As confidentially submitted to the U.S. Securities and Exchange Commission on November 13, 2017

**Registration Statement No. 333-**

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM S-1

**REGISTRATION STATEMENT** 

UNDER

THE SECURITIES ACT OF 1933

### **BioXcel Therapeutics, Inc.**

2834

(Primary Standard Industrial

Classification Code Number)

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 82-1386754 (I.R.S. Employer Identification Number)

780 East Main Street Branford, CT 06405 (203) 643-8060

(Address and telephone number of registrant's principal executive offices)

Vimal Mehta, Ph.D. Chief Executive Officer BioXcel Therapeutics, Inc. 780 East Main Street Branford, CT 06405 (203) 643-8060

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Jeffrey J. Fessler, Esq. Stephen A. Cohen, Esq. Sheppard, Mullin, Richter & Hampton LLP 30 Rockefeller Plaza New York, NY 10112-0015 (212) 653-8700 Peter N. Handrinos, Esq. Keith L. Halverstam, Esq. Latham & Watkins LLP 200 Clarendon Street Boston, MA 02116 (617) 948-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o

Accelerated filer o

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company o Emerging growth company  $\boxtimes$ 

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 to Section 7(a)(2)(B) of the Securities Act.

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>1</sup>	Amount of Registration Fee <sup>2</sup>
Common Stock, par value \$0.001 per share	\$	\$

1

Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes shares of common stock that the underwriters have the option to purchase to cover over-allotments, if any.

<sup>2</sup> Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price of the securities registered hereunder to be sold by the registrant.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated November [ · ], 2017

### PROSPECTUS

Shares



BioXcel Therapeutics, Inc.

Common Stock

This is the initial public offering of shares of common stock of BioXcel Therapeutics, Inc. We are offering shares of our common stock. No public market currently exists for our stock. We anticipate that the initial public offering price will be between \$ and \$ per share.

We intend to apply to list our shares on The Nasdaq Capital Market under the symbol "BTAI." Upon completion of this offering, we will be a "controlled company" as defined in the corporate governance rules of The Nasdaq Capital Market.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 14.

	Per Share	Total
Price to the public	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds to us (before expenses) <sup>1</sup>	\$	\$

<sup>1</sup> We refer you to "Underwriting" beginning on page 158 of this prospectus for additional information regarding underwriting compensation.

We have granted the underwriters a 30-day option to purchase up to less the underwriting discount.

additional shares at the initial public offering price,

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about , 2017.

Joint Book-Running Managers

Barclays

**UBS Investment Bank** 

**BMO** Capital Markets

Lead Manager

### **Canaccord Genuity**

Prospectus dated

, 2017

#### TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY	<u>2</u>
<u>RISK FACTORS</u>	<u>14</u>
INFORMATION REGARDING FORWARD-LOOKING STATEMENTS	<u>58</u>
INDUSTRY AND MARKET DATA	<u>60</u>
USE OF PROCEEDS	<u>61</u>
DIVIDEND POLICY	<u>63</u>
CAPITALIZATION	<u>64</u>
DILUTION	<u>65</u>
SELECTED FINANCIAL DATA	<u>67</u>
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF	
<u>OPERATIONS</u>	<u>69</u>
BUSINESS	<u>82</u>
MANAGEMENT	<u>130</u>
EXECUTIVE AND DIRECTOR COMPENSATION	<u>138</u>
CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS	145
PRINCIPAL SHAREHOLDERS	148
DESCRIPTION OF CAPITAL STOCK	149
SHARES ELIGIBLE FOR FUTURE SALE	152
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON	
STOCK	154
UNDERWRITING	158
LEGAL MATTERS	164
EXPERTS	164
WHERE YOU CAN FIND MORE INFORMATION	164
INDEX TO FINANCIAL STATEMENTS	F-1
	<u> </u>

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give to you. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of these securities.

### PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the matters set forth under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus. In this prospectus, unless context requires otherwise, references to "we," "us," "our," "BTI" "BioXcel Therapeutics," or "the Company" refer to BioXcel Therapeutics, Inc. and references to "BioXcel" refer to our parent, BioXcel Corporation.

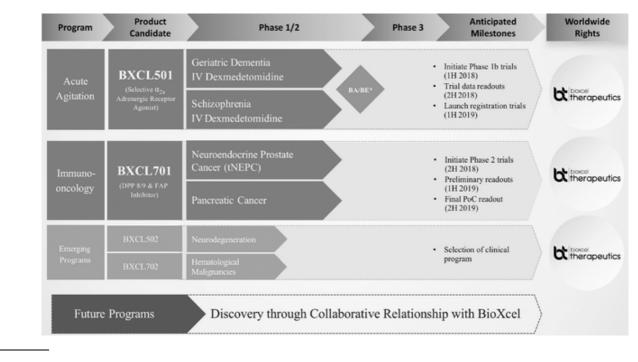
### Overview

We are a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence, or AI, to identify the next wave of medicines across neuroscience and immuno-oncology. Our 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. We believe that this differentiated approach has the potential to reduce the cost and time of drug development in diseases with substantial unmet medical need. Our two most advanced clinical development programs are BXCL501, a sublingual thin film formulation of dexmedetomidine designed for acute treatment of agitation resulting from neurological and psychiatric disorders, and BXCL701, an immuno-oncology agent designed for treatment of a rare form of prostate cancer and for treatment of pancreatic cancer. We intend to commence Phase 2 proof of concept, or PoC, open label clinical trials in 2018 for both programs. We expect that a data readout from the planned Phase 2 PoC clinical trials for the BXCL501 program will be available by the end of 2018, potentially leading to the start of registration trials, and that preliminary data from the planned Phase 2 PoC clinical trial of BXCL701 will be available in the first half of 2019. We retain global development and commercialization rights to these two programs.

We were formed to develop first-in-class, high value therapeutics by leveraging EvolverAI, a research and development engine created and owned by our parent, BioXcel Corporation, or BioXcel. We believe the combination of our therapeutic area expertise and our ability to generate product candidates through our exclusive collaborative relationship with BioXcel in the areas of neuroscience and immuno-oncology gives us a significant competitive advantage. EvolverAI was developed over the last decade and integrates millions of fragmented data points using artificial intelligence and proprietary machine learning algorithms. After evaluating multiple product candidates using EvolverAI, we selected our lead programs because our analysis indicated these drugs may have utility in new therapeutic indices where there is substantial unmet medical needs and limited competition. By focusing on clinical candidates with relevant human data, we believe our approach will help us design more efficient clinical trials, thereby accelerating our product candidates' time to market.

### **Product Candidates**

The following table summarizes our lead development programs. We believe our product candidates have the potential to be first-in-class treatment options for their indications:



\*

Bridging bioavailability/bioequivalence (BA/BE) study for optimizing BXCL501 sublingual thin film dose for Phase 3 registration trials

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

BXCL501 is a potential first-in-class sublingual thin film formulation of the a<sub>2a</sub> adrenergic receptor dexmedetomidine, or Dex, designed for acute treatment of agitation in neurodegenerative and psychiatric disorders. Dex has demonstrated a strong safety profile, having been prescribed in millions of patients as the sedative and anesthetic Precedex and has been studied in over 130 clinical trials to date. BXCL501 is designed to be a non-invasive, easy to administer agent that has a rapid onset of action, which is critical for the acute treatment of agitation. We estimate that over 500,000 patients who suffer from Alzheimer's Disease, or AD, in the United States annually could be eligible for the acute treatment of agitation with BXCL501. In schizophrenia and bipolar disease, we estimate that over 600,000 patients in the United States annually could be eligible for the acute treatment of agitation with BXCL501. The current treatment options for agitation utilize antipsychotics and benzodiazepines, which have suboptimal safety and compliance issues. Antipsychotics have a black box warning for use in the elderly, can produce debilitating side effects when given acutely and should only be considered for invasive intramuscular, or IM, delivery in highly aggressive patients requiring restraint. Benzodiazepines are predominantly in pill form, which require swallowing and can produce excessive sedation. We believe that BXCL501, with its differentiated pharmacology and ease of administration, if approved, could potentially be a first-in-class, non-invasive acute treatment for mild to moderate agitation.

We have designed a dual clinical development program intended to take advantage of the U.S. Food and Drug Administration's, or FDA, Section 505(b)(2) regulatory pathway and leverage the existing clinical and safety dataset of intravenous, or IV, formulation of Dex. We plan to initiate two Phase 1b single ascending or descending dose studies of the IV formulation of Dex in mild probable AD by the first half of 2018 and schizophrenia patients in the first half of 2018, followed by a PoC

open label clinical trial. We expect to report data from both studies by the second half of 2018. We intend to initiate a bridging bioavailability/bioequivalence, or BA/BE, study with the sublingual thin film formulation in the second half of 2018 that, if successful, could potentially lead to the start of a registration trial in the first half of 2019.

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

BXCL701 is a potential first-in-class, highly potent oral small molecule immuno-modulator that is designed to stimulate both the innate and acquired immune systems by inhibiting dipeptidyl peptidase, or DPP, 8/9 and fibroblast activation protein, or FAP. DPP 8/9 have been show recently to behave as an "immuno-checkpoint" of the immune system, as their inhibition results in a potent pro-inflammatory, anti-tumor activity by way of the induction of cell death in the macrophages and the downstream stimulation of multiple tumor-killing immune cells. BXCL701 is differentiated among DPP inhibitors for its specificity to inhibit DPP 8/9 and FAP, whereas most other approved or clinical stage DPP inhibitors, developed to treat diabetes, are selective for DPP 4. Based on our analysis, we believe that BXCL701 establishes a differentiated immuno-oncology platform by modulating multiple steps in the cancer immunity cycle, and in combination with checkpoint inhibitors can convert immuno-resistant tumors to immuno-sensitive tumors ("cold" to "hot" tumors). BXCL701 has been tested in more than 700 healthy subjects and cancer patients across multiple clinical trials, exhibiting a tolerable safety profile, proof of mechanism, and single agent anti-tumor activity in patients with melanoma, an immuno-sensitive tumor. We believe that we can leverage this clinical data to determine the dose to use in future clinical trials and support accelerated clinical development. BXCL701 is a potential novel therapy for treatment-emergent neuroendocrine prostate cancer, or tNEPC, a segment of prostate cancer patients that have progressed on second-generation androgen inhibitors (Zytiga and Xtandi), and is also a potential treatment for pancreatic cancer, both of which are rare diseases. We believe BXCL701 represents a disruptive platform in the field of immuno-oncology with the potential to create a transformative commercial franchise in multiple tumor indications.

We selected tNEPC and pancreatic cancer as our lead indications after evaluating more than 100 different tumor types because they are two of the top three cancers that overexpressed or amplified DPP 8/9 and FAP. Additional data points to a functional role of DPP 8/9 in the biology of tNEPC. The combined global sales of Zytiga and Xtandi were over \$4.5 billion in 2016 and about one in three patients on these drugs are expected to develop tNEPC and be eligible for treatment with BXCL701. In pancreatic cancer, we estimate that approximately 20,000 patients will be eligible for treatment with BXCL701 annually. We plan to initiate two Phase 2 PoC open label clinical trials in the second half of 2018, as a single agent and in combination with Keytruda in patients with tNEPC, and in combination with Keytruda in pancreatic cancer. We expect to receive preliminary data in the first half of 2019 and intend to pursue breakthrough therapy designation and accelerated approval pathways for both indications. BXCL701 has already received orphan drug designation by the FDA for the treatment of pancreatic cancer.

#### **Emerging Programs**

We intend to grow our pipeline with additional development candidates by leveraging our management team's therapeutic area expertise with EvolverAI. We are also exploring development of BXCL502, a novel approach to the treatment of symptoms resulting from neurological disorders, and BXCL702, an immuno-oncology agent targeting hematological malignancies for which we have received orphan drug designation from the FDA for the treatment of acute myeloid leukemia, or AML. We retain global development and commercialization rights to these two programs. We intend to select our next clinical program in 2018 from our emerging or future programs.

### **Our Strategy**

Our goal is to become a leader in the field of neuroscience and immuno-oncology. The key elements to achieving this goal are to:

- Advance BXCL501 for the acute treatment of agitation through the FDA Section 505(b)(2) pathway. We are pursuing a dual clinical development program and plan to initiate two Phase 1b single ascending or descending dose studies of the IV formulation of Dex in mild probable AD and schizophrenia patients in the first half of 2018, followed by PoC open label clinical trials. We intend to initiate a bridging BA/BE study with the sublingual thin film formulation in the second half of 2018 to identify the optimal dose range for our planned registration trial in the first half of 2019.
- Advance BXCL701 into Phase 2 trials to assess its potential to be the first approved therapy for tNEPC and for the treatment of pancreatic cancer. We plan to initiate two Phase 2 PoC open label clinical trials in the second half of 2018, as a single agent and in combination with Keytruda in patients with tNEPC and in combination with Keytruda in pancreatic cancer. We expect to receive preliminary data in the first half of 2019 and intend to pursue breakthrough therapy designation and accelerated approval pathways for both indications.
- Maximize the therapeutic and commercial potential of BXCL501 and BXCL701 by exploring their use for multiple indications. Based on the broad applicability of the mechanisms of action of our two lead product candidates, we intend to explore a series of follow-on indications for BXCL501 (acute treatment of agitation resulting from delirium, substance abuse withdrawal and PTSD) and BXCL701 (potential as a combination agent for multiple tumor indications, offering a "pipeline in a product" platform).
- Identify biomarkers to select patients who have the highest likelihood to respond to our product candidates. Predicting optimal drug responses in patients requires the identification and validation of predictive biomarkers, specifically in cancer. The indications for our product candidate BXCL701 were chosen in part because they are known to overexpress DPP 8/9 and FAP. Our planned PoC clinical trial of BXCL701 will examine biomarkers related to its molecular and cellular targets to identify those that may correlate with clinical efficacy and increase our likelihood of success.
- Enhance our R&D pipeline by leveraging our therapeutic area expertise with EvolverAI to identify, develop and commercialize new product candidates in neuroscience and immuno-oncology. In addition to our leading clinical programs and our emerging and future pipeline, we intend to select our next clinical program during 2018. We have established translational and development expertise, which we believe will help us advance the present and future product candidates in these fields. We may also opportunistically in-license additional product candidates identified through our AI platform approach within our core areas of expertise.
- Maximize the commercial potential of our product candidates. We have worldwide development and commercialization rights to our BXCL501, BXCL701, BXCL502 and BXCL702 product candidates. If BXCL501 and BXCL701 are approved in the United States, we would consider building a specialty sales force in the United States and/or collaborate with third parties to maximize the potential of our product candidates. Furthermore, we intend to commercialize BXCL501 and BXCL701 outside the United States through collaborations with third parties.



#### **Our Team**

We have assembled a management team with extensive experience in the discovery, development and approval of more than 10 drugs and who have held senior executive roles at leading pharmaceutical companies, including: our co-founder and Chief Executive Officer, Vimal Mehta, Ph.D., our Chief Scientific Officer, Frank Yocca, Ph.D., our Chief Medical Officer, Vince O'Neill, M.D., our Vice President—Oncology R&D, Luca Rastelli, Ph.D., and our Chief Financial Officer, Richard Steinhart. We are also supported by our experienced board of directors and advisory board, which includes Drs. Peter Mueller (Vertex, Boehringer Ingelheim), Steven Paul (Voyager Therapeutics, Sage Therapeutics, Eli Lilly) and Sheila Gujrathi (Receptos, Bristol-Myers Squibb, Roche), who contribute to our strategy with their expertise in building public companies. We believe that our team is ideally positioned to leverage our highly differentiated platform to develop the next wave of innovative medicines.

#### Our Relationship with BioXcel

We are currently a 96% owned subsidiary of BioXcel. After the closing of this offering, we expect to be a "controlled company" within the meaning of the corporate governance rules of The Nasdaq Capital Market. Assuming we sell the number of the shares set forth on the cover page of this prospectus, BioXcel will own, in the aggregate, approximately % of our outstanding common shares, or approximately % if the underwriters exercise their option to purchase additional common shares in full. BioXcel will be able to exercise control over all matters requiring shareholder approval, including the election of our directors and approval of significant corporate transactions.

We have entered into an asset contribution agreement, effective June 30, 2017, with BioXcel, as amended and restated on November 7, 2017, or the Contribution Agreement, pursuant to which BioXcel agreed to contribute to us, and we agree to acquire from BioXcel, all of BioXcel's rights, title and interest in and to BXCL501, BXCL701, BXCL502 and BXCL702, collectively, the Candidates, and all of the assets and liabilities associated with the Candidates. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Asset Contribution Agreement with BioXcel" for additional information.

We have entered into a separation and shared services agreement with BioXcel that took effect on June 30, 2017, as amended and restated on November 7, 2017, or the Services Agreement, pursuant to which BioXcel will allow us to continue to use its office space, equipment, services and leased employees based on the agreed upon terms and conditions for a payment of defined monthly and/or hourly fees. Under this agreement, BioXcel will continue to make such product identification and related services available to us for at least five years. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Separation and Shared Services Agreement with BioXcel" for additional information.

We refer to the agreements set forth above and the series of transactions related to our separation from BioXcel, collectively, as the "Separation."

We believe that a distribution of BTI shares by BioXcel to BioXcel shareholders would be advantageous to the market for our shares by increasing liquidity, would accelerate our ability to become independent from BioXcel by decreasing BioXcel's ownership of our common stock and would be beneficial for BioXcel's stockholders who would have a direct opportunity to participate in the BTI value proposition. BioXcel has advised us that, following the completion of this offering and subject to the expiration of any applicable lock-up periods or other agreements we have or may have with BioXcel described herein, it does not have any near-term plans to distribute our shares held by BioXcel to the BioXcel stockholders. The decision to conduct any such distribution is at the sole discretion of BioXcel's board of directors. There is no assurance that the distribution will ever occur. Presently, it is

expected that any potential distribution will be taxable to BioXcel and its stockholders. We refer to any such potential distribution as the "Distribution."

#### **Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common shares. These risks are discussed more fully in the "Risk Factors" section of this prospectus. These risks include the following:

- We have a limited operating history and have never generated any product revenues, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- Even if this offering is successful, we will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We have limited experience in drug discovery and drug development, and we have never had a drug approved.
- In the near term, we are dependent on the success of BXCL501 and BXCL701. If we are unable to initiate or complete the clinical development of, obtain marketing approval for or successfully commercialize BXCL501, BXCL701 and our other product candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- BioXcel's approach to the discovery and development of product candidates based on EvolverAI is novel and unproven, and we do not know whether we will be able to develop any products of commercial value.
- We will be substantially dependent on third parties for the manufacture of our clinical supplies of our product candidates. Therefore the development of our products could be stopped or delayed, and our commercialization of any future product could be stopped or delayed or made less profitable if third party manufacturers fail to provide us with sufficient quantities at acceptable prices.
- BioXcel controls the direction of our business, and the concentrated ownership of our common stock will prevent you and other stockholders from influencing significant decisions.
- Following this offering, we will continue to depend on BioXcel to provide us with certain services for our business.
- We may be a "controlled company" within the meaning of the Nasdaq rules and, as a result, may qualify for, and may rely on, exemptions from certain corporate governance requirements that provide protection to stockholders of other companies.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

- An active trading market for our common stock may not develop, and you may not be able to sell your common stock at or above the initial public offering price.
- We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

#### **Corporate Information**

We were incorporated as a Delaware corporation on March 29, 2017 as a wholly-owned subsidiary of BioXcel. Our principal executive offices are located at 780 East Main St., Branford, CT 06405 and our telephone number is (203) 643-8060. Our website address is www.bioxceltherapeutics.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common shares.

We have proprietary rights to a number of trademarks used in this prospectus which are important to our business, including the BTI logo. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and <sup>TM</sup> symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

#### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.07 billion in revenues during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in 2012. As an emerging growth company, we expect to take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have chosen to opt out of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition periods for complying with new or revised accounting standards is irrevocable.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (i) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act; (ii) scaled executive compensation disclosures; and (iii) the requirement to provide only two years of audited financial statements, instead of three years.

	THE OFFERING				
Common stock offered by us	shares				
Common stock to be outstanding immediately after this offering	shares ( shares if the underwriters exercise their option in full)				
Option to purchase additional shares	The underwriters have an option for a period of 30 days to purchase up to an additional shares of our common stock.				
Use of proceeds	We estimate that the net proceeds from this offering will be approximately \$ , or approximately \$ if the underwriters exercise their over-allotment option in full, at an assumed initial public offering price of \$ per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to fund our planned clinicial development of BXCL501 through Phase 2 clinical development and potentially commence one registration trial, to fund our planned clinical development of BXCL701 through Phase 2 clinical development, to make certain payments to BioXcel, and for general corporate purposes and working capital. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products, however, we have no current commitments or obligations to do so. See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering.				
Controlled company	Upon the closing of this offering, BioXcel Corporation will beneficially own a controlling interest in us and we expect to be a "controlled company" under Nasdaq rules. As a controlled company, we may elect to avail ourselves of the controlled company exemption under the corporate governance requirements of the Nasdaq.				
Risk factors	See "Risk Factors" on page 14 and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.				
Proposed Nasdaq Capital Market symbol	"BTAI"				
	nber of shares of our common stock to be outstanding after this offering is based on 40,000 shares of our common stock outstanding as of 7, and excludes:				
•	the sale of 1,804 shares of common stock in September and October 2017, at a price of \$1,142.86 per share.				

Except as otherwise indicated herein, all information in this prospectus assumes, including the number of shares of common stock that will be outstanding after this offering, assumes or gives effect to
a -for-1 stock split of our common stock effected on ;
no exercise by the underwriters of their option to purchase an additional shares of common stock;
no exercise of outstanding options after June 30, 2017; and
the effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the closing of this offering.

1	1
T	T

#### **Summary Financial Data**

The following table sets forth our summary financial data as of the dates and for the periods indicated. We have derived the summary statement of operations data for the years ended December 31, 2016 and 2015 from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data for the six months ended June 30, 2017 and 2016 and the summary balance sheet data as of June 30, 2017 have been derived from our unaudited financial statements included elsewhere in this prospectus. The following summary financial data should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes and other information included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future and the results for the six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the full fiscal year.

Our historical results of operations presented below may not be reflective of our financial position, results of operations and cash flows had we operated as a stand-alone public company during all periods presented. Prior to June 30, 2017, we operated as part of BioXcel and not as a separate stand-alone entity. Our financial statements prior to June 30, 2017 have been prepared on a "carve-out" basis from the financial statements of BioXcel to represent our financial position and performance as if we had existed on a stand-alone basis during each of the fiscal years presented in the financial statements. These results reflect amounts specifically attributable to our business, including the costs BioXcel incurred for the assets that were contributed to us by our parent under the Contribution Agreement and the Services Agreement. The agreements provide us with certain general and administrative and development support services that became effective June 30, 2017. However, consistent with accounting regulations, we have assumed that we were a separate business within BioXcel and we have reflected the related assets, liabilities and expenses in our results for periods prior to and post incorporation. We believe that such allocations have been made on a reasonable basis, but may not necessarily be indicative of all of the costs that would have been incurred if we had operated on a standalone basis.

#### **Statement of Operations Data:**

(in thousands, except share and per share data)

	_	Years For the Six Month Ended Ended June 30, December 31, (unaudited)		30,			
		2016		2015	 2017		2016
Revenues	\$		\$		\$ 	\$	—
Operating costs and expenses					 		
Research and development		1,399		233	645		650
General and administrative		721		403	449		367
Total operating expenses		2,120	_	636	 1,094	_	1,017
Net loss	\$	(2,120)	\$	(636)	\$ (1,094)	\$	(1,017)
Net loss per share—basic and diluted <sup>1</sup>	\$	(53.00)	\$	(15.90)	\$ (27.35)	\$	(25.43)
Weighted average shares outstanding—basic and diluted $^{1} \$		40,000		40,000	40,000		40,000

<sup>1</sup> See Note 3 to our financial statements for an explanation of the method used to compute basic and diluted net loss per share.



#### **Balance Sheet Data:**

### (in thousands)

	June 30, 2017 (unaudited)
	Pro Forma, Pro As Adjusted <sup>(2)</sup> Actual Forma <sup>(1)</sup> (3)
Cash and cash equivalents	\$ 285 \$ <b>\$</b>
Working capital deficit	(1,009)
Total assets	289
Total liabilities	1,294
Accumulated deficit	(1,005)
Total stockholders' deficit	(1,005)

# <sup>1</sup> On a pro forma basis to reflect the sale of 1,804 shares of common stock, at a price of \$1,142.86 per share in September and October 2017.

- <sup>2</sup> On a pro forma as adjusted basis to give further effect to our issuance and sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- <sup>3</sup> Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by approximately \$ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by approximately \$ .

#### **RISK FACTORS**

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this prospectus, including our financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

#### **Risks Related to Financial Position and Need for Capital**

# We have a limited operating history and have never generated any product revenues, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We were incorporated in March 2017 and our operations to date have been largely focused on organizing and staffing our company, raising capital and acquiring the rights to, and advancing the development of, our product candidates, including conducting preclinical studies. We have not yet demonstrated an ability to successfully complete clinical trials, obtain marketing approvals, manufacture products on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to eventually transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

# We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. Our net loss was \$1.1 million, \$2.1 million and \$0.6 million for the six months ended June 30, 2017 and the years ended December 31, 2016 and 2015, respectively. As of June 30, 2017, we had an accumulated deficit of \$1.0 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. None of our product candidates have been approved for marketing in the United States, or in any other jurisdiction, and may never receive such approval. It could be several years, if ever, before we have a commercialized product that generates significant revenues. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue the development of our product candidates;
- initiate preclinical studies and clinical trials for any additional indications for our current product candidates and any future product candidates that we may pursue;
- continue to build our portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- pursue regulatory approvals for our current and future product candidates that successfully complete clinical trials;

- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- hire additional clinical, regulatory, scientific and accounting personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

To become and remain profitable, we must develop and eventually commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling any current and future product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We are only in the preliminary stages of most of these activities and, in some cases, have not yet commenced certain of these activities. We may never succeed in any or all of these activities and, even if we do, we may never generate sufficient revenue to achieve profitability.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will obtain marketing approval to commercialize any of our product candidates. If we are required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities such as the European Medicines Agency, or EMA, to perform studies and trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current or future product candidates, our expenses could increase and profitability could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

# Even if this offering is successful, we will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We anticipate that our expenses will increase substantially if and as we continue to develop and begin clinical trials with respect to BXCL501, BXCL701 and our other product candidates; seek to identify and develop additional product candidates; acquire or in-license other product candidates or technologies; seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any; establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any; require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization; maintain, expand and protect our intellectual property portfolio; hire and retain additional personnel, such as clinical, quality control and scientific personnel; add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and add equipment and physical infrastructure to support our research and development programs.

We plan to use the net proceeds of this offering primarily to fund our ongoing research and development efforts over the coming months. We will be required to expend significant funds in order to advance the development of BXCL501, BXCL701 and our other product candidates. In addition, while we may seek one or more collaborators for future development of our current product candidate or any future product candidates that we may develop for one or more indications, we may not be able

to enter into a collaboration for any of our product candidates for such indications on suitable terms, on a timely basis or at all. In any event, the net proceeds of this offering and our existing cash and cash equivalents will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of our product candidates or our other preclinical programs. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Other than our grid note with BioXcel, we do not have any committed external source of funds. Further financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents as of June 30, 2017, will enable us to fund our operating expenses and capital expenditure requirements at least through . Our estimate as to how long we expect the net proceeds from this offering, together with our existing cash and cash equivalents, to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials of BXCL501, BXCL701 and our other product candidates;
- our ability to enter into and the terms and timing of any collaborations, licensing agreements or other arrangements;
- the costs, timing and outcome of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- our headcount growth and associated costs as we expand our research and development as well as potentially establish a commercial infrastructure;
- revenue received from commercial sales, if any, of our current and future product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the number of future product candidates that we pursue and their development requirements;
- changes in regulatory policies or laws that may affect our operations;
- changes in physician acceptance or medical society recommendations that may affect commercial efforts;
- the costs of acquiring potential new product candidates or technology; and
- the costs of operating as a public company.

•

### Risks Related to the Discovery and Development of Product Candidates

### We have limited experience in drug discovery and drug development, and we have never had a drug approved.

Prior to the acquisition of our product candidates, we were not involved in and had no control over their preclinical and clinical development. In addition, we are relying upon the parties we have



acquired our product candidates from to have conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of the applicable product candidate, and having correctly collected and interpreted the data from these studies and trials. To the extent any of these has not occurred, our expected development time and costs may be increased, which could adversely affect our prospects for marketing approval of, and receiving any future revenue from, these product candidates.

# In the near term, we are dependent on the success of BXCL501 and BXCL701. If we are unable to initiate or complete the clinical development of, obtain marketing approval for or successfully commercialize BXCL501, BXCL701 and our other product candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.

We currently do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We are investing a significant portion of our efforts and financial resources in the development of BXCL501, BXCL701 and our other product candidates. Our prospects are substantially dependent on our ability, or that of any future collaborator, to develop, obtain marketing approval for and successfully commercialize product candidates in one or more disease indications.

The success of BXCL501, BXCL701 and our other product candidates will depend on several factors, including the following:

- acceptance of an Investigational New Drug, or IND, for the conduct of clinical trials of product candidates and proposed design of future clinical trials;
- initiation, progress, timing, costs and results of clinical trials of our product candidates and potential product candidates;
- establishment of a safety, tolerability and efficacy profile that is satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug product that is appropriately packaged for sale;
- adequate ongoing availability of raw materials and drug product for clinical development and any commercial sales;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

Many of these factors are beyond our control, including the results of clinical trials, the time required for the FDA or any comparable foreign regulatory authorities to review any regulatory submissions we may make, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize BXCL501, BXCL701 and our other product candidates, on our own or with any future collaborator, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

# The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biopharmaceutical industry to suffer significant setbacks in advanced clinical trials due to nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Our future clinical trial results may not be successful, and notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. The historical failure rate for product candidates in our industry is high. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of New Drug Application, or NDA, or other submission or to obtain regulatory approval in the United States or elsewhere; the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or foreign regulatory pathways;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We have not previously initiated or completed a clinical trial of any of our product candidates. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidates are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

# We depend on enrollment of patients in our clinical trials in order for us to continue development of our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Patient enrollment is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the size of the patient population required for analysis of the trial's primary endpoints, the proximity of patients to study sites, our ability to recruit clinical trial investigators with the appropriate competencies and experience, our ability to obtain and maintain patient consents, the risk that patients enrolled in clinical trials will drop out of the trials before completion, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Many pharmaceutical companies are conducting clinical trials in

patients with the disease indications that our potential drug products target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. The delay or inability to meet planned patient enrollment may result in increased costs and delay or termination of our trials, which could have a harmful effect on our ability to develop products.

#### Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Although we are planning for certain clinical trials relating to BXCL501, BXCL701 and our other product candidates, there can be no assurance that the FDA will accept our proposed trial designs. We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- recruiting suitable patients to participate in a trial;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the cost of clinical trials of our product candidates may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to themselves but that are suboptimal for us.

For example, we believe that we will be able to proceed directly to Phase 3 registration trials of BXCL501 if we successfully complete our planned Phase 1b/2 open-label PoC and bridging BA/BE studies. However, the FDA may not agree with our development plans and could require us to perform additional clinical trials or preclinical studies, including additional Phase 1 and/or Phase 2 clinical trials, before permitting us to conduct our planned registration trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Furthermore, we intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we intend to have agreements governing their committed activities. We will have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our current and future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

# Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The clinical evaluation of BXCL501, BXCL701 and our other product candidates in patients is still in the early stages and it is possible that there may be side effects associated with its use. To date, patients treated with our 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. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. For example, the FDA placed Point Therapeutics, Inc.'s IND for BXCL701 on clinical hold following an increase in observed mortality in patients receiving BXCL701 in a Phase 3 trial in patients with non-small cell lung cancer. Though we believe that this result was caused by, among other things, an imbalance in the disease severity of patients enrolled in the active arm of the clinical trial, there is no guarantee that excess mortality will not be observed in future clinical studies. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products;
- we may be required to recall a product or change the way such a product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;

- we may be required to implement Risk Evaluation and Mitigation Strategies, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- our product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or for particular indications of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

# BioXcel's approach to the discovery and development of product candidates based on EvolverAI is novel and unproven, and we do not know whether we will be able to develop any products of commercial value.

We are leveraging EvolverAI to create a pipeline of neuroscience and immuno-oncology product candidates for patients whose diseases have not been adequately addressed to date by other approaches and to design and conduct efficient clinical trials with a higher likelihood of success. While we believe that applying EvolverAI to create medicines for defined patient populations may potentially enable drug research and clinical development that is more efficient than conventional drug research and development, our approach is both novel and unproven. Because our approach is both novel and unproven, the cost and time needed to develop our product candidates is difficult to predict, and our efforts may not result in the discovery and development of commercially viable medicines. We may also be incorrect about the effects of our product candidates on the diseases of our defined patient populations, which may limit the utility of our approach or the perception of the utility of our approach. Furthermore, our estimates of our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our ability to conduct clinical trials and may also adversely affect the size of any market for medicines we may successfully commercialize. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively as expected and therefore we may not be able to commercialize our approach as originally expected.

#### EvolverAI may fail to help us discover and develop additional potential product candidates.

Any drug discovery that we are conducting using EvolverAI may not be successful in identifying compounds that have commercial value or therapeutic utility. EvolverAI may initially show promise in identifying potential product candidates, yet fail to yield viable product candidates for clinical development or commercialization for a number of reasons, including:

- research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;
- compounds found through EvolverAI may not demonstrate efficacy, safety or tolerability;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our potential product candidates non-competitive or less attractive; or

a potential product candidate may not be capable of being produced at an acceptable cost.

# An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

Our product candidates will be submitted to the FDA for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505(b)(2) application would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

#### The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil,

criminal and/or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

# We may seek Fast Track designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. If we seek Fast Track designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

# Even if our product candidates receive regulatory approval, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, our product candidates will remain subject to ongoing requirements governing the manufacturing process, labeling, packaging, storage, advertising, distribution, import, export, promotion, recordkeeping and adverse event reporting. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with good clinical practice, or GCP, requirements for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with Good Manufacturing Practices, or GMP, regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring voluntary or mandatory recalls, additional restrictions on manufacturing or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with a

- issue warning letters;
- impose civil or criminal penalties;



- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products or request us to initiate a product recall; or
- pursue and obtain an injunction.

#### Any failure by us to comply with existing regulations could harm our reputation and operating results.

We will be subject to extensive regulation by U.S. federal and state and foreign governments in each of the markets where we intend to sell BXCL501 and BXCL701 if and after they are approved. For example, we will have to adhere to all regulatory requirements including the FDA's current GCPs, Good Laboratory Practice, or GLP, and GMP requirements. If we fail to comply with applicable regulations, including FDA pre-or post- approval cGMP requirements, then the FDA or other foreign regulatory authorities could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. We expend significant resources on compliance efforts and such expenses are unpredictable and might adversely affect our results.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, we cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order directing all executive agencies, including the FDA, that, for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency

guidance documents., and on September 8, 2017, the FDA published notices in the Federal Register soliciting broad public comment to identify regulations that could be modified in compliance with these Executive Orders. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

### We may be subject to extensive regulations outside the United States and may not obtain marketing approvals for products in Europe and other jurisdictions.

In addition to regulations in the United States, should we or our collaborators pursue marketing approvals for BXCL501, BXCL701 and our other product candidates internationally, we and our collaborators will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we, or our collaborators, obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country.

We expect to pursue marketing approvals for BXCL501, BXCL701 and our other product candidates in Europe and other jurisdictions outside the United States with collaborative partners. The time and process required to obtain regulatory approvals and reimbursement in Europe and other jurisdictions may be different from those in the United States regulatory and approval in one jurisdiction does not ensure approvals in any other jurisdiction; however, negative regulatory decisions in any jurisdiction may have a negative impact on the regulatory process in other jurisdictions.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

# If we are found in violation of federal or state "fraud and abuse" laws, we may be required to pay a penalty and/or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition and results of operations.

In the United States, we will be subject to various federal and state health care "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in federal and state health care programs, which could affect us, particularly upon successful commercialization of our products in the United States. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which



payment may be made under a federal health care program, such as Medicare or Medicaid. Under federal government regulations, some arrangements, known as safe harbors, are deemed not to violate the federal Anti-Kickback Statute. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental health care programs. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several s

Many states have adopted laws similar to the federal anti-kickback statute, some of which apply to the referral of patients for health care services reimbursed by any source, not just governmental payers. Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and if we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in federal or state health care programs, and our business, results of operations and financial condition may be adversely affected.

#### We may be unable to maintain sufficient clinical trial liability insurance.

Our inability to obtain and retain sufficient clinical trial liability insurance at an acceptable cost to protect against potential liability claims could prevent or inhibit our ability to conduct clinical trials for product candidates we develop. We are currently a 96% owned subsidiary of BioXcel and until the closing of this offering, we will be operated as a majority-owned subsidiary of BioXcel, and we are covered under BioXcel's insurance policies. We currently do not have clinical trial liability insurance and would need to secure coverage before commencing patient enrollment for our clinical trials in the United States, which we currently expect to occur in 2018. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. We expect we will supplement our clinical trial coverage with product liability coverage in connection with the commercial launch of BXCL501, BXCL701 or other product candidates we develop in the future; however, we may be unable to obtain such increased coverage on acceptable terms or at all. If we are found liable in a clinical trial lawsuit or a product liability lawsuit in the future, we will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

#### **Risks Related to Commercialization of Our Product Candidates**

#### If our products do not gain market acceptance, our business will suffer because we might not be able to fund future operations.

A number of factors may affect the market acceptance of our products or any other products we develop or acquire, including, among others:

- the price of our products relative to other products for the same or similar treatments;
- the perception by patients, physicians and other members of the health care community of the effectiveness and safety of our products for their indicated applications and treatments;
- our ability to fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts.

If our products do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new product candidates and expanding our sales and marketing efforts for our approved products, which would cause our business to suffer.

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for certain of our product candidates, including BXCL501. The Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

### We expect to rely heavily on orphan drug status to commercialize our product candidates, if approved, but any orphan drug designations we recieve may not confer marketing exclusivity or other expected commercial benefits.

We expect to rely heavily on orphan drug exclusivity for our product candidates. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the

United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances the applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Although we have received orphan designation for BXCL701 for the treatment of pancreatic cancer, BXCL701 has not been granted orphan designation as of the date of this prospectus for the treatment of NEPC.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products, and it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtai

### We may seek a breakthrough therapy designation for BXCL701 or one or more of our other product candidates, we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a breakthrough therapy designation for BXCL701 or one or more of our other product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

# We may seek priority review designation for BXCL701 or one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

# If we are unable to develop satisfactory sales and marketing capabilities, we may not succeed in commercializing BXCL501, BXCL701 or any other product candidate.

We have no experience in marketing and selling drug products. We have not entered into arrangements for the sale and marketing of BXCL501, BXCL701 or any other product candidate. Typically, pharmaceutical companies would employ groups of sales representatives and associated sales and marketing staff numbering in the hundreds to thousands of individuals to call on this large number of physicians and hospitals. We may seek to collaborate with a third party to market our drugs or may seek to market and sell our drugs by ourselves. If we seek to collaborate with a third party, we cannot be sure that a collaborative agreement can be reached on terms acceptable to us. If we seek to market and sell our drugs directly, we will need to hire additional personnel skilled in marketing and sales. We cannot be sure that we will be able to acquire, or establish third party relationships to provide, any or all of these marketing and sales capabilities. The establishment of a direct sales force or a contract sales force or a combination direct and contract sales force to market our products will be expensive and time-consuming and could delay any product launch. Further, we can give no assurances that we may be able to maintain a direct and/or contract sales force for any period of time or that our sales efforts will be sufficient to grow our revenues or that our sales efforts will ever lead to profits.

#### We operate in a highly competitive and rapidly changing industry.

Biopharmaceutical product development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the United States, the European Union and other jurisdictions.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining



qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors.

Competition may further increase as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop.

Established biopharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

# Even if we obtain regulatory approvals to commercialize BXCL501, BXCL701 or our other product candidates, our product candidates may not be accepted by physicians or the medical community in general.

There can be no assurance that BXCL501, BXCL701 and our other product candidates or any other product candidate successfully developed by us, independently or with partners, will be accepted by physicians, hospitals and other health care facilities. BXCL501, BXCL701 and any future product candidates we develop will compete with a number of products manufactured and marketed by major pharmaceutical and biotech companies. The degree of market acceptance of any drugs we develop depends on a number of factors, including:

- our demonstration of the clinical efficacy and safety of BXCL501, BXCL701 and our other product candidates;
- timing of market approval and commercial launch of BXCL501, BXCL701 and our other product candidates;
- the clinical indication(s) for which BXCL501, BXCL701 and our other product candidates are approved;
- product label and package insert requirements;
- advantages and disadvantages of our product candidates compared to existing therapies;
- continued interest in and growth of the market for anti-cancer or anti-agitation drugs;
- strength of sales, marketing, and distribution support;
- product pricing in absolute terms and relative to alternative treatments;
- future changes in health care laws, regulations, and medical policies; and
- availability of reimbursement codes and coverage in select jurisdictions, and future changes to reimbursement policies of government and thirdparty payors.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations.

#### Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA has substantially changed the way healthcare is financed by both government health plans and private insurers, and significantly impacts the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to government programs which we believe will increase the cost of our products. In addition, as part of the PPACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program, we will be required to provide a discount on branded prescription drugs equal to 50% of the government-negotiated price, for drugs provided to certain beneficiaries who fall within the donut hole. Similarly, PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also includes significant changes to the 340B drug discount program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no

assurances that future legislation or regulations will not decrease the coverage and price that we may receive for our proposed products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

#### Risks Related to Our Relationship with BioXcel

### BioXcel controls the direction of our business, and the concentrated ownership of our common stock will prevent you and other stockholders from influencing significant decisions.

Assuming (i) an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and (ii) that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, BioXcel will own % of the economic interest and voting power of our outstanding common stock, or % of the economic interest and voting power of our outstanding common stock, or % of the economic interest and voting power of our outstanding common stock, if the underwriters exercise their option to purchase additional shares in full. As long as BioXcel beneficially controls a majority of the voting power of our outstanding the election and removal of directors. Even if BioXcel were to control less than a majority of the voting power of our outstanding common stock, it may influence the outcome of such corporate actions so long as it owns a significant portion of our common stock. If BioXcel continues to hold its shares of our common stock, it could remain our controlling stockholder for an extended period of time or indefinitely.

# Approval of commercial terms between us and BioXcel does not preclude the possibility of stockholder litigation, including but not limited to derivative litigation nominally against BioXcel and against its directors and officers and also against us and our directors and officers.

The commercial terms of the Services Agreement, the grid note, dated June 30, 2017, or Grid Note, and the Contribution Agreement that we have entered into with BioXcel have been not been negotiated on behalf of BioXcel by persons consisting solely of disinterested BioXcel directors. Notwithstanding the foregoing, we have no basis for believing that the terms of these agreements will not be in the best interests of both BioXcel and its stockholders and also us and our stockholders. Nonetheless, no assurance can be given that any stockholder of BioXcel will not claim in a lawsuit that such terms in fact are not in the best interests of BioXcel and its stockholders, that the directors and officers of BioXcel breached their fiduciary duties in connection with such agreements and that any disclosures by BioXcel to its stockholders regarding these agreements and the relationship between BioXcel and us did not satisfy applicable requirements. In any such instance, we and our directors and

officers may also be named as defendants and we would have to defend ourselves and our directors and officers. While we will seek indemnification from BioXcel under the terms of these agreements against any damages or other costs, which could be substantial, no such indemnification has yet been agreed to or may be agreed to and be in effect. Further, any such litigation would be time-consuming and would divert focus and resources from the development of our product candidates and our business, including but not limited to possibly delaying our clinical trials due to our management having to spend time and attention on such litigation.

### The Distribution may not occur and your investment in our securities may be adversely affected if BioXcel does not distribute the shares of our common stock owned by BioXcel.

BioXcel has advised us that, following the completion of this offering and subject to the expiration of any applicable lock-up periods or other agreements we have or may have with BioXcel, it does not have any near-term plans to distribute the shares of BTI common stock held by BioXcel to the BioXcel stockholders. It is expected that any potential distribution will be taxable to BioXcel and its stockholders. Whether a Distribution is conducted in the future will depend on many factors, including BioXcel's cash position, market capitalization, BioXcel's investment opportunities, taxation to BioXcel and BioXcel's stockholders and the our status and prospects. In addition, the liquidity of the market for our common stock may be constrained for as long as BioXcel continues to hold a significant position in our common stock. Additionally, without a Distribution, there will be limited liquidity in the market for our common stock may adversely affect our stock price and therefore, our ability to raise additional funds in the public markets, which may have a material adverse effect on our ability to grow our business.

#### Following this offering, we will continue to depend on BioXcel to provide us with certain services for our business.

We have operated as a 96% owned subsidiary of BioXcel. Certain administrative services required by us for the operation of our business are currently provided by BioXcel, including services related to insurance and risk management, accounting and human resources. Under the Services Agreement, BioXcel will continue to provide us with various services following the closing of the offering until we are able to build our own capabilities in the transition areas. We believe it is most efficient for BioXcel to provide these services for us to facilitate the efficient operation of our business as we transition to becoming an independent, public company. At our election, or if BioXcel does not or is unable to perform its obligations under the Services Agreement, we will be required to provide these services ourselves or to obtain substitute arrangements with other third parties. We may be unable to provide these services because of financial or other constraints or be unable to implement substitute arrangements on a timely basis on terms that are favorable to us, or at all.

We exercise no control over the activities of BioXcel other than the contractual rights we have pursuant to our Services Agreement and Contribution Agreement. Because of our historical relationship with our parent, our reputation is also tied to BioXcel. We may be subject to reputational harm, or our relationships with existing and potential clients, third-party research organizations, consultants and other business partners could be harmed if BioXcel or any of its affiliates, previously, or in the future, among other things, engages in poor business practices, restructures or files for bankruptcy, becomes subject to litigation or otherwise damages its reputation or business prospects. Any of these events might in turn adversely affect our reputation, revenues and/or business prospects, and may also adversely affect our access to EvolverAI and BioXcel's collaborative services.

We also rely, in part, on BioXcel and access to EvolverAI, a research and development engine created and owned by BioXcel, to identify, research and develop potential product candidates in neuroscience and immuno-oncology. We have the option to enter into a collaborative services agreement with BioXcel, pursuant to which BioXcel shall perform product identification and related services for us utilizing EvolverAI. We have agreed that such agreement will be negotiated in good faith and that such agreement will incorporate reasonable market based terms, including royalty payments on net sales and reasonable development and commercialization milestone payments. In addition, BioXcel has granted us, upon completion of this offering, a first right to negotiate exclusive rights to any additional product candidates in the fields of neuroscience and immuno-oncology that BioXcel may identify on its own and not in connection with BioXcel's provision of services to us under the Services Agreement. This option for first negotiation shall be valid for a period of five years from the date of this offering. If our rights and access to BioXcel's collaborative services and to EvolverAI were to become limited, terminated, or if we were otherwise precluded from conducting research and development using EvolverAI, or if BioXcel is unable to fulfill its obligations under the agreements, such development could materially adversely affect our future operating results, financial condition and prospects. Furthermore, certain individuals conducting services on our behalf are not our employees, and except for remedies available to us under our agreements with BioXcel, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. We also cannot ensure that BioXcel retains sufficient resources of personnel or otherwise to conduct its operations. BioXcel may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting research and development activities, which could impede their ability to devote appropriate time to our research and development programs. In addition, if we fail to comply with our diligence, payment or other obligations under the agreements, any such collaboration may terminate or we may not be able to successfully negotiate agreements for future product candidates or collaborations with BioXcel.

### The ownership by our executive officers and our directors of shares of BioXcel common stock and rights to purchase BioXcel common stock may create, or may create the appearance of, conflicts of interest.

The ownership by our executive officers and our directors of shares of BioXcel common stock, options to purchase shares of BioXcel common stock, or other equity awards of BioXcel may create, or may create the appearance of, conflicts of interest. Our Chief Executive Officer and Vice President—Finance will continue to serve in the same respective roles at BioXcel until the consummation of this offering. Three of our four directors currently serve on both our board of directors of BioXcel. Upon completion of this offering, Sandeep Laumas, M.D. has agreed to step down from BioXcel's board of directors and plans to continue his service on our board of directors. Because of the current (and former, upon the closing) positions of our executive officers and our directors with BioXcel, they own shares of BioXcel common stock, options to purchase shares of BioXcel common stock or other equity awards of BioXcel. Our Chief Executive Officer, Vimal Mehta, Ph.D. and one of our directors, Krishnan Nandabalan, Ph.D., each own approximately 43% and 43%, respectively, of outstanding BioXcel voting stock. Ownership by our executive officers and directors of common stock or options to purchase common stock of BioXcel, or any other equity awards, whether prior to, or following the consummation of this offering, creates, or, may create the appearance of, conflicts of interest when these individuals are faced with decisions that could have different implications for BioXcel than the decisions have for us, including decisions that relate to our Services Agreement, Contribution Agreement, as well as potential agreements relating to future product candidates and AI-related services or collaborations. In connection with the Separation, our chief executive officer has agreed to recuse himself with respect to voting on any matter coming before either BioXcel's or our board of directors related to our relationship with BioXcel, although he will still be permitted to participate in discussions and negotiations. Any perceived conflicts of in

from investors questioning the independence of our management or the integrity of corporate governance procedures may materially affect our stock price.

#### Any disputes that arise between us and BioXcel with respect to our past and ongoing relationships could harm our business operations.

Disputes may arise between BioXcel and us in a number of areas relating to our past and ongoing relationships, including:

- intellectual property, technology and business matters, including failure to make required technology transfers and failure to comply with noncompete provisions applicable to BioXcel and us;
- labor, tax, employee benefit, indemnification and other matters arising from the Separation;
- distribution and supply obligations;
- employee retention and recruiting;
- business combinations involving us;
- sales or distributions by BioXcel of all or any portion of its ownership interest in us;
- the nature, quality and pricing of services BioXcel has agreed to provide us; and
- business opportunities that may be attractive to both BioXcel and us.

We have entered into the Services Agreement with BioXcel related to the separation of our business operations from those of BioXcel that contains certain limitations on BioXcel's ability to control various aspects of our business and operations, notwithstanding BioXcel's substantial ownership position following the offering. This agreement may be amended upon agreement between us and BioXcel.

### We and our stockholders may not achieve some or all of the expected benefits of the Separation.

Drug development is an expensive and time-consuming process, but we believe the knowledge we have gained while operating as a subsidiary of BioXcel has helped expedite this process. However, in order to realize the value proposition of BTI as a drug development company, we intend to target early stage healthcare and pharmaceutical focused investors, who are interested in investing in drug development companies and who appreciate the risks, rewards and typically longer investment timelines associated with such investments. In order to successfully attract this type of new investment, we believe it is critical that we separate from BioXcel, because we believe that doing so will provide us with some or all of the following benefits:

- improving strategic and operational flexibility, increasing management focus and streamlining decision-making by providing the flexibility to implement our strategic plan and to respond more effectively to different customer needs and the changing economic environment;
- allowing us to adopt the capital structure, investment policy and dividend policy best suited to our financial profile and business needs, without competing for capital with BioXcel's other businesses;
- creating an independent equity structure that will facilitate our ability to affect future acquisitions utilizing our common stock; and
- facilitating incentive compensation arrangements for employees more directly tied to the performance of our business, and enhancing employee hiring and retention by, among other

things, improving the alignment of management and employee incentives with performance and growth objectives of our business.

If we are not successful implementing the Separation, we may not be able to achieve the full strategic and financial benefits we expect to receive, or the benefits may be delayed or not occur at all. Even if we are able to achieve stand-alone, independent status as a drug development company, there can be no assurance that investors and analysts will place a greater value on us as a stand-alone drug development company than as a wholly- or substantially-owned subsidiary of BioXcel.

### We may be a "controlled company" within the meaning of the Nasdaq rules and, as a result, may qualify for, and may rely on, exemptions from certain corporate governance requirements that provide protection to stockholders of other companies.

Upon completion of this offering, BioXcel may continue to control a majority of the voting power of our outstanding common stock. As a result, we may be a "controlled company" within the meaning of the corporate governance standards of the Nasdaq rules. Under these rules, a listed company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements.

As a controlled company, we may rely on certain exemptions from the Nasdaq standards that may enable us not to comply with certain Nasdaq corporate governance requirements if BioXcel continues to control a majority of the voting power of our outstanding common stock. Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of The Nasdaq Capital Market.

### The assets and resources that we acquire from BioXcel in the Separation may not be sufficient for us to operate as a stand-alone company, and we may experience difficulty in separating our assets and resources from BioXcel.

Because we have not operated as a stand-alone company in the past, we may have difficulty doing so. We may need to acquire assets and resources in addition to those provided by BioXcel to us, and in connection with the Separation, may also face difficulty in separating our resources from BioXcel's and integrating newly acquired assets into our business. For example, we may need to hire additional personnel to assist with administrative and technical functions, and acquire other office and laboratory equipment for use in the ordinary course operations of our business. If we have difficulty operating as a stand-alone company, fail to acquire assets that we need to run our operations, or incur unexpected costs in separating our business from BioXcel's business or in integrating newly acquired assets into our business, our financial condition and results of operations will be adversely affected.

# You may have difficulty evaluating our business because we have no history as a separate company and our historical financial information may not be representative of our results as a separate company.

The historical financial information included in this prospectus does not necessarily reflect the financial condition, results of operations or cash flows that we would have achieved as a separate company during the periods presented or those that we will achieve in the future. Prior to the contribution of our assets from BioXcel, our research and development activities were conducted by BioXcel as part of its broader operations, rather than as an independent division or subsidiary. BioXcel also performed various corporate functions relating to our business. Our historical financial information reflects allocations of corporate expenses from BioXcel for these and similar functions. We believe that these allocations are comparable to the expenses we would have incurred had we operated as a separate company, although we may incur higher expenses as a separate company.

#### BioXcel may experience challenges with the acquisition, development, enhancement or deployment of technology necessary for EvolverAI.

BioXcel operates in businesses that require sophisticated computer systems and software for data collection, data processing, cloud-based platforms, analytics, statistical projections and forecasting, mobile computing, social media analytics and other applications and technologies. BioXcel seeks to address its technology risks by increasing its reliance on the use of innovations by cross-industry technology leaders and adapt these for their pharmaceutical, specialty-pharma, biotech, biopharmaceutical, diagnostic, medical device and contract research and manufacturing clients. Some of the technologies supporting the industries they serve are changing rapidly and we must continue to adapt to these changes in a timely and effective manner at an acceptable cost. They also must continue to deliver data to its clients in forms that are easy to use while simultaneously providing clear answers to complex questions. There can be no guarantee that we or BioXcel will be able to develop, acquire or integrate new technologies, that these new technologies will meet our and BioXcel's needs or achieve our expected goals, or that we will be able to do so as quickly or cost-effectively as our competitors. Significant technological change could render EvolverAI obsolete. BioXcel's continued success will depend on its ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance, features and reliability of its services in response to changing client and industry demands. BioXcel may experience difficulties that could delay or prevent the successful design, development, testing, and introduction of advanced versions of EvolverAI, limiting our ability to identify new product candidates. New services, or enhancements to existing EvolverAI services, may not adequately meet our requirements. Any of these failures could have a material adverse effect on our operating results and financial condition.

#### **Risks Related to Our Reliance on Third Parties**

We are substantially dependent on third parties for the manufacture of our clinical supplies of our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product candidate. Therefore, our development of our products could be stopped or delayed, and our commercialization of any future product could be stopped or delayed or made less profitable if third party manufacturers fail to obtain approval of the FDA or comparable regulatory authorities or fail to provide us with drug product in sufficient quantities or at acceptable prices.

The manufacture of biotechnology and pharmaceutical products is complex and requires significant expertise, capital investment, process controls and know-how. Common difficulties in biotechnology and pharmaceutical manufacturing may include: sourcing and producing raw materials, transferring technology from chemistry and development activities to production activities, validating initial production designs, scaling manufacturing techniques, improving costs and yields, establishing and maintaining quality controls and stability requirements, eliminating contaminations and operator errors, and maintaining compliance with regulatory requirements. We do not currently have nor do we plan to acquire the infrastructure or capability internally in accordance with cGMP prescribed by the FDA or to produce an adequate supply of compounds to meet future requirements for clinical trials and commercialization of our products. Drug manufacturing facilities are subject to inspection before the FDA will issue an approval to market a new drug product, and all of the manufacturers that we intend to use must adhere to the cGMP regulations prescribed by the FDA.

We expect therefore to rely on third-party manufacturers for clinical supplies of our product candidates that we may develop. These third-party manufacturers will be required to comply with current good manufacturing practices, or GMPs, and other applicable laws and regulations. We will have no control over the ability of these third parties to comply with these requirements, or to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve the facilities of these third parties for the manufacture of our other product candidates or any products that we may successfully develop, or if it withdraws any such

approval, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all. Any of these factors would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates and adversely affect our business.

We and/or our third-party manufacturers may be adversely affected by developments outside of our control, and these developments may delay or prevent further manufacturing of our products. Adverse developments may include labor disputes, resource constraints, shipment delays, inventory shortages, lot failures, unexpected sources of contamination, lawsuits related to our manufacturing techniques, equipment used during manufacturing, or composition of matter, unstable political environments, acts of terrorism, war, natural disasters, and other natural and man-made disasters. If BioXcel, we or our third-party manufacturers were to encounter any of the above difficulties, or otherwise fail to comply with contractual obligations, our ability to provide any product for clinical trial or commercial purposes would be jeopardized. This may increase the costs associated with completing our clinical trials and commercial production. Further, production disruptions may cause us to terminate ongoing clinical trials and/or commence new clinical trials at additional expense. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications or pass safety inspections. If production difficulties cannot be solved with acceptable costs, expenses, and timeframes, we may be forced to abandon our clinical development and commercialization plans, which could have a material adverse effect on our business, prospects, financial condition, and the value of our securities.

# We, or third-party manufacturers on whom we rely, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct clinical trials of our product candidates and commercialize any approved product candidates, we, or our manufacturers, will need to manufacture them in large quantities. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

# Our failure to find third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition and results of operations.

Our strategy for the development and commercialization of our proprietary product candidates may include the formation of collaborative arrangements with third parties. Potential third parties include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future product candidates.



If we are not able to establish further collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our product candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of product candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any product candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

# We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party medical institutions, clinical investigators, contract laboratories and other third party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development.

Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial

prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our GLP preclinical studies or our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

#### **Risks Related to Our Business and Industry**

### We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing growth.

As of June 30, 2017, we employed a total of three full-time employees and our parent, BioXcel, has two employees who are leased to us pursuant to the Services Agreement. In addition, we will have access to certain of BioXcel's employees and resources through the various agreements we have entered into with BioXcel. Our current internal departments include finance, research and development and administration. We intend to expand our management team to include an operation ramp up of additional technical staff required to achieve our business objectives. We will need to expand our managerial, operational, technical and scientific, financial and other resources in order to manage our operations and clinical trials, establish independent manufacturing, continue our research and development activities, and commercialize our product candidate. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth.

Our need to effectively manage our operations, growth and various projects requires that we:

- manage our clinical trials effectively, including our planned clinical trials of BXCL501, BXCL701 and our other product candidates;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
- continue to improve our operational, financial and management controls and reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may utilize the services of third party vendors to perform tasks including pre-clinical and clinical trial management, statistics and analysis, regulatory affairs, medical advisory, market research, formulation development, chemistry, manufacturing and control activities, other drug development functions, legal, auditing, financial advisory, and investor relations. Our growth strategy may also entail expanding our group of contractors or consultants to implement these and other tasks going forward. Because we rely on numerous consultants, to outsource many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage

our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidate or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidate and, accordingly, may not achieve our research, development and commercialization goals.

### We depend on our senior management team, and the loss of one or more of our executive officers or key employees or an inability to attract and retain highly skilled employees could adversely affect our business.

Our success depends largely upon the continued services of our key executive officers, Vimal Mehta, our Chief Executive Officer, President, Secretary and Director and Frank Yocca, our Chief Scientific Officer. We do not maintain "key person" insurance for any of these executive officers or any of our other key employees. We also rely on our leadership team in the areas of research and development, marketing, services and general and administrative functions. From time to time, there may be changes in our executive management and leadership teams resulting from the hiring or departure of executives or other key employees, which could disrupt our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

To continue to execute our growth strategy, we also must attract and retain highly skilled personnel. We might not be successful in maintaining our unique culture and continuing to attract and retain qualified personnel. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and retaining highly skilled personnel with appropriate qualifications. The pool of qualified personnel with SaaS, or experience working with the pharma market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have.

In addition, in making employment decisions, particularly in the internet, biotechnology and high-technology industries, job candidates often consider the value of the stock options or other equity instruments they are to receive in connection with their employment. Volatility in the price of our stock might, therefore, adversely affect our ability to attract or retain highly skilled personnel. Furthermore, the requirement to expense stock options and other equity instruments might discourage us from granting the size or type of stock option or equity awards that job candidates require to join our company. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

### Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with any regulations applicable to us, to provide accurate information to regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, or to report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could



result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risk.

### Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our costs and expenses.

Our operations, and those of our directors, advisors, contractors, consultants, CROs, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics and other natural and man-made disaster or business interruptions. Our phones, electronic devices and computer systems and those of our directors, advisors, contractors, consultants, CROs, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man-made disasters. Operating as a virtual company, our employees conduct business outside of our headquarters and leased or owned facilities. These locations may be subject to additional security and other risk factors due to the limited control of our employees. If such an event as described above were to occur in the future, it may cause interruptions in our operations, delay research and development programs, clinical trials, regulatory activities, manufacturing and quality assurance activities, sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Likewise, we will rely on third parties to manufacture BXCL501 and BXCL701 and conduct clinical trials, and similar events as those described in the prior paragraph relating to their business systems, equipment and facilities could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed or altogether terminated.

### Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this prospectus.

Our audited financial statements at December 31, 2016 and 2015 and for the years then ended were prepared assuming that we will continue as a going concern.

Primarily as a result of our losses and limited cash balances, the report of our independent registered public accounting firm included elsewhere in this prospectus contains an explanatory paragraph on our financial statements stating there is substantial doubt about our ability to continue as a going concern due to recurring losses from operations and deficiencies in working capital and net capital. Such an opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern is contingent upon, among other factors, the sale of the shares of our common stock in this offering or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital.

If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The accompanying financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our proposed business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment.

### Our failure to successfully acquire, develop and market additional product candidates or approved drug products could impair our ability to grow.

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market additional product candidates and technologies. These investments will not constitute a significant portion of our business. However, our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's and technical personnel's time and attention to develop acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any

products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

#### **Risks Related to Our Intellectual Property**

# It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending these patents against third-party challenges. We are the owner of record of patent applications pending in the United States and in certain foreign jurisdictions. We own Patent Cooperation Treaty, or PCT, patent applications relating to our platform technologies covering methods of use and applications of the platform technologies. To date, no patents have been issued to us specifically covering our product candidates, and we cannot be certain that any patents will issue with claims that cover our product candidates. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in foreign jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates, but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- our pending patent applications may not result in issued patents;
- the claims of our issued patents or patent applications when issued may not cover our products or product candidates;
- any patents that we obtain may not provide us with any competitive advantages;

- any granted patents may be held invalid or unenforceable as a result of legal challenges by third parties; and
- the patents of others may have an adverse effect on our business.

# If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.

We may be required to enter into intellectual property license agreements that are important to our business. These license agreements may impose various diligence, milestone payment, royalty and other obligations on us. For example, we may enter into exclusive license agreements with various universities and research institutions, we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and may need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

### We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights.

If we choose to commence a proceeding or litigation to prevent another party from infringing our patents, that party will have the right to ask the examiner or court to rule that our patents are invalid or should not be enforced against them. There is a risk that the examiner or court will decide that our patents are not valid and that we do not have the right to stop the other party from using the related inventions. There is also the risk that, even if the validity of our patents is upheld, the examiner or court will refuse to stop the other party on the ground that such other party's activities do not infringe

our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the U.S. Patent and Trademark Office, or USPTO, in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge to any patents we obtain or license. Any proceedings or litigation to enforce our intellectual property rights or defend ourselves against claims of infringement of third-party intellectual property rights could be costly and divert the attention of managerial and scientific personnel, regardless of whether such litigation is ultimately resolved in our favor. We may not have sufficient resources to bring these actions to a successful conclusion. Moreover, if we are unable to successfully defend against claims that we have infringed the intellectual property rights of others, we may be prevented from using certain intellectual property and may be liable for damages, which in turn could materially adversely affect our business, financial condition or results of operations.

# We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of the relevant product candidate. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

some patent applications in the United States may be maintained in secrecy until the patents are issued;



- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed USpatent applications on inventions similar to ours that claims priority to any applications filed prior to the priority dates of our applications, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

# If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Furthermore, any license agreements we enter into in the future may require us to notify, and in some cases license back to the licensor, certain additional proprietary information or intellectual property that we developed using the rights licensed to us under these agreements. Any such licenses back to the licensor could allow our licensors to use that proprietary information or intellectual property in a manner that could harm our business. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

### We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their

former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

# Our intellectual property may not be sufficient to protect our products from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products.

Our drug re-innovation approach involves the filing of patent applications covering new methods of use and/or new formulations of previously known, studied and/or marketed drugs. Although the protection afforded by our patent applications may be significant with respect to BXCL501 and BXCL701, when looking at our patents' ability to block competition, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents claiming the composition of matter of entirely new chemical structures previously unknown. If a competitor were able to successfully design around any method of use and formulation patents we may have in the future, our business and competitive advantage could be significantly affected.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from BioXcel. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our products; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own; and, the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our product candidates in the future. There can be no assurance that we will be able to successfully defend patents we own in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights and enforcement may be less extensive in jurisdictions outside of the United States; thus, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Changes to patent law, including the Leahy-Smith America Invests Act, AIA or Leahy-Smith Act, of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents, and



prosecution of patents. We can give no assurances that our patents and those of our licensor, BioXcel, can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the U.S. Patent and Trademark Office, courts and foreign government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

### Risks Related to Owning our Common Stock and this Offering

### An active trading market for our common stock may not develop, and you may not be able to sell your common stock at or above the initial public offering price.

Prior to the consummation of this offering, there has been no public market for our common stock. An active trading market for shares of our common stock may never develop or be sustained following this offering. If an active trading market does not develop, you may have difficulty selling your shares of common stock at an attractive price, or at all. The price for our common stock in this offering will be determined by negotiations between us and the underwriters, and it may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell your common stock at or above the initial public offering price or at any other price or at the time that you would like to sell. An inactive market may also impair our ability to raise capital by selling our common stock, and it may impair our ability to attract and motivate our employees through equity incentive awards and our ability to acquire other companies, products or technologies by using our common stock as consideration.

#### The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this prospectus, are:

- sale of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new applications and services by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to attract new customers;
- customer renewal rates and the timing and terms of customer renewals;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;

- commencement, enrollment or results of our clinical trials for our product candidates or any future clinical trials we may conduct;
- changes in the development status of our product candidates;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned preclinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidates;
- unanticipated safety concerns related to the use of our product candidates;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

#### We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this initial public offering, including for any of the currently intended purposes described in the section entitled "Use of Proceeds." Because of the number and variability of factors that will determine our use of the

net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply our cash from this offering in ways that ultimately increase the value of any investment in our securities or enhance shareholder value. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance shareholder value, we may fail to achieve expected financial results, which may result in a decline in the price of our shares of common stock, and, therefore, may negatively impact our ability to raise capital, invest in or expand our business, acquire additional products or licenses, commercialize our products, or continue our operations.

# We may acquire other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We may in the future seek to acquire or invest in businesses, applications and services or technologies that we believe could complement or expand our services, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

In addition, we do not have any experience in acquiring other businesses. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- inability to integrate or benefit from acquired technologies or services in a profitable manner;
- unanticipated costs or liabilities associated with the acquisition;
- difficulty integrating the accounting systems, operations and personnel of the acquired business;
- difficulties and additional expenses associated with supporting legacy products and hosting infrastructure of the acquired business;
- difficulty converting the customers of the acquired business onto our platform and contract terms, including disparities in the revenue, licensing, support or professional services model of the acquired company;
- diversion of management's attention from other business concerns;
- adverse effects to our existing business relationships with business partners and customers as a result of the acquisition;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial position may suffer.



#### Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

# If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock after the closing of this offering, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

### Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

Following this offering, our directors, executive officers and principal stockholders, and their respective affiliates, will beneficially own approximately % of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

### You will incur immediate dilution as a result of this offering.

If you purchase common stock in this offering, you will pay more for your shares than the net tangible book value of your shares. As a result, you will incur immediate dilution of \$ per share, representing the difference between the assumed initial public offering price of \$ per share (the midpoint of the range on the cover of this prospectus) and our estimated net tangible book value per



share as of June 30, 2017 of \$ . Accordingly, should we be liquidated at our book value, you would not receive the full amount of your investment.

# Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

### We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

# We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are not electing to delay such adoption of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of th

#### We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

#### There is no guarantee that our common stock will be listed on Nasdaq.

We intend to apply to have our shares of common stock listed on The Nasdaq Capital Market. Upon completion of this offering, we believe that we will satisfy the listing requirements and expect that our common stock will be listed on The Nasdaq Capital Market. Such listing, however, is not guaranteed. If the application is not approved, we will seek to have our common stock quoted on the OTCQB maintained by the OTC Markets Group, Inc. Even if such listing is approved, there can be no assurance any broker will be interested in trading our common stock. Therefore, it may be difficult to sell any shares you purchase in this offering if you desire or need to sell them. Our lead underwriter, Barclays, is not obligated to make a market in our common stock, and even after making a market, can discontinue market making at any time without notice. Neither we nor the underwriters can provide any assurance that an active and liquid trading market in our common stock will develop or, if developed, that the market will continue.

# Our certificate of incorporation and our bylaws, and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our amended and restated certificate of incorporation and our amended and restated bylaws, to be effective upon completion of the offering, and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. Upon consummation of this offering, we will be authorized to issue up to shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. No preferred stock is currently outstanding. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock and the Notes. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

# Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company that is separate from BioXcel, we will incur significant additional legal, accounting and other expenses that we did not incur as a privately held subsidiary of BioXcel. The obligations of being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage that we had through BioXcel. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

#### INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. You should not place undue reliance on these forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. In some cases, you can identify these forward-looking statements by terms such as "anticipate," "believe," "continue," "could," "depends," "estimate," "expects," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms or other similar expressions, although not all forward-looking statements contain those words. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements concerning the following:

- our plans to initiate clinical trials BXCL501, BXCL701 and our other product candidates;
- our plans for 505(b)(2) regulatory path approval;
- our plans to research, develop and commercialize our current and future product candidates;
- our plans to seek to enter into collaborations for the development and commercialization of certain product candidates;
- the potential benefits of any future collaboration;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our estimates regarding expenses, future revenue, capital requirements and need for additional financing;
- developments relating to our competitors and our industry;
- the impact of government laws and regulations; and
- risks associated with our relationship with BioXcel.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot

guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

### INDUSTRY AND MARKET DATA

This prospectus contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty, including those discussed in "Risk Factors". We caution you not to give undue weight to such projections, assumptions and estimates. Further, industry and general publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these publications, studies and surveys are reliable, we have not independently verified the data contained in them. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source.

#### USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately \$ million, based on an assumed initial public offering price of \$ per share, the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds from this offering will be approximately \$ million.

We intend to use the net proceeds from this offering as follows:

- approximately \$ million to fund BXCL501 through Phase 2 clinical development and potentially commence one registration trial;
- approximately \$ million to fund BXCL701 through Phase 2 clinical development;
- \$ million to be reimbursed to BioXcel pursuant to the Contribution Agreement;
- \$ million to be repaid to BioXcel purusant to the Services Agreement and Grid Note; and
- the balance for working capital and other general corporate purposes.

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share would increase or decrease the net proceeds from this offering by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions.

We believe that the net proceeds from this offering and our existing cash, cash equivalents and investments will be sufficient to fund our current operations through . The amount and timing of our actual expenditures will depend upon numerous factors, including the status and results of our planned Phase 2 PoC open label clinical trials in 2018 for both BXCL501 and BXCL701. Furthermore, we anticipate that we will need to secure additional funding for the further development of BXCL501 and BXCL701, and for the development of any of our other product candidates.

This expected use of the net proceeds from this offering and our existing cash and cash equivalents represents our intentions based upon our current plans, financial condition and business conditions. Predicting the cost necessary to develop product candidates can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development and commercialization efforts, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering and our existing cash and cash equivalents.

In the ordinary course of our business, we expect to from time to time evaluate the acquisition of, investment in or in-license of complementary products, technologies or businesses, and we could use a portion of the net proceeds from this offering for such activities. We currently do not have any agreements, arrangements or commitments with respect to any potential acquisition, investment or license.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and government securities.

In connection with the Services Agreement, we entered into the Grid Note with BioXcel. As of June 30, 2017, we have drawn an amount of \$285,000 under the Grid Note. The Grid Note is payable upon the earlier of (i) the completion of this offering and (ii) December 31, 2018, together with

interest on the unpaid balance of each advance made under the Grid Note, which shall accrue at a rate per annum equal to the applicable federal rate for shortterm loans as of the date hereof, in each case calculated based on a 365-day year and actual days elapsed. We have also agreed to reimburse BioXcel for its contributed services and support to us in connection with our organization and development prior to the date of the Grid Note in the amount of \$562,000, which amount shall be payable upon the earlier of (i) thirty days after the completion of this offering and (ii) December 31, 2018. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Separation and Shared Services Agreement with BioXcel" for additional information.

### DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

### CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2017:

- on an actual basis;
- on a pro forma basis to reflect the sale of 1,804 shares of common stock, at a price of \$1,142.86 per share in September and October 2017; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock included in the shares of common stock being sold in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and our estimated offering expenses.

	June 30, 2017				
<u>(in thousands, except share and per share data)</u> Cash	Actual \$285	Pro Forma \$	Pro Forma, As Adjusted <sup>1</sup> (unaudited) \$		
Short term note payable to related party					
Stockholders' equity:					
Preferred stock, par value \$0.001 per share; no shares authorized, issued or outstanding, actual and pro forma; shares authorized and no shares issued or outstanding, pro forma as adjusted	_		_		
Common stock, par value \$0.001 per share; 100,000 shares authorized, 40,000 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted					
Additional paid-in capital Accumulated deficit	(1,005)				
Total stockholders' deficit Total capitalization	(1,005) \$ (1,005)	\$	\$		

1 A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total shareholders' equity and total capitalization by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total shareholders' equity and total capitalization by \$ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

#### DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of June 30, 2017 we had a historical net tangible book value (deficit) of \$, or \$( ) per share of common stock, based on shares of common stock outstanding at June 30, 2017. Our historical net tangible book value per share is the amount of our total tangible assets less our total liabilities at June 30, 2017, divided by the number of shares of common stock outstanding at June 30, 2017.

Our pro forma net tangible book value as of June 30, 2017 was \$, or \$ per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the sale of 1,804 shares of common stock, at a price of \$1,142.86 per share in September and October 2017.

After giving further effect to the sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at June 30, 2017 would have been \$ million, or \$ per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to existing stockholders and immediate dilution of \$ per share to new investors purchasing shares of common stock in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$
Pro forma net tangible book value per share as of June 30, 2017	\$
Increase in pro forma as adjusted net tangible book value per share attributable to new investors in this offering	
Pro forma as adjusted net tangible book value per share immediately after this offering	
Dilution per share to new investors in this offering	\$

per share, which is the midpoint of the price range set forth on the cover A \$1.00 increase (decrease) in the assumed initial public offering price of \$ page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value after this offering by \$ per share and the dilution to new investors purchasing common stock in this offering by \$ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discount and commissions. An increase of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value after this offering by per share and decrease the dilution to new investors purchasing common stock in this offering by \$ per share, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions. A decrease of 1,000,000 shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value after this offering by \$ per share and increase the dilution to new investors purchasing common stock in this offering by \$ per share, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value per share after giving effect to the offering would be \$ per share. This represents an increase in pro forma as adjusted net tangible book value of \$ per share to existing stockholders and dilution in pro forma as adjusted net tangible book value of \$ per share to new investors.

The following table summarizes, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing shareholders and by new investors in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares	Purchased	Total Co	nsideration	Average Price
	Number	Percentage	Amount	Percentage	Per Share
Existing shareholders		%	\$		%\$
New investors					\$
Total		%	\$		%

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by \$ million and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by \$ percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by \$ percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by \$ percentage points, assuming no change in the assumed initial public offering price.

The table above assumes no exercise of the underwriters' over-allotment option in this offering. If the underwriters' over-allotment option is exercised in full, the number of common shares held by new investors purchasing common stock in this offering would be increased to of common stock outstanding after this offering, and the number of shares held by existing shareholders would be reduced to shares of common stock outstanding after this offering.

To the extent that stock options or warrants are exercised, new stock options are issued under our equity incentive plan, or we issue additional common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

### SELECTED FINANCIAL DATA

The following table sets forth our selected financial data as of the dates and for the periods indicated. We have derived the statement of operations data for the years ended December 31, 2016 and 2015 from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the six months ended June 30, 2017 and 2016 and the balance sheet data as of June 30, 2017 have been derived from our unaudited financial statements included elsewhere in this prospectus. The following summary financial data should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes and other information included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future and the results for the six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the full fiscal year.

Our historical results of operations presented below may not be reflective of our financial position, results of operations and cash flows had we operated as a stand-alone public company during all periods presented. Prior to June 30, 2017, BTI operated as part of BioXcel and not as a separate stand-alone entity. Our financial statement prior to June 30, 2017 have been prepared on a "carve-out" basis from the financial statements of BioXcel to represent our financial position and performance as if we had existed on a stand-alone basis during each of the fiscal years presented in the financial statements. These results reflect amounts specifically attributable to our business, including the costs BioXcel incurred for the assets that were contributed to us by our parent under the Contribution Agreement and the Services Agreement. The agreements provide us with certain general and administrative and development support services that became effective June 30, 2017. However, consistent with accounting regulations, we have assumed that we were a separate business within BioXcel and we have reflected the related assets, liabilities and expenses in our results for periods prior to and post incorporation. We believe that such allocations have been made on a reasonable basis, but may not necessarily be indicative of all of the costs that would have been incurred if we had operated on a standalone basis.

#### **Statement of Operations Data:**

(in thousands, except share and per share data)

	Years Ended December 31,			Six Months Ended June 30, (unaudited)			30,
	 2016	2015		2017			2016
Revenues	\$ —	\$		\$	—	\$	—
Operating costs and expenses		_					
Research and development	1,399		233		645		650
General and administrative	721		403		449		367
Total operating expenses	2,120		636		1,094		1,017
Net loss	\$ (2,120)	\$	(636)	\$	(1,094)	\$	(1,017)
Net loss per share—basic and diluted	\$ (53.00)	\$	(15.90)	\$	(27.35)	\$	(25.43)
Weighted average shares outstanding—basic and diluted $^{1}$	40,000		40,000		40,000		40,000

<sup>1</sup> See Note 3 to our financial statements for an explanation of the method used to compute basic and diluted net loss per share.

### **Balance Sheet Data:**

(in thousands)

		J	une 30,		
	 December 31,			2017	
	 2016 2015		(ա	(unaudited)	
Cash	\$ _	\$ —	\$	285	
Working capital deficit	(329)	(174	)	(1,009)	
Total assets	7	2		289	
Total liabilities	331	175		1,294	
Total net Parent investment	(324)	(173	)		
Accumulated deficit	—			(1,005)	
Total liabilities and net Parent investment/stockholders' deficit	(324)	(173	)	(1,005)	

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF OPERATIONS

You should read the following discussion and analysis of our financial condition and plan of operations together with "Selected Financial Data" and our financial statements and the related notes appearing elsewhere in this prospectus. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this prospectus. All amounts in this report are in U.S. dollars, unless otherwise noted.

#### Overview

We are a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence, or AI, to identify the next wave of medicines across neuroscience and immuno-oncology. Our 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. We believe that this differentiated approach has the potential to reduce the cost and time of drug development in diseases with substantial unmet medical need. Our two most advanced clinical development programs are BXCL501, a sublingual thin film formulation of the a<sub>2a</sub> adrenergic receptor agonist dexmedetomidine, or Dex, for acute treatment of agitation resulting from neurological and psychiatric disorders, and BXCL701, an immuno-oncology agent for treatment of a rare form of prostate cancer and pancreatic cancer. We intend to commence Phase 2 proof of concept, or PoC, open label clinical trials in 2018 for both programs. We expect that a data readout from the planned Phase 2 PoC open label clinical trials for the BXCL501 program will be available by the end of 2018. We intend to initiate a bridging bioavailability, or BA, and bioequivalence, or BE, study for the sublingual thin film formulation in the second half of 2018 that, if successful, could potentially lead to the start of a registration trial in the first half of 2019. Preliminary data from the planned Phase 2 PoC clinical trials of BXCL701 will be available in the first half of 2019. We also acquired the rights to two other product candidates, BXCL502 and BXCL702, which together with BXCL501 and BXCL701 collectively represent the "BTI Business."

We were formed to develop first-in-class, high value therapeutics by leveraging EvolverAI, a research and development engine created and owned by our parent, BioXcel Corporation, or BioXcel. We believe the combination of our therapeutic area expertise, our ability to generate product candidates through our exclusive collaborative relationship with BioXcel in the areas of neuroscience and immuno-oncology gives us a significant competitive advantage. EvolverAI was developed over the last decade and integrates millions of fragmented data points using artificial intelligence and proprietary machine learning algorithms. After evaluating multiple product candidates using EvolverAI, we selected our lead programs because our analysis indicated these drugs may have utility in new therapeutic indices where there is substantial unmet medical needs and limited competition. By focusing on clinical candidates with relevant human data, we believe our approach will help us design more efficient clinical trials, thereby accelerating our product candidates time to market. We retain global development and commercialization rights to these two programs.

To date, we have not generated any revenue, we have incurred net losses and all of our operations have been financed by BioXcel. Our net losses were approximately \$2.1 million and \$0.6 million for the years ended December 31, 2016 and 2015, respectively and approximately \$1.1 million and \$1.0 million for the six months ended June 30, 2017 and June 30, 2016 respectively.

Our net losses have resulted from costs incurred in developing the drugs in our pipeline, planning and preparing for clinical trials and general and administrative activities associated with our operations. We expect to continue to incur significant expenses and corresponding increased operating losses for

the foreseeable future as we continue to develop our pipeline. Our costs may further increase as we conduct clinical trials and seek regulatory approval for and prepare to commercialize our candidates. We expect to incur significant expenses to continue to build the infrastructure necessary to support our expanded operations, clinical trials, commercialization, including manufacturing, marketing, sales and distribution functions. We will also experience increased costs associated with operating as an independent entity and a public company.

We were incorporated on March 29, 2017 as a wholly-owned subsidiary of BioXcel and our operating activities have been funded by BioXcel since January 1, 2015. We have adopted a calendar year-end for reporting purposes.

### Relationship with BioXcel

We have entered into an asset contribution agreement, effective June 30, 2017, with BioXcel, as amended and restated on November 7, 2017, or the Contribution Agreement, pursuant to which BioXcel agreed to contribute to us, and we agreed to acquire from BioXcel, all of BioXcel's rights, title and interest in and to BXCL501, BXCL701, BXCL502 and BXCL702, collectively, the Candidates, and all of the assets and liabilities associated with the Candidates, in consideration for (i) 40,000 shares of our common stock, (ii) \$1 million upon completion of this offering, (iii) \$500,000 upon the later of the 12 month anniversary of this offering and the first dosing of a patient in the bridging bioavailability/bioequivalence study for the BXCL501 program, (iv) \$500,000 upon the later of the 12 month anniversary of this offering and the first dosing of a patient in the Phase 2 PoC open label monotherapy or combination trial with Keytruda for the BXCL701 program and (v) a one-time payment of \$5 million within 60 days after the achievement of \$50 million in cumulative net sales of any product or combination of products resulting from the development and commercialization of any one of the Candidates or a product derived therefrom. In addition, pursuant to the Contribution Agreement, upon completion of this offering, BioXcel will grant us a first right to negotiate exclusive rights to any additional product candidates in the fields of neuroscience and immuno-oncology that BioXcel may identify on its own, excluding the Candidates, and not in connection with BioXcel's provision of services to us under the Services Agreement as defined and described below. This option for first negotiation shall be valid for a period of five years from the date of this offering. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Asset Contribution Agreement with BioXcel" for additional information.

We have entered into a separation and shared services agreement with BioXcel that took effect on June 30, 2017, as amended and restated on November 7, 2017, or the Services Agreement, pursuant to which BioXcel will allow us to continue to use the office space, equipment, services and leased employees based on the agreed upon terms and conditions for a payment of defined monthly and/or hourly fees. The parties have agreed that the services and office space provided under the Services Agreement shall decrease over time until the 12 month anniversary of the date of the Services Agreement, except for services to be provided by BioXcel through its subsidiary in India, which shall decrease until the 24 to 36 month anniversary of the date of the Services Agreement, provided such dates may be extended upon mutual agreement between the parties. On or before December 31, 2019, we shall have the option to enter into a collaborative services agreement with BioXcel pursuant to which BioXcel shall perform product identification and related services for us utilizing EvolverAI. We have agreed that this agreement will be negotiated in good faith and that such agreement will incorporate reasonable market-based terms, including consideration for BioXcel reflecting a low, single-digit royalty on net sales and reasonable development and commercialization milestone payments, provided that (i) development milestones shall not exceed \$10 million in the aggregate and not be payable prior to proof of concept in humans and (ii) commercialization milestones shall be based on reaching annual net sales levels, be limited to 3% of the applicable net sales level, and not exceed \$30 million in the aggregate. BioXcel shall continue to make such product identification and related

services available to us for at least five years from June 30, 2017. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Separation and Shared Services Agreement with BioXcel" for additional information.

In connection with the Services Agreement, BioXcel agreed to provide us a line of credit, which shall be capped at \$1 million, or the Total Funding Amount, pursuant to the terms of a grid note, or the Grid Note. The Grid Note shall be payable upon the earlier of (i) the completion of this offering and (ii) December 31, 2018, together with interest on the unpaid balance of each advance made under the Grid Note, which shall accrue at a rate per annum equal to the applicable federal rate for short-term loans as of the date hereof, in each case calculated based on a 365-day year and actual days elapsed. As of June 30, 2017, we have drawn an amount of \$285,000 under the Grid Note. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Separation and Shared Services Agreement with BioXcel" for additional information.

For the period March 29, 2017 through June 30, 2017 BioXcel paid for expenses on our behalf totaling approximately \$0.6 million. We have agreed to reimburse BioXcel for this amount upon the earlier of (i) 30 days after the completion of this offering and (ii) December 31, 2018. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Separation and Shared Services Agreement with BioXcel" for additional information.

### **Basis of Presentation**

For periods prior to incorporation and through June 30, 2017, our financial statements are presented on a carve-out basis from the financial records of BioXcel. The carve-out includes reasonable allocations of assets and liabilities and expenses attributable to our business. For all periods after June 30, 2017, the allocations of assets, liabilities and expenses attributable to our business shall be made at prevailing prices pursuant to the terms of the Services Agreement, as described below.

These results reflect amounts specifically attributable to the BTI Business, which include expenses, assets and liabilities of BioXcel relating to the Candidates that were contributed to us by BioXcel under the Contribution Agreement for the period from January 1, 2015 until March 29, 2017 (date of incorporation) and further until June 30, 2017. The Services Agreement provides us with certain general and administrative and development support services that became effective June 30, 2017. However, consistent with accounting regulations, we have assumed that we were a separate business within BioXcel and we have reflected the related assets, liabilities and expenses in our results for periods prior to and post incorporation. These financial statements are presented on a carve-out basis and have been derived from the financial statements and accounting records of BioXcel and include reasonable allocations for assets and liabilities and expenses attributable to the business of the product candidates that were contributed.

Management believes the assumptions underlying the allocations of indirect expenses in the carve-out financial information are reasonable, however, our financial position, results of operations and cash flows may have been materially different if it had operated as a stand-alone entity as of and for the fiscal year ended December 31, 2016 and 2015, and for the six months periods ended June 30, 2017 and 2016.

We have calculated our income tax amounts using a separate return methodology and we have presented these amounts as if we were a separate taxpayer from BioXcel for the period since the date of incorporation (March 29, 2017). BioXcel is a standalone S corporation and its tax obligations were passed through to its shareholders and were not a liability of the S corporation. As a result, BioXcel did not require a tax provision for federal or state purposes. Therefore no taxes have been allocated to the financials of the Company which is derived from a carve-out process from the financials of BioXcel. Pursuant to our incorporation as a C corporation, BioXcel became our sole owner and contributed the BTI Business in a tax free transaction. From the date of incorporation, we have been a standalone C corporation subject to corporate income tax and the deferred tax and assets have been calculated accordingly.

We consider our expense methodology and results to be reasonable for all periods we present. However, our allocations may not be indicative of the actual expenses we would have incurred had we operated as an independent, publicly traded company for the periods we present.

### **Components of Our Results of Operations**

### Revenues

We have not recognized any revenue since inception.

### **Operating Costs and Expenses**

### Research and Development

Research and development expenses consist primarily of costs incurred for the research and development of our preclinical and clinical candidates, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred towards consultants, laboratories and investigators that conduct our preclinical research activities;
- the cost of acquiring, developing and manufacturing pre-clinical trial materials and lab supplies; and
- depreciation and other expenses.

We expense research and development costs to operations as incurred. Historically we have not segmented costs associated with our various development programs. The carve-out financials represent the business involving the BTI Business. However, beginning January 1, 2018, we will assign costs to our individual development candidates.

As of June 30, 2017, we had incurred an aggregate of approximately \$2.3 million in research and development expenses related to the development of BXCL501 and BXCL701. We expect that our research and development expenses will increase as we plan for and commence our clinical trials of BXCL501, which we expect to begin in the first half of 2018, and BXCL701, which we also expect to commence in the first half of 2018.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of these or other current or future clinical trials of BXCL501, BXCL701 or our other product candidates. We may never succeed in achieving regulatory approval for BXCL501, BXCL701 or any of our other product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

### General and Administrative

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance and administration, corporate development and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses include accounting and legal services, the cost of various consultants, occupancy costs and information systems costs.

We expect that our general and administrative expenses will increase as we operate both as an independent entity and as a public company. We expect increased administrative costs resulting from our anticipated clinical trials and the potential commercialization of our product candidates. We believe that these increases will likely include increased costs for director and officer liability insurance, hiring additional personnel to support future market research and future product commercialization efforts and increased fees for outside consultants, attorneys and accountants. We also expect to incur increased costs to comply with corporate governance, internal controls, investor relations and disclosures and similar requirements applicable to public companies.

### Financial Operations Overview and Analysis for the Years Ended December 31, 2016 and 2015

(in thousands, except percentages)	Years         Increase           Ended         Increase           December 31,         (Decrease)           2016         2015         \$ %			
Revenues	\$ —	\$ —	\$ —	
Operating costs and expenses				
Research and development	1,399	233	1,166	500%
General and administrative	721	403	318	79%
Total operating expenses	2,120	636	1,484	
Net loss	\$ (2,120)	\$ (636)	\$ (1,484)	

### **Research and Development Expense**

Research and development expenses increased approximately \$1.2 million, or 500%, from \$233,000 for the year ended December 31, 2015 to \$1.4 million for the year ended December 31, 2016. The increase was primarily attributable to a \$371,000 increase in compensation expenses and corresponding non-cash stock-based compensation charges of \$454,000. The increases were a direct result of a greater percentage of BioXcel's personnel resources being allocated to us to reflect an increased level of work done on our product candidates. In addition there was a \$340,000 increase in consulting fees for therapeutic area experts.

### General and Administrative Expense

General and administrative expenses increased approximately \$318,000, or 79%, from \$403,000 for the year ended December 31, 2015 to \$721,000 for the year ended December 31, 2016. The increase was primarily attributable to an increase in employee compensation of \$20,000 and a corresponding increase in non-cash stock-based compensation of \$37,000. These compensation related increases represent additional administrative time allocated to us by BioXcel to support our increased business activity. In addition, we incurred increases in travel, professional and consultants fees and other expenses totaling \$261,000.

### Financial Operations Overview and Analysis for the Six Months Ended June 30, 2017 and 2016

	Six Months			
	Ended June 30, Increase			se
	(unaudited) (Decrease		se)	
(in thousands, except percentages)	2017	2016	\$	%
Revenues	\$ —	\$ —	\$ —	
Operating costs and expenses				
Research and development	645	650	(5)	(1)%
General and administrative	449	367	82	22%
Total operating expenses	1,094	1,017	77	
Net loss	\$ (1,094)	\$ (1,017)	\$ (77)	

### **Research and Development Expense**

Research and development expenses decreased approximately \$5,000, or 1%, from \$650,000 for the six months ended June 30, 2016 to \$645,000 for the six months ended June 30, 2017. The decrease was primarily attributable to a \$52,000 decrease in stock-based compensation allocated from the parent that was mainly due to the completion of the vesting of certain options in 2016. This was partially offset by \$38,000 increase in compensation expenses due to the allocation of a higher percentage of BioXcel personnel resources for increased work performed on our product candidates. In addition there was an increase in drug development expenses of \$9,000.

#### General and Administrative Expense

General and administrative expenses increased approximately \$82,000, or 22%, from \$367,000 for the six months ended June 30, 2016 to \$449,000 for the six months ended June 30, 2017. The increase was primarily attributable to a \$100,000 increase in general marketing expenses, conference fees, legal, professional, accounting and consultant's fees. In addition, there was an increase in compensation expenses of \$40,000 due to higher a percentage and increased cost of salaries allocated to us by BioXcel. This was partially offset by an \$58,000 decrease in stock-based compensation allocated to us mainly due to completion of the vesting of certain options in 2016.

### Liquidity and Capital Resources

We reported a loss of approximately \$1.1 million for the six months ended June 30, 2017 and a loss of approximately \$2.1 million for the year ended December 31, 2016. At June 30, 2017, our accumulated deficit amounted to approximately \$1.0 million. We had a working capital deficit of \$1.0 million as of June 30, 2017 and a working capital deficit of \$0.3 million as of December 31, 2016.

As of June 30, 2017, we had cash and cash equivalents of \$285,000.

We have not yet generated any revenues and we have not yet achieved profitability. These conditions raise substantial doubt about our ability to continue as a going concern. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need to generate significant product revenues to achieve profitability. We may never achieve profitability.

### Sources of Liquidity

Since our inception, until the date of incorporation, all our operations have been financed by our Parent, BioXcel, in the form of net Parent investment. For the period from inception (March 29, 2017)

until June 30, 2017 (effective date of the Services Agreement), our operations have been financed through \$0.6 million in advances from BioXcel. Such advances are payable to BioXcel upon the earlier of (i) 30 days after the completion of this offering, (ii) ten days after receiving funding of at least \$5,000,000 other than through an IPO and (iii) December 31, 2018. On June 30, 2017, BioXcel agreed to provide us a line of credit of \$1 million, pursuant to the terms of the Grid Note. The Grid Note shall be payable upon the earlier of (i) the completion of this offering and (ii) December 31, 2018, together with interest on the unpaid balance of each advance made under the Grid Note, which shall accrue at a rate per annum equal to the applicable federal rate for short-term loans as of the date hereof, in each case calculated based on a 365-day year and actual days elapsed. As of June 30, 2017, we have drawn an amount of \$285,000 under the Grid Note. We had no other source of funds through June 30, 2017.

Our cash and cash equivalents as of June 30, 2017 do not reflect the following transactions that occurred in the third and fourth quarter of 2017: (i) proceeds from issue of common shares amounting to \$0.7 million in September 2017 and (ii) proceeds from the issuance of common shares amounting to \$1.3 million in October 2017.

### Cash Flows

	Ended E		Ended J	Months d June 30, audited)				
(in thousands)		2016	_	2015		2017		2016
Cash provided by (used in) in thousands								
Operating activities	\$	(1,294)	\$	(280)	\$	(776)	\$	(632)
Investing activities		(4)		(1)				—
Financing activities		1,298		281		1,061		632

### **Operating Activities**

For the year ended December 31, 2016, net cash used in operating activities was approximately \$1.3 million, which consisted of a net loss of \$2.1 million partially offset by an increase of \$671,000 in stock-based compensation and an increase in accounts payables and accrued expenses of \$156,000.

For the year ended December 31, 2015, net cash used in operating activities was approximately \$280,000, which consisted of a net loss of \$636,000 partially offset by an increase of \$182,000, in stock-based compensation and an increase in accounts payables and accrued expenses of \$175,000.

For the six months ended June 30, 2017, net cash used in operating activities was approximately \$776,000, which consisted of a net loss of \$1.1 million, offset by an increase in accounts payable and accrued expenses of \$116,000 and an increase in stock-based compensation of \$200,000.

For the six months ended June 30, 2016, net cash used in operating activities was approximately \$632,000, which consisted of a net loss of \$1.0 million partially offset by \$312,000 of stock-based compensation, an increase in accounts payables of \$82,000 and an increase in prepaid expenses and other current assets of \$9,000.

### **Investing Activities**

Net cash used in investing activities for the years ended December 31, 2016 and 2015 was \$4,000, and \$1,000, respectively and consisted primarily of purchase of computer equipment.

We had no significant investing activities during the six months ended June 30, 2017, and June 30, 2016 respectively or the year ended December 31, 2015.

# **Financing Activities**

Net cash provided by financing activities for the year ended December 31, 2016 was approximately \$1.3 million. The net cash provided by financing activities during this period was attributable to investments made by BioXcel.

Net cash provided by financing activities for the year ended December 31, 2015 was \$281,000. The net cash provided by financing activities during this period was attributable to the investments made by BioXcel.

Net cash provided by financing activities for the six months ended June 30, 2017 was approximately \$1.1 million. The net cash provided by financing activities during this period was attributable to the investment made by BioXcel prior to our incorporation of \$214,000, due to BioXcel of \$562,000 for expenses from date of incorporation to June 30, 2017 and \$285,000 drawn by us from the line of credit from BioXcel.

Net cash provided by financing activities for the six months ended June 30, 2016 was approximately \$632,000. The net cash provided by financing activities during this period was primarily attributable to an investment made by the Parent.

### **Operating Capital and Capital Expenditure Requirements**

We believe that the net proceeds of this offering, together with our existing cash, will be sufficient to fund our operations until . We are required to repay the amounts due to BioXcel from the proceeds of this offering for the amounts borrowed under the Grid Note and the amounts due to BioXcel pursuant to the Services Agreement.

We expect to continue to incur significant and increasing operating losses at least for the next several years as we commence our clinical trials of BXCL501 and BXCL701, seek marketing approval for our product candidates and pursue development of our other product candidates. We do not expect to generate revenue unless and until we successfully complete development and obtain regulatory approval for our product candidates. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials and our expenditures on other research and development activities.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. We anticipate that our expenses will increase substantially as we:

- commence our clinical development of BXCL501 and BXCL701;
- conduct additional research and development with our product candidates;
- seek to identify, acquire, develop and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval; and
- begin to operate as a public company.

We expect that we will need to obtain substantial additional funding in order to complete our clinical trials. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development or commercialization of BXCL501, BXCL701 or other product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to BXCL501, BXCL701 or other product candidates that we otherwise would seek to develop or commercialize ourselves.

### **Contractual Obligations**

As on June 30, 2017, there were contingent payments to materials manufacturers for \$460,000 toward supply of clinical candidate materials.

#### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under Securities and Exchange Commission rules.

### **Critical Accounting Policies**

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to exercise its judgment. We exercise considerable judgment with respect to establishing sound accounting policies and in making estimates and assumptions that affect the reported amounts of our assets and liabilities, our recognition of revenues and expenses, and disclosure of commitments and contingencies at the date of the financial statements.

On an ongoing basis, we evaluate our estimates and judgments. We base our estimates and judgments on a variety of factors including our historical experience, knowledge of our business and industry, current and expected economic conditions, the attributes of our products, the regulatory environment, and in certain cases, the results of outside appraisals. We periodically re-evaluate our estimates and assumptions with respect to these judgments and modify our approach when circumstances indicate that modifications are necessary.

While we believe that the factors we evaluate provide us with a meaningful basis for establishing and applying sound accounting policies, we cannot guarantee that the results will always be accurate. Since the determination of these estimates requires the exercise of judgment, actual results could differ from such estimates.

A description of significant accounting policies that require us to make estimates and assumptions in the preparation of our financial statements is as follows:

### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates.

For periods prior to and post incorporation, these financial statements are presented on a carve-out basis and include the financial statements of the Company and financial information derived from the financial statements and accounting records of BioXcel which include reasonable allocations for assets and liabilities and expenses attributable to the BTI Business of product candidates that were contributed.

Accordingly, the historical financial information for the fiscal years ended December 31, 2016 and 2015 and for the six months ended June 30, 2017 and June 30, 2016 have been carved-out of the financial statements of BioXcel. Such financial information is limited to our business activities, assets and liabilities only.

The contribution of the clinical assets by BioXcel to us was deemed a transaction between entities under common control and the business acquired was recorded using the carryover book value of BioXcel. BioXcel recorded such product candidates at a zero-historical cost basis, and therefore they are recorded at a zero basis on our books. The historical financial statements have been presented on a basis that includes the results attributable to the business contributed from BioXcel as if we owned the business for all periods presented.

### **Research and Development**

Research and development expenses are expensed as incurred. Patent costs and patent acquisition costs are expensed as incurred, and included in general and administrative expenses.

### Stock-based Compensation

The financial statements include certain expenses of BioXcel that were carved-out for stock-based compensation based on the percentage of the expense attributable to BTI related activities.

We account for stock-based compensation in accordance with ASC 718, "Compensation—Stock Compensation," which requires the measurement and recognition of compensation expense based on estimated fair market values for all share-based awards made to employees and directors, including stock options. Our stock-based compensation plan was adopted in August 2017 and was not effective for the periods covered by the financial statements.

Our parent, BioXcel, has granted stock options to its employees under its own Equity Incentive Plan. Stock-based compensation expense from the BioXcel plan is allocated to us over the required service period over which those stock option awards vest and are based the on time spent for our activities compared to BioXcel activities which is the same basis used for allocation of salary costs.

The BioXcel stock option awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. The estimated fair value of these BioXcel stock option awards was determined using the Black Scholes option pricing model on the date of grant. Significant judgment and estimates were used to estimate the fair value of these awards, as they are not publicly traded.



Total compensation, inclusive of base salary, fringe benefits and share-based compensation are charged to us at actual cost determined based upon the relative percentage of time utilized on our matters. A significant component of total compensation relates to the stock options issued by BioXcel. As such, because the awards are not based on our shares, they are re-measured at fair value at each reporting period until the awards vest. Significant judgment, estimates and pricing models were used to estimate the fair value of these awards, as the underlying shares in BioXcel are not publicly traded. Our estimation of fair value of the awards considered recent transactions entered into by BioXcel, relevant industry and comparable public company data. Since BioXcel is a non-public entity, the majority of the inputs used to estimate the fair value of the common stock option awards are considered level 3 due to their unobservable nature. Each option award is subject to specified vesting schedules and requirements (a mix of time-based, performance-based and corporate event-based, including financing events). Compensation expense will be charged to us by BioXcel over the required service period to earn the award which is expected to be up to four years, subject to the achievement of performance and event-based vesting requirements. For the years ended December 31, 2016 and 2015 we have incurred share-based compensation expense of \$671,000 and \$182,000, respectively. For the six months ended 30, 2017 and June 30, 2016 our share based compensation expense in our statement of operations.

### 2017 Equity Incentive Plan

Our board of directors adopted the 2017 Equity Incentive Plan, or the Plan, on August 22, 2017. The Plan will expire on August 22, 2027. The purpose of the Plan is to attract and retain key personnel and to provide a means for directors, officers, managers, employees, consultants and advisors to acquire and maintain an interest in our company, which interest may be measured by reference to the value of its common stock. The details of the Plan are explained in the "Executive and Director Compensation" section.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board, or FASB, issued *ASU 2014-09 Revenue form Contracts with Customers*. Under this guidance on the recognition of revenue from customers. Under this guidance, an entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects what the entity expects to receive in exchange for the goods or services. This new guidance also requires more detailed disclosures to enable users of the financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The Company will adopt this guidance beginning on January 1, 2018. The guidance allows selection one of two methods of adoption, either the full retrospective approach, meaning the guidance would be applied to all periods presented, or modified retrospective approach, meaning the cumulative effect of applying the guidance would be recognized as an adjustment to opening accumulated deficit balance. Since the Company has no revenue to date, the Company does not believe the adoption of ASU 2014-09 will have a material impact on its financial statements.

In August 2014, the FASB issued *ASU 2014-15 Disclosures of Uncertainties around an Entity's Ability to Continue as a Going Concern.* This ASU requires management to determine whether substantial doubt exists regarding the entity's going concern presumption, which generally refers to an entity's ability to meets its obligations as they become due. If substantial doubt exists but is not alleviated by management's plan, the footnotes must specifically state that "there is substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued." In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose (a) principal conditions or events that raise substantial doubt about the entity's ability to consideration of management's plans, if any); (b) management's

evaluation of the significance of those conditions or events in relation to the entity's ability to meet its obligations; and (c) management's plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity's ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management's plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The Company has adopted the provisions of ASU 2014-15 beginning January 1, 2016.

In February 2016, the FASB issued *ASU 2016-02 Lease Accounting Topic 842*. This ASU requires us to record all leases longer than one year on our balance sheet. Under the new guidance, when the Company records leases on its balance sheet under it will record a liability with a value equal to the present value of payments it will make over the life of the lease and an asset representing the underlying leased asset. The new accounting guidance requires the Company to determine if its leases are operating or financing leases, similar to current accounting guidance. The Company will record expense for operating type leases on a straight-line basis as an operating expense and it will record expense for finance type leases as interest expense. The new lease standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company must adopt the new standard on a modified retrospective basis, which requires it to reflect its leases on its balance sheet for the earliest comparative period presented. The Company is currently assessing the timing of adoption as well as the effects it will have on its financial statements and disclosures.

In March 2016, the FASB ASU 2016-09, *Compensation- Stock Compensation* simplifying certain aspects of share-based payment accounting. Under the amended guidance, the Company will recognize excess tax benefits and tax deficiencies as income tax expense or benefit in its statement of operations on a prospective basis. As the Company has a valuation allowance, this change will impact the Company's net operating loss carryforward and the valuation allowance disclosures. Additionally, the Company will classify excess tax benefits as an operating activity and classify amounts the Company withholds in shares for the payment of employee taxes as a financing activity on the statement of cash flows for each period presented. The amended guidance allows the Company to account for forfeitures when they occur or continue to estimate them. The Company will continue to estimate its forfeitures. The Company adopted this guidance on January 1, 2017. The amended guidance did not impact its financial results.

### **Quantitative and Qualitative Disclosure About Market Risk**

Our primary exposure to market risk is interest expense sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of Grid Note payable, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our note payable.

We do not believe that our cash has significant risk of default or illiquidity. While we believe our cash does not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash at one or more financial institutions that are in excess of federally insured limits.

Our balance sheet as of June 30, 2017 includes cash of \$0.3 million. We do not participate in any foreign currency hedging activities and we do not have any other derivative financial instruments. We did not recognize any significant exchange rate losses during the year ended December 31, 2016 or the six months ended June 30, 2017.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented.

# JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to opt out of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition periods for complying with new or revised accounting standards is irrevocable.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

### BUSINESS

### Overview

BioXcel Therapeutics, Inc., or BTI, is a clinical stage biopharmaceutical company focused on drug development that utilizes novel artificial intelligence, or AI, to identify the next wave of medicines across neuroscience and immuno-oncology. Our 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. We believe that this differentiated approach has the potential to reduce the cost and time of drug development in diseases with substantial unmet medical need. Our two most advanced clinical development programs are BXCL501, a sublingual thin film formulation of the a<sub>2a</sub> adrenergic receptor agonist dexmedetomidine, or Dex, for acute treatment of agitation resulting from neurological and psychiatric disorders, and BXCL701, an immuno-oncology agent for treatment of a rare form of prostate cancer and pancreatic cancer. We intend to commence Phase 2 proof of concept, or PoC, open label clinical trials in 2018 for both programs. We expect that a data readout from the planned Phase 2 PoC open label clinical trials for the BXCL501 program will be available by the end of 2018. We intend to initiate a bridging bioavailability, or BA, and bioequivalence, or BE, study for the sublingual thin film formulation in the second half of 2018 that, if successful, could potentially lead to the start of a registration trial in the first half of 2019. Preliminary data from the planned Phase 2 PoC clinical trials of BXCL701 will be available in the first half of 2019.

We were formed to develop first-in-class, high value therapeutics by leveraging EvolverAI, a research and development engine created and owned by our parent, BioXcel Corporation, or BioXcel. We believe the combination of our therapeutic area expertise and our ability to generate product candidates through our exclusive collaborative relationship with BioXcel in the areas of neuroscience and immuno-oncology gives us a significant competitive advantage. EvolverAI was developed over the last decade and integrates millions of fragmented data points using artificial intelligence and proprietary machine learning algorithms. After evaluating multiple product candidates using EvolverAI, we selected our lead programs because our analysis indicated these drugs may have utility in new therapeutic indices where there is substantial unmet medical needs and limited competition. By focusing on clinical candidates with relevant human data, we believe our approach will help us design more efficient clinical trials, thereby accelerating our product candidates' time to market. We retain global development and commercialization rights to these two programs.

BXCL501 is a potential first-in-class sublingual thin film formulation of Dex designed for acute treatment of agitation in neurodegenerative and psychiatric disorders. Dex has demonstrated a strong safety profile, having been prescribed in millions of patients as the sedative and anesthetic Precedex and has been studied in over 130 clinical trials. BXCL501 is designed to be a non-invasive, easy to administer agent that has a rapid onset of action, which is critical for the acute treatment of agitation. We estimate that over 500,000 patients who suffer from Alzheimer's Disease, or AD, in the United States annually could be eligible for the acute treatment of agitation with BXCL501. In schizophrenia and bipolar disease, we estimate that over 600,000 patients in the United States annually could be eligible for the acute treatment of agitation with BXCL501. The current treatment options for agitation utilize antipsychotics and benzodiazepines, which have suboptimal safety and compliance issues. Antipsychotics have a black box warning for use in the elderly and can produce debilitating side effects when given acutely, and should only be considered for invasive intramuscular, or IM, delivery in highly aggressive patients requiring restraint. Benzodiazepines are predominantly in pill form, which require swallowing and can produce excessive sedation. We have designed a dual clinical development program that takes advantage of the U.S. Food and Drug Administration's, or FDA, Section 505(b)(2) regulatory pathway and leverages the existing clinical and safety dataset of intravenous, or IV, formulation of Dex. We plan to initiate two Phase 1b single ascending or descending dose studies of the IV formulation of Dex in mild probable AD by the first half of 2018 and schizophrenia patients in

the first half of 2018, followed by PoC open label clinical trials, from both of which we expect to report data by the second half of 2018. We intend to initiate a bridging BA/BE study with the sublingual thin film formulation in the second half of 2018 that, if successful, could potentially lead to the start of a registration trial in the first half of 2019.

BXCL701 is a potential first-in-class, highly potent, oral small molecule immuno-modulator that is designed to stimulate both the innate and acquired immune systems by inhibiting dipeptidyl peptidase, or DPP, 8/9 and fibroblast activation protein, or FAP. DPP 8/9 have been show recently to behave as an "immuno-checkpoint" of the immune system, as their inhibition results in a potent pro-inflammatory, anti-tumor activity by way of the induction of cell death in the macrophages and the downstream stimulation of multiple tumor-killing immune cells. BXCL701 is differentiated among DPP inhibitors because it is designed to inhibit DPP 8/9 and FAP, whereas most other clinical stage DPP inhibitors, which have been developed to treat diabetes, are selective for DPP 4. BXCL701 has been tested in more than 700 healthy subjects and cancer patients across multiple clinical trials, exhibiting a tolerable safety profile, proof of mechanism, and single agent anti-tumor activity in patients with melanoma, an immuno-sensitive tumor. We believe that we can leverage this clinical data to determine the dose to use in future clinical trials and support accelerated clinical development. BXCL701 is a potential novel therapy for treatment-emergent neuroendocrine prostate cancer, or tNEPC, a segment of prostate cancer patients that have progressed on second-generation androgen inhibitors (Zytiga and Xtandi), and is also a potential treatment for pancreatic cancer, both of which are rare diseases. We selected tNEPC and pancreatic cancer as our lead indications after evaluating more than 100 different tumor types because they are two of the top three cancers that overexpressed or amplified DPP 8/9 and FAP. Additional data points to a functional role of DPP 8/9 in the biology of tNEPC. The combined global sales of Zytiga and Xtandi were over \$4.5 billion in 2016 and about one in three patients on these drugs are expected to develop tNEPC and be eligible for treatment with BXCL701. In pancreatic cancer, we estimate that approximately 20,000 patients will be eligible for treatment with BXCL701 annually. Based on our analysis, we believe that BXCL701 may establish a differentiated immuno-oncology platform by modulating multiple steps in the cancer immunity cycle, and in combination with checkpoint inhibitors can convert immuno-resistant tumors to immuno-sensitive tumors ("cold" to "hot" tumors). We plan to initiate two Phase 2 PoC open label clinical trials in the second half of 2018, as a single agent and in combination with Keytruda in patients with tNEPC, and in combination with Keytruda in pancreatic cancer. We expect to receive preliminary data in the first half of 2019 and intend to pursue breakthrough therapy designation and accelerated approval pathways for both indications. BXCL701 has received orphan drug designation by the FDA for the treatment of pancreatic cancer. We believe BXCL701 represents a disruptive platform in the field of immuno-oncology with the potential to create a transformative commercial franchise in multiple tumor indications.

Furthermore, we are growing our pipeline with additional development candidates by leveraging our management team's therapeutic area expertise with EvolverAI. We are also exploring development of BXCL502, a novel approach to the treatment of symptoms resulting from neurological disorders, and BXCL702, an immuno-oncology agent targeting hematological malignancies for which we have received orphan drug designation from the FDA for the treatment of acute myeloid leukemia, or AML. We retain global development and commercialization rights to these two programs. We intend to select our next clinical program in 2018 from our emerging or future programs.

We have assembled a management team with extensive experience in the discovery, development and approval of more than 10 drugs and who have held senior executive roles at leading pharmaceutical companies. We are supported by our experienced board of directors and advisory board, which includes Drs. Peter Mueller (Vertex, Boehringer Ingelheim), Steven Paul (Voyager Therapeutics, Sage Therapeutics, Eli Lilly) and Sheila Gujrathi (Receptos, Bristol-Myers Squibb, Roche), who contribute to our strategy with their expertise in building public companies. We believe

that our team is ideally positioned to leverage our highly differentiated platform to develop the next wave of innovative medicines.

### **Our Clinical Programs**

The following table summarizes our lead development programs:

Program	Product Candidate	Phase 1/2	Phase 3	Anticipated Milestones	Worldwide Rights	
Acute	BXCL501	Geriatric Dementia IV Dexmedetomidine		<ul> <li>Initiate Phase 1b trials (1H 2018)</li> <li>Trial data readouts</li> </ul>		
(Selective Agitation Adrenergic R Agonis		Schizophrenia IV Dexmedetomidine	BA/BE*	(2H 2018) • Launch registration trials (1H 2019)	therapeutics	
lmmuno-	BXCL701	Neuroendocrine Prostate Cancer (tNEPC)		<ul> <li>Initiate Phase 2 trials (2H 2018)</li> <li>Preliminary readouts</li> </ul>		
oncology	(DPP 8/9 & FAP Inhibitor)	Pancreatic Cancer		<ul> <li>Preliminary readouts (1H 2019)</li> <li>Final PoC readout (2H 2019)</li> </ul>	- merupeunca	
Emerging	BXCL502	Neurodegeneration		Selection of clinical	had boost	
		Hematological Malignancies		program	therapeutics	

Bridging bioavailability/bioequivalence (BA/BE) study for optimizing BXCL501 sublingual thin film dose for Phase 3 registration trials

# **Our Strategy**

Our goal is to become a leader in the field of neuroscience and immuno-oncology. The key elements to achieving this goal are to:

- Advance BXCL501, a sublingual thin film formulation of Dex, a selective a<sub>2a</sub> adrenergic receptor agonist, designed for acute treatment of agitation, to approval through an accelerated FDA Section 505(b)(2) pathway.
  - **Neurological Disorders.** We believe that BXCL501 has the potential to become the standard of care for the acute treatment of agitation arising from diseases such as AD. 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. We plan to initiate a Phase 1b single ascending and descending dose study of the IV formulation of Dex for evaluating pharmacokinetic/pharmacodynamic, or PK/PD, and safety in mild probable AD patients in the first half of 2018, followed by a PoC open label clinical trial, both of which we expect to report data in the second half of 2018. We also intend to initiate a bridging BA/BE study in the second half of 2018 and potentially initiate a registration trial in the first half of 2019.
  - **Psychiatric Disorders.** We intend to follow a similar development strategy for the acute treatment of agitation in schizophrenia. We plan to conduct a Phase 1b single ascending and descending dose study of the IV formulation of Dex for evaluating PK/PD and safety in



schizophrenia patients being treated with atypical antipsychotics. We expect these studies to begin in the first half of 2018, and will commence a PoC open label clinical trial in agitated schizophrenia patients in the second half of 2018. We intend to initiate a bridging BA/BE study in the second half of 2018 that, if successful, could potentially lead to the start of a registration trial in the first half of 2019.

• Additional Indications. We also plan to expand into additional indications for acute treatment of agitation resulting from delirium, alcohol or opiate withdrawal, and post-traumatic stress disorder, or PTSD, as well as explore the use of BXCL501 in patients who are claustrophobic and anxious awaiting an MRI.

# Advance BXCL701 into Phase 2 trials to assess its potential to be the first approved therapy for tNEPC and for the treatment of pancreatic cancer.

- **tNEPC (Orphan Segment of Prostate Cancer).** BXCL701 was previously studied in multiple clinical trials and demonstrated single agent anti-tumor activity in melanoma, an immuno-sensitive tumor. In our preclinical studies, BXCL701 has demonstrated the ability to synergistically increase the anti-tumor activity of checkpoint inhibitors. We believe the existing preclinical and clinical data for BXCL701 may significantly reduce our development time for this compound. We plan to initiate a Phase 2 PoC open label clinical trial in the second half of 2018, as a single agent and in combination with Keytruda in patients with tNEPC.
- **Pancreatic Cancer.** Data indicates that fibroblast activation protein positive, or FAP+, cells contribute to checkpoint inhibitor resistance in pancreatic cancer, which we believe provides a strong rationale for combining BXCL701 with Keytruda. BXCL701 has been granted orphan drug designation by the FDA for the treatment of pancreatic cancer. We believe the existing clinical and preclinical data for BXCL701 in pancreatic cancer may reduce our development time for this compound. We are planning to initiate clinical development of BXCL701 in pancreatic cancer in the second half of 2018 in collaboration with the Lombardi Cancer Center, starting with a mechanistic study in the neoadjuvant setting (before surgery) followed by an efficacy study in pretreated metastatic patients in combination with Keytruda.
- **Potential for Accelerated Clinical and Regulatory Approval.** Given that both indications have high unmet medical needs and limited or no treatment options, we intend to pursue breakthrough therapy designation and accelerated approval pathways for both indications.
- Additional Indications. We believe BXCL701 is active at multiple stages of the cancer immunity cycle. As such, we believe BXCL701 offers a "pipeline in a product" platform given its potential application across other solid tumor types. We believe existing preclinical and clinical evidence support BXCL701's combination potential with checkpoint inhibitors, programmed cell death protein 1, or PD1, or programmed cell death-ligand 1, or PD-L1, inhibitors, antibody-dependent cell-mediated cytotoxicity, or ADCC, antibodies, and cellular therapies such as chimeric antigen receptor T-cell therapy, or CAR-T, for solid tumors and therapeutic vaccines.

**Identify biomarkers to select patients who have the highest likelihood to respond to our product candidates.** Predicting optimal drug responses in patients requires the identification and validation of predictive biomarkers, specifically in cancer. We believe that our ability to identify patient subsets most likely to respond to our product candidates will increase the clinical benefit to patients and improve the probability of success of our clinical trials. The indications for our lead product candidate BXCL701 were chosen in part because they are known to overexpress DPP 8/9 and FAP. Our planned PoC clinical trial of BXCL701 will examine biomarkers related to its molecular and cellular targets to identify those that may correlate with clinical efficacy and increase our likelihood of success. We are planning to use a similar biomarker-driven approach for future product candidates, including BXCL702.



- Enhance our R&D pipeline by leveraging our therapeutic area expertise with EvolverAI to identify, develop and commercialize new product candidates in neuroscience and immuno-oncology. In addition to our leading clinical programs and our emerging and future pipeline, we intend to select our next clinical program during 2018. We have established translational and development expertise, which we believe will help us advance the present and future product candidates in these fields. We may also opportunistically in-license additional product candidates identified through our AI platform approach within our core areas of expertise.
- **Maximize the commercial potential of our product candidates.** We have worldwide development and commercialization rights to our BXCL501, BXCL701, BXCL502 and BXCL702 product candidates. If BXCL501 and BXCL701 are approved in the United States, we would consider building a specialty sales force in the United States and/or collaborate with third parties to maximize the potential of our product candidates. Furthermore, we intend to commercialize BXCL501 and BXCL701 outside the United States through collaborations with third parties.

### Management, Board and Advisors Experience

Our management team, board members and advisors are industry veterans having combined experience of more than 150 years in drug discovery, development, business development and commercial leadership in neuroscience and oncology and they have been responsible for the development and approval of more than 10 drugs.

Our co-founder and Chief Executive Officer, Vimal Mehta, Ph.D., is a serial entrepreneur who brings over two decades of experience in launching new ventures, corporate strategy and financing, and global partnering including licensing and M&A transactions. Our Chief Scientific Officer, Frank Yocca, Ph.D., brings over three decades of experience in strategy, discovery and development focused on psychiatry, central nervous system, or CNS, and pain at AstraZeneca and Bristol-Myers Squibb where he played a key role in the development of commercialized products including Abilify, BuSpar and Serzone. Our Chief Medical Officer, Vince O'Neill, M.D., brings over two decades of oncology therapeutic and diagnostic product development experience at Sanofi, Genentech and GlaxoSmithKline where he was instrumental in the expanded approval of Genentech's Avastin and Tarceva and the approval of GSK's Mekinist. Our Vice President—Oncology R&D, Luca Rastelli, Ph.D., brings over two decades of drug discovery and development experience in oncology at several companies including CuraGen and EMD Serono, where he played a key role in the novel immuno-oncology anti-PD-L1 Bavencio and discovery of the anti-transmembrane glycoprotein NMB antibody Glembatumumab vedotin. Our Chief Financial Officer, Richard Steinhart, brings over three decades of financial experience at a number of public and private companies in the healthcare industry including Remedy Pharmaceuticals, Inc., MELA Sciences, Inc. and Emisphere Technologies, Inc.

Our Chairman, Dr. Peter Mueller, has a career spanning more than 30 years in executive leadership roles at Vertex Pharmaceuticals and Boehringer Ingelheim where he played a key role in the development of several approved drugs, including Orkambi, Kalydeco, Incivek, Spiriva and Atrovent. Dr. Mueller and his development teams were awarded the prestigious Galenus Preis (Kalydeco—Europe) and Prix Galien (Incivek—US) industry awards recognizing their contributions in cystic fibrosis and Hepatitis C, among others. Our advisor Dr. Steven Paul is President and CEO of Voyager Therapeutics and brings more than three decades in CNS drug discovery and development to support our neuroscience program. Our advisor Dr. Sheila Gujrathi most recently served as Chief Medical Officer of Receptos and brings over two decades of experience in drug discovery, clinical development and commercial leadership in oncology and immunology to our oncology program.

### **Our Novel Drug Re-Innovation Approach**

Our AI-based discovery and development process is the foundation of our drug re-innovation model for identifying the next wave of medicines. Our therapeutic area experts have over 60 years of experience across the drug discovery and development value chain. We believe the combination of our therapeutic area expertise and our ability to generate therapeutic candidates in neuroscience and immuno-oncology through our exclusive collaborative relationship in those areas with BioXcel gives us a significant competitive advantage.

The pharmacological space spans more than 27,000 active pharmaceutical agents and only around 4,000 are approved and marketed drugs benefiting patients. These marketed drugs may be applied to other indications, including rare diseases, and represent an untapped potential for meeting significant unmet medical need and recoupment of research and development investments. A large number of the remaining agents are clinical candidates that are active, shelved or have failed for reasons other than toxicity and can potentially be re-engineered for different indications or patient segments. They potentially represent an unrealized investment of billions of research and development dollars by the private and public sectors, resulting in an immeasurable amount of patient suffering and sacrificing during clinical development.

Traditional drug development is plagued with low success rates (11.3%, according to Tufts Center for the Study of Drug Development White Paper, 2015), long drug development cycles (10-15 years, according to PhRMA Key Facts 2016) and exorbitant development costs (\$2.6 billion per drug, according to PhRMA Key Facts 2016). Furthermore, many serious diseases continue to go unaddressed due to limitations of the current drug discovery paradigm. The recent advent of numerous 'omics' technologies (genomics, proteomics) and rapid advances in science and medicine are generating terabytes of valuable unexploited knowledge that is widely distributed in multiple big data lakes with several orders of complexity and variety. Much of this data is not being systematically applied to the development of next-generation therapeutics, thus preventing the optimization of drug development utilizing the understanding of technology, science, medicine, markets and commercial opportunities. The efficient and intuitive use of big data remains a bottleneck and a challenge to the pharmaceutical industry. Taken together, these factors underscore the need for fundamental new approaches to drug discovery and development. The market opportunity to identify new uses for existing pharmacological agents remains substantial, due to the lack of technology-driven insights. Our parent, BioXcel, has created a proprietary R&D engine, EvolverAI, for drug re-innovation that provides a proprietary systems-based approach designed to unlock the hidden value in drugs. The combination of our therapeutic area expertise and our exclusive collaborative relationship with BioXcel enables us to screen, analyze, and identify the product candidates that we believe have a high likelihood of benefiting patients. The compounds in our pipeline have been identified using this proprietary platform.

EvolverAI is designed to eliminate human bias by scanning millions of data points from disparate data sources to create network maps. The nodes and connections in the network map are weighted and ranked based on the validity of supporting evidence using disease specific algorithms. They are then further analyzed using artificial intelligence and machine learning approaches supplemented by human domain-based expertise to uncover novel connections between disease parameters, molecular targets, mechanisms of actions and product candidates.

This drug re-innovation model is exemplified by the successful development and commercialization of drugs such as Tecfidera (Biogen, Inc.), Thalomid (Celgene Corporation) and Viagra (Pfizer, Inc.). All of these drugs were identified by insights in biology and disease pathophysiology. The successful business models of biotech companies like Puma Biotechnology, Inc. and Corvus Pharmaceuticals, Inc. are based on the re-innovation of existing clinical candidates or marketed drugs to provide novel solutions for patients. Unfortunately, such discoveries have been severely limited in scope due to the lack of a genuinely integrated big data analytics based approach.

We believe that only EvolverAI allows a comprehensive and unbiased evaluation of the complete pharmacological space. Our drug portfolio was identified using EvolverAI and the lead programs were chosen among more than 20 compounds selected using this approach. We believe our drug reinnovation model and exclusive collaborative relationship with BioXcel has the potential to reduce the cost and time of drug development, help us design more efficient trials and accelerate our product candidates' time to market. This assumption is based on capitalizing product candidates with substantial clinical data and mitigated risk due to well-defined safety profiles, known PK/PD properties, and an established manufacturing and regulatory path.

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

### Agitation Overview and Market Opportunity

Agitation is a common symptom of neurological and psychiatric disorders that currently can only be addressed with invasive treatments in institutional facilities. Agitation is characterized by feelings of unease, excessive talking and/or unintentional and purposeless motions, such as wringing of the hands or pacing. People experiencing agitation may also express excitement, hostility, poor impulse control, tension, uncooperativeness and sometimes disruptive behavior, which could lead to aggression and violence. Often, symptoms of agitation are observed with anxiety or aggressive behavior. In many cases, people develop agitation when treatment for their underlying disorder is not working well. Stressful situations or traumatic events can also trigger agitation. Agitation can occur suddenly or slowly and vary in length, lasting for a few minutes or for an extended period of time.

With the agitation issues associated with schizophrenia and bipolar disease coupled with a fast-growing elderly population, the difficulties and expenses of acute treatment of agitation are expected going to grow significantly. Based on our market research, we estimate that the total U.S. healthcare burden in 2016 for agitation across neuroscience disorders, which includes AD, schizophrenia and bipolar disease and delirium, exceeds \$100 billion annually. Below are estimated statistics associated with BTI's initial indications targeting agitation in AD, schizophrenia and bipolar disease.

U.S. Market for Treating Agitation					
	Alzheimer's Disease	Schizophrenia/Bipolar Disease			
Total Patient Population	5,100,000	8,000,000			
Diagnosed Agitated Patients	~1,000,000 (30%)	~4,000,000 (50%)			
Agitated Patients Receiving Treatment	~525,000 (35%)	~2,000,000 (50%)			
Percent Treatable by BXCL501	100%	33%			
BXCL501 Addressable Market	525,000	660,000			
Estimated Annual Usage Per Patient	24	12			
Potential Addressable Annual Usage	12,840,000	7,920,000			

Figure 1. Statistics for U.S. market for treating agitation.

## Limitations of Current Treatments for Agitation

Despite observed suboptimal safety and side effect profile, antipsychotics are currently used off-label to treat agitation in dementia as well as delirium and are currently the standard of care for the acute treatment of agitation in schizophrenia and bipolar disease. IM delivered antipsychotics, such as haloperidol and risperidone, are used extensively in this setting but are invasive and require patient restraint. Furthermore, these treatments include a black box warning for use in elderly patients. While sublingual tablet formulations utilizing antipsychotics have been developed, these sublingual formulations have long half-lives (21-24 hours) and significant side effects when given either acutely or chronically. Oral agents such as benzodiazepines are also used, but have a slower onset of action and are consequently not effective in the acute treatment of agitation. Side effects of these agents include sedation, amnesia, confusion and a paradoxical response. They can intensify cognitive slowing, cause dependence and can contribute to increased risk of falls and fractures. In addition, long-term use of benzodiazepines has been found to be habit-forming and can cause addiction. Non-adherence with oral agents can also be problematic as patients may attempt to spit out these medications. We believe that based on the current method of administration of oral medicine for agitation, the sublingual thin film offers compliance advantages as it will prevent patients from avoiding treatment.

There is precedent for FDA approval of a non-invasive therapy for the acute treatment of agitation. In 2012, Adasuve, an inhaled version of the antipsychotic loxapine, became the first approved non-invasive acute treatment for agitation in patients with schizophrenia and bipolar disease. The number of hospitals and pharmacies that can administer Adasuve is limited due to a risk of management program, and Adasuve also has a high incidence of side effects. Upon launch, Adasuve was priced at \$145 per dose.

The sublingual route of administration is becoming an accepted alternative to oral administration of drug delivery to the CNS when rapid onset or more controlled delivery is required. Currently, there are six products that are approved for sublingual thin film administration. For example, Cynapsus Therapeutics, Inc. (acquired by Sunovion Pharmaceuticals, Inc.), is a specialty CNS pharmaceutical company that developed a fast-acting, easy-to-use, apomorphine sublingual thin film for the on-demand management of debilitating episodes of tremor associated with Parkinson's Disease. We are in the process of developing a differentiated sublingual thin film dosage form of Dex, which, if approved, may offer benefits such as ease of use and quick absorption for rapid therapeutic effects.



### Figure 2. Visual representation of BXCL501 sublingual thin film administration.

### Our Solution: BXCL501 Potential First-in-Class Sublingual Thin Film for the Acute Treatment of Agitation

BXCL501, a sublingual thin film formulation of the sedative and anesthetic agent Dex, is designed to be easily administered and have a rapid onset of action. We believe that BXCL501, with its differentiated pharmacology and ease of administration, if approved, could potentially be a first-in-class, non-invasive acute treatment for agitation that can be rapidly administered by physicians and caregivers. Dex is approved in the United States for the sedation of initially intubated and mechanically ventilated patients during treatment in the Intensive Care Unit, or ICU. It is also used in the intensive care setting and sedation of non-intubated patients prior to and/or during surgical and other invasive procedures. Dex, launched in the United States as Precedex in 1999, is a selective a<sub>2a</sub> adrenergic



receptor agonist that has a strong safety record and has been studied in over 130 clinical trials to date. It has also been launched in the European Union and multiple other countries under the trade name Dexdor as a sedative for intensive care patients. Dex gained approval by the European Medicines Agency, or EMA, for sedation of adult ICU patients (requiring a sedation level no deeper than arousal in response to verbal stimulation). It has been used to prevent or treat hyperactive delirium resulting from anesthesia in the ICU. Given these uses of the IV formulation of Dex, we believe Dex formulated in a sublingual thin film will allow for ease of administration in settings where rapid acute treatment of agitation is needed.

# Mechanism of Action: $a_{2a}$ Adrenergic Receptor and NE Role in Acute Agitation

BXCL501, with its potential ease of administration and mechanism of action, targets brain agitation mechanisms. Agitation is prevalent in numerous indications, including AD, schizophrenia and bipolar disease and follows a similar causal mechanism. Norepinephrine, or NE, levels are elevated when dementia or schizophrenia patients experience agitation. An  $a_{2a}$  receptor agonist, such as Dex, would act to reduce these levels, which would produce a calming effect in patients. It has been well documented that the  $a_{2a}$  adrenergic receptors regulate NE in the central nervous system. They are predominantly involved in the control of brain cell communication. Therefore, agents which interact with the  $a_{2a}$  adrenergic receptor can selectively regulate the NE system, unlike antipsychotics. Dex is highly selective for the  $a_{2a}$  adrenergic receptor, which results in fewer side effects and an acceptable safety profile. The figure below illustrates its mechanism of action.

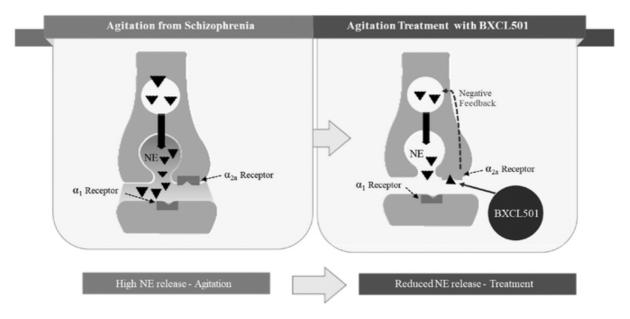


Figure 3. BXCL501 mechanism of action. High norepinephrine, or NE, levels are responsible for agitation. BXCL501 reduces agitation by selectively targeting the **a**<sub>2a</sub>adrenergic receptor to reduce NE release.

### Summary of Existing Dex Clinical Data

Dex has demonstrated efficacy in acute treatment of agitation from delirium and managing pain in patient populations. Approximately 130 trials have been conducted with Dex as an anesthetic agent in patients with diseases and disorders in a variety of patient segments. It has the potential to exhibit strong sedative, analgesic and anxiolytic properties. Furthermore, it demonstrates activity in reducing

agitation associated with delirium, suggesting that it may have the ability to control agitation in neurological and psychiatric diseases.

Clinical studies have provided evidence of Dex's activity in reducing agitation associated with delirium, which we believe suggests that Dex may have the ability to control agitation in psychiatric diseases.

- In a non-randomized Phase 2 clinical trial, patients received an IV bolus of haloperidol and additional doses at intervals of 10-30 minutes until agitation was controlled (Richmond Agitation Sedation Scale, or RASS, score of 0 to –2) or until reaching the maximum total dose of 30 mg. Patients served as their own control. For those patients whose agitation was not controlled by haloperidol, Dex was infused to attain a target RASS score of 0. The haloperidol infusion was then gradually tapered and discontinued, with patients continuing on Dex alone.
  - Dex demonstrated significant reduction in agitation associated with delirium in non-intubated patients who did not respond to haloperidol. Dex alone was more effective than haloperidol alone in its ability to achieve and maintain low agitation scores, as seen in Figure 4 below. There were multiple instances where administration of haloperidol was suspended due to over-sedation (these patients were excluded from the study and are not reflected in the figure below). In contrast, Dex administration did not result in any instances of over-sedation. These results demonstrate that Dex could be a useful treatment for treating agitation without inducing over-sedation. Further, these results suggest that Dex could be useful in treating agitation caused by different diseases, such as AD, schizophrenia and bipolar disease.

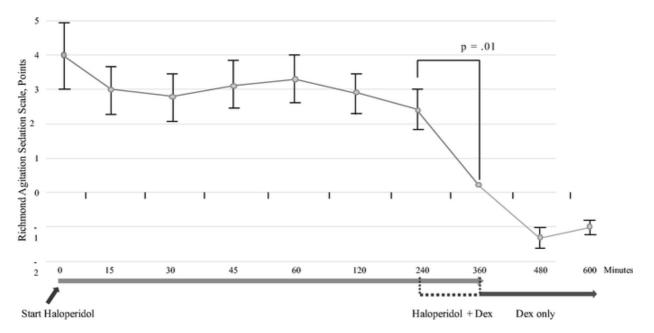


Figure 4. In third party clinical studies, Dex was shown to significantly reduce agitation due to delirium in non-intubated patients that had failed on haloperidol treatment and had better effectiveness and safety than haloperidol. Significant reductions in agitation were produced by Dex in non-responsive patients who were treated with haloperidol and rescued by Dex (p=0.01). Reductions in agitation continued when Dex was given alone.

Patients treated with Dex prior to surgery demonstrated a significant reduction in the incidence of ICU based agitation compared to patients that received propofol or midazolam. Several clinical studies conducted in this manner suggest that Dex reduces delirium and agitation,

without respiratory depression. Patients who experienced emergent agitation and/or delirium were successfully managed with a Dex regimen.

#### Preclinical Studies Performed by BTI with Dex

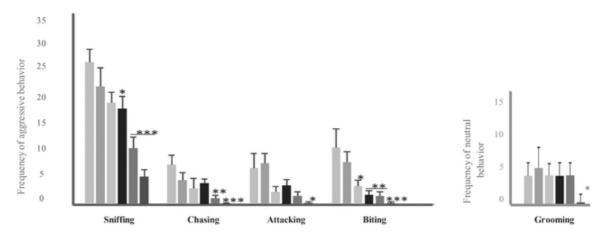
We have conducted two animal studies of Dex. In the first study, we tested sublingual administration of a liquid form of Dex in rats to demonstrate that Dex can be absorbed sublingually and that activity (mimicking arousable sedation) could be achieved in the absence of significant heart rate and blood pressure changes. Additionally, we demonstrated in a rat model of aggression that an IV formulation of Dex inhibited behaviors associated with agitation and aggression in a dose dependent manner without over-sedation.

We also examined the acute effect of sublingual administration of Dex in rats to determine its ability to reduce activity. Hyperactivity in rats represents a preclinical translational behavioral marker for agitation. In the preclinical study, rats were given a sublingual administration of Dex at varying doses (5 - 40 mcg/kg). Parameters such as behavioral assessment (video monitoring of home cage activity (*e.g.*, sleep/wake)), sleep onset latency, total sleep time, motor activity (Rota rod), respiration (tidal volume and frequency), and cardiac activity (heart rate and blood pressure) were measured. Drug plasma concentrations were also measured. Sublingual administration of Dex induced a dose-dependent increase in total sleep time and a significant reduction of latency to sleep. Furthermore, no significant reduction in blood pressure, heart rate or respiratory parameters were observed at doses below 40 mcg. We believe these changes in behavior indicate that Dex was absorbed via the sublingual route and that Dex had an anti-arousal action on rats.

We have also observed the effect of IV administration of Dex in aggressive animals. We used the resident intruder rat model to evaluate the anti-agitation and/or aggression properties of Dex at varying doses. This model was used to study defensive behavior and aggression in mice and rats. When rodents are exposed to a new male in their home cage environment, they perceive the novel male animal as an "intruder" and demonstrate a repertoire of defensive behaviors. By recording the frequencies, durations, latencies and patterns of the observed behavioral acts as well as postures during these confrontations, a detailed quantitative picture (ethogram) of aggression behavior can be evaluated.

Resident animals were administered the IV formulation of Dex at doses of either 0.3, 0.5, 1.0 or 1.5 mcg/kg 15 minutes prior to testing and the response to the intruder rat was examined for agitation for 15 minutes. Parameters such as ano-genital sniffing, chasing, attacking, biting and latency to attack (both frequency and duration of events) were noted along with the estimation of terminal drug plasma concentrations. Administration of Dex resulted in a dose-dependent, significant reduction in the frequency and duration of several behavioral indices of aggression. A significant increase in the latency to attack was also observed at increasing doses of Dex compared to the control group indicating a reduction in aggression. In summary, this preliminary data for Dex dosed intravenously shows a reduction in aggressive behavior of rats in a dose dependent fashion. We believe the reduction in the

overall aggression parameters demonstrates the anxiety/anti-aggression potential of the drug. Future studies are planned with sublingual thin film formulation using the same animal model for aggression.



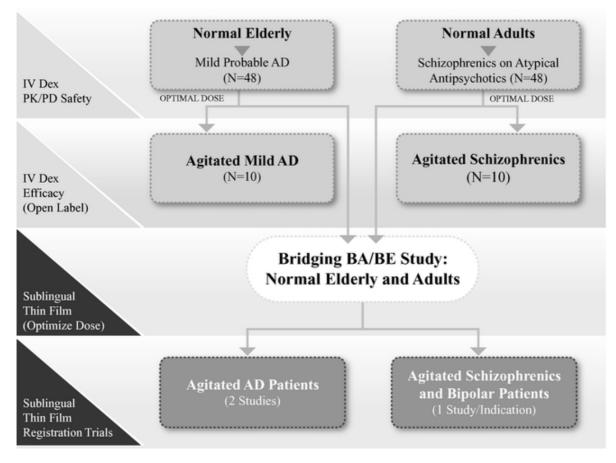
Data expressed as Mean± SEM. One - way ANOVA followed by Dunnett's Test. \*p<0.05, \*\*p<0.01, \*\*\*p<0.01 vs. Vehicle Control group

Vehicle Control	0.3 mcg/kg IV Dex	0.5 mcg/kg IV Dex
1 mcg/kg IV Dex	1.5 mcg/kg IV Dex	3 mg/kg Oral Diazepam

Figure 5. Evaluation of various doses of the IV formulation of Dex for treating aggression in a rat resident intruder model. A dose dependent reduction in frequency and duration of aggressive behavior was observed as compared to controls. Dex also did not induce sedation, while oral diazepam did, as shown using the reduction in the normal grooming behavior as a surrogate of sedation.

### **BXCL501** Clinical Program

Our fully integrated BXCL501 clinical program for treating agitation in AD and schizophrenia is outlined in the figure below. We plan to initially conduct ascending and descending dose studies of the IV formulation of Dex to evaluate PK/PD and safety in mild probable AD patients and schizophrenics on atypical antipsychotics. The planned studies using the IV formulation of Dex in mild probable AD patients and schizophrenics will determine the optimal exposure necessary to produce calm or an arousable sedation and control agitation in these patient groups. Following completion, we plan to initiate a PoC open label study, treating agitated AD and schizophrenia patients with the optimal dose of the IV formulation of Dex determined in the Phase 1b study. This will be followed by a bridging BA/BE study, potentially leading to registration trials with BXCL501, our sublingual thin film formulation of Dex.

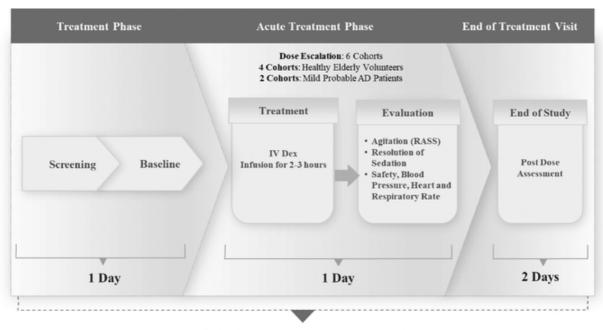


# Figure 6. Integrated clinical development plan (subject to FDA approval) for BXCL501 for acute treatment of agitation in AD, schizophrenia and bipolar disease.

### Agitation in Dementia

By the first half of 2018, we plan to initiate a Phase 1b single ascending or descending dose PK/PD study of an IV formulation of Dex in healthy volunteers followed by patients with mild probable AD, for a total of up to 48 individuals that we expect to be complete in the second half of 2018. The study design entails determining the optimal dose of an IV formulation of Dex and rate of delivery to provide an anti-agitation dose without patients experiencing adverse effects on respiratory drive, blood pressure and cognitive functioning. The primary endpoint will be to determine the optimal dose of an IV formulation of Dex in the target population to achieve the required anti-agitation, arousable sedation effect, as defined using RASS, a widely used method to determine a patient's level of sedation. The study will be double-blind, placebo-controlled and will include up to six cohorts. Each cohort will consist of eight individuals, six treated with IV formulation of Dex and two individuals treated with placebo. The first four cohorts will be healthy elderly volunteers and the last two cohorts will be in patients with mild probable AD. The initial dose of the IV formulation of Dex will be 0.1 mcg/kg/hr with no loading dose. The infusion can be continued for up to three hours with dose increases until arousable sedation is achieved. The subsequent cohorts (healthy volunteers) will enable dose and rate optimization. The optimized dose and rate will then be tested in patients with mild probable AD to

understand whether the underlying pathology affects the activity or safety parameters. These data will be used to optimize our sublingual thin film.



Study Duration: One Week Per Patient

# Figure 7. Initial ascending and descending dose study of the IV formulation of Dex for evaluating PK/PD safety in healthy elderly volunteers and mild probable AD patients. Each patient evaluation is expected to be completed in one week.

The optimal dose and rate from this initial study will subsequently be tested in an open label clinical trial to determine efficacy in AD patients with ongoing agitation. Upon completion of the sublingual thin film formulation, a bridging BA/BE study will be performed to determine the sublingual thin film dose necessary to achieve exposure levels that were found to be optimal for efficacy in these initial studies of the IV formulation of Dex. Following the bridging BA/BE study, the equivalent effective dose in the BXCL501 sublingual thin film formulation will be tested in a potential registration trial for the acute treatment of agitation in dementia, which we expect to commence in the first half of 2019.

### Agitation in Schizophrenia

We plan to conduct a Phase 1b ascending and descending dose PK/PD and safety study with the IV formulation of Dex in schizophrenics currently being treated with an atypical antipsychotic. Following completion, we intend to conduct a PoC open label clinical trial that will be performed in agitated schizophrenics. Following the planned bridging BA/BE study, the equivalent effective dose in the BXCL501 sublingual thin film formulation will be tested in a registration trial for treating agitation in schizophrenia and bipolar disease, which we intend to commence in the first half of 2019.

### Bridging Bioavailability and Bioequivalence Study: BXCL501 Sublingual Thin Film PK Study

The planned studies using the IV formulation of Dex in mild probable AD patients and schizophrenics are expected to determine the optimal exposure necessary to produce calm or an arousable sedation and control agitation in these patient groups. Through a bridging BA/BE study, we will determine the optimal dose of the BXCL501 sublingual thin film that will yield the same blood



•

exposure that achieved efficacy in the IV formulation of Dex study. To achieve this, we plan to perform a randomized, double-blind, placebo controlled dose escalation study to determine the PK, safety and tolerability of a single sublingual thin film formulation of Dex in healthy adult and elderly volunteers. In this dose-escalation study, participants will be randomly assigned to receive four doses of BXCL501 or placebo. We currently expect to have four cohorts and within each group, participants will receive BXCL501 or a sublingual thin film placebo. The safety and tolerability of each dose level will be carefully reviewed before administration of the next higher dose.

### Planned Phase 3 Registration Trials

We intend to conduct Phase 3 registration trials using BXCL501 for acute treatment of agitation in AD, schizophrenia and bipolar disease using the Section 505(b)(2) regulatory pathway. We anticipate that these studies will consist of multicenter, randomized, double-blind, placebo controlled parallel-group studies with a few hundred patients for each of the indications. In the dementia Phase 3 trial, we plan to test two doses of BXCL501 alongside placebo. We believe that RASS is well suited for in-patient settings and can be used to measure the planned primary endpoint, which will be the level of agitation or sedation in a patient. For the schizophrenia and bipolar registration trials, we expect the Brief Psychiatric Ratings Scale, or BPRS, will be used to assess efficacy. The BPRS can capture the change in levels of agitation as the primary endpoint as well measure other psychiatric secondary endpoints. All studies will be designed to be conducted in either a hospital or psychiatric in-patient setting. Depending on the outcome of the pre-IND meeting with the FDA expected in 2018, the planned trial design may need to be adjusted to fit the regulatory path agreed to with the FDA.

### Other Neuropsychiatric/Neurodegenerative Indications

Given the differentiated properties of BXCL501 and its selective mechanism of action, we believe that BXCL501 has the potential for broad applicability across several indications where agitation is a symptom of a condition or underlying disease. Dementia and schizophrenia were chosen as our lead indications. Dementia was chosen based on high unmet medical need and lack of a standard of care for acute treatment of agitation in elderly patients suffering from AD. Schizophrenia was also chosen because of the high incidence of agitation in the emergency room and psychiatric outpatient setting resulting from agitation due to residual psychosis and the need for a non-invasive rapidly acting agent in this setting. There are additional neurological and psychiatric disorders as well as medical conditions where agitation is a symptom that needs treating. If we observe positive efficacy results in dementia and schizophrenia patients, we believe this will provide further proof of concept that BXCL501 has therapeutic potential in other neurodegenerative and psychiatric disorders where agitation is a disruptive symptom for patients and caregivers.

A brief description of potential indications that we could pursue in the future with BXCL501 is summarized below. We will determine the timing and prioritization of additional indications as warranted by emerging data.

**Delirium.** There are a number of studies which suggest that Dex can either prevent or mitigate agitation resulting from delirium. We believe BXCL501 could be used in non-surgical medical situations where hyperactive delirium is an outcome. We also believe BXCL501 would potentially be of high value in elderly patients in many medical situations outside of the ICU, such as the hospital floor and nursing homes. As a result of the delirium studies mentioned in the clinical section above, there is a defined therapeutic index in elderly patients which we believe may allow us to directly initiate a PoC clinical trial, without conducting the IV formulation of Dex study, potentially followed by a registration trial with BXCL501.

Alcohol Withdrawal Syndrome. Acute alcohol withdrawal remains a widespread problem in hospitalized patients. Benzodiazepines remain the primary treatment for alcohol therapy to help

control hyperadrenergic output in patients resulting in withdrawal. These patients are at increased risk of experiencing respiratory depression from benzodiazepine therapy. In clinical trials, IV administration of Dex has shown potential for treating alcohol withdrawal syndrome. We believe that performing a controlled clinical trial with BXCL501 in this population would be a logical next step to develop this product candidate.

- **Hyperarousal in PTSD.** Hyperarousal is a primary symptom of post-traumatic stress disorder, or PTSD. It occurs when a patient becomes hyperaroused as a result of thinking about their trauma. Even though real danger may not be present, their body acts as if it is, causing lasting stress after a traumatic event. The symptoms of hyperarousal include irritability, anger and angry outbursts, constant anxiety and sleeping problems. We believe that BXCL501 has the potential to reduce symptoms which lead to agitation as well to produce a more natural sleep if taken before bedtime.
- **Pretreatment for MRI.** Anxiety, due to feelings of claustrophobia or noise associated with an MRI, is common among patients who will undergo the procedure, which requires the patient to remain still. Currently, short acting oral benzodiazepines are used but must be taken well in advance of the MRI and could be followed by sluggishness and fatigue. We believe that BXCL501 has the potential to calm patients so that they remain still during the procedure.

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

### Neuroendocrine Prostate Cancer Overview and Market Opportunity

Prostate cancer is the most common malignancy and is the second leading cause of cancer death in men in the United States. In 2014, there were an estimated 3 million men with prostate cancer in the United States. According to estimates from Surveillance, Epidemiology and End Results Program, SEER, more than 161,000 men are expected to be diagnosed with and more than 27,000 men are expected to die from prostate cancer in 2017. While the five-year survival rate of local and regional prostate cancer is almost 100%, more aggressive forms of the disease such as metastatic prostate cancer have a five-year survival rate of approximately 30%. These aggressive forms of prostate cancer can initially be treated with androgen deprivation therapy, or ADT, however, almost all patients experience a recurrence in tumor growth. An estimated 180,000 men in the United States are eligible for treatment with the second-generation anti-androgen drugs Zytiga and Xtandi. These drugs have widely become the standard of care and generated combined worldwide sales of over \$4.5 billion in 2016.

Unfortunately, virtually all the patients who respond to Zytiga and Xtandi are expected to progress to even more aggressive forms of prostate cancer requiring further treatment. About one-third of the progressing patients will develop very aggressive, androgen receptor, or AR-independent tumors, or treatment-emergent neuroendocrine prostate cancer, or tNEPC, for which there is no effective treatment. tNEPC specifically displays neuroendocrine differentiation, either pathologically with the presence of the typical neuroendocrine small cells, or molecularly by expressing neuroendocrine markers. As shown in the figure below, BXCL701 is designed to target this tumor segment because tNEPC has specific biology that is addressable by the mechanism of action of BXCL701. We believe

that approximately 30,000 to 40,000 patients in the United States will develop tNEPC who can potentially be treated with BXCL701.

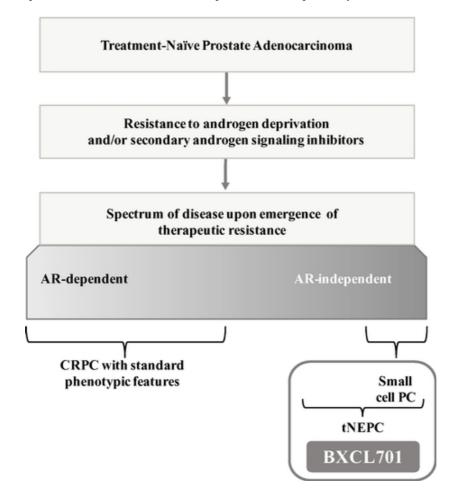


Figure 8. Schematic illustrates tNEPC arising post-ADT therapy treatment. BXCL701 targets this AR-independent subtype where there are no approved therapies and existing/emerging therapies have limited or no efficacy.

### Limitations of Current Treatments for tNEPC

There is no approved therapy for tNEPC and therefore we intend to pursue breakthrough therapy designation for BXCL701. tNEPC patients are treated off-label with cytotoxic chemotherapies, such as platinum-based regimens. These treatments have poor efficacy due to their short duration of response and substantial toxicity. As discussed in more detail below, the immuno-oncology field has made several advances in the treatment of solid tumors. However, several trials of immuno-oncology agents in patients with prostate cancer, and specifically tNEPC, have shown limited or no anti-tumor activity. We believe BXCL701 is a potential first-in-class therapy in tNEPC given its ability to convert immuno-resistant tumors to immuno-sensitive tumors ("cold" to "hot" tumors).

### Immuno-oncology Overview

Immuno-oncology is an emerging approach to treating cancer that is based on stimulating or enhancing an immune response to the tumor. This approach is based on the findings that the mutations occurring in cancer cells may be immunogenic and capable of eliciting an immune response against the



tumor. Immuno-oncology therapies offer several potential advantages over existing cancer therapies. First, the immune system exhibits immunologic diversity and selectivity, which enables it to respond to a large number of potential cancer targets. Second, the immune response can be amplified, offering the potential to enhance the efficacy of treatment. Furthermore, once activated, the immune system possesses immunologic memory, potentially providing for a durable response. Finally, immunotherapies may be widely applicable to many types of cancer as immunotherapy mechanisms are generally broadly applicable across tissues. This enables these agents to be potentially active in a multitude of cancers. Checkpoint inhibitors remove the "breaks" on the immune system and unleash the immune system's broad cancer-destroying properties. Antibodies against CTLA-4, PD-1 receptor (or its ligand), and PD-L1 (collectively checkpoint inhibitors) have shown positive clinical results in many tumor types, leading to multiple FDA approvals, including Yervoy (ipilimumab; anti-CTLA-4) Opdivo (nivolumab; anti-PD-1), Keytruda (pembrolizumab; anti-PD-1), Tecentriq (atezolizumab; anti-PD-L1) and Bavencio (avelumab; anti-PD-L1). These checkpoint inhibitors are now the standard of care in several oncology settings and represent a substantial commercial opportunity for developing new treatments. It is estimated that the market for immuno-oncology therapies could exceed \$27 billion by 2025.

Although checkpoint inhibitors provide benefits to some patients, they also have several limitations. Only a subset of treated patients, typically less than a third, exhibits robust anti-tumor responses (primary resistance). While anti-tumor responses from checkpoint inhibitors are more durable than with traditional therapies, many patients still relapse (secondary resistance). Checkpoint inhibitors have not shown activity as a single agent in patients with prostate cancer due to these resistance mechanisms. The scientific community believes that these resistance mechanisms are related to the immunity cycle. This cycle is a multistep process involving numerous stimulatory and inhibitory factors that amplify and broaden immuno-cell responses as seen in the figure below.

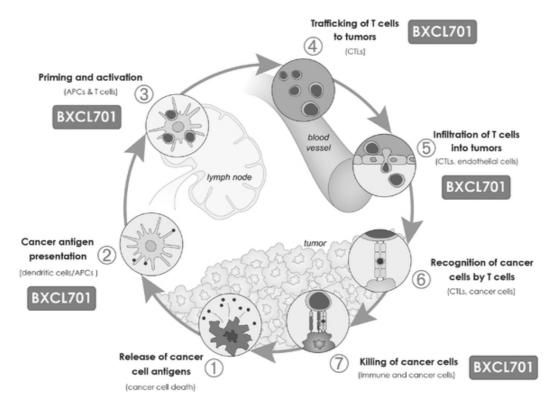


Figure 9a. The cancer immunity cycle as described by Chen and Mellman, Immunity 2013, and those stages where we believe BXCL701 may be active.

Step	Immunity Cycle Step	Potential Role of BXCL701
2	Cancer antigen presentation by dendritic cells	BXCL701 stimulates the trafficking of dendritic cells to tumor draining lymph nodes.
3	Priming and activation of T-cell	BXCL701 accelerates tumor-induced priming of T-cells and the formation of potent cytotoxic T-lymphocytes (CTLs), which can be transferred to secondary hosts.
4	Trafficking of T-cell (and other immune cells) to the tumor	BXCL701 releases the FAP-mediated block of T-cell migration into the tumor.
5	Infiltration of T-cell (and other immune cells) into the tumor	BXCL701 induces the release of chemokines that attract T-effector cells but block T-regulatory cells, and also induce NK cell and neutrophil migration. In addition, the antiangiogenic activity also increases tumor infiltration.
7	Killing of tumor cells	BXCL701 induces the formation of potent CTL and NK cell expressing tumor killing perforin and granzyme and induces the formation of memory T-cells that can reject and kill tumor cells when they return.

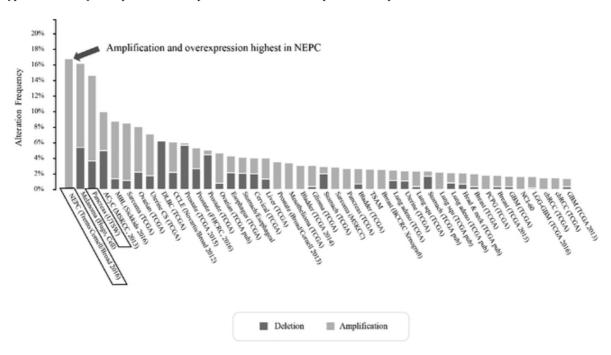
### Figure 9b. BXCL701's potential role in the cancer immunity cycle.

Importantly, checkpoint inhibitors only impact the final step of the immunity cycle (step 7 in the figure above), allowing other targets and pathways to be exploited by the tumor to create a non-responsive tumor micro-environment. Therefore, the scientific community believes that identifying combinations of immuno-oncology agents that target more than one of these steps along the immunity cycle will result in improved efficacy and reduced resistance. For example, the combination therapy of Opdivo (anti-PD-1) and Yervoy (anti-CTLA-4), which targets multiple steps in the immunity cycle, was recently approved for the treatment of melanoma. There are several additional targets that are currently in development in the clinic as combination agents, including targets like indoleamine 2,3-dioxygenase, or IDO, which mediates immuno-suppression in step 7, or in preclinical development, such as the novel target stimulator of interferon genes, or STING, which induces production of interferon gamma resulting in T-cell priming via dendritic cell stimulation.

Whereas most of these targets and their related compounds will only affect one step in the immunity cycle, we believe BXCL701 has the ability to affect multiple steps of the immunity cycle. We believe that this differentiating ability should give it an advantage over other agents when used in conjunction with checkpoint inhibitors in converting immuno-resistant tumors to immuno-sensitive tumors ("cold" to "hot" tumors). This activity should optimize the anti-tumor activity of the approved immune checkpoint inhibitors in a higher percentage of patients, including patients whose tumors show primary and secondary resistance to immune checkpoint treatment.

### DPP 8/9 & FAP Role in tNEPC and Immuno-oncology

DPP 8/9 and FAP are overexpressed in tNEPC and play a significant role in tumor growth. DPP 8/9 regulate the activity of neuropeptide Y, or NPY, a neuroendocrine peptide hormone upregulated in tNEPC. We selected tNEPC and pancreatic cancer as our lead indications after evaluating more than 100 different tumor types because they are represent of the top three cancers that overexpressed or amplified DPP 8/9 and FAP.



# Figure 10. Genetic alteration analysis of DPP 8/9 and FAP (BXCL701 targets) demonstrates that tNEPC and pancreatic cancer have among the highest levels of overexpression and amplification (from The Cancer Genome Atlas).

In addition to this genomic signature, DPP 8/9 and FAP are critical regulators of the immune system and their inhibition causes pro-inflammatory cell death. DPP 8/9 have been shown to limit the activity of macrophages and inhibit the stimulation of the pro-inflammatory anti-tumor response. FAP+ cancerassociated stromal fibroblasts, or FAP+ CAFs, are the main immuno-suppressive cells in tNEPC tumors and blocking their signals leads to improved antitumor response. Depleting FAP+ CAFs can delay or prevent tNEPC development. Similarly, myeloid-derived suppressor cells, or MDSC, plays an immunosuppressive role in the biology of tNEPC. Therefore, we believe inhibition of DPP 8/9 and FAP by BXCL701 can directly lead to tNEPC tumor cell death through the action of the immune system by blocking the activity of the immuno-suppressive cells present in tNEPC.

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

BXCL701 is a potential first-in-class, highly potent, oral small molecule immuno-modulator targeting tNEPC that stimulates both the innate and acquired immune system by inhibiting DPP 8/9 and FAP. BXCL701 is differentiated among DPP inhibitors because it is designed to inhibit DPP 8/9, whereas most other DPP inhibitors, including those that have been developed to treat diabetes, are selective for DPP 4. We are not aware of any clinical stage competitors of BXCL701 in the DPP inhibitor class. The product candidate is designed to address the various ways by which DPP 8/9 and FAP play a role in the biology of tNEPC. Specifically, it is able to directly affect tNEPC tumor cell survival and metastases and modulate immune system activity against tNEPC, as described below.

**Inhibiting tNEPC Growth Factor NPY.** tNEPC is believed to be caused by neuroendocrine cells in the prostate that overexpress NPY. NPY activates the specific G protein-coupled receptor Y1-R, which then selectively stimulates growth of AR-independent, tNEPC-like cancer cells, while reducing growth in AR-dependent cells. NPY is a substrate of DPP 8/9, which cleaves it into biologically active forms. DPP 8/9 inhibition in tumor cells decreases the number of viable tumor cells by reducing NPY cleavage.

**Inhibiting the Formation of tNEPC-type (Osteoclastic) Bone Metastasis.** Prostate cancer is characterized by the presence of bone-forming (osteoblastic) metastasis. In contrast, tNEPC is associated with bone-lysing (osteoclastic) metastasis. BXCL701 is designed to block the bone destruction by osteoclasts through the inhibition of osteoclast differentiation. In an animal model that recapitulated the formation of osteolytic metastasis of tNEPC, BXCL701 was observed to reduce osteoclast activity, bone resorption and tumor burden.

**Exhibiting Immuno-mediated Activity Against tNEPC.** BXCL701 may potentially have the ability to modulate the immune system in multiple ways, several of which are relevant to its ability to treat tNEPC, including:

- stimulating the activation of multiple immune cell types;
- stimulating tumor cell killing by inducing the priming, migration and cytotoxicity of T-cells and the formation of memory T-cells;
- stimulating tumor cell killing by inducing the proliferation and activation of neutrophils;
- inhibiting the immune suppressive FAP+ CAF and MDSC and delaying or preventing tNEPC development; and
- synergistically increasing checkpoint inhibitor anti-tumor activity.

The figure below summarizes the complex, multifaceted immuno-mediated mechanism of BXCL701. Through this mechanism, BXCL701 induces an immuno-permissive tumor microenvironment as it stimulates the priming, migration and cytotoxicity of pro-inflammatory cells while dampening the immuno-suppressive phenotype of negative regulatory cells through a unique cytokine and chemokine cascade.

# BXCL701 **Immune Activation** Block of Immune Evasion CCL19/CCL21 G-CSF IFN-g Lymphotactin CXCL-1, IL-6 TRAD FasL Perfs TRAIL-R PD-L1 MHC Clas CD8°T Cell NK Cell Dendritic Cell Macrophage (M2) Immature TumorCell CD4°T Cell Regulatory T Cell Dendritic Cell Activation Mechanism Myeloid Derived Neutrophil Blocking Mechanism Suppressor Cell

# Figure 11. BXCL701 mechanism of action induces activation of the immune system via its stimulation of T-cells, NK cells and neutrophils which are then able to kill tumor cells. At the same time, BXCL701 blocks the immuno-evasion function of certain suppressor cells (FAP+ CAF and MDSC).

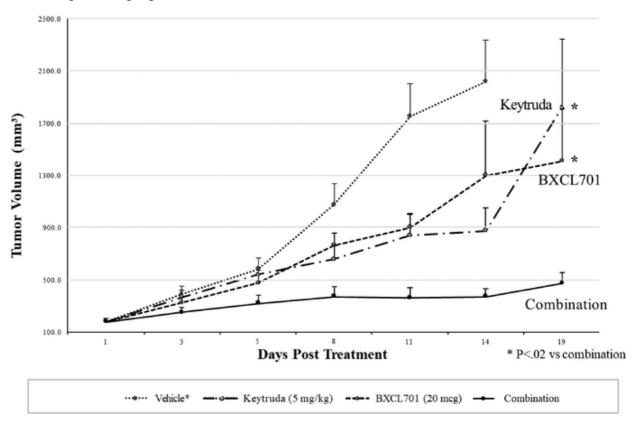
There are numerous aspects of BXCL701's mechanism of action that potentially make it a strong and novel combination agent for checkpoint inhibitors. Several aspects have been clinically validated in cancer patients in addition to healthy volunteers. BXCL701 has been shown to:

- induce a differentiated spectrum of cytokines and chemokines in humans;
- induce neutrophil/granulocyte proliferation and infiltration into tumors in humans, which is important for the anti-tumor activity of Bacillus Calmette-Guerin, or BCG, a well-established immunotherapy for bladder cancer. In addition, checkpoint inhibitors in combination with STING activation have shown synergistic anti-tumor effects mediated by neutrophil infiltration. This suggests that STING-mediated innate immune stimulation is downstream to BXCL701;
- stimulate cytotoxic T-cells in humans and specific memory T-cell responses in animals. While other immuno-oncology agents do increase and activate T-cells, only a few induce memory T-cells;
- inhibit immuno-suppressive cells like MDSC and CAF in animals. MDSC play a major role in the immuno-suppressive tumor microenvironment and the number of MDSC present in a tumor is predictive of patient survival with Yervoy and Opdivo. Other immunooncology agents affect MDSC but do not offer the additional anti-tumor related activities of BXCL701; and
- display direct, single agent anti-tumor effect in humans.

### 103

# **Tumor Microenvironment**

We conducted a preclinical study of BXCL701 as a single agent and in combination with Keytruda to test our hypothesis that combining BXCL701 with checkpoint inhibitors will result in synergistic anti-tumor activity. As shown in the figure below, the combination of Keytruda with BXCL701 produced better tumor control than either agent as a single agent.



# Figure 12. The combination of BXCL701 and a mouse surrogate of Keytruda was tested in MC38 mouse cancer model. Groups of animals were dosed with either BXCL701, Keytruda or the combination of both. The combination achieved a greater reduction in tumor value than either a single agent treatment with significant P-value (<0.02) for both.

The potential of this combination to enhance anti-tumor activity was also observed in a second, more aggressive mouse cancer model, where single agent treatment with Keytruda and BXCL701 alone had no effect while the combination inhibited tumor growth. The molecular and cellular mechanism by which the combination is synergistic has revealed how this synergy could be achieved. At the molecular level, several cytokines known to have strong anti-tumor activity such as Il-2 (an approved immunotherapy), IL-12 and granulocyte-macrophage colony-stimulating factor, appear to be synergistically up-regulated. Also, the combination synergistically increased CXCL9/MIG, which attracts T-effector cells into the tumor. At the cellular level, the combination mobilized activated tumor killing NK cells (expressing perforin and granzyme), from the blood to the tumor. At the same time, treatment with BXCL701 blocked relocation of immuno-suppressive T-regulatory cells to the tumor, an effect that is normally induced by treatment with immune checkpoint inhibitors.

The data and rationale presented above support the use of BXCL701 in combination with Keytruda in tNEPC. This combination could potentially offer tNEPC patients the deep and durable responses and increased survival that has been observed in other tumors upon treatment with immuno-oncology agents. In clinical data to date, BXCL701 has exhibited a tolerable safety profile with no overlapping adverse events with checkpoint inhibitors, limiting potential toxicity of the combination.

### Summary of Existing BXCL701 Clinical Data (Previously Studied as Talabostat)

BXCL701 has been tested in multiple clinical trials, exhibiting a tolerable safety profile, proof of mechanism, and single agent anti-tumor activity in patients with melanoma, an immuno-sensitive tumor. BXCL701 was originally developed by Point Therapeutics, Inc. as Talabostat (PT-100).

Nine of BXCL701's clinical trials were dose finding and human pharmacology studies, which we have leveraged to define the dosing regimen for our clinical trials. The data obtained in these trials provides a comprehensive overview of safety, PK and full target inhibition plus downstream PD effect on cytokine increase and neutrophil stimulation. In addition, several foundational human pharmacology studies were conducted, including relative bioavailability, food effect and anti-acid effect. The key findings from these trials that we believe are relevant to the further development of BXCL701 include:

- predictable and dose proportional PK;
- maximum tolerated dose, or MTD, of 300 mcg dosed twice a day or 600 mcg dosed once a day; and
- target inhibition observed in human subjects with doses above 100 mcg.

Given these data and the strong anti-tumor activity observed in the preclinical studies, the focus shifted to oncology where the agent was tested in six Phase 2 and two Phase 3 clinical trials involving more than 500 patients. These trials provided an important understanding of the behavior of BXCL701 in cancer patients and provided the following key conclusions enabling us to pursue further development:

- evidence that the drug has anti-tumor activity as a single agent in an immuno-sensitive tumor (melanoma);
- recommended safe and tolerable dose to use in our planned Phase 2 efficacy trial; and
- well-defined adverse event profile, that does not overlap with checkpoint inhibitors, which we believe thereby avoiding the need for lengthy dose escalation in the combination arm of our Phase 2 trial.

A wide range of doses between 100 and 600 mcg administered once or twice daily were studied in these trials and the MTD was determined to be 600 mcg administered once daily. Anti-tumor activity was observed both as single agent and in combination in refractory solid tumors. The most frequent adverse events attributable to BXCL701 were fatigue, edema, dizziness, nausea, vomiting and fever. Edema was dose-related and probably related to a mild capillary-leak syndrome secondary to cytokine up-regulation. The edema observed in clinical studies to date has generally resolved within four to five days of interruption of BXCL701 treatment; patients have resumed BXCL701 either without further occurrence of edema or to a lesser degree of recurrence. While objective clinical responses were seen as single agent and in combination in refractory patients, we believe BXCL701's immuno-modulatory activity was most likely limited by the effect of immune checkpoint expression in the tumor. In addition, most of the BXCL701 trials were conducted in combination with cytotoxic agents, which are generally immuno-suppressive. Therefore, we believe these combinations did not optimally leverage BXCL701's immuno-stimulatory prospects.

Point Therapeutics, Inc. (acquired by Midatech Pharma USA, Inc.) terminated the development of BXCL701 after an interim analysis of the two Phase 3 trials showed that the primary and secondary efficacy endpoints would not be met in non-small cell lung cancer, or NSCLC. In the BXCL701 combination trial with docetaxel, the BXCL701 arm of the study showed higher patient mortality than the placebo arm, which caused the FDA to place Point Therapeutics, Inc. IND for BXCL701 on clinical hold. We undertook a complete analysis of the clinical data of both Phase 3 trials and concluded that BXCL701 did not contribute to the excess mortality results. Rather, we attributed the observed

mortality to a statistical imbalance in the randomization of subjects with more advanced disease in the BXCL701 arm. The second NSCLC study, in combination with pemetrexed, conducted in a similar patient population and often in the same clinical site as the BXCL701 combination trial with docetaxel, did not show the same excess mortality. We shared our analysis with the FDA in a pre-IND meeting and in a follow-up type C meeting, who acknowledged our conclusion but indicated the data available could not rule out potential safety issues. However, the agency stated that our plan to initiate clinical trials with BXCL701 appeared reasonable and that it has no objection to our approach to combine BXCL701 with checkpoint inhibitors.

Taken together, we believe this extensive set of clinical data covering safety, PK parameters, target inhibition and downstream PD effect and anti-tumor activity, coupled with the genomic and mechanistic work gave us the confidence to build our BXCL701 clinical program.

### BXCL701 Clinical Program in tNEPC

We anticipate initiating a Phase 2, two-arm, open label, clinical trial testing BXCL701, as both a single agent and in combination with Keytruda, in patients with tNEPC that have progressed on Zytiga or Xtandi and who had previously been treated with chemotherapy.

Based on preclinical and clinical data, we plan to use a dose of 600 mcg, administered once daily, in both arms of our Phase 2 trial. This dose was previously found to be well tolerated, to inhibit the DPP 8/9 and FAP targets and to stimulate the immune system. In addition, the gene expression for DPP 8 and DPP 9 will be analyzed retrospectively. tNEPC patients are characterized by the presence of soft tissue metastasis that is amenable to biopsy. We expect that patients with tNEPC will show high levels of expression of our biomarkers.

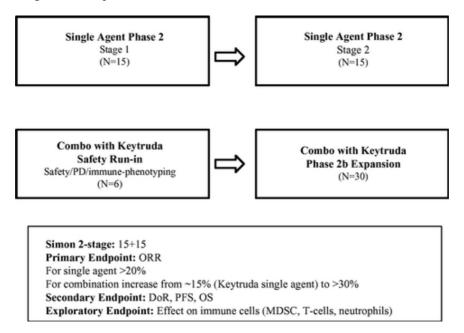


Figure 13. BXCL701 Phase 2 trial design.

As shown in the figure above, the study will consist of two arms:

- **Single agent arm.** Evaluate BXCL701 activity with a Simon 2 stage approach, 15+15 patients. The predictive power of DPP expression as a biomarker will be assessed during the first stage to decide whether it can be used to prospectively select patients for inclusion in the second stage of this trial.
- **Combination arm.** This will consist of a safety run-in that will examine the safety and tolerability of combining BXCL701 and Keytruda in six tNEPC patients. Patients will be dosed with BXCL701 once daily on Days 1-14 of a 21-day cycle plus IV administration of 200 mcg of Keytruda on Day 8 every 21 days. The 7-day BXCL701 rest period is to optimize immune system stimulation. If dose limiting toxicities, or DLTs, are observed during the safety run-in, 400 mcg once daily will be tested.

The Phase 2 primary endpoint will be objective response rate, or ORR. The secondary endpoints will be duration of response, or DoR, progression-free survival, or PFS, and overall survival, or OS. We expect this trial to take approximately two years to complete and to have preliminary data in the first half of 2019 for the single agent arm. The Keytruda prostate cancer single agent trial (Keynote 199), which includes a subset of tNEPC patients, will represent the reference trial to determine the relative range of our primary endpoint.

We plan to request orphan drug designation and breakthrough therapy designation for neuroendocrine prostate cancer as soon as we obtain relevant preliminary efficacy data. We will plan our follow-on clinical strategy based on the results of the PoC trial and discussions with the FDA. The FDA has granted accelerated approval to drugs in tumors like tNEPC that have no available therapies and represent a high unmet medical need based on single arm, ORR-based large Phase 2 or even expanded Phase 1 trials. Therefore we believe there is potential for an accelerated path to approval for BXCL701 if this initial trial shows a relevant percentage of durable responses.

## **BXCL701** for the Treatment of Pancreatic Cancer

### Pancreatic Cancer Overview and Market Opportunity

Pancreatic adenocarcinoma, more commonly referred as pancreatic cancer, represents one of the highest unmet needs in oncology. The American Cancer Society estimates that in 2017 there will be approximately 53,000 new diagnoses and 43,000 deaths. Pancreatic cancer has a median five-year survival rate of only about 8%. Recently, several new therapies have been developed consisting of new formulations of approved chemotherapies. However, these new therapies have limited efficacy with relatively short survival advantages, and well-known toxicities. It is well understood that the development of new efficacious drugs with manageable toxicity is required to achieve durable responses and increase survival in pancreatic cancer. Pancreatic cancer is thought to be a highly immuno-resistant tumor. Multiple attempts to show anti-tumor activity of immunotherapies including immune checkpoints have failed due to primary resistance mechanisms. We believe BXCL701 has the potential to eliminate the resistance to immune checkpoint inhibitors (to convert "cold" tumors "hot") and the combination with Keytruda could generate long and profound responses and the survival increase needed to make a true breakthrough in the treatment of pancreatic cancer.

Abraxane, a new formulation of the chemotherapy agent paclitaxel in combination with gemcitabine, is considered to be the standard of care for newly diagnosed pancreatic cancer in U.S. markets, with annual sales of almost \$1 billion. Onivyde, a liposomal formulation of the chemotherapy agent irinotecan, was recently approved for use in second-line pancreatic cancer based on a two-month survival increase (six months vs. four months) and only 7.7% ORR, with annual sales of approximately \$80 million. Our initial clinical development plan will target second-line or later pretreated patients, specifically the 50% that remain in good clinical condition after first-line treatment



and thus may receive one or more subsequent lines of chemotherapy. Therefore, we believe that the potential number of patients treatable with the combination of BXCL701 and Keytruda, if successfully developed and approved, would be approximately 20,000.

Pancreatic cancer is a high unmet medical need, where approved therapies have limited activity and patients have short survival. In addition, as shown previously in Figure 11 summarizing the genetic data from the The Cancer Genome Atlas database, among all the tumor datasets available for analysis, a high level of overexpression and amplification of DPP 8/9 and FAP is present in pancreatic cancer. Pancreatic cancer is also characterized by the presence of the immuno-suppressive FAP+ CAF. As in tNEPC, single agent immune checkpoint inhibition has not shown single agent anti-tumor activity in pancreatic cancer patients, indicating the need for a molecule like BXCL701 to optimize their activity. Preclinical studies indicate that the combination of FAP and immune checkpoint inhibition is active. BXCL701 has been granted orphan drug designation from the FDA for the treatment of pancreatic cancer.

### FAP Role in Pancreatic Cancer

Pancreatic cancer is characterized by dense fibrotic stroma called desmoplasia (consisting mostly of FAP+ CAFS), which can comprise as much as 90% of tumor mass. It is widely believed that drugs have not been effective in treating pancreatic cancer primarily due to the stroma impeding their ability to penetrate the tumor. As depicted in the figure below, FAP+ CAFs mediate immuno-suppression by producing the chemokine (C-X-C motif) ligand 12 (CXCL12) which binds to the CXCR4 receptor on T-cells. As a result, T-cells are excluded from the tumor and are prevented from killing the tumor cells. As a result of the immuno-suppressive microenvironment driven by FAP+ CAF and MDSC, pancreatic cancer is thought to be the prototypical "cold" tumor. This results in primary resistance to immune checkpoint single agent treatment and limited objective responses.

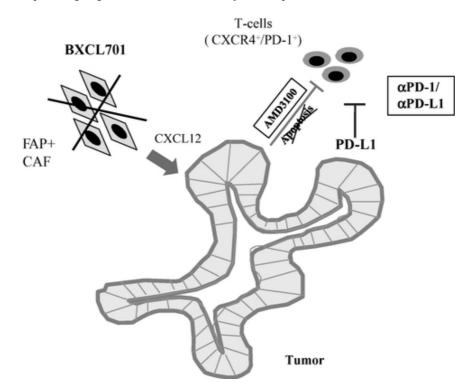


Figure 14. Model of the immuno-suppressive action of FAP+ CAF via secretion of CXCL12 blocking the entrance of T-cells in the tumor. By blocking FAP+ CAF activation, BXCL701 permits T-cells to penetrate the tumor and kill the tumor cells.

Several publications have shown that inhibiting or blocking the activity of these FAP+ CAFs results in decreased tumor growth. Additionally, 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. As a result, these studies indicate that the FAP+ cells may contribute to the resistance to these checkpoint antagonists. BXCL701, which inhibits FAP+ CAF, has been shown to decrease tumor growth of human pancreatic tumors in animal models both as a single agent and in combination with Keytruda. In addition, treatment of pancreatic cancer in the same animal pancreatic model with a triple combination that added a third, non-immuno-checkpoint, immunotherapy agent to the combination of BXCL701 with Keytruda, resulted in the complete regression of the tumors, supporting our belief that BXCL701 is a combination agent that has the potential to improve the anti-tumor activity of immunotherapies beyond immuno-checkpoints. We are not aware of any clinical stage FAP inhibitor competitors of BXCL701.

### BXCL701 Clinical Program in Pancreatic Cancer

The role of FAP+ CAF in mediating immuno-suppression has been well documented by leading investigators, including Dr. Louis Weiner, currently a director at the Lombardi Cancer Center at Georgetown University. We are collaborating with Dr. Weiner and his team to further characterize the activity of BXCL701 in the context of immune checkpoint resistance in combination with Keytruda.

As shown in the figure below, the clinical development plan for BXCL701 in pancreatic cancer, developed in collaboration with Dr. Weiner, will consist of two overlapping trials. We plan to initiate two Phase 2 open label trials with BXCL701 in patients with metastatic pancreatic cancer. The first trial will examine BXCL701 in the neoadjuvant setting (before surgery). We expect to enroll ten patients who will be treated for three weeks with BXCL701 before surgery. The trial will examine immune cell infiltration and activation and is expected to commence in the second half of 2018 with results available in the first half of 2019. The second trial will examine BXCL701 in combination with Keytruda in approximately 30 patients that have previously received gencitabine. We expect the second trial to commence in the second half of 2018 with preliminary results available in the first half of 2019. We believe this trial, if successful, could lay the foundation for a potential follow up registration trial in pancreatic cancer.

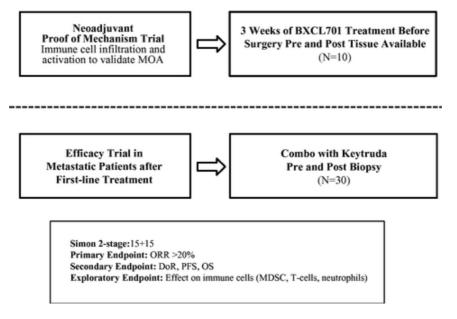


Figure 15. BXCL701 Phase 2 trial design in pancreatic cancer as a single agent (proof of mechanism) and in combination with Keytruda (PoC).

## Other Immuno-oncology Indications

In addition to tNEPC and pancreatic cancer, we plan to leverage our existing preclinical and clinical data to identify other cancer types with high unmet medical need that would benefit from BXCL701's novel mechanism of action. We are prioritizing those where the immuno-suppressive microenvironment is driven by the molecular and cellular targets of BXCL701 and where the single agent activity of approved immune checkpoint inhibitors is limited.

In addition, based on the mechanism of action described in the figure below, we believe BXCL701 provides a platform for combination with immunotherapy modalities that go beyond the currently approved immune checkpoint agents that target the PD-1/PD-L1 axis. Following our PoC trials, we plan to conduct clinical trials covering a broad range of additional combinations with other immunotherapy agents including:

- immune checkpoint inhibitors (other than PD-1/PD-L1);
- cellular therapies (CAR-T and chimeric antigen receptor natural killer cells);
- therapeutic vaccines; and/or
- antibody-dependent cell-mediated cytotoxicity, or ADCC, driven monoclonal antibodies.

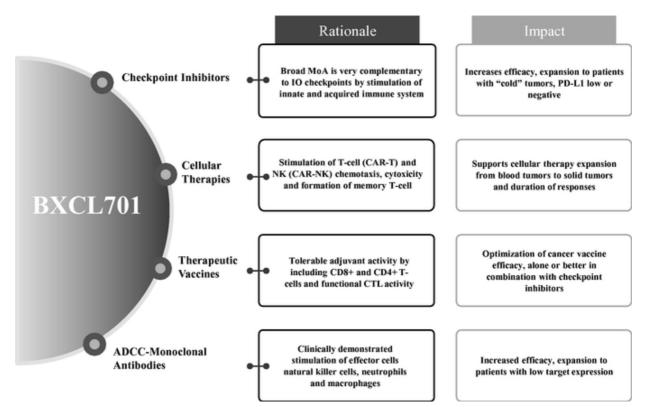


Figure 16. Mechanism of action-based rationale and impact for combination with BXCL701 and immunotherapy modalities beyond anti-PD-1/PD-L1.

# **Other Product Candidates**

#### Neuroscience Program

We are targeting neuroscience disorders where there is high unmet medical need and therefore a requirement for symptom management is a priority (like agitation, seizures, dyskinesias) as well for transformative care for monogenic rare CNS disorders.

For symptomatic approaches, our neuroscience program is developing a FDA Section 505(b)(2) opportunities with a focus on treating symptoms for various neurological and psychiatric disorders. This entails re-innovating existing agents through formulation changes and deuteration. The utilization of EvolverAI has identified several monogenic diseases with available animal models across rare neuroscience diseases. We utilize proprietary algorithms to identify associated mechanisms with existing pharmacology to test whether these agents can improve the disease profile in the animal model either through disease modification or symptomatic manner. The agents identified must be those that we believe are Phase 2 ready with a potential for a short, cost-effective development plan (four to five years to NDA filing).

We have identified our next candidate as a FDA Section 505(b)(2) opportunity, BXCL502, for symptomatic improvement of a CNS disorder with a high unmet medical need. Additional product candidates are routinely screened, prioritized and selected using a combination of specific algorithms and relevant translation research, formulation and deuteration strategies.

### Immuno-oncology Program

Our immuno-oncology program is based on utilizing a comprehensive map of all known relationships that link immuno-evasion and immuno-activation pathways and targets with thousands of pharmacological agents and tumor indications. This comprehensive map has permitted us to select a potential pipeline of candidates based on our ability to alter the tumor micro-environment and the potential to address relevant unmet medical needs for various tumor types.

The lead candidates are clinically validated in oncology and therefore represent opportunities where we believe clinical development risk may be reduced.

BXCL702 is an example of the set of oncology candidates. BXCL702 is designed to have a dual anti-tumor mechanism of action: a direct mechanism to kill tumor cells and an indirect mechanism to stimulate the anti-tumor activity of immuno-therapy agents. We believe BXCL702 offers the opportunity to bring the benefit of immuno-oncology to hematological malignancies with an observed safety profile suitable for the treatment of elderly patients. Based on the preclinical and clinical supporting data, FDA granted BXCL702 orphan drug designation for the treatment of AML.

## Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. The immuno-oncology, neuroscience and rare disease segments of the industry in particular are highly competitive. While we believe that our technology, development experience and scientific knowledge provide competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved medicines than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and in establishing clinical trial

sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, if any, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, have fewer or less severe side effects, are more convenient or less expensive than any medicines we may develop. Our competitors also may obtain FDA or other regulatory approval for their medicines more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic medicines. There are many generic medicines currently on the market for certain of the indications that we are pursuing and additional generics are expected to become available over the coming years. If our therapeutic product candidates are approved, we expect that they will be priced at a significant premium over competitive generic medicines.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. If the product candidates of our priority programs are approved for the indications for which we are currently planning clinical trials, they will compete with the drugs discussed below and will likely compete with other drugs currently in development.

### Neurological and Psychiatric Disorders

Drugs used for the acute treatment of agitation resulting from psychosis in schizophrenia and mania in bipolar disease are atypical antipsychotics administered IM and require patient restraint. These include IM aripiprazole, olanzapine, ziprasidone and haloperidol. Oral products include the benzodiazepines, lorazepam and midazolam. Saphris (sublingual tablet asenapine) is an atypical antipsychotic that has been prescribed for use in children and teens for acute treatment of manic or mixed episodes associated with bipolar disease. Adasuve (inhaled loxapine) from Alexza is also a non-invasive treatment. Avanir is currently in Phase 3 with Nuedexta, a combination of dextromethorphan and quinidine for treating chronic agitation in dementia.

### Immuno-oncology

•

The immuno-oncology field is characterized by the rapid evolution of technologies and products and by fierce competition based on the development of compounds, often with similar mechanisms of action. Clinical development plans are further compounded by the possibility of overlapping intellectual property. A wide variety of commercial players, large pharmaceutical companies, established and emerging biotechnology companies, and several not-for-profit entities are actively developing potentially competitive products in immuno-oncology and in our lead indications.

While we believe our product candidates, technology, knowledge, and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies. Such companies include:

**Major pharmaceutical companies developing multiple immuno-oncology agents:** AstraZeneca PLC, Bristol-Myers Squibb Company, Celgene Corporation, Merck & Co., Inc., Novartis AG, Pfizer Inc., Roche Holding Ltd. and Sanofi SA.



- **Companies developing agents aimed at stimulating the immune response:** AdaptImmune LLC, Idera Pharmaceuticals, Inc., Immune Design Corp., NewLink Genetic Corporation, Advaxis, Inc., Argos Therapeutics, Inc., Biovest International, Inc., ImmunoCellular Therapeutics, Ltd., Immune Design, Inc., Inovio Pharmaceuticals, Inc., Intrexon Corporation and Northwest Biotherapeutics, Inc.
  - **Companies developing cell-based immunotherapy approaches:** Intrexon Corporation, Juno Therapeutics, Inc., Kite Pharma, Inc. (acquired by Gilead Sciences, Inc.), Novartis AG and Pfizer Inc.

## Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical as well as for commercial manufacturing if our product candidates receive marketing approval.

For the commercial supply of Dex for our BXCL501 clinical program, potential vendors have been identified, and GMP and United States Pharmacopeia, or USP, grade material is readily available. ARx LLC, USA is responsible for the development and manufacturing of sublingual thin films for BXCL501, which is currently in progress.

We have contracted to restart the production of a clinical batch of BXCL701 under exclusivity with the original manufacturer Evotec/Aptuit (API) and Pharmafor/Bioduro (tablets). We intend to contact other suppliers, including potential strategic partners for the commercial material.

### Commercialization

We plan to retain our worldwide commercialization rights for some of our key product candidates while for other product candidates we might consider collaboration opportunities to maximize returns.

While we currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company in commercializing products, we intend to build our own commercialization organization and capabilities over time. When appropriate, we will decide whether to build a specialty sales force to manage commercialization for these product candidates on our own or in combination with a larger pharmaceutical partner, to maximize patient coverage in the United States and to support global expansion especially as our programs have substantial opportunity for additional follow-up indications alone or in combinations.

As product candidates advance through our pipeline, our commercial plans may change. Clinical data, the size of the development programs, the size of the target market, the size of a commercial infrastructure and manufacturing needs may all influence our United States, European Union and rest-of-world strategies.

## Our Relationship with BioXcel Corporation

We are currently a 96% owned subsidiary of BioXcel and our pipeline compounds have been identified by applying BioXcel's R&D engine, EvolverAI, for drug re-innovation.

We have entered into an asset contribution agreement, effective June 30, 2017, with BioXcel, as amended and restated on November 7, 2017, or the Contribution Agreement, pursuant to which BioXcel agreed to contribute to us, and we agree to acquire from BioXcel, all of BioXcel's rights, title and interest in and to BXCL501, BXCL701, BXCL502 and BXCL702, collectively, the Candidates, and all of the assets and liabilities associated with the Candidates. In addition, pursuant to the Contribution Agreement, upon completion of this offering, BioXcel will grant us a first right to negotiate exclusive rights to any additional product candidates in the fields of neuroscience and immuno-oncology, that BioXcel may identify on its own, excluding the Candidates, and not in connection with BioXcel's provision of services to us under the Services Agreement as defined and described below. This option for first negotiation shall be valid for a



period of five years from the date of this offering. Prior to the fifth anniversary of our initial public offering, BioXcel has also agreed to not provide product identification collaborative services to third parties in the fields of neuroscience or immuno-oncology when such third parties utilize EvolverAI. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Asset Contribution Agreement with BioXcel" for additional information.

We have entered into a separation and shared services agreement with BioXcel that took effect on June 30, 2017, as amended and restated on November 7, 2017, or the Services Agreement, pursuant to which BioXcel will allow us to continue to use the office space, equipment, services and leased employees based on the agreed upon terms and conditions for a payment of defined monthly and/or hourly fees. The parties have agreed that the services and office space provided under the Services Agreement shall decrease over time until the 12 month anniversary of the date of the Services Agreement, except for services to be provided by BioXcel through its subsidiary in India, which shall decrease until the 24 to 36 month anniversary of the date of the Services Agreement, provided such dates may be extended upon mutual agreement between the parties. On or before December 31, 2019, we shall have the option to enter into a collaborative services agreement with BioXcel pursuant to which BioXcel shall perform product identification and related services for us utilizing EvolverAI. BioXcel shall continue to make such product identification and related services available to us for at least 60 months from June 30, 2017. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Separation and Shared Services Agreement with BioXcel" for additional information.

In connection with the Services Agreement, BioXcel agreed to provide us a line of credit, which shall be capped at \$1 million, or the Total Funding Amount, pursuant to the terms of a grid note, or the Grid Note. The Grid Note shall be payable upon the earlier of (i) the completion of this offering and (ii) December 31, 2018. As of June 30, 2017, we have drawn an amount of \$285,000 under the Grid Note. See the section titled "Certain Relationships and Related Person Transactions—Amended and Restated Separation and Shared Services Agreement with BioXcel" for additional information.

### **Intellectual Property**

Our policy is to protect and enhance the proprietary technologies, inventions, and improvements that are commercially important to our business by filing patent applications in the United States and other jurisdictions related to our proprietary technology, inventions, improvements and product candidates. We also rely on trademarks, trade secrets, and know-how relating to our proprietary technologies and product candidates, continuing innovation and in-licensing technology and products. This reliance is expected to develop, strengthen, and maintain our proprietary position for novel therapeutics and novel formulations of existing therapeutics across multiple therapeutic areas. We also plan to rely on data exclusivity market exclusivity and patent term extensions when available.

# Patent Portfolio

Our patent portfolio is currently comprised of six inventions. This encompasses our proprietary drug programs in immuno-oncology, CNS and agitation. These proprietary products and methods of use are covered in three separate Patent Cooperation Treaty applications, four pending national phase applications and three pending United States provisional applications to date. However, we intend to file national phase patent applications in all other major counties (Europe, Canada, Japan, Australia and China) in the future.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. Depending upon the timing, duration and specifics of FDA approval of our product candidates, a United States patent we own or license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to



five years as compensation for patent term lost during product development and the drug approval regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of a NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

The patent positions of companies such as ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of method of use patents or reformulation patents has emerged in the United States. The relevant patent laws and their interpretation outside of the United States are also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and enforce the patent rights that we license, and also could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use, or the manufacture of those products. Moreover, even the issued patents that we license do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and the issued patents that we in-license and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents that we own or exclusively in-license. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

## Midatech Data Purchase Agreement Related to BXCL701

On January 4, 2016, BioXcel executed a Data Purchase Agreement with Midatech Pharma US Inc., the successor of Dara Biosciences, itself successor of the original developer of talabostat mesylate, or Talabostat, pursuant to which Midatech transferred to BioXcel all rights, title, and interests to all preclinical, clinicial, CMC and any other relevant data related to Talabostat. Subsequently, Midatech also transferred the ownership of Talabostat IND 62379 to BioXcel and communicated such transfer to the FDA. This agreement was assigned to us pursuant to the Contribution Agreement.

# **Government Regulation**

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs and medical devices, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

### U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND application which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's GLP regulations.
   Preclinical testing generally includes evaluation of our products in the laboratory or in animals to characterize the product and determine safety and efficacy;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of a NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to accept the filing for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with cGMP regulations and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval studies.

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of preclinical studies or other human studies, as appropriate, as well as manufacturing information, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may not result in the FDA allowing clinical trials to commence. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the new investigational drug to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Additionally, approval must also be obtained from each clinical trial site's IRB before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- **Phase 1.** Phase 1 includes the initial introduction of an investigational new drug into humans. Phase 1 clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.
- Phase 2. Phase 2 includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.
- Phase 3. Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug product, and to provide an adequate basis for product approval.

A pivotal study is any clinical study, which adequately meets regulatory agency requirements for the evaluation of a product candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are Phase 3 studies but may also be Phase 2 studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications.

The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the NDA submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if

the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee but it typically follows such recommendations.

The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its active pharmaceutical ingredient, or API, will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing

After regulatory approval of a drug product is obtained, we are required to comply with a number of post-approval requirements. As a holder of an approved NDA, we would be required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to ensure and preserve the long-term stability of the drug product. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time,

money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in, among other things,

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs or devices may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Also, from time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

### Marketing Exclusivity

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active pharmaceutical ingredient. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or

obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

### **Available Special Regulatory Procedures**

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

#### Fast Track Designation

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or lifethreatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

## **Priority Review**

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

### **Breakthrough Therapy Designation**

Under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

#### Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict



clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

## The Hatch-Waxman Amendments: 505(b)(2) Approval Process

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings of safety and effectiveness for an approved product that acts as the Reference Listed Drug, or RLD. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the RLD. The FDA may then approve the new product

candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (i) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (ii) such patent has expired; (iii) the date on which such patent expires; or (iv) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired.

Our current and anticipated product candidates will be based on already approved active pharmaceutical ingredients, or APIs, rather than new chemical entities, and a formulation that has been through Phase 1 studies. Accordingly, we expect to be able to rely on information from previously conducted formulation studies involving our clinical development plans and our NDA submissions. For product candidates that involve novel fixed-dose combinations of existing drugs or for studies of an existing product or product candidate in a new indication, we believe we generally will be able to initiate Phase 2/3 studies without conducting any new non-clinical or Phase 1 studies, though the FDA may not agree with our conclusions and may require us to conduct additional clinical or preclinical studies prior to initiating Phase 3 or other pivotal clinical trials. In those instances where our product candidate is a pharmacokinetically enhanced version of an approved API, we will need to conduct certain non-clinical and Phase 1 studies to confirm the pharmacokinetic profile of the product candidate prior to conducting Phase 2/3 studies.

## **Orphan Drug Designation and Exclusivity**

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat rare diseases or conditions, the FDA will grant orphan drug designation for that product for the orphan disease indication. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation,

however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation provides manufacturers with research grants, tax credits and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. If a drug designated as an orphan product receives marketing approval for an indication broader than the orphan drug indication for which it received the designation, it will not be entitled to orphan drug exclusivity. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan drug indication for which the orphan drug product has exclusivity or obtain approval for the same product but for a different indication for which the orphan drug product has exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, we may still be subject to competition. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

### **International Regulations**

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

## **Centralized Procedure**

The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization issued by the European Commission following a favorable opinion by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein, and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: the decentralized procedure and the mutual recognition procedure. Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country for medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following a national authorization, the applicant may seek further marketing authorizations from other EU countries under a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, medicinal products designated as orphan drug products benefit from financial incentives such as reductions in marketing authorization application fees or fee waivers and 10 years of marketing exclusivity following medicinal product approval. For a medicinal product to qualify as orphan drugs: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than five in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

## Accelerated Review (European Union)

Based on results of the Phase 3 clinical trial(s) submitted in an NDA, upon the request of an applicant, the FDA may grant the NDA a priority review designation, which sets the target date for FDA action on the application at six months. Priority review is granted where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are not met for priority review, the NDA is subject to the standard FDA review period of 10 months. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease (e.g. heavy disabling or life-threatening diseases) to be treated; the absence



or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

There can be no assurance that we or any of our partners would be able to satisfy one or more of these requirements to conduct preclinical or clinical trials or receive any regulatory approvals.

### Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the U.S. government enacted legislation providing a partial prescription drug benefit for Medicare beneficiaries, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Further, the Healthcare Reform Law substantially changes the way healthcare is financed in the United States by both government and private insurers. Among other cost containment measures, the Healthcare Reform Law establishes:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period, or the "donut hole"; and
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

We expect that federal, state and local governments in the United States will continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as the product candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which

products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, new products are facing increasingly high barriers to entry. In addition, in some countries, crossborder imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is secured for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

## Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The reach of the Anti-Kickback Statute was broadened by the Healthcare Reform Law, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 USC. §1320a-7b, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Healthcare Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of \$5,500 to \$11,000 for each separate false claim.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including healthcare fraud, and false statements relating to healthcare matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

In addition, we may be subject to, or our marketing activities may be limited by, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and their business associates governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information.

In order to raise sufficient financial resources to continue to advance our product candidates, we will need to address pricing pressures and potential thirdparty reimbursement coverage for our product candidates. In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It is and will continue to be time-consuming and expensive for us or our strategic collaborators to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

### The Physician Payment Sunshine Act

The Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Patient Protection and Affordable Care Act, or the ACA, requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Program, to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made by that entity, or by a third party as directed by that entity, to physicians and teaching hospitals, or to third parties on behalf of physicians or teaching hospitals, during the course of the preceding calendar year. The Final Rule implementing the Sunshine Act, published on February 8, 2013, requires data collection on payments to begin on August 1, 2013. The first annual report, comprised of data collected from August 1, 2013 to December 31, 2013, is due March 31, 2014. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from \$1,000 to \$10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of \$150,000) and from \$10,000 to \$100,000 for each knowing failure to report (up to a maximum per annual report of \$150,000). We will be required to collect data on and report these payments.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control.

### Employees

As of September 30, 2017, we employed a total of three full-time employees and our parent, BioXcel, has two employees who provide services to us pursuant to our separation and shared services agreement between us and BioXcel. In addition, we will have access to certain of BioXcel employees and resources through the various agreements we have entered into with BioXcel. We are not a party



to any collective bargaining agreements. We believe that we maintain good relations with our employees.

### Facilities

Our corporate headquarters and executive offices are provided to us by BioXcel under the shared services agreement discussed above and are located in Branford, Connecticut. We believe that our existing facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

# Legal Proceedings

We may be involved from time to time in ordinary litigation, negotiation, and settlement matters that will not have a material effect on our operations or finances. We are not currently party to any material legal proceedings, and we are not aware of any pending or threatened litigation against us that we believe could have a material adverse effect on our business, operating results or financial condition.

## MANAGEMENT

# **Directors and Executive Officers**

Name	Age	Position
Executive Officers:		
		Chief Executive Officer, President, Secretary and
Vimal Mehta, Ph.D.	56	Director
Vincent J. O'Neill, M.D.	48	Chief Medical Officer
Richard Steinhart	60	Chief Financial Officer
Frank Yocca, Ph.D.	62	Chief Scientific Officer
Key Employees:		
Luca Rastelli, Ph.D.	50	Vice President—Oncology R&D
Chids Mahadevan	46	Vice President—Finance
Non-Employee Directors:		
Peter Mueller, Ph.D.	61	Chairman of the Board of Directors
Sandeep Laumas, M.D.	49	Director
Krishnan Nandabalan, Ph.D.	55	Director

# **Executive Officers**

Vimal Mehta, Ph.D. has served as a director since April 2017 and as our Chief Executive Officer, President and Secretary since May 2017. He is a cofounder of BioXcel Corporation and has served as its Chairman of the Board since 2005 and its Chief Executive Officer since September 2014. Dr. Mehta has held various senior scientific and business development positions, including Senior Vice President of Business Development at London-based Inpharmatica Ltd, a global predictive informatics company, from 2002 to 2006 and Senior Vice President, Business Development for Jubilant Life Sciences, an integrated global pharmaceutical and life sciences company, from 2006 to 2007. Previously, Dr. Mehta served as Business Development Manager at CuraGen Corporation, a biotechnology company, from 1996 to 2002. He held multiple positions in the Department of Radiology at the University of Texas, Southwestern Medical Center from 1989 to 1996, including Postdoctoral Fellow, Instructor and Assistant Professor. Dr. Mehta holds a Ph.D. in Chemistry from the University of Delhi, India and completed a Post-Doctoral Fellowship in Chemistry at the University of Montpellier, France. During the length of his career, Dr. Mehta has garnered a deep understanding of the biopharma and healthcare ecosystem and has been actively involved in diverse global value generating initiatives encompassing corporate strategy and planning, global business development, and corporate fundraising. He has helped to shape the company's strategic and business trajectory and which the Board believes qualifies him to serve as a director of our company.

Vincent J. O'Neill, M.D. has served as our Chief Medical Officer since July 2017. He served as the Chief Medical Officer of Mirna Therapeutics, Inc. from April 2016 to May 2017. From June 2014 to May 2016, he served as the Chief Medical Officer of Exosome Diagnostics, Inc., a diagnostics company. From 2012 to 2014, Dr. O'Neill was global head Personalized of Medicine and Companion Diagnostics at Sanofi S.A., a pharmaceutical company. From 2009 to 2012, Dr. O'Neill served as Group Director at Genentech, Inc. where he was involved in the expanded approval of products such as Avastin and Tarceva. From 2006 to 2009, Dr. O'Neill served as Director, Discovery Medicine at GlaxoSmithkline plc. Dr. O'Neill holds an M.D., MBChd and M.Sc. in Pathology from the University of Glasgow, UK.

**Richard I. Steinhart** has served as our Chief Financial Officer since October 2017. From October 2015 to June 2017 he was Vice President and CFO at Remedy Pharmaceuticals, Inc. From January 2014 to September 2015 Mr. Steinhart worked as a financial and strategic consultant to the



biotechnology and medical device industries. From April 2006 through December 2013, Mr. Steinhart was employed by MELA Sciences, Inc., as their Vice President, Finance and Chief Financial Officer, Treasurer and Secretary from April 2006 to April 2012 and as Sr. Vice President, Finance and Chief Financial Officer from April 2012 to December 2013. From May 1992 until joining MELA Sciences, Mr. Steinhart was a Managing Director of Forest Street Capital/SAE Ventures, a boutique investment banking, venture capital, and management consulting firm focused on healthcare and technology companies. Prior to Forest Street Capital/SAE Ventures, he was Vice President and Chief Financial Officer of Emisphere Technologies, Inc. Mr. Steinhart's other experience includes seven years at CW Group, Inc., a venture capital firm focused on medical technology and biopharmaceutical companies, where he was a General Partner and Chief Financial Officer. Mr. Steinhart is a member of the Board of Directors of Actinium Pharmaceuticals, Inc., a position he assumed in November 2013, and Atossa Genetics, Inc., where he began his service in March 2014. Mr. Steinhart serves as the Chairman of the Audit Committee at Actinium Pharmaceuticals, where he also sits on the Compensation and Corporate Governance Committees. Mr. Steinhart serves as the Chairman of Atossa Genetics Audit Committee and is a member of its Compensation Committee. He holds B.B.A. and M.B.A. degrees from Pace University and is a Certified Public Accountant (inactive).

**Frank D. Yocca, Ph.D.** has served as our Chief Scientific Officer since June 2017. From April 2015 to April 2017, he was Senior Vice President, CNS R&D of BioXcel. From 2005 to 2015, Dr. Yocca held multiple leadership roles at AstraZeneca plc, including Vice President, Strategy and Externalization, Neuroscience Virtual Innovative Medicine Unit (iMed) (2011-2015), Vice President and Head, Strategy Unit, CNS and Pain Innovative Medicine Unit (iMed) (2010 to 2011) and Vice President and Head, CNS Pain Discovery (2005 to 2010). Prior to this he was Executive Director at the Bristol Myers Squibb Pharmaceutical Research Institute from 1984 to 2004 where he served concurrent leadership responsibilities within the Neuroscience Clinical Group for Early and Late Clinical Development Studies. Prior to this Dr. Yocca served as Executive Director, Neuroscience Discovery from 1997 to 2003, where he was a collaborator in the development and implementation of corporate strategic plans and leader for the Neuroscience Biology Department in the discovery of psychiatry and Alzheimer's clinical candidates. He was a core member of the Abilify Product Development and Commercialization Team from 1999 to 2002 and a core member of the Early and Late Discovery and Development Teams from 1984 to 2001. Dr. Yocca holds a B.S. in biochemistry from Manhattan College and an M.S. in pharmacology and a Ph.D. in neuropharmacology for St. John's University.

## Key Employees

**Chids Mahadevan** has served as our Vice President—Finance since June 2017. Since April 2015 he has served as Vice President—Finance and Chief Accounting Officer of BioXcel. Prior to joining BioXcel, From 2010 to 2015, Mr. Mahadevan was the Senior Vice President, Finance at GoldenSource Corp, an enterprise data management software company where he led the global finance and accounting team. From 2007 to 2010, he was the Director of Finance at inVentiv Health Inc., a professional services organization that accelerates the clinical and commercial success of biopharmaceutical companies worldwide. Mr. Mahadevan started his career at Ramco Systems, a provider of adaptive enterprise solutions in a global market in 1996 where he progressed to become Head of Finance for the United States operations and the Finance Lead for the global aviation software segment and remained until 2007. Mr. Mahadevan holds a Bachelors in Commerce from Madras University. Mr. Mahadevan is a Certified Public Accountant in the United States and also a Chartered Accountant from India.

Luca Rastelli, Ph.D. has served as our Vice President—Oncology R&D since June 2017. Previously, he was the Vice President of Oncology R&D of BioXcel from May 2015 to June 2017. Dr. Rastelli has more than 20 years of drug discovery and development experience in pharmaceutical, biotech and start-up companies. Dr. Rastelli has held multiple preclinical and clinical project leadership

positions. He served as Head of Translational Oncology at Boston Strategics Corporation, a pharmaceutical research and development company, from 2013 to 2014, and as Global Project Leader at EMD Serono Inc., a subsidiary of Merck KGaA, Darmstadt, Germany from 2006 to 2013. Dr. Rastelli served as Senior Director Biology from 2003 to 2006 at Sopherion Therapeutics, Inc., a company that designed and developed, and commercialized novel anti-cancer drugs and molecules. Dr. Rastelli holds a Ph.D. in Molecular Biology of Development from the University of Geneva, Switzerland.

### **Non-Employee Directors**

**Peter Mueller, Ph.D.** has served as a director of our company since April 2017 and Chairman of the Board since August 2017. With over 30 years of global pharma and biotech experience, Dr. Mueller is currently the President of the Mueller Health Foundation, a private foundation tackling globally lethal infectious diseases such as tuberculosis by addressing latency and the ever growing challenges of antimicrobial resistance. From 2014 to 2016, he was President of R&D and Chief Scientific Officer of Axcella Health, a biotechnology company. From 2003 to 2014, Dr. Mueller served as Executive Vice President Global Research and Development & Chief Scientific Officer for Vertex Pharmaceuticals, Incorporated, a biotechnology company. He was involved in the development of Incivek (2011), Kalydeco (2012), and Orkambi (2014). Prior to his tenure at Vertex, he served as Senior Vice President, Research and Development, for Boehringer Ingelheim Pharmaceuticals, Inc. overseeing global research programs (immunology, inflammation, cardiovascular diseases and gene therapy) and the development of all drug candidates of the company's worldwide portfolio in North and South America, Canada and Japan, beginning in 1997. He was involved in the development of Spiriva, Combivent, Atrovent and Viramune. Dr. Mueller received both an undergraduate degree and a Ph.D. in Chemistry at the Albert Einstein University of Ulm, Germany, where he also holds a Professorship in Theoretical Organic Chemistry. He completed fellowships in Quantum Pharmacology at Oxford University and in Biophysics at Rochester University. He is a member of various scientific and political societies and currently serves on the Board of Inhibikase Therapeutics and the US-India Chamber of Commerce Biotech. He also services as chairman of the Scientific Advisory Board of BioXcel and is an advisor to the University Iowa (CBB). We believe that Dr. Mueller's extensive experience in the life sciences industry as a scientist and executive qualifies him to serve as a director of

**Sandeep Laumas, M.D.** has served as a director of our company since September 2017. He has served as a Director of BioXcel since May 2013. In August 2007, Dr. Laumas founded Bearing Circle Capital, an investment firm, and has served as its Managing Director since such time. Dr. Laumas was a Managing Director of North Sound Capital from 2003 to 2007, where he was responsible for the global healthcare investment portfolio. Dr. Laumas was an analyst at Balyasny Asset Management from 2001 to 2003. He began his career at Goldman Sachs & Co. in 1996 as an equity analyst in the healthcare investment banking division before transitioning to the healthcare equity research division. From February 2011 to February 2012 he was a member of the board of directors of Super Religare Laboratories Limited, Southeast Asia's largest clinical laboratory service company. Dr. Laumas also served as a Director of Parkway Holdings Ltd. from May to August 2010 and currently has served as a director of Innovate Biopharmaceuticals, Inc. since 2014. Dr. Laumas received his A.B. (Chemistry) from Cornell University in 1990, his M.D. from Albany Medical College, with a research year at the Dana-Farber Cancer Institute and completed his medical internship at the Yale University School of Medicine. Dr. Laumas has a novel industry perspective, particularly in both public and private investments and financial transactions in the healthcare arena, which we believe qualifies him to serve as a director of our company.

Krishnan Nandabalan, Ph.D. has served as a director of our company since May 2017. He is a co-founder of BioXcel and has served as its President and Secretary since 2005 and Chief Scientific Officer since September 2014. He has served as a director of BioXcel since March 2005. From August

2004 to September 2005, Dr. Nandabalan served as the Vice President of Corporate Development at Genaissance Pharmaceuticals, a population genomics company, from October 2000 to August 2004, he was Vice President of Product Development, Alliances and Business Development, and from October 1998 to October 2000, he was Executive Director of Technology Systems. Prior to this, he served as Group Leader of the Functional Genomics Group at CuraGen Corporation from January 1995 to September 1998. Dr. Nandabalan was also a Founding Director of Ayugen BioSciences, a privately held company that specializes in genomic tests and services, from March 2006 to October 2015. Dr. Nandabalan holds a B.Sc. and M.Sc. in agricultural science from Tamil Nadu Agricultural University and a Ph.D. in biochemistry and molecular biology from Indian Institute of Science. During his career, Dr. Nandabalan has acquired a thorough understanding of market trends impacting the global healthcare environment, the pharma value chain, the current unmet medical needs, and in applying novel technologies to solve these needs, which we believe qualifies him to serve as a director of our company.

### **Family Relationships**

There are no family relationships among any of our executive officers or directors.

# **Composition of our Board of Directors**

Our board of directors currently consists of four directors. Our amended and restated certificate of incorporation will provide that the number of directors on our board of directors shall be fixed exclusively by resolution adopted by our board of directors. Our amended and restated certificate of incorporation and amended and restated bylaws will provide that our board of directors will be divided into three classes, as nearly equal in number as possible, with the directors in each class serving for a three-year term, and one class being elected each year by our stockholders.

When considering whether directors have the experience, qualifications, attributes or skills, taken as a whole, to enable our board of directors to satisfy its oversight responsibilities effectively in light of our business and structure, the board of directors focuses primarily on each person's background and experience as reflected in the information discussed in each of the directors' individual biographies set forth above. We believe that our directors provide an appropriate mix of experience and skills relevant to the size and nature of our business.

In accordance with our amended and restated certificate of incorporation and amended and restated bylaws, each of which will be in effect immediately prior to the consummation of this offering, our board of directors will be divided into three classes with staggered three year terms. At each annual meeting of stockholders after the initial classification, the successors to the directors whose terms will then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election. Our directors will be divided among the three classes as follows:

- the Class I directors will be and his/her term will expire at the annual meeting of stockholders to be held in 2018;
- the Class II directors will be Sandeep Laumas and Krishnan Nandabalan, and their terms will expire at the annual meeting of stockholders to be held in 2019; and
- the Class III directors will be Vimal Mehta and Peter Mueller, and their terms will expire at the annual meeting of stockholders to be held in 2020.

Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of onethird of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our Company.

Pursuant to the terms of our amended and restated certificate of incorporation, directors may only be removed for cause by the affirmative vote of the holders of at least a majority of our outstanding shares of common stock which are present in person or by proxy and entitled to vote.

### **Director Independence**

Prior to the consummation of this offering, our board of directors undertook a review of the independence of our directors and considered whether any director has a relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our board of directors has affirmatively determined that , and are each an "independent director," as defined under the Nasdaq rules.

### **Controlled Company Exception**

After the consummation of this offering, BioXcel, will, in the aggregate, have more than 50% of the combined voting power for the election of directors. As a result, we will be a "controlled company" within the meaning of the Nasdaq rules and may elect not to comply with certain corporate governance standards, including that: (i) a majority of our board of directors consists of "independent directors," as defined under the Nasdaq rules; (ii) we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; (iii) we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and (iv) we perform annual performance evaluations of the nominating and corporate governance and compensation committees. We intend to rely on the foregoing exemptions provided to controlled companies under the Nasdaq rules. Therefore, immediately following the consummation of this offering, we may not have a majority of independent directors on our board of directors, an entirely independent nominating and corporate governance evaluations of the nominating and corporate governance and compensation committee or perform annual performance evaluations of the nominating and corporate governance and compensation committees unless and until such time as we are required to do so. Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of these corporate governance requirements. In the event that we cease to be a "controlled company" and our shares continue to be listed on The Nasdaq Stock Market, we will be required to comply with these provisions within the applicable transition periods. See "Risk Factors—Risks Related to Our Relationship with BioXcel" for additional information.

### **Committees of Our Board of Directors**

Our board of directors directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the board of directors and its standing committees. We will have a standing audit committee, nominating and corporate governance committee and compensation committee. In addition, from time to time, special committees may be established under the direction of the board of directors when necessary to address specific issues.

# Audit Committee

Our audit committee will be responsible for, among other things:

- approve and retain the independent auditors to conduct the annual audit of our financial statements;
- review the proposed scope and results of the audit;
- review and pre-approve audit and non-audit fees and services;

- review accounting and financial controls with the independent auditors and our financial and accounting staff;
- review and approve transactions between us and our directors, officers and affiliates;
- establish procedures for complaints received by us regarding accounting matters;
- oversee internal audit functions, if any; and
- prepare the report of the audit committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting
  proxy statement.

Upon the consummation of this offering, our audit committee will consist of and with serving as chair. Rule 10A-3 of the Exchange Act and the Nasdaq rules require that our audit committee have at least one independent member upon the listing of our common stock, have a majority of independent members within 90 days of the date of this prospectus and be composed entirely of independent members within one year of the date of this prospectus. Our board of directors has affirmatively determined that and each meet the definition of "independent director" under the Nasdaq rules, that meets the independence standards under Rule 10A-3, and that does not meet the independence standards under Rule 10A-3. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our board of directors has determined that will qualify as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Our board of directors will adopt a written charter for the audit committee, which will be available on our principal corporate website at substantially concurrently with the consummation of this offering. The information on any of our websites is deemed not to be incorporated in this prospectus or to be part of this prospectus.

### **Compensation Committee**

Our compensation committee is responsible for, among other things:

- review and recommend the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administer our stock incentive plans; and
- prepare the report of the compensation committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

and

and

are "non-employee directors" as defined in Section 16b-3 of the Exchange Act. We intend to avail ourselves of the "controlled company" exception under the Nasdaq rules, which exempts us from the requirement that we have a compensation committee composed entirely of independent directors. Our board of directors will adopt a written charter for the compensation committee, which will be available on our principal corporate website at substantially concurrently with the consummation of this offering. The information on any of our websites is deemed not to be incorporated in this prospectus or to be part of this prospectus.

# Nominating and Governance Committee

Our nominating and governance committee is responsible for, among other things:

- identify and nominate members of the board of directors;
- develop and recommend to the board of directors a set of corporate governance principles applicable to our company; and
- oversee the evaluation of our board of directors.

Upon the consummation of this offering, our nominating and corporate governance committee will consist of

and , with serving as chair. We intend to avail ourselves of the "controlled company" exception under the Nasdaq rules, which exempts us from the requirement that we have a nominating and corporate governance composed entirely of independent directors. Our board of directors will adopt a written charter for the nominating and corporate governance committee, which will be available on our principal corporate website at substantially concurrently with the consummation of this offering. The information on any of our websites is deemed not to be incorporated in this prospectus or to be part of this prospectus.

# **Compensation Committee Interlocks and Insider Participation**

Except for , none of our executive officers serves as a member of the board of directors or compensation committee (or other committee performing equivalent functions) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

### **Code of Ethics and Code of Conduct**

Prior to the completion of this offering, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code will be posted on our website, *www.bioxceltherapeutics.com*. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. The information on any of our websites is deemed not to be incorporated in this prospectus or to be part of this prospectus.

# Limitations on Liability and Indemnification Matters

Upon the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation to be in effect upon the closing of this offering will provide that we are authorized to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws to be in effect upon the closing of this offering will provide that we are required to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director or executive officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify our other officers and employees when determined appropriate by our board of directors. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses, including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon the closing of this offering may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

## EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the year ended December 31, 2016 include our principal executive officer and the next most highly compensated executive officers during the year ended December 31, 2016:

- Vimal Mehta, Ph.D., our Chief Executive Officer; and
- Frank Yocca, Ph.D., our Chief Scientific Officer.

## 2016 Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the year ended December 31, 2016.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Vimal Mehta, Ph.D.(1)	2016	62,250	_		5,098	67,348
Chief Executive Officer, President, Secretary and Director						
Frank Yocca, Ph.D. Chief Scientific Officer	2016	108,000	_	—	—	108,000

(1) Mr. Mehta is an employee of our parent, BioXcel. He provides services to us pursuant to a services agreement between us and BioXcel.

## **Outstanding Equity Awards at December 31, 2016**

No equity awards of the Company were outstanding at December 31, 2016.

# **Non-Employee Director Compensation**

None of our non-employee directors were compensated for their services to the Company during the fiscal year ended December 31, 2016.

Upon completion of this offering, we will pay our non-employee directors \$30,000 for each full year of service, payable in arrears in \$7,500 quarterly increments. Any increase in the aforementioned amount shall be at the sole discretion of the our Board of Directors. We have also agreed to issue each non-employee director options to purchase 157 shares of our common stock upon completion of this offering with an exercise price equal to the initial public offering price of this offering and which shall vest in three equal installments beginning on the first anniversary of the closing date of this offering.

On August 23, 2017, in connection with the appointment of each non-employee director, we granted each of them options to purchase 367 shares of our common stock with an exercise price of \$97.19, which vest as follows: options to purchase 123 shares shall vest of August 22, 2018 and options to purchase 122 shares shall vest on each of August 22, 2019 and August 22, 2020. In addition, on August 23, 2017, in connection with his appointment as chairman of the board of directors, we granted Dr. Mueller options to purchase 157 shares of our common stock with an exercise price of \$97.19, which vest as follows: options to purchase 53 shares shall vest of August 22, 2018 and options to purchase 52 shares shall vest on each of August 22, 2020.

## **Employment Arrangements**

Each of our executive officers, other than Frank Yocca and Richard Steinhart, are employed by our parent, BioXcel, and provide services to us pursuant to the Services Agreement between us and BioXcel. Messrs. Yocca and Steinhart are each employed directly by us. On or prior to the date of this offering, BioXcel will have an employment agreement or offer letter with each of our executive officers that sets forth the initial terms and conditions of employment. These agreements will provide for at-will employment and set forth the executive officer's annual base salary, performance bonus target opportunity, initial equity incentive grant, terms of severance and eligibility for employee benefits. The annual target bonus that each executive officer will be eligible to receive will be payable based on our board of director's assessment of each executive officer's individual performance and overall company performance.

Prior to this offering, our business was owned by BioXcel. Therefore, BioXcel's historical compensation strategy has been determined primarily by BioXcel's Board of Directors. The discussion below of our employment arrangements may serve as a template for our anticipated compensation structure for our named executive officers on after completion of this offering. BioXcel's compensation philosophy may be relevant to us because it is anticipated that the elements of our compensation will be similar to the elements of BioXcel's compensation. However, our compensation committee will review the impact of our separation from BioXcel and will review all aspects of compensation and make appropriate adjustments in structuring our executive compensation arrangements. As of the date hereof, our board of directors has reviewed our executive compensation arrangements however the specifics of our compensation programs and policies have not yet been determined.

### **Employment Agreements with BioXcel**

On September 14, 2014, Vimal Mehta entered into an executive employment agreement with BioXcel in which he agreed to serve as Chief Executive Officer. The term of the agreement was effective as of September 1, 2014, continues until September 1, 2017 and automatically renews for successive one year periods at the end of each term until either party delivers written notice of their intent not to review at least 60 days prior to the expiration of the then effective term. Dr. Mehta's base salary is \$125,000 per year. He is eligible to receive a bonus of up to 50% of his base salary per year at the discretion of the BioXcel Compensation Committee or as agreed to by Dr. Mehta and the Board of Directors. Dr. Mehta is also entitled to a car lease allowance of up to \$750 per month. Dr. Mehta is entitled to participate in any and all benefit plans, from time to time, in effect for senior management, along with vacation, sick and holiday pay in accordance with our policies established and in effect from time to time. Life insurance premium for Dr. Mehta amounting to \$5,673.20 per quarter is paid by us as an additional benefit. The agreement may be terminated by us at any time and for any reason (or no reason), and with or without cause, provided if the agreement is terminated without cause, we are required to provide him at least 60 days prior written notice. Dr. Mehta may terminate the agreement for any reasons (or no reason) upon 60 days prior written notice. If the employment agreement is terminated by us other than for cause or if Dr. Mehta terminates his employment for good reason, which includes a change of control, Dr. Mehta shall receive (i) a severance payment equal to his base compensation for the year; (ii) immediate vesting of all unvested stock options and the extension of the exercise period of such options to the later of the longest period permitted by our stock option plans or ten years following the termination date; (iii) payment in respect of any bonus earned but not yet paid; and (iv) payment of the c

The employment agreement also contains covenants: (i) restricting the executive from engaging in any activity competitive with our business during the term of the employment agreement and in the event of termination for cause or without good reason, for a period of one year thereafter; (ii) prohibiting the executive from disclosing confidential information regarding us; and (iii) soliciting

our suppliers, employees, customers and prospective customers during the term of the employment agreement and for a period of one year thereafter.

### **Employment Agreements with BTI**

BioXcel assigned its employment agreement with Frank Yocca to BTI on June 30, 2017. The term of the agreement was effective as of October 1, 2015 and continues until either party delivers written notice of their intent to terminate the employment relationship upon at least 90 days prior written notice. Mr. Yocca's base salary is \$180,000 per year, and pursuant to his employment agreement, will increase to \$225,000 per year upon completion of this offering. Mr. Yocca is also entitled to participate in any and all benefit plans, from time to time, in effect for employees, along with vacation, sick and holiday pay in accordance with BTI's policies established and in effect from time to time. The agreement may be terminated by BTI at any time and for any reason (or no reason), and with or without cause. If the employment agreement is terminated by BTI other than for cause or if Mr. Yocca terminates his employment for good reason, Mr. Yocca shall receive a lump sum cash severance payment equal to three (3) months of his base salary. The employment agreement also contains covenants: (i) restricting the executive from engaging in any activity competitive with BTI's business during the term of the employment agreement and for a period of one year thereafter; (ii) prohibiting the executive from disclosing confidential information regarding BTI; and (iii) soliciting BTI's suppliers, employees, customers and prospective customers during the term of the employment agreement and for a period of six months thereafter.

### 2017 Equity Incentive Plan

Our board of directors adopted the 2017 Equity Incentive Plan, or the Plan, on August 22, 2017. The Plan will expire on August 21, 2027. The purpose of the Plan is to attract and retain key personnel and to provide a means for directors, officers, managers, employees, consultants and advisors to acquire and maintain an interest in the Company, which interest may be measured by reference to the value of its common stock. The material terms of the 2017 Plan are summarized below.

#### Administration

The Company's board of directors or a committee appointed by the board of directors (the "Committee") will administer the Plan. The Committee will have the authority, without limitation (i) to designate Participants (defined below) to receive awards under the Plan ("Awards"), (ii) determine the types of Awards to be granted to Participants, (iii) determine the number of shares of common stock to be covered by Awards, (iv) determine the terms and conditions of any Awards granted under the Plan, (v) determine to what extent and under what circumstances Awards may be settled in cash, shares of common stock, other securities, other Awards or other property, or canceled, forfeited or suspended, (vi) determine whether, to what extent, and under what circumstances the delivery of cash, common stock, other securities, other Awards or other property and other amounts payable with respect to an Award shall be made; (vii) interpret, administer, reconcile any inconsistency in, settle any controversy regarding, correct any defect in and/or complete any omission in the Plan and any instrument or agreement relating to, or Award granted under, the Plan; (viii) establish, amend, suspend, or waive any rules and regulations and appoint such agents as the Committee shall deem appropriate for the proper administration of the Plan; (ix) accelerate the vesting or exercisability of, payment for or lapse of restrictions on, Awards; (x) reprice existing Awards with shareholder approval or to grant Awards in connection with or in consideration of the cancellation of an outstanding Award with a higher price; and (xi) make any other determination and take any other action that the Committee deems necessary or desirable for the administration of the Plan. The Committee will have full discretion to administer and interpret the Plan and to adopt such rules, regulations and procedures as it deems necessary or

advisable and to determine, among other things, the time or times at which the awards may be exercised and whether and under what circumstances an award may be exercised.

# Eligibility

Employees, directors, officers, advisors and consultants of the Company or its affiliates are eligible to participate in the Plan and are referred to as "Participants". The Committee has the sole and complete authority to determine who will be granted an Award under the Plan, however, it may delegate such authority to one or more officers of the Company under the circumstances set forth in the Plan.

### Number of Shares Authorized

Up to 12,500 shares of common stock may be issued pursuant to awards granted under the Plan.

If an Award is forfeited, canceled, or if any Option terminates, expires or lapses without being exercised, the common stock subject to such Award will again be made available for future grant. However, shares that are used to pay the exercise price of an Option or that are withheld to satisfy the Participant's tax withholding obligation will not be available for re-grant under the Plan.

If there is any change in the Company's corporate capitalization or structure, the Committee in its sole discretion may make substitutions or adjustments to the number of shares of common stock reserved for issuance under the Plan, the number of shares covered by Awards then outstanding under the Plan, the limitations on Awards under the Plan, the exercise price of outstanding Options and such other equitable substitution or adjustments as it may determine appropriate.

The Plan will have a term of ten years and no further Awards may be granted under the Plan after that date.

### Awards Available for Grant

The Committee may grant Awards of Non-Qualified Stock Options, Incentive Stock Options, Stock Appreciation Rights, Restricted Stock Awards, Restricted Stock Units, Stock Bonus Awards, Performance Compensation Awards (including cash bonus awards) or any combination of the foregoing. Notwithstanding, the Committee may not grant to any one person in any one calendar year Awards (i) for more than 50% of the available shares under the Plan in the aggregate or (ii) payable in cash in an amount exceeding \$10,000,000 in the aggregate.

### Options

The Committee will be authorized to grant Options to purchase common stock that are either "qualified," meaning they are intended to satisfy the requirements of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") for Incentive Stock Options, or "non-qualified," meaning they are not intended to satisfy the requirements of Section 422 of the Code. Options granted under the Plan will be subject to the terms and conditions established by the Committee. Under the terms of the Plan, unless the Committee determines otherwise in the case of an Option substituted for another Option in connection with a corporate transaction, the exercise price of the Options will not be less than the fair market value (as determined under the Plan) of the shares of common stock on the date of grant. Options granted under the Plan will be subject to such terms, including the exercise price and the conditions and timing of exercise, as may be determined by the Committee and specified in the applicable award agreement. The maximum term of an Option granted under the Plan will be ten years from the date of grant (or five years in the case of an Incentive Stock Option granted to a 10% stockholder). Payment in respect of the exercise of an Option may be made in cash or by check, by surrender of unrestricted shares of common stock (at their fair market value on the date of exercise)

that have been held by the participant for any period deemed necessary by the Company's accountants to avoid an additional compensation charge or have been purchased on the open market, or the Committee may, in its discretion and to the extent permitted by law, allow such payment to be made through a brokerassisted cashless exercise mechanism, a net exercise method, or by such other method as the Committee may determine to be appropriate.

### **Stock Appreciation Rights**

The Committee will be authorized to award Stock Appreciation Rights (or SARs) under the Plan. SARs will be subject to such terms and conditions as established by the Committee. A SAR is a contractual right that allows a participant to receive, either in the form of cash, shares or any combination of cash and shares, the appreciation, if any, in the value of a share over a certain period of time. A SAR granted under the Plan may be granted in tandem with an option and SARs may also be awarded to a participant independent of the grant of an Option. SARs granted in connection with an Option shall be subject to terms similar to the Option which corresponds to such SARs. SARs shall be subject to terms established by the Committee and reflected in the award agreement.

## **Restricted Stock**

The Committee will be authorized to award Restricted Stock under the Plan. The Committee will determine the terms of such Restricted Stock awards. Restricted Stock are shares of common stock that generally are non-transferable and subject to other restrictions determined by the Committee for a specified period. Unless the Committee determines otherwise or specifies otherwise in an award agreement, if the Participant terminates employment or services during the restricted period, then any unvested restricted stock will be forfeited.

## **Restricted Stock Unit Awards**

The Committee will be authorized to award Restricted Stock Unit awards. The Committee will determine the terms of such Restricted Stock Units. Unless the Committee determines otherwise or specifies otherwise in an award agreement, if the Participant terminates employment or services during the period of time over which all or a portion of the units are to be earned, then any unvested units will be forfeited. At the election of the Committee, the Participant will receive a number of shares of common stock equal to the number of units earned or an amount in cash equal to the fair market value of that number of shares at the expiration of the period over which the units are to be earned or at a later date selected by the Committee.

## **Stock Bonus Awards**

The Committee will be authorized to grant Awards of unrestricted shares of common stock or other Awards denominated in shares of common stock, either alone or in tandem with other Awards, under such terms and conditions as the Committee may determine.

### **Performance Compensation Awards**

The Committee will be authorized to grant any Award under the Plan in the form of a Performance Compensation Award exempt from the requirements of Section 162(m) of the Code by conditioning the vesting of the Award on the attainment of specific performance criteria of the Company and/or one or more affiliates, divisions or operational units, or any combination thereof, as determined by the Committee. The Committee will select the performance criteria based on one or more of the following factors: (i) revenue; (ii) sales; (iii) profit (net profit, gross profit, operating profit, economic profit, profit margins or other corporate profit measures); (iv) earnings (EBIT, EBITDA, earnings per share, or other corporate profit measures); (v) net income (before or after taxes, operating

income or other income measures); (vi) cash (cash flow, cash generation or other cash measures); (vii) stock price or performance; (viii) total stockholder return (stock price appreciation plus reinvested dividends divided by beginning share price); (ix) economic value added; (x) return measures (including, but not limited to, return on assets, capital, equity, investments or sales, and cash flow return on assets, capital, equity, or sales); (xi) market share; (xii) improvements in capital structure; (xiii) expenses (expense management, expense ratio, expense efficiency ratios or other expense measures); (xiv) business expansion or consolidation (acquisitions and divestitures); (xv) internal rate of return or increase in net present value; (xvi) working capital targets relating to inventory and/or accounts receivable; (xvii) inventory management; (xviii) service or product delivery or quality; (xix) customer satisfaction; (xx) employee retention; (xxi) safety standards; (xxii) productivity measures; (xxiii) cost reduction measures; and/or (xxiv) strategic plan development and implementation.

### Transferability

Each Award may be exercised during the Participant's lifetime only by the Participant or, if permissible under applicable law, by the Participant's guardian or legal representative and may not be otherwise transferred or encumbered by a Participant other than by will or by the laws of descent and distribution. The Committee, however, may permit Awards (other than Incentive Stock Options) to be transferred to family members, a trust for the benefit of such family members, a partnership or limited liability company whose partners or stockholders are the Participant and his or her family members or anyone else approved by it.

## Amendment

The Plan will have a term of ten years. The Company's board of directors may amend, suspend or terminate the Plan at any time; however, shareholder approval to amend the Plan may be necessary if the law or SEC so requires. No amendment, suspension or termination will materially and adversely affect the rights of any Participant or recipient of any Award without the consent of the Participant or recipient.

### **Change in Control**

Except to the extent otherwise provided in an Award or required by applicable law, in the event of a Change in Control (as defined in the Plan), upon the occurrence of a Change in Control, the Committee is authorized, but not obligated, to make any of the following adjustments (or any combination thereof) in the terms and conditions of outstanding Awards: (i) continuation or assumption of outstanding Awards by the surviving company; (ii) substitution by the surviving company of equity, equity-based and/or cash awards with substantially the same terms for outstanding Awards; (iii) accelerated exercisability, vesting and/or lapse of restrictions under outstanding Awards immediately prior to the occurrence of the Change in Control; (iv) upon written notice, provide that any outstanding Awards must be exercised, to the extent then exercisable, during a reasonable period determined by the Committee and at the end of such period, any unexercised Awards will terminate; and (v) cancellation of all or any portion of outstanding Awards for fair value (in the form of cash, shares or other property) and which value may be zero.

# 2017 Option Grants

On August 23, 2017, we issued the following options to purchase shares of our common stock and on such vesting terms at a price of \$97.61 per share under the Plan to our executive officers, strategic advisors, directors and key employees as follows:

Name	Options Granted	Vesting Schedule
Vimal Mehta, Ph.D.	2,000	Vests on March 31, 2018.
Krishnan Nandabalan, Ph.D.	2,000	Vests on March 31, 2018.
	2,000	vests on March 51, 2010.
Peter Mueller, Ph.D.	367	Options to purchase 123 shares shall vest of August 22, 2018 and options to purchase 122 shares shall vest on each of August 22, 2019 and August 22, 2020.
Sheila Gujrathi, Ph.D.	367	Options to purchase 123 shares shall vest of August 22, 2018 and options to purchase 122 shares shall vest on each of August 22, 2019 and August 22, 2020.
Steve Paul, M.D.	367	Options to purchase 123 shares shall vest of August 22, 2018 and options to purchase 122 shares shall vest on each of August 22, 2019 and August 22, 2020.
Peter Mueller, Ph.D.	157	Options to purchase 53 shares shall vest of August 22, 2018 and options to purchase 52 shares shall vest on each of August 22, 2019 and August 22, 2020.
Frank Yocca, Ph.D.	630	Options to purchase 157 shares vest on March 31, 2018, and the remaining 473 shares vesting monthly over 36 months from August 23, 2018 through August 22, 2021.
Chids Mahadevan	393	Options to purchase 98 vest on March 31, 2018, and the remaining 295 monthly over 36 months from August 23, 2018 through August 22, 2021.
Vince O'Neill, M.D.	525	Options to purchase 131 on August 22, 2018, and the remaining 394 shares vesting monthly over 36 months from August 23, 2018 through August 22, 2021.
Sandeep Laumas, M.D.	367	Options to purchase 123 shares shall vest of August 22, 2018 and options to purchase 122 shares shall vest on each of August 22, 2019 and August 22, 2020.
Luca Rastelli, Ph.D.	262	Options to purchase 66 shares shall vest on August 22, 2018 and options to purchase 196 shares shall vest over 36 months from August 23, 2018 through August 22, 2021.

We have also agreed to issue our advisors Drs. Paul and Gujrathi options to purchase 157 shares of our common stock upon completion of this offering with an exercise price equal to the initial public offering price of this offering and which shall vest in three installments beginning on the first anniversary of the closing date of this offering.

### CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following is a summary of transactions and series of similar transactions, since our inception on March 29, 2017 to which we have been a participant in which the amount involved exceeded or will exceed \$120,000 and in which any of our director, executive officer, holder of more than 5% of our capital stock, promotor or certain control person or any member of their immediate family had or will have a direct or indirect material interest.

## Amended and Restated Asset Contribution Agreement with BioXcel

We have entered into an asset contribution agreement, effective June 30, 2017, with BioXcel, as amended and restated on November 7, 2017, or the Contribution Agreement, pursuant to which BioXcel agreed to contribute to us, and we agree to acquire from BioXcel, all of BioXcel's rights, title and interest in and to BXCL501, BXCL701, BXCL502 and BXCL702, collectively, the Candidates, and all of the assets and liabilities associated with the Candidates, in consideration for (i) 40,000 shares of our common stock, (ii) \$1 million upon completion of this offering, (ii) \$500,000 upon the later of the 12 month anniversary of this offering and the first dosing of a patient in the bridging bioavailability/bioequivalence study for the BXCL501 program, (iii) \$500,000 upon the later of the 12 month anniversary of this offering and the first dosing of a patient in the Phase 2 PoC open label monotherapy or combination trial with Keytruda for the BXCL701 program and (iv) a one-time payment of \$5 million within 60 days after the achievement of \$50 million in cumulative net sales of any product or combination of products resulting from the development and commercialization of any one of the Candidates or a product derived therefrom.

In addition, pursuant to the Contribution Agreement, upon completion of this offering, BioXcel will grant us a first right to negotiate exclusive rights to any additional product candidates in the fields of neuroscience and immuno-oncology, or the Option Field, that BioXcel may identify on its own, excluding the Candidates, and not in connection with BioXcel's provision of services to us under the Services Agreement as defined and described below. This option for first negotiation shall be valid for a period of five years from the date of this offering. Within 60 days of identifying a potential product candidate in the Option Field, BioXcel shall present such identified candidate to us and we shall then have up to 180 days in which to evaluate such product candidate, or the Evaluation Period. If we wish to negotiate for the exclusive rights to such product candidate, we shall notify BioXcel in writing prior to the end of the Evaluation Period, and upon such notification, we and BioXcel shall negotiate in good faith commercially reasonable terms pursuant to which we can receive BioXcel's rights to develop and/or commercialize such product candidate, BioXcel shall be free to develop and/or commercialize such product candidate either by itself or with one or more third parties. Prior to the fifth anniversary of this offering, BioXcel has also agreed to not provide product identification collaborative services to third parties in the fields of neuroscience or immuno-oncology when such third parties utilize EvolverAI.

## Amended and Restated Separation and Shared Services Agreement

We have entered into a separation and shared services agreement, dated June 30, 2017, or the Effective Date, with BioXcel, as amended and restated on November 7, 2017, or the Services Agreement, pursuant to which BioXcel will provide us with shared office space and equipment, shared services, including the use of EvolverAI, leased employee services and financial support and payment, until the termination of the agreement as described below. In consideration for the use of office space and equipment as well as for general administrative support and payroll services, we have agreed to pay BioXcel a fixed monthly fee set as set forth in the Services Agreement. In addition, any services related to intellectual property prosecution and management along with any services provided by BioXcel through its subsidiary in India will be provided at hourly rates as set forth in the Services Agreement. Finally, BioXcel has agreed provide us the services of Vimal Mehta and Chids Mahadevan, our Chief Executive Officer and

Vice President—Finance, respectively, at the hourly rates as set forth in the Services Agreement. We have agreed to pay invoices generated by BioXcel within 60 days of receipt thereof.

On or before December 31, 2019, we shall have the option to enter into a collaborative services agreement with BioXcel pursuant to which BioXcel shall perform product identification and related services for us utilizing EvolverAI. We have agreed that this agreement will be negotiated in good faith and that such agreement will incorporate reasonable market based terms, including consideration for BioXcel reflecting a low, single-digit royalty on net sales and reasonable development and commercialization milestone payments, provided that (i) development milestones shall not exceed \$10 million in the aggregate and not be payable prior to proof of concept in humans and (ii) commercialization milestones shall be based on reaching annual net sales levels, be limited to 3% of the applicable net sales level, and not exceed \$30 million in the aggregate. BioXcel shall continue to make such product identification and related services available to us for at least 60 months after the Effective Date.

In connection with the Services Agreement, BioXcel agreed to provide us a line of credit, which shall be capped at \$1 million, or the Total Funding Amount, pursuant to the terms of the grid note (as discussed below), or the Grid Note. We have also agreed to reimburse BioXcel for its contributed services and support to us in connection with our organization and development prior to the date of the Grid Note in the amount of \$562,000, which amount shall be payable upon the earlier of (i) 30 days after the completion of this offering and (ii) December 31, 2018.

The parties have agreed that the services and office space provided under the Services Agreement shall decrease over time until the 12 month anniversary of the Effective Date, except for services to be provided by BioXcel through its subsidiary in India, which shall decrease until the 24 to 36 month anniversary of the Effective Date, provided such dates may be extended upon mutual agreement between the parties, collectively, the Term.

The Services Agreement shall terminate at the end of the Term, however, it may be terminated upon the mutual written agreement of the parties. In addition, the Services Agreement may be terminated by the non-defaulting party upon or after the occurrence of a material breach by the other party that is uncured within 30 days after receipt of written notification of such breach. If such breach is not correctable within 30 days, the correction must be initiated within 30 days and thereafter diligently pursued thereafter. Lastly, the shared services agreement may be terminated if either we become bankrupt or insolvent, make any assignment for the benefit of creditors, or if a receive is appointed and such proceeding is not vacated or terminated within 30 days after its commencement or institution.

### **Grid Note**

In connection with the Services Agreement, BioXcel agreed to provide us a line of credit up to the Total Funding Amount pursuant to the terms of the Grid Note. BioXcel shall not be obligated to fund our operations beyond the Total Funding Amount, provided, in the event we determine that we will require additional funding to support our operations and to execute the plan of separation from BioXcel, we and BioXcel will, in good faith, assess increasing the Total Funding Amount, and, shall amend the terms of the Grid Note or execute a new note to reflect any new funding as agreed upon between the parties. The Grid Note shall be payable upon the earlier of (i) the completion of this offering and (ii) December 31, 2018, together with interest on the unpaid balance of each advance, which shall accrue at a rate per annum equal to the applicable federal rate for short-term loans as of the date hereof, in each case calculated based on a 365-day year and actual days elapsed. As of June 30, 2017, we have drawn an amount of \$285,000 under the Grid Note.

## **Other Transactions**

On September 29, 2017, we sold 175 shares of our common stock to Peter Mueller, the chairman of our board of directors, at a price of \$1,142.86 share for aggregate gross proceeds to us of \$200,000.



We have granted stock options to members of our board of directors and executive officers. For a description of these stock options, see the section titled "Executive and Director Compensation."

### **Indemnification Agreements**

In connection with this offering, we will enter into indemnification agreements with each of our directors and executive officers. These indemnification agreements will provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Delaware law. See "Description of Share Capital—Indemnification of Directors and Officers" for additional information regarding indemnification under Delaware law and our amended and restated by-laws.

#### **Related Person Transaction Policy**

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We expect to adopt a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy will become effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

### PRINCIPAL SHAREHOLDERS

The following table sets forth certain information regarding the beneficial ownership of our common stock as of June 30, 2017 by:

- each of our named executive officers;
- each of our directors;
- all of our current directors and executive officers as a group; and
- each stockholder known by us to own beneficially more than five percent of our common stock.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of June 30, 2017, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on shares of common stock outstanding on June 30, 2017, and shares of common stock outstanding after the completion of this offering.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o BioXcel Therapeutics, Inc., 780 East Main Street, Branford, CT 06405.

	Number of Shares	Percentage of C Beneficiall	
Name of Beneficial Owner	Beneficially Owned Prior to Offering	Before Offering	After Offering <sup>1</sup>
Directors and Executive Officers			
Vimal Mehta, Ph.D.		*	*
Peter Mueller, Ph.D.	—	*	*
Frank D. Yocca, Ph.D.	_	*	*
Krishnan Nandabalan, Ph.D.	—	*	*
Sandeep Laumas, M.D.	_	*	*
All current executive officers and directors as a group (7 persons)	—	*	*
5% or Greater Stockholders	_	*	*
BioXcel Corporation			
780 East Main Street, Branford, CT 06405		%	» %

- \* Represents beneficial ownership of less than one percent (1%).
- Assuming the underwriters do not exercise their option to acquire additional securities, as described in the section "Underwriting" below. If they do exercise in full their option to acquire additional securities, we estimate BioXcel will own approximately % of our outstanding shares of common stock immediately after this offering.

## **DESCRIPTION OF CAPITAL STOCK**

### General

Upon completion of this offering, our authorized capital stock will consist of of preferred stock, par value \$0.001 per share. As of June 30, 2017, there were outstanding.

shares of common stock, par value \$0.001 per share, and shares shares of common stock, and no shares of preferred stock issued and

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws to be effective upon the completion of this offering is only a summary. You should also refer to our amended and restated certificate of incorporation, a copy of which is incorporated by reference as an exhibit to the registration statement of which this prospectus is a part, and our amended and restated bylaws, a copy of which is incorporated by reference as an exhibit to the registration statement of which this prospectus is a part.

#### **Common Stock**

We are authorized to issue up to a total of shares of common stock, par value \$0.001 per share. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. Holders of our common stock have no cumulative voting rights.

Further, holders of our common stock have no preemptive or conversion rights or other subscription rights. Upon our liquidation, dissolution or windingup, holders of our common stock are entitled to share in all assets remaining after payment of all liabilities and the liquidation preferences of any of our outstanding shares of preferred stock. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of our assets which are legally available. Such dividends, if any, are payable in cash, in property or in shares of capital stock. Each outstanding share of our common stock is, and all shares of common stock to be issued in this offering when they are paid for will be, fully paid and non-assessable.

The holders of a majority of the shares of our capital stock, represented in person or by proxy, are necessary to constitute a quorum for the transaction of business at any meeting. If a quorum is present, an action by stockholders entitled to vote on a matter is approved if the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, with the exception of the election of directors, which requires a plurality of the votes cast.

### **Preferred Stock**

Our board of directors has the authority, without further action by the stockholders, to issue up to to fix the designations, powers, preferences, privileges, and relative participating, optional, or special rights as well as the qualifications, limitations, or restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, any or all of which may be greater than the rights of the common stock. Our board of directors, without stockholder approval, can issue convertible preferred stock with voting, conversion, or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms calculated to delay or prevent a change of control or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock, and may adversely affect the voting and other rights of the holders of common stock. At present, we have no plans to issue any shares of preferred stock following this offering.

## Options

Our 2017 Equity Incentive Plan, or the Plan, provides for us to sell or issue shares of common stock or restricted shares of common stock, or to grant incentive stock options or nonqualified stock options, stock appreciation rights and restricted stock unit awards for the purchase of shares of common stock, to employees, members of the board of directors and consultants. As of September 30, 2017, options to purchase 9,393 common shares were outstanding. For additional information regarding the terms of the Plan, see "Executive and Director Compensation—2017 Equity Incentive Plan."

### **Piggyback Registration Rights**

We have granted one of our stockholders certain piggyback registration rights with respect to their shares of common stock. If we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders (other than in connection with this offering), such holder will be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement, provided, however, that the Company shall not be required to register the resale of any shares of common stock that are eligible for resale pursuant to Rule 144 under the Securities Act without any requirement for the Company to maintain current public information and without any limitation on volume or manner of sale. 875 shares of our common stock are entitled to these piggyback registration rights.

### Anti-Takeover Provisions of Delaware Law, our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws

### **Delaware** Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly traded Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An interested stockholder is a person who, together with affiliates and associates, owns (or within three years, did own) 15% or more of the corporation's voting stock, subject to certain exceptions. The statute could have the effect of delaying, deferring or preventing a change in control of our company.

### **Board of Directors Vacancies**

Our amended and restated certificate of incorporation and amended and restated bylaws authorize only our board of directors to fill vacant directorships. In addition, the number of directors constituting our board of directors may be set only by resolution of the majority of the incumbent directors.

## Stockholder Action; Special Meeting of Stockholders

Our amended and restated certificate of incorporation and amended and restated bylaws provide that our stockholders may not take action by written consent. Our amended and restated certificate of incorporation and amended and restated bylaws further provide that special meetings of our stockholders may be called by a majority of the board of directors, the Chief Executive Officer, or the Chairman of the board of directors.

## Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our amended and restated bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not later than

the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the day on which a public announcement of the date of such meeting is first made by us. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

## Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval and may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise. If we issue such shares without stockholder approval and in violation of limitations imposed by the Nasdaq Capital Market or any stock exchange on which our stock may then be trading, our stock could be delisted.

## Transfer Agent and Registrar

The transfer agent and registrar for our common stock is

## Stock Market Listing

We intend to apply to have our shares of common stock listed for trading on The Nasdaq Capital Market under the symbol "BTAI." No assurance can be given that such listing will be approved.



### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, or the anticipation of these sales, could materially and adversely affect market prices prevailing from time to time, and could impair our ability to raise capital through sales of equity or equity-related securities.

Only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could materially and adversely affect the prevailing market price of our common stock. Although we intend to apply to list our common stock on The Nasdaq Capital Market, we cannot assure you that there will be an active market for our common stock.

Of the shares to be outstanding immediately after the completion of this offering, we expect that the shares to be sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining shares of our common stock outstanding after this offering will be subject to a 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

## Rule 144

## Affiliate Resales of Restricted Securities

Affiliates of ours must generally comply with Rule 144 if they wish to sell any shares of our common stock in the public market, whether or not those shares are "restricted securities." "Restricted securities" are any securities acquired from us or one of our affiliates in a transaction not involving a public offering. All shares of our common stock issued prior to the closing of the offering made hereby, are considered to be restricted securities. The shares of our common stock sold in this offering are not considered to be restricted securities.

## Non-Affiliate Resales of Restricted Securities

Any person or entity who is not an affiliate of ours and who has not been an affiliate of ours at any time during the three months preceding a sale is only required to comply with Rule 144 in connection with sales of restricted shares of our common stock. Subject to the lock-up agreements described below, those persons may sell shares of our common stock that they have beneficially owned for at least one year without any restrictions under Rule 144 immediately following the effective date of the registration statement of which this prospectus is a part.

Further, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time such person sells shares of our common stock, and has not been an affiliate of ours at any time during the three months preceding such sale, and who has beneficially owned such shares of our common stock, as applicable, for at least six months but less than a year, is entitled to sell such shares so long as there is adequate current public information, as defined in Rule 144, available about us.

Resales of restricted shares of our common stock by non-affiliates are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144, described above.



## Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of ours during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144.

Rule 701 also permits affiliates of ours to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and until expiration of the 180-day lock-up period described below.

### **Equity Incentive Awards**

We intend to file a registration statement on Form S-8 under the Securities Act after the closing of this offering to register the shares of common stock that are issuable pursuant to our Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up arrangement described above, if applicable.

### Lock-Up Agreements

We, each of our directors and executive officers, and the holders of all of our outstanding shares of common stock prior to this offering, have agreed that, without the prior written consent of Barclays Capital Inc., UBS Securities LLC and BMO Capital Markets Corp. on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus, subject to extension in specified circumstances:

- offer, pledge, sell or contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock, whether such transaction is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise;
- make any demand for or exercise any right with respect to the registration of any shares of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock; or
- publicly announce an intention to do any of the foregoing.

The lock-up restrictions, specified exceptions and the circumstances under which the lock-up period may be extended are described in more detail under the caption "Underwriting."



## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. No ruling on the U.S. federal, state, or local tax considerations relevant to our operations or to the purchase, ownership or disposition of our shares, has been requested from the IRS or other tax authority. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax consequences described below.

This summary also does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift and estate tax laws, except to the limited extent set forth below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions, regulated investment companies or real estate investment trusts;
- persons subject to the alternative minimum tax or Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- partnerships or entities classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code; or
- persons deemed to sell our common stock under the constructive sale provisions of the Internal Revenue Code.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase,



ownership and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any state, local, non-U.S., or other taxing jurisdiction or under any applicable tax treaty.

## Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder (other than a partnership) if you are any holder other than:

- an individual citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States, any state thereof, or the District of Columbia, or other entity treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more "U.S. persons" (within the meaning of Section 7701(a)(30) of the Internal Revenue Code) who have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a U.S. person.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

## Distributions

As described in "Dividend Policy," we have never declared or paid cash dividends on our common stock and do not anticipate paying any dividends on our common stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "—Gain on Disposition of Common Stock."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by you in the United States) are generally exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS

Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

## Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by you in the United States);
- you are a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of (i) the five-year period preceding your disposition of our common stock, or (ii) your holding period for our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided you have timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

## Federal Estate Tax

Our common stock beneficially owned by an individual who is not a citizen or resident of the United States (as defined for U.S. federal estate tax purposes) at the time of their death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the United States for U.S. federal estate tax purposes differs from the test used for U.S. federal income tax

purposes. Some individuals, therefore, may be non-U.S. holders for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

### Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding at a current rate of 28% unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

### Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act, or FATCA, imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to "foreign financial institutions" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to a "non-financial foreign entity" (as specially defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transition rules, are expected to apply with respect to the gross proceeds from the sale or other disposition of our common stock and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

## UNDERWRITING

Barclays Capital Inc., UBS Securities LLC and BMO Capital Markets Corp. are acting as the representatives of the underwriters and the book-running managers of this offering. Under the terms of an underwriting agreement, which is filed as an exhibit to the registration statement, each of the underwriters named below has severally agreed to purchase from us the respective number of shares of common stock shown opposite its name below:

<u>Underwriters</u>	Number of Shares
Barclays Capital Inc.	
UBS Securities LLC	
BMO Capital Markets Corp.	
Canaccord Genuity Inc.	
Total	

The underwriting agreement provides that the underwriters' obligation to purchase shares of common stock depends on the satisfaction of the conditions contained in the underwriting agreement including:

- the representations and warranties made by us to the underwriters are true;
- there is no material change in our business or the financial markets; and
- we deliver customary closing documents to the underwriters.

## **Commissions and Expenses**

The following table summarizes the underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares. The underwriting fee is the difference between the initial price to the public and the amount the underwriters pay to us for the shares.

	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

The representatives have advised us that the underwriters propose to offer the shares of common stock directly to the public at the public offering price on the cover of this prospectus and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of \$\$ per share. After the offering, the representatives may change the offering price and other selling terms.

The expenses of this offering that are payable by us are estimated to be approximately \$ (excluding estimated underwriting discounts and commissions). We have also agreed to reimburse the underwriters for certain of their expenses, in an amount up to \$ , incurred in connection with review by the Financial Industry Regulatory Authority, Inc. of the terms of this offering, as set forth in the underwriting agreement.

### **Option to Purchase Additional Shares**

We have granted the underwriters an option exercisable for 30 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price less underwriting discounts and commissions. To the extent that this option is exercised, each underwriter will be obligated, subject to certain conditions, to



purchase its pro rata portion of these additional shares based on the underwriter's percentage underwriting commitment in this offering as indicated in the table at the beginning of this Underwriting Section.

## Lock-Up Agreements

We, all of our directors and executive officers, holders of all of our outstanding stock have agreed that, for a period of 180 days after the date of this prospectus subject to certain limited exceptions, we and they will not directly or indirectly, without the prior written consent of each of Barclays Capital Inc., UBS Securities LLC and BMO Capital Markets Corp., (i) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of common stock (including, without limitation, shares of common stock that may be deemed to be beneficially owned by us or them in accordance with the rules and regulations of the SEC and shares of common stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for common stock, (ii) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of common stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or other securities, in cash or otherwise, (iii) make any demand for or exercise any right or file or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable for common stock or any of our other securities, or (iv) publicly disclose the intention to do any of the foregoing.

Barclays Capital Inc., UBS Securities LLC and BMO Capital Markets Corp., in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release common stock and other securities from lock-up agreements, Barclays Capital Inc., UBS Securities LLC and BMO Capital Markets Corp. will consider, among other factors, the holder's reasons for requesting the release, the number of shares of common stock and other securities for which the release is being requested and market conditions at the time.

## **Offering Price Determination**

Prior to this offering, there has been no public market for our common stock. The initial public offering price was negotiated between the representatives and us. In determining the initial public offering price of our common stock, the representatives considered:

- the history and prospects for the industry in which we compete;
- our financial information;
- the ability of our management and our business potential and earning prospects;
- the prevailing securities markets at the time of this offering; and
- the recent market prices of, and the demand for, publicly traded shares of generally comparable companies.

### Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

## Stabilization, Short Positions and Penalty Bids

The representatives may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
  - A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
  - Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.
  - Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The Nasdaq Capital Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

## **Electronic Distribution**

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the representatives on the same basis as other allocations.

Other than the prospectus in electronic format, the information on any underwriter's or selling group member's web site and any information contained in any other web site maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

# Listing on The Nasdaq Capital Market

We intend to apply to have our common stock listed on The Nasdaq Capital Market under the symbol "BTAI".

### **Discretionary Sales**

The underwriters have informed us that they do not expect to sell more than 5% of the common stock in the aggregate to accounts over which they exercise discretionary authority.

### Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

### **Other Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for the issuer and its affiliates, for which they received or may in the future receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer or its affiliates. If the underwriters or their affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the shares of common stock offered hereby. Any such credit default swaps or short positions could adversely affect future trading prices of the shares of common stock offered hereby. The underwriters and certain of their affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

### Selling Restrictions

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such



offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the shares of common stock or possession or distribution of this prospectus or any other offering or publicity material relating to the shares of common stock in any country or jurisdiction (other than the United States) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any shares of common stock or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of shares of common stock by it will be made on the same terms.

## European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any common stock which are the subject of the offering contemplated herein may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to legal entities which are qualified investors as defined under the Prospectus Directive;
- by the underwriters to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common stock shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any common stock under, the offers contemplated here in this prospectus will be deemed to have represented, warranted and agreed to and with each underwriter and us that:

- it is a qualified investor as defined under the Prospectus Directive; and
- in the case of any common stock acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the common stock acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in the circumstances in which the prior consent of the representatives of the underwriters has been given to the offer or resale or (ii) where common stock have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of such common stock to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of this representation and the provision above, the expression an "offer of common stock to the public" in relation to any common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any common stock to be offered so as to enable an investor to decide to purchase or subscribe for the common stock, as the same may be varied in that Relevant Member State by any measure

implementing the Prospectus Directive in that Relevant Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

## United Kingdom

This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000 (the "FSMA")) as received in connection with the issue or sale of the common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to the common stock in, from or otherwise involving the United Kingdom.

## Notice to Residents of Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.



### LEGAL MATTERS

The validity of the issuance of the common stock offered by us in this offering will be passed upon for us by Sheppard, Mullin, Richter & Hampton LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP.

### EXPERTS

The financial statements of BioXcel Therapeutics, Inc. (the carved-out operations of certain assets and liabilities of BioXcel Corporation) as of December 31, 2016 and 2015 and for each of the years then ended included in this Registration Statement, of which this Prospectus forms a part, have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) appearing elsewhere herein, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and our common stock, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

You may read and copy all or any portion of the registration statement without charge at the public reference room of the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the Securities and Exchange Commission at prescribed rates from the public reference room of the Securities and Exchange Commission at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, registration statements and certain other filings made with the Securities and Exchange Commission electronically are publicly available through the Securities and Exchange Commission's website at *http://www.sec.gov*. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the Securities and Exchange Commission.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and, accordingly, will be required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the Securities and Exchange Commission. You will be able to inspect and copy such periodic reports, proxy statements and other information at the Securities and Exchange Commission's public reference room, and the website of the Securities and Exchange Commission referred to above.

# FINANCIAL STATEMENTS

# **BioXcel Therapeutics, Inc.**

# (Carve-Out of Certain Operations of BioXcel Corporation)

# INDEX TO FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm	<u>F-2</u>
Balance Sheets	<u>F-3</u>
Statements of Operations	<u>F-4</u>
Statements of Changes in Net Parent Investment/Stockholder's Deficit	<u>F-5</u>
Statements of Cash Flows	<u>F-6</u>
Notes to Financial Statements	<u>F-7</u>

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholder of BioXcel Corporation

We have audited the accompanying balance sheets of BioXcel Therapeutics, Inc. (the carved-out operations of certain assets and liabilities of BioXcel Corporation) as of December 31, 2016 and 2015, and the related statements of operations, changes in net parent investment, and cash flows for the years then ended. These financial statements are the responsibility of BioXcel Corporation's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BioXcel Therapeutics, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred significant operating losses and negative cash flows from operations. The Company also had a working capital deficiency of \$329 and an accumulated net parent deficit of \$324 at December 31, 2016. The Company is dependent on obtaining necessary funding in order to continue its operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters also are described in Note 2.

/s/ BDO USA LLP

Woodbridge, New Jersey November 10, 2017

# (Carve-Out of Certain Operations of BioXcel Corporation)

# **BALANCE SHEETS**

# (amount in thousands, except shares and per share data)

	December 31,			June 30, 2017		
	2	2016	2015		U	audited
ASSETS						
Current assets						
Cash	\$	—	\$	—	\$	285
Prepaid expenses and other assets		2		1		
Total current assets		2		1		285
Equipment, net		5		1		4
Total assets	\$	7	\$	2	\$	289
LIABILITIES AND NET PARENT INVESTMENT / STOCKHOLDERS' DEFICIT						
Current liabilities						
Accounts payable		279	1	20		293
Accrued expenses		52		55		154
Notes payable to Parent		—		—		285
Due to Parent		—				562
Total current liabilities		331	1	75		1,294
Total liabilities		331	1	75		1,294
Commitments and contingencies				_		
Net Parent investment / Stockholders' deficit						
Common stock, \$0.001 par value, 100,000 shares authorized; 40,000 shares issued and						
outstanding as of June 30, 2017 (see Note 1)		_				—
Net Parent investment						
Net liabilities assumed from Parent		(324)	(1	73)		
Total net Parent investment		(324)	(1	73)		
Accumulated deficit				_		(1,005)
Total liabilities and net Parent investment / stockholders' deficit	\$	7	\$	2	\$	289

The accompanying notes are an integral part of these financial statements

# (Carve-Out of Certain Operations of BioXcel Corporation)

# STATEMENTS OF OPERATIONS

# (amount in thousands, except share and per share data)

	Years Ended December 31,				Six Mo Ended Ju (unaud			30,
	2	2016 2015		2015 2017		_	2016	
Revenues	\$	\$ —		\$ —		\$ —		—
Operating costs and expenses			_					
Research and development		1,399		233		645		650
General and administrative		721		403		449		367
Total operating expenses		2,120		636		1,094		1,017
Net loss	\$	(2,120)	\$	(636)	\$	(1,094)	\$	(1,017)
Net loss per share attributable to Parent/common stockholder, basic and	_							
diluted	\$	(53.00)	\$	(15.90)	\$	(27.35)	\$	(25.43)
Weighted average common shares outstanding, basic and diluted	4	40,000		40,000		40,000		40,000

The accompanying notes are an integral part of these financial statements.

# (Carve-Out of Certain Operations of BioXcel Corporation)

# STATEMENTS OF CHANGES IN NET PARENT INVESTMENT/STOCKHOLDER'S DEFICIT

# (amount in thousands, except shares and per share data)

	Commo Shares	on Stock Amount	Net Parental Investment	Accumulated Deficit	Total
Balance, January 1, 2015		\$ —	<u>\$                                    </u>	<u>\$                                    </u>	\$ _
Investment from Parent			463		463
Net loss			(636)		(636)
Balance as of December 31, 2015	_		(173)		(173)
Investment from Parent			1,969		1,969
Net loss			(2,120)		(2,120)
Balance as of December 31, 2016	_		(324)		(324)
Investment from Parent			539		539
Net loss <sup>(A)</sup>	_	_	(529)	_	(529)
Balance as of March 29, 2017 (date of incorporation)			(314)		(314)
For the six months period ended June, 30 2017					
(unaudited)					
Issuance of common shares (see Note 1)	40,000		—	—	
Liabilities assumed from Parent	—	—	(126)	—	(126)
Transfer to accumulated deficit	_	_	440	(440)	
Net loss <sup>(A)</sup>	_			(565)	(565)
Balance as of June 30, 2017	40,000	\$	\$	\$ (1,005)	\$ (1,005)

(A) Combined net loss for the period ended June 30, 2017 is \$(1,094)

The accompanying notes are an integral part of these financial statements.

# (Carve-Out of Certain Operations of BioXcel Corporation)

# STATEMENTS OF CASH FLOWS

# (amount in thousands, except shares and per share data)

	Years Ended December 31, 2016 2015			Six Months En June 30, (unaud 2017 2				
CASH FLOWS FROM OPERATING ACTIVITIES:	20	16		2015		2017		2016
Net loss	\$ (2	2,120)	\$	(636)	\$	(1,094)	\$	(1,017)
Reconciliation of net loss to net cash (used in) provided by operating				. ,				( )
activities:								
Stock-based compensation expense		671		182		200		312
Changes in operating assets and liabilities:								
Prepaid expenses and other assets		(1)		(1)		2		(9)
Accounts payable and accrued expenses		156		175		116		82
Net cash used in operating activities	(1	1,294)		(280)		(776)		(632)
CASH FLOWS FROM INVESTING ACTIVITIES:								
Purchase of fixed assets		(4)		(1)		—		—
Net cash used in investing activities		(4)		(1)				
CASH FLOWS FROM FINANCING ACTIVITIES:								
Net Parent investment	1	1,298		281		214		632
Due to Parent		—		—		562		—
Proceeds from note payable—Parent			_			285		
Net cash provided by financing activities	1	1,298		281		1,061		632
Net increase in cash				—		285		—
Cash, beginning of period								
Cash, end of period	\$		\$		\$	285	\$	
Supplemental disclosure								
Reclassification of net Parent investment in the Company to accumulated								
deficit	\$	_	\$	—	\$	440	\$	

The accompanying notes are an integral part of these financial statements.

## (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS

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

### (interim period information is unaudited)

### Note 1. Organization and Principal Activities

BioXcel Therapeutics, Inc. (the "Company" or "BTI") is a clinical stage biopharmaceutical company focused on novel artificial intelligence-based drug development to identify the next wave of medicines across neuroscience and immuno-oncology. The Company'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. The Company is a wholly-owned subsidiary of BioXcel Corporation ("BioXcel") and was incorporated under the laws of the State of Delaware on March 29, 2017—see note 2 basis of presentation for further discussion. The Company's principal office is in Branford, Connecticut.

The Company's primary activities have been the development of a clinical plan and pre-clinical research and development of two advanced programs: BXCL501, a sublingual thin film formulation of dexmedetomidine designed for acute treatment of agitation resulting from neurological and psychiatric disorders, and BXCL701, an immuno-oncology agent designed for treatment of a rare form of prostate cancer and for treatment of pancreatic cancer. These two programs and two emerging programs BXCL502 and BXCL702 (together, "the BTI Business") programs have been contributed to the Company from the parent company BioXcel.

## Note 2. Basis of Presentation and Liquidity

## **Basis of Presentation**

These financial statements consist of the operations of the Company and BioXcel, ("Parent") of the Company, as discussed below.

The financial statements are derived by carving out the historical results of operations and historical cost basis of the, assets and liabilities associated with product candidates BXCL501, BXCL701, BXCL502 and BXCL702 that have been contributed to the Company by BioXcel (the "BTI Business") from the BioXcel's financial statements.

These results reflect amounts specifically attributable to the BTI Business, which include expenses, assets and liabilities of BioXcel relating to the candidates that were contributed to the Company by BioXcel under a contribution agreement, effective June 30, 2017, as amended and restated on November 7, 2017, or the Contribution Agreement, for the period from January 1, 2015 until March 29, 2017 (date of incorporation) and further until June 30, 2017. The Company has entered into a separation and shared services agreement with BioXcel that took effect on June 30, 2017, as amended and restated on November 7, 2017, or the Services Agreement, pursuant to which BioXcel provides the Company with certain general and administrative and development support services effective June 30, 2017. However, consistent with accounting regulations, it has been assumed that the Company was a separate business since January 1, 2015 and accordingly the assets, liabilities and expenses relating to the BTI Business have been separated from the Company in the financial statements for periods prior to and post incorporation. The financial statements include reasonable allocations for assets and liabilities and expenses attributable to the BTI Business.

Accordingly, the historical financial information for the fiscal years ended December 31, 2016 and 2015 and for the six months ended June 30, 2017 and 2016 have been "carved-out" of the financial



## (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

# Note 2. Basis of Presentation and Liquidity (Continued)

statements of BioXcel, and such financial information is limited to business activities, assets and liabilities of the BTI Business.

The Company believes that the assumptions underlying the allocations of direct and indirect expenses in the carve-out financial information are reasonable, however, the financial position, results of operations and cash flows may have been materially different if the Company had operated as a stand-alone entity as of and for the years ended December 31, 2016 and 2015, and for the six month periods ended June 30, 2017 and 2016.

The contribution of the BTI Business by BioXcel to the Company was deemed a transaction between entities under common control and the assets contributed were recorded using the historical book value of BioXcel. The historical financial statements have been presented on a basis that includes the results attributable to the BTI Business as if the Company owned the business for all periods presented.

This carve-out financial information includes both direct and indirect expenses. The historical direct expenses consist primarily of salaries of research and development employees directly involved in the BTI Business activities, stock based compensation for such employees, preclinical and clinical trial related expenses, research expenses and fees paid to scientific advisors. The indirect expenses consist of allocated employee costs, stock-based compensation, legal, professional and consulting fees attributable to the BTI Business and general and administrative overhead charged back to the BTI Business in proportion to the time spent by employees directly involved in the BTI Business, compared to the total time spent by all the employees.

Prepaid expenses, other current assets, fixed assets, accounts payable, accrued wages and salaries and accrued liabilities are presented using the allocation method whereby assets and liabilities directly related to the BTI Business were allocated at 100% to the Company. For compensation related matters, the allocation was based on time spent by employees directly involved in the BTI Business compared to the total time spent by all employees. All other allocations were based on management estimates.

The Company has calculated its income tax amounts using a separate return methodology and it has presented these amounts as if it were a separate taxpayer from BioXcel for the period since the date of incorporation (March 29, 2017). BioXcel is a standalone S corporation and its tax obligations were passed through to its shareholders and were not a liability of the S corporation. As a result, BioXcel did not require a tax provision for federal or state purposes and on the same lines no taxes have been allocated to the financials of the Company which is derived from a carve-out process from the financials of BioXcel. Pursuant to our incorporation as a C corporation, BioXcel became the Company's sole owner and contributed the BTI Business in a tax free transaction. From the date of incorporation, the Company has been a standalone C corporation subject to corporate income tax and the deferred tax and assets have been calculated accordingly.

## **Interim Financial Statements**

The financial statements for the interim periods included herein have been also been carved-out of the financial statements of BioXcel, and such financial information is limited to business activities, assets and liabilities of the BTI Business and are unaudited; however, they contain all adjustments, which in



## (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

### Note 2. Basis of Presentation and Liquidity (Continued)

the opinion of Company management, are necessary to present fairly the financial position of the Company as of June 30, 2017 and the results of its operations and cash flows for the six months ended June 30, 2017 and 2016. The results of operations for the interim periods are not necessarily indicative of results that may be expected for any other interim period or the full year. These unaudited financial statements should be read in conjunction with the accompanying audited financial statements that have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. Earnings per share data presented in the financial statements for the interim period ending June 30, 2017 reflect only the operations of the Company and the share capital structure of the Company at that time.

## Liquidity and Going Concern

The Company incurred net losses of (\$1,094) during the six months ended June 30, 2017 and \$(2,120) and \$(636) during the years ended December 31, 2016 and 2015, respectively. The Company has a working capital deficit of (\$1,009) as of June 30, 2017 and \$(329) as of December 31, 2016 and a stockholders' deficit of \$(1,005) as of June 30, 2017 and net Parent investment of \$(324) as of December 31, 2016. The Company has not yet developed its own funding sources and is dependent on BioXcel for funding. These matters raise substantial doubt about the Company's ability to continue as a going concern. Under the Agreement, BioXcel has agreed to provide a line of credit to the Company in the amount of up to \$1,000 (which can be increased based on a mutual agreement) for working capital purposes.

The Company is obligated to repay BioXcel the amounts drawn down under the Grid Note upon the closing of this offering or 18 months from the date of the note whichever is earlier. As on June 30, 2017 the Company had drawn an amount of \$285. For the period March 29, 2017 through June 29, 2017 the Parent paid certain expenses on the Company's behalf prior to the Grid Note was available totaling approximately \$562. This is to be repaid the earliest to occur of: (x) thirty days after this offering; (y) ten (10) days after the Company receives funding of at least \$5,000 other than through the IPO; and (z) December 31, 2018.

In addition, the Company needs to raise additional capital from either its Parent or from external sources in order to sustain its operations while continuing the longer-term efforts contemplated under its business plan. The Company expects to continue incurring losses for the foreseeable future and must raise additional capital to pursue its product development initiatives, conduct clinical trials and continue as a going concern. The Company cannot provide any assurance that it will raise additional capital. Management believes that the Company has access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means; however, the Company has not secured any commitment for new financing at this time nor can it provide any assurance that new financing will be available on commercially acceptable terms, if at all. If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives and clinical trials and take additional measures to reduce costs in order to conserve available cash in amounts sufficient to sustain operations and meet its obligations. These measures could cause significant delays in the Company's research and development, clinical trials and

## (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

### Note 2. Basis of Presentation and Liquidity (Continued)

regulatory efforts, which is critical to the realization of its business plan and the future operations of the Company. The Company is currently exploring external financing alternatives which will be needed by the Company to fund its operations. The accompanying financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

## Note 3. Summary of Significant Accounting Policies

## **Use of Estimates**

The Company's financial statements are prepared in accordance with GAAP. The preparation of Bioxcel's financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses in our financial statements and accompanying notes. The most significant estimates in the financial statements relate to the fair value of equity awards, the valuation of the Parent's common stock, allocation of expenses, assets and liabilities from the Parent and valuation allowance related to the Company's deferred tax assets and liabilities. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates.

### Cash

Cash is in accounts held at leading U.S. financial institutions that are insured by the Federal Deposit Insurance Corporation (FDIC) up to \$250. Cash balances could exceed insured amounts at any given time; however, the Company has not experienced any such losses and believes the risk of loss is minimal.

## Equipment

Equipment consist of computers that are stated at cost and depreciated using the straight-line method over estimated useful life of 5 years.

The Company follows the guidance provided by FASB ASC Topic 360-10, *Property, Plant, and Equipment*. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell.

Since its inception the Company has not recognized any impairment or disposition of long lived assets.

## **Stock-Based Compensation**

The Company accounts for stock-based compensation in accordance with ASC 718, "*Compensation—Stock Compensation*", which requires the measurement and recognition of compensation expense based on estimated fair market values for all share-based awards made to employees and directors, including stock options. The Company's stock based compensation plan was adopted in August 2017 and was not effective for the periods covered by the financial statements. However, the Parent has granted stock



## (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

#### Note 3. Summary of Significant Accounting Policies (Continued)

options to its employees. Related stock-based compensation expense has been allocated to the Company over the required service period over which these BioXcel stock option awards vest in the same manner salary costs of employees have been allocated to the BTI Business in the carve-out process.

The BioXcel stock option awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. The estimated fair value of these BioXcel stock option awards was determined using the Black-Scholes option pricing model on the date of grant. Significant judgment and estimates were used to estimate the fair value of these awards, as they are not publicly traded.

ASC 718 requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. BioXcel uses the Black-Scholes option-pricing model as its method of determining fair value. This model is affected by BioXcel's stock price as well as assumptions regarding a number of subjective variables. These subjective variables include, but are not limited to, BioXcel's expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. The value of the portion of the award that is ultimately expected to vest is recognized as an expense in the statement of operations over the requisite service period. The periodic expense is then determined based on the valuation of the options, and at that time an estimated forfeiture rate, if any, is used to reduce the expense recorded. The Parent's estimates of pre-vesting forfeitures is primarily based on the its historical experience and is adjusted to reflect actual forfeitures as the options vest.

## **Research and Development Costs**

Research and development expenses include wages, benefits, facilities, supplies, external services, clinical study and manufacturing costs and other expenses that are directly related to its research and development activities. At the end of the reporting period, the Company compares payments made to third party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs. The Company expenses research and development costs as it incurs them.

### Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

#### **Income Taxes**

The Company accounts for income taxes under Accounting Standards Codification ("ASC") 740 Income Taxes ("ASC 740"). Under ASC 740, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating

## (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

### (interim period information is unaudited)

#### Note 3. Summary of Significant Accounting Policies (Continued)

loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Tax benefits claimed or expected to be claimed on a tax return are recorded in the Company's financial statements. A tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. Uncertain tax positions have had no impact on the Company's financial condition, results of operations or cash flows.

## **Fair Value Measurements**

ASC 820 "*Fair Value Measurements*" defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

- Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2—Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.
- Level 3—Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.



### (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

### (interim period information is unaudited)

#### Note 3. Summary of Significant Accounting Policies (Continued)

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

The carrying amounts of cash, accounts payable and accrued expenses approximate fair value due to the short-term nature of these instruments.

### Net Loss per Share

The Company computes basic net loss per share by dividing net loss per share available to common stockholders by the weighted average number of common shares outstanding for the period and excludes the effects of any potentially dilutive securities. Diluted earnings per share, if presented, would include the dilution that would occur upon the exercise or conversion of all potentially dilutive securities into common stock using the "treasury stock" and/or "if converted" methods as applicable. The Company did not have any potentially diluted securities outstanding in any period presented in the accompanying financial statements. The Company was incorporated on March 29, 2017 and loss per common share was calculated for the years ended December 31, 2015 and 2016 and for the six months ended June 30, 2016, assuming the shares issued to the Parent at formation were outstanding for all periods presented.

## **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board, or FASB, issued *ASU 2014-09 Revenue form Contracts with Customers*. Under this guidance on the recognition of revenue from customers. Under this guidance, an entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects what the entity expects to receive in exchange for the goods or services. This new guidance also requires more detailed disclosures to enable users of the financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The Company will adopt this guidance beginning on January 1, 2018. The guidance allows the selection of one of two methods of adoption, either the full retrospective approach, meaning the guidance would be applied to all periods presented, or modified retrospective approach, meaning the cumulative effect of applying the guidance would be recognized as an adjustment to opening accumulated deficit balance. Since the Company has no revenues to date, the Company does not believe the adoption of ASU-214-09 will have a material impact on its financial statements.

In August 2014, the FASB issued *ASU 2014-15 Disclosures of Uncertainties around an Entity's Ability to Continue as a Going Concern*. This ASU requires management to determine whether substantial doubt exists regarding the entity's going concern presumption, which generally refers to an entity's ability to meets its obligations as they become due. If substantial doubt exists but is not alleviated by management's plan, the footnotes must specifically state that "there is substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued." In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must

#### (Carve-Out of Certain Operations of BioXcel Corporation)

### NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

#### Note 3. Summary of Significant Accounting Policies (Continued)

disclose (a) principal conditions or events that raise substantial doubt about the entity's ability to continue as a going concern (before consideration of management's plans, if any); (b) management's evaluation of the significance of those conditions or events in relation to the entity's ability to meet its obligations; and (c) management's plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity's ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management's plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The Company has adopted the provisions of ASU 2014-15 beginning January 1, 2016.

In February 2016, the FASB issued *ASU 2016-02 Lease Accounting Topic 842*. This ASU requires us to record all leases longer than one year on our balance sheet. Under the new guidance, when the Company records leases on its balance sheet under it will record a liability with a value equal to the present value of payments it will make over the life of the lease and an asset representing the underlying leased asset. The new accounting guidance requires the Company to determine if its leases are operating or financing leases, similar to current accounting guidance. The Company will record expense for operating type leases on a straight-line basis as an operating expense and it will record expense for finance type leases as interest expense. The new lease standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company must adopt the new standard on a modified retrospective basis, which requires it to reflect its leases on its balance sheet for the earliest comparative period presented. The Company is currently assessing the timing of adoption as well as the effects it will have on its financial statements and disclosures.

In March 2016, the FASB ASU 2016-09, *Compensation- Stock Compensation* simplifing certain aspects of share-based payment accounting. Under the amended guidance, the Company will recognize excess tax benefits and tax deficiencies as income tax expense or benefit in its statement of operations on a prospective basis. As the Company has a valuation allowance, this change will impact the Company's net operating loss carryforward and the valuation allowance disclosures. Additionally, the Company will classify excess tax benefits as an operating activity and classify amounts the Company withholds in shares for the payment of employee taxes as a financing activity on the statement of cash flows for each period presented. The amended guidance allows the Company to account for forfeitures when they occur or continue to estimate them. The Company will continue to estimate its forfeitures. The amended share-based payment standard is effective for annual and interim periods beginning after December 15, 2016, with early adoption permitted in any interim or annual period. The Company adopted this guidance on January 1, 2017 and does not believe the amended guidance will have a material impact on its financial results.

#### Note 4. Transactions with BioXcel

The Company has entered into an asset contribution agreement, effective June 30, 2017, with BioXcel, as amended and restated on November 6, 2017, or the Contribution Agreement, pursuant to which

#### (Carve-Out of Certain Operations of BioXcel Corporation)

### NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

#### Note 4. Transactions with BioXcel (Continued)

BioXcel agreed to contribute BioXcel's rights, title and interest in BXCL501, BXCL701, BXCL502 and BXCL702, and all of the assets and liabilities associated in consideration for (i) 40,000 shares of our common stock, (ii) \$1 million upon completion of this offering, (iii) \$500 upon the later of the 12 month anniversary of this offering and the first dosing of a patient in the bridging bioavailability/ bioequivalence study for the BXCL501 program, (iv) \$500 upon the later of the 12 month anniversary of this offering and the first dosing of a patient in the Phase 2 PoC open label monotherapy or combination trial with Keytruda for the BXCL701 program and (v) a one-time payment of \$5,000 within 60 days after the achievement of \$50,000 in cumulative net sales of any product or combination of products resulting from the development and commercialization of any one of the Candidates or a product derived therefrom.

The Company has also entered into a separation and shared services agreement with BioXcel that took effect on June 30, 2017, as amended and restated on November 6, 2017, or the Services Agreement, pursuant to which BioXcel will allow the Company to continue to use the office space, equipment, services and leased employees based on the agreed upon terms and conditions for a payment of defined monthly and/or hourly fees.

In connection with the Services Agreement, BioXcel agreed to provide the Company a line of credit, which shall be capped at \$1,000, or the Total Funding Amount, pursuant to the terms of a grid note, or the Grid Note. The Grid Note shall be payable upon the earlier of (i) the completion of this offering and (ii) December 31, 2018, together with interest on the unpaid balance of each advance made under the Grid Note, which shall accrue at a rate per annum equal to the applicable federal rate for short-term loans as of the date hereof, in each case calculated based on a 365-day year and actual days elapsed. As of June 30, 2017, we have drawn an amount of \$285 under the Grid Note.

The Parent has made investments of approximately \$2,971 commencing January 1, 2015 through March 29, 2017 (the date of incorporation of the Company) that relate to the BTI Business which was offset by total losses from the BTI Business of \$3,285 resulting in net Parent investment of \$(314) as on March 29, 2017. Furthermore, the net value of the assets and liabilities amounting to net liabilities of \$126 which pertain to the BTI Business were allocated to the Company have also been classified under net Parent investment. As the Company became a substantive operating entity beginning June 30, 2017, the net Parent investment account totaling an amount of \$440 was reclassified into accumulated deficit for the period ended June 30, 2017.

For the period March 29, 2017 through June 30, 2017, BioXcel paid for expenses on the Company's behalf totaling approximately \$562. The Company has agreed to reimburse BioXcel for this amount upon the earlier of (i) 30 days after the completion of this offering and (ii) December 31, 2018.



#### (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

#### Note 5. Equipment

	Equipment consist of the following				
		December 3 2016	1,	nber 31, 015	ne 30, 2017 maudited)
Computers		\$	5	\$ 1	\$ 5
Accumulated depreciation and amortization					(1)
		\$	5	\$ 1	\$ 4

#### Note 6. Commitments and Contingencies

As of June 30, 2017 there were contingent payments due to materials manufacturers for \$460 toward supply of clinical candidate materials.

The Company is required to pay to BioXcel the amount of \$5,000 within 60 days after the achievement of \$50,000 in cumulative net sales of any product or combination of products resulting from the development and commercialization of any one of the candidates BXCL501, BXCL701, BXCL502, and BXCL702 or a product derived therefrom.

The Company is also required to pay to BioXcel the amount of \$2,000 in connection with the IPO, (x) the first \$1,000 of which the Company shall pay to BioXcel in a lump-sum payment within thirty (30) days after closing of the IPO and (y) the second \$1,000, (i) \$500 of which is payable upon the later of the 12 month anniversary of this offering and the first dosing of a patient in the bridging bioavailability/bioequivalence study for the BXCL501 program and (ii) \$500 of which is payable upon the later of the 12 month anniversary of this offering and the first dosing of a patient in the bridging and the first dosing of a patient in the Phase 2 PoC open label monotherapy or combination trial with Keytruda for the BXCL701 program.

The employment agreements for Frank Yocca, the Chief Scientific Officer and Luca Rastelli, the Vice President—Oncology R&D have been contributed to the Company by the Parent as a part of the Agreement. The employment agreements provide, among other things, for the payment of three and four months respectively of severance compensation for terminations under certain circumstances. With respect to these agreement, at June 30, 2017, potential severance payout amounted to \$104 and aggregated annual salaries amounted to \$340.

### Note 7. Accrued Expenses

Accrued ex	penses consist of the following			
	Decemb 201	/	nber 31, 015	30, 2017 udited)
Accrued salaries and benefits	\$	27	\$ 12	\$ 90
Professional fees		15	39	49
Legal Expenses		10	4	\$ 15
	\$	52	\$ 55	\$ 154

#### (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

#### Note 8. Net Parent Investment / Stockholders Deficit

The Parent has made investments of approximately \$1,969 and \$463 during the years ended, December 31 2016 and 2015, respectively, which were offset by net losses of \$(2,120) and \$(636) during the years ended, December 31, 2016 and 2015, respectively resulting in net Parent investment of \$(324) as on December 31, 2016.

For the period for January 1, 2017 to the date of incorporation (March 29, 2017), the Parent has made an investment of \$539 which was offset by net loss of \$(529). Furthermore, at June 30, 2017, the net value of the assets and liabilities amounting to net liabilities of \$126 which pertain to the BTI Business were allocated to the Company have also been classified under net Parent investment. As the Company became a substantive operating entity beginning June 30, 2017, the net Parent investment account totaling an amount of \$440 was reclassified into accumulated deficit for the period ended June 30, 2017.

	Net Parent Investment
Balance, January 1, 2015	\$
Investment from Parent	463
Net loss	(636)
Balance as of December 31, 2015	(173)
Investment from Parent	1,969
Net loss	(2,120)
Balance as of December 31, 2016	(324)
Unaudited	
Investment from Parent	539
Net loss	(529)
Balance as of March 29, 2017 (date of incorporation)	(314)
For the six months period ended June, 30 2017	
Liabilities assumed from Parent	(126)
Transfer to accumulated deficit	440
Balance as of June 30, 2017	<u>\$                                    </u>

#### **Authorized Capital**

The Company is authorized to issue up to 100,000 shares of common stock with a par value of \$0.001 per share. 40,000 shares were issued to BioXcel pursuant to the Contribution Agreement—see Note 4.



#### (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

#### Note 8. Net Parent Investment / Stockholders Deficit (Continued)

#### **Description of Common Stock**

Each share of common stock has the right to one vote. The holders of common stock are entitled to dividends when funds are legally available and when declared by the board of directors.

#### Note 9. Income Taxes

The Parent is a standalone S corporation and its tax obligations were passed through to its shareholders and were not a liability of the S corporation. As a result, BioXcel does not require a tax provision for federal or state purposes.

Pursuant to incorporation of the Company as a C corporation on March 29, 2017, BioXcel became the sole owner of BioXcel Thereapeutics, Inc., and contributed certain assets to the Company in a tax free transaction. From the date of incorporation, the Company is a standalone C corporation subject to corporate income tax and the deferred taxes of the Company have been calculated accordingly.

The significant components of the Company's net deferred tax assets at June 30, 2017 are shown below. In determining the realizability of the Company's net deferred tax asset, the Company considered numerous factors, including historical profitability, estimated future taxable income, and the industry in which it operates. Based on this information the Company has provided a valuation allowance for the full amount of its net deferred tax asset because the Company has determined that it is more likely than not that it will not be realized.

	2017 nudited)
Federal net operating losses	\$ 141
State net operating losses	25
Federal tax credit	13
Accrued expense	18
Other	13
Total gross deferred tax assets	210
Less valuation allowance	\$ (210)
Net deferred tax assets	\$ 

#### (Carve-Out of Certain Operations of BioXcel Corporation)

#### NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

#### Note 9. Income Taxes (Continued)

A reconciliation between the Company's effective tax rate and the federal statutory rate for the period from inception to June 30, 2017 is as follows:

	2017	
Federal Statutory Rate	(191)	34%
Permanent Differences	23	-4%
Research and Development	(13)	2%
State Taxes		-0%
Valuation Allowance	181	-32%
Effective Tax Rate		0%

At June 30, 2017, the Company had approximately \$416 of gross federal and state net operating loss carry-forwards. If not utilized, the federal and state net operating loss carry-forwards will begin to expire in 2037. The utilization of such net operating loss carry-forwards and realization of tax benefits in future years depends predominantly upon having taxable income. The Company also has approximately \$13 of federal research and development credits which will begin to expire in 2037 if not utilized.

Utilization of the NOL and research tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that has occurred or that could occur in the future, as required by Section 382 of the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and research tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. To date, the Company's NOL's have not been subject to Section 382 limitation.

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of June 30, 2017 there were no uncertain positions. Interest and penalties, if any, as they relate to income taxes assessed, are included in the income tax provision. There was no income tax related interest and penalties included in the income tax provision.

#### Note 10. Subsequent Events

The board of directors adopted the 2017 Equity Incentive Plan, or the Plan, on August 22, 2017 with an option pool of up to 12,500 shares of common stock. The Plan will expire on August 21, 2027. The purpose of the Plan is to attract and retain key personnel and to provide a means for directors, officers, managers, employees, consultants and advisors to acquire and maintain an interest in the Company, which interest may be measured by reference to the value of its common stock.

### (Carve-Out of Certain Operations of BioXcel Corporation)

## NOTES TO FINANCIAL STATEMENTS (Continued)

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

#### (interim period information is unaudited)

#### Note 10. Subsequent Events (Continued)

On August 23, 2017 and September 15, 2017 the Company issued and aggregate of 9,393 options to purchase shares of our common stock at a price of \$97.61 per share under the Plan to executive officers, directors, key employee and consultants.

From September 29, 2017 to October 26, 2017, the Company sold 1,804 shares of common stock at \$1,142.86 per share for cash to certain investors for aggregate proceeds of \$2,100.

Effective November 7, 2017, the Contribution Agreement and Services Agreement were amended. See Note 4 for a complete description.

Shares



## **BIOXCEL THERAPEUTICS, INC.**

Common Stock

Prospectus

, 2017

Joint Book-Running Managers

## **Barclays**

## **UBS Investment Bank**

## **BMO** Capital Markets

Lead Manager

## **Canaccord Genuity**

Until , 2017 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

#### PART II—INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of the securities being registered. All the amounts shown are estimates except the SEC registration fee and the FINRA filing fee.

	Amount to be paid
SEC registration fee	*
FINRA filing fee	*
The Nasdaq Capital Market initial listing fee	*
Blue sky qualification fees and expenses	*
Transfer agent and registrar fees	*
Accounting fees and expenses	*
Legal fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total	

To be filed by amendment.

### Item 14. Indemnification of Directors and Officers

Section 102 of the General Corporation Law of the State of Delaware (the "DGCL") permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides that no director of the Company shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Upon consummation of this offering, our amended and restated certificate of incorporation and amended and restated bylaws will provide indemnification for our directors and officers to the fullest



extent permitted by the DGCL. We will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation and amended and restated bylaws will provide that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

Prior to the consummation of this offering, we intend to enter into separate indemnification agreements with each of our directors and executive officers. Each indemnification agreement will provide, among other things, for indemnification to the fullest extent permitted by law and our amended and restated certificate of incorporation and amended and restated bylaws against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements will provide for the advancement or payment of all expenses to the indemnitee and for the reimbursement to us if it is found that such indemnitee is not entitled to such indemnification under applicable law and our amended and restated certificate of incorporation and amended and restated bylaws.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

#### Item 15. Recent Sales of Unregistered Securities

On March 29, 2017, we issued 40,000 shares of common stock to BioXcel Corporation pursuant to the terms of that certain asset contribution agreement dated June 30, 2017. Such offer, sale and issuance was exempt from registration under Section 4(a)(2) of the Securities Act.

On August 23, 2017, we granted stock options to purchase an aggregate of 9,271 of shares of common stock at an exercise price of \$97.61 per share, to a total of 25 employees, consultants and directors under our 2017 Equity Incentive Plan. All of these options remain outstanding. The offers, sales and issuances of these securities were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 thereunder as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

On September 15, 2017, we granted stock options to purchase 122 shares of common stock at an exercise price of \$97.61 per share, to a consultant under our 2017 Equity Incentive Plan. All of these options remain outstanding. The offers, sales and issuances of these securities were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 thereunder as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

On September 29, 2017, we sold an aggregate of 1,619 shares of our common stock to accredited investors, including 175 shares to Peter Mueller, the chairman of our board of directors, at a price of \$1,142.86 per share for aggregate gross proceeds to the Company of \$1,850,289.84. Such offer, sale and issuance was exempt from registration under Section 4(a)(2) of the Securities Act.

On October 25, 2017, we sold an aggregate of 185 shares of our common stock to an accredited investor at a price of \$1,142.86 per share for aggregate gross proceeds to the Company of \$211,429.10. Such offer, sale and issuance was exempt from registration under Section 4(a)(2) of the Securities Act.

#### Item 16. Exhibits and Financial Statement Schedules

#### EXHIBIT INDEX

Exhibit No.	Description
1.1*	Form of Underwriting Agreement
3.1	Certificate of Incorporation, currently in effect
3.2*	Form of Amended and Restated Certificate of Incorporation, to be effective immediately prior to the closing of this offering
3.3	Bylaws, currently in effect
3.4*	Form of Amended and Restated Bylaws, to be effective immediately prior to the closing of this offering
4.1	Grid Note, dated June 30, 2017
4.2*	Specimen Stock Certificate evidencing the shares of common stock
5.1*	Opinion of Sheppard, Mullin, Richter & Hampton LLP
10.1#	Amended and Restated Separation and Shared Services Agreement, effective November 7, 2017, by and between BioXcel Corporation and BioXcel Therapeutics, Inc.
10.2#	Amended and Restated Asset Contribution Agreement, effective November 7, 2017, by and between BioXcel Corporation and BioXcel Therapeutics, Inc.
10.3+	2017 Equity Incentive Plan
10.4+	Form of Incentive Stock Option Agreement under the 2017 Equity Incentive Plan
10.5+	Form of Non-Statutory Stock Option Agreement under the 2017 Equity Incentive Plan

10.6\*+ Form of Indemnification Agreement with directors and executive officers

### II-3

Table of Contents

Exhib	oit No.	Description
	10.7*+	Employment Agreement, effective September 1, 2014, by and between BioXcel Corporation and Vimal Mehta
	10.8	Form of Stock Purchase Agreement for September and October 2017 Private Placements
	23.1	Consent of BDO USA LLP, independent registered public accounting firm
	23.2*	Consent of Sheppard, Mullin, Richter & Hampton LLP (included in Exhibit 5.1)
	24.1	Power of Attorney (included on the signature page to this registration statement)
*	To be fi	led by Amendment

- + Indicates a management contract or any compensatory plan, contract or arrangement
- # Confidential treatment is being requested for portions of this exhibit. These portions have been omitted from the registration statement and have been filed separately with the Securities and Exchange Commission.

## Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## Item 17. Undertakings

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of BioXcel Therapeutics, Inc. pursuant to the foregoing provisions, or otherwise, BioXcel Therapeutics, Inc. has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by BioXcel Therapeutics, Inc. of expenses incurred or paid by a director, officer or controlling person of BioXcel Therapeutics, Inc. in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, BioXcel Therapeutics, Inc. will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned hereby further undertakes that:

(1) For purposes of determining any liability under the Securities Act the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by BioXcel Therapeutics, Inc. pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

#### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Branford, State of Connecticut, on the of , 2017.

#### **BIOXCEL THERAPEUTICS, INC.**

By:

Vimal Mehta, Ph.D. Chief Executive Officer, President and Secretary and Director

## POWER OF ATTORNEY

Each of the undersigned officers and directors of BioXcel Therapeutics, Inc. hereby constitutes and appoints Vimal Mehta and Richard Steinhart, and each of them any of whom may act without joinder of the other, the individual's true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for the person and in his or her name, place and stead, in any and all capacities, to sign this registration statement of BioXcel Therapeutics, Inc. on Form S-1, and any other registration statement relating to the same offering (including any registration statement, or amendment thereto, that is to become effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended), and any and all amendments thereto (including post-effective amendments to the registration statement), and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated below.

Signature	Title	Date
Vimal Mehta, Ph.D.	Chief Executive Officer, President, Secretary and Director ( <i>Principal Executive Officer</i> )	, 2017
Richard Stenhart	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	, 2017
Peter Mueller, Ph.D.	- Chairman of the Board of Directors	, 2017
	II-5	

Signature	<u>1</u>	<u>Fitle</u>	Date
Krishnan Nandabalan, Ph.D.	- Director		, 2017
Sandeep Laumas, M.D.	- Director II-6		, 2017

#### Delaware The First State

## I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF INCORPORATION OF "BIOXCEL THERAPEUTICS, INC.", FILED IN THIS OFFICE ON THE TWENTY-NINTH DAY OF MARCH, A.D. 2017, AT 4:48 O`CLOCK P.M.

## A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.



/s/ Jeffrey W. Bullock Jeffrey W. Bullock, Secretary of State

> Authentication: 202300675 Date: 03-30-17

State of Delaware Secretary of State Division of Corporations

Delivered 04:48 PM 03/29/2017 FILED 04:48 PM 03/29/2017 SR 20172117681 - File Number 6363738

6363738 8100 SR# 20172117681

You may verify this certificate online at corp.delaware.gov/authver.shtml

1

## **CERTIFICATE OF INCORPORATION**

### OF

## **BIOXCEL THERAPEUTICS, INC.**

**FIRST**: The name of the corporation is BioXcel Therapeutics, Inc. (the "*Corporation*").

**SECOND:** The address of the Corporation's registered office in the State of Delaware is located at 2711 Centerville Road, Suite 400, in the City of Wilmington, County of New Castle, Delaware 19808. The Corporation's registered agent at such address is Corporation Service Company.

**THIRD:** The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law, as the same may be amended and supplemented from time to time (the "*DGCL*").

**FOURTH:** The total number of shares of stock that the Corporation shall have authority to issue is One Hundred Thousand (100,000) shares of common stock, par value of \$0.001 per share. The powers, preferences and rights, and the qualifications, limitations or restrictions thereof shall be determined by the Corporation's Board of Directors.

**FIFTH**: The name and address of the incorporator is as follows:

Diane M. Cooper Wiggin and Dana LLP 265 Church Street New Haven, CT 06510

**SIXTH:** The Corporation's Board of Directors shall have the power to adopt, amend or repeal the bylaws of the Corporation.

**SEVENTH:** Whenever a compromise or arrangement is proposed between this Corporation and its creditors or any class of them and/or between this Corporation and its stockholders or any class of them, any court of equitable jurisdiction within the State of Delaware may, on the application in a summary way of this Corporation or of any creditor or stockholder thereof or on the application of any receiver or receivers appointed for this Corporation under Section 291 of the DGCL or on the application of trustees in dissolution or of any receiver or receivers appointed for this Corporation, as the case may be, to be summoned in such manner as the said court directs. If a majority in number representing three-fourths in value of the creditors or class of creditors, and/or of the stockholders or any compromise or arrangement and to any reorganization of this Corporation as consequence of such compromise or arrangement, the said compromise or arrangement and the said reorganization shall, if sanctioned by the court to which the said application has been made, be

binding on all the creditors or class of creditors, and/or on all the stockholders or class of stockholders, of this Corporation, as the case may be, and also on this Corporation.

**EIGHTH:** To the fullest extent permitted by law, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL or any other law of the State of Delaware is amended after approval by the stockholders of this Article Eighth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL or any such other law of the State of Delaware as so amended. No amendment to or repeal of this Article Eighth shall adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such amendment or repeal.

**NINTH:** The Corporation shall, to the fullest extent permitted by Section 145 of the DGCL, indemnify and advance expenses to (a) its directors and officers and (b) any person who at the request of the Corporation is or was serving as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise from and against any and all of the expenses, liabilities or other matters referred to in or covered by said section as amended or supplemented (or any successor); provided, however, that, except with respect to proceedings to enforce rights to indemnification, the Corporation shall not indemnify any director, officer or such person in connection with a proceeding (or part thereof) initiated by such director, officer or such person unless such proceeding (or part thereof) was authorized by the Board of Directors of the Corporation. The Corporation, by action of its Board of Directors, may provide indemnification or advance expenses to employees and agents of the Corporation or other persons only on such terms and conditions and to the extent determined by its Board of Directors in its sole and absolute discretion. The indemnification provided for herein shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in their official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person. No amendment to or repeal of this Article Ninth shall adversely affect any right or protection of a director, officer or such other indemnified person of the Corporation existing at the time of, or increase the liability of any director, officer or such other indemnified person of the Corporation with respect to any acts or omissions of such direct

**TENTH:** Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Corporation, (b) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (c) any action asserting a claim arising pursuant to any provision of the DGCL or the Corporation's certificate of incorporation or bylaws or (d) any action asserting a claim governed by the internal affairs doctrine.

**ELEVENTH:** The Corporation hereby renounces, to the fullest extent permitted by Section 122(17) of the DGCL, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any business opportunities that are presented to any of its directors or stockholders who are not otherwise employed by the Corporation other than business opportunities that are presented to any director or stockholder acting in his or her capacity as a director or stockholder of the Corporation. No amendment to or repeal of this Article Eleventh shall adversely affect any right or protection of a director or stockholder of this Corporation existing at the time of, or increase the liability of any director or stockholder of this Corporation with respect to any acts or omissions of such director or stockholder occurring prior to, such amendment or repeal.

**I, THE UNDERSIGNED**, being the incorporator, for the purpose of forming a corporation under the DGCL, do make, file and record this Certificate of Incorporation, do certify that the facts herein stated are true and, accordingly, have hereto set my hand this 29th day of March, 2017.

/s/ Diane M. Cooper Diane M. Cooper, Incorporator

#### BYLAWS OF BIOXCEL THERAPEUTICS, INC. (the "Corporation")

#### ARTICLE I Offices

Section 1. <u>Principal Office</u>. The address of the principal office of the Corporation shall be the address of its principal place of business from time to time.

Section 2. <u>Other Offices</u>. The Corporation may also have other offices at such places within or without the State of Delaware as the Board of Directors of the Corporation (the "*Board*") may designate from time to time determine.

## ARTICLE II <u>Meetings of Shareholders</u>

Section 1. <u>Annual Meeting</u>. The annual meeting of shareholders, for the purpose of electing the Board and for the transaction of any other business relating to the affairs of the Corporation which may come before the meeting, shall be held annually on such date and at such time as shall be designated by the Board or, in the absence of action by the Board, by the President.

Section 2. <u>Special Meetings</u>. Special meetings of shareholders may be called at any time by the Board, the Chairman of the Board or the President of the Corporation (the "*President*") or, in the absence or disability of the President, by a Vice President of the Corporation. Upon the written request of not less than one-tenth (1/10) of the voting power of all shares entitled to vote at the meeting, the President shall call a special shareholders' meeting for the purposes specified in such request and cause notice thereof to be given. If the President shall not, within fifteen (15) days after the receipt of such request, so call such meeting, such shareholders may call the same.

Section 3. <u>Notice of Meeting</u>. Written notice of the place, date and time of all meetings of the shareholders shall be given, not less than ten (10) nor more than sixty (60) days before the date on which the meeting is to be held, to each shareholder entitled to vote at such meeting, except as otherwise provided herein or required by the Delaware General Corporation Law (the "*Act*") or the Corporation's Certificate of Incorporation (the "*Certificate of Incorporation*"). Any such notice shall be addressed to such shareholder at his or her last known address as the same appears in the records of the Corporation. Any such notice may be given by a form of electronic transmission consented to by the shareholder to whom the notice is given.

When a meeting is adjourned to another place, date or time, written notice need not be given of the adjourned meeting if the place, date and time thereof are announced at the meeting at which the adjournment is taken; provided, however, that if the date of any adjourned meeting is more than one-hundred twenty (120) days after the date fixed for the original meeting, written notice of the place, date and time of the adjourned meeting shall be given in conformity

herewith. At any adjourned meeting, any business may be transacted which might have been transacted at the original meeting.

Section 4. <u>Place of Meetings</u>. Each annual or special meeting of shareholders shall be held at such place within or without the State of Delaware as the Board or, in the absence of action by the Board, the President may designate. In the absence of such designation with respect to any such meeting, it shall be held at the principal office of the Corporation.

Section 5. <u>Quorum</u>. Unless the Certificate of Incorporation or the Act provide otherwise, a majority of the votes entitled to be cast on any matter constitutes a quorum with respect to such matter. Where a separate vote by a class or classes is required, a majority of the votes entitled to be cast on any matter by such class or classes constitutes a quorum with respect to such matter.

If a quorum shall fail to attend any meeting, the chairman of the meeting or the holders of a majority of the shares of stock entitled to vote who are present, in person or by proxy, may adjourn the meeting to another place, date or time.

Section 6. <u>Voting</u>. Except as provided in the Act or unless the Certificate of Incorporation provides otherwise, each outstanding share, regardless of class, is entitled to one vote on each matter voted on at a shareholders' meeting.

When a quorum is present at any duly held meeting of shareholders, the affirmative vote of the holders of a majority of the voting power of the shares entitled to vote on the subject matter, present in person or by proxy, shall be the act of the shareholders, except where otherwise provided by the Act, the Certificate of Incorporation, these Bylaws or an effective written agreement among the Corporation's shareholders holding a sufficient percentage of outstanding stock, or an applicable class or series outstanding stock, of the Corporation (a "*Shareholders' Agreement*").

Every shareholder entitled to vote may do so in person or by proxy.

Section 7. Organization. The Chairman of the Board or, in his or her absence, such person as the Board may have designated or, in his or her absence, the President or, in his or her absence, such person as may be chosen by the holders of a majority of the shares entitled to vote who are present, in person or by proxy, shall call to order any meeting of the shareholders and act as chairman of the meeting. In the absence of the Secretary of the Corporation (the "*Secretary*"), the secretary of the meeting shall be such person as the chairman of the meeting appoints. The chairman of any meeting of shareholders shall determine the order of business and the procedures at the meeting, including such regulation of the manner of voting and the conduct of discussion as he or she deems to be appropriate.

Section 8. <u>Action Without Meeting</u>. Any action required to be taken at any annual or special meeting of shareholders, or any action which may be taken at any annual or special meeting of such shareholders, may be taken without a meeting, without prior notice and without a vote, if a consent or

consents in writing, setting forth the action so taken shall be (a) signed and dated by the holders of outstanding stock, or by their duly authorized attorneys, having not less than the minimum number of votes that would be necessary to authorize or take such action at a

meeting at which all shares entitled to vote thereon were present and voted and (b) delivered to the Corporation to its registered office in the State of Delaware (in which case delivery shall be by hand or by certified or registered mail, return receipt requested), its principal place of business or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of shareholders are recorded within sixty (60) days of the earliest date on which a consent delivered to the Corporation as required above was signed. Consent may be given by the holders of outstanding stock or their duly authorized attorneys by electronic transmission. Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those shareholders who have not consented in writing. Such consent shall be filed in the corporate minute book and shall have the same effect as a unanimous vote at a shareholders' meeting.

### ARTICLE III Directors

Section 1. <u>General Powers</u>. The business, property and affairs of the Corporation shall be managed by the Board, which may exercise all the powers of the Corporation except such as are by the Act, the Certificate of Incorporation, these Bylaws or a Shareholders' Agreement expressly conferred on or reserved to the shareholders.

Section 2. <u>Number, Election, Tenure and Qualification</u>. Except as otherwise specified in the Certificate of Incorporation or a Shareholders' Agreement, the number of Directors which shall constitute the whole Board shall be determined by resolution of the Board or by the shareholders at the annual meeting or at any special meeting of shareholders. The Directors shall be elected at the annual meeting or at any special meeting of the shareholders, except as provided in Section 5 of this Article, and each Director elected shall hold office until his or her successor is elected and qualified, unless sooner displaced. Directors need not be shareholders.

Section 3. <u>Resignation of Directors</u>. If no time is specified, the resignation of a Director shall be effective immediately upon its receipt by the Corporation at its principal place of business or by the President or Secretary, or at such later time as may be specified in the resignation. In the case of a resignation to take effect at a date later than the receipt thereof by the Corporation, appropriate action to elect a successor to take office when the resignation becomes effective may be taken at any time after such receipt, but the new Director may not take office until the resignation is effective.

Section 4. <u>Removal of Directors</u>. Subject to any contrary provisions in a Shareholders' Agreement, at any special meeting of shareholders called for that purpose any Director may be removed from office with or without cause at any time, regardless of the term for which he or she had been elected, by the affirmative vote of the holders of a majority of the voting power of all shares then having the right to vote for the election of Directors.

Section 5. <u>Vacancies</u>. Subject to any contrary provisions in a Shareholders' Agreement, in case of any vacancy in the Board by reason of death, resignation, removal or failure of the shareholders to elect as many Directors as the number of directorships fixed by them, or otherwise,

the remaining Directors, though less than a quorum, by the concurring vote of a majority of such remaining Directors may elect a successor to hold office until his or her successor has been elected.

Section 6. <u>Regular and Special Meetings</u>. Regular meetings of the Board may be held at such time and places within or without the State of Delaware as the Board may determine.

Special meetings of the Board may be called by the President, and shall be called upon the written request of any Director. Each special meeting shall be held at such time and place within or without the State of Delaware as shall be designated in the notice thereof.

Section 7. <u>Notice of Meetings</u>. Regular meetings of the Board may be held without notice of the date, time, place or purpose of the meeting. Notice of the date, time, place and purpose of each special meeting of the Board shall be given to each Director by whom it is not waived by mailing written notice not less than five (5) days before the meeting or orally, by telegraph, telex, cable, telecopy or other electronic transmission given not less than twenty-four (24) hours before the meeting. Unless otherwise indicated in the notice thereof, any and all business may be transacted at any such special meeting.

Section 8. <u>Quorum</u>. A majority of the fixed number of Directors shall constitute a quorum for the transaction of business. The affirmative vote of a majority of the Directors present at any meeting at which a quorum is present shall be the action of the Board, unless the action of a greater number is required by the Act, the Certificate of Incorporation, any Shareholders' Agreement or any other agreement between the Corporation and its shareholders. In the absence of a quorum, a majority of the Directors present at any meeting may adjourn the meeting from time to time without further notice until a quorum shall be present.

Section 9. <u>Action Without Meeting</u>. Any action required or permitted by the Act to be taken by the Board or any committee thereof may be taken without a meeting if each Director or member of such committee consents thereto in writing or by electronic transmission. The Secretary shall file such consent or consents with the minutes of the meetings of the Board.

Section 10. <u>Participation in Meetings By Conference Telephone</u>. Members of the Board, or any committee thereof, may participate in a meeting of the Board or committee of the Board by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other and such participation shall constitute presence in person at such meeting.

Section 11. <u>Conduct of Business</u>. At any meeting of the Board or any committee thereof, business shall be transacted in such order and manner as the Board or such committee may from time to time determine.

Section 12. <u>Compensation of Directors</u>. Directors, as such, may receive, pursuant to a resolution of the Board, fixed fees and other compensation for their services as Directors, including, without limitation, their services as members of committees of the Board.

4

Section 13. <u>Committees of the Board</u>. Subject to any contrary provisions in a Shareholders' Agreement, the Board may from time to time designate committees of the Board, with such lawfully delegable powers and duties as it thereby confers, to serve at the pleasure of the Board and shall, for those committees and any others provided for herein, elect a Director or Directors to serve as the member or members, designating, if it desires, other Directors as alternate members who may replace any absent or disqualified member at any meeting of the committee. Except as otherwise provided by the Act, any such committee, to the extent provided in the resolution of the Board, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize any seal of the Corporation to be affixed to all papers which may require it. Subject to any contrary provisions in a Shareholders' Agreement, in the absence or disqualification of any member of any committee and any alternate member in his or her place, the member or members of the committee present at the meeting and not disqualified from voting, whether or not he or she or they constitute a quorum, may by unanimous vote appoint another member of the Board to act at the meeting in the place of the absent or disqualified member. Adequate provision shall be made for notice to committee members of all meetings; a majority of the committee members shall constitute a quorum; and all matters shall be determined by a majority vote of the members present.

### ARTICLE IV Officers, Agents and Attorneys

Section 1. <u>Officers</u>. The officers of the Corporation shall be a President and Secretary, both of whom shall be elected by the Board. The Board may also elect or may authorize the appointment of such additional officers, including but not limited to a Chief Executive Officer, a Chairman of the Board, a Treasurer, one or more Vice Presidents, Assistant Secretaries and Assistant Treasurers as in its judgment may be necessary or advisable. Any two or more offices may be held by the same person. The election or appointment of an officer for a given term shall not of itself create contract rights. Each officer elected or appointed by the Board shall hold office until his or her successor is elected or appointed and qualified, or until he or she dies, resigns, is removed or becomes disqualified, unless a shorter term is specified in the vote electing or appointing said officer.

Section 2. <u>Powers and Duties of Officers</u>. The officers of the Corporation shall have such powers and duties as provided by these Bylaws and as the shareholders or the Board may from time to time confer and designate.

Section 3. <u>Resignation of Officers</u>. If no time is specified, the resignation of an officer shall be effective immediately upon its receipt by the Corporation at its principal place of business, or at such later time as may be specified in the resignation. In the case of a resignation to take effect at a date later than the receipt thereof by the Corporation, appropriate action to elect a successor to take office when the resignation becomes effective may be taken at any time after such receipt, but the successor may not take office until the resignation is effective.

Section 4. <u>Removal of Officers</u>. Officers may be removed from office, with or without cause at any time, by the affirmative vote of the Board, but without prejudice to their contract rights, if any.

5

Section 5. Vacancies. All vacancies among the officers from whatsoever cause may be filled by the Board.

Section 6. <u>Agents and Attorneys</u>. The Board may appoint such agents and attorneys with such powers and to perform such acts and duties on behalf of the Corporation as the Board may determine.

#### ARTICLE V Shares and Shareholders

Section 1. <u>Certificates</u>. Every shareholder shall be entitled to a certificate or certificates certifying the number and class of shares owned by him, her or it in the Corporation. Each such certificate may be under seal, or facsimile seal, of the Corporation and shall be signed, which signature may be by facsimile, by the President or a Vice President, and by the Secretary or an Assistant Secretary or the Treasurer or Assistant Treasurer.

Section 2. <u>Transfers</u>. Except as otherwise provided by law, the Certificate of Incorporation or in a Shareholders' Agreement, shares shall be transferable on the records of the Corporation by the holder of record thereof, or by his, her or its attorney thereunto duly authorized, upon the surrender and cancellation of a certificate or certificates for a like number of shares of the same class with such proof of the authenticity of the signature of such holder or of such attorney and such proof of the authority of such attorney as the Corporation or its transfer agent, transfer clerk or registrar may reasonably require.

Section 3. <u>Holders of Record</u>. The Corporation shall be entitled to treat the holder of record of any share or shares as the owner and holder thereof in fact, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it has actual or other notice thereof, except as and to the extent otherwise provided by the Act.

Section 4. <u>Record Date</u>. The Board by resolution may fix a date as the record date for the purpose of determining the shareholders entitled to notice of and to vote at any meeting of shareholders or any adjournment thereof, or entitled to receive payment of any dividend or other distribution, or for any other purpose, such date in any case to be not less than ten (10) nor more than sixty (60) days before the meeting or action requiring a determination of shareholders. If no record date is so fixed, the date on which notice of a meeting is mailed shall be the record date for the determination of shareholders entitled to receive payment of such dividend or other distribution is adopted shall be the record date for the determination of shareholders entitled to receive payment of such dividend or other distribution. Shareholders actually of record at a record date shall be the only shareholders entitled to receive notice of or to vote at the meeting, or receive the dividend or other distribution, or otherwise participate in respect of the event or transaction, to which such date relates, except as otherwise provided by law. A determination of shareholders of record entitled to notice of or to vote at a meeting of shareholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for the adjourned meeting.

Section 5. Lost Certificates. If a share certificate is lost or destroyed, another may be issued in its stead upon proof of such loss or destruction, upon the giving of a bond of indemnity satisfactory to the Corporation, unless these requirements are dispensed with by the Board, and upon compliance with such other conditions as the Board may reasonably require.

## ARTICLE VI Liability and Indemnification

Section 1. <u>Liability</u>. To the fullest extent permitted by law, no Director shall be personally liable to the Corporation or its shareholders for monetary damages for breach of fiduciary duty as a Director. If the Act or any other law of the State of Delaware is amended after approval by the shareholders of this Article to authorize corporate action further eliminating or limiting the personal liability of Directors, then the liability of a Director shall be eliminated or limited to the fullest extent permitted by the Act or any such other law of the State of Delaware as so amended. No amendment to or repeal of this Article shall adversely affect any right or protection of a Director existing at the time of, or increase the liability of any Director with respect to any acts or omissions of such Director occurring prior to, such amendment or repeal.

Section 2. Indemnification. The Corporation shall, to the fullest extent permitted by Section 145 of the Act, indemnify and advance expenses to (a) its Directors and officers and (b) any person who at the request of the Corporation is or was serving as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise from and against any and all of the expenses, liabilities or other matters referred to in or covered by said section as amended or supplemented (or any successor); provided, however, that, except with respect to proceedings to enforce rights to indemnification, the Corporation shall not indemnify any director, officer or such person in connection with a proceeding (or part thereof) initiated by such director, officer or such person unless such proceeding (or part thereof) was authorized by the Board. The Corporation, by action of the Board, may provide indemnification or advance expenses to employees and agents of the Corporation or other persons only on such terms and conditions and to the extent determined by the Board in its sole and absolute discretion. The indemnification provided for herein shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any bylaw, agreement, vote of shareholders or disinterested directors or otherwise, both as to action in their official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

Section 3. <u>Insurance</u>. The Board may authorize, by a vote of the majority of the full Board, the Corporation to purchase and maintain insurance on behalf of any person who is or was a Director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify him or her against such liability under the provisions of this Article.

7

### ARTICLE VII Transactions with Interested Parties

No contract or transaction between the Corporation and one (1) or more of its Directors or officers, or between the Corporation and any other corporation, partnership, association or other organization in which one or more of its Directors or officers are directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the Director or officer is present at or participates in the meeting of the Board or committee thereof which authorizes the contract or transaction, or solely because the votes of such Director or officer are counted for such purpose, if:

(a) The material facts as to his or her relationship or interest and as to the contract or transaction are disclosed or are known to the Board or the committee, and the Board or committee in good faith authorizes the contract or transaction by the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum;

(b) The material facts as to his or her relationship or interest and as to the contract or transaction are disclosed or are known to the shareholders entitled to vote thereon, and the contract or transaction is specifically approved in good faith by vote of the shareholders; or

(c) The contract or transaction is fair as to the Corporation as of the time it is authorized, approved or ratified by the Board, a committee thereof or the shareholders.

Interested Directors may be counted in determining the presence of a quorum at a meeting of the Board or of a committee which authorizes the contract or transaction.

### ARTICLE VIII Miscellaneous

Section 1. <u>Fiscal Year</u>. Except as otherwise determined by the Board from time to time, the fiscal year of the Corporation shall begin on the first day of January in each year and shall end on the last day of December in each year.

Section 2. <u>Waiver of Notice</u>. Whenever any notice of time, place, purpose or any other matter, including any special notice or form of notice, is required or permitted to be given to any person by the Act, the Certificate of Incorporation, these Bylaws or a resolution of shareholders or Directors, a written waiver of notice signed by the person or persons entitled to such notice, or a waiver of notice by electronic transmission by the person or persons entitled to such notice, or a waiver of notice of such notice. The Secretary shall cause any such waiver to be filed with or entered upon the records of the Corporation or, in the case of a waiver of notice of a meeting, the records of the meeting. The attendance of any person at a meeting without protesting, prior to or at the commencement of the meeting, the lack of proper notice shall be deemed to be a waiver by such person of notice of such.

## ARTICLE IX <u>Amendments</u>

Except as otherwise provided by the Act or a Shareholders' Agreement, these Bylaws may be amended, repealed or added to at any meeting or by written consent of the shareholders or the Board, by the affirmative vote or written consent of the holders of a majority of the voting power of shares entitled to vote thereon or a majority of the directorships.

#### **GRID NOTE**

### Up to US \$1,000,000

June 30, 2017

**FOR VALUE RECEIVED**, the undersigned, BioXcel Therapeutics, Inc., a Delaware corporation with an office at 780 East Main Street, Branford, CT 06405 ("*Payor*"), unconditionally promises to pay to the order of BioXcel Corporation, a Delaware corporation with an office at 780 East Main Street, Branford, CT 06405 ("*Payee*"), the principal sum of ONE MILLION DOLLARS (\$1,000,000), or so much thereof as shall have been advanced by Payee to or on behalf of Payor, together with interest on the unpaid balance of each advance, which shall accrue at a rate per annum equal to the applicable federal rate for short-term loans as of the date hereof, in each case calculated based on a 365-day year and actual days elapsed. The obligations of Payor under this Grid Note (this "*Note*") shall be senior indebtedness of Payor and shall rank senior to all other indebtedness.

This Note evidences a revolving line of credit. Advances under this Note may be requested either orally or in writing by Payor, for the exclusive benefit of Payor in furtherance of conducting its business. All advances under this Note require the prior written approval of Payee and a record thereof shall be maintained in **Exhibit A** to this Note, *provided, however*, that the failure to so record shall in no way limit Payor's obligations with respect to repayment of principal or interest on any advance.

The entire balance of principal and accrued interest thereon shall be due and payable within 18 months upon execution or receiving a cumulative amount of TEN MILLION DOLLARS (\$10,000,000) of financing, whichever is earlier.

If this Note is not paid on demand, Payor agrees to pay, in addition to the unpaid principal and accrued interest, all reasonable costs and expenses incurred in attempting or effecting payment or collection hereunder, including, but not limited to, reasonable attorneys' fees, whether or not suit is instituted.

Payor shall have the right at any time to prepay this Note, in whole or in part, without penalty, subject to the qualification, however, that no partial prepayment of the original sum shall in any way release, discharge or affect the obligation of Payor to make full payment in the amount of the balance of said principal sum at time of demand. Each and every payment (including all partial payments or prepayments) received by the Payee hereunder shall be applied first to any penalties for which the Payor is responsible under this Note which have not yet been paid, then to outstanding interest and then to outstanding principal. If any payment under this Note shall be specified to be made on a day which is not a business day, it shall be made on the next succeeding day which is a business day.

The amounts due hereunder are payable in lawful money of the United States of America to Payee at his address above, or at such other place as the holder of this Note shall from time to time designate, in immediately available funds.

No failure on the part of Payee or any other holder of this Note to exercise and no delay in

exercise by Payee or any other holder of this Note of any right, remedy or power hereunder preclude any other or future exercise of any other right, remedy or power.

This Note shall be binding upon Payor and its successors and assigns.

THIS NOTE IS AND SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CONNECTICUT. ANY CLAIMS OR LEGAL ACTIONS BY ONE PARTY AGAINST THE OTHER ARISING OUT OF THIS NOTE SHALL BE COMMENCED AND MAINTAINED IN ANY STATE OR FEDERAL COURT LOCATED IN THE STATE OF CONNECTICUT, AND PAYOR HEREBY EXPRESSLY, IRREVOCABLY AND UNCONDITIONALLY CONSENTS TO THE JURISDICTION OF SUCH COURTS AND HEREBY WAIVES TRIAL BY JURY IN ANY SUCH LEGAL ACTION OR PROCEEDING.

Diligence, presentment, demand, protest and notice of any kind are hereby waived by Payor and all sureties, guarantors and endorsers hereof, if any.

In the event that any one or more of the provisions of this Note shall for any reason be held to be invalid, illegal or unenforceable, in whole or in part, or in any respect, or in the event that any one or more of the provisions of this Note shall operate, or would prospectively operate, to invalidate this Note, then, and in any such event, such provision or provisions only shall be deemed null and void and of no force or effect and shall not affect any other provision of this Note, and the remaining provisions of this Note shall remain operative and in full force and effect, shall be valid, legal and enforceable, and shall in no way be affected, prejudiced or disturbed thereby.

IN WITNESS WHEREOF, Payor has caused this Note to be executed as of the date and year first above written.

## **BIOXCEL THERAPEUTICS, INC.**

/s/ Vimal Mehta By: Vimal Mehta Its: CEO

EXHIBIT A

Amount of

Date of

Amount of

Date of

 Advance	Advance	Repayment	Repayment	]	Remaining
\$ 299,500	06/30/2017			\$	299,500
		3			

## Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

#### AMENDED & RESTATED SEPARATION AND SHARED SERVICES AGREEMENT

This Amended & Restated Shared Services Agreement (this "*Agreement*") is entered into as of November 7, 2017 (the "*Execution Date*"), by and between BioXcel Corporation, a Delaware corporation located at 780 East Main Street, Branford, CT 06405 ("*BioXcel*"), and BioXcel Therapeutics, Inc., a Delaware corporation located at 780 East Main Street, Branford, CT 06405 ("*BioXcel*"), and BioXcel Therapeutics, Inc., a Delaware corporation located at 780 East Main Street, Branford, CT 06405 ("*BioXcel*"), and BioXcel Therapeutics, Inc., a Delaware corporation located at 780 East Main Street, Branford, CT 06405 ("*BTI*") in order to amend and restate the obligations of each of BioXcel and BTI under that certain Separation and Shared Services Agreement (the "*SSA*") entered into by BioXcel and BTI as of June 30, 2017 (the "*Effective Date*"). BioXcel and BTI are sometimes referred to individually as a "*Party*" and collectively as the "*Parties*."

### RECITALS

WHEREAS, BioXcel identified a number of therapeutic candidates using its proprietary artificial intelligence-powered research and development engine known as 'EvolverAI'; and

WHEREAS, the Board of Directors of BioXcel determined that it was in BioXcel's best interest to restructure its business in order to realize the full potential of its assets, including such therapeutic candidates; and

WHEREAS, in accordance with the restructuring plan, BioXcel formed BTI, a product development biotechnology company, to develop and commercialize certain of the therapeutic candidates; and

WHEREAS, BioXcel and BTI entered into that certain Amended & Restated Contribution Agreement, which is attached as **Exhibit A**, (the "*Contribution Agreement*") whereby BioXcel contributed certain therapeutic candidates and other assets and liabilities to BTI; and

WHEREAS, BTI plans to develop and commercialize such therapeutic candidates; and

WHEREAS, to allow such work to be carried out by BTI, BioXcel desires to furnish the office space, equipment, services and leased employees described herein subject to the terms and conditions of this Agreement; and

WHEREAS, BioXcel desires to provide and BTI wishes to accept certain other financial support from BioXcel to support the efforts of BTI and to assist BTI with paying for the office space, equipment, services and leased employees described herein; and

WHEREAS, BTI desires to cease accepting space, equipment, services, leased employees and financial support pursuant to a separation plan, which is attached as **Exhibit B** (the "*Separation Plan*") and BioXcel desires to adhere to the Separation Plan.

NOW, THEREFORE, in consideration of the foregoing recitals and the terms and conditions set forth herein, the Parties hereto, intending to be legally bound, hereby agree to amend and restate the terms and conditions of the SSA as follows:

## 1. Shared Office Space and Equipment.

a. <u>Office Space</u>. BioXcel shall make available to BTI sufficient space in the office leased by BioXcel and located at 780 East Main Street, Branford, CT 06405 (the "*Office*") during the Term (as defined below), including space for four (4) executives and three (3) hoteling seats (the "*BTI Space*"), to use for all purposes related to the conduct of BTI's

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

### Exhibit A

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

## AMENDED & RESTATED ASSET CONTRIBUTION AGREEMENT

This Amended & Restated Asset Contribution Agreement (this "*Agreement*") is entered into as of November 7, 2017 (the "*Execution Date*"), by and between BioXcel Corporation, a Delaware corporation located at 780 East Main Street, Branford, CT 06405 ("*BioXcel*"), and BioXcel Therapeutics, Inc., a Delaware corporation located at 780 East Main Street, Branford, CT 06405 ("*BTI*").

WHEREAS, BioXcel identified a number of therapeutic candidates using its proprietary artificial intelligence-powered research and development engine known as 'EvolverAI'; and

WHEREAS, the Board of Directors of BioXcel determined that it was in BioXcel's best interest to restructure its business in order to realize the full potential of its assets, including such therapeutic candidates; and

WHEREAS, in accordance with the restructuring plan, BioXcel formed BTI, a product development biotechnology company, to develop and commercialize certain of the therapeutic candidates; and

WHEREAS, to allow such work to be carried out by BTI, BioXcel and BTI entered into certain agreements including an Asset Contribution Agreement, dated as of June 30, 2017 (the "*Effective Date*"), by which BioXcel contributed certain assets and liabilities to BTI pursuant to the terms and conditions thereof (the "*ACA*"); and

WHEREAS, BTI accepted certain assets and liabilities from BioXcel pursuant to the terms and conditions of the ACA; and

WHEREAS, BioXcel desires to transfer to BTI certain additional assets and liabilities and grant to BTI certain rights in future therapeutic candidates identified by BioXcel pursuant to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the covenants contained herein, and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties now agree to amend and restate the ACA as follows:

- 1. <u>Contribution of Assets & Option</u>.
  - A. <u>Initial Contribution of Assets</u>. On the terms and subject to the conditions set forth in this Agreement, BioXcel hereby agrees to sell, contribute, assign, transfer, convey and deliver to BTI, and BTI agrees to acquire from BioXcel, all of BioXcel's right, title and interest in and to BXCL701, BXCL702, BXCL501, and BXCL502 (collectively, the "*Candidates*"), and all of the assets associated with the Candidates, other than those specified to be Retained Assets (as defined below), (collectively, the "*Assets*"), free and clear of any security interest, lien, charge, option, claim or other encumbrance (each, a "*Lien*"), other than those Liens listed on <u>Schedule 1</u> (collectively, the "*Permitted Liens*"). The Assets include the following to the extent used or held for use in connection with the Candidates as of the Effective Date:
    - a. The intellectual property set forth on <u>Schedule 1(a)</u> (collectively, the "Intellectual Property");
    - b. All goodwill associated with the Assets;

## Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

- c. Except as set forth in Section 4 below, all of BioXcel's rights under the Contracts (as defined below);
- d. All documentation, notebooks, logs, data and records associated with the Assets, and any other information necessary for the development of the Assets;
- e. All marketing and advertising materials in hard or soft copy, including without limitation, printed promotional materials and labels associated with the Assets;
- f. All claims, causes of action, rights of recovery, rights of setoff and rights of recoupment, whether or not known as of the Effective Date, relating to BioXcel's ownership of the Assets; and
- g. All rights under or pursuant to all warranties, indemnities, representations, guarantees and similar rights, whether or not known as of the Effective Date, in favor of BioXcel with respect to the Candidates or the Assets;
- h. The Tangible Assets (as defined below); and
- i. The assets specifically identified in <u>Schedule 1(i)</u>.
- B. Option to Negotiate for Additional Product Candidates. BioXcel hereby grants to BTI a first right to negotiate exclusive rights to any additional product candidates in the fields of Neuroscience and Immuno-oncology (the "Option Field") that BioXcel may identify wholly on its own or under arrangements with third parties, and not in connection with BioXcel's provision of services to BTI under the Parties' Amended & Restated Separation and Shared Services Agreement. For clarity, this option shall not apply to any additional product candidates identified by BioXcel in connection with services BioXcel provides to BTI pursuant to the Parties' Amended & Restated Separation and Shared Services Agreement (including, without limitation services that involve the use of EvolverAI) because all such additional product candidates identified in connection with such services would be considered to be "Developments" (as defined in that agreement) already owned by BTI. This option for first negotiation shall be valid for a period of five (5) years from the date of the IPO (as defined below). Within sixty (60) days of identifying a potential product candidate in the Option Field, BioXcel shall present such identified candidate to BTI. BTI shall then have up to one hundred eighty (180) days in which to evaluate such product candidate (the "Evaluation Period"). If BTI wishes to negotiate for the exclusive rights to such product candidate, BTI shall so notify BioXcel in writing prior to the end of the Evaluation Period, and if BTI so notifies BioXcel, BTI and BioXcel shall negotiate in good faith commercially reasonable terms by which BTI can receive BioXcel's rights to such product candidate. If BioXcel and BTI are unable to mutually agree, in writing, within ninety (90) days after the end of the Evaluation Period to terms regarding BTI's rights to develop and/or commercialize such product candidate. BioXcel shall be free to develop and/or commercialize such product candidate either by itself or with one or more third parties. Notwithstanding anything contained herein to the contrary, BTI's rights and obligations set forth in this Section 1.B shall apply and be effective only from and after BTI's completion, on or before December 31, 2018, of a firm commitment underwritten public offering of share of common stock (and any other securities of BTI that may be sold along with such shares of common stock in any such public offering) ("IPO").
- C. <u>Exclusivity in Option Field</u>. Prior to the fifth (5<sup>th</sup>) anniversary of the IPO, BioXcel shall not develop drugs, or engage in preclinical discovery for the purpose of developing drugs, in the Option Field for or on behalf of a third party, utilizing EvolverAI or otherwise. In support of the foregoing, BioXcel shall inform third parties with which it enters into collaborations or other arrangements that BTI holds a first right to negotiate for BioXcel's rights in product candidates in the Option Field and the

# Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

duration of such right of BTI. BioXcel's covenant as set forth in this Section 1.C and BTI's right of first negotiation as set forth in Section 1.B shall not prevent or interfere with BioXcel's rights to the EvolverAI platform or use of the EvolverAI platform by third parties as long as BioXcel does not provide collaborative services to, or actively support, such third party in its evaluation of the results of the EvolverAI research and development engine to develop drugs in the Option Field.

- 2. <u>Retained Assets</u>. The assets set forth on <u>Schedule 2</u> shall be retained by BioXcel and shall not be sold or assigned to BTI (the "*Retained Assets*").
- 3. <u>Assumption of Liabilities</u>. As of the Effective Date, BTI shall assume and will be responsible for and pay, perform, and discharge when due all liabilities associated with the Assets, including without limitation, payment of any fees required to maintain any registrations and applications for registration arising from the ownership or use of the Intellectual Property due on and after the Effective Date, and all obligations and liabilities of BioXcel under the Contracts to the extent that those obligations and liabilities relate to the period after the Effective Date, in each case exclusive of any liability or obligation arising thereunder as a result of any breach, default or failure of BioXcel to perform any covenants or obligations required to be performed by BioXcel prior to the Effective Date. In addition to the liabilities described in the previous sentence, in consideration of BioXcel's contribution of the Assets to BTI, BTI shall assume from BioXcel and be responsible for all liabilities set forth on <u>Schedule 3</u>, hereto (all liabilities assumed by BTI, including liabilities set forth on <u>Schedule 3</u>, the "Assumed Liabilities").
- 4. Assignment of Contracts. To the extent that any Contract is not capable of being assigned or transferred without the consent or waiver of the other party thereto or any third party, or if such assignment or transfer, or attempted assignment or transfer would constitute a breach thereof, this Agreement shall not constitute an assignment or transfer thereof, or an attempted assignment or transfer of any such Contract. Schedule 4 lists those Contracts that BioXcel believes are not assignable without the written consent of the other party thereto (the "*Required Consents*"). To the extent permitted by applicable law, any consents and approvals of third parties required for the transfer to BTI of any of the Assets, including the Required Consents, that are not obtained or cannot be obtained without any conditions adverse to BTI or without any obligations imposed on BTI not specified in the Contract for which consent is being obtained prior to the Effective Date (the "*Non-Assignable Contracts*"), such Non-Assignable Contracts shall be held, as of and from the Effective Date, by BioXcel in trust for BTI and the covenants and obligations thereunder shall be performed by BTI in BioXcel's name and all benefits and obligations existing thereunder shall be for BTI's account. BioXcel shall take or cause to be taken at BTI's expense such actions in its name or otherwise as BTI may reasonably request so as to provide BTI with the benefits of the Non-Assignable Contracts, and bioXcel shall promptly pay over to BTI all money or other consideration that becomes due and payable under the Non-Assignable Contracts, at BTI's expense, to perform all of the obligations and receive all the benefits of BioXcel under the Non-Assignable Contracts, at BTI's expense, to perform all of the obligations and receive all the benefits of BioXcel under the Non-Assignable Contracts, at BTI's expense, to perform all of the obligations and receive all the benefits of BioXcel under the Non-Assignable Contracts.
- 5. <u>Intellectual Property Registrations</u>. BioXcel shall authorize and request that any officials of any state or foreign country whose duty it is to issue intellectual property registrations (including letters patent) (a) issue all registrations from any from any applications for registrations, and (b) transfer any applications or registration as applicable, in each case that are included in the Intellectual Property to BTI at BioXcel's expense.
- 6. <u>Consideration</u>. The full consideration for the contribution of the Assets hereunder shall be:
  - a. The issuance by BTI to BioXcel of Forty Thousand (40,000) shares of common stock of BTI.

# Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

- b. A one-time, lump-sum payment by BTI to BioXcel of Five Million Dollars (\$5,000,000) upon the achievement of Fifty Million Dollars (\$50,000,000) in cumulative Net Sales of any product or combination of products resulting from the development and commercialization of any one of the Candidates or a product derived therefrom. "Net Sales" shall mean the actual amounts received by BTI or its sublicensees on all sales of the product(s) in the world to third parties, less any of the following to the extent included in such amounts: (i) normal and customary trade and quantity discounts actually given; and, in case of returns or rejections of the product(s), the associated credits and price adjustments; (ii) rebates or commissions allowed or granted, and administrative fees paid, to government agencies or trade customers, including wholesalers and chain buying groups; (iii) prepaid freight, postage, shipping, customs duties and insurance charges; and (iv) sales, value-added, and excise taxes, tariffs, and other taxes and government charges directly related to the sale of the product(s) and actually borne by BTI or its sublicensees without reimbursement from any third party, excluding any taxes assessed against the income derived from such sale. Such amounts shall be determined in accordance with from the books and records of the applicable party using generally accepted accounting principles, consistently applied, and may include using accrual accounting where applicable.
- c. BTI shall pay to BioXcel the amount due under Section 6.b within sixty (60) days after the achievement of Fifty Million Dollars (\$50,000,000) in cumulative Net Sales as set forth above.
- d. BTI shall pay BioXcel One Million Dollars (\$1,000,000) as a lump sum within thirty (30) days after closing of the IPO.
- e. BTI shall pay BioXcel (x) Five Hundred Thousand Dollars (\$500,000) within thirty (30) days after the later of the twelve (12) month anniversary of the IPO and the first dosing of a patient in the bridging bioavailability/bioequivalence study for the BXCL501 program and (y) Five Hundred Thousand Dollars (\$500,000) within thirty (30) days after the later of the twelve (12) month anniversary of the IPO and the first dosing of a patient in the Phase 2 PoC open label monotherapy or combination trial with Keytruda for the BXCL701 program.
- 7. <u>Deliveries</u>. Each party shall execute and deliver to the other party any such documents and instruments as shall be reasonably requested by the other party or the other party's counsel that are reasonably necessary to complete the transactions set forth herein.

- 8. <u>Representations and Warranties of BioXcel</u>.
  - a. BioXcel has full power and authority to enter into this Agreement and to consummate the transactions contemplated herein. BioXcel has taken all action required by law, by the organizational documents of BioXcel, or otherwise, to authorize the transactions contemplated herein. This Agreement, when executed and delivered by BioXcel, will constitute a valid and legally binding obligation, enforceable against BioXcel in accordance with its terms, except as the same may be restricted, limited or delayed by applicable bankruptcy or other laws affecting creditors' rights generally or by equitable principles and except as to the remedy of specific performance which may not be available under the laws of various jurisdictions.
  - b. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereunder will not (i) violate any provision of, result in a breach of, or constitute a default under, any law or any order, writ, injunction or decree of any court, governmental agency or arbitration tribunal applicable to BioXcel; (ii) constitute a violation of or a default under, or a conflict with, any term or provision of the governing documents of BioXcel;

## Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

or (iii) constitute a violation of or a default under any contract, commitment, indenture, lease, instrument or other agreement, or any other restriction of any kind to which BioXcel is a party or is bound.

- c. BioXcel has taken all action reasonably necessary to prosecute its existing intellectual property applications material to the Candidates and to maintain all Intellectual Property in full force and effect as of the Effective Date, and has not taken or failed to take any action that could reasonably have the effect of waiving any material rights to the Candidates or the Intellectual Property. As of the Effective Date, no Intellectual Property is or has been involved in any interference, opposition, cancellation, concurrent use, invalidity, reissue, reexamination, revocation, litigation or other proceeding, in which the scope, validity or enforceability of Intellectual Property is being or has been contested or challenged, and to BioXcel's knowledge, no such proceeding has been threatened with respect to any Intellectual Property.
- d. BioXcel has not received any written notice from any person, and does not have any knowledge of, any claim, regarding the use of, or challenging or questioning BioXcel's right or title in, any of the Intellectual Property or alleging infringement or misappropriation of any Intellectual Property.
- e. There is no claim, litigation, proceeding or governmental investigation pending or, to BioXcel's knowledge, threatened, or any order, injunction, or decree outstanding, against BioXcel, that would prevent or have a material adverse effect on the rights, duties or obligations of the parties as set forth in this Agreement.
- f. <u>Schedule 8(f)</u> sets forth a complete and accurate list of all equipment (including computers, computer servers, information systems, telephone systems and database systems and office equipment), supplies, furniture, fixtures, and all other tangible personal property, wherever located (collectively, "*Tangible Assets*"). Any Tangible Assets to be contributed to BTI pursuant to this Agreement are in good operating condition and in good repair, normal wear and tear excepted.
- g. <u>Schedule 8(g)</u> contains a complete list of the contracts, commitments, understandings, open purchase orders, contractor agreements or other agreements, including license agreements, equipment leases and manufacturers' and vendors' warranties relating to items included in the Assets and all similar rights against third parties relating to items included in the Assets (collectively, the "*Contracts*"). True and complete copies of all Contracts have been delivered to BTI. All Contracts listed on <u>Schedule 8(g)</u> were entered into in connection with and in the ordinary course of BioXcel's business, consistent with past practice. All the Contracts listed on <u>Schedule 8(g)</u> are in full force and effect and, to BioXcel's knowledge, there is no breach of any of the provisions of the Contracts by any party thereto. To BioXcel's knowledge, no condition exists that, with notice or lapse of time or both, would constitute a default by any party to any of those Contracts. To BioXcel's knowledge, no party to any of the Contracts listed on <u>Schedule 8(g)</u> has made, asserted or has any defense, set-off or counterclaim under any of the Contracts or has exercised any option granted to it to cancel or terminate its agreement, to shorten the term of its agreement or to renew or extend the term of its agreement, and BioXcel has not received any notice to that effect.

### 9. <u>Representations and Warranties of BTI</u>.

a. BTI has full power and authority to enter into this Agreement and to consummate the transactions contemplated herein. BTI has taken all action required by law, by the organizational documents

## Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

of BTI, or otherwise, to authorize the transactions contemplated herein. This Agreement, when executed and delivered by BTI, will constitute a valid and legally binding obligation, enforceable against BTI in accordance with its terms, except as the same may be restricted, limited or delayed by applicable bankruptcy or other laws affecting creditors' rights generally or by equitable principles and except as to the remedy of specific performance which may not be available under the laws of various jurisdictions.

b. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereunder will not (i) violate any provision of, result in a breach of, or constitute a default under, any law or any order, writ, injunction or decree of any court, governmental agency or arbitration tribunal applicable to BTI; (ii) constitute a violation of or a default under, or a conflict with, any term or provision of the governing documents of BTI; or (iii) constitute a violation of or a default under any contract, commitment, indenture, lease, instrument or other agreement, or any other restriction of any kind to which BTI is a party or is bound.

c. There is no claim, litigation, proceeding or governmental investigation pending or, to BTI's knowledge, threatened, or any order, injunction, or decree outstanding, against BTI, that would prevent or have a material adverse effect on the rights, duties or obligations of the parties as set forth in this Agreement.

## 10. Indemnification.

- a. BioXcel shall indemnify and hold harmless BTI, and its directors, officers, employees, agents, and other representatives, from and against all loss, liability, claims, expenses, damages, fines, or penalties (including reasonable attorneys' fees) (collectively, "*Losses*") arising from or related to (i) BioXcel's breach of this Agreement, and (ii) any other liability or claim, whether commenced before or after the Effective Date, arising out of BioXcel's ownership of the Candidates and the Assets prior to the Effective Date (regardless of whether such liability or claim was known by BTI as of the Effective Date).
- b. BTI shall indemnify and hold harmless BioXcel, and its directors, officers, employees, agents, and other representatives, from and against all Losses arising from or related to (i) BTI's breach of this Agreement, (ii) the failure by BTI to pay, perform or discharge when due any of the Assumed Liabilities, and (iii) BTI's ownership, development and commercialization of the Assets after the Effective Date.
- 11. <u>Recusal</u>. The Parties covenant and agree that as long as Vimal Mehta is a member of senior management or the governing board of both BioXcel and BTI, he may participate in discussions at the senior management and governing board levels for each of BioXcel and BTI but shall not vote on matters coming before either governing board material to this Agreement, the Amended & Restated Separation and Shared Services Agreement or other agreements relating to the relationship between the Parties. Each Party shall ensure that Vimal Mehta recuses himself with respect to governing board matters consistent with this Section 11.
- 12. <u>Confidentiality</u>. Each party shall maintain the confidentiality of all data, information, records, reports and all other nonpublic information provided to it by the other party (the "*Confidential Information*"), and shall not disclose any Confidential Information to third parties for any reason unless and only to the extent jointly agreed to, in writing, by the parties or as required by law. The foregoing applies to information communicated orally, in writing, by computer processes, and includes without limitation, this

# Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

Agreement, any and all meeting notes, business plans, financial statements, analyses and/or research materials, corporate documents, and correspondence.

- 13. <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the law of the State of Connecticut, without giving effect to principles governing conflicts of law.
- 14. <u>Specific Performance</u>. Each of the parties acknowledges and agrees that the other party would be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached. Accordingly, each of the parties agrees that the other party shall be entitled to an injunction or injunctions to prevent breaches of the provisions of this Agreement and to enforce specifically this Agreement and the terms and provisions hereof in any action instituted in any court of the United States or any state thereof having jurisdiction over the parties and the matter in addition to any other remedy to which they may be entitled, at law or in equity.
- 15. <u>Assignment</u>. No party may assign any of its rights or delegate any of its duties under this Agreement without the prior written consent of the other party, except that either party may, without such consent, assign its rights and delegate its duties to a successor to such party's entire business.
- 16. <u>Entire Agreement</u>. This Agreement, including the schedules hereto, contains a complete statement of all the arrangements between the parties with respect to its subject matter, supersedes any previous agreements between them relating to that subject matter, and cannot be amended, modified or terminated except in a written document executed by the parties.
- 17. <u>Severability</u>. The invalidity of any provision or portion of a provision of this Agreement shall not affect the validity of any other provision of this Agreement or the remaining portion of the applicable provision. If any provision of this Agreement or the application of a particular provision to any party or circumstances shall be determined by any court of competent jurisdiction to be invalid or unenforceable to any extent, the remainder of this Agreement, or the application of such provision to such party or circumstances other than those to which it is determined to be invalid or enforceable, shall not be affected thereby, and each provision hereof shall be enforced to the fullest extent permitted by applicable law.
- 18. <u>Amendments and Waivers</u>. No amendment of any provision of this Agreement shall be valid unless the same shall be in writing and signed by the parties. No waiver by either party of any default, misrepresentation or breach of warranty or covenant hereunder, whether intentional or not, shall be deemed to extend to any prior or subsequent default, misrepresentation or breach of warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence.
- 19. <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, which together shall constitute a single instrument. Facsimile or electronic delivery of an executed counterpart shall be valid and binding for all purposes.

[Signature page follows]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

IN WITNESS WHEREOF, the undersigned have caused this Amended & Restated Asset Contribution Agreement to be duly executed as of the Execution Date.

## **BIOXCEL CORPORATION**

/s/ Krishnan Nandabalan	/s/ Peter Mueller	
Signature	Signature	
Krishnan Nandabalan	Peter Mueller	
Name Printed	Name Printed	
President	Chairman	
Title	Title	
	Title Ige to Amended and Restated Asset Contribution Agreement]	

**BIOXCEL THERAPEUTICS, INC.** 

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

## Schedule 1

Permitted Liens

None

[Schedule 1 to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

### Schedule 1(a)

### Intellectual Property

Invention		Country			Priority App.no &	Complete	Publication No. &
No	Project	name/stage	Title	Applicant	Filing date	Application No. & Filing date	Date
1	[***]	[***]	[***]	[***]	[***]	[***]	[***]
		[***]				[***]	[***]
		[***]				[***]	[***]
		[***]				[***]	[***]
2	[***]	[***]	[***]	[***]	[***]	[***]	[***]
3	[***]	[***]	[***]	[***]	[***]	[***]	[***]
						[***]	[***]
4	[***]	[***]	[***]	[***]	[***]	[***]	[***]
5	[***]	[***]	[***]	[***]	[***]	[***]	[***]
6	[***]	[***]	[***]	[***]	[***]	[***]	[***]
7	[***]	[***]	[***]	[***]	[***]	[***]	[***]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

## <u>Schedule 1(i)</u>

All Other Assets

Prepaid Expenses transferred to BTI: \$46,105

[Schedule 1(i) to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

### Schedule 2

**Retained Assets** 

None

[Schedule 2 to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

#### Schedule 3

#### Assumed Liabilities

List of Liabilities	\$			
Capital one- 2191	2,685			
Amex -42004	44,568			
Amex- 32001	1,945			
Accrued Expenses	55,244			
Account Payable	244,190			
Accrued Wages	90,408			
Total Liabilities	439,040			

[Schedule 3 to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

#### Schedule 4

**Required Consents** 

[Schedule 4 to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended <u>Schedule 8(f)</u>

Tangible Assets

List of Tangible Assets	\$
Fixed Assets	5,309
Accumulated Depreciation	(923)
Total Assets	4,386

[Schedule 8(f) to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

## Schedule 8(g)

Contracts

3. **[\*\*\*]**.

- 4. [\*\*\*]
- 5. [\*\*\*]

6. Second Amended and Restated Employment Agreement between BioXcel and Luca Rastelli, dated as of June 27, 2016.

- 7. First Amended and Restated Employment Agreement between BioXcel and Frank D. Yocca, dated as of March 1, 2016.
- 8. Data Purchase Agreement between BioXcel and Midatech Pharma US Inc., effective as of January 4, 2016.

[Schedule 8(g) to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

<u>Exhibit E</u>

### Exhibit E

### **GRID NOTE**

Up to US \$1,000,000

June 30, 2017

**FOR VALUE RECEIVED**, the undersigned, BioXcel Therapeutics, Inc., a Delaware corporation with an office at 780 East Main Street, Branford, CT 06405 ("*Payor*"), unconditionally promises to pay to the order of BioXcel Corporation, a Delaware corporation with an office at 780 East Main Street, Branford, CT 06405 ("*Payee*"), the principal sum of ONE MILLION DOLLARS (\$1,000,000), or so much thereof as shall have been advanced by Payee to or on behalf of Payor, together with interest on the unpaid balance of each advance, which shall accrue at a rate per annum equal to the applicable federal rate for short-term loans as of the date hereof, in each case calculated based on a 365-day year and actual days elapsed. The obligations of Payor under this Grid Note (this "*Note*") shall be senior indebtedness of Payor and shall rank senior to all other indebtedness.

This Note evidences a revolving line of credit. Advances under this Note may be requested either orally or in writing by Payor, for the exclusive benefit of Payor in furtherance of conducting its business. All advances under this Note require the prior written approval of Payee and a record thereof shall be maintained in **Exhibit A** to this Note, *provided, however*, that the failure to so record shall in no way limit Payor's obligations with respect to repayment of principal or interest on any advance.

The entire balance of principal and accrued interest thereon shall be due and payable within 18 months upon execution or receiving a cumulative amount of TEN MILLION DOLLARS (\$10,000,000) of financing, whichever is earlier.

If this Note is not paid on demand, Payor agrees to pay, in addition to the unpaid principal and accrued interest, all reasonable costs and expenses incurred in attempting or effecting payment or collection hereunder, including, but not limited to, reasonable attorneys' fees, whether or not suit is instituted.

Payor shall have the right at any time to prepay this Note, in whole or in part, without penalty, subject to the qualification, however, that no partial prepayment of the original sum shall in any way release, discharge or affect the obligation of Payor to make full payment in the amount of the balance of said principal sum at time of demand. Each and every payment (including all partial payments or prepayments) received by the Payee hereunder shall be applied first to any penalties for which the Payor is responsible under this Note which have not yet been paid, then to outstanding interest and then to outstanding principal. If any payment under this Note shall be specified to be made on a day which is not a business day, it shall be made on the next succeeding day which is a business day.

The amounts due hereunder are payable in lawful money of the United States of America to Payee at his address above, or at such other place as the holder of this Note shall from time to time designate, in immediately available funds.

No failure on the part of Payee or any other holder of this Note to exercise and no delay in

exercise by Payee or any other holder of this Note of any right, remedy or power hereunder preclude any other or future exercise of any other right, remedy or power.

This Note shall be binding upon Payor and its successors and assigns.

THIS NOTE IS AND SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CONNECTICUT. ANY CLAIMS OR LEGAL ACTIONS BY ONE PARTY AGAINST THE OTHER ARISING OUT OF THIS NOTE SHALL BE COMMENCED AND MAINTAINED IN ANY STATE OR FEDERAL COURT LOCATED IN THE STATE OF CONNECTICUT, AND PAYOR HEREBY EXPRESSLY, IRREVOCABLY AND UNCONDITIONALLY CONSENTS TO THE JURISDICTION OF SUCH COURTS AND HEREBY WAIVES TRIAL BY JURY IN ANY SUCH LEGAL ACTION OR PROCEEDING.

Diligence, presentment, demand, protest and notice of any kind are hereby waived by Payor and all sureties, guarantors and endorsers hereof, if

In the event that any one or more of the provisions of this Note shall for any reason be held to be invalid, illegal or unenforceable, in whole or in part, or in any respect, or in the event that any one or more of the provisions of this Note shall operate, or would prospectively operate, to invalidate this Note, then, and in any such event, such provision or provisions only shall be deemed null and void and of no force or effect and shall not affect any other provision of this Note, and the remaining provisions of this Note shall remain operative and in full force and effect, shall be valid, legal and enforceable, and shall in no way be affected, prejudiced or disturbed thereby.

IN WITNESS WHEREOF, Payor has caused this Note to be executed as of the date and year first above written.

## **BIOXCEL THERAPEUTICS, INC.**

/s/ Vimal Mehta By: Vimal Mehta	
-	
Its: CEO	
2	

### EXHIBIT A

\$ Amount of Advance 299,500	Date of Advance 06/30/2017	Amount of Repayment	Date of Repayment	\$ Balance Remaining 299,500
		3		

## Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

### AMENDED & RESTATED ASSET CONTRIBUTION AGREEMENT

This Amended & Restated Asset Contribution Agreement (this "*Agreement*") is entered into as of November 7, 2017 (the "*Execution Date*"), by and between BioXcel Corporation, a Delaware corporation located at 780 East Main Street, Branford, CT 06405 ("*BioXcel*"), and BioXcel Therapeutics, Inc., a Delaware corporation located at 780 East Main Street, Branford, CT 06405 ("*BIT*").

WHEREAS, BioXcel identified a number of therapeutic candidates using its proprietary artificial intelligence-powered research and development engine known as 'EvolverAI'; and

WHEREAS, the Board of Directors of BioXcel determined that it was in BioXcel's best interest to restructure its business in order to realize the full potential of its assets, including such therapeutic candidates; and

WHEREAS, in accordance with the restructuring plan, BioXcel formed BTI, a product development biotechnology company, to develop and commercialize certain of the therapeutic candidates; and

WHEREAS, to allow such work to be carried out by BTI, BioXcel and BTI entered into certain agreements including an Asset Contribution Agreement, dated as of June 30, 2017 (the "*Effective Date*"), by which BioXcel contributed certain assets and liabilities to BTI pursuant to the terms and conditions thereof (the "*ACA*"); and

WHEREAS, BTI accepted certain assets and liabilities from BioXcel pursuant to the terms and conditions of the ACA; and

WHEREAS, BioXcel desires to transfer to BTI certain additional assets and liabilities and grant to BTI certain rights in future therapeutic candidates identified by BioXcel pursuant to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the covenants contained herein, and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties now agree to amend and restate the ACA as follows:

- 1. <u>Contribution of Assets & Option</u>.
  - A. <u>Initial Contribution of Assets</u>. On the terms and subject to the conditions set forth in this Agreement, BioXcel hereby agrees to sell, contribute, assign, transfer, convey and deliver to BTI, and BTI agrees to acquire from BioXcel, all of BioXcel's right, title and interest in and to BXCL701, BXCL702, BXCL501, and BXCL502 (collectively, the "*Candidates*"), and all of the assets associated with the Candidates, other than those specified to be Retained Assets (as defined below), (collectively, the "*Assets*"), free and clear of any security interest, lien, charge, option, claim or other encumbrance (each, a "*Lien*"), other than those Liens listed on <u>Schedule 1</u> (collectively, the "*Permitted Liens*"). The Assets include the following to the extent used or held for use in connection with the Candidates as of the Effective Date:
    - a. The intellectual property set forth on <u>Schedule 1(a)</u> (collectively, the "Intellectual Property");
    - b. All goodwill associated with the Assets;

## Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

- c. Except as set forth in Section 4 below, all of BioXcel's rights under the Contracts (as defined below);
- d. All documentation, notebooks, logs, data and records associated with the Assets, and any other information necessary for the development of the Assets;
- e. All marketing and advertising materials in hard or soft copy, including without limitation, printed promotional materials and labels associated with the Assets;
- f. All claims, causes of action, rights of recovery, rights of setoff and rights of recoupment, whether or not known as of the Effective Date, relating to BioXcel's ownership of the Assets; and
- g. All rights under or pursuant to all warranties, indemnities, representations, guarantees and similar rights, whether or not known as of the Effective Date, in favor of BioXcel with respect to the Candidates or the Assets;
- h. The Tangible Assets (as defined below); and
- i. The assets specifically identified in <u>Schedule 1(i)</u>.
- B. <u>Option to Negotiate for Additional Product Candidates</u>. BioXcel hereby grants to BTI a first right to negotiate exclusive rights to any additional product candidates in the fields of Neuroscience and Immuno-oncology (the "**Option Field**") that BioXcel may identify wholly on its own or under arrangements with third parties, and not in connection with BioXcel's provision of services to BTI under the Parties' Amended & Restated Separation and Shared Services Agreement. For clarity, this option shall not apply to any additional product candidates identified by BioXcel in connection with services BioXcel provides to BTI pursuant to the Parties' Amended & Restated Separation and Shared Services that involve the use of EvolverAI) because all such additional product

candidates identified in connection with such services would be considered to be "Developments" (as defined in that agreement) already owned by BTI. This option for first negotiation shall be valid for a period of five (5) years from the date of the IPO (as defined below). Within sixty (60) days of identifying a potential product candidate in the Option Field, BioXcel shall present such identified candidate to BTI. BTI shall then have up to one hundred eighty (180) days in which to evaluate such product candidate (the "*Evaluation Period*"). If BTI wishes to negotiate for the exclusive rights to such product candidate, BTI shall so notify BioXcel in writing prior to the end of the Evaluation Period, and if BTI so notifies BioXcel, BTI and BioXcel shall negotiate in good faith commercially reasonable terms by which BTI can receive BioXcel's rights to such product candidate. If BioXcel and BTI are unable to mutually agree, in writing, within ninety (90) days after the end of the Evaluation Period to terms regarding BTI's rights to develop and/or commercialize such product candidate, BioXcel shall be free to develop and/or commercialize such product candidate either by itself or with one or more third parties. Notwithstanding anything contained herein to the contrary, BTI's rights and obligations set forth in this Section 1.B shall apply and be effective only from and after BTI's completion, on or before December 31, 2018, of a firm commitment underwritten public offering of share of common stock (and any other securities of BTI that may be sold along with such shares of common stock in any such public offering) ("**IPO**").

C. <u>Exclusivity in Option Field</u>. Prior to the fifth (5<sup>th</sup>) anniversary of the IPO, BioXcel shall not develop drugs, or engage in preclinical discovery for the purpose of developing drugs, in the Option Field for or on behalf of a third party, utilizing EvolverAI or otherwise. In support of the foregoing, BioXcel shall inform third parties with which it enters into collaborations or other arrangements that BTI holds a first right to negotiate for BioXcel's rights in product candidates in the Option Field and the

## Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

duration of such right of BTI. BioXcel's covenant as set forth in this Section 1.C and BTI's right of first negotiation as set forth in Section 1.B shall not prevent or interfere with BioXcel's rights to the EvolverAI platform or use of the EvolverAI platform by third parties as long as BioXcel does not provide collaborative services to, or actively support, such third party in its evaluation of the results of the EvolverAI research and development engine to develop drugs in the Option Field.

- 2. <u>Retained Assets</u>. The assets set forth on <u>Schedule 2</u> shall be retained by BioXcel and shall not be sold or assigned to BTI (the "Retained Assets").
- 3. <u>Assumption of Liabilities</u>. As of the Effective Date, BTI shall assume and will be responsible for and pay, perform, and discharge when due all liabilities associated with the Assets, including without limitation, payment of any fees required to maintain any registrations and applications for registration arising from the ownership or use of the Intellectual Property due on and after the Effective Date, and all obligations and liabilities of BioXcel under the Contracts to the extent that those obligations and liabilities relate to the period after the Effective Date, in each case exclusive of any liability or obligation arising thereunder as a result of any breach, default or failure of BioXcel to perform any covenants or obligations required to be performed by BioXcel prior to the Effective Date. In addition to the liabilities described in the previous sentence, in consideration of BioXcel's contribution of the Assets to BTI, BTI shall assume from BioXcel and be responsible for all liabilities set forth on <u>Schedule 3</u>, hereto (all liabilities assumed by BTI, including liabilities set forth on <u>Schedule 3</u>, the "Assumed Liabilities").
- Assignment of Contracts. To the extent that any Contract is not capable of being assigned or transferred without the consent or waiver of the other 4. party thereto or any third party, or if such assignment or transfer, or attempted assignment or transfer would constitute a breach thereof, this Agreement shall not constitute an assignment or transfer thereof, or an attempted assignment or transfer of any such Contract. Schedule 4 lists those Contracts that BioXcel believes are not assignable without the written consent of the other party thereto (the "Required Consents"). To the extent permitted by applicable law, any consents and approvals of third parties required for the transfer to BTI of any of the Assets, including the Required Consents, that are not obtained or cannot be obtained without any conditions adverse to BTI or without any obligations imposed on BTI not specified in the Contract for which consent is being obtained prior to the Effective Date (the "Non-Assignable Contracts"), such Non-Assignable Contracts shall be held, as of and from the Effective Date, by BioXcel in trust for BTI and the covenants and obligations thereunder shall be performed by BTI in BioXcel's name and all benefits and obligations existing thereunder shall be for BTI's account. BioXcel shall take or cause to be taken at BTI's expense such actions in its name or otherwise as BTI may reasonably request so as to provide BTI with the benefits of the Non-Assignable Contracts and to effect collection of money or other consideration that becomes due and payable under the Non-Assignable Contracts, and BioXcel shall promptly pay over to BTI all money or other consideration received by it in respect of the Non-Assignable Contracts. As of and from the Effective Date, BioXcel authorizes BTI, to the extent permitted by applicable law and the terms of the Non-Assignable Contracts, at BTI's expense, to perform all of the obligations and receive all the benefits of BioXcel under the Non-Assignable Contracts.
- 5. <u>Intellectual Property Registrations</u>. BioXcel shall authorize and request that any officials of any state or foreign country whose duty it is to issue intellectual property registrations (including letters patent) (a) issue all registrations from any from any applications for registrations, and (b) transfer any applications or registration as applicable, in each case that are included in the Intellectual Property to BTI at BioXcel's expense.
- 6. <u>Consideration</u>. The full consideration for the contribution of the Assets hereunder shall be:
  - a. The issuance by BTI to BioXcel of Forty Thousand (40,000) shares of common stock of BTI.

## Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

A one-time, lump-sum payment by BTI to BioXcel of Five Million Dollars (\$5,000,000) upon the achievement of Fifty Million Dollars (\$50,000,000) in cumulative Net Sales of any product or combination of products resulting from the development and commercialization of any one of the Candidates or a product derived therefrom. "Net Sales" shall mean the actual amounts received by BTI or its sublicensees on all sales of the product(s) in the world to third parties, less any of the following to the extent included in such amounts: (i) normal and customary trade and quantity discounts actually given; and, in case of returns or rejections of the product(s), the associated credits and price adjustments; (ii) rebates or commissions allowed or granted, and administrative fees paid, to government agencies or

trade customers, including wholesalers and chain buying groups; (iii) prepaid freight, postage, shipping, customs duties and insurance charges; and (iv) sales, value-added, and excise taxes, tariffs, and other taxes and government charges directly related to the sale of the product(s) and actually borne by BTI or its sublicensees without reimbursement from any third party, excluding any taxes assessed against the income derived from such sale. Such amounts shall be determined in accordance with from the books and records of the applicable party using generally accepted accounting principles, consistently applied, and may include using accrual accounting where applicable.

- c. BTI shall pay to BioXcel the amount due under Section 6.b within sixty (60) days after the achievement of Fifty Million Dollars (\$50,000,000) in cumulative Net Sales as set forth above.
- d. BTI shall pay BioXcel One Million Dollars (\$1,000,000) as a lump sum within thirty (30) days after closing of the IPO.
- e. BTI shall pay BioXcel (x) Five Hundred Thousand Dollars (\$500,000) within thirty (30) days after the later of the twelve (12) month anniversary of the IPO and the first dosing of a patient in the bridging bioavailability/bioequivalence study for the BXCL501 program and (y) Five Hundred Thousand Dollars (\$500,000) within thirty (30) days after the later of the twelve (12) month anniversary of the IPO and the first dosing of a patient in the Phase 2 PoC open label monotherapy or combination trial with Keytruda for the BXCL701 program.
- 7. <u>Deliveries</u>. Each party shall execute and deliver to the other party any such documents and instruments as shall be reasonably requested by the other party or the other party's counsel that are reasonably necessary to complete the transactions set forth herein.
- 8. <u>Representations and Warranties of BioXcel</u>.
  - a. BioXcel has full power and authority to enter into this Agreement and to consummate the transactions contemplated herein. BioXcel has taken all action required by law, by the organizational documents of BioXcel, or otherwise, to authorize the transactions contemplated herein. This Agreement, when executed and delivered by BioXcel, will constitute a valid and legally binding obligation, enforceable against BioXcel in accordance with its terms, except as the same may be restricted, limited or delayed by applicable bankruptcy or other laws affecting creditors' rights generally or by equitable principles and except as to the remedy of specific performance which may not be available under the laws of various jurisdictions.
  - b. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereunder will not (i) violate any provision of, result in a breach of, or constitute a default under, any law or any order, writ, injunction or decree of any court, governmental agency or arbitration tribunal applicable to BioXcel; (ii) constitute a violation of or a default under, or a conflict with, any term or provision of the governing documents of BioXcel;

# Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

or (iii) constitute a violation of or a default under any contract, commitment, indenture, lease, instrument or other agreement, or any other restriction of any kind to which BioXcel is a party or is bound.

- c. BioXcel has taken all action reasonably necessary to prosecute its existing intellectual property applications material to the Candidates and to maintain all Intellectual Property in full force and effect as of the Effective Date, and has not taken or failed to take any action that could reasonably have the effect of waiving any material rights to the Candidates or the Intellectual Property. As of the Effective Date, no Intellectual Property is or has been involved in any interference, opposition, cancellation, concurrent use, invalidity, reissue, reexamination, revocation, litigation or other proceeding, in which the scope, validity or enforceability of Intellectual Property is being or has been contested or challenged, and to BioXcel's knowledge, no such proceeding has been threatened with respect to any Intellectual Property.
- d. BioXcel has not received any written notice from any person, and does not have any knowledge of, any claim, regarding the use of, or challenging or questioning BioXcel's right or title in, any of the Intellectual Property or alleging infringement or misappropriation of any Intellectual Property.
- e. There is no claim, litigation, proceeding or governmental investigation pending or, to BioXcel's knowledge, threatened, or any order, injunction, or decree outstanding, against BioXcel, that would prevent or have a material adverse effect on the rights, duties or obligations of the parties as set forth in this Agreement.
- f. <u>Schedule 8(f)</u> sets forth a complete and accurate list of all equipment (including computers, computer servers, information systems, telephone systems and database systems and office equipment), supplies, furniture, fixtures, and all other tangible personal property, wherever located (collectively, "*Tangible Assets*"). Any Tangible Assets to be contributed to BTI pursuant to this Agreement are in good operating condition and in good repair, normal wear and tear excepted.
- g. <u>Schedule 8(g)</u> contains a complete list of the contracts, commitments, understandings, open purchase orders, contractor agreements or other agreements, including license agreements, equipment leases and manufacturers' and vendors' warranties relating to items included in the Assets and all similar rights against third parties relating to items included in the Assets (collectively, the "*Contracts*"). True and complete copies of all Contracts have been delivered to BTI. All Contracts listed on <u>Schedule 8(g)</u> were entered into in connection with and in the ordinary course of BioXcel's business, consistent with past practice. All the Contracts listed on <u>Schedule 8(g)</u> are in full force and effect and, to BioXcel's knowledge, there is no breach of any of the provisions of the Contracts by any party thereto. To BioXcel's knowledge, no condition exists that, with notice or lapse of time or both, would constitute a default by any party to any of those Contracts. To BioXcel's knowledge, no party to any of the Contracts listed on <u>Schedule 8(g)</u> has made, asserted or has any defense, set-off or counterclaim under any of the Contracts or has exercised any option granted to it to cancel or terminate its agreement, to shorten the term of its agreement or to renew or extend the term of its agreement, and BioXcel has not received any notice to that effect.

#### 9. <u>Representations and Warranties of BTI</u>.

a. BTI has full power and authority to enter into this Agreement and to consummate the transactions contemplated herein. BTI has taken all action required by law, by the organizational documents

# Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

of BTI, or otherwise, to authorize the transactions contemplated herein. This Agreement, when executed and delivered by BTI, will constitute a valid and legally binding obligation, enforceable against BTI in accordance with its terms, except as the same may be restricted, limited or delayed by applicable bankruptcy or other laws affecting creditors' rights generally or by equitable principles and except as to the remedy of specific performance which may not be available under the laws of various jurisdictions.

- b. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereunder will not (i) violate any provision of, result in a breach of, or constitute a default under, any law or any order, writ, injunction or decree of any court, governmental agency or arbitration tribunal applicable to BTI; (ii) constitute a violation of or a default under, or a conflict with, any term or provision of the governing documents of BTI; or (iii) constitute a violation of or a default under any contract, commitment, indenture, lease, instrument or other agreement, or any other restriction of any kind to which BTI is a party or is bound.
- c. There is no claim, litigation, proceeding or governmental investigation pending or, to BTI's knowledge, threatened, or any order, injunction, or decree outstanding, against BTI, that would prevent or have a material adverse effect on the rights, duties or obligations of the parties as set forth in this Agreement.

# 10. Indemnification.

- a. BioXcel shall indemnify and hold harmless BTI, and its directors, officers, employees, agents, and other representatives, from and against all loss, liability, claims, expenses, damages, fines, or penalties (including reasonable attorneys' fees) (collectively, "*Losses*") arising from or related to (i) BioXcel's breach of this Agreement, and (ii) any other liability or claim, whether commenced before or after the Effective Date, arising out of BioXcel's ownership of the Candidates and the Assets prior to the Effective Date (regardless of whether such liability or claim was known by BTI as of the Effective Date).
- b. BTI shall indemnify and hold harmless BioXcel, and its directors, officers, employees, agents, and other representatives, from and against all Losses arising from or related to (i) BTI's breach of this Agreement, (ii) the failure by BTI to pay, perform or discharge when due any of the Assumed Liabilities, and (iii) BTI's ownership, development and commercialization of the Assets after the Effective Date.
- 11. <u>Recusal</u>. The Parties covenant and agree that as long as Vimal Mehta is a member of senior management or the governing board of both BioXcel and BTI, he may participate in discussions at the senior management and governing board levels for each of BioXcel and BTI but shall not vote on matters coming before either governing board material to this Agreement, the Amended & Restated Separation and Shared Services Agreement or other agreements relating to the relationship between the Parties. Each Party shall ensure that Vimal Mehta recuses himself with respect to governing board matters consistent with this Section 11.
- 12. <u>Confidentiality</u>. Each party shall maintain the confidentiality of all data, information, records, reports and all other nonpublic information provided to it by the other party (the "*Confidential Information*"), and shall not disclose any Confidential Information to third parties for any reason unless and only to the extent jointly agreed to, in writing, by the parties or as required by law. The foregoing applies to information communicated orally, in writing, by computer processes, and includes without limitation, this

# Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

Agreement, any and all meeting notes, business plans, financial statements, analyses and/or research materials, corporate documents, and correspondence.

- 13. <u>Governing Law</u>. This Agreement shall be governed by and construed in accordance with the law of the State of Connecticut, without giving effect to principles governing conflicts of law.
- 14. <u>Specific Performance</u>. Each of the parties acknowledges and agrees that the other party would be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached. Accordingly, each of the parties agrees that the other party shall be entitled to an injunction or injunctions to prevent breaches of the provisions of this Agreement and to enforce specifically this Agreement and the terms and provisions hereof in any action instituted in any court of the United States or any state thereof having jurisdiction over the parties and the matter in addition to any other remedy to which they may be entitled, at law or in equity.
- 15. <u>Assignment</u>. No party may assign any of its rights or delegate any of its duties under this Agreement without the prior written consent of the other party, except that either party may, without such consent, assign its rights and delegate its duties to a successor to such party's entire business.
- 16. <u>Entire Agreement</u>. This Agreement, including the schedules hereto, contains a complete statement of all the arrangements between the parties with respect to its subject matter, supersedes any previous agreements between them relating to that subject matter, and cannot be amended, modified or terminated except in a written document executed by the parties.
- 17. <u>Severability</u>. The invalidity of any provision or portion of a provision of this Agreement shall not affect the validity of any other provision of this Agreement or the remaining portion of the applicable provision. If any provision of this Agreement or the application of a particular provision to any party or circumstances shall be determined by any court of competent jurisdiction to be invalid or unenforceable to any extent, the remainder

of this Agreement, or the application of such provision to such party or circumstances other than those to which it is determined to be invalid or enforceable, shall not be affected thereby, and each provision hereof shall be enforced to the fullest extent permitted by applicable law.

- 18. <u>Amendments and Waivers</u>. No amendment of any provision of this Agreement shall be valid unless the same shall be in writing and signed by the parties. No waiver by either party of any default, misrepresentation or breach of warranty or covenant hereunder, whether intentional or not, shall be deemed to extend to any prior or subsequent default, misrepresentation or breach of warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence.
- 19. <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, which together shall constitute a single instrument. Facsimile or electronic delivery of an executed counterpart shall be valid and binding for all purposes.

[Signature page follows]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

IN WITNESS WHEREOF, the undersigned have caused this Amended & Restated Asset Contribution Agreement to be duly executed as of the Execution Date.

# BIOXCEL CORPORATION BIOXCEL THERAPEUTICS, INC. /s/ Krishnan Nandabalan /s/ Peter Mueller Signature Signature Krishnan Nandabalan Peter Mueller Name Printed Peter Mueller President Name Printed Title Chairman Isignature page to Amended and Restatet Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

Schedule 1

Permitted Liens

None

[Schedule 1 to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

Schedule 1(a)

Intellectual Property

Invention No	Project	Country name/stage	Title	Applicant	Priority App.no & Filing date	Complete Application No. & Filing date	Publication No. & Date
1	[***]	[***]	[***]	[***]	[***]	[***]	[***]
		[***]				[***]	[***]
		[***]				[***]	[***]
		[***]				[***]	[***]
2	[***]	[***]	[***]	[***]	[***]	[***]	[***]
3	[***]	[***]	[***]	[***]	[***]	[***]	[***]
						[***]	[***]
4	[***]	[***]	[***]	[***]	[***]	[***]	[***]

5	[***]	[***]	[***]	[***]	[***]	[***]	[***]
6	[***]	[***]	[***]	[***]	[***]	[***]	[***]
7	[***]	[***]	[***]	[***]	[***]	[***]	[***]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

#### Schedule 1(i)

All Other Assets

Prepaid Expenses transferred to BTI: \$46,105

[Schedule 1(i) to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

Schedule 2

**Retained Assets** 

None

[Schedule 2 to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

# Schedule 3

Assumed Liabilities

List of Liabilities	\$
Capital one- 2191	2,685
Amex -42004	44,568
Amex- 32001	1,945
Accrued Expenses	55,244
Account Payable	244,190
Accrued Wages	90,408
Total Liabilities	439,040

[Schedule 3 to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

# Schedule 4

**Required Consents** 

[Schedule 4 to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended Schedule 8(f)

## Tangible Assets

List of Tangible Assets	\$
Fixed Assets	5,309
Accumulated Depreciation	(923)
Total Assets	4,386

[Schedule 8(f) to Asset Contribution Agreement]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

#### Schedule 8(g)

Contracts

- [\*\*\*] 1.
- [\*\*\*] 2.
- 3. [\*\*\*]
- 4. [\*\*\*]
- 5. [\*\*\*].

Second Amended and Restated Employment Agreement between BioXcel and Luca Rastelli, dated as of June 27, 2016. 6.

- First Amended and Restated Employment Agreement between BioXcel and Frank D. Yocca, dated as of March 1, 2016. 7. Data Purchase Agreement between BioXcel and Midatech Pharma US Inc., effective as of January 4, 2016.
- 8.

[Schedule 8(g) to Asset Contribution Agreement]

#### 2017 EQUITY INCENTIVE PLAN

1. *Purpose*. The purpose of the BioXcel Therapeutics, Inc. 2017 Equity Incentive Plan is to provide a means through which the Company and its Affiliates may attract and retain key personnel and to provide a means whereby directors, officers, managers, employees, consultants and advisors of the Company and its Affiliates can acquire and maintain an equity interest in the Company, or be paid incentive compensation, which may (but need not) be measured by reference to the value of Common Shares, thereby strengthening their commitment to the welfare of the Company and its Affiliates and aligning their interests with those of the Company's stockholders.

2. *Definitions*. The following definitions shall be applicable throughout this Plan:

(a) "<u>Affiliate</u>" means (i) any person or entity that directly or indirectly controls, is controlled by or is under common control with the Company and/or (ii) to the extent provided by the Committee, any person or entity in which the Company has a significant interest as determined by the Committee in its discretion. The term "control" (including, with correlative meaning, the terms "controlled by" and "under common control with"), as applied to any person or entity, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such person or entity, whether through the ownership of voting or other securities, by contract or otherwise.

(b) "<u>Award</u>" means, individually or collectively, any Incentive Stock Option, Nonqualified Stock Option, Stock Appreciation Right, Restricted Stock, Restricted Stock Unit, Stock Bonus Award or Performance Compensation Award granted under this Plan.

(c) "*Award Agreement*" means an agreement made and delivered in accordance with Section 15(a) of this Plan evidencing the grant of an Award hereunder.

(d) "Board" means the Board of Directors of the Company.

(e) "*Business Day*" means any day other than a Saturday, a Sunday or a day on which banking institutions in New York City are authorized or obligated by federal law or executive order to be closed.

(f) "*Cause*" means, in the case of a particular Award, unless the applicable Award Agreement states otherwise, (i) the Company or an Affiliate having "cause" to terminate a Participant's employment or service, as defined in any employment or consulting agreement or similar document or policy between the Participant and the Company or an Affiliate in effect at the time of such termination or (ii) in the absence of any such employment or consulting agreement, document or policy (or the absence of any definition of "Cause" contained therein), (A) a material breach or material default (including, without limitation, any material dereliction of duty) by Participant of any agreement between the Participant and the Company, except for any such breach or default which is caused by the physical disability of the Participant (as determined by a neutral physician), or a repeated failure by the Participant to follow the direction of a duly authorized representative of the Company; (B) gross negligence, willful misfeasance or breach of fiduciary duty to the Company or Affiliate of the Company by the Participant; (C) the commission by the Participant of an act or omission involving fraud, embezzlement, misappropriation or dishonesty in connection with the Participant's duties to the Company or Affiliate of the Company or that is otherwise likely to be injurious to the business or reputation of the Company or

1

its Affiliates; or (D) the Participant's conviction of, indictment for, or pleading guilty or *nolo contendere* to, any (x) felony or (y) other crime involving fraud or moral turpitude. Any determination of whether Cause exists shall be made by the Committee in its sole discretion.

(g) "*Change in Control*" shall, in the case of a particular Award, unless the applicable Award Agreement states otherwise or contains a different definition of "Change in Control," be deemed to occur upon:

(i) A tender offer (or series of related offers) shall be made and consummated for the ownership of 50% or more of the outstanding voting securities of the Company, unless as a result of such tender offer more than 50% of the outstanding voting securities of the surviving or resulting corporation or entity shall be owned in the aggregate by (A) the shareholders of the Company (as of the time immediately prior to the commencement of such offer), or (B) any employee benefit plan of the Company or its Subsidiaries, and their Affiliates;

(ii) The Company shall be merged or consolidated with another corporation, unless as a result of such merger or consolidation more than 50% of the outstanding voting securities of the surviving or resulting corporation or entity shall be owned in the aggregate by (A) the shareholders of the Company (as of the time immediately prior to such transaction); provided, that a merger or consolidation of the Company with another company which is controlled by persons owning more than 50% of the outstanding voting securities of the Company shall constitute a Change in Control unless the Committee, in its discretion, determine otherwise, or (B) any employee benefit plan of the Company or its Subsidiaries, and their Affiliates;

(iii) The Company shall sell substantially all of its assets to another entity that is not wholly owned by the Company, unless as a result of such sale more than 50% of such assets shall be owned in the aggregate by (A) the shareholders of the Company (as of the time immediately prior to such transaction), or (B) any employee benefit plan of the Company or its Subsidiaries, and their Affiliates;

(iv) A Person (as defined below) shall acquire 50% or more of the outstanding voting securities of the Company (whether directly, indirectly, beneficially or of record), unless as a result of such acquisition more than 50% of the outstanding voting securities of the surviving or resulting corporation or entity shall be owned in the aggregate by (A) the shareholders of the Company (as of the time immediately prior to the first acquisition of such securities by such Person), or (B) any employee benefit plan of the Company or its Subsidiaries, and their Affiliates; or

(v) The individuals who, as of the date hereof, constitute the members of the Board (the "Current Board Members") cease, by reason of a financing, merger, combination, acquisition, takeover or other non-ordinary course transaction affecting the Company, to constitute at

least a majority of the members of the Board unless such change is approved by the Current Board Members.

For purposes of this Section 2(g), ownership of voting securities shall take into account and shall include ownership as determined by applying the provisions of Rule 13d-3(d)(I)(i) (as in effect on the date hereof) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In addition, for such purposes, "Person" shall have the meaning given in Section 3(a)(9) of the Exchange Act, as modified and used in Sections 13(d) and 14(d) thereof; however, a Person shall not include (A) the Company or any of its Subsidiaries; (B) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or any of its Subsidiaries; (C) an underwriter temporarily holding securities pursuant to an offering of such securities; or (D) a corporation owned, directly or indirectly, by

the shareholders of the Company in substantially the same proportion as their ownership of stock of the Company. If the timing of payments provided under an Award Agreement is based on or triggered by a Change in Control then, to extent necessary to avoid violating Section 409A, a Change in Control must also constitute a Change in Control Event as defined under Section 409A.

(h) "*Code*" means the Internal Revenue Code of 1986, as amended, and any successor thereto. References in this Plan to any section of the Code shall be deemed to include any regulations or other interpretative guidance issued by any governmental authority under such section, and any amendments or successor provisions to such section, regulations or guidance.

(i) "*Committee*" means a committee of at least two people as the Board may appoint to administer this Plan or, if no such committee has been appointed by the Board, the Board. Unless altered by an action of the Board, the Committee shall be the Compensation Committee of the Board.

(j) "*Common Shares*" means the common stock, par value \$0.001 per share, of the Company (and any stock or other securities into which such common shares may be converted or into which they may be exchanged).

(k) "Company" means BioXcel Therapeutics, Inc., a Delaware corporation, together with its successors and assigns.

(l) "<u>Current Board Members</u>" has the meaning given such term in the definition of "Change in Control."

authorization.

(n) "*Disability*" means, in the case of a particular Award, unless the applicable Award Agreement states otherwise, (i) "Disability" as

(m) "Date of Grant" means the date on which the granting of an Award is authorized, or such other date as may be specified in such

defined in any employment or consulting agreement or similar document or policy in effect between the Participant and the Company or an Affiliate or (ii) in the absence of any such employment or consulting agreement, document or policy (or the absence of any definition of "Disability" contained therein), the inability of the Participant to perform the essential functions of the Participant's job by reason of a physical or mental infirmity, for a period of three (3) consecutive months or for an aggregate of six (6) months in any twelve (12) consecutive month period. The determination of whether a Participant has incurred a permanent and total disability shall be made by a physician designated by the Committee, whose determination shall be final and binding.

(o) "*Effective Date*" means the date as of which this Plan is adopted by the Board, subject to Section 3 of this Plan.

(p) "*Eligible Director*" means a person who is (i) a "non-employee director" within the meaning of Rule 16b-3 under the Exchange Act, and (ii) an "outside director" within the meaning of Section 162(m) of the Code.

(q) "<u>Eligible Person</u>" means any (i) individual employed by the Company, a Subsidiary or an Affiliate; *provided*, *however*, that no such employee covered by a collective bargaining agreement shall be an Eligible Person unless and to the extent that such eligibility is set forth in such collective bargaining agreement or in an agreement relating thereto; (ii) director of the Company, a Subsidiary or an Affiliate; or (iii) consultant or advisor to the Company or an Affiliate, provided that if the Securities Act applies such persons must be eligible to be offered securities registrable on Form S-8 under the Securities Act.

3

(r) "*Exchange Act*" has the meaning given such term in the definition of "Change in Control," and any reference in this Plan to any section of (or rule promulgated under) the Exchange Act shall be deemed to include any rules, regulations or other interpretative guidance issued by any governmental authority under such section or rule, and any amendments or successor provisions to such section, rules, regulations or guidance.

(s) "*Exercise Price*" has the meaning given such term in Section 7(b) of this Plan.

(t) "*Fair Market Value*", unless otherwise provided by the Committee in accordance with all applicable laws, rules regulations and standards, means, on a given date, (i) if the Common Shares are listed on a national securities exchange, the closing sales price on the principal exchange of the Common Shares on such date or, in the absence of reported sales on such date, the closing sales price on the immediately preceding date on which sales were reported, or (ii) if the Common Shares are not listed on a national securities exchange, the mean between the bid and offered prices as quoted by any nationally recognized interdealer quotation system for such date, provided that if the Common Shares are not quoted on an interdealer quotation system or it is determined that the fair market value is not properly reflected by such quotations, Fair Market Value will be determined by such other method as the Committee determines in good faith to be reasonable and in compliance with Section 409A.

(u) "*Immediate Family Members*" shall have the meaning set forth in Section 15(b) of this Plan.

(v) "*Incentive Stock Option*" means an Option that is designated by the Committee as an incentive stock option as described in Section 422 of the Code and otherwise meets the requirements set forth in this Plan.

(w) "Indemnifiable Person" shall have the meaning set forth in Section 4(e) of this Plan.

(x) "<u>Negative Discretion</u>" shall mean the discretion authorized by this Plan to be applied by the Committee to eliminate or reduce the size of a Performance Compensation Award consistent with Section 162(m) of the Code.

(y) "*Nonqualified Stock Option*" means an Option that is not designated by the Committee as an Incentive Stock Option.

(z) "Option" means an Award granted under Section 7 of this Plan.

(aa) "Option Period" has the meaning given such term in Section 7(c) of this Plan.

(bb) "*Participant*" means an Eligible Person who has been selected by the Committee to participate in this Plan and to receive an Award pursuant to Section 6 of this Plan.

(cc) "*Performance Compensation Award*" shall mean any Award designated by the Committee as a Performance Compensation Award pursuant to Section 11 of this Plan.

(dd) "*Performance Criteria*" shall mean the criterion or criteria that the Committee shall select for purposes of establishing the Performance Goal(s) for a Performance Period with respect to any Performance Compensation Award under this Plan.

(ee) "*Performance Formula*" shall mean, for a Performance Period, the one or more objective formulae applied against the relevant Performance Goal to determine, with regard to the

4

Performance Compensation Award of a particular Participant, whether all, some portion but less than all, or none of the Performance Compensation Award has been earned for the Performance Period.

(ff) "*Performance Goals*" shall mean, for a Performance Period, the one or more goals established by the Committee for the Performance Period based upon the Performance Criteria.

(gg) "<u>Performance Period</u>" shall mean the one or more periods of time, as the Committee may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to, and the payment of, a Performance Compensation Award.

(hh) "Permitted Transferee" shall have the meaning set forth in Section 15(b) of this Plan.

(ii) "*Person*" has the meaning given such term in the definition of "Change in Control."

(jj) "*Plan*" means this BioXcel Therapeutics, Inc. 2017 Equity Incentive Plan, as amended from time to time.

(kk) "<u>Retirement</u>" means the fulfillment of each of the following conditions: (i) the Participant is in good standing with the Company and/or an Affiliate of the Company as determined by the Committee; (ii) the voluntary termination by a Participant of such Participant's employment or service to the Company and/or an Affiliate and (iii) that at the time of such voluntary termination, the sum of: (A) the Participant's age (calculated to the nearest month, with any resulting fraction of a year being calculated as the number of months in the year divided by 12) and (B) the Participant's years of employment or service with the Company (calculated to the nearest month, with any resulting fraction of a year being calculated as the number of months in the year divided by 12) equals at least 62 (provided that, in any case, the foregoing shall only be applicable if, at the time of such Retirement, the Participant shall be at least 55 years of age and shall have been employed by or served with the Company for no less than five years).

(ll) "<u>Restricted Period</u>" means the period of time determined by the Committee during which an Award is subject to restrictions or, as applicable, the period of time within which performance is measured for purposes of determining whether an Award has been earned.

(mm) "<u>Restricted Stock Unit</u>" means an unfunded and unsecured promise to deliver Common Shares, cash, other securities or other property, subject to certain restrictions (including, without limitation, a requirement that the Participant remain continuously employed or provide continuous services for a specified period of time), granted under Section 9 of this Plan.

(nn) "*Restricted Stock*" means Common Shares, subject to certain specified restrictions (including, without limitation, a requirement that the Participant remain continuously employed or provide continuous services for a specified period of time), granted under Section 9 of this Plan.

(oo) "SAR Period" has the meaning given such term in Section 8(c) of this Plan.

(pp) "*Section 409A*" means Section 409A of the Code (together with all Treasury Regulations, guidance, compliance programs, and other interpretative authority thereunder.

(qq) "<u>Securities Act</u>" means the Securities Act of 1933, as amended, and any successor thereto. Reference in this Plan to any section of the Securities Act shall be deemed to include any rules, regulations or other official interpretative guidance issued by any governmental authority under such section, and any amendments or successor provisions to such section, rules, regulations or guidance.

(rr) "*Stock Appreciation Right*" or "*SAR*" means an Award granted under Section 8 of this Plan which meets all of the requirements of Section 1.409A-1(b)(5)(i)(B) of the Treasury Regulations.

(ss) "Stock Bonus Award" means an Award granted under Section 10 of this Plan.

(tt) "<u>Strike Price</u>" means, except as otherwise provided by the Committee in the case of Substitute Awards, (i) in the case of a SAR granted in tandem with an Option, the Exercise Price of the related Option, or (ii) in the case of a SAR granted independent of an Option, the Fair Market Value of Common Shares on the Date of Grant.

(uu) "*Subsidiary*" means, with respect to any specified Person:

(i) any corporation, association or other business entity of which more than 50% of the total voting power of shares of voting securities (without regard to the occurrence of any contingency and after giving effect to any voting agreement or stockholders' agreement that effectively transfers voting power) is at the time owned or controlled, directly or indirectly, by that Person or one or more of the other Subsidiaries of that Person (or a combination thereof); and

(ii) any partnership or limited liability company (or any comparable foreign entity) (a) the sole general partner or managing member (or functional equivalent thereof) or the managing general partner of which is such Person or Subsidiary of such Person or (b) the only general partners or managing members (or functional equivalents thereof) of which are that Person or one or more Subsidiaries of that Person (or any combination thereof).

(vv) "*Substitute Award*" has the meaning given such term in Section 5(e).

(ww) "*Treasury Regulations*" means any regulations, whether proposed, temporary or final, promulgated by the U.S. Department of Treasury under the Code, and any successor provisions.

3. *Effective Date; Duration.* The Plan shall be effective on August 22, 2017, the date on which it is approved by the stockholders of the Company, which date shall be within twelve (12) months before or after the date of the Plan's adoption by the Board. The expiration date of this Plan, on and after which date no Awards may be granted hereunder, shall be August 21, 2027, the tenth anniversary of the date on which the Plan was approved by the stockholders of the Company; *provided, however*, that such expiration shall not affect Awards then outstanding, and the terms and conditions of this Plan shall continue to apply to such Awards.

#### 4. Administration.

(a) The Committee shall administer this Plan. To the extent required to comply with the provisions of Rule 16b-3 promulgated under the Exchange Act (if the Board is not acting as the Committee under this Plan) or necessary to obtain the exception for performance-based compensation under Section 162(m) of the Code, as applicable, it is intended that each member of the Committee shall, at the time he takes any action with respect to an Award under this Plan, be an Eligible Director. However, the fact that a Committee member shall fail to qualify as an Eligible Director shall not

6

invalidate any Award granted by the Committee that is otherwise validly granted under this Plan. The acts of a majority of the members present at any meeting at which a quorum is present or acts approved in writing by a majority of the Committee shall be deemed the acts of the Committee. Whether a quorum is present shall be determined based on the Committee's charter as approved by the Board.

(b) Subject to the provisions of this Plan and applicable law, the Committee shall have the sole and plenary authority, in addition to other express powers and authorizations conferred on the Committee by this Plan and its charter, to: (i) designate Participants; (ii) determine the type or types of Awards to be granted to a Participant; (iii) determine the number of Common Shares to be covered by, or with respect to which payments, rights, or other matters are to be calculated in connection with, Awards; (iv) determine the terms and conditions of any Award; (v) determine whether, to what extent, and under what circumstances Awards may be settled or exercised in cash, Common Shares, other securities, other Awards or other property, or canceled, forfeited, or suspended, and the method or methods by which Awards may be settled, exercised, canceled, forfeited, or suspended; (vi) determine whether, to what extent, and under what circumstances the delivery of cash, Common Shares, other securities, other Awards or other property and other amounts payable with respect to an Award shall be made; (vii) interpret, administer, reconcile any inconsistency in, settle any controversy regarding, correct any defect in and/or complete any omission in this Plan and any instrument or agreement relating to, or Award granted under, this Plan; (viii) establish, amend, suspend, or waive any rules and regulations and appoint such agents as the Committee shall deem appropriate for the proper administration of this Plan; (ix) accelerate the vesting or exercisability of, payment for or lapse of restrictions on, Awards; and (x) make any other determination and take any other action that the Committee deems necessary or desirable for the administration of this Plan.

(c) The Committee may, by resolution, expressly delegate to a special committee, consisting of one or more directors who may but need not be officers of the Company, the authority, within specified parameters as to the number and types of Awards, to (i) designate officers and/or employees of the Company or any of its Affiliates to be recipients of Awards under this Plan, and (ii) to determine the number of such Awards to be received by any such Participants; provided, however, that such delegation of duties and responsibilities may not be made with respect to grants of Awards to persons (i) subject to Section 16 of the Exchange Act or (ii) who are, or who are reasonably expected to be, "covered employees" for purposes of Section 162(m) of the Code. The acts of such delegates shall be treated as acts of the Committee, and such delegates shall report regularly to the Board and the Committee regarding the delegated duties and responsibilities and any Awards granted.

(d) Unless otherwise expressly provided in this Plan, all designations, determinations, interpretations, and other decisions under or with respect to this Plan or any Award or any documents evidencing Awards granted pursuant to this Plan shall be within the sole discretion of the Committee, may be made at any time and shall be final, conclusive and binding upon all persons or entities, including, without limitation, the Company, any Affiliate, any Participant, any holder or beneficiary of any Award, and any stockholder of the Company.

(e) No member of the Board, the Committee, delegate of the Committee or any employee, advisor or agent of the Company or the Board or the Committee (each such person, an "<u>Indemnifiable Person</u>") shall be liable for any action taken or omitted to be taken or any determination made in good faith with respect to this Plan or any Award hereunder. Each Indemnifiable Person shall be indemnified and held harmless by the Company against and from (and the Company shall pay or reimburse on demand for) any loss, cost, liability, or expense (including court costs and attorneys' fees) that may be imposed upon or incurred by such Indemnifiable Person in connection with or resulting from any action, suit or proceeding to which such

Indemnifiable Person may be a party or in which such Indemnifiable Person may be involved by reason of any action taken or omitted to be taken under this

7

Plan or any Award Agreement and against and from any and all amounts paid by such Indemnifiable Person with the Company's approval, in settlement thereof, or paid by such Indemnifiable Person in satisfaction of any judgment in any such action, suit or proceeding against such Indemnifiable Person, provided, that the Company shall have the right, at its own expense, to assume and defend any such action, suit or proceeding and once the Company gives notice of its intent to assume the defense, the Company shall have sole control over such defense with counsel of the Company's choice. The foregoing right of indemnification shall not be available to an Indemnifiable Person to the extent that a final judgment or other final adjudication (in either case not subject to further appeal) binding upon such Indemnifiable Person determines that the acts or omissions of such Indemnifiable Person giving rise to the indemnification claim resulted from such Indemnifiable Person's bad faith, fraud or willful criminal act or omission or that such right of indemnification is otherwise prohibited by law or by the Company's Certificate of Incorporation or Bylaws. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which any such Indemnifiable Person may be entitled under the Company's Certificate of Incorporation or Bylaws, as a matter of law, or otherwise, or any other power that the Company may have to indemnify such Indemnifiable Persons or hold them harmless.

(f) Notwithstanding anything to the contrary contained in this Plan, the Board may, in its sole discretion, at any time and from time to time, grant Awards and administer this Plan with respect to such Awards. In any such case, the Board shall have all the authority granted to the Committee under this Plan.

#### 5. Grant of Awards; Shares Subject to this Plan; Limitations.

(a) The Committee may, from time to time, grant Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Stock Bonus Awards and/or Performance Compensation Awards to one or more Eligible Persons. No Participant shall be eligible to receive or accrue dividends or dividend equivalent rights with respect to the Common Shares subject to an unvested Award, including without limitation, an Award of Stock Appreciation Rights or Restricted Stock Units.

Shares.

(b) Subject to Section 12 of this Plan, the Committee is authorized to deliver under this Plan an aggregate of 12,500 Common

(c) Common Shares underlying Awards under this Plan that are forfeited, cancelled, expire unexercised, or are settled in cash shall be available again for Awards under this Plan at the same ratio at which they were previously granted. Notwithstanding the foregoing, the following Common Shares shall not be available again for Awards under the Plan: (i) shares tendered or held back upon the exercise of an Option or settlement of an Award to cover the Exercise Price of an Award; (ii) shares that are used or withheld to satisfy tax withholding obligations of the Participant; (iii) shares subject to a Stock Appreciation Right that are not issued in connection with the stock settlement of the SAR upon exercise thereof; and (iv) shares purchased in the open market using proceeds received upon the exercise of an Option.

(d) Common Shares delivered by the Company in settlement of Awards may be authorized and unissued shares, shares held in the treasury of the Company, shares purchased on the open market or by private purchase, or any combination of the foregoing.

(e) Subject to compliance with Section 1.409A-3(f) of the Treasury Regulations, Awards may, in the sole discretion of the Committee, be granted under this Plan in assumption of, or in substitution for, outstanding awards previously granted by an entity acquired by the Company or with which the Company combines ("Substitute Awards"). The number of Common Shares underlying any

8

Substitute Awards shall be counted against the aggregate number of Common Shares available for Awards under this Plan.

(f) Notwithstanding any provision in the Plan to the contrary (but subject to adjustment as provided in Section 12), the Committee shall not grant to any one Eligible Person in any one calendar year Awards (i) for more than 50% of the Available Shares in the aggregate or (ii) payable in cash in an amount exceeding \$10,000,000 in the aggregate.

6. Eligibility. Participation shall be limited to Eligible Persons who have entered into an Award Agreement or who have received written notification from the Committee, or from a person designated by the Committee, that they have been selected to participate in this Plan.

7. Options.

(a) Generally. Each Option granted under this Plan shall be evidenced by an Award Agreement (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)). Each Option so granted shall be subject to the conditions set forth in this Section 7, and to such other conditions not inconsistent with this Plan as may be reflected in the applicable Award Agreement. All Options granted under this Plan shall be Nonqualified Stock Options unless the applicable Award Agreement expressly states that the Option is intended to be an Incentive Stock Option. Notwithstanding any designation of an Option, to the extent that the aggregate Fair Market Value of Common Shares with respect to which Options designated as Incentive Stock Options are exercisable for the first time by any Participant during any calendar year (under all plans of the Company or any Subsidiary) exceeds \$100,000, such excess Options shall be treated as Nonqualified Stock Options. Incentive Stock Options shall be granted only to Eligible Persons who are employees of the Company, its Subsidiaries and its Affiliates, and no Incentive Stock Option shall be granted to any Eligible Person who is ineligible to receive an Incentive Stock Option under the Code. No Option shall be treated as an Incentive Stock Option unless this Plan has been approved by the stockholders of the Company in a manner intended to comply with the stockholder approval requirements of Section 422(b)(1) of the Code, provided that any Option intended to be an Incentive Stock Option shall not fail to be effective solely on account of a failure to obtain such approval, but rather such Option shall be treated as a Nonqualified Stock Option unless and until such approval is obtained. In the case of an Incentive Stock Option, the terms and conditions of such grant shall be subject to and comply with such rules as may be prescribed by Section 422 of the Code. If for any reason an Option intended to be an Incentive Stock Option (or any portion thereof) shall not qualify as

an Incentive Stock Option, then, to the extent of such nonqualification, such Option or portion thereof shall be regarded as a Nonqualified Stock Option appropriately granted under this Plan.

(b) *Exercise Price*. The exercise price ("*Exercise Price*") per Common Share for each Option shall not be less than 100% of the Fair Market Value of such share determined as of the Date of Grant; *provided, however*, that in the case of an Incentive Stock Option granted to an employee who, at the time of the grant of such Option, owns shares representing more than 10% of the voting power of all classes of shares of the Company or any Affiliate, the Exercise Price per share shall not be less than 110% of the Fair Market Value per share on the Date of Grant; *and, provided further*, that notwithstanding any provision herein to the contrary, the Exercise Price shall not be less than the par value per Common Share.

(c) <u>Vesting and Expiration</u>. Options shall vest and become exercisable in such manner and on such date or dates determined by the Committee and as set forth in the applicable Award Agreement, and shall expire after such period, not to exceed ten (10) years from the Date of Grant, as may be determined by the Committee (the "<u>Option Period</u>"); provided, however, that the Option Period shall

9

not exceed five (5) years from the Date of Grant in the case of an Incentive Stock Option granted to a Participant who on the Date of Grant owns shares representing more than 10% of the voting power of all classes of shares of the Company or any Affiliate; *and, provided, further,* that notwithstanding any vesting dates set by the Committee, the Committee may, in its sole discretion, accelerate the exercisability of any Option, which acceleration shall not affect the terms and conditions of such Option other than with respect to exercisability. Unless otherwise provided by the Committee in an Award Agreement:

(i) the unvested portion of an Option shall expire upon termination of employment or service of the Participant granted the Option, and the vested portion of such Option shall remain exercisable for:

(A) one year following termination of employment or service by reason of such Participant's death or Disability (with the determination of Disability to be made by the Committee on a case by case basis), or, with respect to an Incentive Stock Option, three (3) months following such termination, but not later than the expiration of the Option Period;

(B) for directors, officers and employees of the Company only, for six (6) months following termination of employment or service by reason of such Participant's Retirement, or, with respect to an Incentive Stock Option, three (3) months following such termination, but not later than the expiration of the Option Period;

(C) ninety (90) days following termination of employment or service for any reason other than such Participant's death, Disability or Retirement, and other than such Participant's termination of employment or service for Cause, but not later than the expiration of the Option Period; and

(ii) both the unvested and the vested portion of an Option shall immediately expire upon the termination of the Participant's employment or service by the Company for Cause.

Notwithstanding the foregoing provisions of Section 7(c) and consistent with the requirements of applicable law, the Committee, in its sole discretion, may extend the post-termination of employment period during which a Participant may exercise vested Options.

(d) <u>Method of Exercise and Form of Payment</u>. No Common Shares shall be delivered pursuant to the exercise of an Option until payment in full of the Exercise Price therefor is received by the Company and the Participant has paid to the Company an amount equal to any federal, state, local and/or foreign income and employment taxes required to be withheld. Options that have become exercisable may be exercised by delivery of written or electronic notice of exercise to the Company in accordance with the terms of the Award Agreement accompanied by payment of the Exercise Price. The Exercise Price shall be payable (i) in cash, check (subject to collection), cash equivalent and/or vested Common Shares valued at the Fair Market Value at the time the Option is exercised (including, pursuant to procedures approved by the Committee, by means of attestation of ownership of a sufficient number of Common Shares in lieu of actual delivery of such shares to the Company); *provided, however*, that such Common Shares are not subject to any pledge or other security interest and; (ii) by such other method as the Committee may permit in accordance with applicable law, in its sole discretion, including without limitation: (A) in other property having a fair market value (as determined by the Committee in its discretion) on the date of exercise equal to the Exercise Price or (B) if there is a public market for the Common Shares at such time, by means of a broker-assisted "cashless exercise" pursuant to which the Company is delivered a copy of irrevocable instructions to a stockbroker to sell the Common Shares otherwise deliverable upon the exercise of the Option and to deliver promptly to the Company an amount equal to the Exercise Price or

10

(C) by a "net exercise" method whereby the Company withholds from the delivery of the Common Shares for which the Option was exercised that number of Common Shares having a Fair Market Value equal to the aggregate Exercise Price for the Common Shares for which the Option was exercised. Any fractional Common Shares shall be settled in cash.

(e) <u>Notification upon Disqualifying Disposition of an Incentive Stock Option</u>. Each Participant awarded an Incentive Stock Option under this Plan shall notify the Company in writing immediately after the date he makes a disqualifying disposition of any Common Shares acquired pursuant to the exercise of such Incentive Stock Option. A disqualifying disposition is any disposition (including, without limitation, any sale) of such Common Shares before the later of (A) two years after the Date of Grant of the Incentive Stock Option or (B) one year after the date of exercise of the Incentive Stock Option. The Company may, if determined by the Committee and in accordance with procedures established by the Committee, retain possession of any Common Shares acquired pursuant to the exercise of an Incentive Stock Option as agent for the applicable Participant until the end of the period described in the preceding sentence.

(f) <u>Compliance with Laws, etc</u>. Notwithstanding the foregoing, in no event shall a Participant be permitted to exercise an Option in a manner that the Committee determines would violate the Sarbanes-Oxley Act of 2002, if applicable, or any other applicable law or the applicable rules and regulations of the Securities and Exchange Commission or the applicable rules and regulations of any securities exchange or inter-dealer quotation system on which the securities of the Company are listed or traded.

#### 8. Stock Appreciation Rights.

(a) <u>Generally</u>. Each SAR granted under this Plan shall be evidenced by an Award Agreement (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)). Each SAR so granted shall be subject to the conditions set forth in this Section 8, and to such other conditions not inconsistent with this Plan as may be reflected in the applicable Award Agreement. Any Option granted under this Plan may include tandem SARs (i.e., SARs granted in conjunction with an Award of Options under this Plan). The Committee also may award SARs to Eligible Persons independent of any Option.

(b) *Exercise Price*. The Exercise Price per Common Share for each Option granted in connection with a SAR shall not be less than 100% of the Fair Market Value of such share determined as of the Date of Grant.

(c) <u>Vesting and Expiration</u>. A SAR granted in connection with an Option shall become exercisable and shall expire according to the same vesting schedule and expiration provisions as the corresponding Option. A SAR granted independent of an Option shall vest and become exercisable and shall expire in such manner and on such date or dates determined by the Committee and shall expire after such period, not to exceed ten years, as may be determined by the Committee (the "<u>SAR Period</u>"); provided, however, that notwithstanding any vesting dates set by the Committee, the Committee may, in its sole discretion, accelerate the exercisability of any SAR, which acceleration shall not affect the terms and conditions of such SAR other than with respect to exercisability. Unless otherwise provided by the Committee in an Award Agreement:

(i) the unvested portion of a SAR shall expire upon termination of employment or service of the Participant granted the SAR, and the vested portion of such SAR shall remain exercisable for:

11

(A) one year following termination of employment or service by reason of such Participant's death or Disability (with the determination of Disability to be made by the Committee on a case by case basis), but not later than the expiration of the SAR Period;

(B) for directors, officers and employees of the Company only, for six (6) months following termination of employment or service by reason of such Participant's Retirement, but not later than the expiration of the SAR Period;

(C) ninety (90) days following termination of employment or service for any reason other than such Participant's death, Disability or Retirement, and other than such Participant's termination of employment or service for Cause, but not later than the expiration of the SAR Period; and

(ii) both the unvested and the vested portion of a SAR shall expire immediately upon the termination of the Participant's employment or service by the Company for Cause.

(d) <u>Method of Exercise</u>. SARs that have become exercisable may be exercised by delivery of written or electronic notice of exercise to the Company in accordance with the terms of the Award, specifying the number of SARs to be exercised and the date on which such SARs were awarded. Notwithstanding the foregoing, if on the last day of the Option Period (or in the case of a SAR independent of an Option, the SAR Period), the Fair Market Value exceeds the Strike Price, the Participant has not exercised the SAR or the corresponding Option (if applicable), and neither the SAR nor the corresponding Option (if applicable) has expired, such SAR shall be deemed to have been exercised by the Participant on such last day and the Company shall make the appropriate payment therefor.

(e) <u>Payment</u>. Upon the exercise of a SAR, the Company shall pay to the Participant an amount equal to the number of Common Shares subject to the SAR that are being exercised multiplied by the excess, if any, of the Fair Market Value of one Common Share on the exercise date over the Strike Price, less an amount equal to any federal, state, local and non-U.S. income and employment taxes required to be withheld. The Company shall pay such amount in cash, in Common Shares valued at Fair Market Value, or any combination thereof, as determined by the Committee. Any fractional Common Share shall be settled in cash.

# 9. Restricted Stock and Restricted Stock Units.

(a) <u>Generally</u>. Each grant of Restricted Stock and Restricted Stock Units shall be evidenced by an Award Agreement (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)). Each such grant shall be subject to the conditions set forth in this Section 9, and to such other conditions not inconsistent with this Plan as may be reflected in the applicable Award Agreement. Restricted Stock and Restricted Stock Units shall be subject to such restrictions on transferability and other restrictions as the Committee may impose (including, for example, that holders of Restricted Stock may not vote or receive dividends on the Restricted Stock). These restrictions may lapse separately or in combination at such times, under such circumstances, in such installments, upon the satisfaction of Performance Goals or otherwise, as the Committee determines at the time of the grant of an Award or thereafter. Except as otherwise provided in an Award Agreement, a Participant shall have none of the rights of a stockholder with respect to Restricted Stock Units until such time as Common Shares are paid in settlement of such Awards.

(b) <u>Restricted Accounts; Escrow or Similar Arrangement</u>. Unless otherwise determined by the Committee, upon the grant of Restricted Stock, a book entry in a restricted account shall be established in the Participant's name at the Company's transfer agent and, if the Committee determines that the Restricted Stock shall be held by the Company or in escrow rather than held in such restricted account pending the release of the applicable restrictions, the Committee may require the Participant to additionally execute and deliver to the Company (i) an escrow agreement satisfactory to the Committee, if applicable, and (ii) the appropriate share power (endorsed in blank) with respect to the Restricted Stock covered by such agreement. If a Participant shall fail to execute an agreement evidencing an Award of Restricted Stock and, if applicable, an escrow agreement and blank share power within the amount of time specified by the Committee, the Award shall be null and void *ab initio*. No Participant shall have voting rights with respect to any Awards of Restricted Stock. A Participant holding Restricted Stock granted hereunder shall not have the right to receive dividends on the Restricted Stock during the Restriction Period. To the extent shares of Restricted Stock are forfeited, any share certificates issued to the Participant evidencing such

shares shall be returned to the Company, and all rights of the Participant to such shares and as a stockholder with respect thereto shall terminate without further obligation on the part of the Company.

(c) <u>Vesting; Acceleration of Lapse of Restrictions</u>. Unless otherwise provided by the Committee in an Award Agreement, the unvested portion of Restricted Stock and Restricted Stock Units shall terminate and be forfeited upon the termination of employment or service of the Participant granted the applicable Award.

(d) <u>Delivery of Restricted Stock and Settlement of Restricted Stock Units</u>. (i) Upon the expiration of the Restricted Period with respect to any shares of Restricted Stock, the restrictions set forth in the applicable Award Agreement shall be of no further force or effect with respect to such shares, except as set forth in the applicable Award Agreement. If an escrow arrangement is used, upon such expiration, the Company shall deliver to the Participant, or his beneficiary, without charge, the share certificate evidencing the shares of Restricted Stock that have not then been forfeited and with respect to which the Restricted Period has expired (rounded down to the nearest full share).

(ii) Unless otherwise provided by the Committee in an Award Agreement, upon the expiration of the Restricted Period with respect to any outstanding Restricted Stock Units, the Company shall deliver to the Participant, or his beneficiary, without charge, one Common Share for each such outstanding Restricted Stock Unit; *provided, however*, that the Committee may, in its sole discretion and subject to the requirements of Section 409A, elect to (i) pay cash or part cash and part Common Share in lieu of delivering only Common Shares in respect of such Restricted Stock Units or (ii) defer the delivery of Common Shares (or cash or part Common Shares and part cash, as the case may be) beyond the expiration of the Restricted Period if such delivery would result in a violation of applicable law until such time as is no longer the case. If a cash payment is made in lieu of delivering Common Shares, the amount of such payment shall be equal to the Fair Market Value of the Common Shares as of the date on which the Restricted Period lapsed with respect to such Restricted Stock Units, less an amount equal to any federal, state, local and non-U.S. income and employment taxes required to be withheld.

10. *Stock Bonus Awards*. The Committee may issue unrestricted Common Shares, or other Awards denominated in Common Shares, under this Plan to Eligible Persons, either alone or in tandem with other awards, in such amounts as the Committee shall from time to time in its sole discretion determine. Each Stock Bonus Award granted under this Plan shall be evidenced by an Award Agreement (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)). Each Stock Bonus Award so granted shall be subject to such conditions not inconsistent with this Plan as may be reflected in the applicable Award Agreement.

13

#### 11. Performance Compensation Awards.

(a) *Generally.* The provisions of the Plan are intended to enable Options and Stock Appreciation Rights granted hereunder to certain Eligible Persons to qualify for an exemption under Section 162(m) of the Code. The Committee shall have the authority, at the time of grant of any Award described in Sections 7 through 10 of this Plan, to designate such Award as a Performance Compensation Award intended to qualify as "performance-based compensation" under Section 162(m) of the Code. The Committee shall have the authority to make an award of a cash bonus to any Participant and designate such Award as a Performance Compensation Award intended to qualify as "performance-based compensation" under Section 162(m) of the Code.

(b) <u>Discretion of Committee with Respect to Performance Compensation Awards</u>. With regard to a particular Performance Period, the Committee shall have sole discretion to select the length of such Performance Period, the type(s) of Performance Compensation Awards to be issued, the Performance Criteria that will be used to establish the Performance Goal(s), the kind(s) and/or level(s) of the Performance Goals(s) that is (are) to apply and the Performance Formula. Within the first 90 calendar days of a Performance Period (or, if longer or shorter, within the maximum period allowed under Section 162(m) of the Code, if applicable), the Committee shall, with regard to the Performance Compensation Awards to be issued for such Performance Period, exercise its discretion with respect to each of the matters enumerated in the immediately preceding sentence and record the same in writing.

(c) <u>Performance Criteria</u>. The Performance Criteria that will be used to establish the Performance Goal(s) shall be based on the attainment of specific levels of performance of the Company and/or one or more Affiliates, divisions or operational units, or any combination of the foregoing, as determined by the Committee, which criteria may be based on one or more of the following business criteria: (i) revenue; (ii) sales; (iii) profit (net profit, gross profit, operating profit, economic profit, profit margins or other corporate profit measures); (iv) earnings (EBIT, EBITDA, earnings per share, or other corporate earnings measures); (v) net income (before or after taxes, operating income or other income measures); (vi) cash (cash flow, cash generation or other cash measures); (vii) stock price or performance; (viii) total stockholder return (stock price appreciation plus reinvested dividends divided by beginning share price); (ix) economic value added; (x) return measures (including, but not limited to, return on assets, capital, equity, investments or sales, and cash flow return on assets, capital, equity, or sales); (xi) market share; (xii) improvements in capital structure; (xiii) expenses (expense management, expense ratio, expense efficiency ratios or other expense measures); (xiv) business expansion or consolidation (acquisitions and divestitures); (xv) internal rate of return or increase in net present value; (xvi) working capital targets relating to inventory and/or accounts receivable; (xvii) inventory management; (xviii) service or product delivery or quality; (xix) customer satisfaction; (xx) employee retention; (xxi) safety standards; (xxii) productivity measures; (xxiii) cost reduction measures; and/or (xxiv) strategic plan development and implementation. Any one or more of the Performance Criteria adopted by the Committee may be used on an absolute or relative basis to measure the performance of the Company and/or one or more Affiliates as a whole or any business unit(s) of the Company and/or one or more Affiliates or any combination thereof, as the Committee may deem appropriate, or any of the above Performance Criteria may be compared to the performance of a selected group of comparison companies, or a published or special index that the Committee, in its sole discretion, deems appropriate, or as compared to various stock market indices. The Committee also has the authority to provide for accelerated vesting of any Award based on the achievement of Performance Goals pursuant to the Performance Criteria specified in this paragraph. To the extent required under Section 162(m) of the Code, the Committee shall, within the first 90 calendar days of a Performance Period (or, if longer or shorter, within the maximum period allowed under Section 162(m) of the Code), define in an objective fashion the manner of calculating the Performance Criteria it selects to use for such Performance Period and thereafter promptly communicate such Performance Criteria to the Participant.

(d) <u>Modification of Performance Goal(s)</u>. In the event that applicable tax and/or securities laws change to permit Committee discretion to alter the governing Performance Criteria without obtaining stockholder approval of such alterations, the Committee shall have sole discretion to make such alterations without obtaining stockholder approval. The Committee is authorized at any time during the first 90 calendar days of a

Performance Period (or, if longer or shorter, within the maximum period allowed under Section 162(m) of the Code, if applicable), or at any time thereafter to the extent the exercise of such authority at such time would not cause the Performance Compensation Awards granted to any Participant for such Performance Period to fail to qualify as "performance-based compensation" under Section 162(m) of the Code, in its sole discretion, to adjust or modify the calculation of a Performance Goal for such Performance Period, based on and in order to appropriately reflect the following events: (i) asset write-downs; (ii) litigation or claim judgments or settlements; (iii) the effect of changes in tax laws, accounting principles, or other laws or regulatory rules affecting reported results; (iv) any reorganization and restructuring programs; (v) extraordinary nonrecurring items as described in Accounting Principles Board Opinion No. 30 (or any successor pronouncement thereto) and/or in management's discussion and analysis of financial condition and results of operations appearing in the Company's annual report to stockholders for the applicable year; (vi) acquisitions or divestitures; (vii) any other specific unusual or nonrecurring events, or objectively determinable category thereof; (viii) foreign exchange gains and losses; and (ix) a change in the Company's fiscal year.

#### (e) Payment of Performance Compensation Awards.

(i) <u>Condition to Receipt of Payment</u>. Unless otherwise provided in the applicable Award Agreement, a Participant must be employed by, or in service to, the Company on the last day of a Performance Period to be eligible for payment in respect of a Performance Compensation Award for such Performance Period.

(ii) *Limitation*. A Participant shall be eligible to receive payment in respect of a Performance Compensation Award only to the extent that: (A) the Performance Goals for such period are achieved; and (B) all or some of the portion of such Participant's Performance Compensation Award has been earned for the Performance Period based on the application of the Performance Formula to such achieved Performance Goals.

(iii) <u>Certification</u>. Following the completion of a Performance Period, the Committee shall review and certify in writing whether, and to what extent, the Performance Goals for the Performance Period have been achieved and, if so, calculate and certify in writing that amount of the Performance Compensation Awards earned for the period based upon the Performance Formula. The Committee shall then determine the amount of each Participant's Performance Compensation Award actually payable for the Performance Period and, in so doing, may apply Negative Discretion.

(iv) <u>Use of Negative Discretion</u>. In determining the actual amount of an individual Participant's Performance Compensation Award for a Performance Period, the Committee may reduce or eliminate the amount of the Performance Compensation Award earned under the Performance Formula in the Performance Period through the use of Negative Discretion if, in its sole judgment, such reduction or elimination is appropriate. The Committee shall not have the discretion, except as is otherwise provided in this Plan, to (A) grant or provide payment in respect of Performance Compensation Awards for a Performance Period if the Performance Goals for such Performance Period have not been attained; or (B) increase a Performance Compensation Award above the applicable limitations set forth in Section 5 of this Plan.

(f) *<u>Timing of Award Payments</u>*. Performance Compensation Awards granted for a Performance Period shall be paid to Participants as soon as administratively practicable following

completion of the certifications required by this Section 11, but in no event later than two-and-one-half months following the end of the fiscal year during which the Performance Period is completed in order to comply with the short-term deferral rules under Section 1.409A-1(b)(4) of the Treasury Regulations. Notwithstanding the foregoing, payment of a Performance Compensation Award may be delayed, as permitted by Section 1.409A-2(b)(7)(i) of the Treasury Regulations, to the extent that the Company reasonably anticipates that if such payment were made as scheduled, the Company's tax deduction with respect to such payment would not be permitted due to the application of Section 162(m) of the Code.

12. Changes in Capital Structure and Similar Events. In the event of (a) any dividend or other distribution (whether in the form of cash, Common Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, amalgamation, consolidation, split-up, split-off, combination, repurchase or exchange of Common Shares or other securities of the Company, issuance of warrants or other rights to acquire Common Shares or other securities of the Company, or other similar corporate transaction or event (including, without limitation, a Change in Control) that affects the Common Shares, or (b) unusual or nonrecurring events (including, without limitation, a Change in Control) affecting the Company, any Affiliate, or the financial statements of the Company or any Affiliate, or changes in applicable rules, rulings, regulations or other requirements of any governmental body or securities exchange or inter-dealer quotation system, accounting principles or law, such that in either case an adjustment is determined by the Committee in its sole discretion to be necessary or appropriate in order to prevent dilution or enlargement of rights, then the Committee shall make any such adjustments that are equitable, including, without limitation, adjusting any or all of (A) the number of Common Shares or other securities of the Company (or number and kind of other securities or other property) that may be delivered in respect of Awards or with respect to which Awards may be granted under this Plan (including, without limitation, adjusting any or all of the limitations under Section 5 of this Plan) and (B) the terms of any outstanding Award, including, without limitation, (1) the number of Common Shares or other securities of the Company (or number and kind of other securities or other property) subject to outstanding Awards or to which outstanding Awards relate, (2) the Exercise Price or Strike Price with respect to any Award or (3) any applicable performance measures (including, with

13. *Effect of Change in Control.* Upon the occurrence of a Change in Control, unless otherwise specifically prohibited under applicable laws or by the rules and regulations of any governing governmental agencies or national securities exchanges, or unless the Committee shall specify otherwise in the Award Agreement, the Committee is authorized (but not obligated) to make any of the following adjustments (or any combination thereof) in the terms and conditions of outstanding Awards: (a) continuation or assumption of such outstanding Awards under the Plan by the Company (if it is the surviving company or corporation) or by the surviving company or corporation or its parent; (b) substitution by the surviving company or corporation or its parent of equity, equity-based and/or cash awards with substantially the same terms for outstanding Awards (excluding the security deliverable upon settlement of the Awards), including, in the case of Options, substitution by the surviving company or corporation or its parent of such outstanding Awards (excluding the security deliverable upon settlement of the Awards), including, in the case of Options, substitution by the surviving company or corporation or its parent of restricted stock or other equity, which may be subject to substantially the same vesting and/or forfeiture terms as such Options, in an amount equal to the intrinsic value of such Options; (c) accelerated exercisability, vesting and/or lapse of restrictions under outstanding Awards immediately prior to the occurrence of such event; (d) upon written notice, provide that any outstanding Awards must be exercised, to the extent then exercisable, during a reasonable period of time immediately prior to the scheduled consummation of the event or such other period as determined by the Committee (contingent upon the consummation of the event), and at the end of such period, such Awards shall terminate to the extent not so exercised within the relevant period; and (e) cancellation of all or any portion of outstanding Awar

case of Options and Stock Appreciation Rights or similar Awards, (x) such fair value may equal the excess, if any, of the value of the consideration to be paid in the Change in Control transaction to holders of the same number of Common Shares subject to such Awards (or, if no such consideration is paid, the Fair Market Value of the Common Shares subject to such outstanding Awards or portion thereof being canceled) over the aggregate Exercise Price or Strike Price, as applicable, with respect to such Awards or the portion thereof being canceled (or if no such excess, zero), and (y) to the extent that the Options, Stock Appreciation Rights or similar Awards are not then vested, such excess may be paid in restricted stock or other equity, which may be subject to substantially the same vesting and/or forfeiture terms as such Options, Stock Appreciation Rights or similar awards, in an amount equal to the intrinsic value of such Options, Stock Appreciation Rights or similar Awards.

#### 14. Amendments and Termination.

(a) <u>Amendment and Termination of this Plan</u>. The Board may amend, alter, suspend, discontinue, or terminate this Plan or any portion thereof at any time; <u>provided</u>, that (i) no amendment to the definition of Eligible Person in Section 2(q), Section 5(b), Section 11(c) or Section 14(b) (to the extent required by the proviso in such Section 14(b)) shall be made without stockholder approval and (ii) no such amendment, alteration, suspension, discontinuation or termination shall be made without stockholder approval is necessary to comply with any tax or regulatory requirement applicable to this Plan (including, without limitation, as necessary to comply with any rules or requirements of any national securities exchange or inter-dealer quotation system on which the Common Shares may be listed or quoted or to prevent the Company from being denied a tax deduction under Section 162(m) of the Code); *and, provided, further*, that any such amendment, alteration, suspension, discontinuance or termination that would materially and adversely affect the rights of any Participant or any holder or beneficiary of any Award theretofore granted shall not to that extent be effective without the prior written consent of the affected Participant, holder or beneficiary.

(b) <u>Amendment of Award Agreements</u>. The Committee may, to the extent consistent with the terms of any applicable Award Agreement, waive any conditions or rights under, amend any terms of, or alter, suspend, discontinue, cancel or terminate, any Award theretofore granted or the associated Award Agreement, prospectively or retroactively; *provided, however* that any such waiver, amendment, alteration, suspension, discontinuance, cancellation or termination that would materially and adversely affect the rights of any Participant with respect to any Award theretofore granted shall not to that extent be effective without the consent of the affected Participant.

(c) <u>Prohibition on Repricing</u>. Subject to Section 5, the Committee shall not, without the approval of the stockholders of the Company (i) reduce the exercise price, or cancel and reissue options so as to in effect reduce the exercise price or (ii) change the manner of determining the exercise price so that the exercise price is less than the fair market value per share of Common Stock.

#### 15. General.

(a) <u>Award Agreements</u>. Each Award under this Plan shall be evidenced by an Award Agreement, which shall be delivered to the Participant (whether in paper or electronic medium (including email or the posting on a web site maintained by the Company or a third party under contract with the Company)) and shall specify the terms and conditions of the Award and any rules applicable thereto, including without limitation, the effect on such Award of the death, Disability or termination of employment or service of a Participant, or of such other events as may be determined by the Committee. The Company's failure to specify any term of any Award in any particular Award Agreement shall not invalidate such term, provided such terms was duly adopted by the Board or the Committee.

17

#### (b) Non-transferability; Trading Restrictions.

(i) Each Award shall be exercisable only by a Participant during the Participant's lifetime, or, if permissible under applicable law, by the Participant's legal guardian or representative. No Award may be assigned, alienated, pledged, attached, sold or otherwise transferred or encumbered by a Participant other than by will or by the laws of descent and distribution and any such purported assignment, alienation, pledge, attachment, sale, transfer or encumbrance shall be void and unenforceable against the Company or an Affiliate; provided that the designation of a beneficiary shall not constitute an assignment, alienation, pledge, attachment, sale, transfer or encumbrance.

(ii) Notwithstanding the foregoing, the Committee may, in its sole discretion, permit Awards (other than Incentive Stock Options) to be transferred by a Participant, with or without consideration, subject to such rules as the Committee may adopt consistent with any applicable Award Agreement to preserve the purposes of this Plan, to: (A) any person who is a "family member" of the Participant, as such term is used in the instructions to Form S-8 under the Securities Act (collectively, the "*Immediate Family Members*"); (B) a trust solely for the benefit of the Participant and his or her Immediate Family Members; or (C) a partnership or limited liability company whose only partners or stockholders are the Participant and his or her Immediate Family Members; or (D) any other transferee as may be approved either (I) by the Board or the Committee in its sole discretion, or (II) as provided in the applicable Award Agreement (each transferee described in clauses (A), (B), (C) and (D) above is hereinafter referred to as a "*Permitted Transferee*"); provided, that the Participant gives the Committee advance written notice describing the terms and conditions of the proposed transfer and the Committee notifies the Participant in writing that such a transfer would comply with the requirements of this Plan.

(iii) The terms of any Award transferred in accordance with subparagraph (ii) above shall apply to the Permitted Transferee, and any reference in this Plan, or in any applicable Award Agreement, to a Participant shall be deemed to refer to the Permitted Transferee, except that (A) Permitted Transferees shall not be entitled to transfer any Award, other than by will or the laws of descent and distribution; (B) Permitted Transferees shall not be entitled to exercise any transferred Option unless there shall be in effect a registration statement on an appropriate form covering the Common Shares to be acquired pursuant to the exercise of such Option if the Committee determines, consistent with any applicable Award Agreement, that such a registration statement is necessary or appropriate; (C) the Committee or the Company shall not be required to provide any notice to a Permitted Transferee, whether or not such notice is or would otherwise have been required to be given to the Participant under this Plan or otherwise; and (D) the consequences of the termination of the Participant's employment by, or services to, the Company or an Affiliate under the terms of this Plan and the applicable Award Agreement shall continue to be applied with respect to the Participant, including, without limitation, that an Option shall be exercisable by the Permitted Transferee only to the extent, and for the periods, specified in this Plan and the applicable Award Agreement.

(iv) The Committee shall have the right, either on an Award-by-Award basis or as a matter of policy for all Awards or one or more classes of Awards, to condition the delivery of vested Common Shares received in connection with such Award on the Participant's agreement to such restrictions as the Committee may determine.

# (c) Tax Withholding.

(i) A Participant shall be required to pay to the Company or any Affiliate, or the Company or any Affiliate shall have the right and is hereby authorized to withhold, from any cash, Common Shares, other securities or other property deliverable under any Award or from any compensation or other amounts owing to a Participant, the amount (in cash, Common Shares, other

18

securities or other property) of any required withholding taxes in respect of an Award, its exercise, or any payment or transfer under an Award or under this Plan and to take such other action as may be necessary in the opinion of the Committee or the Company to satisfy all obligations for the payment of such withholding and taxes. In addition, the Committee, in its discretion, may make arrangements mutually agreeable with a Participant who is not an employee of the Company or an Affiliate to facilitate the payment of applicable income and self-employment taxes.

(ii) Without limiting the generality of clause (i) above, the Committee may, in its sole discretion, permit a Participant to satisfy, in whole or in part, the foregoing withholding liability by (A) the delivery of Common Shares (which are not subject to any pledge or other security interest) owned by the Participant having a fair market value equal to such withholding liability or (B) having the Company withhold from the number of Common Shares otherwise issuable or deliverable pursuant to the exercise or settlement of the Award a number of shares with a fair market value equal to such withholding liability (but no more than the minimum required statutory withholding liability).

(d) *No Claim to Awards; No Rights to Continued Employment; Waiver*. No employee of the Company or an Affiliate, or other person, shall have any claim or right to be granted an Award under this Plan or, having been selected for the grant of an Award, to be selected for a grant of any other Award. There is no obligation for uniformity of treatment of Participants or holders or beneficiaries of Awards. The terms and conditions of Awards and the Committee's determinations and interpretations with respect thereto need not be the same with respect to each Participant and may be made selectively among Participants, whether or not such Participants are similarly situated. Neither this Plan nor any action taken hereunder shall be construed as giving any Participant any right to be retained in the employ or service of the Company or an Affiliate, nor shall it be construed as giving any Participant any rights to continued service on the Board. The Company or any of its Affiliates may at any time dismiss a Participant from employment or discontinue any consulting relationship, free from any liability or any claim under this Plan, unless otherwise expressly provided in this Plan or any Award Agreement. By accepting an Award under this Plan, a Participant shall thereby be deemed to have waived any claim to continued exercise or vesting of an Award or to damages or severance entitlement related to non-continuation of the Award beyond the period provided under this Plan or any Award Agreement, notwithstanding any provision to the contrary in any written employment contract or other agreement between the Company and its Affiliates and the Participant, whether any such agreement is executed before, on or after the Date of Grant.

(e) <u>International Participants</u>. With respect to Participants who reside or work outside of the United States of America and who are not (and who are not expected to be) "covered employees" within the meaning of Section 162(m) of the Code, the Committee may in its sole discretion amend the terms of this Plan or outstanding Awards (or establish a sub-plan) with respect to such Participants in order to conform such terms with the requirements of local law or to obtain more favorable tax or other treatment for such Participants, the Company or its Affiliates.

(f) <u>Designation and Change of Beneficiary</u>. Each Participant may file with the Committee a written designation of one or more persons as the beneficiary(ies) who shall be entitled to receive the amounts payable with respect to an Award, if any, due under this Plan upon his or her death. A Participant may, from time to time, revoke or change his or her beneficiary designation without the consent of any prior beneficiary by filing a new designation with the Committee. The last such designation filed with the Committee shall be controlling; *provided, however*, that no designation, or change or revocation thereof, shall be effective unless received by the Committee prior to the Participant's death, and in no event shall it be effective as of a date prior to such receipt. If no beneficiary designation is filed by a Participant, the beneficiary shall be deemed to be his or her spouse or, if the Participant is unmarried at the time of death, his or her estate. Upon the occurrence of a Participant's

19

divorce (as evidenced by a final order or decree of divorce), any spousal designation previously given by such Participant shall automatically terminate.

(g) <u>Termination of Employment/Service</u>. Unless determined otherwise by the Committee at any point following such event: (i) neither a temporary absence from employment or service due to illness, vacation or leave of absence nor a transfer from employment or service with the Company to employment or service with an Affiliate (or vice-versa) shall be considered a termination of employment or service with the Company or an Affiliate; and (ii) if a Participant's employment with the Company and its Affiliates terminates, but such Participant continues to provide services to the Company and its Affiliates in a non-employee capacity (or vice-versa), such change in status shall not be considered a termination of employment with the Company or an Affiliate for purposes of this Plan unless the Committee, in its discretion, determines otherwise.

(h) <u>No Rights as a Stockholder</u>. Except as otherwise specifically provided in this Plan or any Award Agreement, no person shall be entitled to the privileges of ownership in respect of Common Shares that are subject to Awards hereunder until such shares have been issued or delivered to that person.

# (i) Government and Other Regulations.

(i) The obligation of the Company to settle Awards in Common Shares or other consideration shall be subject to all applicable laws, rules, and regulations, and to such approvals by governmental agencies as may be required. Notwithstanding any terms or conditions of any Award to the contrary, the Company shall be under no obligation to offer to sell or to sell, and shall be prohibited from offering to sell or selling, any Common Shares pursuant to an Award unless such shares have been properly registered for sale pursuant to the Securities Act with the Securities and Exchange Commission or unless the Company has received an opinion of counsel, satisfactory to the Company, that such shares may be offered or sold without such registration pursuant to an available exemption therefrom and the terms and conditions of such exemption have been fully complied with. The Company shall be under no obligation to register for sale under the Securities Act any of the Common Shares to be offered or sold under this Plan. The Committee shall have the authority to provide that all certificates for Common Shares or other securities of the Company or any Affiliate delivered under this Plan shall be subject to such stop transfer orders and other restrictions as the Committee may deem advisable under this Plan, the applicable Award Agreement, the federal securities laws, or the rules, regulations and other requirements of the Securities and Exchange Commission, any securities exchange or inter-dealer quotation system upon which such shares or other securities are then listed or quoted and any other applicable federal, state, local or non-U.S. laws, and, without limiting the generality of Section 9 of this Plan, the Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions. Notwithstanding any provision in this Plan to the contrary, the Committee reserves the right to add any additional terms or provisions to any Award granted under this Plan that it in its sole discretion deems necessary or advisable in order that such Award complies with the legal requirements of any governmental entity to whose jurisdiction the Award is subject.

(ii) The Committee may cancel an Award or any portion thereof if it determines, in its sole discretion, that legal or contractual restrictions and/or blockage and/or other market considerations would make the Company's acquisition of Common Shares from the public markets, the Company's issuance of Common Shares to the Participant, the Participant's acquisition of Common Shares from the Company and/or the Participant's sale of Common Shares to the public markets, illegal, impracticable or inadvisable. If the Committee determines to cancel all or any portion of an Award in accordance with the foregoing, unless doing so would violate Section 409A, the Company shall pay to the Participant an amount equal to the excess of (A) the aggregate Fair Market Value of the Common Shares

20

subject to such Award or portion thereof canceled (determined as of the applicable exercise date, or the date that the shares would have been vested or delivered, as applicable), over (B) the aggregate Exercise Price or Strike Price (in the case of an Option or SAR, respectively) or any amount payable as a condition of delivery of Common Shares (in the case of any other Award). Such amount shall be delivered to the Participant as soon as practicable following the cancellation of such Award or portion thereof. The Committee shall have the discretion to consider and take action to mitigate the tax consequence to the Participant in cancelling an Award in accordance with this clause.

(j) <u>Payments to Persons Other Than Participants</u>. If the Committee shall find that any person to whom any amount is payable under this Plan is unable to care for his affairs because of illness or accident, or is a minor, or has died, then any payment due to such person or his estate (unless a prior claim therefor has been made by a duly appointed legal representative) may, if the Committee so directs the Company, be paid to his spouse, child, relative, an institution maintaining or having custody of such person, or any other person deemed by the Committee to be a proper recipient on behalf of such person otherwise entitled to payment. Any such payment shall be a complete discharge of the liability of the Committee and the Company therefor.

(k) <u>Non exclusivity of this Plan</u>. Neither the adoption of this Plan by the Board nor the submission of this Plan to the stockholders of the Company for approval shall be construed as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of stock options or other equity-based awards otherwise than under this Plan, and such arrangements may be either applicable generally or only in specific cases.

(1) <u>No Trust or Fund Created</u>. Neither this Plan nor any Award shall create or be construed to create a trust or separate fund of any kind or a fiduciary relationship between the Company or any Affiliate, on the one hand, and a Participant or other person or entity, on the other hand. No provision of this Plan or any Award shall require the Company, for the purpose of satisfying any obligations under this Plan, to purchase assets or place any assets in a trust or other entity to which contributions are made or otherwise to segregate any assets, nor shall the Company maintain separate bank accounts, books, records or other evidence of the existence of a segregated or separately maintained or administered fund for such purposes. Participants shall have no rights under this Plan other than as general unsecured creditors of the Company, except that insofar as they may have become entitled to payment of additional compensation by performance of services, they shall have the same rights as other employees under general law.

(m) <u>Reliance on Reports</u>. Each member of the Committee and each member of the Board shall be fully justified in acting or failing to act, as the case may be, and shall not be liable for having so acted or failed to act in good faith, in reliance upon any report made by the independent public accountant of the Company and/or its Affiliates and/or any other information furnished in connection with this Plan by any agent of the Company or the Committee or the Board, other than himself.

(n) <u>*Relationship to Other Benefits*</u>. No payment under this Plan shall be taken into account in determining any benefits under any pension, retirement, profit sharing, group insurance or other benefit plan of the Company except as otherwise specifically provided in such other plan.

(o) *Governing Law*. The provisions of this Plan shall be governed by and construed in accordance with the laws of the State of Delaware without regard to its conflicts of laws principles.

(p) <u>Severability</u>. If any provision of this Plan or any Award or Award Agreement is or becomes or is deemed to be invalid, illegal, or unenforceable in any jurisdiction or as to any person or

21

entity or Award, or would disqualify this Plan or any Award under any law deemed applicable by the Committee, such provision shall be construed or deemed amended to conform to the applicable laws in the manner that most closely reflects the original intent of the Award or the Plan, or if it cannot be construed or deemed amended without, in the determination of the Committee, materially altering the intent of this Plan or the Award, such provision shall be construed or deemed stricken as to such jurisdiction, person or entity or Award and the remainder of this Plan and any such Award shall remain in full force and effect.

(q) <u>Obligations Binding on Successors</u>. The obligations of the Company under this Plan shall be binding upon any successor corporation or organization resulting from the merger, amalgamation, consolidation or other reorganization of the Company, or upon any successor corporation or organization succeeding to substantially all of the assets and business of the Company.

(r) *Code Section 162(m) Approval*. If so determined by the Committee, the provisions of this Plan regarding Performance Compensation Awards shall be disclosed and reapproved by stockholders no later than the first stockholder meeting that occurs in the fifth year following

the year in which stockholders previously approved such provisions, in each case in order for certain Awards granted after such time to be exempt from the deduction limitations of Section 162(m) of the Code. Nothing in this clause, however, shall affect the validity of Awards granted after such time if such stockholder approval has not been obtained.

(s) *Expenses; Gender; Titles and Headings*. The expenses of administering this Plan shall be borne by the Company and its Affiliates. Masculine pronouns and other words of masculine gender shall refer to both men and women. The titles and headings of the sections in this Plan are for convenience of reference only, and in the event of any conflict, the text of this Plan, rather than such titles or headings shall control.

(t) <u>Other Agreements</u>. Notwithstanding the above, the Committee may require, as a condition to the grant of and/or the receipt of Common Shares under an Award, that the Participant execute lock-up, stockholder or other agreements, as it may determine in its sole and absolute discretion.

(u) <u>Section 409A</u>. The Plan and all Awards granted hereunder are intended to comply with, or otherwise be exempt from, the requirements of Section 409A. The Plan and all Awards granted under this Plan shall be administered, interpreted, and construed in a manner consistent with Section 409A to the extent necessary to avoid the imposition of additional taxes under Section 409A(a)(1)(B) of the Code. In no event shall the Company or any of its Affiliates be liable for any additional tax, interest or penalties that may be imposed on a Participant under Section 409A or any damages for failing to comply with Section 409A. Notwithstanding any contrary provision in the Plan or Award Agreement, any payment(s) of nonqualified deferred compensation (within the meaning of Section 409A) that are otherwise required to be made under the Plan to a "specified employee" (within the meaning of Section 1.409A-1(i) of the Treasury Regulations) as a result of his or her separation from service (other than a payment that is not subject to Section 409A) shall be delayed for the first six months following such separation from service (or, if earlier, until the date of death of the specified employee) and shall instead be paid (in a manner set forth in the Award Agreement) on the day that immediately follows the end of such sixmonth period or as soon as administratively practicable thereafter. Any remaining payments of nonqualified deferred compensation shall be paid without delay and at the time or times such payments are otherwise scheduled to be made. A termination of employment or service shall not be deemed to have occurred for purposes of any provision of the Plan or any Award Agreement providing for the payment of any amounts or benefits that are considered nonqualified deferred compensation under Section 409A upon or following a termination of employment or service, unless such termination is also a "separation from service" within the meaning of Section 409A and the payment

22

thereof prior to a "separation from service" would violate Section 409A. For purposes of any such provision of the Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment," "termination of service," or like terms shall mean "separation from service."

(v) *Payments*. Participants shall be required to pay, to the extent required by applicable law, any amounts required to receive Common Shares under any Award made under this Plan.

23

#### INCENTIVE STOCK OPTION AGREEMENT

Option No.

Date of Grant: Shares:

To:

We are pleased to notify you that **BIOXCEL THERAPEUTICS, INC.** (the "Company") has granted to you an incentive stock option under the 2017 Equity Incentive Plan (the "Plan"), to purchase all or any part of an aggregate of shares of the Common Stock of the Company (the "Optioned Shares") at a price of \$ per share, subject to the terms and conditions of the Plan and of this Agreement set forth hereinafter.

 1.
 Vesting, Term and Exercise of Option.
 Subject to the provisions of this Agreement, this option may be exercised for up to the number of vested Optioned Shares by you or the representative of your estate on or prior to 10 years from the date of grant ("Last Exercise Date").
 of the Optioned Shares vest on

2. Any portion of the Optioned Shares that you do not exercise shall accumulate and can be exercised by you any time prior to the Last Exercise Date. You may not exercise your option to purchase a fractional share, and you may only exercise your option by purchasing shares in increments of 100 shares unless the remaining shares purchasable are less than 100 shares.

This option may be exercised by delivering to the Secretary of the Company (i) a written Notice of Intention to Exercise in the form attached hereto as Exhibit A signed by you and specifying the number of Optioned Shares you desire to purchase, (ii) payment in full of the exercise price for all such Optioned Shares in cash, certified check or surrender of shares of Common Stock of the Company having a value equal to the exercise price of the Optioned Shares as to which you are exercising this option, provided that such surrendered shares, if previously acquired by exercise of a Company stock option, have been held by you at least six months prior to their surrender. As a holder of an option, you shall have the rights of a shareholder with respect to the Optioned Shares only after they shall have been issued to you upon the exercise of this option. Subject to the terms and provisions of this Agreement and the Plan, the Company shall use its best efforts to cause the Optioned Shares to be issued as promptly as practicable after receipt of your Notice of Intention to Exercise.

3. <u>Death or Termination of Employment or Services.</u> If the employment or services of the Optionee by the Company or a subsidiary corporation of the Company shall be terminated voluntarily by the Optionee or for cause by the Company, this Option shall expire forthwith, but if such employment or services shall be terminated for any other reason (except death or disability), then this Option may not be exercised at any time later than three (3) months after such termination of the Optionee's employment. If the Optionee dies (i) while employed by or in the service of the Company or a subsidiary corporation of the Company, or (ii) within three (3)

months after termination of the Optionee's employment or services, then this Option may be exercised by the estate of the Optionee, or by a person who acquired the right to exercise this Option by bequest or inheritance or by reason of the death of the Optionee, at any time within one (1) year after such death. If the Optionee's employment or services with the Company or such subsidiary are terminated because of permanent and total disability while employed by or in the service of the Company or such subsidiary, this Option may be exercised at any time within one (1) year after termination of the Optionee's employment or service due to the disability, provided, however, that nothing in this Section 4 shall extend the right to purchase Optioned Shares which could not be purchased by the Optionee prior to the termination of his employment with the Company or such subsidiary.

4. <u>Non-transferability of Option</u>. This Option shall not be transferable and may be exercised during your lifetime only by you. Any purported transfer or assignment of this option shall be void and of no effect, and shall give the Company the right to terminate this option as of the date of such purported transfer or assignment. No transfer of an option by you by will or by the laws of descent and distribution shall be effective unless the Company have been furnished with written notice thereof, and such other evidence as the Board of Directors may deem necessary to establish the validity of the transfer and conditions of the option, and to establish compliance with any laws or regulations pertaining thereto.

5. <u>Plan Provisions to Prevail</u>. This Agreement shall be subject to all of the terms and provisions of the Plan. If there is any inconsistency between the provisions of this Agreement and the Plan, the provisions of the Plan shall govern.

6. <u>Certain Rights and Restrictions With Respect to Common Stock</u>. The Optioned Shares which you may acquire upon the exercise of this option will not be registered under the Securities Act of 1933, as amended, or under state securities laws and the resale by you of such Optioned Shares will, therefore, be restricted. You will be unable to transfer such Optioned Shares without either registration under such Act and compliance with applicable state securities laws or the availability of an exemption therefrom. Accordingly, you represent and warrant to the Company that all shares of Common Stock you may acquire upon the exercise of this option will be acquired by you or your estate in the event of your death for your own account for investment and that you will not sell or otherwise dispose of any such shares except in compliance with all applicable federal and state securities laws. The Company may place a legend to such effect upon each certificate representing Optioned Shares acquired by you upon the exercise of this option.

7. <u>Disputes</u>. Any dispute which may arise under or as a result of or pursuant to this Agreement shall be finally and conclusively determined in good faith by the Board of Directors of the Company in its sole discretion, and such determination shall be binding upon all parties.

8. <u>Governing Law</u>. The provisions of this Plan shall be governed by and construed in accordance with the laws of the State of Delaware without regard to its conflicts of laws principles.

By:

3

## Exhibit A

#### NOTICE OF INTENTION TO EXERCISE STOCK OPTIONS

The undersigned grantee of a BioXcel Therapeutics, Inc. Stock Option Agreement dated as of , 2017 to purchase shares of BioXcel Therapeutics, Inc. common stock hereby gives notice of his or her intention to exercise the Stock Option (or a portion thereof) and elects to purchase shares of BioXcel Therapeutics, Inc. common stock.

Shares should be issued in the name of the undersigned and should be sent to the undersigned at:

(Address where you want stock certificates mailed to)

Date:

Social Security Number

Signature

INSTRUCTIONS: The exercise of these Stock Options is effective on the date the Company has received all of (1) this Notice of Intention to Exercise Stock Options, and (2) payment in full in cash of the exercise price for all shares being purchased pursuant to this Notice.

4

#### NON-STATUTORY STOCK OPTION AGREEMENT

Option No.

Date of Grant: As of , 2017 Shares:

To:

We are pleased to notify you that **BIOXCEL THERAPEUTICS, INC.** (the "Company") has granted to you an non-statutory stock option under the 2017 Equity Incentive Plan (the "Plan"), to purchase all or any part of an aggregate of Shares") at a price of \$ per share, subject to the terms and conditions of the Plan and of this Agreement set forth hereinafter.

 1.
 Vesting, Term and Exercise of Option.
 Subject to the provisions of this Agreement, this option may be exercised for up to the number of vested Optioned Shares by you or the representative of your estate on or prior to 10 years from the date of grant ("Last Exercise Date").
 of the Optioned Shares vest on

2. Any portion of the Optioned Shares that you do not exercise shall accumulate and can be exercised by you any time prior to the Last Exercise Date. You may not exercise your option to purchase a fractional share, and you may only exercise your option by purchasing shares in increments of 100 shares unless the remaining shares purchasable are less than 100 shares.

This option may be exercised by delivering to the Secretary of the Company (i) a written Notice of Intention to Exercise in the form attached hereto as Exhibit A signed by you and specifying the number of Optioned Shares you desire to purchase, (ii) payment in full of the exercise price for all such Optioned Shares in cash, certified check or surrender of shares of Common Stock of the Company having a value equal to the exercise price of the Optioned Shares as to which you are exercising this option, provided that such surrendered shares, if previously acquired by exercise of a Company stock option, have been held by you at least six months prior to their surrender. As a holder of an option, you shall have the rights of a shareholder with respect to the Optioned Shares only after they shall have been issued to you upon the exercise of this option. Subject to the terms and provisions of this Agreement and the Plan, the Company shall use its best efforts to cause the Optioned Shares to be issued as promptly as practicable after receipt of your Notice of Intention to Exercise.

3. <u>Death or Termination of Employment or Services.</u> If the employment or services of the Optionee by the Company or a subsidiary corporation of the Company shall be terminated voluntarily by the Optionee or for cause by the Company, this Option shall expire forthwith, but if such employment or services shall be terminated for any other reason (except death or disability), then this Option may not be exercised at any time later than three (3) months after such termination of the Optionee's employment. If the Optionee dies (i) while employed by or in the service of the Company or a subsidiary corporation of the Company, or (ii) within three (3)

months after termination of the Optionee's employment or services, then this Option may be exercised by the estate of the Optionee, or by a person who acquired the right to exercise this Option by bequest or inheritance or by reason of the death of the Optionee, at any time within one (1) year after such death. If the Optionee's employment or services with the Company or such subsidiary are terminated because of permanent and total disability while employed by or in the service of the Company or such subsidiary, this Option may be exercised at any time within one (1) year after termination of the Optionee's employment or service due to the disability, provided, however, that nothing in this Section 4 shall extend the right to purchase Optioned Shares which could not be purchased by the Optionee prior to the termination of his employment with the Company or such subsidiary.

4. <u>Non-transferability of Option</u>. This Option shall not be transferable and may be exercised during your lifetime only by you. Any purported transfer or assignment of this option shall be void and of no effect, and shall give the Company the right to terminate this option as of the date of such purported transfer or assignment. No transfer of an option by you by will or by the laws of descent and distribution shall be effective unless the Company have been furnished with written notice thereof, and such other evidence as the Board of Directors may deem necessary to establish the validity of the transfer and conditions of the option, and to establish compliance with any laws or regulations pertaining thereto.

5. <u>Plan Provisions to Prevail</u>. This Agreement shall be subject to all of the terms and provisions of the Plan. If there is any inconsistency between the provisions of this Agreement and the Plan, the provisions of the Plan shall govern.

6. <u>Certain Rights and Restrictions With Respect to Common Stock</u>. The Optioned Shares which you may acquire upon the exercise of this option will not be registered under the Securities Act of 1933, as amended, or under state securities laws and the resale by you of such Optioned Shares will, therefore, be restricted. You will be unable to transfer such Optioned Shares without either registration under such Act and compliance with applicable state securities laws or the availability of an exemption therefrom. Accordingly, you represent and warrant to the Company that all shares of Common Stock you may acquire upon the exercise of this option will be acquired by you or your estate in the event of your death for your own account for investment and that you will not sell or otherwise dispose of any such shares except in compliance with all applicable federal and state securities laws. The Company may place a legend to such effect upon each certificate representing Optioned Shares acquired by you upon the exercise of this option.

7. <u>Disputes</u>. Any dispute which may arise under or as a result of or pursuant to this Agreement shall be finally and conclusively determined in good faith by the Board of Directors of the Company in its sole discretion, and such determination shall be binding upon all parties.

8. <u>Governing Law</u>. The provisions of this Plan shall be governed by and construed in accordance with the laws of the State of Delaware without regard to its conflicts of laws principles.

By:

3

## Exhibit A

#### NOTICE OF INTENTION TO EXERCISE STOCK OPTIONS

The undersigned grantee of a BioXcel Therapeutics, Inc. Stock Option Agreement dated as of , 2017 to purchase shares of BioXcel Therapeutics, Inc. common stock hereby gives notice of his or her intention to exercise the Stock Option (or a portion thereof) and elects to purchase shares of BioXcel Therapeutics, Inc. common stock.

Shares should be issued in the name of the undersigned and should be sent to the undersigned at:

(Address where you want stock certificates mailed to)

Date:

Social Security Number

Signature

INSTRUCTIONS: The exercise of these Stock Options is effective on the date the Company has received all of (1) this Notice of Intention to Exercise Stock Options, and (2) payment in full in cash of the exercise price for all shares being purchased pursuant to this Notice.

4

#### STOCK PURCHASE AGREEMENT

THIS AGREEMENT, dated as of , (this "<u>Agreement</u>"), is entered into by and between BioXcel Therapeutics, Inc., a Delaware corporation (the "<u>Company</u>"), and the investors identified on <u>Schedule 1</u> attached hereto (the "<u>Investors</u>").

WHEREAS, the Investors desire to purchase shares of the Company's common stock, par value \$0.001 per share (the "<u>Common Stock</u>"), and the Company desires to sell Common Stock to the Investors pursuant to the terms set forth in this Agreement.

NOW, THEREFORE, the parties agree as follows:

- 1. <u>Purchase and Sale</u>. Subject to the provisions of this Agreement, on the Closing Date (as hereinafter defined) the Company shall sell to the Investors, and the Investors shall purchase from the Company, the number of shares of Common Stock set forth opposite such Investor's name on <u>Schedule 1</u> annexed hereto, at a purchase price of \$1,142.86 per share.
- 2. <u>Closing of Purchase and Sale</u>.
  - 2.1. <u>Closing; Closing Date</u>. The purchase and sale of the Common Stock pursuant to <u>Section 1</u> (the "<u>Closing</u>") shall take place at the offices of BioXcel Therapeutics Inc., 780 East Main Street, Branford CT, or at such other place as may be agreed upon by the Company and the Investors, at 11:00 a.m. local time on the date of this Agreement or at such other time as may be agreed upon by the Company and the Investors (the "<u>Closing Date</u>").
  - 2.2. <u>Transactions at Closing</u>. At the Closing, the Company shall deliver to the Investors or their representatives certificates in the name of each Investor representing the Common Stock being purchased hereunder and each Investor shall deliver to the Company, by check or wire transfer of immediately available funds, the amount of the purchase price set forth opposite such Investor's name on <u>Schedule 1</u> hereto, or such other consideration agreed upon by the Company.
- 3. <u>Representations and Warranties of the Company</u>. The Company represents and warrants, as of the date of this Agreement, that:
  - 3.1. <u>Organization, Standing and Qualification</u>. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has full corporate power and authority to own, lease and operate its property and assets and to conduct its business as proposed to be conducted by it. The Company has all requisite corporate power and authority to enter into and perform its obligations under this Agreement and to carry out the transactions contemplated by this Agreement. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a material adverse effect on the Company.
  - 3.2. <u>Capitalization</u>. The authorized capital stock of the Company as of , 2017, consisted of 100,000 shares of Common Stock, of which were issued and outstanding. As of , 2017, up to 12,500 shares of Common Stock may be acquired from the Company pursuant to options, warrants, convertible securities or other agreements.
  - 3.3. Validity of Shares. The Common Stock, when issued, sold and delivered in accordance with

1
-

the terms of this Agreement, will be duly and validly issued, fully paid and non-assessable.

- 3.4. <u>Authorization; Approvals</u>. All corporate action on the part of the Company necessary for the authorization, execution, delivery and performance of all its obligations under this Agreement and for the authorization, issuance and delivery of the Common Stock has been (or will be) taken prior to the Closing. This Agreement, when executed and delivered by or on behalf of the Company, will constitute the valid and legally binding obligation of the Company, legally enforceable against the Company in accordance with its terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance or other laws of general application relating to or affecting the enforcement of creditors' rights generally or (b) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies. The Company has obtained or will obtain prior to the Closing, all necessary consents, authorizations, approvals and orders, and has made all registrations, qualifications, designations, declarations or filings with all federal, state or other relevant governmental authorities required on the part of the Company to be made prior to the Closing in connection with the consummation of the transactions contemplated by this Agreement.
- 3.5. <u>No Conflict with Other Instruments</u>. The execution, delivery and performance of this Agreement will not result in any violation of, be in conflict with, or constitute a default under any terms or provision of: (a) the Company's Certificate of Incorporation, as amended; (b) any judgment, decree or order to which the Company is a party; (c) any agreement, contract, understanding, indenture or other instrument to which the Company is a party, the effect of which would give rise to a material adverse effect on the Company; or (d) any statute, rule or governmental regulation applicable to the Company.
- 3.6. <u>Fees and Commissions</u>. The Company has not retained, or otherwise authorized to act, any finder, broker, agent, financial advisor or other intermediary (each, an "<u>Intermediary</u>") in connection with the transactions contemplated by this Agreement and the Company shall indemnify and hold harmless the Investors from liability for any compensation to any Intermediary retained or otherwise authorized to act by, or on behalf of, the Company, and the fees and expenses of defending against such liability or alleged liability.
- 4. <u>Anti-dilution</u>. In the event that, between , 2017 and 2018, the Company issued or issues additional securities at a purchase price of less than \$1,142.86 per share of common stock of Common Stock (a "<u>Dilutive Issuance</u>"), the Investor will be issued additional shares of Common Stock in accordance with the following formula:

Where:

NS = The number of shares of Common Stock the Investor will receive in addition to the shares issued under this Agreement;

CS = The number of shares of Common Stock issued to the Investor under this Agreement;

A = The number of shares of Common Stock deemed to be outstanding immediately prior to a Dilutive Issuance. This includes all outstanding Common Stock, all outstanding preferred shares on an as-converted basis, all outstanding options on an as-exercised basis and all other securities convertible into Common Stock;

B = The aggregate consideration received by the Company with respect to a Dilutive Issuance, divided by\$1,142.86; and

2

C = The number of new shares of Common Stock issued in a Dilutive Issuance.

The Investor's rights under this Section 4 shall terminate upon the consummation of an initial public offering of the Company's equity securities and the listing of the Company's equity securities on a national securities exchange.

- 5. <u>Representations and Warranties of the Investors</u>. Each Investor, severally and not jointly, represents and warrants, as of the date hereof, that:
  - 5.1. <u>Authorization</u>. The Investor has full power and authority to enter into this Agreement. This Agreement, when executed and delivered by the Investor, will constitute a valid and legally binding obligation of the Investor, enforceable against the Investor in accordance with its terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or fraudulent conveyance and any other laws of general application relating to or affecting the enforcement of creditors' rights generally or (b) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.
  - 5.2. <u>Purchase Entirely for Own Account</u>. The Investor understands that the shares of Common Stock (the "Shares") to be acquired by the Investor are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Shares as principal for its own account and not with a view to or for distributing or reselling such Shares or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Shares in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Shares in violation of the Securities Act or any applicable state securities law. The Investor is acquiring the Shares hereunder in the ordinary course of its business.
  - 5.3. <u>Disclosure of Information</u>. The Investor has had an opportunity to discuss the Company's, business, management, financial affairs and the terms and conditions of the offering of the Shares with the Company's management and has had an opportunity to review the Company's facilities, and the Investor has been furnished with copies of documents relating thereto that the Investor has requested. The foregoing, however, does not limit or modify the representations and warranties of the Company in Section 2 of this Agreement or the right of the Investors to rely thereon.
  - 5.4. Lack of Liquidity. The Investor is presently able (a) to bear the economic risk of the Investor's investment in the Shares, (b) to hold the Shares for an indefinite period of time and (c) to afford a complete loss of the Investor's investment. The Investor has sufficient liquid assets so that the illiquidity associated with the Investor's investment in the Shares will not cause any financial difficulties for the Investor or affect the Investor's ability to provide for the Investor's current needs and possible financial contingencies. The Investor is able to bear the high degree of economic risk of this investment including, but not limited to, the possible complete loss of Investor's entire investment and the limited transferability of the Shares, which may make liquidation of this investment impossible for the indefinite future. The Investor's commitment to speculative investments (including the investment by the Investor in the Shares) is reasonable in relation to the Investor's net worth or investment portfolio.
  - 5.5. <u>Knowledge and Experience</u>. The Investor has such knowledge and experience in financial and business matters that the Investor is capable of evaluating the merits and risks of a speculative investment which involves a high degree of risk of loss of the entire investment,

3

such as an investment in the Shares, and of making an informed investment decision with respect thereto.

- 5.6. <u>Restricted Securities</u>. The Investor understands that the Shares have not been, and will not be, registered under the Securities Act of 1933, as amended (the "<u>Securities Act</u>"), by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Investor's representations as expressed herein. The Investor understands that the Shares are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, the Investor must hold the Shares indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities or an exemption from such registration and qualification requirements is available. The Investor acknowledges that the Company has no obligation to register or qualify the Shares for resale. The Investor further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Shares and on requirements relating to the Company which are outside of the Investor's control, and which the Company is under no obligation and may not be able to satisfy.
- 5.7. <u>No Public Market</u>. The Investor understands that no public market now exists for the Shares and that the Company has made no assurances that a public market will ever exist for the Shares.
- 5.8. <u>Legends</u>. The Investor understands that the Shares and any securities issued in respect of or exchange for the Shares may bear, in addition to any legend required by the securities laws of any state to the extent such laws are applicable to the Shares represented by the certificate so legended, a

#### legend similar to the following:

- 5.8.1. "THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "<u>SECURITIES ACT</u>"), AND HAVE BEEN ISSUED IN RELIANCE ON AN EXEMPTION FROM REGISTRATION PROVIDED FROM REGULATIONS UNDER THE SECURITIES ACT. THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE OFFERED OR SOLD, DIRECTLY OR INDIRECTLY, EXCEPT (A) PURSUANT TO AND IN CONFORMITY WITH (I) AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR (II) ANY THEN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS UNDER THE SECURITIES ACT AND (B) PURSUANT TO AND IN CONFORMITY WITH ANY APPLICABLE STATE SECURITIES OR BLUE SKY LAWS. OTHER THAN PURSUANT TO AND IN CONFORMITY WITH AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT, NO SUCH OFFER OR SALE OF THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY BE MADE UNLESS, IF REQUESTED BY IT, BIOXCEL THERAPEUTICS, INC. HAS RECEIVED A WRITTEN LEGAL OPINION OF COUNSEL (SUCH COUNSEL AND OPINION REASONABLY ACCEPTABLE TO IT) TO THE EFFECT THAT SUCH OFFER OR SALE DOES NOT VIOLATE THE SECURITIES ACT OR ANY APPLICABLE STATE SECURITIES OR BLUE SKY LAWS."
- 5.9. Accredited Investor. The Investor is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act.
- 5.10. <u>Foreign Investors</u>. If the Investor is not a United States person (as defined by Section 7701(a)(30) of the Code), the Investor hereby represents that it has satisfied itself

#### 4

as to the full observance of the laws of its jurisdiction in connection with any invitation to subscribe for the Shares or any use of this Agreement, including (a) the legal requirements within its jurisdiction for the purchase of the Shares, (b) any foreign exchange restrictions applicable to such purchase, (c) any governmental or other consents that may need to be obtained and (d) the income tax and other tax consequences, if any, that may be relevant to the purchase, holding, redemption, sale or transfer of the Shares. The Investor's subscription and payment for and continued beneficial ownership of the Shares will not violate any applicable securities or other laws of the Investor's jurisdiction.

- 5.11. <u>No General Solicitation</u>. Neither the Investor, nor any of its officers, directors, managers, employees, agents, stockholders, members or partners has, either directly or indirectly, including through a broker or finder (a) engaged in any general solicitation or, (b) published any advertisement in connection with the offer and sale of the Shares.
- 5.12. Exculpation Among Investors. The Investor acknowledges that it is not relying upon any person, other than the Company and its officers and directors, in making its investment or decision to invest in the Company. The Investor agrees that neither any Investor nor the respective controlling persons, officers, directors, partners, agents or employees of any Investor shall be liable to any other Investor for any action heretofore taken or omitted to be taken by any of them in connection with the purchase of the Shares.
- 5.13. <u>Residence</u>. If the Investor is an individual, then the Investor resides in the state, province or other jurisdiction identified in the address of the Investor set forth on <u>Schedule 1</u>; if the Investor is a partnership, corporation, limited liability company or other entity, then the office, or offices of the Investor in which its principal place of business is located is identified in the address or addresses of the Investor set forth on <u>Schedule 1</u>. The Investor is a citizen of the United States of America or otherwise qualifies as a holder of stock of an S corporation under the Code.
- . [Registration Rights. If, at any time after the Closing, the Company shall propose to file with the Commission a registration statement under the Securities Act (whether for itself or in connection with a sale of securities by any other stockholder) other than on Form S-1 in connection with the Company's IPO (as defined herein), Forms S-4 or S-8 (or any successor to such forms), the Company shall give notice to each Investor and include in such registration statement (and the prospectus included therein) all or any part of the Shares that such Purchaser requests to be registered; provided, however, that the Company shall not be required to register the resale of any Shares pursuant to that are eligible for resale pursuant to Rule 144 under the Securities Act without any requirement for the Company to maintain current public information and without any limitation on volume or manner of sale.]
- 7. [<u>Reports Under Exchange Act</u>. With a view to making available to the Investor the benefits of Rule 144 and any other rule or regulation of the Commission that may at any time permit the Investor to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:
  - 7.1. make and keep available adequate current public information, as those terms are understood and defined in Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;
  - 7.2. use commercially reasonable efforts to file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Securities Exchange Act of 1934, as amended (the "Exchange Act") (at any time after the Company has become subject to such reporting requirements); and
  - 7.3. furnish to the Investor, so long as the Investor owns any Shares, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies); and (ii) such other information as may be reasonably requested in availing the Investor of any rule or regulation of the Commission that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).]
- 8. <u>Lock-Up Agreement</u>. Investors agree that, if Company completes an IPO (the "IPO") on or before December 31, 2018, Investors will enter into a lockup agreement for the benefit of such underwriter(s) in accordance with this Section (the "Lock-Up Agreement"). Pursuant to such Lock-Up Agreement, Investors will agree that they shall not, during the period beginning on the date of the prospectus for the delivery of shares of Common

Stock pursuant to the IPO and ending either (i) one hundred eighty (180) days thereafter, or (ii) if any Company director, executive officer or stockholder is subject to any lock-up agreement that ends on a date earlier than one hundred eighty (180) days after the date of the prospectus for the delivery of shares of Common Stock pursuant to the IPO, such earlier date: (a) offer, pledge, sell, announce the intention to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, any shares of Common Stock; (b) enter into any swap or other arrangement that transfers to another Person, in whole or in part, any of the economic consequences of ownership of shares of Common Stock; or (c) make any demand for, or exercise any right with respect to, the registration of any shares of Common Stock; in any case, whether any such transaction is to be settled by delivery of shares of Common Stock or other securities, in cash or otherwise. In addition, upon the Closing and prior to the earlier of (x) the effectiveness of the restrictions set forth in the Lock-Up Agreement, or (y) December 31, 2018, Investors agree that it shall not transfer or dispose of any shares of Common Stock (other than pursuant to this Agreement) unless and until the proposed transferee(s) has agreed in writing to be bound by this Section with respect to the shares of Common Stock acquired by such transferee. No transfer in violation of the preceding sentence shall be of any force or effect, and no such transfer shall be made or recorded on the books of Company. Investor acknowledges that its covenants in this Section are a material inducement for Company to enter

5

into this Agreement and to consummate this transaction.

9. <u>Modifications; Waiver Notices</u>. All notices, requests, consents and other communications herein shall be in writing and shall be deemed to be delivered (i) on the date delivered, if personally delivered; (ii) on the business day after the date sent, if sent by recognized overnight courier service and (iii) on the fifth day after the date sent, if mailed by first-class certified mail, postage prepaid and return receipt requested , as follows, or to such other addresses as each of the parties hereto may provide from time to time in writing to the other parties:

If to the Company:

BioXcel Therapeutics Inc. 780 East Main Street Branford, Connecticut 06405 Attention: Company Secretary

If to the Investor(s):

At their respective addresses set forth in <u>Schedule 1</u> hereto.

- 10. <u>Modifications; Waiver</u>. Neither this Agreement nor any provision hereof may be changed, waived, discharged or terminated orally or in writing, except that any provision of this Agreement may be amended and the observance of any such provision may be waived (either generally or in a particular instance and either retroactively or prospectively) with (but only with) the written consent of (a) the Company and (b) the holders of at least a majority of the Shares, provided, that, in the event that any modification, amendment or waiver of any terms of this Agreement that materially adversely affects the obligations and/or rights of an Investor hereunder in a manner materially different than other Investors hereto, such modification, amendment or waiver shall also require the written consent of the adversely affected Investor.
- 11. <u>Entire Agreement; Aggregation</u>. This Agreement, together with the schedule attached hereto and made a part hereof contains the entire agreement between the parties with respect to the transactions contemplated hereby, and supersedes all negotiations, agreements, representations, warranties, commitments, whether in writing or oral, prior to the date hereof.
- 12. <u>Successors and Assigns</u>. Except as otherwise expressly provided in this Agreement, all of the terms of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective successors, assigns and permitted transferees of the parties hereto.
- 13. Execution and Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, and all such counterparts together shall constitute one instrument.
- 14. <u>Governing Law and Severability</u>. This Agreement shall be governed by the internal laws of the State of Connecticut, without regard to principles of conflicts of law. In the event any provision of this Agreement or the application of any such provision to any party shall be held by a court of competent jurisdiction to be contrary to law, the remaining provisions of this Agreement shall remain in full force and effect.
- 15. <u>Headings</u>. The descriptive headings of the sections hereof and the schedule hereto are inserted

6

for convenience only and do not constitute a part of this Agreement.

[Signature Pages Follow]

7

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

BIOXCEL THERAPEUTICS, INC.

	Vimal Mehta, CEO	
	INVESTOR(S)	
	Name:	
	By:	
	8	
	SCHEDULE 1 <u>Investors</u>	
Name and Address	Purchase Price	Number of Shares
	9	

# **Consent of Independent Registered Public Accounting Firm**

Board of Directors and Shareholder BioXcel Corporation

We hereby consent to the use in the Prospectus constituting a part of this Registration Statement of our report dated November 10, 2017, relating to the financial statements of BioXcel Therapeutics, Inc. (the carved-out operations of certain assets and liabilities of BioXcel Corporation) as of December 31, 2016 and 2015 and for each of the years then ended, which is contained in that Prospectus. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ BDO USA, LLP

Woodbridge, New Jersey November 10, 2017