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)
August 6, 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)

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 August 6, 2019, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the three and six months ended June 30, 2019 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 August 6, 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: August 6, 2019

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Reports Second Quarter 2019 Financial Results and Provides Business Update

BXCL501 met primary endpoint in agitated schizophrenia patients with clinically meaningful, rapid and durable reduction in PEC score maintained for 4 to 6 hours in its Phase 1b, randomized, double blind, placebo controlled clinical trial

On track to initiate BXCL501 Phase 3 pivotal trial in Q4 2019in agitated schizophrenia and bipolar patients subject to discussion with U.S. FDA; data readout expected 1H 2020

BXCL501 Phase 1b trial in agitated Alzheimer's disease/dementia patients expected to initiate in Q4 2019

BXCL701 has two ongoing Phase 1b/2 clinical trials in pancreatic cancer and treatment emergent neuroendocrine prostate cancer (tNEPC); data readouts expected in 2H 2019 and 1H 2020

BTI added to the Russell 2000® and 3000® Indexes

Conference call scheduled for August 6h at 8:30 AM ET

NEW HAVEN, Conn., Aug 6, 2019 — BioXcel Therapeutics, Inc. ("BTI" or "Company") (Nasdaq: BTAI), today announced its quarterly results for the second quarter ended June 30, 2019 and provided an update on key strategic and operational initiatives. 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.

Second Quarter 2019 and Recent Highlights

(BXCL501)-Neuroscience Program-

- BXCL501 adaptive Phase 1b, randomized, double blind, placebo-controlled, multi-center, U.S. trial reported positive topline data as a potential therapy for acute treatment of agitation in schizophrenia patients;
- BXCL501 met primary endpoint and demonstrated statistically significant and clinically meaningful rapid mean reduction in PEC (PANSS or the Positive and Negative Syndrome Scale, Excitatory Component) score at two hours compared to placebo following a single dose of 80 mcg (p=0.0152), 120 mcg (p=0.0003) and 180 mcg (p<0.0001);
- Results from secondary analyses showed statistically significant calming as measured by the ACES (Agitation-Calmness Evaluation Scale) at two hours compared to placebo

following a single dose of 80 mcg (p=0.0156), 120 mcg (P=0.0005) and 180 mcg (P<0.0001);
- Well tolerated with no serious or severe adverse events across the entire dose range;
- Trial results support the potential to advance the BXCL501 program to Phase 3 pivotal studies in agitated schizophrenia and bipolar patients, subject to a pre-Phase 3 meeting with the FDA;
- Phase 3 Pivotal trials are anticipated to enroll approximately 600 to 700 patients (300-350 each in schizophrenia and bipolar disorder), designed to measure reduction in PEC at two hours as the primary endpoint, as used in clinical trials of other approved agents. A data readout is expected in 1H 2020;
- BXCL501 adaptive Phase 1b trial in agitated Alzheimer's disease/dementia patients is expected to begin in Q4 2019;
- Development plans for the acute treatment of agitation with BXCL501 in hyperactive delirium and opioid withdrawal are underway

(BXCL701)-Immuno-Oncology Program-

- Currently enrolling patients in the U.S. in the double combination of BXCL701 and Keytruda® clinical trial for treatment emergent Neuroendocrine Prostate Cancer (tNEPC). Multiple patients have been treated in the safety and escalation portion of the trial which will be followed by a two-stage efficacy portion of the clinical program. A data read out is expected in 2H 2019;

- Clinical Trial Application (CTA) was accepted by the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") for the double combination trial of BXCL701 and Keytruda® in tNEPC patients. Expected to activate clinical sites, subject to approval from local U.K. authorities. This approval is the first step in our plan to expand our clinical trials globally;

- FDA authorized the IND application for the triple combination of BXCL701, bempegaldesleukin (produced by Nektar Therapeutics, Inc., or Nektar) and BAVENCIO® (avelumab, Merck KGaA, Darmstadt, Germany and Pfizer) in pancreatic cancer. The safety escalation portion of the trial is ongoing and will be followed by a two-stage efficacy portion. A data read-out is expected in 1H 2020;

- Pursuing a clinical proof of mechanism study with BXCL701 in pancreatic cancer patients to characterize immune cell infiltration and activation and the circulating cytokines elicited in order to validate it's mechanism of action;

- Continuing to explore additional indications for BXCL701 with synergistic combinations

“We are excited by the clinical achievements we made during this quarter by advancing both our lead neuroscience program, BXCL501, and our immuno-oncology program, BXCL701,” commented Vimal Mehta, President and Chief Executive Officer of BTI.

“In our BXCL501 program, we recently announced positive top-line data from our adaptive Phase 1b, randomized, double-blind, placebo-controlled, multi-center, U.S. trial demonstrating statistically significant reductions in the PEC score at two hours compared to placebo for multiple dosages and displayed rapid and durable calming effect without excessive sedation for such dosages. The drug was also well tolerated across all doses tested. We are pleased by these results which reflect significant progress in developing a non-invasive, easy to administer therapy, and which provide evidence supporting BXCL501’s potential as a rapid-onset treatment for acute agitation. Based on these results, we intend to have discussions with the FDA to determine the path forward for the BXCL501 program. We anticipate moving into the pivotal Phase 3 trial in the fourth quarter of 2019 and expect a data readout during the first half of 2020. Additionally, we are also planning to begin a Phase 1b trial in agitated Alzheimer’s disease/dementia patients that we expect to initiate in the fourth quarter of 2019. With all these positive developments, we remain confident in our strategic plan to submit our first NDA for BXCL501 during the second half of 2020.”

Dr. Mehta added, “We are also committed to driving progress in our immuno-oncology program for BXCL701 with two ongoing Phase 1b/2 trials. We are evaluating the combination of BXCL701 and Keytruda® in tNEPC, an aggressive form of prostate cancer with limited treatment options. We are enrolling patients in this Phase 1b/2 study of BXCL701 combined with Keytruda® in the United States, and multiple patients have been treated in the safety and escalation portion of the trial. A data readout for this study is anticipated in the second half of 2019. Further, the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) accepted our clinical trial authorization to evaluate BXCL701 plus Keytruda® in tNEPC which allows us to expand the development of this double combination into other geographies. Following the FDA authorization of our IND application for the combination of BXCL701, bempegaldesleukin and BAVENCIO® as a second line therapy for pancreatic cancer, we initiated a clinical study for which data readouts are expected in the first half of 2020. Our collaboration with Nektar Therapeutics, Merck KGaA, Darmstadt, Germany and Pfizer enables us to pursue our mutual goal of advancing the triple combination of immuno-oncology agents in pancreatic cancer to bring an effective therapeutic option in this large, underserved indication.”

“With the achievement of these value driving milestones in both of our lead programs, we are extremely pleased with our performance during the second quarter. We also raised our visibility in the financial community through BTI’s addition to the Russell 2000® and 3000® Indexes. As we continue to effectively manage our cash position, we believe it will be sufficient

to fund key milestones and operations to mid-2020. We remain confident in our strategy and believe we are positioned for continued growth."

Second Quarter 2019 Financial Results

BTI reported a net loss of $8.5 million for the second quarter of 2019, compared to a net loss of $3.0 million for the same period in 2018.

Research and development expenses were $6.5 million for the second quarter of 2019, as compared to $1.8 million for the same period in 2018. The increase was primarily due to an expansion of research and development activities, including increased personnel costs, clinical trials expenses, manufacturing costs, and professional fees, associated with BTI's two lead product candidates.

General and administrative expenses were $2.1 million for the second quarter of 2019, as compared to $1.5 million for the same period in 2018. The increase was primarily due to additional payroll and payroll-related expenses, professional fees and costs associated with operating as a public company.

These results include approximately $1.0 million in non-cash stock based compensation.

As of June 30, 2019, cash and cash equivalents totaled approximately $30.0 million. BTI is well positioned to execute on key milestones with sufficient cash to fund operations through mid-2020.

Conference Call:

BTI will host a conference call and webcast today at 8:30 a.m. ET. To access the call please dial (800) 239-9838 (domestic) and (323) 994-2093 (international) and provide the passcode 2198753. A live webcast of the call will be available on the Investors sections of the BTI website at www.bioxceltherapeutics.com. The archived webcast will be available through September 6, 2019.

About BXCL501:

BXCL501 is a potential first-in-class, proprietary sublingual thin film of dexmedetomidine, a selective alpha-2a receptor agonist for the treatment of acute agitation. BTI believes that BXCL501 directly targets a causal agitation mechanism and the Company has observed anti-agitation effects in multiple clinical studies across multiple neuropsychiatric indications. BXCL501 is currently being developed for agitation associated with schizophrenia and bipolar disorders followed by Alzheimer's/dementia.

About BXCL701:

BXCL701 is an investigational orally-available systemic innate immunity activator with dual mechanisms of action. It has demonstrated single agent activity in melanoma and safety has been evaluated in more than 700 healthy subjects and cancer patients. Designed to stimulate both the innate and acquired immune systems, BXCL701 inhibits dipeptidyl peptidase (DPP) 8/9 and blocks immune evasion by targeting Fibroblast Activation Protein (FAP). BXCL701, is currently being developed for treatment of a rare form of prostate cancer and for pancreatic cancer in combination with other immuno-oncology agents

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 and advance the next wave of medicines 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, a sublingual thin film formulation designed for acute treatment of agitation resulting from neuropsychiatric disorders, and BXCL701, an orally administered systemic innate immunity activator designed 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 Company's the timing and data from clinical development initiatives and trials for BXCL501 and BXCL701, the Company's discussions with the FDA, the Company's future growth and the Company's available funding through mid-2020. 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; 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; 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, 2019 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.

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.

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BIOXCEL THERAPEUTICS, INC.

BALANCE SHEETS

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

	June 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 29,965	$ 42,565
Prepaid expenses and other current assets	1,500	491
Due from Parent	46	115
Total current assets	31,511	43,171
Deferred offering expenses	378	—
Property and equipment, net	1,092	327
Operating lease right-of-use asset	1,246	—
Other assets	51	51
Total assets	**$ 34,278**	**$ 43,549**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,979	$ 1,604
Accrued expenses	3,371	3,056
Other current liabilities	659	—
Total current liabilities	8,009	4,660
Operating lease liability	1,112	—
Total liabilities	**9,121**	**4,660**
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value, 50,000,000 shares authorized; 15,687,546 and 15,663,221 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	16	16
Additional paid-in-capital	64,536	62,593
Accumulated deficit	(39,395)	(23,720)
Total stockholders' equity	25,157	38,889
Total liabilities and stockholders' equity	**$ 34,278**	**$ 43,549**

BIOXCEL THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses				
Research and development	6,506	1,781	12,180	4,719
General and administrative	2,129	1,463	3,874	2,811
Total operating expenses	8,635	3,244	16,054	7,530
Loss from operations	(8,635)	(3,244)	(16,054)	(7,530)
Other income				
Dividend and interest income, net	164	218	379	222
Net loss	$ (8,471)	$ (3,026)	$ (15,675)	$ (7,308)
Net loss per share attributable to common stockholders basic and diluted	$ (0.54)	$ (0.19)	$ (1.00)	$ (0.54)
Weighted average shares outstanding - basic and diluted	15,668,588	15,645,545	15,666,190	13,507,770

BIOXCEL THERAPEUTICS, INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY / DEFICIT

(amounts in thousands, except shares)
(unaudited)

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance as of December 31, 2017	9,907,548	$ 10	$ 3,458	$ (4,450)	$ (982)
Issuance of common shares	283,452	1	1,949	—	1,950
Issuance of common shares, upon completion of Initial Public Offering, net of issuance costs of $5,898	5,454,545	5	54,097	—	54,102
Stock-based compensation	—	—	1,319	—	1,319
Net loss	—	—	—	(4,282)	(4,282)
Balance as of March 31, 2018	15,645,545	$ 16	$ 60,823	$ (8,732)	$ 52,107
Stock-based compensation	—	—	740	—	740
Net loss	—	—	—	(3,026)	(3,026)
Balance as of June 30, 2018	15,645,545	$ 16	$ 61,563	$ (11,758)	$ 49,821
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
Issuance of common shares	21,744	—	230	—	230
Stock-based compensation	—	—	1,030	—	1,030
Net loss	—	—	—	(8,471)	(8,471)
Balance as of June 30, 2019	15,687,546	$ 16	$ 64,536	$ (39,395)	$ 25,157

BIOXCEL THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

(amounts in thousands)
(unaudited)

	Six months ended June 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (15,675)	$ (7,308)
Reconciliation of net loss to net cash used in operating activities		
Depreciation and amortization	122	2
Stock-based compensation expense	1,712	2,059
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,009)	(666)
Accounts payable, accrued expenses and other	3,153	(69)
Net cash used in operating activities	(11,697)	(5,982)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment and leasehold improvements	(825)	(120)
Net cash used in investing activities	(825)	(120)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net	230	56,512
Deferred offering costs	(378)	—
Exercise of options	1	—
Due to/from Parent	69	(577)
Note Payable — Parent	—	(371)
Net cash (used in) provided by financing activities	(78)	55,564
Net (decrease) increase in cash and cash equivalents	(12,600)	49,462
Cash and cash equivalents, beginning of the period	42,565	887
Cash and cash equivalents, end of the period	$ 29,965	$ 50,349
Supplemental cash flow information:		
Interest paid	$ 29	$ 1
Supplemental disclosure of non-cash Financing Activity:		
Deferred issuance costs, unpaid as of December 31, 2017	$ —	$ 391
Deferred issuance costs reclassified to additional paid-in-capital upon completion of initial public offering.	$ —	$ 461
Reclassification of net Parent Investment in the Company to accumulated deficit.	$ —	$ 440