biased agonist ("NKTR-214") and a checkpoint inhibitor as a potential therapy for pancreatic cancer and such other clinical trials evaluating the combined therapy as may be mutually agreed upon by the parties (each, a "Combined Therapy Trial").

Under the Collaboration Agreement, the parties will split all out-of-pocket costs reasonably incurred from third parties in connection with the performance of a Combined Therapy Trial, including, but not limited to, third party contract research organizations, laboratories, clinical sites and institutional review boards. Each party will otherwise be responsible for its own internal costs, including internal personnel costs, incurred in connection with each Combined Therapy Trial. The Company and Nektar will use commercially reasonable efforts to manufacture and supply its compound for each Combined Therapy Trial and will bear the costs related thereto. The parties will form a joint development committee to oversee clinical trial design, regulatory strategy, and other activities necessary to conduct and support the Combined Therapy Trials. The Company will act as sponsor of each Combined Therapy Trial.

Ownership of, and global commercial rights to, BXCL701 remains solely with the Company under the Collaboration Agreement. Ownership of any patent rights and study data that does not relate exclusively to BXCL701 or NKTR-214 shall be jointly owned by the parties.

Each party grants to the other party a non-exclusive, worldwide, non-transferable and royalty-free research and development license to such licensing party's patent rights, technology and regulatory documentation to use its compound solely to the extent necessary to discharge its obligations under the Agreement with respect to the conduct of the Combined Therapy Trials.

Subject to termination rights for breach, bankruptcy or a material safety issue/clinical hold, the term of the Agreement will continue in effect until completion by all centers or institutions participating in the Combined Therapy Trials, the delivery of study data to both parties and the completion of any then agreed upon protocol, statistical analysis and bioanalysis plan.

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the Collaboration Agreement, a copy of which, subject to any applicable confidential treatment, will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ending September 30, 2018. Readers should review such agreement for a complete understanding of the terms and conditions associated with this transaction.

**Item 8.01 Other Events**

On September 24, 2018, the Company and Nektar jointly issued a press release announcing the entry into the Collaboration Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated September 24, 2018 |



**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: September 26, 2018

**BIOXCEL THERAPEUTICS, INC.**

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

**Exhibit 99.1**

**BioXcel Therapeutics Expands Immuno-Oncology Partnership with Nektar into Clinical Development in Pancreatic Cancer**

*Clinical partnership to develop triple combination of BioXcel Therapeutics' BXCL701, Nektar's NKTR-214 and a checkpoint inhibitor*

NEW HAVEN, Conn; September 24, 2018— BioXcel Therapeutics, Inc. ("BTI") (Nasdaq: BTAI), a clinical stage biopharmaceutical development company utilizing novel artificial intelligence approaches to identify the next wave of medicines across neuroscience and immuno-oncology, and Nektar Therapeutics (Nasdaq: NKTR) announced today that the companies are expanding their ongoing research collaboration into a new clinical partnership. The collaboration will clinically evaluate the novel combination of BTI's BXCL701, a small molecule immune-modulator, DPP 8/9 and FAP inhibitor; Nektar's NKTR-214, a CD122-biased agonist; and a checkpoint inhibitor as a potential therapy for pancreatic cancer.

Under the terms of the expanded collaboration agreement, BTI will be responsible for initiating and managing the clinical program. The primary objectives of the study are to evaluate safety and efficacy of the triplet combination of BXCL701, NKTR-214 and a checkpoint inhibitor for the treatment of patients with unresectable or metastatic pancreatic cancer. Additionally, correlative immune activation markers will also be evaluated in blood and tumor tissue.

"We are excited to expand our collaboration with Nektar to initiate a clinical program for this novel triplet combination regimen," said Vimal Mehta, Chief Executive Officer of BTI. "Mechanistically, we believe the action of BXCL701 on macrophages and neutrophils within the tumor tissue can activate the innate immune system and then in combination with NKTR-214 and an anti-PD1, we can then prime adaptive immune cells in order to trigger T-cell driven anti-cancer activity and the generation of T-cell memory. The exciting preclinical data presented at this year's ASCO Meeting highlighted the complementary mechanisms by which these three agents can synergize to generate durable responses in various animal models."

"We believe it is essential to target multiple dimensions of the immune system in parallel in order to address the multi-faceted etiologies underlying cancer cell growth in difficult-to-treat tumors such as pancreatic cancer," said Jonathan Zalevsky, Senior Vice President, Biology & Preclinical Development of Nektar Therapeutics. "This experimental triplet combination regimen of BXCL701, NKTR-214 and a checkpoint inhibitor is designed to leverage multiple mechanisms of action at once to better fight pancreatic cancer while potentially generating long-term cancer immunity. We're pleased to be working with BTI on this program."

BTI and Nektar Therapeutics initially announced a preclinical research collaboration in November 2017. This collaboration focused on utilizing the complementary mechanisms of BXCL701 and NKTR-214 to stimulate the body's own immune system to overcome immunosuppressive mechanisms in the tumor microenvironment.

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**About BioXcel Therapeutics, Inc.:**

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence approaches to identify the next wave of medicines across neuroscience and 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 indices. The Company's two most advanced clinical development programs are BXCL501, a sublingual thin film formulation designed for acute treatment of agitation resulting from neurological and psychiatric disorders, and BXCL701, an immuno-oncology agent designed for treatment of a rare form of prostate cancer and for treatment of pancreatic cancer. 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, statements that relate to the advancement and development of BXCL701, the commencement of clinical trials, the availability of data from clinical trials and other information that is not historical information. When used herein, words such as "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, market conditions and the factors described under the caption "Risk Factors" in BioXcel's 10 Q for the Quarter ended June 30, 2018 and BioXcel's other filings made with the Securities and Exchange Commission. Consequently, forward-looking statements should be regarded solely as BioXcel's current plans, estimates and beliefs. Investors should not place undue reliance on forward-looking statements. BioXcel cannot guarantee future results, events, levels of activity, performance or achievements. BioXcel does not undertake and specifically declines any obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by law.

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