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 4, 2019

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)

(475) 238-6837
(Registrant's telephone number, including area code)

(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 8.01 Other Events.

On March 4, 2019, BioXcel Therapeutics, Inc. issued a press release announcing the addition of Merck KGaA, Darmstadt, Germany, which operates its biopharmaceutical business as EMD Serono in the USA and Canada, and Pfizer Inc. (PFE) to its Nektar Therapeutics (NKTR) clinical collaboration to evaluate a novel triple combination therapy in pancreatic cancer. 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 March 4, 2019

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 4, 2019

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Announces Addition of Merck KGaA, Darmstadt, Germany, and Pfizer to Clinical Collaboration with Nektar for Development of Triple-combination Therapy in Pancreatic Cancer

Clinical partnership to evaluate triple combination of BioXcel Therapeutics' BXCL701, Nektar's NKTR-214 and avelumab (Merck KGaA, Darmstadt, Germany and Pfizer) in pancreatic cancer

Merck KGaA, Darmstadt, Germany and Pfizer to supply checkpoint inhibitor immunotherapy, avelumab

NEW HAVEN, Conn., March 04, 2019 (GLOBE NEWSWIRE) — BioXcel Therapeutics, Inc. ("BTI") (BTAI) today announced the addition of Merck KGaA, Darmstadt, Germany, which operates its biopharmaceutical business as EMD Serono in the USA and Canada, and Pfizer Inc. (PFE) to its Nektar Therapeutics (NKTR) clinical collaboration to evaluate a novel triple combination therapy in pancreatic cancer. The collaboration now includes avelumab*, BXCL701 and NKTR-214 as a potential combination therapy for pancreatic cancer. Avelumab is a human anti-programmed death ligand (PD-L1) co-developed and co-commercialized by Merck KGaA Darmstadt, Germany and Pfizer. BXCL701 is an orally-available systemic innate-immune activator that inhibits dipeptidyl peptidase (DPP) 8/9 and FAP developed by BTI. NKTR-214 is a CD122-biased agonist developed by Nektar. BTI is a clinical stage biopharmaceutical development company utilizing novel artificial intelligence approaches to identify the next wave of medicines across neuroscience and immuno-oncology.

Under the collaboration, BTI will be responsible for initiating and managing the clinical program, with Merck KGaA, Darmstadt, Germany and Pfizer supplying avelumab and Nektar supplying NKTR-214. BTI and Nektar will equally share all development costs. The primary objectives of the study are to evaluate safety and efficacy of the triple combination of BXCL701, NKTR-214 and avelumab for the treatment of patients with pancreatic cancer. Additionally, correlative immune activation markers will be evaluated in blood and tumor tissue.

"We are excited to welcome Merck KGaA, Darmstadt, Germany and Pfizer as partners for the development of this novel triple combination regimen with Nektar," said Vimal Mehta, Chief Executive Officer of BTI. "We believe that the expansion of this clinical collaboration provides clear evidence of industry enthusiasm toward BXCL701. We look forward to working closely with Merck KGaA, Darmstadt, Germany and Pfizer as well as Nektar to leverage their clinical and regulatory expertise as we establish the development plan for the triple combination in pancreatic cancer."

"We believe it is essential to target multiple dimensions of the immune system in parallel to address the multi-faceted etiologies underlying cancer cell growth in difficult-to-treat tumors such as pancreatic cancer," said Jonathan Zalevsky, Chief Scientific Officer of Nektar Therapeutics. "This experimental triple combination regimen of BXCL701, NKTR-214 and avelumab is designed to leverage multiple mechanisms of action to better fight pancreatic cancer while potentially generating long-term cancer immunity. We're pleased to be working with BTI as well as Merck KGaA, Darmstadt, Germany and Pfizer on this program."

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*Avelumab is under clinical investigation for the treatment of pancreatic cancer and has not been demonstrated to be safe and effective for these uses. There is no guarantee that avelumab will be approved for pancreatic cancer by any health authority worldwide.

About BXCL701

BXCL701 is an orally-available systemic innate-immune activator with dual mechanisms of action. It has demonstrated single agent activity in melanoma, with an established safety profile from 700 healthy subjects and cancer patients. Designed to stimulate both the innate and acquired immune systems, BXCL701 works by inhibiting dipeptidyl peptidase (DPP) 8/9 and blocking immune evasion by targeting Fibroblast Activation Protein (FAP). Preclinical combination data evaluating BXCL701, a checkpoint inhibitor and other immuno-oncology agents has demonstrated encouraging anti-tumor activity in multiple tumor types and formation of functional immunological memory. BXCL701's primary mechanism of action has recently been highlighted in multiple peer reviewed journals, providing an important validation of the scientific rationale behind BXCL701.

About NKTR-214

NKTR-214 preferentially binds to the CD122 receptor on the surface of cancer-fighting immune cells in order to stimulate their proliferation. In clinical and preclinical studies, treatment with NKTR-214 resulted in expansion of these cells and mobilization into the tumor micro-environment. NKTR-214 has an antibody-like dosing regimen similar to the existing checkpoint inhibitor class of approved medicines.

About Avelumab

Avelumab is a human anti-programmed death ligand-1 (PD-L1) antibody. Avelumab has been shown in preclinical models to engage both the adaptive and innate immune functions. By blocking the interaction of PD-L1 with PD-1 receptors, avelumab has been shown to release the suppression of the T cell-mediated antitumor immune response in preclinical models.(1)-(3) Avelumab has also been shown to induce NK cell-mediated direct tumor cell lysis via antibody-dependent cell-mediated cytotoxicity (ADCC) *in vitro*.(3)-(5) In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

Approved Indications

The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab is currently approved for patients with MCC in more than 45 countries globally, with the majority of these approvals in a broad indication that is not limited to a specific line of treatment.

Important Safety Information from the US FDA-Approved Label

The warnings and precautions for avelumab (BAVENCIO®) include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions), infusion-related reactions and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO® for mMCC and patients with locally advanced or metastatic UC include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash.

For full prescribing information and medication guide for BAVENCIO®, please see www.BAVENCIO.com.

About BioXcel Therapeutics, Inc.:

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence to identify the next wave of medicines across neuroscience and immuno-oncology. BTI'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. BTI'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 BXCL501 and 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 Form 10Q for the period ending September 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.

References

1 Dolan DE, Gupta S. PD-1 pathway inhibitors: changing the landscape of cancer immunotherapy. Cancer Control 2014;21(3):231-7.
2 Dahan R, Sega E, Engelhardt J et al. FcγRs modulate the anti-tumor activity of antibodies targeting the PD-1/PD-L1 axis. Cancer Cell 2015;28(3):285-95.
3 Boyerinas B, Jochems C, Fantini M et al. Antibody-dependent cellular cytotoxicity activity of a novel anti-PD-L1 antibody avelumab (MSB0010718C) on human tumor cells. Cancer Immunol Res 2015;3(10):1148-57.
4 Kohrt HE, Houot R, Marabelle A et al. Combination strategies to enhance antitumor ADCC. Immunotherapy 2012;4(5):511-27.
5 Hamilton G, Rath B. Avelumab: combining immune checkpoint inhibition and antibody-dependent cytotoxicity. Expert Opin Biol Ther 2017;17(4):515-7

Contact Information:

BioXcel Therapeutics
The Ruth Group
Lee Roth/ Janhavi Mohite
646-536-7012/ 7026
lroth@theruthgroup.com/ jmohite@theruthgroup.com