



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

December 11, 2017

Vimal Mehta, Ph.D.  
Chief Executive Officer  
BioXcel Therapeutics, Inc.  
780 East Main Street  
Branford, CT 06405

**Re: BioXcel Therapeutics, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted November 13, 2017**  
**CIK No. 0001720893**

Dear Dr. Mehta:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Prospectus Summary, page 2

1. We note your reference in this section and elsewhere in the prospectus to a "strong safety profile," a "tolerable safety profile" and an "acceptable safety profile." Please remove statements suggesting that your product candidates are safe and effective as approval by the FDA and other regulatory agencies is dependent on such agencies making this determination.

2. We note your disclosure on page 96 regarding a potential pre-IND meeting with the FDA expected in 2018 for BXCL501. Please clarify in the Summary whether you have any active INDs related to BXCL501, BXCL701, BXCL502 and BXCL702, and disclose the status of any such IND. Please also disclose in the Business section the date of filing for each IND, the sponsor, and the subject matter. Please include similar disclosure with respect to the EMA or any other drug regulatory authorities.
3. We note your disclosure in the first paragraph of the Overview section and the first paragraph on page 82 that you intend to commence Phase 2 proof of concept open label clinical trials in 2018 for both product candidates. Please make it clear, if correct, that you intend to initiate two Phase 1b trial dose studies for BXCL501 before doing so.
4. Please describe here and in the Business section what makes the artificial intelligence you are utilizing "novel."

Implications of Being an Emerging Growth Company, page 8

5. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Risk Factors

Our product candidates may cause undesirable side effects, page 22

6. We note your disclosure that the FDA placed Point Therapeutics, Inc.'s IND for BXCL701 on a clinical hold following an increase in observed mortality in patients with non-small cell lung cancer receiving BXCL701 in a Phase 3 trial. Please revise the Business section to disclose when BXCL701 was placed on a clinical hold by the FDA and when the clinical hold was lifted.

Use of Proceeds, page 61

7. We note your disclosure of the intended uses of proceeds in this section. If any material amounts of other funds are necessary to accomplish the specified purposes for which the proceeds are to be obtained, state the amounts and sources of such other funds needed for each such specified purpose and the sources thereof. Refer to Instruction 3 to Item 504 of Regulation S-K.

Critical Accounting Policies

Stock-Based Compensation, page 78

8. Once you have an estimated offering price or range, please explain to us the reasons for any differences between the recent valuations of your common stock leading up to the

initial public offer and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation.

Business, page 82

9. We note your disclosure on page 22 that patients treated with your product candidates have experienced drug-related side effects including hypotension, transient hypertension, bradycardia, dry mouth, acute respiratory distress syndrome, respiratory failure and agitation related to BXCL501, and edema/peripheral swelling, hypotension, dizziness, hypovolemia fatigue, nausea, vomiting, pyrexia rigors and rash related to BXCL701. Please specify in this section in which studies or trials patients experienced these side effects and how many patients experienced them. Please also clarify whether any of these events were considered serious adverse events.

Overview, page 82

10. Please provide the basis for your disclosure that one in three patients on Zytiga and Xtandi is expected to develop tNEPC and be eligible for treatment with BXCL701 and your estimate that approximately 20,000 patients with pancreatic cancer will be eligible for treatment with BXCL701 annually.
11. Please explain what you mean regarding your belief that BXCL701 represents a "disruptive platform."
12. Please tell us how the combined global sales for Zytiga and Xtandi of \$4.5 billion in 2016 is relevant to BXCL701. From the disclosure it is currently unclear whether BXCL701, once approved, would compete with Zytiga or Xtandi as an alternative treatment for the tNEPC indication. It is also unclear whether the combined sales figure includes sales made for additional indications.

Our Strategy, page 84

13. Please provide the basis for your statement that Dex has been shown to significantly reduce agitation in elderly patients experiencing anesthetic-induced delirium who did not respond to treatment with haloperidol, a potent antipsychotic that is used to treat symptoms for schizophrenia.

BXCL501, Potential First-in-Class Sublingual Thin Film, a2aAdrenergic Receptor Agonist, for Acute Treatment of Agitation, page 88

14. Where you disclose the "total healthcare burden" for agitation across all neuroscience disorders, please revise to disclose the portion of the \$100 billion figure that is attributable to Alzheimer's, Schizophrenia and Bipolar Disease. Please also clarify what you mean by the term "total healthcare burden."

Summary of Existing Dex Clinical Data, page 90

15. Please disclose the dates (or a range of dates) and sponsors for the third party clinical studies summarized in this section. Please also disclose all severe or serious adverse effects that occurred in these studies and how many patients experienced such events.

Preclinical Studies Performed by BTI with Dex, page 92

16. Please disclose the sponsor, date and duration for each of the preclinical studies discussed in this section. Please also revise the legend below the table on page 93 to better differentiate the colors identifying the various doses.

Other Neuropsychiatric/Neurodegenerative Indications, page 96

17. We note your disclosure that there are a number of studies which suggest that Dex can either prevent or mitigate agitation resulting from delirium and that IV administration of Dex has shown potential for treating alcohol withdrawal syndrome in clinical trials. Please identify such studies and trials.

BXCL701, Potential First-in-Class DPP 8/9 and FAP Inhibitor for the Treatment of tNEPC and Pancreatic Cancer, page 97

18. Please explain what CRPC stands for in the table on page 98.

Our Solution: BXCL701, Potential First-in-Class, Oral, Small Molecule Inhibitor of DPP 8/9 and FAP, page 101

19. We note your disclosure that you conducted a preclinical study of BXCL701 as a single agent and in combination with Keytruda to test your hypothesis that combining BXCL701 with checkpoint inhibitors would result in synergistic anti-tumor activity. Please disclose the sponsor, date and duration for this study, any serious adverse events reported and the number of patients who reported such events.
20. We note your disclosure on page 103 that several aspects of BXCL701's mechanism of action have been clinically validated in cancer patients in addition to healthy volunteers. Please provide the basis for this statement.

Summary of Existing BXCL701 Clinical Data (Previously Studied as Talabostat), page 105

21. Please revise this section to clearly disclose specific details and parameters of each of the referenced trials, including the date(s) and duration of the studies, any established endpoints, metrics used, specific measurements and observations including those relating to tumor formation, migration, metastasis and vascularization, and statistical significance. Please disclose how many patients experienced the adverse events disclosed in this section.

FAP Role in Pancreatic Cancer, page 108

22. We note your disclosure that several publications have shown that inhibiting or blocking the activity of FAP + CAFs results in decreased tumor growth. Please identify the publications that you reference in this section. We also note your disclosure that preclinical studies have demonstrated that eliminating FAP+ cells combined with the administration of CTLA-4 or PD-L1 acts synergistically to decrease pancreatic cancer growth in animal models. Please identify these trials and disclose the sponsor, date and duration of each.

BXCL701 Clinical Program in Pancreatic Cancer, page 109

23. Please define what MOA stands for in the table.

Intellectual Property, page 114

24. Please disclose the patent expiration date for the each of your issued patents, the specific products, product groups and technologies to which such patents relate, whether the patents are owned or licensed from third parties, the type of patent (composition of matter, use or process), and the applicable jurisdictions for each patent.

Midatech Data Purchase Agreement Related to BXCL701, page 115

25. Please explain what CMC stands for in this section.

Certain Relationships and Related Person Transactions

Amended and Restated Separation and Shared Services Agreement, page 145

26. Please revise this section to specify the fixed monthly fee, hourly rates for the services of Messrs. Mehta and Mahadevan and the hourly rates for any services related to intellectual property prosecution and management along with any services provided by BioXcel through its subsidiary in India that you have agreed to pay BioXcel pursuant this agreement.

Notes to Financial Statements

Note 2. Basis of Presentation and Liquidity, page F-8

27. We note that your audited financial statements for the years ended December 31, 2016 and 2015, and unaudited interim financial statements for the six months ended June 30, 2017 and 2016 are presented on a carve-out basis and reflect the business activities, assets and liabilities of the BTI Business of BioXcel Corporation. We also note your disclosure on page F-8 that the contribution of the BTI Business by BioXcel Corporation, which occurred on June 30, 2017, was deemed a transaction between entities under common control. Please explain how your presentation complies with ASC 805-50-45.

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Exhibits

28. It does not appear that the full Amended and Restated Separation and Shared Services Agreement has been included in Exhibit 10.1. For instance, certain schedules and exhibits appear to have been omitted. Please re-file this agreement in its entirety or advise.

General

29. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

You may contact Bonnie Baynes at 202-551-4924 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmiento at 202-551-3798 or Mary Beth Breslin at 202-551-3625 with any other questions.

Division of Corporation Finance  
Office of Healthcare & Insurance

cc: Jeffrey Fessler