UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-38410

BioXcel Therapeutics, Inc

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-1386754**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
555 Long Wharf Drive New Haven CT	**06511**
(Address of principal executive offices)	(Zip Code)

(475) 238-6837
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Small reporting company ☐
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of the registrant's common stock, $0.001 par value per share, outstanding at November 7, 2018 was 15,645,545.

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BIOXCEL THERAPEUTICS, INC.

BALANCE SHEETS

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

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 47,122	$ 887
Prepaid expenses and other current assets	467	3
Due from Parent	49	—
Total current assets	47,638	890
Deferred offering expenses	—	461
Equipment, net	177	4
Other assets	51	—
Total assets	**$ 47,866**	**$ 1,355**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 1,213	$ 444
Accrued expenses	830	1,015
Payable to Parent for services	—	67
Note payable to Parent	—	371
Due to Parent	—	440
Total current liabilities	2,043	2,337
Total liabilities	**2,043**	**2,337**
Stockholders' equity (deficit)		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value, 50,000,000 shares authorized; 15,645,545 and 9,907,548 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	16	10
Additional paid-in-capital	62,452	3,458
Accumulated deficit	(16,645)	(4,450)
Total stockholders' equity (deficit)	45,823	(982)
Total liabilities and stockholders' equity (deficit)	**$ 47,866**	**$ 1,355**

The accompanying notes are an integral part of these financial statements.

BIOXCEL THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	$ —	$ —	$ —	$ —
Operating costs and expenses				
Research and development	3,821	619	8,540	1,264
General and administrative	1,298	298	4,109	747
Total operating expenses	5,119	917	12,649	2,011
Loss from operations	(5,119)	(917)	(12,649)	(2,011)
Other income				
Dividend and interest income, net	232	—	454	—
Net loss	$ (4,887)	$ (917)	$ (12,195)	$ (2,011)
Net loss per share attributable to common stockholders/ Parent basic and diluted	$ (0.31)	$ (0.10)	$ (0.86)	$ (0.21)
Weighted average shares outstanding - basic and diluted	15,645,545	9,483,318	14,228,192	9,483,318

The accompanying notes are an integral part of these financial statements.

BIOXCEL THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS

(amounts in thousands)
(unaudited)

	Nine months ended September 30,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,195)	$ (2,011)
Reconciliation of net loss to net cash used in operating activities		
Depreciation and amortization	9	1
Stock-based compensation expense	2,949	516
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(515)	(9)
Accounts payable and accrued expenses	584	405
Net cash used in operating activities	(9,168)	(1,098)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of equipment	(182)	—
Net cash used in investing activities	(182)	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net	56,512	751
Net Parent Investment	—	214
Payable to Parent for services	(67)	88
Due to Parent	(489)	430
Note Payable — Parent	(371)	369
Net cash provided by financing activities	55,585	1,852
Net increase in cash and cash equivalents	46,235	754
Cash and cash equivalents, beginning of the period	887	—
Cash and cash equivalents, end of the period	$ 47,122	$ 754
Supplemental cash flow information:		
Interest paid	$ 1	$ —
Supplemental disclosure of non-cash Financing Activity:		
Deferred issuance costs reclassified to additional paid-in-capital upon completion of initial public offering.	$ 461	$ —
Reclassification of net Parent Investment in the Company to accumulated deficit.	$ —	$ 440

The accompanying notes are an integral part of these financial statements.

BIOXCEL THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

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

Note 1. Organization and Principal Activities

BioXcel Therapeutics, Inc. (the "Company" or "BTI") is a clinical stage biopharmaceutical company utilizing novel artificial intelligence-based approaches 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 majority-owned subsidiary of BioXcel Corporation ("BioXcel" or "Parent") and was incorporated under the laws of the State of Delaware on March 29, 2017. The Company's principal office is in New Haven, Connecticut. Unless otherwise indicated or the context requires otherwise, references in this report to "we," "our," "us" and similar expressions refer to BioXcel Therapeutics, Inc.

The unaudited financial information for the three and nine months ended September 30, 2018 and 2017 is presented on the same basis as the financial statements included in the Company's registration statement on Form S-1 relating to its initial public offering of its common shares.

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") have been contributed to the Company from the Parent pursuant to a contribution agreement.

Note 2. Initial Public Offering

On March 7, 2018, the Company's registration statement on Form S-1 relating to its initial public offering of its common shares (the "IPO") was declared effective by the Securities and Exchange Commission ("SEC"). The IPO closed on March 12, 2018, and the Company issued and sold 5,454,545 common shares at a public offering price of $11.00 per share. Gross proceeds totaled $60,000 and net proceeds totaled $54,102 after deducting underwriting discounts and commissions of $4,200 and other offering expenses of approximately $1,698.

In connection with and effective upon the completion of its IPO, the Company effectuated a 237 to one stock split. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements have been adjusted retroactively, where applicable, to reflect the stock split.

Also, in connection with the completion of its IPO, the Company amended its articles of incorporation to authorize the issuance of up to 50,000,000 shares of common stock with a par value of $.001 each and 10,000,000 shares of preferred stock with a par value of $.001 each.

Note 3. Basis of Presentation and Liquidity

Basis of Presentation

The financial statements of the Company for the period through June 30, 2017 are derived by carving out the historical results of operations and historical cost basis of the assets and liabilities associated with the BTI Business that have been contributed to the Company by BioXcel, from the financial statements of BioXcel.

These results reflect amounts specifically attributable to the BTI Business 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 June 30, 2017. 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 7, 2017, or the Services Agreement, pursuant to which BioXcel provides the Company with certain general and administrative and development support services. 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 Parent in the financial statements for periods prior to and post incorporation through June 30, 2017. The financial statements for the nine-month period ended September 30, 2017, include reasonable allocations for assets and liabilities and expenses attributable to the BTI Business.

For the three and nine months ended September 30, 2018, the results are on a stand-alone entity basis. All assets and liabilities contributed by BioXcel to the Company have been recorded at historical book value.

The balance sheet information as of December 31, 2017, was derived from the audited financial statements which include the accounts of BioXcel Therapeutics Inc. but does not include all disclosures required by accounting principles generally accepted in the United States ("GAAP"). The unaudited financial information should be read in conjunction with the financial statements and notes included in the Company's S-1.

Liquidity and Going Concern

In accordance with Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

Management believes that as a result of the proceeds received in connection with its IPO and a review of projected project timing that it has sufficient liquidity to meet its obligations as they come due for at least eighteen months.

Note 4. 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 its financial statements and the accompanying notes. The most significant estimates in the financial statements relate to the fair value of equity awards and valuation allowance related to the Company's deferred tax assets and liabilities. For the nine months ended September 30, 2018 and 2017, the most significant estimates include the valuation of the Parent's common stock, allocation of expenses, assets and liabilities from the Parent. 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.

Unaudited Interim Financial Information

The accompanying unaudited financial statements do not include all of the information and footnotes required by GAAP. The accompanying year-end balance sheet was derived from audited financial statements but does not include all disclosures required by GAAP. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2018, and the results of its operations for the three and nine months ended September 30, 2018 and 2017 and its cash flows for the nine months ended September 30, 2018 and 2017, respectively. The results for the nine months ended September 30, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, any other interim periods or any future year or period.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. As of September 30, 2018, cash equivalents were comprised of money market funds.

Deferred Offering Costs

The Company capitalized certain legal, professional accounting and other third-party fees that were directly associated with in-process equity financings as deferred offering costs until the equity financing was consummated. After consummation of an equity financing, these costs were recorded in shareholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. As of December 31, 2017, the Company recorded deferred offering costs relating to its IPO of $461. The Company's IPO was completed in March 2018, and these costs, as well as additional IPO costs including commissions of $4,200 and an additional $1,237 of other expenses incurred in 2018, were recorded as a reduction to shareholders' equity.

Equipment

Equipment consists of computers and related equipment and furniture that are stated at cost and depreciated using the straight-line method over estimated useful life of 5 years. Leasehold improvements will be amortized over the life of the lease.

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 undiscounted 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 and became effective in August 2017. Prior to the Company adopting its stock-based compensation plan the Parent granted stock options to its employees. As a result, 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.

Both BioXcel and the Company's 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 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 were not publicly traded. Stock awards granted by the Company subsequent to the IPO are valued using market prices at the date of grant.

Stock-based awards to non-employees are re-measured at fair value each financial reporting date until performance is complete.

ASC 718 requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. The Black-Scholes option-pricing model was used as its method of determining fair value. This model is affected by the Company's stock price as well as assumptions regarding a number of subjective variables. These subjective variables include, but are not limited to, the expected stock price volatility over the term of the awards, and

actual and projected employee stock option exercise behaviors. The value of the award 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.

The Company adopted FASB ASU 2016-09 as of January 1, 2018 and has elected to account for forfeitures as they occur, by reversing compensation cost when the award is forfeited.

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 incurred.

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.

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.

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 considering 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 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 potential dilutive securities included outstanding options (for both employees and non-employees) for the three and nine months ended September 30, 2018 and 2017. Such securities have not been included in the loss per share calculation since their impact would be anti-dilutive. There were 2,682,545 and 2,525,811 shares of options that were excluded from the calculation of the loss per share for the three and nine months ended September 30, 2018, respectively. The Company was incorporated on March 29, 2017 and net loss per common share for the three and nine months ending September 30, 2017, was calculated as if the shares to the Parent were issued at formation.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued *ASU 2014-09 Revenue from Contracts with 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 adopted 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. There was no impact to the Company as a result of the adoption.

In February 2016, the FASB issued *ASU 2016-02 Lease Accounting Topic 842*. This ASU requires the Company to record all leases longer than one year on its balance sheet. Under the new guidance, when the Company records leases on its balance sheet 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. There was no impact to the Company as a result of the adoption.

The SEC staff issued Staff Accounting Bulletin ("SAB") 118, which provides guidance on accounting for the tax effects of the U.S. tax reform announced on December 22, 2017 by the U.S. Government commonly referred to as the Tax Cuts and Jobs Act. SAB 118 provides a measurement period that should not extend beyond one year from the U.S. tax reform enactment date for companies to complete the accounting under Accounting Standards Codification ("ASC") 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the U.S. tax reform for which the accounting under ASC 740 is complete. Specifically, the Company revalued its U.S. deferred tax assets and liabilities due to the federal income tax rate reduction from 35 percent to 21 percent. Since the Company has provided a full valuation allowance against its deferred tax assets, the revaluation of the deferred tax assets did not have a material impact on any period presented.

In June 2018 the FASB issued *ASU 2018-07 Compensation - Stock Compensation Topic 718.* This ASU was issued as part of the FASB's simplification initiative. The amendments in this Update expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based

payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, Revenue from Contracts with Customers. The Company is currently assessing the timing of adoption as well as the effects it will have on its financial statements and disclosures.

Note 5. Transactions with BioXcel

The Company has 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 BioXcel's rights, title and interest in BXCL501, BXCL701, BXCL502 and BXCL702, and all of the assets and liabilities associated in consideration for (i) 9,480,000 shares of our common stock, (ii) $1,000 upon completion of an initial public offering, (iii) $500 upon the later of the 12 month anniversary of an initial public 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 an initial public 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. With the completion of the Company's IPO in March 2018, $1 million was charged to Research and Development costs in connection with (ii) above and was paid on April 5, 2018.

We 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. The office space and equipment portion of the Services Agreement ended effectively on April 30, 2018 when the Company moved to new office space to accommodate additional personnel that had been hired. Services to be provided by BioXcel through its subsidiary in India, were originally expected to decrease through June 30, 2019 provided such dates may be extended upon mutual agreement between the parties. The parties are currently discussing extending the term of these services provided however no definitive agreement has been agreed upon as of the date hereof. There can be no assurance that the parties will agree to any extension to the Services Agreement in the future.

On or before December 31, 2019, the Company will 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. The parties are currently discussing extending the product identification and related services that BioXcel would provide however no definitive agreement has been agreed upon as of the date hereof. There can be no assurance that the parties will agree to any extension to the collaborative services agreement in the future.

In connection with the Services Agreement, BioXcel had agreed to provide the Company a line of credit, which was capped at $1,000, or the Total Funding Amount, pursuant to the terms of a grid note, or the Grid Note. The Grid Note was payable upon the earlier of (i) the completion of an initial public offering and (ii) December 31, 2018, together with interest on the unpaid balance of each advance made under the Grid Note, which would 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 December 31, 2017, the Company had drawn down $371 under the Grid Note.

All amounts due to BioXcel under the line of credit, the Grid Note, and for expenses paid on the Company's behalf were paid following the completion of the Company's IPO on March 20, 2018.

Note 6. Equipment

	September 30, 2018	December 31, 2017
	Unaudited	
Computers and related equipment	$ 169	$ 5
Furniture	4	—
Leasehold improvements	14	
	187	5
Accumulated depreciation	(10)	(1)
	$ 177	$ 4

Note 7. Commitments and Contingencies

The Company is required to pay to BioXcel $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 $2,000 in connection with the IPO, (x) the first $1,000 was charged to Research and Development expenses during the three months ended March 31, 2018 and paid to BioXcel on April 5, 2018 and (y) the second $1,000, (i) $500 of which is payable upon the later of the 12 month anniversary of an 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 an 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.

Note 8. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2018	December 31, 2017
	(Unaudited)	
Accrued salaries, benefits and travel related costs	$ 476	$ 79
Professional and consultant fees	113	120
Legal expenses	85	413
Drugs and clinical trial expenses	156	403
	$ 830	$ 1,015

Note 9. Stockholders' Equity (Deficit)

Authorized Capital

The Company is authorized to issue up to 10,000,000 preferred shares with a par value of $0.001 per share. No preferred shares are issued and outstanding.

The Company is authorized to issue up to 50,000,000 shares of common stock with a par value of $0.001 per share. The Company had 15,645,545 shares of common stock outstanding as of September 30, 2018.

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.

Common Stock Issuances

On March 7, 2018, the Company's registration statement on Form S-1 relating to the Company's IPO was declared effective by the SEC. The IPO closed on March 12, 2018, and the Company issued and sold 5,454,545 shares of common stock at a public offering price of $11.00 per share, for gross proceeds of $60,000 and net proceeds of $54,102 after deducting underwriting discounts and commissions of $4,200 and other offering expenses of $1,698.

In January and February 2018, the Company issued 283,452 shares of common stock with an issuance price of $6.88 per share for gross and net proceeds of $1,950.

In October 2017, the Company sold 271,839 shares of common stock with an issuance price of $4.82 per share with gross and net proceeds of $1,311.

In September 2017, the Company sold 155,709 shares of common stock with an issuance price of $4.82 per share with gross and net proceeds of $751.

Note 10. Stock-Based Compensation

Stock Options

The Company's 2017 Stock Incentive Plan (the "2017 Stock Plan") became effective in August 2017 and will expire in August 2027. Under the 2017 Stock Plan, the Company may grant incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards.

As of September 30, 2018, there were 3,462,570 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan. Options granted under the 2017 Stock Plan have a term of ten years with vesting term determined by the board of directors, which is generally four years.

The fair value of options granted during the nine months ended September 30, 2018 was estimated using the Black-Scholes option-pricing model with the following assumptions.

Employees

	(Unaudited) For the Nine Months Ended September 30, 2018
Exercise price per share	$ 0.41 - $ 11.00
Expected stock price volatility	77.12 % - 81.49 %
Risk-free rate of interest	2.68 % - 2.95 %
Fair value of grants per share	$ 5.11 - $ 10.82
Expected Term (years)	4.7 - 7.0

Non-Employees

	(Unaudited) For the Nine Months Ended September 30, 2018
Exercise price per share	$ 0.41 - $ 11.00
Expected stock price volatility	79.03 % - 79.22 %
Risk-free rate of interest	3.04 % - 3.05 %
Fair value of grants per share	$ 5.87 - $ 7.44
Expected Term (years)	8.9 - 9.9

Since the Company recently completed its IPO, it does not have a history of market prices of its common stock and, as such, volatility was estimated using historical volatilities of similar public companies. The expected term of the employee awards is estimated based on the simplified method, which calculates the expected term based upon the midpoint of the term of the award and the vesting period. The Company uses the simplified method because it does not have sufficient option exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term of non-employee awards represents the awards contractual term. The expected dividend yield is 0% as the Company has no history of paying dividends nor does management expect to pay dividends over the contractual terms of these options. The risk-free interest rates are based on the United States Treasury yield curve in effect at the time of grant, with maturities approximating the expected term of the stock options.

The following table summarizes information about stock option activity during the period the Plan was in effect (in thousands, except share and per share data):

Employee Options

	Number of Shares	Weighted Average Exercise Price per Share	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2018	1,813,524	$ 0.65	$ 13,894,762	9.7
Employee options granted	143,148	$ 11.00	$ —	10.0
Outstanding as of March 31, 2018	1,956,672	$ 1.41	$ 17,395,705	9.4
Employee options granted	100,000	$ 10.06	$ 16,100	9.9
Options reclassified from Non-employee	154,178	$ 2.45	$ 1,093,696	9.3
Outstanding as of June 30, 2018	2,210,850	$ 1.87	$ 16,619,436	9.2
Employee options granted	120,000	$ 9.52	$ —	9.9
Options reclassified to Non-employee	(62,094)	$ 0.41	—	—
Outstanding as of September 30, 2018	2,268,756	$ 2.31	$ 13,168,713	9.0
Options vested and exercisable as of September 30, 2018	1,471,041	$ 0.43	$ 10,637,435	8.9

Non-employee Options

	Number of Shares	Weighted Average Exercise Price per Share	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2018	496,515	$ 0.41	$ 3,922,238	9.6
Non-employee options granted	68,256	$ 11.00	$ —	10.0
Non-employee options forfeited	(6,162)	$ 0.41	$ —	—
Outstanding as of March 31, 2018	558,609	$ 1.70	$ 4,820,170	9.5
Non-employee options reclassified to Employee	(154,178)	$ 2.45	$ —	—
Outstanding as of June 30, 2018	404,431	$ 1.42	$ 3,216,507	9.2
Non-employee options granted	37,209	$ 9.20	$ —	9.9
Non-employee options forfeited	(6,162)	$ 0.41	$ —	—
Options reclassified from Employee	62,094	$ 0.41	$ 450,182	8.9
Outstanding as of September 30, 2018	497,572	$ 1.89	$ 3,058,485	9.0
Options vested and exercisable as of September 30, 2018	136,622	$ 0.50	$ 977,546	8.9

The Company granted 468,613 options to purchase shares of common stock during the nine months ended September 30, 2018. No options were exercised during the nine months ended September 30, 2018. There were 696,242 shares available for grant as of September 30, 2018.

The Company recognized stock-based compensation expense under the 2017 Stock Plan of $917 and $2,778 for the three and nine months ended September 30, 2018. The Company recognized stock-based compensation expense under the 2017 Stock Plan of $230 for the three and nine months ended September 30, 2017.

The total grant-date fair value of options was $4,081 and $1,311 for employees and non-employees, respectively, for the nine months ended September 30, 2018.

Unrecognized compensation expense related to unvested awards as of September 30, 2018 was $3,249 for employees and $1,636 for non-employees and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 1.9 years for employees and 1.5 years for non-employees.

BioXcel Charges

BioXcel has granted stock options to its employees under its own Equity Incentive Plan (“BioXcel Plan”). Stock-based compensation expense from the BioXcel Plan is allocated to the Company over the period over which those stock option awards vest and are based the on the percentage of time spent on Company 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.

Share based compensation expense (income), net of forfeitures, recognized by the Company in its statements of operations related to BioXcel equity awards totaled approximately $(27) and $86 for the three months ended September 30, 2018 and 2017, respectively and $172 and $286 for the nine months ended September 30, 2018 and 2017, respectively.

Total share based compensation charges were approximately $889 and $316 for the three months ended September 30, 2018 and 2017, respectively and $2,949 and $516 for the nine months ended September 30, 2018 and 2017, respectively.

Note 11. Income Taxes

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. No income tax liabilities existed as of September 30, 2018 and December 31, 2017 due to the Company's continuing operating losses.

Note 12. Leases

The Company entered into a "Swing Space" agreement on June 21, 2018 to lease approximately 5,300 square feet of office space on the 5th floor (the "5th Floor Lease") of the building located at 555 Long Wharf Drive, New Haven, Connecticut. On August 20, 2018, the Company entered into an agreement to lease approximately 11,040 square feet of space (the "12th Floor Lease")

The term of the 5th Floor Lease is through the earlier of the date the Company conducts business in the 12th Floor space, or April 30, 2019. No base rent is payable during this period, however, the Company is obligated to pay a pro-rata electricity charge each month.

The landlord is required to deliver the 12th Floor premises to the Company as soon as practicable after the current tenant vacates the premises (the "Commencement Date").

The initial term of the 12th floor lease continues from the Commencement Date through the last day of the calendar month immediately following the seventh (7th) anniversary of the date which the earliest of (x) ninety (90) days from the Commencement Date, (y) the date on which Tenant's Work (as defined in the Lease) is substantially completed and (z) the date on which the Company first occupies any portion of the Premises for the conduct of its business (the "Rent Commencement Date").

The Company's improvement costs are expected to aggregate approximately $600.

Future minimum lease payments under this non-cancelable operating lease are as follows as of the Rent Commencement Date:

Lease Year		Amount
1	$	187
2		192
3		215
4		220
5		225
Thereafter		468
	$	1,507

The Company has an option to renew the lease for one additional five-year term at 95% of the then prevailing market rates but not less than the rental rate at the end of the initial lease term.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans to initiate clinical trials for 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.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. “Risk Factors” and elsewhere in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Quarterly Report and our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission, or the SEC, on March 9, 2018. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

All dollar amounts in this discussion and analysis are to the nearest thousand unless otherwise noted.

Overview

We are a clinical stage biopharmaceutical company utilizing novel artificial intelligence-based approaches 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 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.

During the third quarter of 2018, the Company made several advances in the development of its two lead clinical programs, BXCL501, a proprietary sublingual thin film formulation of dexmedetomidine (Dex), and BXCL701, an orally-available systemic innate-immune activator.

(BXCL501)-Neuroscience Program

The Company began planning for a first-in-human pharmacokinetic (bioavailability) and safety study for the sublingual thin film formulation of Dex that is expected to be initiated by the end of 2018 following approval of the investigational new drug (IND) application. A data read-out from this study is expected in the first half of 2019.

In addition, the Company;

- Received valuable feedback and guidance on further development of BXCL501 during a pre-investigational new drug meeting with FDA;
- Appointed a clinical research organization (CRO) to support the company in conducting and managing the pharmacokinetic and safety clinical study;
- Completed manufacturing of Company's proprietary sublingual thin film formulation of Dex, and the drug is available for clinical studies

In June 2018, the Company announced positive results from its Phase 1b pharmacokinetic, or PK safety study using the IV formulation of Dex in healthy elderly subjects. This was the first part of a trial supporting potential dosing strengths for the sublingual thin film for Dex. We also announced the initiation of Phase 1b PK safety study using the IV formulation of Dex in schizophrenia patients and senile dementia of the Alzheimer's type (SDAT) or SADT, patients. We expect to report data from both schizophrenia and SDAT studies during the fourth quarter of 2018.

(BXCL701)-Immuno-Oncology Program-

In September 2018 we filed an IND application with the FDA for a Phase 1b/2 clinical study to evaluate BXCL 701 in combination with pembrolizumab (Keytruda®) in treatment emergent neuroendocrine prostate cancer, (tNEPC). In October we received notice from the FDA that the Company may proceed with its planned human clinical investigation, which we expect to initiate prior to year-end. Data from the pharmacokinetic safety and efficacy study of BXCL701 in tNEPC is expected to be available throughout 2019.

In connection with this trial the Company also:

- Completed manufacturing of BXCL701 drug product, available for clinical studies; and
- Selected a leading CRO to support the company in conducting and managing clinical studies;

Also, in September 2018, we entered an immuno-oncology partnership with Nektar Therapeutics to develop combination of BXCL701, Nektar Therapeutics' NKTR-214 and a checkpoint inhibitor as a potential treatment for pancreatic cancer. Under the terms of the expanded collaboration agreement, the Company will be responsible for initiating and managing the clinical program. The Company and Nektar will share the cost of trials. The primary objectives of the study are to evaluate safety and efficacy of the triplet combination of BXCL701, NKTR-214 and a checkpoint inhibitor for the treatment of patients with unresectable or metastatic pancreatic cancer. Additionally, correlative immune activation markers will also be evaluated in blood and tumor tissue. This trial will commence following approval of an IND application.

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.

Since our inception in March 2017, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and developing product candidates and related intellectual property rights, planning for commercialization, and conducting research and development activities for our product candidates. We do not have any products approved for sale and have not generated any revenue from product sales. Prior to our IPO in March 2018, we funded our operations primarily through the sales of approximately $4.0 million of common shares through private placement and loans from our Parent.

On March 7, 2018, our registration statement on Form S-1 relating to our IPO was declared effective by the SEC. The IPO closed on March 12, 2018 and we issued and sold 5,454,545 shares of common stock at a public offering price of $11.00 per share. Gross proceeds totaled $60.0 million and net proceeds were $54.1 million after deducting underwriting discounts and commissions of $4.2 million and other offering expenses of approximately $1.7 million. All offering costs directly associated with the offering were recorded in stockholders' equity as a reduction of the gross proceeds. The other offering expenses included legal, accounting, printing and filing fees.

To date, we have not generated any revenue, we have incurred net losses and all of our operations have been financed by loans and advances from BioXcel and sales of our common stock. Our net losses were approximately $12.2 million and $2.0 million for the nine months ended September 30, 2018 and 2017, respectively.

Our net losses have resulted from costs incurred in developing the drugs in our pipeline, planning, preparing and conducting 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 not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. We expect to continue to incur significant expenses for at least the next several years as we advance our product candidates from discovery through preclinical development and clinical trials and seek regulatory approval and pursue commercialization of any approved product candidate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates. We also expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the public or private sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2018, we had cash of approximately $47.1 million, which we believe will enable us to fund our operating expenses and capital expenditure requirements for at least eighteen months from the date of this Quarterly Report on Form 10-Q. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

We were incorporated on March 29, 2017, as a wholly-owned subsidiary of BioXcel. Prior to our March 2018 IPO our activities were funded by BioXcel and a series of private placements of shares of our common stock which include the following:

In January and February 2018, we issued 283,452 shares of common stock with an issuance price of $6.88 per share for gross and net proceeds of $1,950.

In October 2017 we sold 271,839 shares of common stock with an issuance price of $4.82 per share with gross and net proceeds of $1,311.

On September 29, 2017, we sold 155,709 shares of common stock with an issuance price of $4.82 per share with gross and net proceeds of $751.

Relationship with BioXcel

We 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) 9,480,000 shares of our common stock, (ii) $1.0 million upon completion of our IPO, (iii) $500.0 upon the later of the 12 month anniversary of our IPO and the first dosing of a patient in the bridging bioavailability/bioequivalence study for the BXCL501 program, (iv) $500.0 upon the later of the 12 month anniversary of our 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 and (v) a one-time payment of $5.0 million within 60 days after the achievement of $50.0 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 our IPO, BioXcel granted 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 our IPO. With the completion of our IPO in March 2018, $1.0 million was charged to Research and Development costs and included in accounts payable in connection with the Contribution Agreement and was paid on April 5, 2018.

We 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. The office space and equipment portion of the Services Agreement ended effectively on April 30, 2018 when the Company moved to new office space to accommodate additional personnel that had been hired. Services to be provided by BioXcel through its subsidiary in India, were originally expected to decrease through June 30, 2019 provided such dates may be extended upon mutual agreement between the parties. The parties are currently discussing extending the term of these services provided however no definitive agreement has been agreed upon as of the date hereof. There can be no assurance that the parties will agree to any extension to the Services Agreement in the future.

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. The parties are currently discussing extending the product identification and related services that BioXcel would provide however no definitive agreement has been agreed upon as of the date hereof. There can be no assurance that the parties will agree to any extension to the collaborative services agreement in the future.

In connection with the Services Agreement, BioXcel agreed to provide us a line of credit, which was capped at $1.0 million, or the Total Funding Amount, pursuant to the terms of a grid note, or the Grid Note. The Grid Note was payable upon the earlier of (i) the completion of an IPO 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.

All amounts due to BioXcel under the line of credit, the Grid Note, and for expenses paid on our behalf were paid to the Parent following the completion of our IPO on March 20, 2018.

Basis of Presentation

For periods prior to 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

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 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. For the nine month period ending September 30, 2017 results include carve-out amounts from our parent for the period January 1, 2017 through June 30, 2017 and as a standalone entity for the period July 1, 2017 through September 30, 2017. For the nine months ended September 30, 2018 the results are on a stand-alone entity basis.

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 clinical and pre-clinical candidates, which includes payments to BioXcel, our Parent.

- employee-related expenses, including salaries, benefits and stock-based compensation expense and travel expenses for employees engaged in research and development functions
- expenses incurred under agreements with contract research organizations, or CROs, and sites that conduct our non-clinical studies and clinical trials
- costs of outside consultants engaged in research and development activities, including their fees, stock-based compensation and travel expenses
- the cost of acquiring, developing and manufacturing pre-clinical and clinical trial materials and lab supplies
- 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, however, beginning January 1, 2018, we have begun assigning costs to our individual development candidates.

Our research and development costs by program for the nine months ended September 30, 2018 are as follows:

BXCL 501	$	3,431
BXCL 701		2,755
BXCL 502		53

BXCL 702	77
Other research and development programs	397
Research and development support services	1,827
Total research and development expenses	$ 8,540

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. However, we do expect that our research and development costs will increase as we plan for and begin clinical trials for our current and future 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 also expect increased administrative costs, including payroll and related expenses, as we continue to increase our headcount to support the expected growth in our business, expand our operations and organizational capabilities 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.

Summary Results of Operations

	(Unaudited)							
	Three months ended September 30,				Nine months ended September 30,			
(amounts in thousands, except percentage)	2018	2017	Change		2018	2017	Change	
Net sales	$ —	$ —	$ —	—	$ —	$ —	$ —	—
Operating costs and expenses								
Research and development	3,821	619	3,202	517 %	8,540	1,264	7,276	576 %
General and administrative	1,298	298	1,000	336 %	4,109	747	3,362	450 %
Total operating expenses	5,119	917	4,202	458 %	12,649	2,011	10,638	529 %
Loss from operations	(5,119)	(917)	(4,202)	458 %	(12,649)	(2,011)	(10,638)	529 %
Other income								
Interest income, net	232	—	232	-	454	—	454	-
Net loss	$ (4,887)	$ (917)	$ (3,970)	433 %	$(12,195)	$ (2,011)	$(10,184)	506 %

Comparison of the Three Months Ended September 30, 2018 and 2017

Research and Development Expense

Research and development expenses for the three months ended September 30, 2018 were $3,821, compared to $619 for the three months ended September 30, 2017. The increase of $3,202 is attributable to the costs described in the table below:

	Three Months Ended September 30,		
	2018	2017	Change
Salaries, bonus & related costs	$ 934	$ 141	$ 793
Non-cash stock-based compensation	679	184	495
Professional research & project related costs	790	71	719
Clinical trials expense	241	—	241
Chemical, manufacturing and controls cost ("CMC")	892	181	711
All other	285	42	243
Total research and development expenses	$ 3,821	$ 619	$ 3,202

Salaries, bonus and related costs increased due to higher bonus accruals, increases in headcount, payroll taxes, recruiting fees and travel related costs.

Non-cash stock-based compensation has increased as a result of options granted to a significantly increased headcount in the six months following our IPO.

Professional research, project related costs, clinical trials expenses and CMC costs increased due to the acceleration of research and development activities.

General and Administrative Expense

General and administrative expenses for the three months ended September 30, 2018 were $1,298, compared to $298 for the three months ended September 30, 2017. The increase of $1,000 is attributable to the costs described in the table below:

	Three Months Ended September 30,		
	2018	2017	Change
Salaries, bonus & related costs	$ 324	$ 83	$ 241
Non-cash stock-based compensation	210	132	78
Professional fees	459	15	444
Insurance	209	—	209
All other	96	68	28
Total general and administrative expenses	$ 1,298	$ 298	$ 1,000

Salaries, bonus and related costs increased due to higher bonus accruals, increases in headcount, payroll taxes, recruiting fees and travel related costs.

Non-cash stock-based compensation has increased as a result of options granted to a significantly increased headcount in the six months following our IPO.

Professional fees increased due to expanding operations and operating as a public company. Higher legal, audit, investor relations, licensing and information technology costs were incurred during the current period.

Insurance costs increased primarily due to Director and Officer liability insurance.

Comparison of the Nine Months Ended September 30, 2018 and 2017

Research and development expenses

Research and development expenses for the nine months ended September 30, 2018 were $8,540, compared to $1,264 for the nine months ended September 30, 2017. The increase of $7,276 is attributable to the costs described in the table below:

	Nine Months Ended September 30,		
	2018	2017	Change
Salaries, bonus & related costs	$ 1,796	$ 455	$ 1,341
Non-cash stock-based compensation	1,890	336	1,554
Professional research & project related costs	1,438	154	1,284
Drug acquisition costs	1,000	—	1,000
Clinical trials expense	834	—	834
Chemical, manufacturing and controls cost ("CMC")	1,036	181	855
All other	546	138	408
Total research and development expenses	$ 8,540	$ 1,264	$ 7,276

Salaries, bonus and related costs increased due to higher bonus accruals, increases in headcount, payroll taxes, recruiting fees and travel related costs.

Non-cash stock-based compensation has increased as a result of options granted to a significantly increased headcount in the six months following our IPO.

Professional research, project related costs, clinical trials expenses and CMC costs increased due to the acceleration of research and development activities.

Drug acquisition expenses included a payment to Bioxcel of $1,000 pursuant to an asset contribution agreement for the BTI business programs.

General and Administrative Expense

General and administrative expenses for the nine months ended September 30, 2018 were $4,109, compared to $747 for the nine months ended September 30, 2017. The increase of $2,362 is attributable to the costs described in the table below:

	Nine Months Ended September 30,		
	2018	2017	Change
Salaries, bonus & related costs	$ 1,024	$ 254	$ 770
Non-cash stock-based compensation	1,059	180	879
Professional fees	1,307	173	1,134
Insurance	473	16	457
All other	246	124	122
Total general and administrative expenses	$ 4,109	$ 747	$ 3,362

Salaries, bonus and related costs increased due to higher bonus accruals, increases in headcount, payroll taxes, recruiting fees and travel related costs.

Non-cash stock-based compensation has increased as a result of options granted to a significantly increased headcount in the six months following our IPO.

Professional fees increased due to expanding operations and operating as a public company. Higher legal, audit, investor relations, licensing and information technology costs were incurred during the current period.

Insurance costs increased primarily due to Director and Officer liability insurance.

Liquidity and Capital Resources

We reported losses of approximately $12,195 and $2,011 for the nine months ended September 30, 2018 and 2017, respectively. At September 30, 2018, the Company had shareholders' equity of $45,823, working capital of $45,595 and cash of $47,122.

We have not yet generated any revenues and we have not yet achieved profitability. 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

We have focused our efforts on raising capital and building the products in our pipeline. Since our inception, and through our recently completed IPO, all our operations have been financed by our Parent, BioXcel, or the sales of our common stock in a series of private placements and a public offering. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and will need to do so in future periods.

Cash Flows

	(Unaudited) Nine Months Ended September 30,	
(in thousands)	2018	2017
Cash provided by (used in) in thousands:		
Operating activities	$ (9,168)	$ (1,098)
Investing activities	(182)	—
Financing activities	55,585	1,852

Operating Activities

For the nine months ended September 30, 2018, net cash used in operating activities was approximately $9,168 which consisted of a net loss of $12,195 partially offset by $2,949 in stock-based compensation and $9 of depreciation. Reductions in accounts payable and accrued expenses of $584 were offset in part by increases in prepaid expenses primarily for insurance premiums and other assets of $515 accounted for the remainder.

For the nine months ended September 30, 2017, net cash used in operating activities was approximately $1,098, which consisted of a net loss of $2,011 partially offset by $516 in stock-based compensation. Increases in accounts payable, reductions in prepaid expense and depreciation accounted for the remainder.

Investing Activities

We purchased servers, computers and related equipment for technical research and for additional headcount during the nine months ended September 30, 2018. In addition, the Company incurred design charges for future space occupancy.

Financing Activities

The net cash provided by financing activities was approximately $55,585 for the nine months ended September 30, 2018 which was mainly attributable to the proceeds from issuance of common stock in our IPO offset in part by repayment of loans to our Parent.

Net cash provided by financing activities for the nine months ended September 30, 2017 was approximately $1,852, which was attributable to investments and loans made by BioXcel.

Operating Capital and Capital Expenditure Requirements

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:

- continue our clinical development of BXCL501 and commence clinical development of 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
- continue 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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, nor do we currently have, any off-balance sheet arrangements as defined under SEC 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.

Our significant accounting policies are described in the notes to the financial statements included in the registration statement on Form S-1. As of September 30, 2018, there have been no material changes to any of the critical accounting policies contained therein.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is set forth in Note 4, “Summary of Significant Accounting Policies,” in the accompanying Notes to Financial Statements included in Item 1of Part 1 of this Quarterly Report.

Quantitative and Qualitative Disclosure About Market Risk

Our balance sheet as of September 30, 2018 includes cash and cash equivalents of $47.1 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 nine months ended September 30, 2018 and 2017, respectively.

We do not believe that our cash has significant risk of default or illiquidity. While we believe our cash and cash equivalents 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.

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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

The market risk inherent in our financial instruments and in our financial position has historically been the potential loss arising from adverse changes in interest rates. As of September 30, 2018 and December 31, 2017, we had cash of $47.1 million and $0.9 million, respectively. As of September 30, 2018, we held our cash in primarily in money market accounts and accordingly, the value of these accounts is subject to fluctuation in interest rates.

We do not engage in any hedging activities against changes in interest rates. We do not have any foreign currency or other derivative financial instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

In connection with the audit of our financial statements for the years ended December 31, 2017 and 2016, our management concluded that we had a material weakness in our internal controls because we lacked adequately designed internal controls over the financial reporting and SEC filing process. The lack of an adequately designed internal control process made it difficult for management to ensure the timely preparation and review of the accounting for certain transactions, especially those that are technically complex, non-routine transactions or transactions subject to management estimates and judgement. In addition, we did not have adequately designed and documented financial close and management review controls to properly detect and prevent certain accounting errors and omitted disclosures in the financial statements and related footnotes. We believe we have addressed this weakness during the quarter ended March 31, 2018 by establishing proper closing procedures involving account reconciliations, engaging a third party to assist us with analyzing technically complex and non-routine transactions, the creation of a larger finance function with additional personnel, including the recruitment of a controller, assistant controller and administrative support personnel.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures are effective.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting other than that describes above.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Quarterly Report on Form 10-Q. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Related to Financial Position and Need for Additional 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 $12.2 million, and $2.0 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had Stockholders' equity of $45.8 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.

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.

Our current cash will be used 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 our IPO and our existing cash 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. 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 our existing cash as of September 30, 2018, and a review of projected project timing, will enable us to fund our operating expenses and capital expenditure requirements for at least eighteen months from the date of this Quarterly Report on Form 10-Q. Our estimate as to how long we expect our existing cash 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 an 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 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, 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 or may restrict its distribution. 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 a 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. They may not perform as required.

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 their use. To date, based on information available in the package insert for Dex, patients treated with Dex have experienced drug-related side effects including hypotension, transient hypertension, bradycardia, dry mouth, acute respiratory distress syndrome, respiratory failure and agitation with hypotension, bradycardia and dry mouth considered serious adverse events. In addition, based on the investigator brochure for Talabostat, patients treated with Talabostat have experienced edema/peripheral swelling, hypotension, dizziness, hypovolemia fatigue, nausea, vomiting, pyrexia rigors and rash with edema and fatigue representing the most frequently observed serious adverse events. 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 or distribution 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 a branded reference drug with the same active ingredient. 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 branded reference drug 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 product 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 drug 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 applicable regulatory requirements, a regulatory agency may:

- 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 states.

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 currently have clinical trial liability insurance for our IV Dex trials. However, we do not have clinical trial liability insurance for our BXCL 701 program. We may be unable to obtain appropriate levels of such insurance. Even if we do secure clinical trial liability insurance for our programs, we may not be able to achieve sufficient levels of such insurance. 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 some of our product candidates, if approved, but any orphan drug designations we receive 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 September 30, 2018 for the treatment of tNEPC.

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 obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation.

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 third-party 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.

As of September 30, 2018, BioXcel owns approximately 60.6% of the economic interest and voting power of our outstanding common stock. As long as BioXcel beneficially controls a majority of the voting power of our outstanding common stock, it will generally be able to determine the outcome of all corporate actions requiring stockholder approval, including 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 Amended Services Agreement dated November 7, 2017, 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.

We continue to depend on BioXcel to provide us with certain services for our business.

Certain administrative services required by us for the operation of our business have historically been provided by BioXcel, including services related to insurance and risk management, accounting and human resources. Under the Services Agreement, BioXcel has provided us with various services and will continue to do so until we are able to build our own capabilities in the transition areas. We believe it has been 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. Virtually all of these administrative services have transitioned to our control. However we may be unable to continue to provide these services

because of financial or other constraints or we may 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 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 our initial public 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 continues to serve in the same respective roles at BioXcel. Two of our four directors currently serve on both our board of directors and the board of directors of BioXcel. Because of the current positions of our executive officer 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 42% and 42%, 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, 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 interest resulting 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 non-compete 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 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. 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 a separation from Bioxcel.

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 are 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.

BioXcel controls a majority of the voting power of our outstanding common stock. As a result, we are 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 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 acquired from BioXcel 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.

Our historical financial information 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. We are a party to two collaboration agreements (Research and Clinical) with Nektar Therapeutics, Inc., or Nektar, relating to Nektar's NKTR-214 compound and BXCL 701. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third party collaborators 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 September 30, 2018, we employed a total of sixteen full-time employees. In addition, we 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 have been expanding our management team to include an operation ramp up of additional technical staff required to achieve our business objectives. We will need to continue 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. Several of 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 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 US patent 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

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, 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 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, 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.

As of September 30, 2018, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 62% 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.

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 the completion of our initial public 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.

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.

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 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. We are authorized to issue up to 10,000,000 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 requires 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.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures in the future, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Our management determined that our disclosure controls and procedures and internal controls were ineffective as of December 31, 2017 and 2016 and if they continue to be ineffective could result in material misstatements in our financial statements.

Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to comply with the rules under the Sarbanes-Oxley Act related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. In connection with the audit of our financial statements for the years ended December 31, 2017 and 2016, our management concluded that we had material weaknesses in its internal controls because we did not have adequately designed internal controls to ensure the timely preparation and review of the accounting for certain complex, non-routine transactions by those with appropriate technical expertise, which was necessary to provide reasonable assurance that our financial statements and related disclosures would be prepared in accordance with generally accepted accounting principles in the United States of America. In addition, we did not have adequately designed and documented financial close and management review controls to properly detect and prevent certain accounting errors and omitted disclosures in the financial statements and related footnotes. We believe we have addressed this weakness by establishing proper closing procedures involving account reconciliations, engaging a third party to assist us with analyzing technically complex and non-routine transactions, the creation of a larger finance function with additional personnel, including the recruitment of a controller, assistant controller and administrative support personnel. This investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or

prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive federal income tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, a permanent reduction to the corporate income tax rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. This Quarterly Report on Form 10-Q does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

Item 6. Exhibits

Exhibit No.	Description
10.1#	Clinical Trial Collaboration Agreement, dated September 21, 2018, by and between BioXcel Therapeutics, Inc. and Nektar Therapeutics
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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* Filed Herewith

\# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934..

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BioXcel Therapeutics, Inc.

Dated: November 9, 2018

By:
/s/ Vimal Mehta
Vimal Mehta
Chief Executive Officer
(Principal Executive Officer)

Dated: November 9, 2018

By:
/s/ Richard Steinhart
Richard Steinhart, Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

EXECUTION VERSION
CONFIDENTIAL

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

CLINICAL TRIAL COLLABORATION AGREEMENT

This **CLINICAL TRIAL COLLABORATION AGREEMENT** (the "***Agreement***") is made and entered into effective as of September 21, 2018 (the "***Effective Date***") by and between BioXcel Therapeutics, a Delaware corporation, headquartered at 780 East Main Street, Branford, CT 06405 ("***BioXcel***"), and Nektar Therapeutics, a Delaware corporation, headquartered at 455 Mission Bay Boulevard South, San Francisco, CA 94158 ("***Nektar***"). BioXcel and Nektar may be referred to herein individually as a "***Party***," or collectively as the "***Parties***."

RECITALS

WHEREAS, BioXcel and Nektar desire to collaborate on one or more clinical trials of a combination therapy using Nektar's IL2-based CD122-biased agonist, known as "***NKTR-214***", BioXcel's small molecule inhibitor of dipeptidyl peptidase 8-9 (DPP8-9) and fibroblast activation protein (FAP), known as "***BXCL701***", and a CPI Compound to be mutually agreed by the Parties;

WHEREAS, Nektar and BMS have previously entered into that certain Strategic Collaboration Agreement with an effective date of April 3, 2018 (the "***SCA***"), for the collaboration on clinical development and commercialization of, *inter alia*, a combination therapy of NKTR-214 and BMS's human monoclonal antibody that binds PD-1 known as "***Nivolumab***"; and

WHEREAS, Nektar has obtained any necessary consent from BMS to enter into this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1.1 "***Affiliate***" shall mean, with respect to a particular Entity, any other Entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such particular Entity, but only for so long as such Entity meets the definition of Affiliate hereunder. As used in this section, the term "controls" (with correlative meanings for the terms "controlled by" or "under common control with") means (a) that an Entity owns, directly or indirectly, more than fifty percent (50%) of the voting stock of another Entity, or (b) that such Entity otherwise has the actual ability to control and direct the management of the other Entity, whether by contract or otherwise.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.2 "***Aggregate Safety Information***" shall mean, with respect to a Party's Single Agent Compound, the (a) safety and toxicity information for such Single Agent Compound that is Combined Therapy Study Data, plus (b) safety and toxicity information from all other clinical trials of such Single Agent Compound, whether alone or in combination with another pharmaceutical agent, in each case including information related to serious adverse events, adverse drug reactions, adverse events, discontinuations due to adverse events and Grade 3 and Grade 4 laboratory abnormalities. Aggregate Safety Information shall be provided by a Party to the other in the same format as is contained in the investigators' brochures prepared by such Party for its Compound in each country where a Combined Therapy Trial will be conducted.

1.3 "***Agreement***" shall have the meaning set forth in the preamble to this Agreement, as it may be amended by the Parties from time to time.

1.4 "***Applicable Law***" shall mean all applicable laws, rules and regulations (whether federal, state or local) that may be in effect from time to time and applicable to conduct under this Agreement, including current Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

1.5 "***Arbitration Matter***" shall mean any disputed matter that relates to or arises out of the validity, interpretation or construction of, or the compliance with or breach of, this Agreement; *provided that* such disputed matter has been considered, but not resolved, by the Executive Officers as set forth in Section 13.3(a). For clarity, no JDC Dispute that is subject to Sections 2.8(a) or 2.8(b), no Publication Dispute nor any other matter requiring mutual agreement of both Parties shall be an Arbitration Matter.

1.6 "***Bioanalysis Plan***" shall mean the bioanalysis plan for any Samples as may be contemplated by a Combined Therapy Trial, Protocol or another subsequent written agreement between the Parties, as described in Section 13.7.

1.7 "***BioXcel***" shall have the meaning set forth in the preamble to this Agreement.

1.8 "***BioXcel Compound***" shall mean BXCL701, as set forth on the attached Exhibit E.

1.9 "***BioXcel Indemnitees***" shall have the meaning set forth in Section 11.1 of this Agreement.

1.10 "***BioXcel Independent Patent Rights***" shall mean any Patent Rights Controlled by BioXcel (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement that Cover the use (whether alone or in combination with other agents), manufacture, formulation, or composition of matter of the BioXcel Compound, but which do not Cover any Collaboration Invention.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.11 "***BioXcel Regulatory Documentation***" shall mean any Regulatory Documentation related to the BioXcel Compound that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

1.12 "***BioXcel Study Data***" shall have the meaning set forth in Section 8.2 of this Agreement.

1.13 "***BioXcel Study Invention***" shall mean any invention or Technology that would be a Collaboration Invention (except for the exclusion set forth therein) *and* that relates to (a) the composition of matter of the BioXcel Compound (and not the Nektar Compound or the CPI Compound), (b) method of manufacture or formulation of the BioXcel Compound (and not the Nektar Compound or the CPI Compound) as a single agent, or (c) a method of use of the BioXcel Compound (and not the Nektar Compound) as a monotherapy or in combination with the CPI Compound (and not the Nektar Compound) or other agents, antibodies or compounds (other than a Collaboration Invention comprising, whether generically or specifically, the use of the CPI Compound (and/or any other antibodies that are designed to selectively bind to PD-1 or PD-L1), the Nektar Compound (and/or any other IL2-based CD122 agonist), and a BioXcel Compound (and/or any other inhibitor of dipeptidyl peptidase 8-9 (DPP8-9) and fibroblast activation protein (FAP))).

1.14 "***BioXcel Study Patent Rights***" shall mean any Patent Rights that are Controlled by BioXcel and Cover any BioXcel Study Invention (and not a Nektar Study Invention or a Combined Therapy Trial Invention) or BioXcel Study Data, excluding BioXcel Independent Patent Rights and BioXcel Technology. For avoidance of doubt, any Patent Rights that Cover both (x) a BioXcel Study Invention and (y) any other type of Collaboration Invention are included within the Combined Therapy Patent Rights.

1.15 "***BioXcel Technology***" shall mean all Technology Controlled by BioXcel (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement related to the BioXcel Compound or the Combined Therapy and necessary for the conduct of the Combined Therapy Trials. For clarity, BioXcel Technology does not include (a) Collaboration Inventions, (b) Study Data, or (c) Combined Therapy Trial Regulatory Documentation.

1.16 "***BMS***" shall mean Bristol-Meyers Squibb Company, a Delaware corporation, headquartered at 345 Park Avenue, New York, New York 10154.

1.17 "***Business Day***" shall mean a day other than Saturday, Sunday or any day on which commercial banks located in New York, NY are authorized or obligated by Applicable Law to close.

1.18 "***Clinical Hold***" shall mean (i) an order issued by the FDA to a Party pursuant to 21 CFR §312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of the Combined Therapy or such Party's Single Agent Compound in the United

States or (ii) an equivalent order to that set forth in (i) issued by a Regulatory Authority other than the FDA in any other country or group of countries.

1.19 "***Collaboration Invention***" shall mean any invention or Technology, whether or not patentable, that is made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together (including by a Third Party in the performance of the Combined Therapy Trial), in the performance of the Combined Therapy Trials, Statistical Analysis Plan or Bioanalysis Plan to be conducted under this Agreement, but excluding any Study Data, or any BioXcel Study Invention or Nektar Study Invention.

1.20 "***Combined Therapy***" shall mean a therapy using the BioXcel Compound, the Nektar Compound and the CPI Compound in combination use as individual formulations, for use in the Field, with or without another agent.

1.21 "***Combined Therapy IND***" shall have the meaning set forth in Section 2.1(b).

1.22 "***Combined Therapy Trial Invention(s)***" shall mean all Collaboration Inventions that are not BioXcel Study Inventions or Nektar Study Inventions. For clarity, Combined Therapy Trial Inventions include any Collaboration Invention comprising, whether generically or specifically, the use of both the Nektar Compound (and/or any other inhibitors of dipeptidyl peptidase 8-9 (DPP8-9) and fibroblast activation protein (FAP)) and a BioXcel Compound (and/or any other IL2-based CD122 agonist), and optionally, the CPI Compound (and/or any other checkpoint inhibitor).

1.23 "***Combined Therapy Patent Right(s)***" shall mean any Patent Rights that are Controlled by either Party that Cover any Combined Therapy Trial Invention or Combined Therapy Study Data, excluding Nektar Independent Patent Rights or BioXcel Independent Patent Rights.

1.24 "***Combined Therapy Study Data***" shall have the meaning set forth in Section 8.2 of this Agreement.

1.25 "***Combined Therapy Trial***" or "***Combined Therapy Trials***" shall have the meaning set forth in Section 2.1(a) of this Agreement.

1.26 "***Combined Therapy Trial Regulatory Documentation***" shall mean any Regulatory Documentation to be submitted for the conduct of the Combined Therapy Trial, but excluding (a) any BioXcel Regulatory Documentation and (b) any Nektar Regulatory Documentation.

1.27 "***Commercially Reasonable Efforts***" means: (a) the carrying out of a Party's obligations or tasks, other than as set forth in clause (b), with a level of efforts and resources consistent with the commercially reasonable practices normally devoted by a similarly situated company, subject to and in accordance with the terms and conditions of this Agreement; and (b) where applied to a Party's efforts to conduct any Combined Therapy Trial under the applicable

Protocol, the level of effort and resources normally devoted by such Party to conduct a clinical trial for a biopharmaceutical product or compound that is owned by it or to which it has rights, which is of similar market potential, profit potential or strategic value and at a similar stage in its development or product life based on conditions then prevailing.

1.28 "***Confidential Information***" shall have the meaning set forth in Section 9.1 of this Agreement.

1.29 "***Control***" or "***Controlled***" shall mean, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.30 "***Cover***" means, with respect to a Patent, that, but for rights granted to a Person under such Patent, the practice by such Person of an invention described in such Patent would infringe a claim included in such Patent, or in the case of a Patent that is a patent application, would infringe a claim in such patent application if it were to issue as a patent. "***Covered***" or "***Covering***" shall have correlative meanings.

1.31 "***CPI Compound***" means a form of cancer treatment which blocks inhibitory checkpoints in the immune system thereby restoring immune system function.

1.32 "***CRO***" means any Third Party contract research organization used to conduct a Combined Therapy Trial, including laboratories and Third Parties used to maintain the Global Safety Database from a Combined Therapy Trial, but, for clarity, excluding clinical trial sites and any Third Parties who are individuals.

1.33 "***Database Lock***" means, with respect to each Combined Therapy Trial, such actions as are taken with approval of the JDC to prevent any modification to the database of Study Data generated in the course of such Combined Therapy Trial.

1.34 "***Disclosing Party***" shall have the meaning set forth in Section 9.1 of this Agreement.

1.35 "***Effective Date***" shall have the meaning set forth in the preamble to this Agreement.

1.36 "***Entity***" means a partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.37 "***Executive Officers***" shall mean the Chief Medical Officer of BioXcel and the Senior Vice President, Global Development & Medical Affairs of Nektar (or their respective designees).

1.38 "***FDA***" shall mean the United States Food and Drug Administration, or any successor agency having the same or similar authority.

1.39 "***Field***" shall mean treatment of patients with pancreatic cancer.

1.40 "***Global Safety Database***" shall mean the database containing serious adverse events, serious adverse drug reactions and pregnancy reports for the Combined Therapy, and shall be the authoritative data source for regulatory reporting and responding to regulatory queries.

1.41 "***Good Clinical Practices***" or "***GCP***" shall mean the standards, practices and procedures set forth in the International Conference on Harmonization guidelines entitled in "Good Clinical Practice: Consolidated Guideline," including related regulatory requirements imposed by the FDA and (as applicable) any equivalent or similar standards in jurisdictions outside the United States, to the extent that such standards are applicable in the jurisdiction in which the relevant Combined Therapy Trial is conducted or required to be followed in the jurisdiction in which Regulatory Authority approval of a product will be sought.

1.42 "***Good Laboratory Practices***" or "***GLP***" shall mean the regulations set forth in 21 C.F.R. Part 58 and the requirements expressed or implied thereunder imposed by the FDA and (as applicable) any equivalent or similar standards in jurisdictions outside the United States.

1.43 "***Good Manufacturing Practices***" or "***GMP***" means the regulations set forth in 21 C.F.R. Parts 210–211, and the requirements thereunder imposed by the FDA, and, as applicable, any similar or equivalent regulations and requirements in jurisdictions outside the United States.

1.44 "***IND***" shall mean (a) an Investigational New Drug Application as defined in the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States; (b) a counterpart of such an Investigational New Drug Application that is required in any other country before beginning clinical testing of a drug in humans in such country, including, for clarity, a "Clinical Trial Application" in the European Union; and (c) all supplements and amendments to any of the foregoing.

1.45 "***Initiation***" shall mean dosing of the first patient in any Combined Therapy Trial.

1.46 "***Manufacture***" or "***Manufacturing***" shall mean manufacturing, processing, formulating, packaging, labeling, holding (including storage), and quality control testing of a Single Agent Compound or the Combined Therapy, in each case so as to be suitable for use in the Combined Therapy Trials under Applicable Law.

1.47 "***Material Safety Issue***" means a Party's good faith belief that there is an unacceptable risk for harm in humans based upon: (i) pre-clinical safety data, including data from animal toxicology studies; or (ii) the observation of serious adverse effects in humans after the CPI Compound, BioXcel Compound or the Nektar Compound, either as a single agent or in combination with another pharmaceutical agent (including as the Combined Therapy), has been administered to or taken by humans, such as during the Combined Therapy Trial.

1.48 "***Nektar***" shall have the meaning set forth in the preamble to this Agreement.

1.49 "***Nektar Compound***" shall mean NKTR-214, as set forth on the attached Exhibit D.

1.50 "***Nektar Indemnitees***" shall have the meaning set forth in Section 11.2 of this Agreement.

1.51 "***Nektar Independent Patent Rights***" shall mean any Patent Rights Controlled by Nektar (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement or the SCA that Cover the use (whether alone or in combination with other agents), manufacture, formulation or composition of matter of the Nektar Compound, but which do not Cover any Collaboration Invention.

1.52 "***Nektar Regulatory Documentation***" shall mean any Regulatory Documentation related to the Nektar Compound that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

1.53 "***Nektar Study Data***" shall have the meaning set forth in Section 8.2 of this Agreement.

1.54 "***Nektar Study Invention***" shall mean any invention or Technology that would be a Collaboration Invention (except for the exclusion set forth therein) *and* that relates to (a) the composition of matter of the Nektar Compound (and not the BioXcel Compound or CPI Compound), (b) method of manufacture or formulation of the Nektar Compound (and not the BioXcel Compound or the CPI Compound) as a single agent, and/or (c) a method of use of the Nektar Compound (and not the BioXcel Compound) as a monotherapy or in combination with the CPI Compound (and not the BioXcel Compound) or other agents, antibodies or compounds (other than a Collaboration Invention comprising, whether generically or specifically, the use of the CPI Compound (and/or any other antibodies that are designed to selectively bind to PD-1 or PD-L1), the Nektar Compound (and/or any other IL2-based CD122 agonist), and a BioXcel Compound (and/or any other inhibitor of dipeptidyl peptidase 8-9 (DPP8-9) and fibroblast activation protein (FAP))).

1.55 "***Nektar Study Patent Rights***" shall mean any Patent Rights that are Controlled by Nektar and Cover any Nektar Study Invention (and not a BioXcel Study Invention or Combined Therapy Trial Invention) or Nektar Study Data, excluding Nektar Independent Patent Rights and Nektar Technology. For avoidance of doubt, any such Patent Rights that Cover both (x) a Nektar

Study Invention and (y) any other type of Collaboration Invention are included within the Combined Therapy Patent Rights.

1.56 "***Nektar Technology***" shall mean all Technology Controlled by Nektar (or its Affiliates) as of the Effective Date or during the Term through efforts outside of this Agreement related to the Nektar Compound or the Combined Therapy and necessary for the conduct of the Combined Therapy Trials. For clarity, Nektar Technology does not include (a) Collaboration Inventions, (b) Study Data, or (c) Combined Therapy Trial Regulatory Documentation.

1.57 "***Party***" or "***Parties***" shall have the meaning set forth in the preamble to this Agreement.

1.58 "***Patent Rights***" shall mean any and all (a) United States or foreign patents; (b) United States or foreign patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon; (c) United States or foreign patents-of-addition, reissues, reexaminations (including *ex parte* reexaminations, *inter partes* reviews, *inter partes* reexaminations, post grant reviews and supplemental examinations) and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates, patent term extensions, or the equivalents thereof; and (d) any other form of government-issued right substantially similar to any of the foregoing, and "***Patent***" shall mean any of the foregoing issued or granted rights.

1.59 "***PD-1***" shall mean programmed cell death protein 1.

1.60 "***PD-L1***" shall mean programmed death-ligand 1.

1.61 "***Person***" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, Entity or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.62 "***Receiving Party***" shall have the meaning set forth in Section 9.1 of this Agreement.

1.63 "***Regulatory Authority***" shall mean the FDA or any other governmental authority outside the United States (whether national, federal, provincial and/or local) that is the counterpart to the FDA, including the European Medicines Agency for the European Union.

1.64 "***Regulatory Documentation***" shall mean, with respect to a product containing the Nektar Compound as monotherapy, the BioXcel Compound as monotherapy or the Nektar Compound and BioXcel Compound in combination use as individual formulations, all submissions to Regulatory Authorities in connection with the development of such product, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with

regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents with respect to clinical data).

1.65 "***Right of Cross-Reference***" shall mean, with regard to a Party, an authorization that permits an applicable Regulatory Authority in a country to rely on to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to such Party's Single Agent Compound (including, in the case of Nektar, the BioXcel IND and the Combined Therapy IND), only to the extent necessary for the conduct of a Combined Therapy Trial in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder, and, except as to information contained in the BioXcel IND relating to the Combined Therapy or the Combined Therapy IND, without the disclosure of such information to such Party.

1.66 "***Samples***" shall mean biological specimens collected from Combined Therapy Trial study subjects (including fresh and/or archived tumor samples, serum, peripheral blood mononuclear cells, plasma, and whole blood for RNA and DNA sample isolation).

1.67 "***Single Agent Compound***" or "***Compound***" shall mean, (a) with respect to BioXcel, the BioXcel Compound, (b) with respect to Nektar, the Nektar Compound, and (c) with respect to the supplier of the CPI Compound, the CPI Compound.

1.68 "***Statistical Analysis Plan***" shall mean the set of analyses of the Study Data for each Combined Therapy Trial conducted hereunder prepared by BioXcel (in consultation with Nektar) and approved by the JDC and shall include safety analyses for the Combined Therapy in each Combined Therapy Trial. The Statistical Analysis Plan document for a Combined Therapy Trial will be agreed to by the JDC before Database Lock and any material amendments thereto will require JDC approval.

1.69 "***Technology***" shall mean information, inventions, discoveries, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results not generally known to the public (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, whether or not patentable, in written, electronic or any other form now known or hereafter developed, materials, data and results, including Regulatory Documentation.

1.70 "***Third Party***" shall mean any Person or Entity other than BioXcel and Nektar and their respective Affiliates.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.71 "***Third Party License Payments***" shall mean any payments (e.g., upfront payments, maintenance payments, milestones, royalties) due to any Third Party under license agreements or other written agreements granting rights to intellectual property owned or controlled by such Third Party to the extent that such rights are necessary for (i) the making, using or importing of a Party's or CPI Compound Supplier's Single Agent Compound for the conduct of the Combined Therapy Trial, or (ii) the conduct of any Combined Therapy Trial.

Additional Definitions. In addition to those terms defined above, definitions for each of the following terms are found in the body of this Agreement as indicated below:

Defined Term	Section
AAA	13.3(b)
Alliance Manager	2.7
Annual Report	9.3
BioXcel IND	2.1(b)
Breaching Party	12.2(a)
CDA	9.1(a)
Co-Chair	2.3
Combined Therapy IND	2.1(b)
Combined Therapy Trial	2.1(a)
CSRs	5.1(a)(xvi)
CRO Agreement	2.4(o)
Cure Period	12.2(a)
Current Report	9.3
Diligence Targets	2.6(a)
Dispute	13.3(a)
Finance Representatives	7.2(a)(i)
Indemnify	11.1
Informed Consent Form (ICF)	2.6(a)
Infringe* or *Infringement	6.3(a)
Initial Trial	2.1(a)
IRBs	9.3(d)
JDC* or *Joint Development Committee	2.3
JDC Dispute	2.8

Licensee	13.10(b)
Losses	11.1
Non-Breaching Party	12.2(a)
Officials	10.9
Operational Matters	2.6(a)
Payment	10.9
Protocol	2.1(a)
Publication Dispute	9.5(b)
Quality Agreement	4.3
Quarterly Patent Costs Report	7.2
Quarterly Report	7.2
Research Agreement	6.1
Results	9.5(b)
SEC	9.3
Safety Data Exchange Agreement	2.2
Site/CRO List	2.6(d)
Study Data	8.1
Supply Agreement	4.4
Term	12.1
Third Party Claim	11.1
Third Party Study Costs	7.1

ARTICLE 2
COLLABORATION SCOPE; GOVERNANCE

2.1 Scope of Collaboration; Governance of Agreement.

(a) The Parties shall, pursuant to this Agreement, collaborate to conduct the following clinical trials (each, a "***Combined Therapy Trial***") (i) a Phase 1/2 clinical trial evaluating the Combined Therapy (the "***Initial Trial***"), and (ii) such other clinical trials evaluating the Combined Therapy as may be mutually agreed upon by the Parties. Each Combined Therapy Trial shall be conducted in accordance with a protocol (each, a "***Protocol***") to be drafted by BioXcel (in consultation with Nektar) and mutually agreed upon by the Parties at a meeting of the JDC. No

Protocol, including the Protocol for the Initial Trial, shall be approved by the JDC unless the corresponding budget is also approved by the JDC either in advance of the approval of the Protocol or contemporaneously with the approval of the Protocol. Any substantive amendments to each Protocol and related budget will be subject to mutual agreement of the Parties at a meeting of the JDC or by written agreement (including by email acknowledgment) of the JDC Co-Chairs without a meeting. A trial overview ("***Trial Overview*** ") for the Initial Trial is attached hereto as Exhibit A, which shall be used by BioXcel for the drafting of the Protocol for the Initial Trial, for submission to the JDC.

(b) The Combined Therapy Trials shall be conducted under either (1) BioXcel's existing IND as of the Effective Date for the BioXcel Compound (the "***BioXcel IND***") or (2) a new IND, for which BioXcel will be the sponsor of record (the "***Combined Therapy IND***").

(i) BioXcel IND. BioXcel shall have complete legal interest in and control of the BioXcel IND. In no event will BioXcel be required to obtain the consent of Nektar to transfer or encumber the BioXcel IND, and BioXcel shall not have any obligation to share with Nektar any consideration received in connection with the sale, license, use or other conveyance of the BioXcel IND. BioXcel shall have complete control as to any Right of Cross-Reference granted by BioXcel to a Third Party with respect to any portion of the BioXcel IND relating to the BioXcel Compound for use as monotherapy or for use in combination with any other molecules (other than for use with the Nektar Compound).

(ii) Combined Therapy IND. Each Party shall have a beneficial one-half interest in such Combined Therapy IND; *provided, however,* that: (i) in no event will either Party be required to obtain the consent of the other Party to transfer or encumber its interest in the Combined Therapy IND; *provided* that (a) the transferee or encumbrance holder agrees to abide by the terms and conditions of this Agreement, (b) any transfer occurs only in connection with, and to the same transferee of, a transfer of all of a Party's rights in its Single Agent Compound, and (c) each Party provide written notice of such transfer or encumbrance to the other Party within thirty (30) calendar days of such transfer or encumbrance; (ii) BioXcel shall be the sole holder of all legal interests in the Combined Therapy IND, and neither Party shall have any obligation to share with the other Party any consideration received in connection with the sale, license or use of its interest in the Combined Therapy IND where permitted by this Agreement; and (iii) neither Party shall be permitted to grant any third Person any Right of Cross-Reference with respect to any portion of the Combined Therapy IND relating to the other Party's Single Agent Compound for use as monotherapy or for use in combination with any other molecules (other than for use with NKTR-214, in the case of Nektar, or BXCL701, in the case of BioXcel, in each case as permitted by this Agreement), except as required by a governmental authority. Each Party shall provide a Right of Cross-Reference to its existing respective IND for its respective Single Agent Compound as necessary to allow the Combined Therapy Trials to be conducted under the Combined Therapy IND. The Parties shall discuss the approach for obtaining for BioXcel a Right of Cross-Reference to the CPI Compound as necessary to allow the Combined Therapy Trials to be conducted under the Combined Therapy IND. For the avoidance of doubt, each Party shall be responsible for

(x) drafting and updating as necessary the investigator's brochure for its respective Single Agent Compound, and (y) filing all necessary Regulatory Documentation to the existing IND for its respective Single Agent Compound, including the submission to such existing IND of serious adverse event and adverse drug reaction cases emerging from any Combined Therapy Trial.

(c) *Information to be Provided by BioXcel.*

(i) BioXcel shall provide Nektar with the following relating to the BioXcel Compound: (i) the latest investigator's brochure (and annual updates), list of ongoing clinical studies and clinically relevant safety information that emerges from other clinical studies, in each case within ten (10) Business Days (or as soon as reasonably practicable) after general distribution of final versions of such documents within BioXcel, and further to the extent any applicable confidentiality obligations relating to other combination therapy trials involving the BioXcel Compound and a Third Party's compound do not prevent BioXcel from sharing such documents with Nektar, (ii) reasonably prompt notice of any material safety related communications with any Regulatory Authority and the substance of such communications regarding any clinical trials of the BioXcel Compound during the Term; (iii) a summary of all new clinically relevant toxicology study data on the BioXcel Compound within ten (10) Business Days (or as soon as reasonably practicable) after generation within BioXcel; and (iv) Aggregate Safety Information from all other clinical trials of the BioXcel Compound (if not provided elsewhere) on an annual basis or as otherwise agreed to by the JDC. Nektar shall use any such data provided pursuant to this Section 2.1(c)(i) solely to evaluate the safety of (x) the BioXcel Compound for use in the Combined Therapy Trials and (y) the Combined Therapy. All such disclosures are Confidential Information of BioXcel.

(ii) BioXcel shall provide Nektar with safety analyses for each Combined Therapy Trial in accordance with the applicable Statistical Analysis Plan. Each Party shall use any such data provided pursuant to this Section 2.1(c)(ii) solely to evaluate the safety of (x) its own Compound for use in the Combined Therapy Trials, (y) the Combined Therapy and (z) as permitted elsewhere in this Agreement. All such disclosures are Confidential Information of both Parties.

(iii) BioXcel shall provide Nektar with safety analyses for the Nektar Compound and, if necessary for Nektar to comply with a contractual obligation existing as of the Effective Date, the CPI Compound, as monotherapy from each Combined Therapy Trial in accordance with the applicable Statistical Analysis Plan. Nektar may use such information relating to the Nektar Compound for any purpose, and all such information and data relating to the Nektar Compound, shall be Confidential Information of Nektar.

(d) *Information to be Provided by Nektar.* Nektar shall provide BioXcel with the following relating to the Nektar Compound: (i) the latest investigator's brochure (and annual updates), list of ongoing clinical studies and clinically relevant safety information that emerges from other clinical studies, in each case within ten (10) Business Days (or as soon as reasonably practicable) after general distribution of final versions of such documents within Nektar, and further

to the extent any applicable confidentiality obligations relating to other combination therapy trials involving the Nektar Compound and/or a Third Party's compound do not prevent Nektar from sharing such documents with BioXcel, (ii) reasonably prompt notice of any material safety related communications with any Regulatory Authority and the substance of such communications regarding any clinical trials of the Nektar Compound; (iii) a summary of all new clinically relevant toxicology study data on the Nektar Compound within ten (10) Business Days (or as soon as reasonably practicable) after generation within Nektar; and (iv) Aggregate Safety Information from all other clinical trials of the Nektar Compound (if not provided elsewhere) on an annual basis or as otherwise agreed to by the JDC. BioXcel shall use any such data provided pursuant to this Section 2.1(d) solely to evaluate the safety of (1) the Nektar Compound for use in the Combined Therapy Trials and (2) the Combined Therapy. As between BioXcel and Nektar, all such disclosures are Confidential Information of Nektar.

(e) If further studies, including toxicity studies, are required or suggested by a Regulatory Authority as a prerequisite for conducting any of the Combined Therapy Trials, then the Parties agree to hold good faith discussions in a timely manner to agree upon a protocol for such studies, each of which will be considered a Combined Therapy Trial and conducted on substantially the same terms as set forth herein (including the cost-sharing provisions of Section 7.1); *provided that*, if the Parties are unable to agree upon a protocol for such study or if the conduct of such study shall cause a delay deemed unsatisfactory by either Party, then any disputed matters precluding agreement shall be referred to the Executive Officers (or their respective designees) for resolution. If the Executive Officers are unable to reach resolution within ten (10) Business Days after such referral to them (and do not mutually agree to an extension of time to arrive at such resolution), then this Agreement shall automatically terminate following the conclusion of any then-active Combined Therapy Trial (unless and until the Protocol for such required/suggested study(ies) is finalized by mutual agreement prior to the completion of such Combined Therapy Trial) and the provisions of Section 12.8 shall apply to any such termination.

2.2 Safety Reporting – Safety Data Exchange Agreement. Within three (3) months of the Effective Date, or as soon as practicable thereafter, and in any event prior to Initiation of the first Combined Therapy Trial, the Parties (under the guidance of their respective safety departments, or equivalents thereof) shall define and finalize their respective responsibilities to protect patients and promote their well-being in connection with the use of the Nektar Compound and the BioXcel Compound in the framework of this Agreement, and to execute a "***Safety Data Exchange Agreement.***" Such Safety Data Exchange Agreement shall include mutually acceptable procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of the Nektar Compound, the BioXcel Compound and the CPI Compound. Such procedures shall be in accordance with, and enable the Parties and their Affiliates, to fulfill, local and international regulatory reporting obligations to government authorities. Furthermore, such agreed procedures shall be consistent with relevant International Council for Harmonization (ICH) guidelines, except where said guidelines may conflict with existing local regulatory safety reporting requirements or Applicable Law, in which case local reporting requirements or

Applicable Law shall prevail. To the extent any provision set forth in the Safety Data Exchange Agreement conflicts with any provision in this Agreement, the provision set forth in the Safety Data Exchange Agreement shall control as related to the exchange and reporting of safety information associated with use of the Nektar Compound, the BioXcel Compound and the CPI Compound, as well as product safety surveillance. In the event that this Agreement is terminated, the Parties agree to implement the necessary procedures and practices to ensure that any outstanding pharmacovigilance reporting obligations are fulfilled.

2.3 Joint Development Committee. Promptly after the Effective Date the Parties shall form a Joint Development Committee (the "***JDC***"). The JDC shall consist of an equal number of representatives of each Party. Each Party shall be responsible for determining the qualifications and substitutions of its JDC members. It is anticipated that each Party's representatives may include experts in finance, clinical development, patient safety and regulatory affairs and CMC. The JDC shall be co-chaired with one chairperson designated by each Party (each, a "***Co-Chair***"). The JDC shall meet at least quarterly or at such other frequency as the JDC agrees (and it may appoint subteams to meet more frequently), provided that either Party through its Co-Chair may request a meeting of the JDC at any time upon five (5) Business Days notice to the other Party, with the understanding that the other Party will use reasonable efforts to comply with such request but such other Party will not be in breach of this Agreement in the event that it is unable to comply with such request but is using reasonable efforts to conduct a JDC meeting as promptly as practicable. JDC meetings shall be held by audio or video teleconference, or face-to-face, as agreed upon by the Parties; provided that face-to-face meetings shall alternate between Branford, CT and San Francisco, CA unless otherwise agreed upon by the Parties. There must be a minimum of two (2) representatives from each Party at any meeting of the JDC. No fewer than five (5) Business Days prior to each meeting, and in any event as soon as reasonably practicable, each Party shall use good faith efforts to disclose to the other Party any proposed agenda items together with appropriate supporting information. The JDC Co-Chairs shall alternate responsibility for preparing and circulating definitive minutes of each meeting of the JDC. Such minutes shall provide a description, in reasonable detail, of the discussions at the meeting, a list of material actions and decisions made by the JDC, a list of action items made by the JDC and a list of material issues not resolved by the JDC. The JDC Co-Chair who drafts the minutes shall provide the other Co-Chair and each Party's Alliance Managers with the initial draft meeting minutes, who shall return the draft with any proposed changes, and this process shall be repeated until a final version of the meeting minutes is agreed upon and signed (or acknowledged as final via email) by the two Co-Chairs. The Parties shall reasonably cooperate to complete and agree upon a final version of meeting minutes within twenty (20) Business Days from the date of the relevant meeting. The final version of the meeting minutes shall be signed (or acknowledged as final via email) by the two Co-Chairs, and each Party shall be provided with a copy of the final meeting minutes for its safekeeping. A reasonable number of additional representatives of a Party may attend meetings of the JDC in advisory capacity with the prior written consent of the other Party; provided that any JDC meetings that includes representatives of either Party who are not JDC members may, at the request of any JDC member, include a closed session consisting of only JDC members and Alliance Managers. All representatives to the JDC or attending JDC meetings shall be subject to confidentiality and nonuse restrictions at least as restrictive as those set forth herein.

2.4 Responsibilities of the Joint Development Committee. Each Party shall use Commercially Reasonable Efforts to keep the JDC informed about activities performed by that Party hereunder. The JDC (or in the absence of a formal JDC meeting the Co-Chairs) shall be responsible for the following:

(a) overseeing the activities of the Parties with respect to the Combination Therapy Trials, and providing a forum for the Parties to discuss, monitor and coordinate all activities and communications regarding the Combined Therapy Trials;

(b) prior to or contemporaneously with the approval of each Protocol, preparing (through the Finance Representatives of the Parties), discussing and approving a budget for each Combined Therapy Trial, and approving any material amendments to any previously approved budget, including reviewing and approving any costs for a given budget of a Combined Therapy Trial that are reasonably anticipated to be greater than ten percent (10%) of the JDC-approved budget;

(c) reviewing (i) the progress of each Combined Therapy Trial, (ii) the proposed plan for medical monitoring and site audits (with BioXcel to take comments of the JDC members to such proposed plan into account) and (iii) the results of such medical monitoring and site audits;

(d) reviewing and approving with respect to each Combined Therapy Trial (i) the applicable Protocol and the Statistical Analysis Plan, and any proposed substantive amendment thereto and (ii) the CRO Agreement(s) and, to the extent provided in Section 2.4(o), proposed material amendments thereto;

(e) reviewing and approving any immunogenicity analysis for each Combined Therapy Trial, including protocol and Entity to do the analysis;

(f) reviewing and approving any Bioanalysis Plan not set forth in the Protocol, and any material amendments thereto;

(g) reviewing and providing timely comments to proposed communication strategies and communications with any Regulatory Authority regarding the conduct of the Combined Therapy Trials and, if applicable, approving such proposed communications and communication strategies;

(h) approving any IND submitted for a Combined Therapy Trial, as well as reviewing material submissions to any such IND in accordance with Article 5;

(i) reviewing any Combined Therapy Trial Regulatory Documentation, or portions thereof, that relate to the Combined Therapy, in accordance with Article 5;

(j) subject to Section 2.6(d), agreeing on the final list of proposed clinical trial sites pursuant to Section 2.6(d), and agreeing on communications to clinical trial sites or IRBs relating to patient safety or early termination/cessation of a Combined Therapy Trial;

(k) appointing working teams, including a clinical execution working team, to be made up of an equal number of representatives from each Party, that will hold telephone discussions at a mutually agreed-upon frequency to review clinical development, patient safety and regulatory issues that arise in the course of the Combined Therapy Trials, and delegating certain decision-making authority to such working teams;

(l) determining the quantities of BioXcel Compound, Nektar Compound, CPI Compound and any co-medications, necessary for the Combined Therapy Trials within a sufficient minimum lead time and coordinating the supply of such quantities by the respective Party in accordance with Article 4 and the Supply Agreement;

(m) reviewing and approving, in advance, any additional analyses of, or that include, the Combined Therapy Study Data proposed by either Party that are not included in the Statistical Analysis Plan; *provided* that, for clarity, such review and approval shall not apply to analyses by a Party of the monotherapy data for its own Compound from a Combined Therapy Trial;

(n) reviewing and approving use of any Samples in accordance with Section 8.5 that are not described in the Protocol and ICF, so long as the JDC remains in force and effect;

(o) for any CROs or Third Party contactors engaged after the Effective Date, reviewing and approving (1) the selection of any such CRO and Third Party contractor (other than individuals in a Party's workforce who are engaged on an independent contractor basis) that has a material role in each Combined Therapy Trial pursuant to Section 2.6(d) and (2) the terms of any such CRO contract or pharmacovigilance contract ("***CRO Agreement***") with a Third Party;

(p) reviewing and approving the template ICF form, template case report form and template clinical site study agreement to be used in a given Combined Therapy Trial;

(q) reviewing and approving any changes that clinical sites or IRBs propose to the risk sections of any ICF describing adverse effects of the Nektar Compound, either alone or in combination with the BioXcel Compound and/or the CPI Compound;

(r) reviewing and approving the countries in which each Combined Therapy Trial will be conducted, as set forth in Section 2.6(d);

(s) approving the final clinical trial report (and/or final statistical analysis in accordance with the Statistical Analysis Plan) from each Combined Therapy Trial; and

(t) discussing any other topics or issues relating to the Combined Therapy Trials that either Party requests that cannot be resolved at the working team level.

2.5 Joint Development Committee Authority.

(a) The JDC shall take action by unanimous consent, with each Party having a single vote, irrespective of the number of its representatives actually in attendance at a meeting. In the absence of a formal meeting, the Co-Chairs shall have decision-making authority for the JDC, so long as any decisions are documented as provided below.

(b) The JDC shall have the right to make only those determinations expressly enumerated as decisions of the JDC in this Agreement; *provided that* such determinations are documented in the written minutes signed (or acknowledged as final via email) by the JDC Co-Chairs.

(c) Notwithstanding anything to the contrary in this Agreement, the JDC will have no power (i) to amend this Agreement, the Quality Agreement or the Supply Agreement, or (ii) to modify either Party's obligations with regard to the Combined Therapy Trials without such Party's prior written consent; in each case, except by a writing (and that is not the minutes of a meeting) signed by both Parties.

2.6 BioXcel Operational Authority Generally; Diligence Targets.

(a) BioXcel shall, subject to the oversight and determinations of the JDC as provided in Sections 2.3 and 2.4, the terms of the applicable Combined Therapy Protocol, the decisions and guidance of applicable committee(s) and/or working teams, and applicable terms and conditions of this Agreement: (i) manage and be primarily responsible for the conduct of the Combined Therapy Trials; (ii) be the Sponsor and regulatory lead with respect to the Combined Therapy Trials; and (iii) as between the Parties, be the lead with respect to (1) the selection and management of clinical study sites (including budget negotiations with vendors, timelines and contingency planning), subject to Sections 5.1(a)(x) and 5.1(b)(vi) with respect to site selection and subject to Nektar's consent as to the country(ies) where each Combined Therapy Trial will be conducted, (2) conducting clinical study start-up activities, communicating with and obtaining approval from institutional review boards and/or ethics committees, as applicable, and drafting for both Parties' approval the template informed consent form ("***ICF***") for each Combined Therapy Trial, (3) subject recruitment and retention activities, (4) ongoing site monitoring and quality assurance audits, (5) management of safety reporting by contract research organizations and clinical study sites, (6) ongoing medical monitoring, (7) management, monitoring and audits of CROs in connection with each CRO involved in the conduct of the Combined Therapy Trial, and (8) inquiries from clinical study subjects ((1)-(8), collectively, the "***Operational Matters***"). BioXcel shall use Commercially Reasonable Efforts to perform such Operational Matters and to promptly commence and complete the Initial Trial. BioXcel shall use Commercially Reasonable Efforts to meet the following time goals for commencing and completing the Initial Trial: (A) enter into definitive agreements with the CRO and at least one (1) clinical site within

four (4) months of the Effective Date if both the CRO and the clinical site are listed on Exhibit C as of the Effective Date, or enter into the definitive agreements with the CRO and at least one (1) clinical site within four (4) months of JDC approval of the CRO and/or clinical site if either or both are not listed on Exhibit C as of the Effective Date; (B) initiate dosing of the first patient within ninety (90) days of the later of (i) IRB approval, and (ii) delivery of the Nektar Compound to the BioXcel clinical packaging site under the Supply Agreement; (C) enroll the last patient by the later of the following: (i) twenty-four (24) months following the Effective Date, and (ii) the target enrollment date set for the last patient established by the JDC; (D) achieve database lock by the target date established by the JDC; and (E) provide Nektar with the final study report within ninety (90) days of database lock ((A) – (E) collectively the "***Diligence Targets***" and each a ***Diligence Target***"); provided that to the extent any circumstances arise that cause a delay in achieving any Diligence Target that are not within BioXcel's control, the time periods for achieving such Diligence Target shall be extended for the period of time caused by such circumstance that was not within BioXcel's control. The JDC shall set up a mechanism for Nektar or a working team of the JDC to be informed and updated on a timely periodic basis regarding Operational Matters, so that if Nektar has any concerns or disagreements regarding same, the matter can be escalated to the JDC for review. The Diligence Targets are aspirational and for planning purposes only and if it becomes apparent that during the course of this Agreement that any Diligence Target will not be achieved, other than as a result of BioXcel's failure to use Commercially Reasonable Efforts to achieve the same, or BioXcel's breach or negligence, the JDC shall discuss such Diligence Target and the JDC shall establish a reasonable extension of the timeline for achieving such Diligence Target.

(b) Each Party shall be responsible for paying the full amount of any Third Party License Payments that it is obligated to pay pursuant to its agreement with a Third Party on account of the conduct of any Combined Therapy Trial and/or pursuant to Sections 4.1(a) and 4.2(a).

(c) BioXcel shall provide Nektar with access to the safety information and Study Data in accordance with Sections 5.1(a)(xvi) and 5.1(a)(xvii).

(d) Nektar acknowledges that BioXcel, prior to the Effective Date, has, solely with respect to the Initial Trial, (i) selected and entered into agreements with a certain CRO, investigators and Third Party contractors, (ii) identified a number of investigators and clinical trial sites, and (iii) completed study initiation visits, in each case (i) – (iii) for the clinical trial sites listed on Exhibit C, and Nektar approves of such clinical trial sites and CRO. Nektar acknowledges that the CRO Agreements and/or any other documents related to such CROs, investigators, Third Party contractors and clinical trial sites have been made available to Nektar prior to the Effective Date, and Nektar hereby approves the continuation of such agreements on their terms (including the budgets and pricing included therein), and hereby ratifies, on behalf of its appointees to the JDC, the decisions taken by BioXcel prior to the Effective Date that would otherwise be under the purview of the JDC pursuant to this Agreement. For any additional or change in CROs, investigators, Third Party contractors or clinical trial sites proposed after the Effective Date, BioXcel, after discussion with Nektar, will create and provide the JDC with a proposed list of potential clinical trial site(s), CROs, investigators (including IMS grant plan analysis and/or a model

investigator grant budget) and Third Party contractors that may be used to conduct each Combined Therapy Trial, with the final list to be subject to JDC (or Co-Chairs) approval (such JDC-approved list being the "***Site/CRO List***"). Except as otherwise noted in this Section 2.6(d), the proposed Site/CRO List will be provided to the JDC prior to BioXcel initiating site selection negotiations or visits (for sites/investigators) or CRO negotiations (for CROs). BioXcel shall have the authority to select the final clinical trial sites, CROs, investigators and Third Party contractors from the Site/CRO List. In the event that additional sites, CROs, investigators or Third Party contractors need to be added after the initial list is approved, a new list will be created by BioXcel that includes the proposed new sites, CROs, investigators or Third Party contractors and such list will be provided to the JDC for approval by the JDC (or Co-Chairs) per this Section 2.6(d).

2.7 Alliance Managers. Each of the Parties will appoint one representative to act as its Alliance Manager (each, an "***Alliance Manager***"). The role of the Alliance Manager is to act as a primary point of contact between the Parties to assure a successful relationship between the Parties. The Alliance Managers will attend all meetings of the JDC and support the JDC in the discharge of its responsibilities. An Alliance Manager may bring any matter concerning a Party's performance under this Agreement to the attention of the JDC if the Alliance Manager reasonably believes that such attention is warranted. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of such Alliance Manager upon written notice to the other Party's Alliance Manager. Each Alliance Manager will be charged with creating and maintaining a collaborative work environment within the JDC. Each Alliance Manager also will:

(a) be the point of first referral in all matters of dispute resolution in accordance with Section 13.3;

(b) provide a point of communication both internally within its respective Party's organizations and between the Parties regarding the Combined Therapy Trials;

(c) assist in coordinating any collaborative efforts under this Agreement, if any, and any external communications; and

(d) take responsibility for ensuring that JDC activities, such as the conduct of required JDC meetings, occur as set forth in this Agreement and that relevant action items, if any, resulting from such meetings are appropriately carried out or otherwise addressed.

2.8 Dispute Resolution. The representatives of the JDC shall attempt in good faith to reach consensus on all matters properly brought before the JDC. Except as otherwise provided in this Agreement, if, after a good faith, reasonable and open discussion among the members of the JDC, the JDC is unable to agree on a matter that has been properly before it for a period of ten (10) Business Days and that calls for a decision, either Party may refer the dispute (a "***JDC Dispute***") to the Executive Officers for resolution. If the Executive Officers are unable to reach a resolution within ten (10) Business Days of such referral, then the JDC Dispute will be referred to the Chief Executive Officer and Chief Medical Officer of BioXcel or his or her designee and the Chief

Scientific Officer of Nektar or his or her designee for attempted resolution by good faith negotiations within fifteen (15) calendar days after such referral is made. In the event such officers are unable to resolve such JDC Dispute within such fifteen (15) calendar day period then:

(a) if such JDC Dispute regards whether or not to commence a new Combined Therapy Trial, then such Combined Therapy Trial shall not proceed absent mutual agreement of the Parties; provided that any then-active Combined Therapy Trial shall continue;

(b) if such JDC Dispute occurs subsequent to the commencement of a Combined Therapy Trial, and relates to either (1) a material amendment requiring mutual agreement proposed by either Party to an agreed-upon Protocol or Trial Overview, CRO Agreement, Bioanalysis Plan or Statistical Analysis Plan relating to such Combined Therapy Trial or (2) any other matter relating to the strategy, conduct, rationale, or safety of such Combined Therapy Trial, there shall be no decision on the matter and the then existing terms of the applicable Protocol, Trial Overview, CRO Agreement, Bioanalysis Plan or Statistical Analysis Plan relating to such Combined Therapy Trial shall govern. Notwithstanding the foregoing, neither Party shall be required to continue a Combined Therapy Trial if a Party reasonably deems there to be a Material Safety Issue for such Combined Therapy Trial. Each Party's safety committee shall, to the extent practicable, meet and discuss in good faith the Material Safety Issue and if unresolved within fifteen (15) Business Days escalate such Material Safety Issue to the Executive Officers. If the Executive Officers are unable to reach a resolution within ten (10) Business Days of such referral, then the dispute will be referred to the Chief Executive Officer and Chief Medical Officer of BioXcel or his or her designee and the Chief Scientific Officer of Nektar or his or her designee for attempted resolution by good faith negotiations within fifteen calendar days after such referral is made. In the event such officers are unable to resolve the Material Safety Issue, the applicable Combined Therapy Trial shall be discontinued. The Parties shall use reasonable efforts to wind down activities related solely to such discontinued Combined Therapy Trial in accordance with Section 12.8; and

(c) if such JDC Dispute is not otherwise addressed by Section 2.8(a) or (b), the dispute shall be resolved through arbitration as provided for in Section 13.3.

2.9 Conduct. Each Party shall use Commercially Reasonable Efforts to perform and fulfill its respective activities under this Agreement, and shall do so in accordance with Applicable Law, including GCP, GLP and GMP.

2.10 Nektar Performance Restriction related to SCA. Notwithstanding anything in this Agreement to the contrary, nothing in this Agreement shall require Nektar to take any action or refrain from taking any action that would cause Nektar to be in breach of the SCA. As of the Effective Date, Nektar represents that (i) there are no obligations set forth in this Agreement that Nektar would be unable to perform as a result of the SCA, and (ii) Nektar shall in good faith use Commercially Reasonable Efforts in carrying out its obligations under the SCA to avoid causing any material impact on this Agreement. In the event that Nektar becomes aware of any performance obligations of Nektar set forth in this Agreement that Nektar is unable to perform due to its obligations to BMS under the SCA, Nektar will promptly provide written notice to BioXcel,

and the Parties shall through the JDC determine how best to resolve any such conflicts subject to preserving the rights that BioXcel receives under this Agreement, *provided that* (a) any such resolution will be effective only if approved by the JDC; and (b) if no resolution is agreed through the JDC, then Nektar will not be required to take the action or refrain from taking the action that in Nektar's reasonable opinion would cause Nektar to be in breach of the SCA.

ARTICLE 3
LICENSE GRANTS

3.1 Grant by Nektar. Subject to the terms of this Agreement, Nektar hereby grants, and shall cause its Affiliates to grant, to BioXcel (and BioXcel hereby accepts) a non-exclusive, worldwide, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the Nektar Independent Patent Rights, Nektar Technology, and Nektar Regulatory Documentation to use the Nektar Compound, solely to the extent necessary to discharge BioXcel's obligations under this Agreement with respect to the conduct of the Combined Therapy Trials.

3.2 Grant by BioXcel. Subject to the terms of this Agreement, BioXcel hereby grants, and shall cause its Affiliates to grant, to Nektar (and Nektar hereby accepts) a non-exclusive, worldwide, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the BioXcel Independent Patent Rights, BioXcel Technology, and BioXcel Regulatory Documentation to use the BioXcel Compound, solely to the extent necessary to discharge Nektar's obligations under this Agreement with respect to the conduct of the Combined Therapy Trials.

3.3 Sublicensing.

(a) Subject to Section 3.3(b), each Party shall have the right to grant sublicenses under the licenses granted to it under Section 3.1 to Affiliates and, if required for a Third Party to perform its duties with respect to the conduct of the Combined Therapy Trials (and agreed to by the other Party, such consent not to be unreasonably withheld), to Third Parties, solely as necessary to assist a Party in carrying out its responsibilities with respect to the Combined Therapy Trials.

(b) With regard to any such sublicenses permitted and made under this Agreement, (i) such sublicensees, except Affiliates (so long as they remain Affiliates of a Party), shall be subject to written agreements that bind such sublicensees to obligations that are consistent with a Party's obligations under this Agreement including confidentiality and non-use provisions no less restrictive than those set forth in Sections 8.2 and 8.3 and Article 9, and provisions regarding intellectual property that ensure that the Parties will have the rights, title, and interest provided under this Agreement to any intellectual property created by such sublicensee, (ii) each Party shall provide written notice to the other of any such sublicense (and obtain approval for sublicenses to Third Parties); and (iii) the licensing Party shall remain liable for all actions or inactions of its sublicensees.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

3.4 No Implied Licenses. Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any intellectual property of the other Party, including Confidential Information disclosed to it under this Agreement or under any Patent Rights Controlled by the other Party or its Affiliates.

ARTICLE 4
MANUFACTURE AND SUPPLY

4.1 BioXcel Compound.

(a) Manufacture and Supply. BioXcel shall use Commercially Reasonable Efforts to Manufacture or have Manufactured the BioXcel Compound in drug product form in reasonable quantities, within minimum lead times and at the points in time as agreed by the JDC for each Combined Therapy Trial. BioXcel or a Third Party conducting activities on behalf of BioXcel will package, label and distribute the BioXcel Compound for use in the Combined Therapy Trials, with associated costs and expenses (and any related taxes) of such activities to be split between the Parties in accordance with Sections 7.1 and 7.2(a)(ii). The cost of Manufacture and supply (including shipping, taxes and duty, if applicable) of BioXcel Compound for the Combined Therapy Trials shall be borne solely by BioXcel, and BioXcel shall bear the risk of loss for the BioXcel Compound. BioXcel shall also be responsible for the payment of any Third Party License Payments that may be due exclusively on the supply of BioXcel Compound for the Combined Therapy Trials. The BioXcel Compound shall be Manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the BioXcel Compound used by BioXcel for its other clinical trials of the BioXcel Compound. BioXcel shall deliver to Nektar certificates of analysis, and any other documents specified in the Quality Agreement, including such documentation as is necessary to allow Nektar to compare the BioXcel Compound certificate of analysis to the BioXcel Compound specifications.

4.2 Nektar Compound.

(a) Manufacture and Supply of Nektar Compound. Nektar shall use Commercially Reasonable Efforts to Manufacture or have Manufactured the Nektar Compound in drug product form in reasonable quantities, within minimum lead times and at the points in time as agreed by the JDC for each Combined Therapy Trial, and shall supply such Nektar Compound in unlabeled vials to BioXcel or its designee for clinical labeling and packaging, and use in the Combined Therapy Trials. All Nektar Compound supplied to BioXcel shall have expiration dates as mutually agreed by the parties. BioXcel or a Third Party conducting activities on behalf of BioXcel will package, label and distribute the Nektar Compound for use in the Combined Therapy Trials, with associated costs and expenses (and any related taxes) of such activities to be split between the Parties in accordance with Sections 7.1 and 7.2(a)(ii). The cost of Manufacture, supply and distribution (including shipping, taxes and duty, if applicable) of the Nektar Compound to BioXcel shall be borne solely by Nektar, and Nektar shall bear the risk of loss for the Nektar Compound at all times during the Term; except that BioXcel shall bear the risk of loss of the Nektar Compound to the extent that the loss arises or results from the gross negligence or intentional

misconduct of BioXcel or of any Third Party conducting packaging, labeling or distribution activities on behalf of BioXcel. As between Nektar and BioXcel, Nektar shall also be responsible for the payment of any Third Party License Payments that may be due to Third Parties exclusively on the supply of Nektar Compound hereunder for the Combined Therapy Trials. The Nektar Compound shall be Manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the Nektar Compound used by Nektar for its other clinical trials of the Nektar Compound. Nektar shall deliver to BioXcel certificates of analysis, and any other documents specified in the Quality Agreement, including such documentation as is necessary to allow BioXcel to compare the Nektar Compound certificate of analysis to the Nektar Compound specifications, as applicable. The Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to the Nektar Compound in connection with this Agreement. Nektar will provide BioXcel with country-specific customs valuations for the Nektar Compound, which BioXcel must use for deliveries to each country. BioXcel must request these valuations at least [***] ([***]) calendar days prior to each shipment through Nektar's clinical supply organization.

(b) Use of Nektar Compound by BioXcel. BioXcel shall use the quantities of Nektar Compound supplied to it under this Agreement solely as necessary for, and in accordance with, this Agreement and the Protocols, and for no other purpose, including without limitation as a reagent or tool to facilitate its internal research efforts, for any commercial purpose, or for other research unrelated to the Combined Therapy Trials. Except as may be required under this Agreement, a Bioanalysis Plan, or a Protocol, BioXcel shall not perform, and shall not allow any Third Parties to perform, any analytical testing of the quantities of Nektar Compound supplied to it under this Agreement.

4.3 Quality Agreement. No later than the date of the first shipment of Nektar Compound to BioXcel for use in the Combined Therapy Trials, the Parties shall enter into a quality agreement (the "***Quality Agreement***"). The Quality Agreement shall outline the additional roles and responsibilities relative to the quality of BioXcel Compound and Nektar Compound in support of the Combined Therapy Trials. The Quality Agreement shall include the responsibility for quality elements including, by way of example, audits & inspections, sub-contractors and suppliers, change control, OOS results, deviations and investigations required to conduct the Combined Therapy Trials. In addition, the Quality Agreement shall detail the documentation required for each shipment of Nektar Compound supplied to BioXcel or its designee for use in the Combined Therapy Trials. The Quality Agreement shall also indicate whether any required transfer from Nektar to BioXcel of analytical methods will be necessary to support identity testing by BioXcel of the Nektar Compound supplied to BioXcel under this Agreement.

4.4 Supply Agreement. Within sixty (60) days after the Effective Date (or as soon thereafter as practicable), the Parties shall enter into a supply agreement (the "***Supply Agreement***"). The Supply Agreement shall govern forecasting, ordering, expiration dates, procedures for acceptance and rejection and other customary provisions for the supply of the Nektar Compound for the Combined Therapy Trials.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

4.5 Supply of the CPI Compound; Termination and Replacement of this Agreement. Promptly following the Effective Date, the Parties shall agree in writing on the CPI Compound to be used by BioXcel to conduct the Combined Therapy Trials, the terms on which the CPI Compound will be obtained, and which Party shall be responsible for contracting with the supplier of the CPI Compound for such supply, including provisions covering forecasting, ordering, expiration dates, procedures for acceptance and rejection, quality and other customary provisions for the supply of pharmaceutical products for use in clinical trials in the United States. In the event that Nivolumab is mutually agreed by the Parties as the CPI Compound for use in Combined Therapy Trials, then the Parties agree that on written notice from either Party to the other this Agreement shall terminate and be replaced in its entirety with that certain Clinical Trial Collaboration Agreement – Nivolumab, which has been fully negotiated by the Parties, and which both Parties shall both execute and deliver promptly following the termination of this Agreement.

ARTICLE 5
RESPONSIBILITIES

5.1 Specific Responsibilities of the Parties. Subject to the terms of this Agreement, each Party shall use Commercially Reasonable Efforts to (i) supply the quantities of its Compound as needed to conduct a Combined Therapy Trial on a timely basis, with BioXcel packaging, labeling and delivering same to study sites, in accordance with the time frame(s) established by the JDC; (ii) to conduct and complete each Combined Therapy Trial and any Statistical Analysis Plans and Bioanalysis Plans relating thereto on a timely basis in accordance with the Protocol, Bioanalysis Plans, Statistical Analysis Plans and Third Party agreements relating thereto, and (iii) to timely provide Rights of Cross-Reference where required by this Agreement. Each Party shall be responsible for activities assigned to it by the Protocol and/or JDC that such Party is not otherwise obligated to perform by this Agreement, *provided that*, except as set forth in this Agreement, in no event shall either Party be obligated to perform any such assigned activities without its prior written consent (which may be reflected in the minutes of meetings of the JDC or in the Protocol). As of the Effective Date, each Party shall be responsible for the following activities:

(a) Responsibilities of BioXcel. Subject to JDC direction and oversight as provided in Section 2.4 and BioXcel's Commercially Reasonably Efforts, BioXcel shall be responsible for the following activities, subject in each case (except as expressly provided in Section 4.1(a) with respect to the Manufacture and supply of the BioXcel Compound) to the Parties sharing the applicable Third Party Study Costs related to such activities in accordance with Section 7.1:

(i) (A) Manufacturing, packaging and labeling the BioXcel Compound for use in the Combined Therapy Trials, (B) packaging and labeling the vials provided by Nektar of the Nektar Compound and vials provided by the CPI Compound supplier of the CPI Compound for use in the Combined Therapy Trials, and (C) providing the JDC (or a working team designated by the JDC) on a monthly basis with a clinical drug supply forecast for the Nektar Compound and

the CPI Compound and the BioXcel Compound that includes strategy for drug supply overages, drug supply quantity and required delivery dates;

(ii) with the cooperation of Nektar, compiling, amending and filing all necessary Combined Therapy Trial Regulatory Documentation with Regulatory Authority(ies), maintaining and acting as the sponsor of record as provided in 21 C.F.R. 312.50 (and applicable comparable ex-US laws) with responsibility, unless otherwise delegated in accordance with 21 CFR 312.52 (and applicable comparable ex-US laws), for each Combined Therapy Trial and making all required submissions to Regulatory Authorities related thereto on a timely basis;

(iii) with the cooperation of Nektar, and subject to the provisions of Section 9.5, listing any Combined Therapy Trial required to be listed on a public database such as www.clinicaltrials.gov or other public registry in any country in which such Combined Therapy Trial is being conducted in accordance with Applicable Law and in accordance with BioXcel's internal policies relating to clinical trial registration; *provided that* Nektar shall provide BioXcel with written notice of any comments to a proposed listing within ten (10) Business Da**ys** of the date on which BioXcel provides the applicable information to Nektar;

(iv) providing Nektar with reasonable advance notice of scheduled meetings or other material non-written communications with a Regulatory Authority and the opportunity to participate in each such meeting or other non-written communication, to the extent that it relates to the Combined Therapy or the Nektar Compound, and providing Nektar with the opportunity to review, provide comments to BioXcel within ten (10) Business Days on, and, if inconsistent with the applicable Protocol(s) or JDC guidance, approve all submissions and written correspondence with a Regulatory Authority that relates to the Combined Therapy or the Nektar Compound; *provided, however,* in no event shall BioXcel or any Affiliate of BioXcel initiate communications with or respond to any communications initiated by any Regulatory Authority solely with respect to the Nektar Compound without the prior written consent of Nektar and *provided further that* Nektar, if requested, shall step out of any portions of such meetings or other non-written communications with a Regulatory Authority that relate solely to the use of the BioXcel Compound as a monotherapy or in combination with other compounds and BioXcel, if requested, shall step out of any portions of such meetings or other non-written communications with a Regulatory Authority that relate solely to the use of the Nektar Compound as a monotherapy or in combination with other compounds;

(v) providing to Nektar a written summary of meetings or a summary of other non-written communications with a Regulatory Authority within ten (10) calendar days of such meeting or communication, and copies of any official correspondence to or from a Regulatory Authority within two (2) Business Days of receipt or provision, in each case to the extent that it relates to the Combined Therapy or the Nektar Compound (or, to the extent the communication would adversely impact the performance of a Combined Therapy Trial, the BioXcel Compound), and copies of all Combined Therapy Trial Regulatory Documentation that

relate to the Combined Therapy or the Nektar Compound within five (5) Business Days of submission to Regulatory Authorities;

(vi) drafting, and, subject to Sections 2.4 and 2.6(d), providing to Nektar (through the JDC or otherwise) for its review and approval, each Protocol and investigator's brochure for a Combined Therapy Trial, and the related template ICF, template clinical site agreement, Bioanalysis Plan and Statistical Analysis Plan, and any material amendments to each of the foregoing (*provided that* Nektar shall provide BioXcel such approval or rejection within ten (10) Business Days of the date on which BioXcel provides the applicable document to Nektar);

(vii) coordinating with Nektar and providing to the JDC (or a subcommittee designated by the JDC for such purpose) drafts of (1) submissions to the BioXcel IND (if applicable) and/or the Combined Therapy IND (if applicable); and (2) Combined Therapy Trial Regulatory Documentation, or portions thereof, that relate to the Combined Therapy or the Nektar Compound, for JDC review and approval, and providing Nektar with the opportunity to review, comment on and approve all other written correspondence with a Regulatory Authority relating to the Combined Therapy Trials, to the extent such correspondence relates to the Combined Therapy or the Nektar Compound; *provided that* Nektar shall provide BioXcel with written notice of any such comments (and, where applicable, approvals or rejections) within ten (10) Business Days of the date on which BioXcel provides the applicable document to Nektar;

(viii) to the extent necessary for the conduct of any Combined Therapy Trial, providing Nektar a Right of Cross-Reference to the relevant Regulatory Documentation for the BioXcel Compound, provided that, such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement for purposes of conducting any new clinical studies, except that in the case of termination for a Material Safety Issue pursuant to Section 12.4, such Right of Cross-Reference shall remain in effect solely (1) to the extent necessary to permit BioXcel to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (2) as necessary to permit BioXcel to continue to dose subjects enrolled in each Combined Therapy Trial through completion of the applicable Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws;

(ix) managing the operations of the Combined Therapy Trials in accordance with the applicable Protocol, including overseeing compliance by any CRO with the terms of its agreement with BioXcel relating to the Combined Therapy Trial;

(x) subject to Sections 2.4 and 2.6(d), providing to Nektar a list of all proposed clinical trial sites and principal investigator(s) for each Combined Therapy Trial;

(xi) subject to Sections 2.4 and 2.6(d), ensuring that all clinical trial service agreements and clinical trial site agreements (A) contain intellectual property provisions that retain each of the Parties' respective intellectual property rights in the BioXcel Compound, Nektar Compound, and Combined Therapy, and (B) allow for Nektar, as well as BioXcel, to the extent permitted by Applicable Law and any Third Party confidentiality restrictions or obligations,

to audit Combined Therapy Trial study sites for quality assurance and to inspect and copy data, documentation and work products relating to the activities performed by the site, including the medical records of any patient participating in any clinical study; *provided that* should Nektar seek to audit a study site (1) Nektar shall solely bear the cost and expense for such audit, (2) BioXcel shall accompany Nektar to such audit, at date and time mutually agreed upon by the Parties and the applicable study site, and (3) Nektar shall provide BioXcel with a copy of any reports resulting from such audit. This right to inspect and copy data, documentation, and work products of a study site may be exercised at any time during the Term, or such longer period as shall be required by Applicable Law;

(xii) providing Nektar with copies of each final site template ICF (if requested by Nektar);

(xiii) providing Nektar with minutes from any and all external drug safety monitoring boards for the Combined Therapy Trials, if applicable, within two (2) Business Days (or as soon as practicable) after receipt by BioXcel;

(xiv) providing Nektar with updates on the status of the Combined Therapy Trials at each teleconference for the clinical execution working group, or upon Nektar's reasonable request, including information regarding the number and status of study sites, the number of screened subjects (actual to target), the number of randomized subjects (actual to target), the number of dosed, ongoing, discontinued and completed subjects, and any safety updates as contemplated by the applicable Protocol, Section 2.1(c), and/or routinely performed by a Party in its normal course of trial management and reporting;

(xv) subject to the provisions of Section 2.2, owning and being responsible for (or appointing a Third Party reasonably acceptable to Nektar to be responsible for) the maintenance of the Global Safety Database and safety reporting for the Combined Therapy, collecting, evaluating and reporting serious adverse events, other safety data and any further pharmacovigilance information from the Combined Therapy Trials, and providing Nektar with the opportunity to participate in and comment on such pharmacovigilance activities;

(xvi) providing Nektar with access to all safety information (including any updates to the investigator's brochure for the BioXcel Compound) in the Global Safety Database through the provision of case safety reports ("***CSRs***") and listings related to the Combined Therapy or the Nektar Compound during the Combined Therapy Trials in accordance with Section 2.2;

(xvii) analyzing the Study Data in a timely fashion and providing Nektar with access to the Study Data from the applicable Combined Therapy Trial as follows:

(1) pursuant to an appropriate timetable determined by the JDC : (A) sharing with Nektar for review and comment drafts of interim, ongoing and/or final clinical trial reports (and/or statistical analyses in accordance with the Statistical Analysis Plan) from the Combined Therapy Trial and (B) providing the raw Study Data in electronic or other mutually agreed format;

(2) providing Nektar with a report of the safety data;

(3) within approximately six (6) weeks from the completion of the Combined Therapy Trial, provide to Nektar case report forms or patient profiles for all patients in each Combined Therapy Trial;

(4) within sixty (60) calendar days of the creation of a quality checked and closed database for the Combined Therapy Trial, copies of the Form 1572s, financial disclosures and other relevant documents required to meet regulatory requirements related to the Combined Therapy Trial (including any data or documents that may be required to provide Aggregate Safety Information to a Regulatory Authority with respect to the Nektar Compound);

(5) within approximately six (6) weeks of the creation of an electronic quality checked and closed database for the Combined Therapy Trial, an electronic copy of the such database; and

(6) providing Nektar with any programs or SAS codes to be used for the Statistical Analysis Plan for the Combined Therapy Trial;

(xviii) obtaining supplies of any co-medications, to the extent any such co-medications are required for use in any Combined Therapy Trial, and providing to Nektar any information related to each Combined Therapy Trial that is provided to the manufacturer of any co-medication pursuant to Section 9.5 herein within five (5) Business Days after the provision of the information to the manufacturer;

(xix) providing Nektar with any information regarding the pharmacokinetics, efficacy and safety of the Nektar Compound alone or in combination with the BioXcel Compound and/or the CPI Compound;

(xx) providing for the release by a Qualified Person (as such term will be defined in the Quality Agreement), or providing the necessary documentation in support of such quality release, of the BioXcel Compound if such release is required for any Combined Therapy Trial;

(xxi) performing either directly or through Third Parties collection of Samples; and

(xxii) such other responsibilities as may be agreed to by the Parties or determined by the JDC.

(b) Responsibilities of Nektar. Subject to JDC direction as provided in Section 2.4 and Nektar's Commercially Reasonably Efforts, Nektar shall be responsible for the following activities, subject in each case (except as expressly provided in Section 4.2(a) with respect to the Manufacture and supply of the Nektar Compound) to the Parties sharing the applicable Third Party Study Costs related to such activities in accordance with Section 7.1:

(i) manufacturing and supplying unlabeled vials of the Nektar Compound, as further described in Article 4, and providing for the release by a Qualified Person or providing the necessary documentation in support of quality release, of the Nektar Compound if such release is required for the Combined Therapy Trial;

(ii) promptly reviewing and providing comments on and communicating its approval (or rejection) of each Protocol, the Nektar and BioXcel investigator's brochures for each Combined Therapy Trial (as it relates to the Nektar Compound and the Combined Therapy), any template ICF, Bioanalysis Plan and Statistical Analysis Plan, and any amendments to each of the foregoing (provided that Nektar shall provide BioXcel with written notice of any such comments (and, where applicable, approvals or rejections) within ten (10) Business Days of the date on which BioXcel provides the applicable document to Nektar;

(iii) to the extent necessary for the conduct of any Combined Therapy Trial, providing BioXcel a Right of Cross-Reference to the relevant Regulatory Documentation for the Nektar Compound, provided that, except as provided in Section 3.2, such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement for purposes of conducting any new clinical studies, except that in the case of termination for a Material Safety Issue pursuant to Section 12.4, such Right of Cross-Reference shall remain in effect solely (1) to the extent necessary to permit BioXcel to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (2) as necessary to permit BioXcel to continue to dose subjects enrolled in each Combined Therapy Trial through completion of the applicable Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws;

(iv) jointly reviewing, providing comments to BioXcel within [***] ([***]) Business Days on, and (if inconsistent with the applicable Protocol(s)) approving all Combined Therapy Trial Regulatory Documentation and providing BioXcel with copies of Nektar Regulatory Documentation, as both Parties agree is necessary or reasonably expected to be necessary, and is requested by BioXcel, (1) to obtain and maintain the IND for the Combined Therapy Trials and prepare and file any Combined Therapy Trial Regulatory Documentation in accordance with this Agreement, or (2) to comply with Applicable Law with regard to the BioXcel Compound and the Combined Therapy Trials, which may include information regarding the pharmacokinetics, efficacy and safety of the Nektar Compound alone or in combination with the BioXcel Compound and/or the CPI Compound (*provided that* Nektar shall provide BioXcel with written notice of any such comments (and, where applicable, approvals or rejections) within [***] ([***]) Business Days of the date on which BioXcel provides the applicable document to Nektar;

(v) providing comment and input on the management of each Combined Therapy Trial pursuant to the applicable Protocol;

(vi) reviewing and, if applicable, suggesting alternatives to BioXcel's proposed list of clinical trial sites and principal investigator(s) for each Combined Therapy Trial;

(vii) providing BioXcel with access to an investigator's brochure for the Nektar Compound as determined by Nektar (and any updates thereto), as well as all relevant safety information for the Nektar Compound;

(viii) providing and making available as necessary information and/or persons with knowledge concerning the Nektar Compound to support the Combined Therapy Trials, including any interactions with a Regulatory Authority; and

(ix) such other responsibilities as may be agreed to by the Parties or determined by the JDC.

5.2 Documents and Combined Therapy Trial Contracts.

(a) The Parties agree that BioXcel bears primary responsibility for conduct of each Combined Therapy Trial and the analysis of the Study Data under the applicable Statistical Analysis Plan. In consultation with Nektar, BioXcel shall draft the Protocols and Statistical Analysis Plans, and any amendments to each of the foregoing, and shall provide such documents to Nektar for review, comment, and if applicable, approval pursuant to Section 5.1(a)(vi) and Sections 2.4 and 2.6(d). Nektar shall have [***] ([***]) Business Days from the date on which BioXcel provides the applicable document to Nektar to provide any comments, and if applicable, approvals or rejections to BioXcel concerning the applicable draft Protocol or Statistical Analysis Plan, or any amendment to each of the foregoing.

(b) Subject to Sections 2.4 and 2.6(d), BioXcel shall be responsible for negotiating and entering into contracts for services relating to the Combined Therapy Trials, including selecting vendors, approving contract deliverables and managing contract performance, including site contracts, obtaining IRB approval for site informed consent forms, obtaining signed informed consents, monitoring plans, etc. BioXcel will be responsible for ensuring that any such contracts allow BioXcel to provide Nektar and BMS with access to and use of Study Data, Samples, and other information and documents as required pursuant to this Agreement (and in no event not less than the same access or use as is granted to BioXcel).

5.3 Other Clinical Trials. Except for the Combined Therapy Trials, each clinical trial for the Nektar Compound and the CPI Compound and the BioXcel Compound, alone or in combination with other pharmaceutical agents, is independently conducted and shall not be subject to this Agreement (but without limiting each Party's obligation to share relevant safety information as provided in Section 2.1(c), Section 2.1(d) and Section 2.2). The Nektar Compound provided to BioXcel under this Agreement shall not be used for such other clinical trials. Nothing in this

Agreement shall preclude either Party from conducting any such other clinical trials as it may determine in its discretion, so long as it does not use or rely on the Confidential Information of the other Party in doing so.

5.4 Additional Studies. After completion of the Combined Therapy Trials, the Parties agree to discuss in good faith additional clinical trials (other than clinical trials contemplated by Section 2.1(a)) of the Combined Therapy. If the Parties jointly agree to conduct any such further clinical trials, such further clinical trials will be conducted in accordance with a separate agreement between the Parties. For clarity, no Party shall be obligated to collaborate with the other Party or agree on terms with the other Party with respect to such additional clinical trials.

ARTICLE 6
INTELLECTUAL PROPERTY

6.1 Collaboration Inventions. Prior to the Effective Date of this Agreement, Nektar and BioXcel entered into a certain Collaborative Research Agreement, dated August 27, 2017 ("***Research Agreement***"). To the extent the ownership of intellectual property (including the rights of filing, prosecution, enforcement, maintenance and defense of any applicable Patent Rights) is related to the use of both the BioXcel Compound and the Nektar Compound, to the use of the BioXcel Compound, the Nektar Compound and the CPI Compound, or to a combination comprising the BioXcel Compound and the Nektar Compound, or a combination comprising the BioXcel Compound, the Nektar Compound and the CPI Compound, the Research Agreement is hereby superseded and replaced by the terms of this Agreement. All rights to Collaboration Inventions shall be allocated as follows:

(a) BioXcel Ownership. Subject to the terms of this Agreement, all BioXcel Study Inventions shall be owned solely by BioXcel, and BioXcel will have the full right to exploit such BioXcel Study Inventions without the consent of, or any obligation to account to, Nektar. Nektar shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all right, title and interest in any BioXcel Study Inventions to BioXcel. Any assignments necessary to accomplish the foregoing are hereby made, and Nektar shall execute such further documents and provide other assistance as may be reasonably requested by BioXcel to perfect BioXcel's rights in such BioXcel Study Inventions, all at BioXcel's expense. BioXcel shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any BioXcel Study Patent Rights at its own expense.

(b) Nektar Ownership. Subject to the terms of this Agreement, all Nektar Study Inventions shall be owned solely by Nektar, and Nektar will have the full right to exploit such Nektar Study Inventions without the consent of, or any obligation to account to, BioXcel. BioXcel shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all right, title and interest in any Nektar Study Inventions to Nektar. Any assignments necessary to accomplish the foregoing are hereby made, and BioXcel shall execute such further

documents and provide other assistance as may be reasonably requested by Nektar to perfect Nektar's rights in such Nektar Study Inventions, all at Nektar's expense. As between Nektar and BioXcel, Nektar shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any Nektar Study Patent Rights at its own expense.

(c) Combined Therapy Trial Inventions. All Combined Therapy Trial Inventions shall be jointly owned by the Parties, and either Party shall have the right to freely exploit the Combined Therapy Trial Inventions and Combined Therapy Patent Rights, both within and outside the scope of this Agreement, without accounting or any other obligation to the other Party (except as expressly set forth in this Section 6.1(c) and Section 6.3(d) with regard to the filing, prosecution, maintenance and enforcement of Combined Therapy Patent Rights) and each Party may use, exploit and grant licenses (with right to sublicense) to Third Parties under its interest in such Combined Therapy Trial Inventions and Combined Therapy Patent Rights. Nektar, using outside counsel acceptable to both Parties, shall be responsible for preparing, prosecuting, obtaining and maintaining Patent applications and Patents within the Combined Therapy Patent Rights. Nektar shall keep BioXcel advised as to material developments and all steps to be taken with respect to any such Patent applications and Patents and shall furnish BioXcel with copies of applications for such Patents, amendments thereto and other related correspondence to and from Patent offices, and permit BioXcel a reasonable opportunity to review and offer comments. Nektar shall implement such comments of BioXcel with respect to all such Patent applications and amendments thereto, so long as such comments are reasonable and would not cause Nektar to be in breach of the SCA if implemented. BioXcel shall reasonably assist and cooperate with Nektar in preparing, prosecuting, obtaining and maintaining Patent applications and Patents within the Combined Therapy Patent Rights. Notwithstanding the foregoing, Nektar shall not take any position in a submission to a Patent office that interprets the scope of a Patent of BioXcel related to the BioXcel Compound without the prior written consent of BioXcel. Nektar shall have the right to disclose to BMS, subject to the confidentiality provisions of the SCA governing disclosures of Nektar confidential information to BMS, applications for Patents, amendments thereto and other related correspondence to and from Patent offices contemplated by this Section to the extent necessary to comply with Nektar's obligations under the SCA, *provided* that Nektar shall not disclose any confidential information of the CPI Compound supplier in connection therewith (to be clear, nothing in the foregoing proviso shall prohibit Nektar from disclosing the Combined Therapy Study Data to BMS on the terms provided herein); and *provided further,* that Nektar remains liable to BioXcel for any breach by BMS of such confidentiality provisions. Nektar shall be reimbursed for any Third Party costs and expenses incurred in preparing, filing, and prosecuting Combined Therapy Patent Rights and the subsequent maintenance of Combined Therapy Patent Rights by BioXcel such that BioXcel shall be responsible for [***] percent ([***]%) of such costs and expenses and Nektar shall be responsible for [***] percent ([***]%) of such costs and expenses. Nektar will report all such costs and expenses to BioXcel in accordance with Sections 7.1 and 7.2.

(i) Abandonment of Patent or Patent application. If Nektar determines either: (a) not to continue the preparation, prosecution or maintenance of a Patent application or Patent within the Combined Therapy Patent Rights; or (b) not to file any new Patent application within the Combined Therapy Patent Rights as requested to be filed by BioXcel, in each case, other than to optimize overall Patent protection of claimed inventions, Nektar shall provide BioXcel with notice of this decision within [***] ([***]) days of any decision not to file a new Patent application, or at least [***] ([***]) days prior to any pending lapse or abandonment of an existing Patent application or Patent. In such event, Nektar shall provide BioXcel with an opportunity to assume responsibility for all costs associated with the filing or further preparation, prosecution and maintenance of such Patent application or any Patent issuing thereon (such filing to occur prior to the issuance of the Patent to which the application claims priority or expiration of the applicable filing deadline, as set forth above). If BioXcel assumes such responsibility for such preparation, filing, prosecution and maintenance costs, BioXcel shall have the right to transfer the responsibility for such preparation, filing, prosecution and maintenance of such Patent applications and/or Patents to patent counsel selected by it and reasonably acceptable to Nektar. In such case, Section 6.1(c) shall apply to such Patent applications and Patents *mutatis mutandis*. Such Patent applications and Patents shall otherwise continue to be subject to all of the terms and conditions of this Agreement in the same manner and to the same extent as the other Patent applications and Patents within the Combined Therapy Patent Rights.

(ii) Failure to Reimburse. If a Party elects not to reimburse the other Party for [***] percent ([***]%) of the costs and expenses of preparation, filing, prosecution and maintenance of a Patent application or Patent within the Combined Therapy Patent Rights in a given country, the non-reimbursed Party shall have the right, but not an obligation, to prepare, file, prosecute or maintain such Patent application or Patent in such country in its own name and at its own expense, with the prior written consent of the other Party (which shall not be unreasonably withheld) and the other Party shall promptly assign, without additional consideration, all of its rights, title and interest to the Patent application or Patent in said country and any inventions covered by such Patent application or Patent to the non-reimbursed Party if the non-reimbursed Party wishes to prepare, file, prosecute or maintain said Patent application or Patent. After giving effect to such assignment, such assigned invention and any corresponding Combined Therapy Patent Rights thereto shall be the treated as a BioXcel Independent Patent Rights or Nektar Independent Patent Rights, as applicable. The Party who does not wish to prepare, file, prosecute or maintain a Patent application or Patent within the Combined Therapy Patent in any country shall assist in the timely provision of all documents required under national provisions to register said assignment of rights with the corresponding national authorities at the sole expense of the Party who wished to prepare, file, prosecute or maintain such Patent application or Patent in that given country. Nektar shall have the right to disclose to BMS, subject to the confidentiality provisions of the SCA governing disclosures of Nektar confidential information to BMS, applications for Patents, amendments thereto, assignment-related documents and other related correspondence to and from Patent offices contemplated by this subsection (ii) to the extent necessary to comply with Nektar's obligations under the SCA, *provided* that Nektar shall not disclose any confidential information of the CPI Compound supplier in connection therewith (to

be clear, nothing in the foregoing proviso shall prohibit Nektar from disclosing the Combined Therapy Study Data to BMS on the terms provided herein); and *provided further,* that Nektar remains liable to BioXcel for any breach by BMS of such confidentiality provisions.

(d) Separation of Patent Rights. In order to more efficiently enable the prosecution and maintenance of the Nektar Study Patent Rights, BioXcel Study Patent Rights and Combined Therapy Patent Rights relating to Collaboration Inventions as described above, the Parties will use good faith efforts to separate Nektar Study Patent Rights, BioXcel Study Patent Rights, Combined Therapy Patent Rights, Nektar Independent Patent Rights and BioXcel Independent Patent Rights into separate patent filings to the extent possible and without adversely impacting such prosecution and maintenance. Nektar shall have the right to disclose to BMS, subject to the confidentiality provisions of the SCA governing disclosures of Nektar confidential information to BMS, applications for Patents, amendments thereto and other related correspondence to and from Patent offices contemplated by this subsection (d) to the extent necessary to comply with Nektar's obligations under the SCA, *provided* that Nektar shall not disclose any confidential information of the CPI Compound supplier in connection therewith (to be clear, nothing in the foregoing proviso shall prohibit Nektar from disclosing the Combined Therapy Study Data to BMS on the terms provided herein); and *provided further,* that Nektar remains liable to BioXcel for any breach by BMS of such confidentiality provisions.

6.2 Disclosure and Assignment of Collaboration Inventions. Each Party shall disclose promptly to the other Party in writing and on a confidential basis all Collaboration Inventions, prior to any public disclosure or filing of Patent applications and allowing sufficient time for comment by the other Party. Nektar shall have the right to disclose to BMS, subject to the confidentiality provisions of the SCA governing disclosures of Nektar confidential information to BMS, all Collaboration Inventions, prior to any public disclosure or filing of patent applications, to the extent necessary to comply with Nektar's obligations under the SCA, *provided* that Nektar shall not disclose any confidential information of the CPI Compound supplier in connection therewith (to be clear, nothing in the foregoing proviso shall prohibit Nektar from disclosing the Combined Therapy Study Data to BMS on the terms provided herein); and *provided further,* that Nektar remains liable to BioXcel for any breach by BMS of such confidentiality provisions. In addition, each Party shall, and does hereby, assign, and shall cause its Affiliates and contractors to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Collaboration Inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership provided for in Sections 6.1(a) and 6.1(b) and the joint ownership provided for in Section 6.1(c).

6.3 Infringement of Patent Rights by Third Parties.

(a) Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened (in writing) infringement, or misappropriation by a Third Party, of Combined Therapy Patent Rights, of which its in-house patent counsel becomes aware (such infringement, "***Infringement,***" and "***Infringe***" shall be interpreted accordingly).

(b) Infringement of BioXcel Study Patent Rights. For all Infringement of BioXcel Study Patent Rights or BioXcel Independent Patent Rights anywhere in the world, BioXcel shall have the exclusive right to prosecute such Infringement as it may determine in its sole and absolute discretion, and BioXcel shall bear all related expenses and retain all related recoveries. Nektar shall reasonably cooperate with BioXcel or its designee (to the extent Nektar has relevant information arising out of this Agreement), at BioXcel's request and expense, in any such action.

(c) Infringement of Nektar Study Patent Rights. For all Infringement of Nektar Study Patent Rights or Nektar Independent Patent Rights anywhere in the world, Nektar shall have the exclusive right to prosecute such Infringement as it may determine in its sole and absolute discretion, and Nektar shall bear all related expenses and retain all related recoveries. BioXcel shall reasonably cooperate with Nektar or its designee (to the extent BioXcel has relevant information arising out of this Agreement), at Nektar's request and expense, in any such action.

(d) Infringement of Combined Therapy Patent Rights.

(i) With respect to Infringement of Combined Therapy Patent Rights, the Parties shall mutually agree as to whether to bring an enforcement action to seek the removal or prevention of such Infringement and damages therefor and, if so, which Party shall bring such action, with any costs and expenses relating thereto to be allocated in accordance with Section 6.3(d)(ii).

(ii) Regardless of which Party brings an enforcement action pursuant to Section 6.3(d)(i), the other Party hereby agrees to cooperate reasonably in any such action, including, if required, by bringing a legal action or furnishing a power of attorney. If the Parties mutually agree to bring an enforcement action, Nektar shall be responsible for [***] percent ([***]%), and BioXcel shall be responsible for [***] percent ([***]%), of the reasonable and verifiable costs and expenses incurred in connection with any such action. If either Party recovers monetary damages from any Third Party in an action approved by the Parties and brought under this Section 6.3(d)(ii), such recovery shall be allocated first to the reimbursement of any actual, unreimbursed costs and expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), then pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split [***] percent ([***]%) to BioXcel and [***] percent ([***]%) to Nektar, unless the Parties agree in writing to a different allocation. In connection with any proceeding under this Section 6.3(d), neither Party shall enter into any settlement without the prior written consent of the other Party.

6.4 Infringement of Third Party Rights.

(a) Notice. If the activities relating to the Combined Therapy Trials become the subject of a claim of infringement of a patent, copyright or other proprietary right by a Third Party anywhere in the world, the Party first having notice of the claim shall promptly notify the

other Party and, without regard to which Party is charged with said infringement and the venue of such claim, the Parties shall promptly confer to discuss the claim.

(b) Defense. If both Parties are charged with infringement pursuant to a claim described in Section 6.4(a), the Parties shall defend such claim jointly, unless they agree otherwise. If only one Party is charged with infringement, such Party will have the first right but not the obligation to defend such claim. If the charged Party does not commence actions to defend such claim within [***] ([***]) calendar days after being so charged, then the other Party shall have the right, but not the obligation, to defend any such claim. In any event, the non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim and shall have the right to participate with separate counsel at its own expense, and the defending Party shall consider comments by the non-defending Party in good faith. The Party defending the claim shall bear the cost and expenses of the defense of any such Third Party infringement claim and shall have sole rights to any recovery. If the Parties jointly defend the claim, BioXcel shall bear [***] percent ([***]%), and Nektar shall bear [***] percent ([***]%) of any costs and expenses of the defense of any such Third Party infringement claim; *provided, however,* that, notwithstanding the foregoing, if the claim relates solely to one Party's Compound, such Party will bear one hundred percent (100%) of the costs and expenses of the defense of such claim, shall have sole rights to any recovery and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. If either Party recovers monetary damages from any Third Party while jointly defending the claim, such recovery shall be allocated first to the reimbursement of any actual, unreimbursed costs and expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel) pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split [***] percent ([***]%) to BioXcel and [***] percent ([***]%) to Nektar, unless the Parties agree in writing to a different allocation. Neither Party shall enter into any settlement concerning activities under this Agreement or the Combined Therapy that affects the other Party's rights under this Agreement or imposes any obligations on the other Party, including any admissions of wrongdoing on behalf of the other Party, without such other Party's prior written consent, not to be unreasonably withheld or delayed, except that a Party may settle any claim that solely relates to its Compound without the consent of the other Party as long as such other Party's rights under this Agreement are not adversely impacted (in which case, it will obtain such other Party's prior written consent, not to be unreasonably withheld or delayed).

6.5 Combined Therapy Trial Regulatory Documentation. Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, BioXcel and Nektar shall jointly own all right, title and interest in and to the Combined Therapy Trial Regulatory Documentation; *provided, however,* that Nektar shall retain sole and exclusive ownership of any Nektar Regulatory Documentation provided to BioXcel under this Agreement that is submitted with or referenced in the Combined Therapy Trial Regulatory Documentation and that BioXcel shall retain sole and exclusive ownership of any BioXcel Regulatory Documentation that is submitted with or referenced in the Combined Therapy Trial Regulatory Documentation. This Section 6.5 is without limitation of any other disclosure obligations under this Agreement.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

ARTICLE 7
COLLABORATION COSTS AND EXPENSES

7.1 Combined Therapy Trial Expenses. Expenses incurred as described in Article 4 (regarding Manufacturing and supply up to the point where the applicable BioXcel Compound or Nektar Compound arrives at the BioXcel labeling and distribution facility for the applicable Combined Therapy Trial), and Article 6 (regarding intellectual property) shall be borne or shared by the Parties as provided in such Articles. In addition, each Party shall bear its own Third Party License Payments as set forth in Section 2.6(b). For all other expenses that are directly attributable or reasonably allocable to the conduct of the Combined Therapy Trials, (a) Nektar will be responsible for [***] percent ([***]%) of all out-of-pocket costs paid to Third Parties (including taxes, to the extent non-creditable to BioXcel) reasonably incurred in connection with Third Party Contractors, CROs, laboratories and clinical sites/IRBs or otherwise by either Party in connection with the performance of the Combined Therapy Trials including, but not limited to, BioXcel's out-of-pocket costs of labeling and packaging the unlabeled vials of the Nektar Compound provided by Nektar, labeling and packaging the commercially labeled vials of the CPI Compound provided by the CPI Compound supplier, and labeling and packaging the BioXcel Compound, in each case for distribution to clinical sites, and those costs described under Section 8.5, and that are incurred consistent with the JDC-approved budget for each Combined Therapy Trial ("***Third Party Study Costs***"); and (b) each Party shall be solely responsible for all of its own internal costs (including all internal full-time equivalents and all costs of individuals engaged as independent contractors) incurred by such Party or any of its Affiliates in the performance of each Combined Therapy Trial, to the extent not included in the definition of Third Party Study Costs. For the avoidance of doubt, Third Party Study Costs does not include Third Party License Payments by Nektar, Third Party License Payments by BioXcel or any Third Party Claims.

7.2 Invoicing; Payment.

(a) Designation of Finance Representatives; Reconciliation.

(i) Each of the Parties shall designate a representative from its Finance Department to interact with the designee of the other Party concerning preparation of the budget for each Combined Therapy Trial (including the Initial Trial) for approval by the JDC, reconciliation of costs incurred in the conduct of each Combined Therapy Trial, the method to be used by both Parties to determine the amounts to be invoiced by BioXcel to Nektar hereunder, and to act as the point of contact for any other matters arising between the Parties under Article 7 (the "***Finance Representatives***"). Nektar shall reimburse BioXcel, on a quarterly basis in arrears, for Nektar's [***] percent ([***]%) share of all Third Party Study Costs under U.S. Generally Accepted Accounting Principles incurred by BioXcel during the prior quarter. Without the prior written consent of Nektar, the amount to be reimbursed by Nektar for its [***] percent ([***]%) share of Third Party Study Costs as provided in the previous sentence shall not exceed [***] United

States dollars ($[***]) per patient completing Combined Therapy in accordance with the Protocol. In the event BioXcel becomes aware that its actual Third Party Study Costs would cause the cap on Nektar's reimbursement obligation to be exceeded, BioXcel shall promptly notify Nektar through its JDC representatives, and the Parties, through the JDC, shall discuss whether to adjust the budget and whether the cap on Nektar's reimbursement obligation should be revised to cover [***] percent ([***]%) of BioXcel's actual Third Party Study Costs. Within [***] ([***]) Business Days after the end of each quarter BioXcel shall submit to Nektar an estimate of Nektar's [***] percent ([***]%) share of Third Party Study Costs for the prior quarter. Within [***] ([***]) Business Days of the end of each quarter BioXcel shall submit to Nektar (1) a final invoice for Nektar's [***] percent ([***]%) share of Third Party Study costs for the prior quarter, and (2) an electronic report that specifies in reasonable detail all such expenses included in such Third Party Study Costs, and all Section 5.1(a) and Section 8.5 costs during such prior quarter (a "***Quarterly Report***"). All BioXcel invoices to Nektar shall be in United States dollars. Third Party Study Costs incurred by BioXcel in a currency other than United States dollars shall be converted to United States dollars by BioXcel using BioXcel's standard currency conversion methodology consistently applied. Nektar agrees to accept electronic copies of invoices and reports, in .pdf format, emailed to Nektar at AP@Nektar.com as sufficient delivery thereof to process payments to BioXcel. If requested by Nektar in writing, BioXcel shall provide invoices or other appropriate supporting documentation for any payments to a Third Party exceeding [***] United States dollars ($[***]). If requested by Nektar in writing, BioXcel shall provide a reconciliation between the cumulative amounts paid and the expenses recorded by BioXcel for the Combined Therapy Trial as reported under U.S. Generally Accepted Accounting Principles. The Parties shall seek to resolve any questions related to such invoices and/or Quarterly Reports within [***] ([***]) Business Days following receipt by Nektar of BioXcel's invoice and Quarterly Report hereunder. Based on the invoices and reports, payment will be made by Nektar within [***] ([***]) calendar days after the delivery of such invoice and Quarterly Report. If Nektar disputes an amount due on an invoice, Nektar will notify BioXcel of such dispute within [***] ([***]) Business Days of receipt of such invoice and shall pay the amount not in dispute after BioXcel submits a new invoice for the undisputed amount. The Parties shall use good faith efforts to discuss and resolve any disputed amounts. Any undisputed invoiced amount which is not paid by its due date shall be assessed a late payment fee at the rate of one percent (1%) per month, compounded monthly, or at the highest rate permitted under Applicable Law, if less.

(ii) BioXcel shall reimburse Nektar, on a quarterly basis in arrears, for BioXcel's [***] percent ([***]%) share of all costs and expenses incurred by Nektar under Article 6, actually invoiced to Nektar by Third Parties during the prior quarter. Within [***] ([***]) Business Days of the end of each quarter, Nektar shall (1) submit to BioXcel an invoice for BioXcel's [***] percent ([***]%) share of all such Article 6 costs and expenses, and (2) an electronic report that specifies in reasonable detail all such Article 6 costs expenses during such quarter (a "***Quarterly Patent Costs Report***"). All Nektar invoices to BioXcel shall be in United States dollars. Third Party expenses incurred by Nektar in a currency other than United States dollars shall be converted to United States dollars by Nektar using Nektar's standard currency conversion methodology consistently applied. BioXcel agrees to accept electronic copies of

invoices and reports, in .pdf format, emailed to BioXcel at an address provided by the BioXcel Alliance Manager as sufficient delivery thereof to process payments to Nektar. If requested by BioXcel in writing, Nektar shall provide invoices or other appropriate supporting documentation for any payments to a Third Party exceeding $[***]. If requested by BioXcel in writing, Nektar shall provide a reconciliation between the cumulative amounts invoiced to BioXcel and the expenses recorded by Nektar for the Combined Therapy Trial as reported under U.S. Generally Accepted Accounting Principles. The Parties shall seek to resolve any questions related to such invoices and/or Quarterly Patent Costs Reports within [***] ([***]) Business Days following receipt by BioXcel of Nektar's invoice and Quarterly Patent Costs Report hereunder. Based on the invoices and reports, payment will be made by BioXcel within [***] ([***]) calendar days after the delivery of such invoice and Quarterly Patent Costs Report. If BioXcel disputes an amount due on an invoice, BioXcel will notify Nektar of such dispute within [***] ([***]) Business Days of receipt of such invoice and shall pay the amount not in dispute after Nektar submits a new invoice for the undisputed amount. The Parties shall use good faith efforts to discuss and resolve any disputed amounts. Any undisputed invoiced amount which is not paid by its due date shall be assessed a late payment fee at the rate of one percent (1%) per month, compounded monthly, or at the highest rate permitted under Applicable Law, if less.

(b) Payment Method by Nektar. Nektar shall pay all amounts due hereunder to BioXcel in United States dollars by check or by electronic funds transmission to the BioXcel account below or such bank account BioXcel designates in writing from time to time.

BioXcel Tax ID # 82-1386754
BioXcel Bank Account Information:
Account Name: [***]
Account No. [***]
ABA Routing No. [***]

(c) Payment Method by BioXcel. BioXcel shall pay all amounts due hereunder to Nektar in United States dollars by check or by electronic funds transmission to the Nektar account below or such bank account Nektar designates in writing from time to time.

Nektar Tax ID # 94-3134940
Nektar Bank Account Information:
[***]
Account No. [***]
Routing No. [***]
Swift Code (international wires) [***]

7.3 Audit. At the request (and expense) of Nektar, BioXcel shall permit an independent certified public accountant appointed by Nektar and reasonably acceptable to BioXcel (*provided* that such accountant shall be compensated on the basis of time spent on the audit and not on a contingency basis, and shall have entered into a confidentiality agreement with BioXcel),

at reasonable times and upon reasonable notice, to examine only those records as may be reasonably necessary to determine, with respect to any calendar year ending not more than [***] ([***]) years prior to Nektar's request, the correctness or completeness of any invoice submitted to Nektar or other payment made to BioXcel pursuant to this Agreement. The foregoing right of review may be exercised only once per year and only once with respect to each such periodic report and payment. Results of any such examination shall be: (a) made available to both Parties; and (b) subject to Article 9. Nektar shall bear the full cost of the performance of any such audit, unless such audit discloses a variance of more than [***]percent (+/- [***]%) from the amount of the original report or payment calculation, in which case, BioXcel shall bear the full cost of the performance of such audit. BioXcel shall have reciprocal audit rights for any Article 6 costs and expenses incurred by Nektar and invoiced to BioXcel hereunder. If, as a result of any audit, it is shown that payments received by the Parties under this Agreement were less or more than the amount which should have been received, then the appropriate Party shall make or refund all payments required to be made to eliminate any discrepancy revealed by said audit within [***] ([***]) calendar days.

ARTICLE 8
RECORDS AND STUDY DATA

8.1 Records. Each Party shall maintain complete and accurate records of all work conducted with respect to the Combined Therapy Trials and of all results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments made by or provided to either Party, or by the Parties together, in the course of such Party(ies)' efforts with respect to the Combined Therapy Trials (including the Statistical Analysis Plan and any Bioanalysis Plan to be conducted pursuant to this Agreement) (such results, information, data, data analyses, reports, case report forms, adverse event reports, trial records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, developments, and each Protocol referred to as the "***Study Data***"). Such records shall fully and properly reflect all work done and results achieved in the performance of the Combined Therapy Trials in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

8.2 Ownership of Study Data. Nektar shall own the Study Data to the extent that it relates exclusively to the Nektar Compound ("***Nektar Study Data***"), and BioXcel shall own the Study Data to the extent that it relates exclusively to the BioXcel Compound ("***BioXcel Study Data***"). Both Parties shall jointly own any Study Data that does not relate exclusively to the BioXcel Compound or the Nektar Compound ("***Combined Therapy Study Data***"). Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Study Data as is necessary to fully effect the foregoing, and agrees to execute all instruments as may be reasonably necessary to effect same. Nektar shall have the right to disclose the Combined Therapy Study Data to BMS, and BMS shall have the right to use the Combined Therapy Study Data as provided in the SCA; *provided* that Nektar shall not disclose any confidential information of the CPI Compound supplier

in connection therewith, including any data, results or information relating solely to the CPI Compound or any pharmacokinetic information relating to the CPI Compound (to be clear, nothing in the foregoing proviso shall prohibit Nektar from disclosing the Combined Therapy Study Data to BMS on the terms provided herein).

8.3 Use of Study Data.

(a) Use of a Party's Own Study Data. Each Party may use and analyze its own Study Data for any purpose without obligation or accounting to the other.

(b) Use of Combined Therapy Study Data by Nektar. Nektar and its Affiliates and each of their respective (sub)licensees shall have the right to use and analyze the Combined Therapy Study Data (x) in connection with its independent development, commercialization or other exploitation of the Nektar Compound (alone or in combination with other compounds) and/or for inclusion in the safety database for the Nektar Compound, as applicable, in each case without the consent of, or any obligation to account to, BioXcel, and (y) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such analyses or uses shall be owned by Nektar, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in writing. Nektar, its Affiliates and licensees shall also be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings and seek approvals for the Nektar Compound, either alone or in combination with other compounds and (2) to promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the Nektar Compound, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; *provided*, that nothing in the foregoing is intended or shall be construed as granting Nektar any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the BioXcel Compound. BioXcel grants Nektar, its Affiliates and licensees of the Nektar Compound an irrevocable Right of Cross-Reference to the relevant Regulatory Documentation Controlled by BioXcel for the BioXcel Compound or the Combined Therapy to the extent necessary for Nektar, its Affiliates and licensees of the Nektar Compound to exercise the rights under clause (1) and clause (2) of this Section 8.3(b), which right shall survive any expiration or termination of this Agreement. If requested by Nektar in writing, BioXcel (or if applicable a BioXcel Affiliate or Third Party collaborator) shall provide Nektar with a signed statement, in form and content reasonably acceptable to Nektar, confirming the rights of Nektar, its Affiliates and licensees of the Nektar Compound to exercise the Right of Cross-Reference to Regulatory Documentation Controlled by BioXcel, BioXcel Affiliates and their Third Party collaborators as provided in this Section 8.3(b).

(c) Use of Combined Therapy Study Data by BioXcel. BioXcel its Affiliates and each of its and their respective (sub)licensees shall have the right to use and analyze the Combined Therapy Study Data (x) in connection with its independent development, commercialization or other exploitation of the BioXcel Compound (alone or in combination with other compounds) and/or for inclusion in the safety database for the BioXcel Compound, in each case without the consent of, or any obligation to account to, Nektar and (y) to conduct studies with

Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such analyses or uses shall be owned by BioXcel, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in writing. BioXcel, its Affiliates and licensees shall be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings and seek approvals for the BioXcel Compound, either alone or in combination with other compounds and (2) to promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the BioXcel Compound, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; *provided* that nothing in the foregoing is intended or shall be construed as granting BioXcel any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the Nektar Compound. Nektar grants BioXcel, its Affiliates and licensees of the BioXcel Compound an irrevocable Right of Cross-Reference to the relevant Regulatory Documentation Controlled by Nektar for the Nektar Compound to the extent necessary for BioXcel, its Affiliates and licensees of the BioXcel Compound to exercise the rights under clause (1) and clause (2) of this Section 8.3(c), which right shall survive any expiration or termination of this Agreement. If requested by BioXcel in writing, Nektar (or if applicable a Nektar Affiliate or Third Party collaborator) shall provide BioXcel with a signed statement, in form and content reasonably acceptable to BioXcel, confirming the rights of BioXcel, its Affiliates and licensees of the BioXcel Compound to exercise the Right of Cross-Reference to Regulatory Documentation Controlled by Nektar, Nektar Affiliates and their Third Party collaborators as provided in this Section 8.3(c).

(d) Biomarker/Diagnostic Agent Development. Each Party may use and disclose to a Third Party the Combined Therapy Study Data and its Compound's Study Data, under obligations of confidentiality consistent with this Agreement, to develop and commercialize a biomarker or diagnostic test for use with its Compound and/or the Combined Therapy, and, unless otherwise mutually agreed by the Parties in writing, will own any intellectual property arising out of the work funded or conducted by it with or through such Third Party. The Parties will discuss in good faith any opportunities to jointly participate in the development of any such biomarker or diagnostic test for use with the Combined Therapy.

(e) No Other Uses. All other uses of Study Data are limited solely to those permitted by this Agreement, and neither Party may use Study Data for any other purpose without the written consent of the other Party during and after the Term of this Agreement.

8.4 Access to Study Data. Subject to the provisions of Sections 2.2, 5.1(a)(xvi) and 5.1(a)(xvii), each Party and BMS shall have access to all Combined Therapy Study Data (including de-identified patient records) as soon as reasonably practicable after such Study Data is reasonably available to or generated by the Party responsible for generating or collecting such Study Data.

8.5 Samples. Samples collected in the course of activities conducted under this Agreement shall be jointly owned by the Parties (to the extent not owned by the patient and/or the clinical trial site). Any such Samples shall be collected in accordance with the applicable Protocol and ICFs. Neither Party shall be permitted to use such Samples for any purpose without the prior

written consent of the other Party, which consent shall not be unreasonably withheld if such use is directed to the Combined Therapy and with the terms of such use to be set forth in a written agreement between the Parties setting forth the Samples to be used, and any appropriate terms/restrictions on such use. Any data and intellectual property arising out of such Sample use shall be owned by the Party conducting such study using same; *provided* that to the extent that any such data or intellectual property relates solely to the Combined Therapy (or biomarkers solely for use with the Combined Therapy), such data or intellectual property shall be considered Combined Therapy Study Data or Combined Therapy Trial Inventions/Combined Therapy Patent Rights, as the case may be. Samples for PK and ADA serum analysis will be stored for future use in BioXcel's sample repository (with the expectation that Nektar will store, at its own expense, those samples that it expects to use in studies), *provided*, that if the Party holding the Samples determines that it no longer has a use for the Samples and the other Party determines that it does, then the Samples shall, subject to Applicable Law and the terms of the signed ICFs, be transferred to the other Party and may be used solely thereafter by the other Party. If neither Party has any further use for the Samples, then the remaining Samples will be destroyed pursuant to the respective Party's standard operating procedures for sample retention and destruction, subject to the terms of and permission(s) granted in the ICFs by the subjects contributing the Samples in the Combined Therapy Trials. All Third Party Study Costs for collecting, testing and storing the Samples will be split between the Parties in accordance with Sections 7.1 and 7.2, except as otherwise noted in this Section 8.5.

ARTICLE 9
CONFIDENTIALITY

9.1 Nondisclosure of Confidential Information.

(a) Prior to the Effective Date of this Agreement, BioXcel and Nektar entered into a certain Mutual Confidentiality Agreement dated July 27, 2016, as amended July 18, 2018 ("***CDA***"). As it relates to disclosures involving BXCL701 and NKTR-214 only, the CDA is hereby terminated and replaced by the terms of this Agreement. Any Confidential Information relating thereto previously disclosed by the Parties pursuant to the CDA shall now be Confidential Information for purposes of this Agreement and the Parties shall treat it as such in accordance with the terms hereof. All written, visual, oral and electronic data, information, know-how or other proprietary information or materials, both technical and non-technical, disclosed by one Party (the "***Disclosing Party***") to any other Party (the "***Receiving Party***") pursuant to this Agreement that (a) if in tangible form, is labeled in writing as "proprietary" or "confidential" (or similar reference); or (b) if in oral or visual form, is identified as proprietary or confidential or for internal use only at the time of disclosure or within thirty (30) calendar days thereafter shall be "***Confidential Information***" of the Disclosing Party, and all Study Data and Collaboration Inventions shall be the Confidential Information of the Party owning such Study Data or Collaboration Invention (as provided in Section 8.2 with regard to Study Data and Section 6.1 with regard to Collaboration Inventions). For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other, (i) all BioXcel Study Inventions, BioXcel Technology and BioXcel

Regulatory Documentation shall be Confidential Information of BioXcel and Nektar shall be deemed the Receiving Party, (ii) all Nektar Study Inventions, Nektar Technology, and Nektar Regulatory Documentation shall be Confidential Information of Nektar and BioXcel shall be deemed the Receiving Party, and (iii) all Combined Therapy Inventions, Combined Therapy Study Data and Combined Therapy Trial Regulatory Documentation shall be Confidential Information of each Party.

(b) Except to the extent expressly authorized in this Section 9.1 and Sections 9.2, 9.3 and 9.5 below, or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of [***] ([***]) years thereafter (or for any Confidential Information that is identified in writing at the time of disclosure as a trade secret related to each Party's Compound, for as long as it is not part of the public domain), it shall (x) keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information owned by the Disclosing Party, (y) treat the Disclosing Party's Confidential Information with the same degree of care the Receiving Party uses for its own confidential information but in no event with less than a reasonable degree of care; and (z) reproduce the Disclosing Party's Confidential Information solely to the extent necessary to accomplish the Receiving Party's obligations under this Agreement, with all such reproductions being considered the Disclosing Party's Confidential Information.

(c) Notwithstanding anything to the contrary in this Section 9.1, and subject to Section 8.3, the Receiving Party may disclose the Disclosing Party's Confidential Information to its employees, consultants, agents or permitted sublicensees solely on a need-to-know basis for the purpose of fulfilling the Receiving Party's obligations under this Agreement; *provided*, *however*, that (1) any such employees, consultants, agents or permitted sublicensees are bound by obligations of confidentiality at least as restrictive as those set forth in this Agreement, and (2) the Receiving Party remains liable for the compliance of such employees, consultants, agents or permitted sublicensees with such obligations. Each Receiving Party acknowledges that in connection with its and its representatives examination of the Confidential Information of the Disclosing Party, the Receiving Party and its representatives may have access to material, non-public information, and that the Receiving Party is aware, and will advise its representatives who are informed as to the matters that are the subject of this Agreement, that State and Federal laws, including United States securities laws, impose restrictions on the dissemination of such information and trading in securities when in possession of such information. Each Receiving Party agrees that it will not, and will advise its representatives who are informed as to the matters that are the subject of this Agreement to not, purchase or sell any security of the Disclosing Party on the basis of the Confidential Information to the extent such Confidential Information constitutes material non-public information about the Disclosing Party or such security.

9.2 Exceptions. The obligations in Section 9.1 shall not apply with respect to any portion of Confidential Information that the Receiving Party can demonstrate by contemporaneous tangible records or other competent proof:

(a) was already known to the Receiving Party (or its Affiliates), other than under an obligation of confidentiality, either (i) at the time of disclosure by the Disclosing Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(b) was generally available to the public or otherwise part of the public domain either (i) at the time of its disclosure to the Receiving Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement;

(d) was disclosed to the Receiving Party (or its Affiliates), other than under an obligation of confidentiality, by a Third Party who had no obligation to the Party owning or Controlling the information not to disclose such information to others; or

(e) was independently discovered or developed by the Receiving Party (or its Affiliates) without the use of or reference to the Confidential Information belonging to the Disclosing Party.

9.3 Authorized Disclosure. Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information solely owned by the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patent Rights;

(b) prosecuting or defending litigation;

(c) complying with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed;

(d) disclosure, in connection with the performance of this Agreement, to Affiliates, permitted sublicensees, contractors, ethics committees and institutional review boards (collectively, "***IRBs***"), CROs, academic institutions, consultants, agents, investigators, and employees and contractors engaged by study sites and investigators involved with the Combined Therapy Trials, each of whom, subject to Section 2.6(d), prior to disclosure must be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9;

(e) disclosure that is deemed necessary by either Party to be disclosed to its respective Affiliates, agents, consultants or actual or prospective licensees (or other bona fide collaborators) in furtherance of the development, manufacture and/or commercialization of such Party's Compound, on the condition that such Third Parties agree to be bound by confidentiality

and non-use obligations that are substantially consistent with the confidentiality and non-use provisions contained in this Agreement;

(f) disclosure to its attorneys, accountants, auditors and other advisors on a need to know basis provided such individuals or Entities are bound to confidentiality and nondisclosure requirements by professional rules of conduct or nondisclosure agreements, and to actual or prospective acquirers, lenders, financers, or investors as may be necessary to comply with the terms, or in connection with their evaluation, of such potential or actual acquisition, loan, financing, or investment; on the condition that such acquires, lenders, financers, or investors agree to be bound by confidentiality and non-use obligations that are substantially consistent with the confidentiality and non-use provisions contained in this Agreement;

(g) disclosure of the Combined Therapy Study Data, Combined Therapy Trial Inventions and Combined Therapy Patent Rights to Regulatory Authorities in connection with the development of the Combined Therapy, the BioXcel Compound or the Nektar Compound; and

(h) disclosure of relevant safety information contained within the Combined Therapy Study Data to investigators, IRBs/or ethics committees and Regulatory Authorities that are involved in other clinical trials of the BioXcel Compound with respect to BioXcel, and the Nektar Compound with respect to Nektar, and (in the event of a Material Safety Issue) to Third Parties that are collaborating with BioXcel or Nektar, respectively in the conduct of such other clinical trials of the BioXcel Compound or the Nektar Compound, in each case solely to the extent necessary for the conduct of such clinical trials and/or to comply with Applicable Law and regulatory requirements.

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of the Disclosing Party's Confidential Information pursuant to Section 9.3(b) and/or Section 9.3(c), it shall give advance notice to the Disclosing Party of such impending disclosure and endeavor in good faith to secure confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment.

9.4 Disclosure to BMS. Notwithstanding anything in this Agreement to the contrary, Nektar shall have the right, subject to the confidentiality provisions of the SCA governing disclosure of Nektar Confidential Information to BMS, to disclose to BMS any Trial Overview, Protocol, budget, Combined Therapy Study Data and all information disclosed to Nektar by BioXcel pursuant to Article 2 and Article 5 for any Combined Therapy Trial, *provided* that Nektar shall not disclose any confidential information of the CPI Compound supplier in connection therewith, including any data, results or information relating solely to the CPI Compound or any pharmacokinetic information relating to the CPI Compound (to be clear, nothing in the foregoing proviso shall prohibit Nektar from disclosing the Combined Therapy Study Data to BMS on the terms provided herein); and *provided further,* that Nektar remains liable to BioXcel for any breach by BMS of such confidentiality provisions.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

9.5 Press Releases and Publications.

(a) The Parties shall jointly agree to the content and timing of all external communications with respect to this Agreement (including an initial press release, the content of which shall be as attached hereto as Exhibit B, subsequent press releases, Q&As, and the content and wording of any listing any Combined Therapy Trial required to be listed on a public database or other public registry such as www.clinicaltrials.gov). For clarity, if either Party terminates this Agreement pursuant to Section 12.4, the Parties shall mutually agree upon any external communication related to such termination, which shall not include the rationale for such termination unless (and to the extent) mutually agreed by the Parties. Notwithstanding any provision of this Agreement to the contrary, each Party shall be permitted to publicly disclose information that such Party determines in good faith is necessary to be disclosed to comply with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock may be listed, or pursuant to an order of a court or governmental entity.

(b) BioXcel and Nektar agree to collaborate to publicly disclose, publish or present (1) top-line results from each Combined Therapy Trial, limited if possible to avoid jeopardizing the future publication of the Study Data at a scientific conference or in a scientific journal, solely for the purpose of disclosing, as soon as reasonably practicable, the safety or efficacy results and conclusions that are material to either Party under applicable securities laws, and (2) the conclusions and outcomes (the "***Results***") of each Combined Therapy Trial at a scientific conference as soon as reasonably practicable following the completion of such Combined Therapy Trial, subject in the case of (2) to the following terms and conditions. The Party proposing to disclose, publish or present the Results shall deliver to the other Party a copy of (i) any abstract or press release at least [***] ([***]) Business Days before submission to a Third Party and (ii) any proposed slide presentation, publication, poster presentation or any other disclosure, publication or presentation at least [***] ([***]) Business Days before submission to a Third Party. The reviewing Party shall determine whether any of its Confidential Information that may be contained in such disclosure, publication or presentation should be modified or deleted, whether to file a patent application on any BioXcel Study Invention (solely with respect to BioXcel) or Nektar Study Invention (solely with respect to Nektar) or Combined Therapy Trial Invention disclosed therein. If practicable, the disclosure, publication or presentation shall be delayed for an additional [***] ([***]) Business Days if the reviewing Party reasonably requests such extension to allow time for the preparation and filing of relevant patent applications. If the reviewing Party reasonably requests modifications to the disclosure, publication or presentation to prevent the disclosure of a material trade secret or proprietary business information, the publishing Party shall edit such publication to prevent the disclosure of such information prior to submission of the disclosure, publication or presentation. In the event of a disagreement as to content, timing and/or venue or forum for any disclosure, publication or presentation of the Results, such dispute (a "***Publication Dispute***") shall be referred to the Executive Officers (or their respective designees); *provided that*, in the absence of agreement after such good faith discussions, and upon expiration of the additional [***] ([***]) Business Days (to the extent provided pursuant to the above), (A) academic collaborators engaged by BioXcel in connection with the performance of the Combined Therapy Trials may publish

Combined Therapy Study Data obtained by such academic collaborator solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between BioXcel and such academic collaborator relating to the conduct of Combined Therapy Trials and (B) the publishing Party may proceed with the disclosure, publication or presentation provided that such disclosure, publication or presentation is consistent with its internal publication guidelines and customary industry practices for the publication of similar data. Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed disclosure, publication or presentation. The Parties agree that they shall make reasonable efforts to prevent publication of a press release that could jeopardize the future publication of Study Data at a scientific conference or in a scientific journal but in no way will this or any other provision of this Agreement supersede the requirements of any Applicable Law or the rules or regulations of any securities exchange or listing entity on which a Party's stock is listed (including any such rule or regulation that may require a Party to make public disclosures about interim or ongoing results of a Combined Therapy Trial). Notwithstanding the foregoing, BioXcel hereby authorizes disclosure to BMS in accordance with Section 9.4 above. Notwithstanding the foregoing, nothing herein shall prevent or restrict BMS from making any disclosures of published Study Data disclosed to it by Nektar pursuant to Section 9.4 or of the existence of this Agreement, in each case in order for BMS to comply with requirements of Applicable Law, the rules or regulations of any securities exchange or listing entity on which its stock may be traded or pursuant to an order of a court or governmental entity to publicly disclose the existence of the Agreement and the Study Data.

9.6 Destruction of Confidential Information. Upon expiration or termination of the Agreement, the Receiving Party shall, upon request by the Disclosing Party, immediately destroy or return all of the Disclosing Party's Confidential Information relating solely to its Compound as monotherapy (but not to the Combined Therapy or the Combined Therapy Study Data) in its possession; *provided, however,* that the Receiving Party shall be entitled to retain one (1) copy of Confidential Information solely for record-keeping purposes and shall not be required to destroy any off-site computer files created during automatic system back up which are subsequently stored securely by the Receiving Party.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES

10.1 Authority and Binding Agreement. BioXcel and Nektar each represents and warrants to the other that (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (c) the Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium, and similar laws of general application affecting the enforcement of creditors' rights generally, and subject to general equitable principles,

including the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

10.2 No Conflicts. BioXcel and Nektar each represents and warrants that, to the best of its knowledge as of the Effective Date, it has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement, or that would otherwise materially conflict with or materially adversely affect the rights granted to the other Party under this Agreement.

10.3 Litigation. BioXcel and Nektar each represents and warrants that, to the best of its knowledge as of the Effective Date, it is not aware of any pending or threatened litigation (and has not received any communication) that alleges that its activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement it would violate, any of the intellectual property rights of any other Person (after giving effect to the license grants in this Agreement).

10.4 No Adverse Proceedings. Except as otherwise notified to the other Party, there is not pending or, to the knowledge of such Party as of the Effective Date, threatened, against such Party, any claim, suit, action or governmental proceeding that would, if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement.

10.5 Consents. BioXcel and Nektar each represents and warrants that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (i) required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained (or will have been obtained prior to such execution and delivery) and (ii) required to be obtained by such Party in connection with the performance of its obligations under this Agreement have been obtained or will be obtained prior to such performance.

10.6 No Debarment. Each Party hereby certifies to the other that it has not used, and will not use the services of any person disqualified, debarred, banned, subject to debarment or convicted of a crime for which a person could be debarred by the FDA under 21 U.S.C. 335a, as amended (or subject to a similar sanction of any other Regulatory Authority), in any capacity in connection with any of the services or work provided under any Combined Therapy Trial and that this certification may be relied upon in any applications to the FDA or any other Regulatory Authority. It is understood and agreed that this certification imposes a continuing obligation upon each Party to notify the other promptly of any change in the truth of this certification. Upon request by a Party, the other Party agrees to provide a list of persons used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its Affiliates pursuant to this Agreement who, within the five years preceding the Effective Date, or subsequent to the Effective Date, were or are convicted of one of the criminal offenses required by 21 U.S.C. 335a, as amended, to be listed in any application for approval of an abbreviated application for drug approval.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

10.7 Compliance with Applicable Law. BioXcel and Nektar each represents and warrants that it shall comply with all Applicable Laws of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder, including those pertaining to the production and handling of drug products and reporting of information, such as those set forth by the Regulatory Agencies, as applicable, and the applicable terms of this Agreement, in the performance of its obligations hereunder.

10.8 Affiliates. BioXcel and Nektar each represents and warrants that, to the extent the intellectual property, Regulatory Documentation or Technology licensed by it hereunder are Controlled by its Affiliates or a Third Party, it has the right to use, and has the right to grant (sub)licenses to the other Party to use, such intellectual property, Regulatory Documentation or Technology in accordance with the terms of this Agreement and subject to any restrictions expressly disclosed in writing to the other Party.

10.9 Ethical Business Practices. BioXcel and Nektar each represents and warrants that neither it nor its Affiliates will make any payment, either directly or indirectly, of money or other assets, including the compensation such Party derives from this Agreement (collectively a "***Payment***"), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or Persons acting on behalf of any of the foregoing (collectively "***Officials***") where such Payment would constitute violation of any law, including the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq. In addition, regardless of legality, neither it nor its Affiliates will make any Payment either directly or indirectly to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement. All activities will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute.

10.10 Single Agent Compound Safety Issues. Each Party represents and warrants that, to the best of its knowledge, it is not aware of any material safety or toxicity issue with respect to its Single Agent Compound that are not reflected in the investigator's brochure for its Single Agent Compound existing as of the Effective Date.

10.11 Accounting. Each Party represents and warrants that all transactions under the Agreement shall be properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects.

10.12 DISCLAIMER OF WARRANTY. THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 10 ARE IN LIEU OF, AND THE PARTIES DO HEREBY DISCLAIM, ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 11
INDEMNIFICATION

11.1 Nektar Indemnification. Nektar hereby agrees to defend, hold harmless and indemnify (collectively, "***Indemnify***") BioXcel, its Affiliates, and its and their agents, directors, officers, and employees (the "***BioXcel Indemnitees***") from and against any and all liabilities, expenses and/or losses, including reasonable cost of investigations, experts, legal expenses and attorneys' fees (collectively "***Losses***") resulting from Third Party suits, claims, actions and demands (each, a "***Third Party Claim***") to the extent that they arise or result from (a) the gross negligence or intentional misconduct of Nektar, any Nektar Indemnitee or any (sub)licensee of Nektar conducting activities on behalf of Nektar under this Agreement or pursuant to a (sub)license granted by Nektar; (b) any breach by Nektar of any representation, warranty or covenant set forth in Article 10, or any material breach by Nektar of any provision of this Agreement; (c) any injury to a subject in a Combined Therapy Trial caused solely by the development, use or manufacture of the Nektar Compound; (d) any injury to a subject in a Combined Therapy Trial where it ultimately cannot be or is not determined if such injury is the direct result of the Nektar Compound on the one hand or the BioXcel Compound on the other hand, *provided that*, in the case of this clause (d), Nektar shall only Indemnify the BioXcel Indemnitees for [***] percent ([***]%) of any such Loss; or (e) the use by Nektar, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Nektar Study Data, Nektar Study Inventions, Nektar Study Patent Rights, Combined Therapy Trial Inventions and Combined Therapy Patent Rights outside the scope of this Agreement (other than with respect to Third Party Claims that are covered under Section 6.4)); but excluding, in each case with respect to clauses (a) through (c), or (e), any such Losses to the extent BioXcel is obligated to Indemnify the Nektar Indemnitees pursuant to Section 11.2.

11.2 BioXcel Indemnification. BioXcel hereby agrees to Indemnify Nektar, its Affiliates, and its and their agents, directors, officers, and employees (the "***Nektar Indemnitees***") from and against any and all Losses resulting from Third Party Claims to the extent that they arise or result from (a) the gross negligence or intentional misconduct of BioXcel or any BioXcel Indemnitee or any (sub) licensee of BioXcel conducting activities on behalf of BioXcel under this Agreement or pursuant to a (sub)license granted by BioXcel; (b) any breach by BioXcel of any representation, warranty or covenant set forth in Article 10, or any material breach by BioXcel of any provision of this Agreement; (c) any injury to a subject in a Combined Therapy Trial caused solely by the development, use or manufacture of the BioXcel Compound; (d) any injury to a subject in a Combined Therapy Trial where it ultimately cannot be or is not determined if such injury is the direct result of the BioXcel Compound on the one hand or the Nektar Compound on the other hand; *provided that*, in the case of this clause (d), BioXcel shall only Indemnify the Nektar Indemnitees for [***] percent ([***]%) of any such Loss; or (e) the use by BioXcel, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, BioXcel Study Data, BioXcel Study Inventions, BioXcel Study Patent Rights, Combined Therapy Trial Inventions and Combined Therapy Patent Rights outside the scope of this Agreement (other than with respect to Third Party Claims that are covered under Section 6.4)), but excluding, in each case with respect

to clauses (a) through (c), or (e), any such Losses to the extent Nektar is obligated to Indemnify the BioXcel Indemnitees pursuant to Section 11.1.

11.3 Indemnification Procedure. Each Party's agreement to Indemnify the other Party is conditioned on the performance of the following by the Party seeking indemnification: (a) providing written notice to the Indemnifying Party of any Loss of the types set forth in Section 11.1 and 11.2 within ninety (90) calendar days after the Party seeking indemnification has knowledge of such Third Party Claim; *provided that*, any delay in complying with the requirements of this clause (a) will only limit the Indemnifying Party's obligation to the extent of the prejudice caused to the Indemnifying Party by such delay; (b) permitting the Indemnifying Party to assume full responsibility (but without any reservation of rights or recovery against the Indemnified Party) to investigate, prepare for and defend against any such Loss; (c) providing reasonable assistance to the Indemnifying Party, at the Indemnifying Party's expense, in the investigation of, preparation for and defense of any Loss; and (d) not compromising or settling such Loss without the Indemnifying Party's written consent, such consent not to be unreasonably withheld or delayed.

11.4 Separate Defense of Claims. In the event that the Parties cannot agree as to the application of Sections 11.1, 11.2 and/or 11.3 to any particular Loss, the Parties may conduct separate defenses of such Loss. Each Party further reserves the right to claim indemnity from the other in accordance with Sections 11.1, 11.2 and/or 11.3 upon resolution of the underlying claim, notwithstanding clause (b) of Section 11.3.

11.5 Insurance. Each Party shall maintain commercially reasonable levels of insurance or other adequate and commercially reasonable forms of protection or self-insurance to satisfy its indemnification obligations under this Agreement. Each Party shall provide the other Party with written notice at least thirty (30) calendar days prior to the cancellation, non-renewal or material change in such insurance or self-insurance that would materially adversely affect the rights of the other Party hereunder. The maintenance of any insurance shall not constitute any limit or restriction on damages available to a Party under this Agreement.

11.6 LIMITATION OF LIABILITY.

(a) NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT AND/OR SUCH PARTY'S PERFORMANCE HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE). NOTHING IN THIS SECTION 11.6(a) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 11.1 OR 11.2, OR DAMAGES AVAILABLE FOR BREACHES OF PAYMENT OBLIGATIONS IN SECTIONS 7.1 OR 7.2, CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9 OR FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(b) EACH PARTY'S MAXIMUM, CUMULATIVE LIABILITY ARISING OUT OF OR RELATING TO A GIVEN COMBINED THERAPY TRIAL PERFORMED PURSUANT TO THIS AGREEMENT AND/OR SUCH PARTY'S PERFORMANCE RELATING THERETO, REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY, INDEMNITY OR OTHERWISE), WILL NOT EXCEED IN THE AGGREGATE FOR ALL CLAIMS RELATING TO SUCH COMBINED THERAPY TRIAL THE SUM OF TWO MILLION UNITED STATES DOLLARS (US$2,000,000.00) PROVIDED, HOWEVER, THAT NOTHING IN THIS SECTION 11.6(b) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 11.1 OR 11.2, OR ANY DAMAGES AVAILABLE FOR BREACHES OF PAYMENT OBLIGATIONS IN SECTIONS 7.1 OR 7.2, CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9 OR FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and, unless earlier terminated pursuant to Sections 12.2, 12.3 or 12.4 or any other termination right expressly stated in this Agreement, shall continue in effect until completion by all centers or institutions participating in the Combined Therapy Trials, the delivery of all Study Data, including all completed case report forms, all final analyses and all final clinical study reports contemplated by the Combined Therapy Trials, to both Parties, and the completion of any then agreed upon Protocol, Statistical Analysis and Bioanalysis Plan (the "***Term***"); *provided* that if termination language in Sections 2.1(e) applies, then the Term shall expire.

12.2 Termination for Material Breach.

(a) Notice and Cure Period. If a Party (the "***Breaching Party***") is in material breach, the other Party (the "***Non-Breaching Party***") shall have the right to give the Breaching Party notice specifying the nature of such material breach. The Breaching Party shall have a period of [***] ([***]) calendar days after receipt of such notice to cure such material breach (the "***Cure Period***") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

(b) Termination Right. The Non-Breaching Party shall have the right to terminate this Agreement, upon written notice, in the event that the Breaching Party has not cured such material breach within the Cure Period, *provided, however,* that if such breach is capable of cure but cannot reasonably be cured within the Cure Period, and the Breaching Party notifies the non-Breaching Party of its intent to cure such material breach, commences actions to cure such material breach within the Cure Period and thereafter diligently continues such actions, the Breaching Party shall have an additional [***] ([***]) calendar days to cure such breach. If a Party contests such termination pursuant to the dispute resolution procedures under Section 13.3, such

termination shall not be effective until a conclusion of the dispute resolution procedures in Section 13.3, as applicable, resulting in a determination that there has been a material breach that was not cured within the Cure Period (or, if earlier, abandonment of the dispute by such Party).

12.3 Termination for Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of such other Party's assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within [***] ([***]) calendar days after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

12.4 Termination due to Material Safety Issue; Clinical Hold.

(a) Either Party shall have the right to terminate this Agreement immediately upon written notice if it reasonably deems it necessary to protect the safety, health or welfare of subjects enrolled in any Combined Therapy Trial due to the existence of a Material Safety Issue. In the event of a termination due to a Material Safety Issue, prior to the terminating Party providing written notice, each Party's safety committee shall, to the extent practicable, meet and discuss in good faith the safety concerns raised by the terminating Party and consider in good faith the input, questions and advice of the non-terminating Party, but should any dispute arise in such discussion, the dispute resolution processes set forth in Sections 2.8 or 13.3 shall not apply to such dispute and the terminating Party shall have the right to issue such notice and such termination shall take effect without the Parties first following the procedures set forth in Sections 2.8 or 13.3.

(b) If a Clinical Hold with respect to the Nektar Compound, CPI Compound or the BioXcel Compound should arise at any time after the Effective Date, the Parties will meet and discuss the basis for the Clinical Hold, how long the Clinical Hold is expected to last, and how they might address the issue that caused the Clinical Hold. If, after ninety (90) calendar days of discussions following the Clinical Hold, either Party reasonably concludes that the issue is not solvable or that unacceptable and material additional costs/delays have been and/or will continue to be incurred in the conduct of the Combined Therapy Trial, then such Party may immediately terminate this Agreement.

12.5 Termination by Nektar for Breach of SCA. In the event that Nektar receives a notice from BMS that any action taken or that the taking of any action under this Agreement by either Nektar of BioXcel has caused or will cause Nektar to be in breach of the SCA, and such breach cannot be cured in accordance with the terms of the SCA, Nektar shall have the right to terminate this Agreement on at least [***] ([***]) days prior written notice to BioXcel.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

12.6 Termination by Nektar related to BioXcel Diligence Failure. Nektar shall have the right to terminate this Agreement on at least [***] ([***]) days prior written notice to BioXcel in the event that BioXcel fails to achieve any of the Diligence Targets for the Initial Trial within [***] ([***]) days of the target date set forth in Section 2.6(a), *provided*, that (a) Nektar's notice of termination under this Section shall specifically cite the Diligence Target or Diligence Targets that BioXcel failed to achieve, (b) prior to Nektar terminating pursuant to this Section, the JDC shall meet and discuss the reason for such failure, and if the reason was other than due to BioXcel's breach or negligence, the JDC shall extend the time period(s) for achieving such Diligence Target(s) for the period of time caused by such circumstance that was not due BioXcel's breach or negligence, and (c) Nektar's right to terminate this Agreement pursuant to this Section 12.6 shall not be available to Nektar in the event that BioXcel's failure to meet a Diligence Target cited in the Nektar notice of termination was due in whole or in part to (i) the failure of Nektar to perform an obligation of Nektar set forth in this Agreement or Nektar's breach or misconduct; or (ii) the failure of the Parties to agree on terms for obtaining a CPI Compound.

12.7 Termination by Either Party if no CPI Compound Agreed. Either Party shall have the right to terminate this Agreement on at least [***] ([***]) days notice to the other Party in the event the Parties have not agreed in writing on the terms for obtaining a CPI Compound by November 30, 2018, or such later date as may be mutually agreed by the Parties in writing.

12.8 Effect of Termination. Upon expiration or termination of this Agreement, (a) the licenses granted to each Party to conduct a Combined Therapy Trial in Sections 3.1 and 3.2 shall terminate, and (b) the Parties shall use reasonable efforts to wind down activities under this Agreement in a medically reasonable manner and avoid incurring any additional expenditures or non-cancellable obligations; *provided that*, if sufficient quantities of the Nektar Compound and the CPI Compound are available, (i) in the case of termination pursuant to Section 12.4, BioXcel may continue to dose subjects enrolled in any then ongoing Combined Therapy Trial through completion of the applicable Protocol if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law(s); and (ii) in the case of termination by Nektar pursuant to Section 12.5, BioXcel may continue to dose subjects enrolled prior to receipt of the termination notice from Nektar in any then ongoing Combined Therapy Trial through completion of the applicable Protocol. Any such wind-down activities will include the return to Nektar, or destruction, of all Nektar Compound provided to BioXcel and not consumed in the Combined Therapy Trials. If applicable, upon termination of this Agreement, the Parties shall remain responsible pursuant to the terms of this Agreement for any expenses incurred prior to such termination and that are associated with terminating any ongoing clinical trial work and/or result from such ongoing activities under this Agreement solely to the extent such activities are deemed necessary by BioXcel (after discussion at a meeting of the JDC) based on reasonable medical judgment to protect the health of subjects participating in any Combined Therapy Trial.

12.9 Survival. The following Articles and Sections of this Agreement and all definitions relating thereto shall survive any expiration or termination of this Agreement for any reason: Section 2.1(b)(i), Section 2.1(b)(ii) (first sentence), Section 2.2 ("*Safety Reporting*"),

Section 5.1(a)(viii), Section 5.1(b)(iii), Article 6 ("*Intellectual Property*"), Section 7.1 ("*Combined Therapy Trial Expenses*"), Section 7.2 ("*Invoicing; Payment*"), Section 8.1 ("*Records*"), Section 8.2 ("*Ownership of Study Data*"), Section 8.3 ("*Use of Study Data*"), Section 8.4 ("*Access to Study Data*"), Section 8.5 ("*Samples*"), Article 9 ("*Confidentiality*"); Article 10 ("*Representations and Warranties*"), Article 11 ("*Indemnification*"), Section 12.8 ("*Effect of Termination*"), Section 12.9 ("*Survival*"), Section 13.1 ("*Entire Agreement*"), Section 13.2 ("*Governing Law*"), Section 13.3 ("*Dispute Resolution*"), Section 13.4 ("*Injunctive Relief*"), Section 13.6 ("*Notices*"), Section 13.7 ("*No Waiver; Modifications*"), Section 13.8 ("*No Strict Construction*"), Section 13.9 ("*Independent Contractor*"), Section 13.10 ("*Assignment; Licensees*"), Section 13.11 ("*Headings*"), Section 13.13 ("*Severability*"), Section 13.14 ("*Further Assurance*"), Section 13.15 ("*No Benefit to Third Parties*") and Section 13.16 ("*Construction*").

ARTICLE 13
MISCELLANEOUS

13.1 Entire Agreement. The Parties acknowledge that this Agreement shall govern all activities of the Parties with respect to the Combined Therapy Trials from the Effective Date forward. This Agreement, including the Exhibits hereto and together with the Protocol, Quality Agreement, Statistical Analysis Plan, and Supply Agreement, sets forth the complete, final and exclusive agreement between the Parties concerning the subject matter hereof and supersedes all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth in this Agreement. All Exhibits attached hereto are incorporated herein as part of this Agreement.

13.2 Governing Law. This Agreement and all claims relating to or arising out of this Agreement or the breach thereof shall be governed and construed in accordance with the internal laws of the State of New York, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

13.3 Dispute Resolution.

(a) In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement (each a "***Dispute***"), other than a JDC Dispute or a Publication Dispute or a dispute as to whether a Material Safety Issue exists, the Parties shall refer such Dispute promptly to the Alliance Managers for resolution. If the Alliance Managers are unable to resolve such Dispute within ten (10) calendar days after a matter has been presented to them, then upon the request of either Party by written notice, the Parties shall refer such Dispute to the Executive Officers. This Agreement shall remain in effect during the pendency of any such dispute. In the event that no resolution is made by them in good faith negotiations within ten (10) calendar days after such referral to them, such unresolved Dispute shall be referred to the Chief Executive Officer of BioXcel or his or her designee and the Chief Scientific Officer of Nektar or his or her designee for attempted resolution by good faith negotiations within fifteen (15) calendar

days after such referral is made. In the event such officers are unable to resolve such Dispute within such fifteen (15) calendar day period then, if such Dispute constitutes an Arbitration Matter, such Dispute shall be resolved through arbitration in accordance with Section 13.3(b); *provided*, *however*, that with respect to any such Dispute that relates to a matter described in Section 13.4, either Party shall have the right to seek an injunction or other equitable relief without waiting for the expiration of such fifteen (15) calendar day negotiation period, and with respect to any JDC Dispute or Publication Dispute, the specific dispute resolution processes contained in Sections 2.8 or 9.5(b), as applicable, will apply.

(b) If a Dispute that constitutes an Arbitration Matter remains unresolved after escalation to the senior executives as described above, either Party may refer the matter to arbitration as described herein, the results of which shall be binding upon the Parties. Any arbitration under this Agreement shall be conducted under the auspices of the American Arbitration Association ("***AAA***") by a panel of three (3) arbitrators pursuant to that organization's Commercial Arbitration Rules then in effect; *provided*, *however*, that the Parties hereby agree that the time schedule for the appointment of arbitrators and the time schedule for submission of the statement of defense shall follow the American Arbitration Association Arbitration Rules. The fees and expenses of the arbitrators shall be borne in equal shares by the Parties. Each Party shall bear the fees and expenses of its legal representation in the arbitration. The arbitral tribunal shall not reallocate either the fees and expenses of the arbitrators or of the Parties' legal representation. The arbitration shall be held in New York, New York, USA, which shall be the seat of the arbitration. The language of the arbitration shall be English. Notwithstanding anything to the contrary in this Agreement, each Party shall be entitled to recover its attorneys' fees and arbitration fees and expenses to the extent it is successful in bringing an action to enforce its rights to indemnification under this Agreement against the other Party.

13.4 Injunctive Relief. Notwithstanding anything herein to the contrary, a Party may seek an injunction or other injunctive relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis. For the avoidance of doubt, if either Party (a) discloses Confidential Information of the other Party other than as permitted under Article 9, (b) uses (in the case of BioXcel) the Nektar Compound or Nektar Technology or (in the case of Nektar) the BioXcel Compound or BioXcel Technology in any manner other than as expressly permitted under this Agreement or (c) otherwise is in material breach of this Agreement and such material breach could cause immediate harm to the value of the BioXcel Compound (by Nektar) or the Nektar Compound (by BioXcel), the other Party shall have the right to seek an injunction or other equitable relief precluding the other Party from continuing its activities related to the applicable activity without waiting for the conclusion of the dispute resolution procedures under Section 13.3.

13.5 Force Majeure. The Parties shall be excused from the performance of their obligations under this Agreement (other than the payment of monies owed to the other Party) to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so

long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean acts of God, strikes or other concerted acts of workers (except for strikes or other concerted acts of a Party's respective workers), civil disturbances, fires, earthquakes, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the control of the Parties.

13.6 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if such notice is timely and is:(a) mailed by first class certified or registered mail, postage prepaid, return receipt requested, (b) sent by express delivery service, or (c) personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For BioXcel:	BioXcel Therapeutics 555 Long Wharf Drive 5th Floor New Haven, CT 06405 Attention: Vimal Mehta, Ph.D.
With a copy to:	BioXcel Therapeutics 555 Long Wharf Drive 5th Floor New Haven, CT 06405 Attention: General Counsel
For Nektar:	Nektar Therapeutics 455 Mission Bay Boulevard South San Francisco, CA 94158 Attention: Chief Medical Officer
With a copy to:	Nektar Therapeutics 455 Mission Bay Boulevard South San Francisco, CA 94158 Attention: General Counsel

Any such communication shall be deemed to have been received when delivered. It is understood and agreed that this Section 13.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

13.7 No Waiver; Modifications. It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. The failure of either Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of any such obligation. No amendment, modification, release or discharge to this Agreement, the Quality Agreement or any material amendment, modification, release or discharge to a Bioanalysis Plan, a Statistical Analysis Plan, or a CRO Agreement (to the extent provided in Section 2.4(o)) shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.8 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

13.9 Independent Contractor; No BioXcel Third Party Beneficiary Rights. The Parties are independent contractors of each other, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall be the agent of the other or have any authority to act for, or on behalf of, the other Party in any matter. BioXcel shall not be a third party beneficiary under any agreement between Nektar and BMS, including without limitation the SCA.

13.10 Assignment; Licensees.

(a) Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, *except* that a Party may make such an assignment without the other Party's consent, provided that such Party provide written notice of such assignment to the other Party within thirty (30) calendar days of such assignment, (a) to an Affiliate, (b) to a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party or (c) to a Third Party that acquires all the rights to the BioXcel Compound, in the case of BioXcel, or the Nektar Compound, in the case of Nektar. Any assignment or attempted assignment by any Party in violation of the terms of this Section 13.10 shall be null and void and of no legal effect.

(b) Licensees. If a Party grants its or the other Party's Affiliate or a Third Party a license (other than a license solely to make a Product for a Party) to develop and commercialize its Single Agent Compound on a worldwide basis or in any geographic region and/or for all purposes or a limited field, (a "**Licensee**"), such Party will obtain the Licensee's agreement to abide by the terms of this Agreement in the same manner as the licensor Party.

13.11 Headings. The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

13.12 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronic (e.g., .pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

13.13 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

13.14 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Agreement.

13.15 No Benefit to Third Parties. The representations, warranties and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other parties.

13.16 Construction.

(a) General. Except as otherwise explicitly specified to the contrary, (a) references to a Section, Article or Exhibit means a Section or Article of, or Exhibit to, this Agreement and all subsections thereof, unless another agreement is specified; (b) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case including the then-current amendments thereto; (c) words in the singular or plural form include the plural and singular form, respectively; (d) the terms "including," "include(s)," "such as," and "for example" used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; and (e) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(b) No Response. Where a provision of this Agreement provides for a Party to respond within a designated period following written notice from the other Party (e.g., Sections 5.1(a)(vi) and 5.1(b)(iv)), and if such Party fails to respond within the designated period, then the failure to respond shall create or imply: (i) that the non-responding Party agrees with the proposed action to be taken by the other Party, or (ii) consent that an action proposed to be taken may be taken, except if such consent expressly conflicts with the terms of this Agreement.

[*Signature page follows*]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

BioXcel Therapeutics	**Nektar Therapeutics**
By: _____	By: _____
Name: Vimal Mehta, Ph.D	Name: Howard Robin
Title: CEO	Title: President and CEO
	By: _____
	Name: Gil M. Labrucherie
	Title: Senior Vice President and CFO

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Index of Exhibits and Schedules

Attached:

Exhibit A : Initial Trial Overview
Exhibit B : Press Release
Exhibit C : BioXcel CRO and Sites
Exhibit D : Nektar Compound
Exhibit E : BioXcel Compound

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EXHIBIT A

INITIAL TRIAL OVERVIEW

- Open-label, single arm 36 patient Phase 1/2 study conducted at a single center to determine the safety and ORR of BXCL-701 administered orally in combination with NKTR-214 and a checkpoint inhibitor (TBD). The study will also assess other efficacy parameters, such as PFS, OS and DOR.

- Lead-in Stage (safety run-in) will be conducted followed by Efficacy and Biomarker Stage in which patients with mPaC will receive the 3 drugs, BXCL701 being given at the dose (400mcg or 600mcg) identified in the safety run-in.

- $[***] estimated cost

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EXHIBIT B

FORM OF PRESS RELEASE

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT C

BIOXCEL CRO AND

CLINICAL SITES

CRO: Novella Clinical LLC

Hospital
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EXHIBIT D

NEKTAR COMPOUND

NKTR-214, a CD122-biased cytokine agonist conjugated with multiple releasable chains of polyethylene glycol (PEG)

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WHERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT E

BIOXCEL COMPOUND

BXCL-701 (talabostat mesylate); valine-proline boronic acid formulated as the methanesulfonate salt

Name of active ingredient (BXCL701):
(2R)-1-[(2S)-2-amino-3-methyl-1-oxobutyl]-2-pyrrolidinyl]boronic acid, methanesulfonate salt

Exhibit 31.1

CERTIFICATIONS

I, Vimal Mehta, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioXcel Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)):

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2018

By: /s/ Vimal Mehta
Vimal Mehta, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Richard Steinhart, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioXcel Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)):

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2018

By: /s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of BioXcel Therapeutics, Inc. (the "Company") for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Vimal Mehta, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2018

By: /s/ Vimal Mehta
Vimal Mehta, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of BioXcel Therapeutics, Inc. (the "Company") for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard Steinhart, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2018

By: /s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer
(Principal Financial Officer)