
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): June 7, 2019

ACHIEVE LIFE SCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

033-80623
(Commission
File Number)

95-4343413
(IRS Employer
Identification No.)

1040 West Georgia Street, Suite 1030,
Vancouver, B.C. V6E 4H1
(Address of Principal Executive Offices)

V6E 4H1
(Zip Code)

Registrant's Telephone Number, Including Area Code: (604)210-2217

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 (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, par value \$0.001 per share	ACHV	The NASDAQ Capital Market

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

Emerging growth company

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

Item 1.01 Entry into a Material Definitive Agreement.

On June 7, 2019, Achieve Life Sciences, Inc. (the “Company”), entered into an At The Market Offering Agreement (the “Offering Agreement”) with H.C. Wainwright & Co., LLC, as agent (“H.C. Wainwright”), pursuant to which the Company may offer and sell, from time to time through H.C. Wainwright shares of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), having an aggregate offering price of up to \$6.0 million (the “Shares”).

The offer and sale of the Shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus (File No. 333-229019) filed by the Company with the Securities and Exchange Commission (the “SEC”) on December 26, 2018 and declared effective by the SEC on February 11, 2019, as supplemented by a prospectus supplement dated June 7, 2019 and filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the “Securities Act”).

Pursuant to the Offering Agreement, H.C. Wainwright may sell the Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act, including sales made by means of ordinary brokers’ transactions, including on The Nasdaq Capital Market, at market prices or as otherwise agreed with H.C. Wainwright. H.C. Wainwright will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the Shares from time to time, based upon instructions from the Company, including any price or size limits or other customary parameters or conditions the Company may impose.

The Company is not obligated to make any sales of the Shares under the Offering Agreement. The offering of Shares pursuant to the Offering Agreement will terminate upon the earliest of (a) the sale of all of the Shares subject to the Offering Agreement, (b) the termination of the Offering Agreement by H.C. Wainwright or the Company, as permitted therein, or (c) June 7, 2022.

The Company will pay H.C. Wainwright a commission rate equal to 3.0% of the aggregate gross proceeds from each sale of Shares and have agreed to provide H.C. Wainwright with customary indemnification and contribution rights. The Company will also reimburse H.C. Wainwright for certain specified expenses in connection with entering into the Offering Agreement. The Offering Agreement contains customary representations and warranties and conditions to the placements of the Shares pursuant thereto.

The foregoing description of the Offering Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed herewith as Exhibit 1.1 to this Current Report on Form 8-K and is incorporated herein by reference. The opinion of the Company’s counsel regarding the validity of the Shares that will be issued pursuant to the Offering Agreement is also filed herewith as Exhibit 5.1.

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy the Common Stock discussed herein, nor shall there be any offer, solicitation, or sale of common stock 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.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
1.1	<u>At The Market Offering Agreement, dated June 7, 2019, by and between Achieve Life Sciences, Inc. and H.C. Wainwright & Co., LLC.</u>
5.1	<u>Opinion of Fenwick & West LLP.</u>
23.1	<u>Consent of Fenwick & West LLP (contained in Exhibit 5.1).</u>

SIGNATURES

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

Date: June 7, 2019

ACHIEVE LIFE SCIENCES, INC.

/s/ John Bencich

John Bencich
Chief Financial and Operating Officer

AT THE MARKET OFFERING AGREEMENT

June 7, 2019

H.C. Wainwright & Co., LLC
430 Park Avenue
New York, NY 10022

Ladies and Gentlemen:

Achieve Life Sciences, Inc., a corporation organized under the laws of Delaware (the "Company"), confirms its agreement (this "Agreement") with H.C. Wainwright & Co., LLC (the "Manager") as follows:

1. Definitions. The terms that follow, when used in this Agreement and any Terms Agreement, shall have the meanings indicated.

"Accountants" shall have the meaning ascribed to such term in Section 4(m).

"Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Action" shall have the meaning ascribed to such term in Section 3(q).

"Affiliate" shall have the meaning ascribed to such term in Section 3(p).

"Applicable Time" shall mean, with respect to any Shares, the time of sale of such Shares pursuant to this Agreement or any relevant Terms Agreement.

"Base Prospectus" shall mean the base prospectus contained in the Registration Statement at the Execution Time.

"Board" shall have the meaning ascribed to such term in Section 2(b)(iii).

"Broker Fee" shall have the meaning ascribed to such term in Section 2(b)(v).

"Business Day" shall mean any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions or trust companies are authorized or obligated by law to close in New York City.

"Commission" shall mean the United States Securities and Exchange Commission.

“Common Stock” shall have the meaning ascribed to such term in Section 2.

“Common Stock Equivalents” shall have the meaning ascribed to such term in Section 3(g).

“Company Counsel” shall have the meaning ascribed to such term in Section 4(l).

“DTC” shall have the meaning ascribed to such term in Section 2(b)(vii).

“Effective Date” shall mean each date and time that the Registration Statement and any post-effective amendment or amendments thereto became or becomes effective.

“Exchange Act” shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission promulgated thereunder.

“Execution Time” shall mean the date and time that this Agreement is executed and delivered by the parties hereto.

“Filing Date” shall have the meaning ascribed to such term in Section 4(w).

“Free Writing Prospectus” shall mean a free writing prospectus, as defined in Rule 405.

“GAAP” shall have the meaning ascribed to such term in Section 3(n).

“Incorporated Documents” shall mean the documents or portions thereof filed with the Commission on or prior to the Effective Date that are incorporated by reference in the Registration Statement or the Prospectus and any documents or portions thereof filed with the Commission after the Effective Date that are deemed to be incorporated by reference in the Registration Statement or the Prospectus.

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3(v).

“Issuer Free Writing Prospectus” shall mean an issuer free writing prospectus, as defined in Rule 433.

“Losses” shall have the meaning ascribed to such term in Section 7(d).

“Material Adverse Effect” shall have the meaning ascribed to such term in Section 3(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3(t).

“Net Proceeds” shall have the meaning ascribed to such term in Section 2(b)(v).

“Permitted Free Writing Prospectus” shall have the meaning ascribed to such term in Section 4(g).

“Placement” shall have the meaning ascribed to such term in Section 2(c).

“Proceeding” shall have the meaning ascribed to such term in Section 3(b).

“Prospectus” shall mean the Base Prospectus, as supplemented by the most recently filed Prospectus Supplement (if any).

“Prospectus Supplement” shall mean each prospectus supplement relating to the Shares prepared and filed pursuant to Rule 424(b) from time to time.

“Registration Statement” shall mean the shelf registration statement (File Number 333-229019) on Form S-3, including exhibits and financial statements and any prospectus supplement relating to the Shares that is filed with the Commission pursuant to Rule 424(b) and deemed part of such registration statement pursuant to Rule 430B, as amended on each Effective Date and, in the event any post-effective amendment thereto becomes effective, shall also mean such registration statement as so amended.

“Representation Date” shall have the meaning ascribed to such term in Section 4(k).

“Required Approvals” shall have the meaning ascribed to such term in Section 3(e).

“Rule 158”, “Rule 163”, “Rule 164”, “Rule 172”, “Rule 173”, “Rule 405”, “Rule 415”, “Rule 424”, “Rule 430B” and “Rule 433” refer to such rules under the Act.

“Sales Notice” shall have the meaning ascribed to such term in Section 2(b)(i).

“SEC Reports” shall have the meaning ascribed to such term in Section 3(m).

“Settlement Date” shall have the meaning ascribed to such term in Section 2(b)(vii).

“Subsidiary” shall have the meaning ascribed to such term in Section 3(a).

“Terms Agreement” shall have the meaning ascribed to such term in Section 2(a).

“Time of Delivery” shall have the meaning ascribed to such term in Section 2(c).

“Trading Day” means a day on which the Trading Market is open for trading.

“Trading Market” means Nasdaq Capital Market.

2. Sale and Delivery of Shares. The Company proposes to issue and sell through or to the Manager, as sales agent and/or principal, up to \$6,000,000 of shares (the “Shares”) of the Company’s common stock, \$0.001 par value (“Common Stock”), from time to time during the term of this Agreement and on the terms set forth herein; provided, however, that in no event shall the Company issue or sell through the Manager such number of Shares that (a) exceeds the number or dollar amount of shares of Common Stock registered on the Registration Statement, pursuant to which the offering is being made, (b) exceeds the number of authorized but unissued shares of Common Stock or (c) would cause the Company or the offering of the Shares to not satisfy the eligibility and transaction requirements for use of Form S-3 (including, if applicable, General Instruction I.B.6 of Registration Statement on Form S-3 (the lesser of (a), (b) and (c), the “Maximum Amount”). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 2 on the number and aggregate sales price of Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that the Manager shall have no obligation in connection with such compliance.

(a) Appointment of Manager as Selling Agent; Terms Agreement. For purposes of selling the Shares through the Manager, the Company hereby appoints the Manager as exclusive agent of the Company for the purpose of selling the Shares of the Company pursuant to this Agreement and the Manager agrees to use its commercially reasonable efforts to sell the Shares on the terms and subject to the conditions stated herein. The Company agrees that, whenever it determines to sell the Shares directly to the Manager as principal, it will enter into a separate agreement (each, a “Terms Agreement”) in substantially the form of Annex I hereto, relating to such sale in accordance with Section 2 of this Agreement.

(b) Agent Sales. Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company will issue and agrees to sell Shares from time to time through the Manager, acting as sales agent, and the Manager agrees to use its commercially reasonable efforts to sell, as sales agent for the Company, on the following terms:

(i) The Shares are to be sold on a daily basis or otherwise as shall be agreed to by the Company and the Manager on any day that (A) is a Trading Day, (B) the Company has instructed the Manager by electronic mail to make such sales ("Sales Notice") and (C) the Company has satisfied its obligations under Section 6 of this Agreement. The Company will designate the maximum amount of the Shares to be sold by the Manager daily (subject to the limitations set forth in Section 2(d)) and the minimum price per Share at which such Shares may be sold. Subject to the terms and conditions hereof, the Manager shall use its commercially reasonable efforts to sell on a particular day all of the Shares designated for the sale by the Company on such day. The gross sales price of the Shares sold under this Section 2(b) shall be the market price for the shares of Common Stock sold by the Manager under this Section 2(b) on the Trading Market at the time of sale of such Shares.

(ii) The Company acknowledges and agrees that (A) there can be no assurance that the Manager will be successful in selling the Shares, (B) the Manager will incur no liability or obligation to the Company or any other person or entity if it does not sell the Shares for any reason other than a failure by the Manager to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Shares as required under this Agreement, and (C) the Manager shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Manager and the Company pursuant to a Terms Agreement.

(iii) The Company shall not authorize the issuance and sale of, and the Manager shall not be obligated to use its commercially reasonable efforts to sell, any Share at a price lower than the minimum price therefor designated from time to time by the Company's Board of Directors (the "Board"), or a duly authorized committee thereof, or such duly authorized officers of the Company, and notified to the Manager in writing. The Company or the Manager may, upon notice to the other party hereto by telephone (confirmed promptly by electronic mail), suspend the offering of the Shares for any reason and at any time; provided, however, that such suspension or termination shall not affect or impair the parties' respective obligations with respect to the Shares sold hereunder prior to the giving of such notice.

(iv) The Manager may sell Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 under the Act, including without limitation sales made directly on the Trading Market, on any other existing trading market for the Common Stock or to or through a market maker. The Manager may also sell Shares in privately negotiated transactions, provided that the Manager receives the Company’s prior written approval for any sales in privately negotiated transactions and if so provided in the “Plan of Distribution” section of the Prospectus Supplement.

(v) The compensation to the Manager for sales of the Shares under this Section 2(b) shall be a placement fee of 3% of the gross sales price of the Shares sold pursuant to this Section 2(b) (“Broker Fee”). The foregoing rate of compensation shall not apply when the Manager acts as principal, in which case the Company may sell Shares to the Manager as principal at a price agreed upon at the relevant Applicable Time pursuant to a Terms Agreement. The remaining proceeds, after deduction of the Broker Fee and deduction of any transaction fees imposed by any clearing firm, execution broker, or governmental or self-regulatory organization in respect of such sales, shall constitute the net proceeds to the Company for such Shares (the “Net Proceeds”).

(vi) The Manager shall provide written confirmation (which may be by facsimile or electronic mail) to the Company following the close of trading on the Trading Market each day in which the Shares are sold under this Section 2(b) setting forth the number of the Shares sold on such day, the aggregate gross sales proceeds and the Net Proceeds to the Company, and the compensation payable by the Company to the Manager with respect to such sales.

(vii) Unless otherwise agreed between the Company and the Manager, settlement for sales of the Shares will occur at 10:00 a.m. (New York City time) on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a “Settlement Date”). On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically make available the Shares being sold to the Manager’s or its designee’s account (provided that the Manager shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) via The Depository Trust Company (“DTC”) through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which Shares in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Manager will deliver the related Net Proceeds in same day funds to an account designated by the Company to the Manager. The Company agrees that, if

the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Shares on a Settlement Date, in addition to and in no way limiting the rights and obligations set forth in Section 7 hereto, the Company will (i) hold the Manager harmless against any loss, claim, damage, or reasonable, documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company, and (ii) pay to the Manager any commission, discount or other compensation to which the Manager would otherwise have been entitled absent such default (for purposes of clarity, without any duplication of amounts paid under clause (i) herein).

(viii) At each Applicable Time, Settlement Date, Representation Date and Filing Date, the Company shall be deemed to have affirmed each representation and warranty contained in this Agreement as if such representation and warranty were made as of such date, modified as necessary to relate to the Registration Statement and the Prospectus as amended or supplemented as of such date. Any obligation of the Manager to use its commercially reasonable efforts to sell the Shares on behalf of the Company shall be subject to the continuing accuracy of the representations and warranties of the Company herein, to the performance by the Company of its obligations hereunder and to the continuing satisfaction of the additional conditions specified in Section 6 of this Agreement.

(c) Term Sales. If the Company wishes to sell the Shares pursuant to this Agreement but other than as set forth in Section 2(b) of this Agreement (each, a "Placement"), the Company will notify the Manager of the proposed terms of such Placement. If the Manager, acting as principal, wishes to accept such proposed terms (which it may decline to do for any reason in its sole discretion) or, following discussions with the Company wishes to accept amended terms, the Manager and the Company will enter into a Terms Agreement setting forth the terms of such Placement. The terms set forth in a Terms Agreement will not be binding on the Company or the Manager unless and until the Company and the Manager have each executed such Terms Agreement accepting all of the terms of such Terms Agreement. In the event of a conflict between the terms of this Agreement and the terms of a Terms Agreement, the terms of such Terms Agreement will control. A Terms Agreement may also specify certain provisions relating to the reoffering of such Shares by the Manager. The commitment of the Manager to purchase the Shares pursuant to any Terms Agreement shall be deemed to have been made on the basis of the representations and warranties of the Company herein contained and shall be subject to the terms and conditions herein set forth, as such may be modified pursuant to a Terms Agreement. Each Terms Agreement shall specify the number of the Shares to be purchased by the Manager pursuant thereto, the price to be paid to the Company for such Shares, any provisions relating to rights of, and default by, underwriters acting together with the Manager in the reoffering of the Shares, and the time and date (each such

time and date being referred to herein as a “Time of Delivery”) and place of delivery of and payment for such Shares. Such Terms Agreement shall also specify any requirements for opinions of counsel, accountants’ letters and officers’ certificates pursuant to Section 6 of this Agreement and any other information or documents reasonably required by the Manager.

(d) Maximum Number of Shares. Under no circumstances shall the Company cause or request the offer or sale of any Shares if, after giving effect to the sale of such Shares, the aggregate amount of Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Shares under this Agreement, the Maximum Amount, (B) the amount then available for offer and sale under the currently effective Registration Statement and (C) the amount authorized from time to time to be issued and sold under this Agreement by the Board, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Manager in writing. Under no circumstances shall the Company cause or request the offer or sale of any Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Board, a duly authorized committee thereof or a duly authorized executive officer, and notified to the Manager in writing. Further, under no circumstances shall the Company cause or permit the aggregate offering amount of Shares sold pursuant to this Agreement to exceed the Maximum Amount.

(e) Regulation M Notice. Unless the exceptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are satisfied with respect to the Shares, the Company shall give the Manager at least one Business Day’s prior notice of its intent to sell any Shares in order to allow the Manager time to comply with Regulation M.

3. Representations and Warranties. The Company represents and warrants to, and agrees with, the Manager at the Execution Time and on each such time the following representations and warranties are repeated or deemed to be made pursuant to this Agreement as set forth below, except as set forth in the Registration Statement, the Prospectus or the Incorporated Documents:

(a) Subsidiaries. All of the “significant subsidiaries” (as defined in Regulation S-X promulgated under the Securities Act) (individually, a “Subsidiary”) of the Company are set forth on Exhibit 21.1 to the Company’s most recent Annual Report on Form 10-K filed with the Commission. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any “Liens” (which for purposes of this Agreement shall mean a lien, charge, security interest, encumbrance, right of first refusal, preemptive right or other restriction on the ownership of such capital stock, but shall specifically exclude any general security interest over the assets of the Company and/or its Subsidiaries), and all the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization (as applicable), with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation or default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not reasonably be expected to result in (i) a material adverse effect on the legality, validity or enforceability of this Agreement, (ii) a material adverse change in the results of operations, assets, business or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, from that set forth in the Registration Statement, the Base Prospectus, any Prospectus Supplement, the Prospectus or the Incorporated Documents, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under this Agreement (any of (i), (ii) or (iii), a "Material Adverse Effect") and no "Proceeding" (which for purposes of this Agreement shall mean any action, claim, suit, investigation or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition)) has been instituted, or, to the Company's knowledge, threatened, in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization and Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder. The execution and delivery of this Agreement by the Company and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board or its stockholders in connection herewith other than in connection with the Required Approvals. This Agreement has been duly executed and delivered by the Company and constitutes the valid and binding obligation of the Company enforceable against the Company in accordance with its terms except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance of this Agreement by the Company, the issuance and sale of the Shares and the consummation by the Company of the other transactions contemplated herein do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any applicable law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected, except in the case of each of clauses (ii) and (iii), such as could not reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other "Person" (defined as an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind, including the Trading Market) in connection with the execution, delivery and performance by the Company of this Agreement, other than (i) the filings required by this Agreement, (ii) the filing with the Commission of the Prospectus Supplement, (iii) any periodic reports or filings by the Company that may be required under the Exchange Act, (iv) the filing of application(s) to and approval by the Trading Market for the listing of the Shares for trading thereon in the time and manner required thereby, and (v) such filings as are required to be made under applicable state securities laws and the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("FINRA") (collectively, the "Required Approvals").

(f) Issuance of Shares. The Shares are duly authorized and, when issued and paid for in accordance with this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement. The issuance by the Company of the Shares has been registered

under the Act and all of the Shares are freely transferable and tradable by the purchasers thereof without restriction (other than any restrictions arising solely from an act or omission of such a purchaser). The Shares are being issued pursuant to the Registration Statement and the issuance of the Shares has been registered by the Company under the Act. Upon receipt of the Shares, the purchasers of such Shares will have good and marketable title to such Shares and the Shares will be freely tradable on the Trading Market.

(g) Capitalization. The capitalization of the Company is as set forth in the Registration Statement, the Base Prospectus, the Prospectus Supplement and the Prospectus. The Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options or settlement of restricted stock unit awards granted under the Company's equity incentive plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plan, pursuant to the conversion or exercise of securities exercisable, exchangeable or convertible into Common Stock ("Common Stock Equivalents") or pursuant to that certain Purchase Agreement (the "LPC Purchase Agreement"), dated September 14, 2017, by and between the Company and Lincoln Park Capital Fund, LLC.. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by this Agreement. Except (i) pursuant to the Company's equity incentive plans and (ii) pursuant to agreements or instruments filed as exhibits to Incorporated Documents, there are no outstanding options, warrants, script rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents. The issuance and sale of the Shares will not obligate the Company to issue shares of Common Stock or other securities to any Person. Except for securities or instruments that are exhibits to the Incorporated Documents, there are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. All of the outstanding shares of capital stock of the Company are validly issued, fully paid and nonassessable, have been issued in compliance with all applicable federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) Registration Statement. The Company meets the requirements for use of Form S-3 under the Act and has prepared and filed with the Commission the Registration Statement, including a related Base Prospectus, for registration under the Act of the offering and sale of the Shares. Such Registration Statement is effective and available for the offer and sale of the Shares as of the date hereof. As filed, the Base Prospectus contains all material information required by the Act and the rules thereunder, and, except to the extent the Manager shall agree in writing to a modification, shall be in all substantive respects in the form furnished to the Manager prior to the Execution Time or prior to any such time this representation is repeated or deemed to be made. The Registration Statement, at the Execution Time, each such time this representation is repeated or deemed to be made, and at all times during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172, 173 or any similar rule) in connection with any offer or sale of the Shares, meets the requirements set forth in Rule 415(a)(1)(x). The initial Effective Date of the Registration Statement was not earlier than the date three years before the Execution Time. The Company meets the transaction requirements with respect to the aggregate market value of securities being sold pursuant to this offering and during the twelve (12) months prior to this offering, as set forth in General Instruction I.B.6 of Form S-3.

(i) Accuracy of Incorporated Documents. The Incorporated Documents, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the rules thereunder, and none of the Incorporated Documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Registration Statement, the Base Prospectus, the Prospectus Supplement or the Prospectus, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the rules thereunder, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(j) Ineligible Issuer. (i) At the earliest time after the filing of the Registration Statement that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2)) of the Shares and (ii) as of the Execution Time and on each such time this representation is repeated or deemed to be made (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an Ineligible Issuer (as defined in Rule 405), without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an Ineligible Issuer.

(k) Free Writing Prospectus. The Company is eligible to use Issuer Free Writing Prospectuses. Each Issuer Free Writing Prospectus does not include any information the substance of which conflicts with the information contained in the Registration Statement, including any Incorporated Documents and any prospectus supplement deemed to be a part thereof that has not been superseded or modified; and each Issuer Free Writing Prospectus does not contain any 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, not misleading. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Manager specifically for use therein. Any Issuer Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) has been, or will be, filed with the Commission in accordance with the requirements of the Act and the rules thereunder. Each Issuer Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) or that was prepared by or behalf of or used by the Company complies or will comply in all material respects with the requirements of the Act and the rules thereunder. The Company will not, without the prior consent of the Manager, prepare, use or refer to, any Issuer Free Writing Prospectuses.

(l) Proceedings Related to Registration Statement. The Registration Statement is not the subject of a pending proceeding or examination under Section 8(d) or 8(e) of the Act, and the Company is not the subject of a pending proceeding under Section 8A of the Act in connection with the offering of the Shares. The Company has not received any notice that the Commission has issued or intends to issue a stop-order with respect to the Registration Statement or that the Commission otherwise has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, or intends or has threatened in writing to do so.

(m) SEC Reports. The Company has complied in all material respects with requirements to file all reports, schedules, forms, statements and other documents required to be filed by it under the Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the “SEC Reports”) on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension.

(n) Financial Statements. The consolidated financial statements incorporated by reference in the Registration Statement, the Prospectus or the Incorporated Documents and any amendments thereof or supplements thereto comply in all material respects with applicable accounting requirements and the

rules and regulations of the Commission with respect thereto as in effect at the time of filing or as amended or corrected in a subsequent filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(o) Accountants. The Company’s accountants are PricewaterhouseCoopers LLP. To the knowledge of the Company, such accountants, which the Company expects will express their opinion with respect to the financial statements to be included in the Company’s next Annual Report on Form 10-K, are a registered public accounting firm as required by the Act.

(p) Material Adverse Events. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in a subsequent SEC Report filed prior to the date hereof, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company’s financial statements pursuant to GAAP or required to be disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or “Affiliate” (defined as any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 144 under the Act), except pursuant to existing Company equity incentive plans. The Company does not have pending before the Commission any request for confidential treatment of information. No event, liability or development has occurred or exists with respect to the Company or its Subsidiaries or their respective business, properties, operations or financial condition, that would be required to be disclosed by the Company under applicable securities laws at the time this representation is deemed made that has not been publicly disclosed on the date that this representation is deemed made.

(q) Litigation. There is no action, suit, inquiry, notice of violation, Proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their

respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of this Agreement or the Shares or (ii) would, if there were an unfavorable decision, reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor, to the knowledge of the Company, any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Act.

(r) Labor Relations. No material labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. No executive officer, to the knowledge of the Company, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all applicable U.S. federal, state, local, Canadian, British Columbia and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(s) No Existing Defaults. Neither the Company nor any Subsidiary (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any order of any court, arbitrator or governmental body, or (iii) is or has been in violation of any statute, rule or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection,

occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not reasonably be expected to result in a Material Adverse Effect.

(t) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect (“Material Permits”), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit. For clarity, the Company has not received the approval of any regulatory agency to market any of its product candidates.

(u) Title to Assets. Except as disclosed in the SEC Reports, the Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them that is material to the business of the Company and the Subsidiaries and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for Liens 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 and the Subsidiaries and Liens for the payment of federal, state or other taxes, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases of which the Company and the Subsidiaries are in compliance, except where such non-compliance would not reasonably be expected to have a Material Adverse Effect.

(v) Intellectual Property. Except as disclosed in the SEC Reports, the Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other similar intellectual property rights necessary or material for use in connection with their respective businesses as described in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus and which the failure to so have could reasonably be expected to have a Material Adverse Effect (collectively, the “Intellectual Property Rights”). Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a notice (written or otherwise) that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as would not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable (other than patent and trademark applications) and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken

commercially reasonable security measures to protect the secrecy, confidentiality and value of all of their Intellectual Property Rights, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(w) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary for companies of similar size as the Company in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. To the knowledge of the Company, such insurance contracts and policies are accurate and complete. Neither the Company nor any Subsidiary has any 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 without a significant increase in cost.

(x) Affiliate Transactions. Except as set forth in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus, none of the officers or directors of the Company and, to the knowledge of the Company, none of the employees of the Company is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee or partner, in each case in excess of \$120,000, other than (i) for payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) for other employee benefits, including stock option agreements under any equity incentive plan of the Company.

(y) Sarbanes Oxley Compliance. Except as disclosed in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus, the Company is in material compliance with all provisions of the Sarbanes-Oxley Act of 2002 which are applicable to it as of the Effective Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that:

(i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the

Company and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by the Company's most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the Company's internal control over financial reporting (as such term is defined in the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(z) Finder's Fees. Other than payments to be made to the Manager, no brokerage or finder's fees or commissions are or will be payable by the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by this Agreement. The Manager shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by this Agreement.

(aa) No Other Sales Agency Agreement. The Company has not entered into any other sales agency agreements or other similar arrangements with any agent or any other representative in respect of at the market offerings of the Shares.

(bb) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares or (iii) paid or agreed to pay to any person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Manager in connection with the placement of the Shares.

(cc) Listing and Maintenance Requirements. The issuance and sale of the Shares as contemplated in this Agreement does not contravene the rules and regulations of the Trading Market. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the

Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus, the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market.

(dd) Application of Takeover Protections. Except as set forth in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus, the Company and its Board have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's Certificate of Incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the purchasers of the Shares.

(ee) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Shares, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company currently intends to conduct its business in a manner so that it will not become subject to the Investment Company Act of 1940, as amended.

(ff) Solvency. Based on the financial condition of the Company as of the Effective Date, (i) the Company's fair saleable value of its assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its debt when such amounts are required to be paid. Within one year of the Effective Date, the Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The SEC Reports set forth as of the dates thereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments, as required by the Exchange Act and the regulations thereunder. For the purposes of this Agreement, "Indebtedness" shall mean (a) any liabilities for borrowed money or amounts owed in excess of \$50,000 (other than accrued liabilities and trade accounts payable incurred in the ordinary course of business), (b) all guaranties,

endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (e) the present value of any lease payments in excess of \$50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(gg) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and each Subsidiary (i) have made or filed all necessary United States federal, and state income and all foreign income and franchise tax returns and have paid or accrued all taxes shown as due thereon, and the Company has no knowledge of a tax deficiency which has been asserted or threatened against the Company or any report and declaration required by any jurisdiction to which it is subject, (ii) have paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) have set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(hh) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its subsidiaries (each such product, a "Pharmaceutical Product"), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in material compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of the Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or

orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company.

(ii) Foreign Corrupt Practices. Neither the Company, nor to the knowledge of the Company, any agent or other person acting on behalf of the Company, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.

(jj) FINRA Member Shareholders. There are no affiliations with any FINRA member firm among the Company's officers, directors or, to the knowledge of the Company, any five percent (5%) or greater stockholder of the Company, except as set forth in the Registration Statement, the Base Prospectus, any Prospectus Supplement or the Prospectus.

4. Agreements. The Company agrees with the Manager that:

(a) Right to Review Amendments and Supplements to Registration Statement and Prospectus During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act in connection with the offering or the sale of Shares, the Company will not file any amendment to the Registration Statement or supplement (including any Prospectus Supplement) to the Base Prospectus unless the Company has furnished to the Manager a copy for its review prior to filing and will not file any such proposed amendment or supplement to which the Manager reasonably objects; provided, however, that the Company will have no obligation to provide the Manager any advance copy of a filing or to provide the Manager an opportunity to object to a filing if such filing does not name the Manager and does not relate to the transactions contemplated herein. The

Company has properly completed the Prospectus, in a form approved by the Manager, and will file such Prospectus, as amended at the Execution Time, with the Commission pursuant to the applicable paragraph of Rule 424(b) promptly following the Execution Time and will cause any supplement to the Prospectus to be properly completed, in a form approved by the Manager, and will file such supplement with the Commission pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed thereby and will provide evidence reasonably satisfactory to the Manager of such timely filing. The Company will promptly advise the Manager (i) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the Commission pursuant to Rule 424(b), (ii) when, during any period when the delivery of a prospectus (whether physically or through compliance with Rule 172, 173 or any similar rule) is required under the Act in connection with the offering or sale of the Shares, any amendment to the Registration Statement shall have been filed or become effective (other than any annual report of the Company filed pursuant to Section 13(a) or 15(d) of the Exchange Act), (iii) of any request by the Commission or its staff for any amendment of the Registration Statement, or any Rule 462(b) Registration Statement, or for any supplement to the Prospectus or for any additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any notice objecting to its use or the institution or threatening of any proceeding for that purpose and (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the institution or threatening of any proceeding for such purpose. The Company will use its commercially reasonable efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain as soon as possible the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or a new registration statement and using its commercially reasonable efforts to have such amendment or new registration statement declared effective as soon as commercially practicable.

(b) Subsequent Events. If, at any time on or after an Applicable Time but prior to the related Settlement Date, any event occurs as a result of which the Registration Statement or Prospectus would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Manager so that any use of the Registration Statement or Prospectus may cease until such are amended or supplemented; (ii) amend or supplement the Registration Statement or Prospectus to correct such statement or omission; and (iii) supply any amendment or supplement to the Manager in such quantities as the Manager may reasonably request.

(c) Notification of Subsequent Filings. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act, if any event occurs as a result of which the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made not misleading, or if it shall be necessary to amend the Registration Statement, file a new registration statement or supplement the Prospectus to comply with the Act or the Exchange Act or the respective rules thereunder, including in connection with use or delivery of the Prospectus, the Company promptly will (i) notify the Manager of any such event (provided that such notification to the Manager shall not be required if a Sales Notice is not pending at the time of such event and if there have been no sale of Shares under this Agreement at the time of or following such event but prior to Company's knowledge of such event, but such notification shall be required prior to delivery by the Company of any instruction to the Manager to sell Shares hereunder), (ii) subject to Section 4(a), prepare and file with the Commission an amendment or supplement or new registration statement which will correct such statement or omission or effect such compliance, (iii) use its commercially reasonable efforts to have any amendment to the Registration Statement or new registration statement declared effective as soon as commercially practicable in order to avoid any disruption in use of the Prospectus and (iv) supply any supplemented Prospectus to the Manager in such quantities as the Manager may reasonably request.

(d) Earnings Statements. As soon as commercially practicable, the Company will make generally available to its security holders and to the Manager an earnings statement or statements of the Company and its Subsidiaries which will satisfy the provisions of Section 11(a) of the Act and Rule 158. For the avoidance of doubt, the Company's compliance with the reporting requirements of the Exchange Act shall be deemed to satisfy the requirements of this Section 4(d).

(e) Delivery of Registration Statement. Upon the request of the Manager, the Company will furnish to the Manager and counsel for the Manager, without charge, signed copies of the Registration Statement (including exhibits thereto) and, so long as delivery of a prospectus by the Manager or dealer may be required by the Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule), as many copies of the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Manager may reasonably request. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) Qualification of Shares. The Company will arrange, if necessary, for the qualification of the Shares for sale under the laws of such jurisdictions in the United States of America as the Manager may designate and will maintain such qualifications in effect so long as required for the distribution of the Shares; provided that in no event shall the Company be obligated to qualify to do business

in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Shares, in any jurisdiction where it is not now so subject.

(g) Free Writing Prospectus. The Company agrees that, unless it has or shall have obtained the prior written consent of the Manager, and the Manager agrees with the Company that, unless it has or shall have obtained, as the case may be, the prior written consent of the Company, it has not made and will not make any offer relating to the Shares that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a “free writing prospectus” (as defined in Rule 405) required to be filed by the Company with the Commission or retained by the Company under Rule 433. Any such free writing prospectus consented to by the Manager or the Company is hereinafter referred to as a “Permitted Free Writing Prospectus.” The Company agrees that (i) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (ii) it has complied and will comply, as the case may be, with the requirements of Rules 164 and 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping.

(h) Subsequent Equity Issuances. The Company shall not deliver any Sales Notice hereunder for at least two (2) Business Days (provided that, if a sale of Shares hereunder has occurred but not yet settled, for at least three (3) Business Days prior to such date) prior to the date on which the Company or any Subsidiary offers, sells, issues, contracts to sell, contracts to issue or otherwise disposes of, directly or indirectly, any other shares of Common Stock or any Common Stock Equivalents (other than the Shares), subject to Manager’s right to waive this obligation, provided that, without compliance with the foregoing obligation, (w) the Company may issue and sell Common Stock pursuant to any employee equity incentive plan, stock ownership plan or dividend reinvestment plan of the Company in effect at the Execution Time without notice to the Manager, (x) the Company may issue Common Stock issuable upon the conversion or exercise of Common Stock Equivalents, (y) the Company may issue Common Stock to employees, directors, officers, consultants and advisors as compensation for employment or services in the ordinary course of business, and (z) the Company may issue and sell Common Stock pursuant to other agreements outstanding on the Execution Date, including the LPC Purchase Agreement.

(i) Market Manipulation. Until the termination of this Agreement, the Company will not take, directly or indirectly, any action designed to or that would constitute or that would reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation in violation of the Act, Exchange Act or the rules and regulations thereunder of the price of any security of the Company to facilitate the sale or resale of the Shares or otherwise violate any provision of Regulation M under the Exchange Act.

(j) Notification of Incorrect Certificate. The Company will, at any time during the term of this Agreement, as supplemented from time to time, advise the Manager immediately after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect any opinion, certificate, letter and other document provided to the Manager pursuant to Section 6 herein, provided that such notification to the Manager shall not be required if a Sales Notice is not pending at the time of such notice or knowledge of such information or fact, but such notification shall be required prior to delivery by the Company of any instruction to the Manager to sell Shares hereunder.

(k) Certification of Accuracy of Disclosure. Prior to the delivery of the first Sales Notice delivered under this Agreement (and prior to the delivery of the first Sales Notice delivered upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder lasting more than 30 Trading Days), and each time that (i) the Registration Statement or Prospectus shall be amended or supplemented, other than by means of Incorporated Documents (other than a supplement unrelated to the offer and sale of Shares as contemplated herein), (ii) the Company files its Annual Report on Form 10-K under the Exchange Act, (iii) the Company files its quarterly reports on Form 10-Q under the Exchange Act and the Manager provides a written request, (iv) the Company files a Current Report on Form 8-K containing amended financial information (other than information that is furnished and not filed), if the Manager reasonably determines that the information in such Form 8-K is material, or (v) the Shares are delivered to the Manager as principal at the Time of Delivery pursuant to a Terms Agreement (such commencement or recommencement date and each such date referred to in (i), (ii), (iii), (iv) and (v) above, a "Representation Date"), unless waived by the Manager, the Company shall furnish or cause to be furnished to the Manager forthwith a certificate dated and delivered within five (5) Business Days of the Representation Date, in form reasonably satisfactory to the Manager to the effect that the statements contained in the certificate referred to in Section 6(c) of this Agreement which were last furnished to the Manager are true and correct at the Representation Date, as though made at and as of such date (except that such statements shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented to such date) or, in lieu of such certificate, a certificate of the same tenor as the certificate referred to in said Section 6, modified as necessary to relate to the Registration Statement and the Prospectus as amended and supplemented to the date of delivery of such certificate.

(l) Bring Down Negative Assurance. Within five (5) Business Days of each Representation Date, unless waived by the Manager, the Company shall furnish or cause to be furnished forthwith to the Manager a negative assurance representation letter from counsel to the Company ("Company Counsel") addressed to the Manager and dated on and delivered as of such date, in form and substance reasonably satisfactory to the Manager. The requirement to furnish or

cause to be furnished a negative assurance representation letter under this Section 4(l) shall be waived for any Representation Date occurring on a date on which no instruction to the Manager to sell Shares pursuant to this Agreement has been delivered by the Company or is pending. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following any Representation Date when the Company relied on such waiver and did not provide the Manager a negative assurance representation letter pursuant to this Section 4(l), then before the Company instructs the Manager to sell Shares pursuant to this Agreement, the Company shall provide the Manager such negative assurance representation letter.

(m) Auditor Bring Down "Comfort" Letter. Within five (5) Business Days of each Representation Date, unless waived by the Manager, the Company shall cause the Company's auditors (the "Accountants"), or other independent accountants satisfactory to the Manager forthwith to furnish the Manager a letter dated as of such date, in form satisfactory to the Manager, of the same tenor as the letters referred to in Section 6(d) of this Agreement but modified to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letters and certificate. The requirement to furnish or cause to be furnished a "comfort" letter under this Section 4(m) shall be waived for any Representation Date occurring on a date on which no instruction to the Manager to sell Shares pursuant to this Agreement has been delivered by the Company or is pending. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following any Representation Date when the Company relied on such waiver and did not provide the Manager a "comfort" letter pursuant to this Section 4(m), then before the Company instructs the Manager to sell Shares pursuant to this Agreement, the Company shall provide the Manager such "comfort" letter.

(n) Due Diligence Session. Upon commencement of the offering of the Shares under this Agreement (and upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder lasting more than 30 Trading Days), and within five (5) Business Days of each Representation Date, the Company will conduct a due diligence session, in form and substance, reasonably satisfactory to the Manager, which shall include representatives of management and Accountants. The Company shall cooperate timely with any reasonable due diligence request from or review conducted by the Manager or its agents from time to time in connection with the transactions contemplated by this Agreement, including, without limitation, providing information and available documents and access to appropriate corporate officers and the Company's agents during regular business hours and at the Company's principal offices, and timely furnishing or causing to be furnished such certificates, letters and opinions from the Company, its officers and its agents, as the Manager may reasonably request. The Company shall reimburse the Manager for all of Manager's counsels' time in each such due diligence update session, up to an aggregate maximum of \$2,500 per update.

(o) Acknowledgment of Trading. The Company consents to the Manager trading in the Common Stock for the Manager's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement or pursuant to a Terms Agreement.

(p) Disclosure of Shares Sold. The Company will disclose in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, as applicable, the number of Shares sold through the Manager under this Agreement, the Net Proceeds to the Company and the compensation paid by the Company with respect to sales of Shares pursuant to this Agreement during the relevant quarter; and, if required by any subsequent change in Commission policy or request, more frequently by means of a Current Report on Form 8-K or a further Prospectus Supplement.

(q) Rescission Right. If to the knowledge of the Company, the conditions set forth in Section 6 shall not have been satisfied as of the applicable Settlement Date, the Company will offer to any person who has agreed to purchase Shares from the Company as the result of an offer to purchase solicited by the Manager the right to refuse to purchase and pay for such Shares.

(r) Bring Down of Representations and Warranties. Each acceptance by the Company of an offer to purchase the Shares hereunder, and each execution and delivery by the Company of a Terms Agreement, shall be deemed to be an affirmation to the Manager 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 acceptance or of such Terms Agreement as though made at and as of such date, and an undertaking that such representations and warranties will be true and correct as of the Settlement Date for the Shares relating to such acceptance or as of the Time of Delivery relating to such sale, as the case may be, as though made at and as of 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).

(s) Reservation of Shares. The Company shall ensure that there are at all times sufficient shares of Common Stock to provide for the issuance, free of any preemptive rights, out of its authorized but unissued shares of Common Stock or shares of Common Stock held in treasury, of the maximum aggregate number of Shares authorized for issuance by the Board pursuant to the terms of this Agreement. The Company will use its commercially reasonable efforts to cause the Shares to be listed for trading on the Trading Market and to maintain such listing.

(t) Obligation Under Exchange Act. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act, the Company will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act and the regulations thereunder.

(u) DTC Facility. The Company shall cooperate with Manager and use its commercially reasonable efforts to permit the Shares to be eligible for clearance and settlement through the facilities of DTC.

(v) Use of Proceeds. The Company will apply the Net Proceeds from the sale of the Shares in the manner set forth in the Prospectus.

(w) Filing of Prospectus Supplement. If any sales of Shares are made pursuant to this Agreement which are not made in “at the market” offerings as defined in Rule 415, including, without limitation, any Placement pursuant to a Terms Agreement, the Company shall file a Prospectus Supplement describing the terms of such transaction, the amount of Shares sold, the price thereof, the Manager’s compensation, and such other information as may be required pursuant to Rule 424 and Rule 430B, as applicable, within the time required by Rule 424.

(x) Additional Registration Statement. To the extent that the Registration Statement is not available for the sales of the Shares as contemplated by this Agreement, the Company shall file a new registration statement with respect to any additional shares of Common Stock necessary to complete such sales of the Shares and shall cause such registration statement to become effective as promptly as practicable. After the effectiveness of any such registration statement, all references to “Registration Statement” included in this Agreement shall be deemed to include such new registration statement, including all documents incorporated by reference therein pursuant to Item 12 of Form S-3, and all references to “Base Prospectus” included in this Agreement shall be deemed to include the final form of prospectus, including all documents incorporated therein by reference, included in any such registration statement at the time such registration statement became effective.

5. Payment of Expenses. The Company agrees to pay the costs and expenses incident to the performance of its obligations under this Agreement, whether or not the transactions contemplated hereby are consummated, including without limitation: (i) the preparation, printing or reproduction and filing with the Commission of the Registration Statement (including financial statements and exhibits thereto), the Prospectus and each Issuer Free Writing Prospectus, and each amendment or supplement to any of them; (ii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Registration Statement, the Prospectus, and each Issuer Free Writing Prospectus, and all amendments or supplements to any of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Shares; (iii) the preparation, printing, authentication, issuance and delivery of certificates for the Shares, including any stamp or transfer taxes in connection with the original issuance and sale of the Shares; (iv) the printing (or

reproduction) and delivery of this Agreement, any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Shares; (v) the registration of the Shares under the Exchange Act, if applicable, and the listing of the Shares on the Trading Market; (vi) any registration or qualification of the Shares for offer and sale under the securities or blue sky laws of the several states (including filing fees and the reasonable fees and expenses of counsel for the Manager relating to such registration and qualification); (vii) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Shares; (viii) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; (ix) the filing fee under FINRA Rule 5110; (x) the reasonable fees and expenses of all of the Manager's counsels, not to exceed an aggregate of \$50,000 (excluding any periodic due diligence fees provided for under Section 4(n)), which shall be payable on the Execution Time; and (xi) all other costs and expenses incident to the performance by the Company of its obligations hereunder.

6. Conditions to the Obligations of the Manager. The obligations of the Manager under this Agreement and any Terms Agreement shall be subject to (i) the accuracy of the representations and warranties on the part of the Company contained herein as of the Execution Time, each Representation Date, and as of each Applicable Time, Settlement Date and Time of Delivery, (ii) the performance by the Company of its obligations hereunder and (iii) the following additional conditions:

(a) Filing of Prospectus Supplement. The Prospectus, and any supplement thereto, required by Rule 424 to be filed with the Commission have been filed in the manner and within the time period required by Rule 424(b) with respect to any sale of Shares; each Prospectus Supplement shall have been filed in the manner required by Rule 424(b) within the time period required hereunder and under the Act; any other material required to be filed by the Company pursuant to Rule 433(d) under the Act, shall have been filed with the Commission within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use shall have been issued and no proceedings for that purpose shall have been instituted or threatened.

(b) Delivery of Opinion. Prior to the delivery of the first Sales Notice under this Agreement, the Company shall have caused the Company Counsel to furnish to the Manager its opinion (including a negative assurance statement), dated as of such date and addressed to the Manager in form and substance reasonably acceptable to the Manager.

(c) Delivery of Officer's Certificate. Prior to the delivery of the first Sales Notice under this Agreement, the Company shall have furnished or caused to be furnished to the Manager a certificate of the Company signed by the Chief Executive Officer and Chief Financial Officer of the Company, dated as the date hereof, to the effect that the signers of such certificate have carefully examined the Registration Statement, the Prospectus, any Prospectus Supplement and any

documents incorporated by reference therein and any supplements or amendments thereto and this Agreement and that:

- (i) the representations and warranties of the Company in this Agreement are true and correct on and as of the date hereof and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to the date hereof;
- (ii) no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use has been issued and no proceedings for that purpose have been instituted or, to the Company's knowledge, threatened; and
- (iii) since the date of the most recent financial statements included in the Registration Statement, the Prospectus and the Incorporated Documents, there has been no Material Adverse Effect on the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Registration Statement and the Prospectus.
- (d) Delivery of Accountants' "Comfort" Letter. Prior to the delivery of the first Sales Notice under this Agreement, the Company shall have requested and caused the Accountants to have furnished to the Manager letters (which may refer to letters previously delivered to the Manager), dated as of such date, in form and substance reasonably satisfactory to the Manager, confirming that they are independent accountants within the meaning of the Act and the Exchange Act and the respective applicable rules and regulations adopted by the Commission thereunder and that they have performed a review of any unaudited interim financial information of the Company included or incorporated by reference in the Registration Statement and the Prospectus and provide customary "comfort" as to such review in form and substance satisfactory to the Manager.
- (e) No Material Adverse Event. Since the respective dates as of which information is disclosed in the Registration Statement, the Prospectus and the Incorporated Documents, except as otherwise stated therein, there shall not have been (i) any change or decrease in previously reported results specified in the letter or letters referred to in paragraph (d) of this Section 6 or (ii) any change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Registration Statement, the Prospectus and the Incorporated Documents (exclusive of any amendment or supplement thereto) the effect of which, in any case referred to in clause (i) or (ii) above, is, in the sole judgment of the Manager,

so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Registration Statement (exclusive of any amendment thereof), the Incorporated Documents and the Prospectus (exclusive of any amendment or supplement thereto).

(f) [RESERVED]

(g) No FINRA Objections. FINRA shall not have raised any objection with respect to the fairness and reasonableness of the terms and arrangements under this Agreement.

(h) Shares Listed on Trading Market. The Shares shall have been listed and admitted and authorized for trading on the Trading Market, and satisfactory evidence of such actions shall have been provided to the Manager.

(i) Other Assurances. Prior to each Settlement Date and Time of Delivery, as applicable, the Company shall have furnished to the Manager such further information, certificates and documents as the Manager may reasonably request.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Manager and counsel for the Manager, this Agreement and all obligations of the Manager hereunder may be canceled at, or at any time prior to, any Settlement Date or Time of Delivery, as applicable, by the Manager. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 shall be delivered to the office of Ellenoff Grossman & Schole LLP, counsel for the Manager, at 1345 Avenue of the Americas, New York, New York 10105, on each such date as provided in this Agreement.

7. Indemnification and Contribution.

(a) Indemnification by Company. The Company agrees to indemnify and hold harmless the Manager, the directors, officers, employees and agents of the Manager and each person who controls the Manager within the meaning of either the Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement for the registration of the Shares as originally filed or in

any amendment thereof, or in the Base Prospectus, any Prospectus Supplement, the Prospectus, any Issuer Free Writing Prospectus, or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or result from or relate to any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement, and agrees to reimburse each such indemnified party for the legal expenses of one counsel (plus local counsel) and other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by the Manager specifically for inclusion therein. This indemnity agreement will be in addition to any liability that the Company may otherwise have.

(b) Indemnification by Manager. The Manager agrees to indemnify and hold harmless the Company, each of its directors, each of its officers, and each person who controls the Company within the meaning of either the Act or the Exchange Act, to the same extent as the foregoing indemnity from the Company to the Manager, but only with reference to written information relating to the Manager furnished to the Company by the Manager specifically for inclusion in the documents referred to in the foregoing indemnity; provided, however, that in no case shall the Manager be responsible for any amount in excess of the Broker Fee applicable to the Shares and paid hereunder. This indemnity agreement will be in addition to any liability which the Manager may otherwise have.

(c) Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 7 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 7, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraph (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel retained by the indemnified party or parties except as set forth below); provided,

however, that such counsel shall be reasonably satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel to represent the indemnified party in an action, the indemnified party shall have the right to employ one separate counsel (plus local counsel), and the indemnifying party shall bear the documented and reasonable fees, costs and expenses of such separate counsel if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest, (ii) the actual or potential defendants in, or targets of, any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded 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, (iii) 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 the institution of such action or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding.

(d) Contribution. In the event that the indemnity provided in paragraph (a), (b) or (c) of this Section 7 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company and the Manager agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with investigating or defending the same) (collectively "Losses") to which the Company and the Manager may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and by the Manager on the other from the offering of the Shares; provided, however, that in no case shall the Manager be responsible for any amount in excess of the Broker Fee applicable to the Shares and paid hereunder. If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Manager severally shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and of the Manager on the other in connection with the statements or omissions which resulted in such Losses as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by it, and benefits received by the Manager shall be deemed to be equal to the Broker Fee applicable to the Shares and paid hereunder as determined by this Agreement. Relative fault shall be determined by reference to, among other things, whether

any untrue or any alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company on the one hand or the Manager on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Manager agree that it would not be just and equitable if contribution were determined by pro rata allocation or any other method of allocation which does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (d), no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 7, each person who controls the Manager within the meaning of either the Act or the Exchange Act and each director, officer, employee and agent of the Manager shall have the same rights to contribution as the Manager, and each person who controls the Company within the meaning of either the Act or the Exchange Act, each officer of the Company and each director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (d).

8. Termination.

(a) The Company shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that (i) with respect to any pending sale, through the Manager for the Company, the obligations of the Company, including in respect of compensation of the Manager, shall remain in full force and effect notwithstanding the termination and (ii) the provisions of Sections 5, 7, 8, 9, 10, 12 and 14 of this Agreement shall remain in full force and effect notwithstanding such termination.

(b) The Manager shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that the provisions of Sections 5, 7, 8, 9, 10, 12 and 14 of this Agreement shall remain in full force and effect notwithstanding such termination.

(c) This Agreement shall remain in full force and effect until the earliest of June 7, 2022, such date that this Agreement is terminated pursuant to Sections 8(a) or (b) above or the date on which all of the Shares covered by this Agreement have been sold or otherwise by mutual agreement of the parties, provided that any such termination by mutual agreement shall in all cases be deemed to provide that Sections 5, 7, 8, 9, 10, 12 and 14 shall remain in full force and effect.

(d) Any termination of this Agreement shall be effective on the date specified in such notice of termination, provided that such termination shall not be effective until the close of business on the date of receipt of such notice by the Manager or the Company, as the case may be. If such termination shall occur prior to the Settlement Date or Time of Delivery for any sale of the Shares, such sale of the Shares shall settle in accordance with the provisions of Section 2(b) of this Agreement.

(e) In the case of any purchase of Shares by the Manager pursuant to a Terms Agreement, the obligations of the Manager pursuant to such Terms Agreement shall be subject to termination, in the absolute discretion of the Manager, by prompt oral notice given to the Company prior to the Time of Delivery relating to such Shares, if any, and confirmed promptly by facsimile or electronic mail, if since the time of execution of the Terms Agreement and prior to such delivery and payment, (i) trading in the Common Stock shall have been suspended by the Commission or the Trading Market or trading in securities generally on the Trading Market shall have been suspended or limited or minimum prices shall have been established on such exchange, (ii) a banking moratorium shall have been declared either by Federal or New York State authorities or (iii) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States of a national emergency or war, or other calamity or crisis the effect of which on financial markets is such as to make it, in the sole judgment of the Manager, impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Prospectus (exclusive of any amendment or supplement thereto).

9. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company or its officers and of the Manager set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by the Manager or the Company or any of the officers, directors, employees, agents or controlling persons referred to in Section 7, and will survive delivery of and payment for the Shares.

10. Notices. All communications hereunder will be in writing and effective only on receipt, and will be mailed, delivered, e-mailed or facsimiled to the addresses of the Company and the Manager, respectively, set forth on the signature page hereto.

11. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 7, and no other person will have any right or obligation hereunder.

12. No Fiduciary Duty. The Company hereby acknowledges that (a) the purchase and sale of the Shares pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Manager and any affiliate through which it may be acting, on the other, (b) the Manager is acting solely

as sales agent and/or principal in connection with the purchase and sale of the Company's securities and not as a fiduciary of the Company and (c) the Company's engagement of the Manager in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether the Manager has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Manager has rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

13. **Integration.** This Agreement and any Terms Agreement supersede all prior agreements and understandings (whether written or oral) between the Company and the Manager with respect to the subject matter hereof.

14. **Applicable Law.** This Agreement and any Terms Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York. If either party shall commence an action or proceeding to enforce any provision of this Agreement, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its reasonable attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding. Each of the Company and the Manager: (i) agrees that any legal suit, action or proceeding arising out of or relating to this Agreement shall be instituted exclusively in New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, (ii) waives any objection which it may have or hereafter to the venue of any such suit, action or proceeding, and (iii) irrevocably consents to the jurisdiction of the New York Supreme Court, County of New York, and the United States District Court for the Southern District of New York in any such suit, action or proceeding. Each of the Company and the Manager further agrees to accept and acknowledge service of any and all process which may be served in any such suit, action or proceeding in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York and agrees that service of process upon the Company mailed by certified mail to the Company's address shall be deemed in every respect effective service of process upon the Company, in any such suit, action or proceeding, and service of process upon the Manager mailed by certified mail to the Manager's address shall be deemed in every respect effective service process upon the Manager, in any such suit, action or proceeding. If either party shall commence an action or proceeding to enforce any provision of this Agreement, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its reasonable attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

15. **WAIVER OF JURY TRIAL.** EACH OF THE COMPANY AND THE MANAGER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY

JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, ANY TERMS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

16. Counterparts. This Agreement and any Terms Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, which may be delivered by facsimile or in .pdf file via e-mail.

17. **Headings.** The section headings used in this Agreement and any Terms Agreement are for convenience only and shall not affect the construction hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the Manager.

Very truly yours,

ACHIEVE LIFE SCIENCES, INC.

By: /s/ John Bencich
Name: John Bencich
Title: Chief Financial and Operating Officer

Address for Notice:
1040 West Georgia Street, Suite 1030
Vancouver, B.C. V6E 4H1
Canada
Attention: Chief Financial Officer
Email: jbencich@achievelifesciences.com

The foregoing Agreement is hereby confirmed and accepted as of the date first written above.

H.C. WAINWRIGHT & CO., LLC

By: /s/ Edward D. Silvera
Name: Edward D. Silvera
Title: Chief Operating Officer

Address for Notice:

430 Park Avenue
New York, New York 10022
Attention: Chief Executive Officer
E-mail: notices@hewco.com

Form of Terms Agreement
ANNEX I
ACHIEVE LIFE SCIENCES, INC.
TERMS AGREEMENT

Dear Sirs:

Achieve Life Sciences, Inc. (the "Company") proposes, subject to the terms and conditions stated herein and in the At The Market Offering Agreement, dated June 7, 2019 (the "At The Market Offering Agreement"), between the Company and H.C. Wainwright & Co., LLC ("Manager"), to issue and sell to Manager the securities specified in the Schedule I hereto (the "Purchased Shares").

Each of the provisions of the At The Market Offering Agreement not specifically related to the solicitation by Manager, as agent of the Company, of offers to purchase securities is incorporated herein by reference in its entirety, and shall be deemed to be part of this Terms Agreement to the same extent as if such provisions had been set forth in full herein. Each of the representations and warranties set forth therein shall be deemed to have been made at and as of the date of this Terms Agreement and the Time of Delivery, except that each representation and warranty in Section 3 of the At The Market Offering Agreement which makes reference to the Prospectus (as therein defined) shall be deemed to be a representation and warranty as of the date of the At The Market Offering Agreement in relation to the Prospectus, and also a representation and warranty as of the date of this Terms Agreement and the Time of Delivery in relation to the Prospectus as amended and supplemented to relate to the Purchased Shares.

An amendment to the Registration Statement (as defined in the At The Market Offering Agreement), or a supplement to the Prospectus, as the case may be, relating to the Purchased Shares, in the form heretofore delivered to the Manager is now proposed to be filed with the Securities and Exchange Commission.

Subject to the terms and conditions set forth herein and in the At The Market Offering Agreement which are incorporated herein by reference, the Company agrees to issue and sell to Manager and the latter agrees to purchase from the Company the number of shares of the Purchased Shares at the time and place and at the purchase price set forth in the Schedule I hereto.

If the foregoing is in accordance with your understanding, please sign and return to us a counterpart hereof, whereupon this Terms Agreement, including those provisions of the At The Market Offering Agreement incorporated herein by reference, shall constitute a binding agreement between the Manager and the Company.

ACHIEVE LIFE SCIENCES, INC.

By: _____
Name:
Title:

ACCEPTED as of the date first written above.

H.C. WAINWRIGHT & CO., LLC

By: _____
Name:
Title:



1191 SECOND AVENUE, 10TH FLOOR SEATTLE, WA 98101
TEL 206.389.4510 FAX 206.389.4511 WWW.FENWICK.COM

June 7, 2019

Achieve Life Sciences, Inc.
1040 West Georgia Street, Suite 1030
Vancouver, B.C. V6E 4H1
Canada

Gentlemen/Ladies:

We deliver this opinion with respect to certain matters in connection with the offering by Achieve Life Sciences, Inc., a Delaware corporation (the "**Company**"), of the Company's common stock, par value \$0.001 per share (the "**Common Stock**"), with an aggregate maximum offering price of up to \$6.0 million (the "**Placement Shares**"), to be issued from time to time pursuant to that certain At the Market Offering Agreement (the "**Offering Agreement**"), dated as of even date herewith, between the Company and H.C. Wainwright & Co., LLC. The Placement Shares were registered pursuant to the Registration Statement on Form S-3 (File No. 333-229019) filed by the Company with the Securities and Exchange Commission (the "**Commission**") on December 26, 2018 and declared effective on February 11, 2019 (the "**Registration Statement**") under the Securities Act of 1933, as amended (the "**Securities Act**"), the base prospectus dated February 11, 2019 included therein (the "**Base Prospectus**"), and the related prospectus supplement dated June 7, 2019 filed with the Commission pursuant to Rule 424(b) under the Securities Act (the "**Prospectus Supplement**," and together with the Base Prospectus, the "**Prospectus**"). The offering of the Placement Shares is referred to herein as the "**Offering**." The Placement Shares are to be sold by the Company as described in the Registration Statement, the Prospectus and the Offering Agreement.

In connection with our opinion expressed below, we have examined originals or copies of the Company's Second Amended and Restated Certificate of Incorporation, as amended (the "**Certificate**") and Sixth Amended and Restated Bylaws, as amended (the "**Bylaws**" and, together with the Certificate, as each may be amended, modified or restated, the "**Charter Documents**"), certain corporate proceedings of the Company's board of directors (the "**Board**") and stockholders relating to the Registration Statement, the Charter Documents, and such other agreements, documents, certificates and statements of the Company, its transfer agent and public or government officials, as we have deemed advisable, and have examined such questions of law as we have considered necessary. We have assumed, and express no opinion as to, the genuineness of all signatures on documents submitted to us, the authenticity and completeness of all documents submitted to us as originals, the conformity to originals and completeness of all documents submitted to us as copies, the legal capacity of all persons or entities executing the same, the absence of any undisclosed termination, modification, waiver or amendment to any document reviewed by us, the absence of any other extrinsic agreements or documents that might change or affect the interpretation or terms of documents we have reviewed, and the due authorization, execution and delivery of all such documents where due authorization, execution and delivery are prerequisites to the effectiveness thereof. In giving our opinion, we have also relied upon a good standing certificate regarding the Company issued by the Delaware Secretary of State dated June [], 2019 and a management certificate addressed to us and dated of even date herewith executed by the Company containing certain factual representations (the "**Management Certificate**").

As to matters of fact relevant to this opinion, we have relied solely upon our examination of the documents referred to above and the Management Certificate and have assumed the current accuracy and completeness of the information obtained from the documents referred to above and the representations and warranties made by representatives of the Company to us, including but not limited to those set forth in the Management Certificate. We have made no independent investigation or other attempt to verify the accuracy of any of such information or to determine the existence or non-existence of any other factual matters.

We render this opinion only with respect to, and express no opinion herein concerning the application or effect of the laws of any jurisdiction other than the existing laws of the Delaware General Corporation Law (the “*Applicable Laws*”). Without limitation, we express no opinion with respect to the federal laws of the United States of America or the securities or “blue sky” laws of any state or any local or regional laws.

In connection with our opinions expressed below, we have assumed that, (i) at or prior to the time of the delivery of any of the Placement Shares, there will not have occurred any change in the law or the facts affecting the validity of the Placement Shares, (ii) at the time of the offer, issuance and sale of any Placement Shares, no stop order suspending the Registration Statement’s effectiveness will have been issued and remain in effect, (iii) no future amendments will be made to the Charter Documents that would be in conflict with or inconsistent with the Company’s right and ability to issue the Placement Shares, (iv) at the time of each offer, issuance and sale of any Placement Shares, the Company will have a sufficient number of authorized and unissued and unreserved shares of the applicable class or series of its capital stock included in (or purchasable upon exercise or conversion of) the Placement Shares so issued and sold (after taking into account all other outstanding securities of the Company which may require the Company to issue shares of such applicable class or series) to be able to issue all such shares, and (v) the purchaser of the Placement Shares will timely pay in full to the Company all amounts they have agreed to pay to purchase such Placement Shares, as approved by the Board or a duly authorized committee thereof, and that the purchase price of any Placement Shares will not be less than the par value thereof.

The Company has informed us that the Company intends to issue the Placement Shares, from time to time on a delayed or continuous basis. This opinion is limited to the Applicable Laws, including the rules and regulations thereunder, as in effect on the date hereof.

Based upon the foregoing, we are of the opinion that the Placement Shares to be issued and sold by the Company, when issued, sold and delivered in the manner and for the consideration stated in the Registration Statement and the Prospectus and in accordance with the resolutions adopted and to be adopted by the Board or a committee thereof, will be validly issued, fully paid and nonassessable.

We consent to the use of this opinion as an exhibit to the Form8-K and further consent to all references to us, if any, in the Registration Statement, the Prospectus constituting a part thereof and any amendments or supplements thereto. We do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

[Concluding Paragraph Follows on Next Page]

This opinion is intended solely for use in connection with the issuance and sale of the Placement Shares subject to the Offering Agreement and is not to be relied upon for any other purpose. In providing this letter, we are opining only as to the specific legal issues expressly set forth above, and no opinion shall be inferred as to any other matter or matters. This opinion is rendered on, and speaks only as of, the date of this letter first written above, is based solely on our understanding of facts in existence as of such date after the aforementioned examination and does not address any potential changes in facts, circumstance or law that may occur after the date of this opinion letter. We assume no obligation to advise you of any fact, circumstance, event or change in the law or the facts that may hereafter be brought to our attention whether or not such occurrence would affect or modify any of the opinions expressed herein

Very truly yours,

/s/ Fenwick & West LLP

FENWICK & WEST LLP