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) May 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 May 12, 2020, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the three months ended March 31, 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 May 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: May 12, 2020

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1

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

Enrollment of the pivotal SERENITY trials is progressing well, with topline data expected in mid-2020

The Company is assessing data for dose escalation in the TRANQUILITY study and is on track to report results in mid-2020

Recommended Phase 2 dose of BXCL701 identified for combination study with KEYTRUDA®, leading to the initiation of the Phase 2 efficacy trial for advanced prostate cancer

Strengthened balance sheet through follow-on offering raising approximately $60 million in net proceeds

NEW HAVEN, Conn., May 12, 2020 -- BioXcel Therapeutics, Inc. ("BTI" or "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 first quarter ended March 31, 2020 and provided an update on key strategic and operational initiatives.

"BioXcel continued to advance on its key milestones for 2020," stated Vimal Mehta, Chief Executive Officer of BTAI. "Beginning with our neuroscience program, we have made significant progress advancing BXCL501, as evidenced by our three ongoing clinical trials, SERENITY I & II and TRANQUILITY, and our Phase 1b/2 RELEASE trial initiating shortly. In parallel, we are investigating biomarkers associated with agitation in hopes of expanding the potential market for BXCL501 to additional indications. These significant achievements showcase the versatility of this candidate and we believe provides the foundation for creating a highly valuable neuroscience franchise. In addition, we have made great strides with our immuno-oncology program, identifying the recommended dose of BXCL701 when used in combination with KEYTRUDA® for our Phase 2 efficacy trial for treatment emergent Neuroendocrine Prostate Cancer. We believe this candidate has the potential to provide a treatment for this advanced prostate cancer that currently does not have an effective standard of care."

Dr. Mehta added, "In light of the COVID-19 pandemic, we are continuously monitoring the safety of our team, as well as its potential impact on our clinical and corporate plans. To date, we have not experienced any significant delays with our ongoing clinical trials and have developed a risk mitigation strategy to manage business operations."

First Quarter 2020 and Recent Highlights

BXCL501-Neuroscience Program

BXCL501 is an investigational sublingual thin film of dexmedetomidine, a selective alpha-2A adrenergic receptor agonist, designed for the treatment of acute agitation. The Company believes BXCL501 may directly target a causal agitation mechanism.

- The SERENITY program, two Phase 3 studies of BXCL501 for the acute treatment of agitation in patients with schizophrenia and bipolar disorder, is ongoing, with more than one-third of the patients enrolled and treated as of March 19, 2020. Enrollment is progressing as planned, and the Company is on track to report topline data from both Phase 3 trials in mid-2020.
- In January 2020, the first patient was enrolled in the TRANQUILITY study, a Phase 1b/2 trial of BXCL501 for the acute treatment of agitation associated with geriatric dementia. BTI is currently assessing safety and tolerability data in order to choose the next tested dose, and the Company expects to report topline results in mid-2020.

- Our Investigational New Drug application for the treatment of opioid withdrawal symptoms, a fourth indication for BXCL501, received clearance from the U.S. Food and Drug Administration in February 2020. The Company is planning to initiate the Phase 1b/2 RELEASE trial for the treatment of opioid withdrawal symptoms shortly.
- In February 2020, researchers at Yale University initiated a Phase 2 study designed to measure biomarkers associated with agitation in patients with schizophrenia and their response to treatment with BXCL501.
- The Company is currently completing the clinical planning stage for its fifth indication, agitation associated with hyperactive delirium, and is preparing to initiate a Phase 1b/2 trial of BXCL501 in the second half of 2020.

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.

- After completing the Phase 1b safety lead-in, the Company has initiated the Phase 2 portion of the Phase 1b/2 trial of BXCL701 in combination with pembrolizumab (KEYTRUDA®) for treatment emergent Neuroendocrine Prostate Cancer (tNEPC). 0.3 mg of BXCL701 twice daily (BID) was found to be the recommended dose when used in combination with KEYTRUDA® and this dose regime will be used for the efficacy assessment of the clinical program. The Company expects to report initial data from this trial in the fourth quarter of 2020.
- The open label Phase 2 basket trial evaluating the combination of BXCL701 and KEYTRUDA® in patients with advanced solid cancers has been initiated. This study, which is being conducted at the MD Anderson Cancer Center, is following the dosing schedule used in the Phase 1b/2 study for tNEPC.
- 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 pancreatic cancer is expected to begin following Nektar and Pfizer's Phase 1b safety trial of a double combination of bempegaldesleukin and avelumab and the outcome of that trial.

Strengthened Balance Sheet

- In February 2020, the Company raised net proceeds of approximately $60 million in connection with its common stock offering. BTI believes that proceeds from this offering, together with current reserves, provide cash runway to fund key clinical, regulatory and operational milestones into 2021.

COVID-19

During the first quarter of 2020, the Company took steps in line with guidance from the U.S. Centers for Disease Control and Prevention (CDC) and the State of Connecticut to protect the health and safety of its employees and the community. In particular, the Company implemented a work-from-home policy for all employees and has restricted on-site activities to certain chemical, manufacturing and control ("CMC") and clinical trial activities. To date, the Company has not experienced any significant delays to its ongoing or planned clinical trials; however, this could rapidly change.

First Quarter 2020 Financial Results

BTI reported a net loss of $14.9 million for the first quarter of 2020, compared to a net loss of $7.2 million for the same period in 2019. The first quarter 2020 results include approximately $0.8 million in non-cash stock-based compensation.

Research and development expenses were $12.4 million for the first quarter of 2020, as compared to $5.7 million for the same period in 2019. The increase was primarily due to an increase in clinical trial expenses, salaries, bonus and related costs, professional research and project-related costs and chemical, manufacturing and controls costs related to our BXCL501 and BXCL701 product candidates.

General and administrative expenses were $2.6 million for the first quarter of 2020, as compared to $1.7 million for the same period in 2019. The increase was primarily due to professional fees for additional legal and patent services.

Total operating expenses for the first quarter of 2020 were approximately $15.0 million, as compared to total operating expenses of approximately $7.4 million for the same period in 2019.

As of March 31, 2020, cash and cash equivalents totaled approximately $80.1 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 May 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 evaluated 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 sublingual thin film formulation in development for acute treatment of agitation resulting from neuropsychiatric disorders, and BXCL701, an investigational orally administered systemic innate immunity activator in development for treatment of a rare form of prostate cancer and for treatment of pancreatic cancer in combination with other immuno-oncology agents. 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 and trials for BXCL501 and BXCL701, the Company’s cash runway, the impact of the COVID-19 pandemic on the Company’s business, financial results and financial condition and the Company’s future growth 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 March 31, 2020 as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC’s website at *www.sec.gov* and Investors sections 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.

BALANCE SHEETS

(amounts in thousands)

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 80,079	$ 32,426
Prepaid expenses and other current assets	3,519	1,681
Total current assets	83,598	34,107
Property and equipment, net	1,010	1,041
Operating lease right-of-use asset	1,153	1,193
Other assets	51	51
Total assets	**$ 85,812**	**$ 36,392**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 6,733	$ 4,953
Accrued expenses	3,600	3,120
Due to Parent	—	64
Other current liabilities	1,932	331
Total current liabilities	12,265	8,468
Operating lease liability	961	1,029
Total liabilities	**13,226**	**9,497**
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value, 50,000,000 shares authorized; 20,182,382 and 18,087,382 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	20	18
Additional paid-in-capital	144,165	83,565
Accumulated deficit	(71,599)	(56,688)
Total stockholders' equity	72,586	26,895
Total liabilities and stockholders' equity	**$ 85,812**	**$ 36,392**

BIOXCEL THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

(amounts in thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Revenues	$ —	$ —
Operating costs and expenses		
Research and development	12,371	5,674
General and administrative	2,625	1,745
Total operating expenses	14,996	7,419
Loss from operations	(14,996)	(7,419)
Other income		
Dividend and interest income, net	85	215
Net loss	$ (14,911)	$ (7,204)
Net loss per share attributable to common stockholders basic and diluted	$ (0.79)	$ (0.46)
Weighted average shares outstanding - basic and diluted	18,968,096	15,663,795

BIOXCEL THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

(amounts in thousands, except share and per share data)

(unaudited)

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance as of December 31, 2018	15,663,221	$ 16	$ 62,593	$ (23,720)	$ 38,889
Stock-based compensation	—	—	682	—	682
Exercise of stock options	2,581	—	1	—	1
Net loss	—	—	—	(7,204)	(7,204)
Balance as of March 31, 2019	15,665,802	$ 16	$ 63,276	$ (30,924)	$ 32,368
Balance as of December 31, 2019	18,087,382	$ 18	$ 83,565	$ (56,688)	$ 26,895
Issuance of common stock, net of issuance costs of $4,789	2,300,000	2	68,809		68,811
Purchase and cancellation of shares from BioXcel Corporation	(300,000)	—	(9,024)		(9,024)
Stock-based compensation	—	—	776	—	776
Exercise of stock options	95,000	—	39	—	39
Net loss	—	—	—	(14,911)	(14,911)
Balance as of March 31, 2020	20,182,382	$ 20	$ 144,165	$ (71,599)	$ 72,586

BIOXCEL THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

(amounts in thousands)

(unaudited)

	Three months ended March 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (14,911)	$ (7,204)
Reconciliation of net loss to net cash used in operating activities		
Depreciation and amortization	47	37
Stock-based compensation expense	776	682
Due to Parent under asset contribution agreement	—	500
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,838)	(1,292)
Accounts payable, accrued expenses and other	3,769	1,607
Net cash used in operating activities	(12,157)	(5,670)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment and leasehold improvements	(16)	(600)
Net cash used in investing activities	(16)	(600)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs of $4,789	68,811	—
Purchase and cancellation of shares from BioXcel Corporation	(9,024)	—
Exercise of options	39	1
Net cash provided by financing activities	59,826	1
Net (decrease) increase in cash and cash equivalents	47,653	(6,269)
Cash and cash equivalents, beginning of the period	32,426	42,565
Cash and cash equivalents, end of the period	$ 80,079	$ 36,296
Supplemental cash flow information:		
Interest paid	$ 3	$ 8

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