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) November 12, 2020

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)

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 2.02 Results of Operations and Financial Condition.

On November 12, 2020, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the three and nine months ended September 30, 2020 and other matters described in the press release. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated November 12, 2020.

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: November 12, 2020

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
By: Richard Steinhart
Title: Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Reports Third Quarter 2020 Financial Results and Provides Business Update

Complete NDA submission for BXCL501 for the acute treatment of agitation in patients with schizophrenia and bipolar disorders on track for Q1 2021

TRANQUILITY and RELEASE studies are on track; Preparing to initiate a Phase 2 trial with BXCL501 in patients with agitation associated with delirium

Encouraging data from the two ongoing combination trials of BXCL701 and KEYTRUDA® was presented at the Society for Immunotherapy of Cancer's 35th Anniversary Annual Meeting ("SITC")

Strong cash position of $233 million to fund key milestones well into 2022

Company to host conference call today at 8:30 a.m. ET

NEW HAVEN, Conn., Nov. 12, 2020 -- BioXcel Therapeutics, Inc. ("BTI" or the "Company") (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence to identify improved therapies in neuroscience and immuno-oncology, today announced its quarterly results for the third quarter ended September 30, 2020 and provided an update on key strategic and operational initiatives.

"Building on the successful data readout from the Phase 3 SERENITY trials earlier this year, we have continued to make substantial progress with BXCL501's development as a treatment for agitation across neuropsychiatric conditions," stated Vimal Mehta, Chief Executive Officer of BTI. "Recently, we completed our pre-NDA meeting with the FDA and have initiated rolling submission of the NDA. This is a key milestone for our neuroscience franchise, laying a strong foundation for multiple follow-on indications and a catalyst for the ongoing build of our commercial infrastructure. While the TRANQUILITY and RELEASE trials advance, we are preparing to initiate a Phase 2 trial for agitation associated with delirium. Together, we believe that these trials, along with our strong cash position, will help to support our long-term strategy of establishing BXCL501 as an innovative treatment for agitation regardless of the patient's underlying diagnosis."

Dr. Mehta continued, "We are also making excellent strides advancing our immuno-oncology program, with two combination therapy trials progressing well. Earlier this week, we presented encouraging preliminary efficacy and safety data at SITC from both the Phase 1b/2 trial of BXCL701 and KEYTRUDA® for the treatment of advanced prostate cancer and the MD Anderson-led Phase 2 basket trial in advanced solid tumors. Across both trials, we have already seen promising signals of activity in numerous difficult-to-treat tumors."

Third Quarter 2020 and Recent Highlights

BXCL501-Neuroscience Program

BXCL501 is an investigational, proprietary, orally dissolving, sublingual thin film formulation of dexmedetomidine, a selective alpha-2 adrenergic receptor agonist, designed for the treatment of agitation and opioid withdrawal symptoms. The Company believes BXCL501 may directly target a causal agitation mechanism.

- Following the recently announced positive topline results from the Phase 3 SERENITY trials, last month, BTI completed a successful pre-NDA meeting with the FDA for BXCL501 for the acute treatment of agitation in patients with schizophrenia and bipolar disorders. The FDA agreed to a rolling review of the NDA and BTI has already submitted part of the application to the FDA, with plans to submit the complete application in the first quarter of 2021.
- The Company initiated the third dose cohort (90 mcg) in the TRANQUILITY study, a Phase 1b/2 trial of BXCL501 for the acute treatment of agitation associated with dementia. Based on the findings, the Company expects to report topline results in the fourth quarter of 2020, or, if needed, proceed to an additional dose cohort.
- The RELEASE study, a Phase 1b/2 trial of BXCL501 for the treatment of opioid withdrawal symptoms, is ongoing, with enrollment of the dose cohorts progressing well. The Company expects to report topline results from the study in the first quarter of 2021.
- In October, BTI received FDA clearance of its Investigational New Drug ("IND") application for BXCL501 for the treatment of hospitalized patients with agitation associated with delirium, including COVID-19 patients. The Company plans to initiate a Phase 2 trial within the next several months.
- BTI recently analyzed topline data from a cross-over study in healthy volunteers comparing the bioavailability of BXCL501 administered sublingually with the film placed drug-side down under the tongue, compared to the film placed drug-side up under the tongue, and administered buccally (between the lower lip and the gum). It was determined that all three administrations of BXCL501 are bioequivalent and were rapidly absorbed into the systemic circulation. Also, drinking water starting at 15 minutes following sublingual administration did not have any affect on bioavailability.
- The Company was issued U.S. patent No. 10,792,24 on October 6, 2020, which covers film formulations containing Dex and methods of treating agitation using such film formulations. The patent is expected to extend intellectual property ("IP") protection until 2039.

BXCL701-Immuno-Oncology Program

BXCL701 is an orally-delivered small molecule, innate immunity activator designed to inhibit dipeptidyl peptidase (DPP) 8/9 and block immune evasion by targeting Fibroblast Activation Protein (FAP). It has shown single agent activity in melanoma and safety has been evaluated in more than 700 healthy subjects and cancer patients.

- The Phase 2 portion of the Phase 1b/2 trial of BXCL701 in combination with pembrolizumab (KEYTRUDA®) for treatment emergent Neuroendocrine Prostate Cancer ("tNEPC") and castrate-resistant prostate cancer ("CRPC") is advancing. Data from the 1b portion of this trial was presented recently at SITC, with an additional efficacy update planned.
- The MD Anderson-led Phase 2 open label basket trial evaluating the combination of BXCL701 and KEYTRUDA® in patients with advanced solid tumors is progressing well, and has already moved to the stage-2 efficacy phase. Preliminary efficacy data on 14 patients (5 patients in the checkpoint naïve cohort and 9 patients in the checkpoint pretreated cohort) was presented earlier this week at SITC.
- The BXCL701 phase of the triple combination study of BXCL701, bempegaldesleukin (NKTR-214, Nektar Therapeutics, Inc.) and BAVENCIO® (avelumab, Merck KGaA, Darmstadt, Germany and Pfizer) in second line pancreatic cancer was planned to initiate following Nektar and Pfizer's Phase 1B dose-escalation trial of bempegaldesleukin and avelumab, which was delayed. All parties have agreed to discontinue activities on the triple combination study and instead reallocate resources to other studies and development programs. The parties terminated their clinical trial collaboration agreement, effective November 10, 2020.

Corporate Highlight

- In July 2020, the Company raised net proceeds of approximately $187 million in connection with its common stock offering. BTI believes that the proceeds from this offering, together with current reserves, provide the cash runway to fund key clinical, regulatory, operational, and commercial activities well into 2022.

Third Quarter 2020 Financial Results

BTI reported a net loss of $24.8 million for the third quarter of 2020 compared to a net loss of $9.0 million for the same period in 2019. The third quarter 2020 results include approximately $5.3 million in non-cash stock-based compensation compared to $0.8 million for the same period in 2019.

Research and development expenses were $16.3 million for the third quarter of 2020, compared to $7.1 million for the same period in 2019. The increase was primarily attributable to increased clinical trial costs and professional research related to the acceleration of the Company's research and development activities, primarily related to its SERENITY I and II clinical trials as well increased costs associated with its TRANQUILITY and RELEASE clinical trials for BXCL501. These amounts were partially offset by reduced costs related to the BXCL701 pancreatic cancer trial.

Personnel costs also increased, primarily related to the growth of BTI's clinical team as the Company continues to expand its clinical programs, and in preparation of the potential commercial launch of BXCL501 in the U.S. Non-cash stock-based compensation also increased as result of the additional personnel combined with increased grant date fair values arising from higher market prices of the Company's common stock.

General and administrative expenses were $8.5 million for the third quarter of 2020, compared to $2.0 million for the same period in 2019. The increase was primarily due to increased non-cash stock-based compensation and personnel costs related to the growth of BTI's operations combined with increased grant date fair values arising from higher market prices of the Company's common stock. Professional fees also increased which is primarily attributable to increased corporate legal and investor relations fees combined with increased insurance premiums.

Total operating expenses for the third quarter of 2020 were approximately $24.8 million, compared to total operating expenses of approximately $9.1 million for the same period in 2019.

As of September 30, 2020, cash and cash equivalents totaled approximately $233.4 million.

Conference Call:

BTI will host a conference call and webcast today at 8:30 a.m. ET. To access the call, please dial 877-407-2985 (domestic) and 201-378-4915 (international). A live webcast of the call will be available on the Investors sections of the BTI website at www.bioxceltherapeutics.com. The replay will be available through at least November 26, 2020.

About BioXcel Therapeutics, Inc.:

BioXcel Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on drug development that utilizes artificial intelligence to identify improved therapies in 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, an investigational, proprietary, orally dissolving, sublingual 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 and data from clinical development initiatives, applications and trials for BXCL501 and BXCL701, the timing of the Company’s NDA submission for BXCL501 for the acute treatment of agitation in patients with schizophrenia and bipolar disorders, the Company’s cash runway and the Company’s future growth, corporate strategy and position to execute on key milestones. 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 BTI's current expectations and various assumptions. BTI believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BTI 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 BTI'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 June 30, 2020 as such factors may be updated from time to time in its other filings with the SEC, including, but not limited to, its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 to be filed with the SEC, each 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 BTI 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 BTI's views as of any date subsequent to the date of this press release.

BioXcel Therapeutics, Inc. (BTAI)

Statement of Operations

(Unaudited, in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenues	$ –	$ –	$ –	$ –
Operating Expenses				
Research and Development	$ 16,317	$ 7,122	$ 46,595	$ 19,302
General and administrative	8,451	2,012	14,605	5,886
Total operating expenses	24,768	9,134	61,200	25,188
Loss from Operations	(24,768)	(9,134)	(61,200)	(25,188)
Other Income (expense)				
Divided and interest income	20	134	140	542
Interest expense	(5)	(18)	(23)	(47)
Net loss	$ (24,753)	$ (9,018)	$ (61,083)	$ (24,693)
Net loss per – basic and diluted	$ (1.07)	$ (0.57)	$ (2.94)	$ (1.57)
Weighted average shares outstanding – basic and diluted	23,050	15,752	20,779	15,695

BioXcel Therapeutics, Inc.

Condensed Balance Sheet

(Unaudited, in thousands)

	September 30, 2020	December 31, 2019
Cash and cash equivalents	233,428	32,426
Working capital	219,789	25,639
Total assets	238,749	36,392
Long-term liabilities	1,467	1,029
Total liabilities	17,811	9,497
Total stockholders' equity	220,938	26,895

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