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 11, 2021

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 March 11, 2021, BioXcel Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the three months and year ended December 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 March 11, 2021.

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 11, 2021

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart

By: Richard Steinhart
Title: Chief Financial Officer

Exhibit 99.1

BioXcel Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

New Drug Application ("NDA") submitted to the U.S. Food and Drug Administration ("FDA") for BXCL501 for the acute treatment of schizophrenia and bipolar disorder related agitation

TRANQUILITY achieved primary and secondary endpoints with both doses of BXCL501; End of Phase 2 meeting with the FDA planned for Q2 2021

RELEASE trial on track to report topline results in Q1 2021

Topline results from two ongoing trials with BXCL701 in aggressive forms of prostate cancer and advanced solid tumors are expected in mid-2021

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

NEW HAVEN, Conn., March 11, 2021 -- BioXcel Therapeutics, Inc. ("BioXcel" or the "Company") (Nasdaq: BTAI), a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology, today announced its quarterly results for the fourth quarter and full year ended December 31, 2020 and provided an update on key strategic and operational initiatives.

"Over the last 12 months, we have made significant progress with our leading neuroscience program, BXCL501, including reporting successful data readouts, submitting our first NDA, as well as advancing other potential indications," stated Vimal Mehta, Chief Executive Officer of BioXcel. "In addition to submitting our NDA for the acute treatment of schizophrenia and bipolar disorder related agitation, we also announced positive data from the TRANQUILITY Phase 1b/2 trial in dementia related agitation and will be discussing our plans for a pivotal Phase 3 program with the FDA in the second quarter of 2021. In parallel, we continue to evaluate BXCL501's potential in a wide range of neuropsychiatric conditions with ongoing trials in opioid withdrawal symptoms and delirium related agitation. As we develop the commercial infrastructure needed to bring this potential candidate to market, we continue to execute on our clinical and corporate milestones, as well as leverage our unique AI platform to reach new patient populations where there are large unmet medical needs."

Dr. Mehta continued, "Moreover, our immuno-oncology candidate, BXCL701, has demonstrated encouraging signals of activity in difficult-to-treat tumors across both combination trials. We expect to report topline data from the ongoing trials in mid-2021, in hopes of further demonstrating this candidate's potential at enhancing an individual's innate immunity."

Fourth Quarter and Full Year 2020 and Recent Highlights

BXCL501-Neuroscience Program

BXCL501 is an investigational, proprietary, orally dissolving 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.

- BioXcel recently completed the rolling submission of its NDA to the FDA for BXCL501 for the acute treatment of schizophrenia and bipolar disorder related agitation. Leveraging the Company's AI-based platform, BioXcel was able to develop this program from the first-in-human trial to NDA submission in just over 2 years.

- The Company met the primary and secondary endpoints of the TRANQUILITY trial, a Phase 1b/2 trial of BXCL501 for the acute treatment of dementia related agitation. Topline results showed that BXCL501 was generally well tolerated, with statistically significant and clinically meaningful reductions in agitation achieved with both the 30 mcg and 60 mcg doses at 2 hours as measured by the PEC, PAS and Mod-CMAI scales. The end of Phase 2 meeting with the FDA is planned for Q2 2021, with the goal of initiating a registrational program in the H2 2021.

    - BioXcel has initiated a supplemental cohort investigating a 40 mcg dose of BXCL501 in 46 patients (1:1 randomization) as an expansion of TRANQUILITY to further inform its clinical development strategy.

- The RELEASE study, a Phase 1b/2 trial of BXCL501 for the treatment of opioid withdrawal symptoms, is progressing on track, with the topline readout expected this month.

- BioXcel has initiated the PLACIDITY trial, a Phase 2 trial of BXCL501 for the treatment of hospitalized patients with delirium related agitation. The Company expects to report topline results from this trial in Q1 2022.

- BioXcel and its collaborators, the VA Connecticut Healthcare System and the Yale University Medical School, were awarded a grant by the U.S. Department of Defense's ("DOD") Congressionally Directed Medical Research Programs ("CDMRP") to evaluate BXCL501 in patients suffering from post-traumatic stress disorder ("PTSD") related to alcohol and substance abuse disorder ("ASUD"). This will be the first time the Company is investigating BXCL501 as a potential chronic treatment.

- 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.

Commercial Highlights

- Readiness initiatives for the potential launch of BXCL501 in schizophrenia and bipolar disorder related agitation continue to progress, including the infrastructure needed to support commercialization, the design of our sales force structure and size, as well as market research with both healthcare professionals and payers to inform launch strategy, communications and the BXCL501 value proposition.

- The launch of our educational campaign on schizophrenia and bipolar disorder related agitation is planned for May 2021, in sync with Mental Health Awareness Month.

Medical Affairs Initiatives

- Our Medical Science Liaison (“MSL”) and Medical Manage Care (“MMC”) teams are completing their training and will be deployed this month to begin scientific medical to medical exchange with healthcare professionals and payers, respectively.

- Two abstracts on SERENITY I and II have been accepted for presentation at the American Psychiatric Association (“APA”) Annual Meeting in May 2021.

BXCL701-Immuno-Oncology Program

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

- The Phase 2 efficacy 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, with topline results expected in mid-2021. In November 2020, interim data from this trial was presented at the Society for Immunotherapy of Cancer’s 35th Anniversary Annual Meeting (“SITC”), with an efficacy update presented last month at the 2021 ASCO Genitourinary Cancers Symposium.

- Preliminary efficacy data from the MD Anderson-led Phase 2 open label basket trial evaluating the combination of BXCL701 and KEYTRUDA® in patients with advanced solid tumors was presented at SITC. Topline results from the trial are expected in mid-2021.

- In January, the FDA granted orphan drug designation to BXCL701 for the treatment of soft tissue sarcoma.

Corporate Highlights

- BioXcel continues to integrate and evolve its neuroscience AI machine learning and drug development platform, focusing on symptoms resulting from stress-related behaviors. This platform led to the identification and rapid development of BXCL501, leading to the submission of its first NDA. The Company continues to leverage the platform to identify and develop new neuroscience programs.

- In March 2021, June Bray was appointed to the Company’s Board of Directors. Ms. Bray brings over forty years of extensive U.S. and global regulatory experience across all therapeutics areas, including psychiatry and neurology.

- In February 2021, Javier Rodriguez was appointed as Chief Legal Officer and Corporate Secretary of BioXcel. Mr. Rodriguez joins the Company with over 20 years of extensive strategic and legal experience within the biopharmaceutical industry.

Fourth Quarter and Full Year 2020 Financial Results

BioXcel reported a net loss of $21.1 million for the fourth quarter of 2020, compared to a net loss of $8.3 million for the same period in 2019. For the full year, BioXcel reported a net loss of $82.2 million, compared to a net loss of $33.0 million for the same period in 2019.

For the fourth quarter of 2020, research and development expenses were $11.4 million as compared to $6.5 million for the same period in 2019. The increase was primarily attributable to increased personnel, clinical trial and professional research costs primarily related to our BXCL501 studies.

Research and development expenses were $58.0 million for the full year 2020, as compared to $25.8 million for the same period in 2019. The increase for the year ended December 31, 2020 was generally attributable to increased clinical trial costs, compensation costs and professional research costs associated with BXCL501, as the Company continues to expand its clinical programs.

General and administrative expenses were $9.7 million for the fourth quarter of 2020, as compared to $1.9 million for the same period in 2019. The increase was primarily due to an increase in compensation costs related to the growth of BioXcel's operations. Professional fees also increased primarily related to costs associated with preparation for the potential commercial launch of BXCL501.

General and administrative expenses were $24.3 million for full year 2020, as compared to $7.8 million for the same period in 2019. The increase was primarily due to the growth of BioXcel's operations. Professional and consulting fees also increased due to the expansion of our corporate activities.

The fourth quarter 2020 results include approximately $6.6 million in non-cash stock-based compensation costs. For the full year, non-cash stock-based compensation costs totaled $14.6 million.

As of December 31, 2020, cash and cash equivalents totaled approximately $213.1 million.

Conference Call:

BioXcel 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 BioXcel website at www.bioxceltherapeutics.com. The replay will be available through at least March 25, 2021.

About BioXcel Therapeutics, Inc.:

BioXcel Therapeutics, Inc. is a clinical-stage biopharmaceutical company utilizing artificial intelligence approaches to develop transformative medicines in neuroscience and immuno-oncology. BioXcel'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. BioXcel's two most advanced clinical development programs are BXCL501, an investigational, proprietary, orally dissolving 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 trials for BXCL501 and BXCL701, the Company’s planned commercial structure, the potential value of BXCL501 and BXCL701 as treatment options, and the outcome of the Company’s new drug application. 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 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, 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 BioXcel’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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020 as will be updated by its Annual Report on Form 10-K for the year ended December 31 2020, as such factors may further be updated from time to time in its other filings with the SEC, accessible on the SEC’s website at www.sec.gov and the Investors section of BioXcel’s 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 BioXcel 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 BioXcel’s views as of any date subsequent to the date of this press release.

BioXcel Therapeutics, Inc.

Statement of Operations

(Unaudited, in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
Revenues	$ –	$ –	$ –	$ –
Operating Expenses				
Research and Development	$ 11,401	$ 6,495	$ 57,995	$ 25,797
General and administrative	9,696	1,918	24,302	7,804
Total operating expenses	21,097	8,413	82,297	33,601
Loss from Operations	(21,097)	(8,413)	(82,297)	(33,601)
Other Income (expense)				
Interest income, net	11	138	128	633
Net loss	$ (21,086)	$ (8,275)	$ (82,169)	$ (32,968)
Net loss per share – basic and diluted	$ (0.87)	$ (0.45)	$ (3.79)	$ (2.02)
Weighted average shares outstanding – basic and diluted	24,375	18,051	21,683	16,289

BioXcel Therapeutics, Inc.

Condensed Balance Sheet

(Unaudited, in thousands)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	213,119	32,426
Working capital	205,223	25,639
Total assets	219,936	36,392
Long-term liabilities	1,398	1,029
Total liabilities	13,240	9,497
Total stockholders' equity	206,696	26,895

Contact Information:

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