UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) May 20, 2019

BioXcel Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) **001-38410** (Commission File Number) **82-1386754** (I. R. S. Employer Identification No.)

555 Long Wharf Drive

New Haven, CT 06511 (Address of principal executive offices, including Zip Code)

(475) 238-6837

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	BTAI	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 1.01 Entry into a Material Definitive Agreement.

On May 20, 2019, BioXcel Therapeutics, Inc. (the "Company") entered into an Open Market Sale AgreementSM (the "Sale Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company may offer and sell shares of its common stock, par value \$0.001 per share (the "Common Stock"), having aggregate gross sales proceeds of up to \$20.0 million (the "Shares"), from time to time, through an "at the market offering" program under which Jefferies will act as sales agent. The shares of Common Stock that may be sold pursuant to the Sale Agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-230674), as supplemented by the prospectus supplement dated May 20, 2019 relating to the sale of the Common Stock (the "Prospectus Supplement").

Under the Sale Agreement, the Company will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitations on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sale Agreement, Jefferies may sell the Shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on or through the Nasdaq Capital Market or any other existing trading market for the Common Stock. The Company has agreed to pay Jefferies a commission equal to 3.00% of the gross sales proceeds of any shares of Common Stock sold through Jefferies under the Sale Agreement, and also has provided Jefferies with customary indemnification and contribution rights. The Sale Agreement may be terminated at any time by either party upon prior written notice to the other party.

The representations and warranties contained in the Sale Agreement were made only for purposes of the transactions contemplated by the Sale Agreement as of specific dates and may have been qualified by certain disclosures between the parties and a contractual standard of materiality different from those generally applicable under securities laws, among other limitations. The representations and warranties were made for purposes of allocating contractual risk between the parties to the Sale Agreement and should not be relied upon as a disclosure of factual information relating to the Company, Jefferies or the transactions described in this Current Report on Form 8-K.

The foregoing description of the material terms of the Sale Agreement is qualified in its entirety by reference to the full agreement, a copy of which is filed as Exhibit 1.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The Shares will be sold pursuant to the Registration Statement, and offerings of the Shares will be made only by means of the Prospectus Supplement. This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of any offer to buy the securities discussed herein, nor shall there be any offer, solicitation or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

A legal opinion relating to the Shares is included as Exhibit 5.1 to this Current Report.

Item 9.01	Financial Statements and Exhibits.
(d) Exhibits.	
Exhibit No.	Description
<u>1.1</u> <u>5.1</u> <u>23.1</u>	<u>Open Market Sale Agreement, dated as of May 20, 2019, by and between BioXcel Therapeutics, Inc. and Jefferies LLC.</u> <u>Opinion of Latham & Watkins LLP regarding the validity of the Shares.</u> <u>Consent of Latham & Watkins LLP (included in Exhibit 5.1 hereto).</u>
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SIGNATURES

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

Date: May 20, 2019

BIOXCEL THERAPEUTICS, INC.

/s/ Richard Steinhart Richard Steinhart Chief Financial Officer

OPEN MARKET SALE AGREEMENTSM

Ladies and Gentlemen:

BioXcel Therapeutics, Inc., a Delaware corporation (the "**Company**"), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through Jefferies LLC, as sales agent and/or principal (the "**Agent**"), shares of the Company's common stock, par value \$0.001 per share (the "**Common Shares**"), having an aggregate offering price of up to the Maximum Program Amount (as defined herein) on the terms set forth in this agreement (this "**Agreement**").

Section 1. DEFINITIONS

(a) <u>Certain Definitions</u>. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:

"Affiliate" of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first- mentioned Person. The term "control" (including the terms "controlling," "controlled by" and "under common control with") means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"**Agency Period**" means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement, (y) the date this Agreement is terminated pursuant to <u>Section 7</u> and (z) the third anniversary of the date of this Agreement.

"**Agent**" has the meaning set forth in the introductory paragraph of this Agreement.

"Agreement" has the meaning set forth in the introductory paragraph of this Agreement.

"Base Prospectus" has the meaning set forth in <u>Section 2(a)</u>.

"Blackout Period" has the meaning set forth in Section 3(b)(viii).

"Code" has the meaning set forth in <u>Section 2(ff)</u>.

"Commission" means the U.S. Securities and Exchange Commission.

SM "Open Market Sale Agreement" is a service mark of Jefferies LLC

"Common Shares" has the meaning set forth in the introductory paragraph of this Agreement.

"Company" has the meaning set forth in the introductory paragraph of this Agreement.

"**Default**" has the meaning set forth in <u>Section 2(r)</u>.

"EDGAR" has the meaning set forth in <u>Section 2(b)</u>.

"Emerging Growth Company" has the meaning set forth in <u>Section 2(f)</u>.

"Environmental Laws" has the meaning set forth in Section 2(ee).

"ERISA" has the meaning set forth in Section 2(ff).

"ERISA Affiliate" has the meaning set forth in Section 2(ff).

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.

"Existing Instrument" has the meaning set forth in Section 2(r).

"FCPA" has the meaning set forth in Section 2(jj).

"FDA" has the meaning set forth in <u>Section 2(u)</u>.

"FDCA" has the meaning set forth in <u>Section 2(ii)</u>.

"FINRA" has the meaning set forth in Section 2(bb).

"**Floor Price**" means the minimum price set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable Selling Period, which may be adjusted by the Company at any time during the Selling Period by delivering written notice of such change to the Agent and which in no event shall be less than \$1.00 without the prior written consent of the Agent, which may be withheld in the Agent's sole discretion.

"Free Writing Prospectus" has the meaning set forth in Section 4(e).

"Issuance Amount" means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

"**Issuance Notice**" means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as <u>Exhibit A</u> that is executed by its Chief Executive Officer, President or Chief Financial Officer.

"Issuance Notice Date" means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).

"Issuance Price" means the Sales Price less the Selling Commission.

"Intellectual Property Rights" has the meaning set forth in <u>Section 2(s)</u>.

"Investment Company Act" has the meaning set forth in Section 2(x).

"Material Adverse Change" has the meaning set forth in Section 2(1).

"Material Adverse Effect" has the meaning set forth in <u>Section 2(o)</u>.

"**Maximum Program Amount**" means Common Shares with an aggregate Sales Price of the lesser of (1) \$20,000,000, (2) the aggregate amount of Shares registered under the Registration Statement and (3) the number or dollar amount of Common Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable).

"Money Laundering Laws" has the meaning set forth in Section 2(kk).

"OFAC" has the meaning set forth in <u>Section 2(kk)</u>.

"Original Registration Statement" has the meaning set forth in Section 2(a).

"Other Offering Amendment" means an amendment or supplement to the Registration Statement or Prospectus relating solely to the issuance or offering of securities other than the Common Shares.

"**Permits**" has the meaning set forth in <u>Section 2(u)</u>.

"**Person**" means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.

"Principal Market" means the Nasdaq Capital Market or such other national securities exchange on which the Common Shares, including any Shares, are then listed.

"Prospectus" has the meaning set forth in <u>Section 2(a)</u>.

"**Registration Statement**" has the meaning set forth in <u>Section 2(a)</u>.

"Regulation M" has the meaning set forth in <u>Section 2(z)</u>.

"Regulatory Agencies" has the meaning set forth in Section 2(u).

"Related Judgment" has the meaning set forth in Section 8(g).

"Related Proceedings" has the meaning set forth in <u>Section 8(g)</u>.

"Representation Date" has the meaning set forth in the introductory paragraph of Section 2.

"Rule 102" has the meaning set forth in <u>Section 4(u)</u>.

"Sales Price" means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.

"Sanctions" has the meaning set forth in Section 2(mm).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.

"Selling Commission" means three percent (3.0%) of the gross proceeds for any Shares sold pursuant to this Agreement.

"**Selling Period**" means the period of one (1) to twenty (20) consecutive Trading Days (as determined by the Company in the Company's sole discretion and specified in the applicable Issuance Notice) including the Trading Day on which an Issuance Notice is delivered pursuant to <u>Section 3(b)(i)</u>, if such notice is delivered prior to 3:00 p.m. (New York City time) and otherwise, following the Trading Day on which an Issuance Notice is delivered pursuant to <u>Section 3(b)(i)</u>.

"Settlement Date" means the second business day following each Trading Day during the Selling Period on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.

"Shares" means the Company's Common Shares issued or issuable pursuant to this Agreement.

"Specified Courts" has the meaning set forth in <u>Section 8(g)</u>.

"Time of Sale" has the meaning set forth in <u>Section 3(b)(v)</u>.

"Time of Sale Information" has the meaning set forth in Section 2(b).

"Trading Day" means any day on which the Principal Market is open for trading.

"Triggering Event Date" has the meaning set forth in <u>Section 4(o)</u>.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to, and agrees with, the Agent that as of (1) the date of this Agreement, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to <u>Section 4(0)</u> and (5) as of each Time of Sale (each of the times referenced above is referred to herein as a "**Representation Date**"), except as may be disclosed in the Time of Sale Information (including any documents incorporated by reference in the Prospectus and any supplements thereto) on or before a Representation Date:

(a) <u>Registration Statement</u>. The Company has prepared and filed with the Commission a shelf registration statement on Form S-3 (File No. 333-230674) that contains a

base prospectus (the "**Base Prospectus**"). Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. Such registration statement, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act as from time to time amended or supplemented, is herein referred to as the "**Registration Statement**," and the Base Prospectus together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the "**Prospectus**," except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term "**Prospectus**" shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally became effective is herein called the "**Original Registration Statement**." As used in this Agreement, the terms "amendment" or "supplement" when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference.

All references in this Agreement to financial statements and schedules and other information that is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing of any document under the Exchange Act which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as of any specified date. The Company's obligations under this Agreement to furnish, provide, deliver or make available (and all other references of like import) copies of any report or statement shall be deemed satisfied if the same is filed with the Commission through EDGAR.

At the time the Registration Statement was originally declared effective, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. During the Agency Period, each time the Company files an annual report on Form 10-K the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) <u>Compliance with Registration Requirements</u>. The Original Registration Statement has been declared effective by the Commission under the Securities Act. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information with respect to the Registration Statement. No stop order suspending the effectiveness of the Registration Statement is in effect and no proceedings for

such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission.

The Prospectus when filed complied in all material respects with the Securities Act and, if filed by electronic transmission pursuant to the Commission's Electronic Data Gathering, Analysis, and Retrieval System ("EDGAR") (except as may be permitted by Regulation S-T under the Securities Act), was identical to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became effective and at each Representation Date, complied and will comply, as the case may be, in all material respects with the Securities Act and did not and will not, as the case may be, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading (except that the foregoing shall not apply to those parts of the Registration Statement that constitute the Statement of Eligibility (Form T-1) under the Trust Indenture Act of 1939). As of the date of this Agreement, the Prospectus and any Free Writing Prospectus considered together (collectively, the "Time of Sale Information") did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and at each Representation Date, did not and will not, as the case may be, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement or any post-effective amendment thereto, or the Prospectus or any Free Writing Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in <u>Section 6</u> below. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said Rule.

(c) <u>Ineligible Issuer Status</u>. The Company is not an "ineligible issuer" in connection with the offering of the Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Any Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or behalf of or used or referred to by the Company complies or will comply, as the case may be, in all material respects with the requirements of Rule 433 under the Securities Act, including timely filing with the Commission or retention where required and legending, and each such Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the issuance and sale of the Shares did not, does not and will not include any information that conflicted, conflicts with or will conflict with the information contained in the Registration

Statement or the Prospectus, as then amended and supplemented, including as amended or supplemented by any document incorporated by reference therein. Except for the Free Writing Prospectuses, if any, and electronic road shows, if any, furnished to the Agent before first use, the Company has not prepared, used or referred to, and will not, without the Agent's prior consent, prepare, use or refer to, any Free Writing Prospectus.

(d) <u>Incorporated Documents</u>. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, at the time they were filed with the Commission, complied in all material respects with the requirements of the Exchange Act, as applicable, and, when read together with the other information in the Prospectus, do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(e) <u>Exchange Act Compliance</u>. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, and any Free Writing Prospectus or amendment or supplement thereto complied or will comply at the time of such filing in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the time the Registration Statement and any amendments thereto become effective and at each Representation Date, as the case may be, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(f) <u>Emerging Growth Company Status</u>. From the time of filing of the Registration Statement with the Commission through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**").

(g) <u>Statistical and Market-Related Data</u>. The statistical and market-related data included in the most recent Prospectus and the financial statements of the Company included in the most recent Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects.

(h) Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting.

(a) The Company maintains a system of internal control over financial reporting (as such term is defined in Rule 13a-15(f) of the Exchange Act) that complies with the requirements of the Exchange Act and that has been designed by, or under the supervision of, the Company's principal executive and principal financial officers, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. The Company maintains internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external purposes in

accordance with generally accepted accounting principles in the United States, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorization, (ii) transactions are recorded as necessary to permit preparation of the Company's financial statements in conformity with accounting principles generally accepted in the United States and to maintain accountability for its assets, (iii) access to the Company's assets is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for the Company's assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. As of the date of the most recent balance sheet of the Company reviewed or audited by BDO USA, LLP and the audit committee of the board of directors of the Company (the "**Audit Committee**"), there were no material weaknesses in the Company's internal controls.

(b) (i) The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act), (ii) such disclosure controls and procedures are designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and its principal financial officer by others within those entities, (iii) such disclosure controls and procedures have been evaluated by management of the Company for effectiveness as of the end of the Company's most recent fiscal quarter and (iv) such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established.

(c) Since the date of the most recent balance sheet of the Company reviewed or audited by BDO USA, LLP and the Audit Committee, (i) the Company has not been advised of or become aware of (A) any significant deficiencies in the design or operation of internal controls that could adversely affect the ability of the Company to record, process, summarize and report financial data, or any material weaknesses in internal controls, or (B) any fraud, whether or not material, that involves management or other employees who have a significant role in the internal controls of the Company; and (ii) there have been no significant changes in internal controls or in other factors that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

(d) The section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies" set forth in the most recent quarterly report on Form 10-Q or annual report on Form 10-K that is incorporated by reference in the Prospectus accurately and fully describes (i) the accounting policies that the Company believes are the most important in the portrayal of the Company's financial condition and results of operations and that require management's most difficult, subjective or complex judgments ("**Critical Accounting Policies**"); (ii) the judgments and uncertainties affecting the application of Critical Accounting Policies; and (iii) the likelihood that materially different amounts would be reported under different conditions or using different assumptions and an explanation thereof.

(i) <u>The Agreement</u>. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(j) <u>Authorization of the Shares</u>. The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Shares.

(k) <u>No Applicable Registration or Other Similar Rights</u>. There are no contracts, agreements or understandings between the Company and any person granting such person the right (other than rights that have been waived in writing or otherwise satisfied) to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person or to require the Company to include such securities in the securities registered pursuant to the Registration Statement or in any securities being registered pursuant to any other registration statement filed by the Company under the Securities Act.

(1) <u>No Material Adverse Change</u>. Except as otherwise disclosed in the Registration Statement and Prospectus (including as incorporated by reference into the Registration Statement and the Prospectus), subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus: (i) there has been no material adverse change, or any development that could reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, operations or prospects, whether or not arising from transactions in the ordinary course of business, of the Company (any such change is called a "**Material Adverse Change**"); (ii) the Company has not incurred any material liability or obligation, indirect, direct or contingent, not in the ordinary course of business nor entered into any material transaction or agreement not in the ordinary course of business; and (iii) there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of capital stock.

(m) <u>Independent Accountants</u>. BDO USA, LLP, who have expressed their opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) of the Company filed with the Commission as a part of the Registration Statement and incorporated by reference in the Prospectus are (i) independent public accountants as required by the Securities Act and the Exchange Act, (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X and (iii) a registered public accounting firm as defined by the Public Company Accounting Oversight Board (the "**PCAOB**") whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(n) <u>Preparation of the Financial Statements</u>. The historical financial statements (including the related notes and supporting schedules) incorporated by reference in the Prospectus comply as to form in all material respects with the requirements of Regulation S-X under the Securities Act and present fairly the financial condition, results of operations and cash flows of the Company purported to be shown thereby at the dates and for the periods indicated and have been prepared in conformity with accounting principles generally accepted in the United States applied on a consistent basis throughout the periods involved. The selected financial data included in the Prospectus present fairly in all material respects the information shown therein and such data have been compiled on a basis consistent with that of the financial statements incorporated by reference therein and the books and records of the Company.

(o) Incorporation and Good Standing of the Company. The Company has been duly organized, is validly existing and in good standing as a corporation or other business entity under the laws of its jurisdiction of organization and is duly qualified to do business and in good standing as a foreign corporation or other business entity in each jurisdiction in which its ownership or lease of property or the conduct of its businesses requires such qualification, except where the failure to be so qualified or in good standing (i) could not, in the aggregate, reasonably be expected to have a material adverse effect on the condition (financial or otherwise), results of operations, stockholders' equity, properties, business or prospects of the Company taken as a whole or (ii) could not, in the aggregate, impair in any material respect the ability of the Company to perform its obligations under this Agreement or to consummate any transactions contemplated by this Agreement or the Time of Sale Information (any such effect as described in clauses (i) or (ii), a "**Material Adverse Effect**"). The Company has all power and authority necessary to own or hold its properties and to conduct the businesses in which it is engaged. The Company does not own or control, directly or indirectly, any corporation, association or other entity

(p) <u>Capitalization and Other Capital Stock Matters</u>. The Company has an authorized capitalization as set forth in the Prospectus, and all of the issued shares of capital stock of the Company have been duly authorized and validly issued, are fully paid and non-assessable, conform in all material respects to the description thereof contained in the Prospectus and were issued in compliance with federal and state securities laws and not in violation of any preemptive right, resale right, right of first refusal or similar right. All of the Company's options, warrants and other rights to purchase or exchange any securities for shares of the Company's capital stock have been duly authorized and validly issued, conform to the description thereof contained in the Prospectus and were issued in compliance with federal and state securities laws. The description of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Prospectus accurately and fairly presents the information required to be shown with respect to such plans, arrangements, options and rights.

(q) <u>Stock Exchange Listing</u>. The Common Shares are registered pursuant to Section 12(b) of the Exchange Act and are listed on the Nasdaq Capital Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Shares under the Exchange Act or delisting the Common Shares from the Nasdaq Capital Market, nor has the Company received any notification that the Commission or the Nasdaq Capital Market is contemplating terminating such registration or listing.

(r) <u>Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required</u>. The Company is not in violation of its charter or bylaws or in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, mortgage, loan or credit agreement, note, contract, franchise, lease or other instrument to which the Company is a party or by which it may be bound (including, without limitation, any credit agreement, indenture, pledge agreement, security agreement or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness of the Company), or to which any of the property or assets of the Company is subject (each, an "**Existing Instrument**"), except for such Defaults as would not, individually or in the aggregate, result in a Material Adverse Effect. The Company's execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Prospectus and the issuance and sale of the Shares (i) have been duly authorized by all necessary corporate action and will not result in any violation of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, or require the consent of any other party to, any Existing Instrument and (ii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act, applicable state securities or blue sky laws and from FINRA.

(s) <u>No Material Actions or Proceedings</u>. There are no legal or governmental proceedings pending to which the Company is a party or of which any property or assets of the Company is the subject that could, in the aggregate, reasonably be expected to result in a Material Adverse Effect; and to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or others.

(t) Intellectual Property Rights. To the Company's knowledge, the Company owns or possesses, or can acquire on reasonable terms, adequate rights to use all patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, know-how, software, systems and technology (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) (collectively, "Intellectual Property Rights") necessary for or material to the conduct of its business now conducted or proposed in the Registration Statement or the Prospectus to be conducted, and has no reason to believe that the conduct of its business will conflict with, and has not received any notice of any claim of conflict with, any such rights of others. The expected expiration of any such Intellectual Property Rights owned by the Company are invalid or unenforceable, in whole or in part, and the Company is unaware of any facts that would form a reasonable basis for such a determination. To the knowledge of the Company, there are no unreleased liens or security interests which have been filed against any of the Intellectual Property Rights owned by or licensed to the Company. Except as disclosed in the Registration Statement or the Prospectus (i) the Company is not obligated to pay a material royalty, grant a license or provide other material

consideration to any third party in connection with the Intellectual Property Rights owned by or licensed to the Company; (ii) to the Company's knowledge, there are no rights of third parties to any of the Intellectual Property Rights owned by or licensed to the Company, in any field of use, other than the respective licensor to the Company of such Intellectual Property Rights; (iii) to the Company's knowledge, there is no material infringement, misappropriation breach, default or other violation, or the occurrence of any event that with notice or the passage of time would constitute any of the foregoing, by the Company, or third parties of any of the Intellectual Property Rights owned by or licensed to the Company; (iv) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others (a) challenging the Company's rights in or to, or the violation of any of the terms of, any of their Intellectual Property Rights; (b) challenging the validity, enforceability or scope of any such Intellectual Property Rights; or (c) that alleges the Company infringes, misappropriates or otherwise violates or conflicts with any Intellectual Property Rights or other proprietary rights of others, and, in each case, the Company is unaware of any facts which would form a reasonable basis for any such claim; (v) none of the Intellectual Property Rights owned by or licensed to the Company in its business has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company; and (vi) to the Company's knowledge, no employee of the Company is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or actions undertaken by the employee while employed with the Company. To the knowledge of the Company, (1) neither the commercial development nor the sale of any of the proposed products or processes of the Company, as described in the Registration Statement or the Prospectus infringes, misappropriates or otherwise violates, or would, upon the commercialization of such proposed products or processes, infringe, misappropriate or otherwise violate, any Intellectual Property Rights of any third party; and (2) each current and former employee and consultant of the Company (a) has executed an inventions assignment and confidentiality agreement with the Company, on or about the respective date of hire, and signed copies of such agreements have been made available to the Agent and its counsel; and (b) has signed or agreed to assign to the Company and all Intellectual Property Rights he or she may possess or may have possessed that are related to the Company's business, as currently conducted and as proposed to be conducted, as described in the Registration Statement or the Prospectus. All patent applications owned by or licensed to the Company or under which the Company has rights have, to the knowledge of the Company, been duly and properly filed and maintained; to the knowledge of the Company, the parties prosecuting such applications have complied with their duty of candor and disclosure to the U.S. Patent and Trademark Office (the "USPTO") in connection with such applications; and the Company is not aware of any facts required to be disclosed to the USPTO that were not disclosed to the USPTO and which would preclude the grant of a patent in connection with any such application or could form the basis of a finding of invalidity with respect to any patents that may be issued with respect to such applications.

(u) <u>All Necessary Permits, etc</u>. The Company possesses such permits, certificates licenses, franchises, clearances, registrations, exemptions, certificates of need and other approvals or authorizations of governmental or regulatory authorities as are necessary under applicable law to own their properties and conduct their businesses in the manner described in

the most recent Prospectus (collectively, "**Permits**"), including without limitation, all such Permits required by the United States Food and Drug Administration ("**FDA**") or any component thereof and/or by any other U.S., state, local or foreign government or drug regulatory agency (collectively, the "**Regulatory Agencies**"), except where failure to so possess would not, in the aggregate, reasonably be expected to result in a Material Adverse Effect. All of the Permits are valid and in full force and effect, except when the invalidity of such Permits or the failure of such governmental licenses to be in full force and effect would not, individually or in the aggregate, result in a Material Adverse Effect. The Company has fulfilled and performed all of its obligations with respect to the Permits, and no event has occurred that allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other impairment of the rights of the holder or any such Permits, except for any of the foregoing that could not reasonably be expected to result in a Material Adverse Effect. The Company has not received notice of proceedings relating to any revocation or modification of any such Permits or has any reason to believe that any such Permits will not be renewed in the ordinary course.

(v) <u>Title to Properties</u>. The Company has good and marketable title in fee simple to all real property and good and marketable title to all personal property owned by them, in each case free and clear of all liens, encumbrances and defects, except such liens, encumbrances and defects as are described in the most recent Prospectus or such as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company. All assets held under lease by the Company are held by them under valid, subsisting and enforceable leases, with such exceptions as do not materially interfere with the use made and proposed to be made of such assets by the Company.

(w) <u>Tax Law Compliance</u>. The Company has filed all federal, state, local and foreign tax returns required to be filed through the date hereof, subject to permitted extensions, and have paid all taxes due, and no tax deficiency has been determined adversely to the Company, nor does the Company have any knowledge of any tax deficiencies that have been, or could reasonably be expected to be asserted against the Company that could, in the aggregate, reasonably be expected to result in a Material Adverse Effect. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in <u>Section 2(n)</u> above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company has not been finally determined, except to the extent of any inadequacy that would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Effect.

(x) <u>Company Not an "Investment Company."</u> The Company is not, and after receipt of payment for the Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Prospectus, will not be, an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended (the "**Investment Company Act**"), and the rules and regulations of the Commission thereunder.

(y) <u>Insurance</u>. Except at would not, in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company carries, or is covered by, insurance from insurers of recognized financial responsibility in such amounts and covering such risks as is adequate for the conduct of its business and the value of their respective properties and as is customary for companies engaged in similar businesses in similar industries. All policies of insurance of the Company are in full force and effect; the Company is in compliance with the terms of such

policies in all material respects; the Company has not received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance; there are no claims by the Company under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that could not reasonably be expected to result in a Material Adverse Effect.

(z) <u>No Price Stabilization or Manipulation; Compliance with Regulation M</u>. The Company has not taken, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Common Shares or any other "**reference security**" (as defined in Rule 100 of Regulation M under the 1934 Act ("**Regulation M**")) whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M. The Company acknowledges that the Agent may engage in passive market making transactions in the Shares on the Nasdaq Capital Market in accordance with Regulation M. The Common Shares are "actively traded securities" (as defined in Regulation M).

(aa) <u>Related Party Transactions</u>. No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company, on the other hand, that is required to be described in the Prospectus which is not so described.

(bb) <u>FINRA Matters</u>. All of the information provided to the Agent or to counsel for the Agent by the Company, its officers and directors and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with letters, filings or other supplemental information provided to Financial Industry Regulatory Authority, Inc. ("**FINRA**") pursuant to FINRA Rules 5110, 5190 and NASD Conduct Rule 2720 is true, complete and correct. The Company meets the requirements for use of Form S-3 under the Securities Act specified in FINRA Rule 5110(b)(7)(C)(i). Neither the Company nor any of its Affiliates directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, or is a person associated with any member firm of FINRA.

(cc) <u>No Unlawful Contributions or Other Payments</u>. Except as otherwise disclosed in the Prospectus, neither the Company nor, to the Company's knowledge, any employee or agent of the Company, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law or of the character required to be disclosed in the Registration Statement and the Prospectus.

(dd) <u>Employee Relations</u>. No labor disturbance by or dispute with the employees of the Company exists or, to the knowledge of the Company, is imminent that could reasonably be expected to result in a Material Adverse Effect.

(ee) <u>Compliance with Environmental Laws</u>. The Company (i) is, and at all times prior hereto was, in compliance with all laws, regulations, ordinances, rules, orders, judgments, decrees, permits or other legal requirements of any governmental authority, including without

limitation any international, foreign, national, state, provincial, regional, or local authority, relating to pollution, the protection of human health or safety, the environment, or natural resources, or to use, handling, storage, manufacturing, transportation, treatment, discharge, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**") applicable to such entity, which compliance includes, without limitation, obtaining, maintaining and complying with all permits and authorizations and approvals required by Environmental Laws to conduct their respective businesses, and (ii) has not received notice or otherwise have knowledge of any actual or alleged violation of Environmental Laws, or of any actual or potential liability for or other obligation concerning the presence, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except in the case of clause (i) or (ii) where such non-compliance, violation, liability, or other obligation could not, in the aggregate, reasonably be expected to result in a Material Adverse Effect. Except as described in the Prospectus, (x) there are no proceedings that are pending, or known to be contemplated, against the Company under Environmental Laws in which a governmental authority is also a party, other than such proceedings regarding compliance with Environmental Laws, including any pending or proposed Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that could reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company, and (z) the Company does not anticipate material capital expenditures relating to Environmental Laws.

ERISA Compliance. (i) Each "employee benefit plan" (within the meaning of Section 3(3) of the Employee Retirement Security Act of (ff) 1974, as amended ("ERISA")) for which the Company or any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Internal Revenue Code of 1986, as amended (the "Code")) would have any liability (each a "Plan") has been maintained in compliance with its terms and with the requirements of all applicable statutes, rules and regulations including ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption; (iii) with respect to each Plan subject to Title IV of ERISA (A) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur. (B) no Plan is or is reasonably expected to be "at risk" status (within the meaning of Section 430 of the Code or Section 303 of ERISA) (C) there has been no filing pursuant to Section 412(c) of the Code or Section 302(c) of ERISA of an application for a waiver of the minimum funding standard with respect to any Plan or the receipt by the Company or any of its ERISA Affiliates from the Pension Benefit Guaranty Corporation or the plan administrator of any notice relating to the intention to terminate any Plan or Plans or to appoint a trustee to administer any Plan, (D) no conditions contained in Section 303(k)(1)(A) of ERISA for imposition of a lien shall have been met with respect to any Plan and (E) neither the Company or any member of its Controlled Group has incurred, or reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guaranty Corporation in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(c)(3) of ERISA) ("Multiemployer Plan"); (iv) no Multiemployer Plan is, or is expected to be, "insolvent"

(within the meaning of Section 4245 of ERISA), in "reorganization" (within the meaning of Section 4241 of ERISA), or in "endangered" or "critical" status (within the meaning of Section 432 of the Code or Section 304 of ERISA); (v) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification; and (vi) there is no pending audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other governmental agency or any foreign regulatory agency with respect to any Plan.

(gg) <u>Brokers</u>. The Company is not a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or the Agent for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares.

(hh) <u>No Outstanding Loans or Other Extensions of Credit</u>. Since the adoption of Section 13(k) of the Exchange Act, the Company has not extended or maintained credit, arranged for the extension of credit, or renewed any extension of credit, in the form of a personal loan, to or for any director or executive officer (or equivalent thereof) of the Company except for such extensions of credit as are expressly permitted by Section 13(k) of the Exchange Act.

Compliance with Laws. Except as otherwise disclosed in the Prospectus, based on the Company's reasonable belief, the Company: (A) has (ii) been in compliance in all material respects with all applicable healthcare laws, rules and regulations, including, without limitation, (i) the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.) (the "FDCA") and the regulations promulgated thereunder (ii) within the last five (5) years has not received any Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from any regulatory agency or any other governmental authority alleging or asserting noncompliance with any applicable healthcare laws or the terms of any Permit, except in each case as would not, individually or in the aggregate, result in a Material Adverse Effect; (B) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any applicable healthcare laws or Permit and have no knowledge that any such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, except in each case as would not, individually or in the aggregate, result in a Material Adverse Effect; (C) (a) has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any applicable healthcare laws or Permits, (b) except as would not, individually or in the aggregate, result in a Material Adverse Effect, all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission), and (c) the Company is not aware of any reasonable basis for any material liability with respect to such filings; and (D) has not, and to the knowledge of the Company, the Company's officers, employees and agents have not, made any untrue statement of a material fact or fraudulent statement to any governmental authority or failed to disclose a material fact required to be disclosed to any governmental authority.

(jj) <u>Foreign Corrupt Practices Act</u>. The Company, nor, to the knowledge of the Company, after due inquiry, any director, officer, agent, employee or other person associated with or acting on behalf of the Company, has in the course of its actions for, or on behalf of, the Company: (i) made any unlawful contribution, gift, or other unlawful expense relating to political activity; (ii) made any direct or indirect bribe, kickback, rebate, payoff, influence payment, or otherwise unlawfully provided anything of value, to any "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (collectively, the "**FCPA**")) or domestic government official; or (iii) violated or is in violation of any provision of the FCPA, the Bribery Act 2010 of the United Kingdom, as amended (the "**Bribery Act 2010**"), or any other applicable anti-bribery statute or regulation. The Company and, to the knowledge of the Company, the Company's affiliates, have conducted their respective businesses in compliance with the FCPA, Bribery Act 2010, and all other applicable anti-bribery statutes and regulations, and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to ensure, continued compliance therewith.

(kk) <u>Money Laundering Laws</u>. The operations of the Company are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(l) <u>Clinical Studies</u>. The descriptions of and information regarding the studies, tests and trials, and the data and results derived therefrom, contained in the Registration Statement or the Prospectus are accurate and complete in all material respects and the Company, after due inquiry, are not aware of any other studies, tests, trials, presentations, publications or other information relating to the Company's products that are not described in the Registration Statement or the Prospectus and that would reasonably call into question the validity, completeness, or accuracy of any study, test, trial, results or data described in the Registration Statement or the Prospectus when viewed in the context in which such studies, tests, trials results, or data are described therein. The studies, tests and trials conducted by or on behalf of or sponsored by the Company or in which the Company or its product candidates have participated were and, if still pending, are being conducted in all material respect in accordance with standard medical and scientific research procedures and all applicable laws, including, but not limited to, the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58 and 312. No investigational new drug application filed by or on behalf of the Company with the FDA has been terminated or suspended by the FDA, and neither the FDA nor any applicable foreign regulatory agency has commenced, or, to the knowledge of the Company, threatened to initiate, any action to place a clinical hold order on, or otherwise terminate, delay or suspend, any proposed or ongoing clinical investigation conducted or proposed to be conducted by or on behalf of the Company.

(mm) <u>OFAC</u>. Neither the Company nor, to the knowledge of the Company, after due inquiry, any director, officer, agent, employee or affiliate of the Company is: (i) currently subject

to or the target of any sanctions administered or enforced by the Office of Foreign Assets Control of the U.S. Treasury Department (**'OFAC**''), the U.S. Department of State, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, **'Sanctions**''); or (ii) located, organized or resident in a country or territory that is the subject or target of Sanctions (including, without limitation, Cuba, Iran, North Korea, Sudan, Syria and Crimea); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other person or entity, for the purpose of financing the activities of any person, or in any country or territory, that currently is the subject or target of Sanctions or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as an underwriter, advisor, investor or otherwise) of Sanctions. The Company has not knowingly engaged in for the past five years, is not now knowingly engaged in, and will not engage in, any dealings or transactions with any individual or entity, or in any country or territory, that at the time of the dealing or transaction, is or was the subject or target of Sanctions.

(nn) <u>Sarbanes-Oxley</u>. There is and has been no failure on the part of the Company and any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith applicable to the Company or its directors or officers.

(oo) <u>Cybersecurity</u>. To the Company's knowledge, there has been no material security breach or other material compromise of or relating to any of the information technology and computer systems, networks, hardware, software, data, equipment or technology owned, held or used by or for the Company (including the data of its customers, employees, suppliers, vendors and any third party data maintained by or on behalf of the Company) (collectively, the "**IT Systems and Data**") and (y) the Company has not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any material security breach or other material compromise to the IT Systems and Data; (ii) the Company has complied, and is presently in compliance, in all material respects, with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to (x) the collection, use, transfer, storage, protection, disposal and/or disclosure of personally identifiable information collected from or provided by third parties, (y) the privacy and security of the IT Systems and Data and (z) the protection of the IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, in the case of this clause (ii), individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) the Company has taken commercially reasonable steps to protect the IT Systems and Data, including by implementing backup, security and disaster recovery plans, procedures and technology consistent with industry standards and practices.

Any certificate signed by any officer of the Company and delivered to the Agent or counsel for the Agent in connection with the offering of the Shares pursuant to this Agreement shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby on the date of such certificate.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to <u>Section 4(o)</u> hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 3. ISSUANCE AND SALE OF COMMON SHARES

(a) (i) <u>Sale of Securities</u>. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent, acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period.

(b) <u>Mechanics of Issuances</u>.

(i) <u>Issuance Notice</u>. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in <u>Section 5</u> shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; *provided, however*, that (A) in no event may the Company deliver an Issuance Notice to the extent that (I) the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would exceed the Maximum Program Amount; and (B) prior to delivery of any Issuance Notice, the Selling Period for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by e-mail to the persons so identified in writing by the Agent and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.

(ii) <u>Agent Efforts</u>. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.

(iii) <u>Method of Offer and Sale</u>. The Shares may be offered and sold (A) in privately negotiated transactions with the consent of the Company, (B) as block transactions or (C) by any other method or payment permitted by law deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act, including sales made directly on the Principal Market or sales made to or through a market maker or through an electronic communications network. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and the method of placement of any Shares by the Agent shall be at the Agent's discretion.

(iv) <u>Confirmation to the Company</u>. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.

(v) <u>Settlement</u>. Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of <u>Section 5</u>, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent or its designee's account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form, the Agent will deliver, by wire transfer of immediately available funds, the related Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a "**Time of Sale**").

(vi) <u>Suspension or Termination of Sales</u>. Consistent with standard market settlement practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable email), suspend any sale of Shares, and the Selling Period shall immediately terminate; *provided, however*, that (A) such suspension and termination shall not affect or impair either party's obligations with respect to any Shares placed or sold hereunder prior to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with <u>Section 3(b)(v)</u> with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Common Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by <u>Section 3(b)(v)</u>, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to <u>Section 3(b)(i)</u>.

(vii) <u>No Guarantee of Placement, Etc.</u> The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares and (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares, and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.

(viii) <u>Material Non-Public Information.</u> Notwithstanding any other provision of this Agreement, the Company and the Agent agree that the Company shall not deliver any Issuance Notice to the Agent, and the Agent shall not be obligated to place any Shares, during any period

in which the Company is in possession of material non-public information. In addition, if the Company wishes to offer or sell any Shares during any period in which the Company prohibits purchases or sales of Common Shares by its officers or directors (whether pursuant to its insider trading policy or otherwise) (each such period, a "**Blackout Period**"), the Company will, as a condition to the giving or continuation of any Issuance Notice, certify in writing to the Agent that the Company is not in possession of any material, non-public information, which certification shall be deemed to remain in effect during the applicable Blackout Period unless withdrawn by the Company.

(c) <u>Fees</u>. As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to <u>Section 3(b)(vi)</u>) by the Agent deducting the Selling Commission from the applicable Issuance Amount.

Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations (d)hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Shares, (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares, (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, any Free Writing Prospectus (as defined below) prepared by or on behalf of, used by, or referred to by the Company, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "Blue Sky Survey" or memorandum and a "Canadian wrapper," and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions, (vii) the reasonable fees and disbursements of the Agent's counsel, including the filing fees incident to, and the reasonable fees and expenses of counsel for the Agent in connection with, FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares, (viii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and of the Agent and any such consultants, and the cost of any aircraft chartered in connection with the road show and (ix) the fees and expenses associated with listing the Shares on the Nasdag Capital Market. The fees and disbursements of the Agent, including but not limited to the fees and disbursements of the Agent's counsel pursuant to Section3(d)(vi), (vii) and (viii), above shall not exceed \$50,000.

Section 4. ADDITIONAL COVENANTS

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

(a) <u>Exchange Act Compliance</u>. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by the Exchange Act and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold through the Agent pursuant to this Agreement and (2) the net proceeds received by the Company from such sales or (B) prepare a prospectus supplement or in such other filing permitted by the Securities Act or Exchange Act (each an "**Interim Prospectus Supplement"**) with such summary information and, at least once a quarter and subject to this <u>Section 4</u>, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act)).

(b) <u>Securities Act Compliance</u>. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission, (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus, any Free Writing Prospectus, (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus or of any order preventing or suspending the use of any Free Writing Prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its reasonable best efforts to obtain the lifting of such order as soon as practicable. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(c) <u>Amendments and Supplements to the Prospectus and Other Securities Act Matters</u>. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to <u>Section 3(b)</u> and <u>Section 3(c)</u>) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not

include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Agent's consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under <u>Section 3(b)</u> or <u>Section 3(c)</u>.

(d) <u>Agent's Review of Proposed Amendments and Supplements</u>. Prior to effecting any amendment or supplement to the Registration Statement (including any registration statement filed under Rule 462(b) under the Securities Act) or the Prospectus (excluding any amendment or supplement through incorporation of any report filed under the Exchange Act) that affects the offer and sale of the Shares as contemplated by this Agreement, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement, and the Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(e) <u>Use of Free Writing Prospectus</u>. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement (any such free writing prospectus being referred to herein as a "**Free Writing Prospectus**").

Free Writing Prospectuses. The Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of (f) filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto to be prepared by or on behalf of, used by, or referred to by the Company and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Agent's consent. The Company shall furnish to the Agent, without charge, as many copies of any free writing prospectus prepared by or on behalf of, or used by the Company, as the Agent may reasonably request. If at any time when a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares (but in any event if at any time through and including the date of this Agreement) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at that subsequent time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict or so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such subsequent time, not misleading, as the case may be; provided, however, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented

free writing prospectus and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Agent's consent.

(g) <u>Filing of Agent Free Writing Prospectuses</u>. The Company shall not to take any action that would result in the Agent or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Agent that the Agent otherwise would not have been required to file thereunder.

Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the (h) Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any Selling Period in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance; provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.

(i) <u>Blue Sky Compliance</u>. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance

of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof as soon as practicable.

(j) <u>Earnings Statement</u>. As soon as practicable, the Company will make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act.

(k) <u>Listing; Reservation of Shares</u>. (a) The Company will maintain the listing of the Shares on the Nasdaq Capital Market and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations pursuant to any outstanding Issuance Notice under this Agreement.

(l) <u>Transfer Agent</u>. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(m) <u>Due Diligence</u>. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices, as the Agent may reasonably request from time to time.

(n) <u>Representations and Warranties</u>. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto), and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(o) <u>Deliverables at Triggering Event Dates; Certificates.</u> The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:

(A) the filing of the Prospectus or the amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section $4(a)(\underline{i})(\underline{B})$), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;

(B) the filing with the Commission of an annual report on Form 10-K or a quarterly report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing amended financial information or a material amendment to the previously filed annual report on Form 10-K or quarterly report on Form 10-Q), in each case, of the Company; or

(C) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information "furnished" pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent's reasonable discretion;

(any such event, a "**Triggering Event Date**"), the Company shall furnish the Agent (but in the case of clause (C) above only if the Agent reasonably determines that the information contained in such current report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in <u>Section 5</u> hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this <u>Section 4(0)</u> shall be automatically waived with no further action of the Agent or Company for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which automatic waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this <u>Section 4(0)</u>, then before the Company delivers the instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this <u>Section 4(0)</u> dated as of the date that the instructions for the sale of Shares are issued.

(p) Legal Opinions. On or prior to the date of the first Issuance Notice and within five (5) Trading Days of each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(0)(A) or Section 4(0)(B) for which no waiver is applicable and excluding the date of this Agreement, the Agent shall have received (i) a negative assurances letter and the written legal opinion of Latham & Watkins LLP, counsel to the Company, and (ii) a negative assurances letter and the written legal opinion of Cooley LLP, patent counsel to the Company, each dated the date of delivery, in form and substance reasonably satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; provided, however, that the Company shall be required to furnish no more than one opinion hereunder per calendar quarter. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the

Company may furnish a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter, modified as appropriate for any passage of time or Triggering Event Date (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date). The Agent shall also have received a negative assurances letter from Wilmer Cutler Pickering Hale and Dorr LLP, counsel to the Agent, dated as of the date of delivery, in form as substance reasonable satisfactory to Agent, and the Company shall have furnished to such counsel such documents as they reasonably request for the purpose of enabling them to give such opinion.

(q) <u>Comfort Letter</u>. On or prior to the date of the first Issuance Notice and within five (5) Trading Days of each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to <u>Section 4(0)(A)</u> or <u>Section 4(0)(B)</u> for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause BDO USA, LLP, the independent registered public accounting firm who has audited the financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. The Company shall be required to furnish no more than one comfort letter hereunder per calendar quarter.

(r) <u>Secretary's Certificate</u>. On or prior to the date of the first Issuance Notice and within five (5) Trading Days of each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to <u>Section 4(0)(A)</u> or <u>Section 4(0)(B)</u> for which no waiver is applicable and excluding the date of this Agreement, the Company shall furnish to the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company, and (iii) containing any other certification that the Agent shall reasonably request.

(s) <u>Agent's Own Account; Clients' Account</u>. The Company consents to the Agent trading, in compliance with applicable law, in the Common Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

(t) <u>Investment Limitation</u>. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company to register as an investment company under the Investment Company Act.

(u) <u>Market Activities</u>. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other reference security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall use commercially reasonable efforts to cause each of its affiliates to, comply with all applicable provisions of Regulation M. If the limitations of Rule 102 of Regulation M ("**Rule 102**") do not apply with respect to the Shares or any other reference security pursuant to any exception set forth in Section (d) of Rule 102, then promptly upon notice from the Agent (or, if later, at the time stated in the notice), the Company will, and shall use commercially reasonable efforts to cause each of its affiliates to, comply with Rule 102 as though such exception were not available but the other provisions of Rule 102 (as interpreted by the Commission) did apply.

Notice of Other Sale. Without the written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to (v)sell, grant any option to sell or otherwise dispose of any Common Shares (other than Shares hereunder) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire Common Shares, during the period beginning on the Trading Day immediately prior to the date on which any Issuance Notice is delivered to the Agent hereunder and ending on the Trading Day immediately following the earlier of (x) the Settlement Date with respect to Shares sold pursuant to such Issuance Notice and (y) the suspension by the Company of such Selling Period, and will not, directly or indirectly, in any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares (other than the Shares hereunder) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire Common Shares during the Agency Period; provided, however, that such restrictions will not apply in connection with the Company's (i) issuance or sale of Common Shares, options to purchase Common Shares or Common Shares issuable upon the exercise of options or other equity awards pursuant to any employee or director share option, incentive or benefit plan, share purchase or ownership plan, long-term incentive plan, dividend reinvestment plan, inducement award under Nasdaq rules or other compensation plan of the Company, as in effect on the date of this Agreement, (ii) issuance or sale of Common Shares issuable upon exchange, conversion or redemption of securities or the exercise or vesting of warrants, options or other equity awards outstanding at the date of this Agreement, (iii) issuance or sale of Common Shares or securities convertible into or exchangeable for Common Shares as consideration for mergers, acquisitions, other business combinations, joint ventures, collaborations or strategic arrangements occurring after the date of this Agreement that are not used for capital raising purposes, (iv) modification of any outstanding options, warrants of any rights to purchase or acquire Common Shares and (v) for the avoidance of doubt, non-public discussions or negotiations with respect to any of the foregoing.

(w) <u>Emerging Growth Company Status</u>. The Company will promptly notify the Agent if the Company ceases to be an Emerging Growth Company at any time during the term of this Agreement.

Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT

The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable Selling Period is subject to the satisfaction, on each Trading Day during the Selling Period, of each of the following conditions:

(a) <u>Accuracy of the Company's Representations and Warranties; Performance by the Company</u>. The Company shall have delivered the certificate required to be delivered pursuant to <u>Section 4(0)</u> on or before the date on which delivery of such certificate is required pursuant to <u>Section 4(0)</u>. The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in <u>Section 4(m)</u>, <u>Section 4(p)</u>, <u>Section 4(q)</u> and <u>Section 4(r)</u>.

(b) <u>No Injunction</u>. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.

(c) <u>Material Adverse Changes</u>. Except as disclosed in the Prospectus, (a) there shall not have occurred any Material Adverse Change that, in the judgment of the Agent, makes it impracticable to market the Shares on the terms and in the manner contemplated in the Prospectus; and (b) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company by any "nationally recognized statistical rating organization" as such term is defined in Section 3(a)(62) of the Exchange Act.

(d) <u>No Suspension of Trading in or Delisting of Common Shares; Other Events</u>. The trading of the Common Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Common Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Principal Market. There shall not have occurred (and be continuing in the case of occurrences under clauses (i) and (ii) below) any of the following: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the Nasdaq Capital Market, or trading in securities generally on either the Nasdaq Capital Market shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or FINRA; (ii) a general banking moratorium shall have been declared by any of federal, New York, Delaware or California authorities; or (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the

United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Agent is material and adverse and makes it impracticable to market the Shares in the manner and on the terms described in the Prospectus or to enforce contracts for the sale of securities;

(e) <u>Documents Required to be Delivered on each Issuance Notice Date</u>. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President or Chief Financial Officer of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice).

(f) <u>No Misstatement or Material Omission</u>. Agent shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

Section 6. INDEMNIFICATION AND CONTRIBUTION

Indemnification of the Agent. The Company agrees to indemnify and hold harmless the Agent, its officers and employees, and each (a) person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such officer, employee or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading, or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, and to reimburse the Agent and each such officer, employee and controlling person for any and all documented expenses (including the fees and disbursements of counsel chosen by the Agent) as such expenses are reasonably incurred by the Agent or such officer, employee or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only

to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in <u>Section 6(b)</u> below. The indemnity agreement set forth in this <u>Section 6(a)</u> shall be in addition to any liabilities that the Company may otherwise have.

Indemnification of the Company, its Directors and Officers. The Agent agrees to indemnify and hold harmless the Company, each of its (h)directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading, or (ii) any untrue statement or alleged untrue statement of a material fact contained in any Free Writing Prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; but only to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, any such Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the final paragraph under the caption "Plan of Distribution" in the Prospectus, and to reimburse the Company and each such director. officer and controlling person for any and all documented expenses (including the fees and disbursements of counsel chosen by the Company) as such expenses are reasonably incurred by the Company or such officer, director or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 6(b) shall be in addition to any liabilities that the Agent or the Company may otherwise have.

(c) <u>Notifications and Other Indemnification Procedures</u>. Promptly after receipt by an indemnified party under this <u>Section 6</u> of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this <u>Section 6</u>, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this <u>Section 6</u> or to the extent it is not prejudiced as a proximate result of

such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any reasonable and documented legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by Jefferies (in the case of counsel for the indemnified parties referred to in Section 6(a) above) or the Company (in the case of counsel for the indemnified parties referred to in Section 6(b) above, (ii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) <u>Settlements</u>. The indemnifying party under this <u>Section 6</u> shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by <u>Section 6(c)</u> hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party,

unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding.

(e) Contribution. If the indemnification provided for in this Section 6 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares (before deducting expenses) received by the Company bear to the total commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in <u>Section 6(c)</u>, any reasonable and documented legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in <u>Section 6(c)</u> with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this <u>Section 6(e)</u>; *provided*, *however*, that no additional notice shall be required with respect to any action for which notice has been given under <u>Section 6(c)</u> for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this <u>Section 6(e)</u> were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this <u>Section 6(e)</u>.

Notwithstanding the provisions of this <u>Section 6(e)</u>, the Agent shall not be required to contribute any amount in excess of the agent fees received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this <u>Section 6(e)</u>, each officer and employee of the Agent and each person, if any, who controls the Agent within the

meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 7. TERMINATION & SURVIVAL

(a) <u>Term</u>. Subject to the provisions of this <u>Section 7</u>, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this <u>Section 7</u>.

(b) <u>Termination; Survival Following Termination</u>.

(i) Either party may terminate this Agreement prior to the end of the Agency Period by giving written notice as required by this Agreement, upon one Trading Day's notice to the other party; provided that, (A) if the Company terminates this Agreement after the Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with <u>Section 3(b)(v)</u> with respect to such Shares and (B) <u>Section 2</u>, <u>Section 6</u>, <u>Section 7</u> and <u>Section 8</u> shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement.

(ii) In addition to the survival provision of <u>Section 7(b)(i)</u>, the respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

Section 8. MISCELLANEOUS

(a) <u>Press Releases and Disclosure</u>. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the date of this Agreement, and may file with the Commission a Current Report on Form 8-K, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. No party hereto shall issue thereafter any press release or like public statement (including, without limitation, any disclosure required in reports filed with the Commission pursuant to the Exchange Act) related to this Agreement or any of the transactions contemplated hereby without the prior written approval of the other party hereto, except as may be necessary or appropriate in the reasonable opinion of the party seeking to make disclosure to comply with the requirements of applicable law or stock exchange rules, including but not limited to the

disclosure required pursuant to <u>Section 4(a)</u> of this Agreement in the Company's quarterly reports on Form 10-Q or annual reports on Form 10-K. If any such press release or like public statement is so required, the party making such disclosure shall consult with the other party prior to making such disclosure, and the parties shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosure that is reasonably satisfactory to all parties hereto.

(b) <u>No Advisory or Fiduciary Relationship</u>. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm's-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

(c) <u>Research Analyst Independence</u>. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

(d) <u>Notices</u>. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

Jefferies LLC 520 Madison Avenue New York, NY 10022 Facsimile: (646) 619-4437 Attention: General Counsel

with a copy (which shall not constitute notice) to:

Wilmer Cutler Pickering Hale and Dorr LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007 Facsimile: (212) 230-8888 Attention: Lisa Firenze, Esg.

If to the Company:

BioXcel Therapeutics, Inc. 555 Long Wharf Drive New Haven, CT 06511 Attention: Chief Executive Officer

with a copy (which shall not constitute notice) to:

Latham & Watkins LLP John Hancock Tower 200 Clarendon Street Boston, MA 02116 Attention: Peter N. Handrinos

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 8(d).

(e) <u>Successors</u>. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in <u>Section 6</u>, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "**successors**" shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.

(f) <u>Partial Unenforceability</u>. The invalidity or unenforceability of any Article, Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Article, Section, paragraph or provision hereof. If any Article, Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

(g) <u>Governing Law Provisions</u>. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("**Related Proceedings**") may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted

in regard to the enforcement of a judgment of any such court (a "**Related Judgment**"), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(h) <u>General Provisions</u>. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

[Signature Page Immediately Follows]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

BIOXCEL THERAPEUTICS, INC.

By:/s/ Richard SteinhartName:Richard SteinhartTitle:Senior Vice President and Chief Financial Officer

[Signature Page to Open Market Sales Agreement]

The foregoing Agreement is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

JEFFERIES LLC

By: /s/ Donald Lynaugh Name: Donald Lynaugh Title: Managing Director

[Signature Page to Open Market Sales Agreement]

EXHIBIT A

ISSUANCE NOTICE

[Date]

Jefferies LLC 520 Madison Avenue New York, New York 10022

]

Attn: [

Reference is made to the Open Market Sale Agreement between BioXcel Therapeutics, Inc. (the "**Company**") and Jefferies LLC (the "**Agent**") dated as of May 20, 2019. The Company confirms that all conditions to the delivery of this Issuance Notice are satisfied as of the date hereof.

Date of Delivery of Issuance Notice (determined pursuant to Section 3(b)(i)):

Issuance Amount (equal to the total Sales Price for such Shares):

\$

Number of Days in Selling Period:

First Date of Selling Period:

Last Date of Selling Period:

Settlement Date(s) if other than standard T+2 settlement:

Floor Price Limitation (in no event less than \$1.00 without the prior written consent of the Agent, which consent may be withheld in the Agent's sole discretion): \$ per share

Comments:

BioXcel Therapeutics, Inc.

By:

Name: Title:

A-1

LATHAM&WATKINS

May 20, 2019

BioXcel Therapeutics, Inc. 555 Long Wharf Drive New Haven, CT 06511

Re: Registration Statement on Form S-3; Shares of Common Stock, \$0.001 par value per share, having an aggregate offering price of up to \$20,000,000

Ladies and Gentlemen:

We have acted as special counsel to BioXcel Therapeutics, Inc., a Delaware corporation (the "*Company*"), in connection with the sale from time to time by the Company of shares (the "*Shares*") of common stock, \$0.001 par value per share (the "*Common Stock*"), having an aggregate offering price of up to \$20,000,000, to be issued pursuant to (i) a registration statement on Form S-3 (the "*Registration Statement*") under the Securities Act of 1933, as amended (the "*Act*"), filed with the Securities and Exchange Commission (the "*Commission*") on April 1, 2019, (ii) a base prospectus (the "*Base Prospectus*") and related prospectus supplement (together with Base Prospectus, the "*Prospectus*") and (iii) that certain Sales Agreement, dated as of May 20, 2019, by and between the Company and Jefferies LLC (the "*Sales Agreement*").

This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

As such counsel, we have examined such matters of fact and questions of law as we have considered appropriate for purposes of this letter. With your consent, we have relied upon certificates and other assurances of officers of the Company and others as to factual matters without having independently verified such factual matters. We are opining herein as to the General Corporation Law of the State of Delaware (the "*DGCL*"), and we express no opinion with respect to the applicability thereto, or the effect thereon, of the laws of any other jurisdiction or, in the case of Delaware, any other laws, or as to any matters of municipal law or the laws of any local agencies within any state.

200 Clarendon Street Boston, Massachusetts 02116 Tel: +1.617.948.6000 Fax: +1.617.948.6001 www.lw.com

FIRM / AFFILIATE OFFICES Beijing Moscow Boston Munich Brussels Century City New York Orange County Chicago Dubai Düsseldorf Paris Riyadh San Diego Frankfurt Hamburg San Francisco Seoul Hong Kong Houston Shanghai Silicon Valley London Singapore Los Angeles Madrid Tokyo Washington, D.C. Milan

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, when the Shares shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers, and have been issued by the Company against payment therefor (not less than par value) in the circumstances contemplated by the Sales Agreement, the issue and sale of the Shares will have been duly authorized by all necessary corporate action of the Company, and the Shares will be validly issued, fully paid and nonassessable. In rendering the foregoing opinion, we have assumed that (i) the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the DGCL and (ii) upon the issuance of any of the Shares, the total number of shares of Common Stock issued and outstanding will not exceed the total number of shares of Common Stock that the Company is then authorized to issue under its Restated Certificate of Incorporation.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Company's Registration Statement and to the reference to our firm in the Prospectus under the heading "Legal Matters." In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Latham & Watkins LLP