

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

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

**Date of Report (Date of Earliest Event Reported): July 29, 2020 (July 27, 2020)**

**Allena Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or other jurisdiction  
of incorporation)

**001-38268**  
(Commission  
File Number)

**45-2729920**  
(I.R.S. Employer  
Identification No.)

**One Newton Executive Park, Suite 202**  
**Newton, Massachusetts**  
(Address of principal executive offices)

**02462**  
(Zip Code)

**Registrant's telephone number, including area code (617) 467-4577**

**Not Applicable**

(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:

- 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 or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading symbol(s)	Name of each exchange on which registered
<b>Common Stock, par value \$0.001 per share</b>	<b>ALNA</b>	<b>The Nasdaq Global Select Market</b>

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

Emerging growth company

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 July 27, 2020, Allena Pharmaceuticals, Inc. (the “Company”) entered into an underwriting agreement with H.C. Wainwright & Co., LLC (“Wainwright”) (as amended and restated, the “Underwriting Agreement”). Pursuant to the Underwriting Agreement, the Company agreed to sell, in an upsized firm commitment offering, 5,125,384 shares (the “Shares”) of the Company’s common stock, \$0.001 par value per share (the “Common Stock”), to Wainwright at an offering price to the public of \$1.30 per share, less underwriting discounts and commissions. In addition, pursuant to the Underwriting Agreement, the Company has granted Wainwright a 30-day option to purchase up to an additional 768,807 shares of Common Stock at the same offering price to the public, less underwriting discounts and commissions. On July 29, 2020, Wainwright exercised its option to purchase additional shares of Common Stock in full.

The Company expects to receive net proceeds from the sale of the Shares, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company, of approximately \$6.7 million, which includes proceeds from the additional shares of Common Stock to be sold pursuant to Wainwright’s exercise in full of its option to purchase additional shares. The Company intends to use the net proceeds from the offering for working capital and other general corporate purposes.

The offering, including the shares to be issued and sold pursuant to the exercise in full of Wainwright’s option to purchase additional shares, is expected to close on July 30, 2020, subject to satisfaction of customary closing conditions.

Wainwright is acting as the sole book-running manager for the offering. The Company will pay Wainwright an underwriting discount equal to 7.5% of the gross proceeds of the offering and a management fee equal to 1% of the gross proceeds of the offering and reimburse Wainwright for a non-accountable expense allowance of \$25,000, up to \$100,000 in legal fees and \$12,900 for the clearing expenses.

The sale of the Shares, including shares sold pursuant to Wainwright’s exercise of its option to purchase additional shares of Common Stock in full, will be made pursuant to the Company’s effective Registration Statement on Form S-3 (Registration No. 333-228656), including a prospectus contained therein dated December 26, 2018, as supplemented by a prospectus supplement, dated July 27, 2020, relating to the offering.

The Underwriting Agreement contains customary representations, warranties, and covenants of the Company and also provides for customary indemnification by each of the Company and Wainwright against certain liabilities and customary contribution provisions in respect of those liabilities.

A copy of the opinion of Goodwin Procter LLP relating to the legality of the issuance and sale of the Shares is attached as Exhibit 5.1 hereto.

The foregoing description of the Underwriting Agreement is qualified in its entirety by reference to the Underwriting Agreement, a copy of which is attached hereto as Exhibit 1.1 and incorporated herein by reference.

**Item 8.01 Other Events.**

On July 27, 2020, the Company issued press releases announcing the pricing and upsizing of the offering. Copies of these press releases are attached hereto as Exhibits 99.1 and 99.2, respectively, and are each incorporated herein by reference.

**Exhibit 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
1.1	<a href="#"><u>Amended and Restated Underwriting Agreement, dated July 27, 2020, between Allena Pharmaceuticals, Inc. and H.C. Wainwright &amp; Co., LLC.</u></a>
5.1	<a href="#"><u>Opinion of Goodwin Procter, LLP</u></a>
23.1	<a href="#"><u>Consent of Goodwin Procter LLP (included in Exhibit 5.1)</u></a>
99.1	<a href="#"><u>Press Release dated July 27, 2020 (announcing pricing of offering)</u></a>
99.2	<a href="#"><u>Press Release dated July 27, 2020 (announcing upsizing of offering)</u></a>

**SIGNATURES**

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

Date: July 29, 2020

**Allena Pharmaceuticals, Inc.**

By: /s/ Edward Wholihan

Edward Wholihan

Chief Financial Officer

**Allena Pharmaceuticals, Inc.**  
5,125,384 Shares of Common Stock  
(par value \$0.001 per share)

**Amended and Restated Underwriting Agreement**

July 27, 2020

H.C. Wainwright & Co., LLC  
As Representative of the several  
Underwriters listed in Schedule  
A hereto  
430 Park Avenue, 4th Floor  
New York, NY 10022

Ladies and Gentlemen:

Allena Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware (the “**Company**”), proposes to issue and sell to the several underwriters named in Schedule A (the “**Underwriters**”) an aggregate of 5,125,384 shares of its common stock, par value \$0.001 per share (the “**Shares**”). The 5,125,384 Shares to be sold by the Company are called the “**Firm Shares**.” In addition, the Company has granted to the Underwriters an option to purchase up to an additional 768,807 Shares as provided in Section 2. The additional 768,807 Shares that may be sold by the Company pursuant to such option are collectively called the “**Optional Shares**.” The Firm Shares and, if and to the extent such option is exercised, the Optional Shares, are collectively called the “**Offered Shares**.” H.C. Wainwright & Co., LLC (“**Wainwright**”) has agreed to act as representative of the several Underwriters (in such capacity, the “**Representative**”) in connection with the offering and sale of the Offered Shares. To the extent there are no additional underwriters listed on Schedule A, the term “Representative” as used herein shall mean you, as Underwriter, and the term “Underwriters” shall mean either the singular or the plural, as the context requires. This Amended and Restated Underwriting Agreement amends, restates and supersedes in its entirety the underwriting agreement, dated as of July 27, 2020, between the Company and the Representative.

The Company has prepared and filed with the U.S. Securities and Exchange Commission (the “**Commission**”) a shelf registration statement on Form S-3, File No. 333-228656, including a base prospectus (the “**Base Prospectus**”) to be used in connection with the public offering and sale of the Offered Shares. Such registration statement, as amended, including the financial statements, exhibits and schedules thereto, in the form in which it became effective under the U.S. Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (collectively, the “**Securities Act**”), including all documents incorporated or deemed to be incorporated by reference therein and any information deemed to be a part thereof at the time of effectiveness pursuant to Rule 430A or Rule 430B under the Securities Act, is called the “**Registration Statement**.” Any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offer and sale of the Offered Shares is called the “**Rule 462(b) Registration Statement**,” and from and after the date and time of filing of any such Rule 462(b) Registration Statement the term “Registration Statement” shall include

the Rule 462(b) Registration Statement. The preliminary prospectus supplement, dated July 27, 2020, describing the Offered Shares and the offering thereof (the “**Preliminary Prospectus Supplement**”), together with the Base Prospectus, is called the “**Preliminary Prospectus**,” and the Preliminary Prospectus and any other prospectus supplement to the Base Prospectus in preliminary form that describes the Offered Shares and the offering thereof and is used prior to the filing of the Prospectus (as defined below), together with the Base Prospectus, is called a “**preliminary prospectus**.” As used herein, the term “**Prospectus**” shall mean the final prospectus supplement to the Base Prospectus that describes the Offered Shares and the offering thereof, together with the Base Prospectus, in the form first used by the Underwriters to confirm sales of the Offered Shares or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act.

As used herein, “**Applicable Time**” is 9:35 p.m. (New York time) on July 27, 2020. As used herein, “**free writing prospectus**” has the meaning set forth in Rule 405 under the Securities Act, and “**Time of Sale Prospectus**” means the Preliminary Prospectus, as amended or supplemented immediately prior to the Applicable Time, together with the free writing prospectuses, if any, identified on Schedule B hereto and the pricing information set forth on Schedule C hereto. As used herein, “**Road Show**” means a “road show” (as defined in Rule 433 under the Securities Act) relating to the offering of the Offered Shares contemplated hereby that is a “written communication” (as defined in Rule 405 under the Securities Act).

All references in this Agreement to financial statements and schedules and other information which are “contained,” “included” or “stated” in, or “part of” the Registration Statement, the Rule 462(b) Registration Statement, the Preliminary Prospectus, any preliminary prospectus, the Base Prospectus, the Time of Sale Prospectus or the Prospectus, and all other references of like import, shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Rule 462(b) Registration Statement, the Preliminary Prospectus, any preliminary prospectus, the Base Prospectus, the Time of Sale Prospectus or the Prospectus, as the case may be.

All references in this Agreement to amendments or supplements to the Registration Statement, the Preliminary Prospectus, any preliminary prospectus, the Base Prospectus, the Time of Sale Prospectus or the Prospectus shall be deemed to mean and include the filing of any document under the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the “**Exchange Act**”) that is or is deemed to be incorporated by reference in the Registration Statement, the Preliminary Prospectus, any preliminary prospectus, the Base Prospectus, or the Prospectus, as the case may be.

All references in this Agreement to (i) the Registration Statement, the Preliminary Prospectus, any preliminary prospectus, the Base Prospectus or the Prospectus, any amendments or supplements to any of the foregoing, or any free writing prospectus, shall include any copy thereof filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System (“**EDGAR**”) and (ii) the Prospectus shall be deemed to include any “electronic Prospectus” provided for use in connection with the offering of the Offered Shares as contemplated by Section 3(n) of this Agreement.

In the event that the Company has only one Subsidiary, then all references herein to “Subsidiaries” of the Company shall be deemed to refer to such single Subsidiary, mutatis mutandis. In the event that the Company has no Subsidiaries, all other references to the Subsidiaries or any of them in this Agreement shall be disregarded.

The Company hereby confirms its agreements with the Underwriters as follows:

1. **Representations and Warranties of the Company.** The Company represents and warrants to each Underwriter as of the date of this Agreement, the Applicable Time, the First Closing Date (as hereinafter defined) and each Option Closing Date (as hereinafter defined), if any, as follows:

(a) **Compliance with Registration Requirements.** The Registration Statement has become effective under the Securities Act. The Company has complied, to the Commission’s satisfaction, with all requests of the Commission for additional or supplemental information, if any. No stop order suspending the effectiveness of the Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission. At the time the Company’s Annual Report on Form 10-K for the year ended December 31, 2019 (the “**Annual Report**”) was filed with the Commission, or, if later, at the time the Registration Statement was originally filed with the Commission, the Company met the then-applicable registrant requirements for use of Form S-3 under the Securities Act. The documents incorporated or deemed to be incorporated by reference in the Registration Statement, the Time of Sale Prospectus and the Prospectus, at the time they were or hereafter are filed with the Commission, or became effective under the Exchange Act, as the case may be, complied and will comply in all material respects with the requirements of the Exchange Act.

(b) **Disclosure.** Each preliminary prospectus and the Prospectus when filed complied in all material respects with the Securities Act and, if filed by electronic transmission pursuant to EDGAR, was identical (except as may be permitted by Regulation S-T under the Securities Act) to the copy thereof delivered to the Underwriters for use in connection with the offer and sale of the Offered Shares. Each of the Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective and at all subsequent times, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Applicable Time, the Time of Sale Prospectus did not, and at the time of each sale of the Offered Shares and at the Closing Date (as defined in Section 2), the Time of Sale Prospectus, as then amended or supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as of its date and (as then amended or supplemented) at all subsequent times, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement or any post-effective amendment thereto, or the Prospectus or the Time of Sale Prospectus, or any

amendments or supplements thereto, made in reliance upon and in conformity with written information relating to any Underwriter furnished to the Company in writing by the Representative expressly for use therein, it being understood and agreed that the only such information consists of the information described in Section 9(a) below. There are no contracts or other documents required to be described in the Time of Sale Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which have not been described or filed as required.

**(c) Free Writing Prospectuses; Road Show.** As of the determination date referenced in Rule 164(h) under the Securities Act, the Company was not, is not or will not be (as applicable) an “ineligible issuer” in connection with the offering of the Offered Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Each free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act, including timely filing with the Commission or retention where required and legending, and each such free writing prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Offered Shares did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Prospectus or any preliminary prospectus and not superseded or modified. Except for the free writing prospectuses, if any, identified in Schedule B, and electronic road shows, if any, furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior written consent, prepare, use or refer to, any free writing prospectus. Each Road Show, when considered together with the Time of Sale Prospectus, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

**(d) Form S-3.** The Company and the transactions contemplated by this Agreement meet the requirements for, and comply with the conditions for the use of, Form S-3 under the Securities Act. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The proposed offering of the Offered Shares may be made pursuant to General Instruction I.B.6. of Form S-3. Without limiting the generality of the foregoing, the aggregate market value of securities sold by or on behalf of the Company pursuant to General Instruction I.B.6 of Form S-3 during the 12-month period immediately prior to, and including, the sale of Offered Shares pursuant to this Agreement is no more than one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Company, as determined pursuant to General Instruction I.B.6 of Form S-3. The Company is not a shell company (as defined in Rule 405 of the Securities Act) and has not been a shell company for at least twelve (12) calendar months previously and if it has been a shell company at any time previously, has filed current Form 10 information (as defined in Instruction I.B.6 of Form S-3) with the Commission at least twelve (12) calendar months previously reflecting its status as an entity that is not a shell company. The Registration Statement meets the requirements set forth in Rule 415(a)(1)(x) under the Securities Act and complies with said Rule, and the Prospectus Supplement will meet the requirements set forth in Rule 424(b).



**(e) Distribution of Offering Material By the Company.** Prior to the later of (i) the expiration or termination of the option granted to the several Underwriters in Section 2, and (ii) the completion of the Underwriters' distribution of the Offered Shares, the Company has not distributed and will not distribute any offering material in connection with the offering and sale of the Offered Shares other than the Registration Statement, the Time of Sale Prospectus, the Prospectus, any free writing prospectus reviewed and consented to by the Representative, and the free writing prospectuses, if any, identified on Schedule B hereto. The Company has not distributed and will not distribute any offering material in connection with the offering other than the Registration Statement and the prospectus supplement to the Base Prospectus that described the offering hereof.

**(f) Financial Information.** The consolidated financial statements of the Company included or incorporated by reference in the Registration Statement, the Time of Sale Prospectus and the Prospectus, if any, together with the related notes and schedules, present fairly, in all material respects, the consolidated financial position of the Company and the Subsidiaries (as defined below) as of the dates indicated and the consolidated results of operations, cash flows and changes in stockholders' equity of the Company for the periods specified and have been prepared in compliance with the requirements of the Securities Act and Exchange Act, and in conformity with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis during the periods involved; there are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement, the Time of Sale Prospectus and the Prospectus that are not included or incorporated by reference as required; the Company and the Subsidiaries (as defined below) do not have any material liabilities or obligations, direct or contingent (including any off-balance sheet obligations), not described in the Registration Statement (excluding the exhibits thereto), the Time of Sale Prospectus and the Prospectus; and all disclosures contained or incorporated by reference in the Registration Statement, the Time of Sale Prospectus and the Prospectus and any free writing prospectuses, if any, regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable. The financial data set forth in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus fairly present the information set forth therein on a basis consistent with that of the audited financial statements contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus. The pro forma condensed consolidated financial statements of the Company and its Subsidiaries and the related notes thereto included or incorporated by reference elsewhere in the Registration Statement, the Time of Sale Prospectus or the Prospectus present fairly the information contained therein, have been prepared in accordance with the Commission's rules and guidelines with respect to pro forma financial statements and have been properly presented on the bases described therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and the Prospectus fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

**(g) Conformity with EDGAR Filing.** The Preliminary Prospectus and Prospectus delivered to the Underwriters for use in connection with the sale of the Offered Shares pursuant to this Agreement will be identical to the versions of the Preliminary Prospectus and Prospectus created to be transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

**(h) Organization.** The Company and each of its Subsidiaries are duly organized, validly existing as a corporation or other entity and in good standing under the laws of their respective jurisdictions of organization. The Company and each of its Subsidiaries are duly licensed or qualified as a foreign corporation or other entity for transaction of business and in good standing under the laws of each other jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate or other organizational power and authority necessary to own or hold their respective properties and to conduct their respective businesses as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, and as currently carried on, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect on the assets, business, operations, earnings, properties, financial condition, stockholders' equity or results of operations of the Company and the Subsidiaries taken as a whole, or prevent or materially interfere with consummation of the transactions contemplated hereby (a "**Material Adverse Effect**").

**(i) Subsidiaries.** The subsidiaries set forth on Schedule D (collectively, the "**Subsidiaries**"), are the Company's only significant subsidiaries (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission). The Company owns, directly or indirectly, all of the equity interests of the Subsidiaries free and clear of any lien, charge, security interest, encumbrance, right of first refusal or other restriction, and all the equity interests of the Subsidiaries are validly issued and are fully paid, nonassessable and free of preemptive and similar rights. Except as set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus, no Subsidiary is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such Subsidiary's capital stock, from repaying to the Company any loans or advances to such Subsidiary from the Company or from transferring any of such Subsidiary's property or assets to the Company or any other Subsidiary of the Company.

**(j) No Violation or Default.** Neither the Company nor any of its Subsidiaries is (i) in violation of its certificate of incorporation, charter or by-laws or any other organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its Subsidiaries is a party or by which the Company or any of its Subsidiaries is bound or to which any of the property or assets of the Company or any of its Subsidiaries are subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any Governmental Authority (as defined below), except, in the case of each of clauses (ii) and (iii) above, for any such violation or default that would not, individually or in the aggregate, have a Material Adverse Effect. To the Company's knowledge, no other party under any material contract or other agreement to which it or any of its Subsidiaries is a party is in default in any respect thereunder where such default would have a Material Adverse Effect.

**(k) No Material Adverse Change.** Subsequent to the respective dates as of which information is given in the Registration Statement, the Time of Sale Prospectus, the Prospectus and the free writing prospectuses, if any (including any document deemed incorporated by reference therein), there has not been (i) any Material Adverse Effect or the occurrence of any development that would reasonably be expected to have a Material Adverse Effect, (ii) any transaction which is material to the Company and the Subsidiaries taken as a whole, (iii) any obligation or liability, direct or contingent (including any off-balance sheet obligations), incurred by the Company or any Subsidiary, which is material to the Company and the Subsidiaries taken as a whole, (iv) any material change in the capital stock or outstanding long-term indebtedness of the Company or any of its Subsidiaries or (v) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company or any Subsidiary, other than in each case above in the ordinary course of business or as otherwise disclosed in the Registration Statement or Prospectus (including any document deemed incorporated by reference therein).

**(l) Capitalization.** The issued and outstanding shares of capital stock of the Company have been validly issued, are fully paid and nonassessable and are not subject to any preemptive rights, rights of first refusal or similar rights. The Company has an authorized, issued and outstanding capitalization as set forth in the Registration Statement and the Prospectus as of the dates referred to therein (other than the grant of additional options under the Company's existing option plans, or changes in the number of outstanding shares of common stock of the Company (the "**Common Stock**") due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, Common Stock outstanding on the date hereof or any anti-dilution provisions of such outstanding securities) and such authorized capital stock conforms in all material respects to the description thereof set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus. The description of the securities of the Company in the Registration Statement, the Time of Sale Prospectus and the Prospectus is complete and accurate in all material respects. Except as disclosed in or contemplated by the Registration Statement, the Time of Sale Prospectus or the Prospectus, as of the date referred to therein, the Company does not have outstanding any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or exchangeable for, or any contracts or commitments to issue or sell, any shares of capital stock or other securities.

**(m) Authorization; Enforceability.** The Company has full legal right, power and authority to enter into this Agreement and perform the transactions contemplated hereby. This Agreement has been duly authorized, executed and delivered by the Company and is a legal, valid and binding agreement of the Company enforceable against the Company in accordance with its terms, except to the extent that enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles.

**(n) Authorization of the Offered Shares.** The Offered Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of any pledge, mortgage, hypothecation, lien, encumbrance, security interest or other claim, including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights, and will be registered pursuant to Section 12 of the Exchange Act. The Offered Shares, when issued, will conform in all material respects to the description thereof set forth in or incorporated into the Registration Statement, the Time of Sale Prospectus and the Prospectus.

**(o) No Consents Required.** No consent, approval, authorization, order, registration or qualification of or with any Governmental Authority is required for the execution, delivery and performance by the Company of this Agreement, the issuance and sale by the Company of the Offered Shares, except for such consents, approvals, authorizations, orders and registrations or qualifications as may be required under applicable state securities laws or by the by-laws and rules of the Financial Industry Regulatory Authority (“**FINRA**”) or the NASDAQ Stock Market (the “**NASDAQ**”) in connection with the sale of the Offered Shares.

**(p) No Preferential Rights.** Except as set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus, or has otherwise been waived, (i) no person, as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act (each, a “**Person**”), has the right, contractual or otherwise, to cause the Company to issue or sell to such Person any Common Stock or shares of any other capital stock or other securities of the Company, (ii) no Person has any preemptive rights, resale rights, rights of first refusal, rights of co-sale, or any other rights (whether pursuant to a “poison pill” provision or otherwise) to purchase any Common Stock or shares of any other capital stock or other securities of the Company, (iii) no Person has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Common Stock, and (iv) no Person has the right, contractual or otherwise, to require the Company to register under the Securities Act, any Common Stock or shares of any other capital stock or other securities of the Company, or to include any such shares or other securities in the Registration Statement or the offering contemplated thereby, whether as a result of the filing or effectiveness of the Registration Statement or the sale of the Offered Shares as contemplated thereby or otherwise.

**(q) Independent Public Accounting Firms.** Ernst & Young, LLP (the “**Accountant**”), whose report on the consolidated financial statements of the Company is filed with the Commission as part of the Company’s most recent Annual Report on Form 10-K filed with the Commission and incorporated by reference into the Registration Statement, the Time of Sale Prospectus and the Prospectus, is and, during the periods covered by its report, was an independent registered public accounting firm within the meaning of the Securities Act and the Public Company Accounting Oversight Board (United States). To the Company’s knowledge, the Accountant is not in violation of the auditor independence requirements of the Sarbanes-Oxley Act of 2002 (the “**Sarbanes-Oxley Act**”).

**(r) Enforceability of Agreements.** All agreements between the Company and third parties expressly referenced in the Registration Statement, the Time of Sale Prospectus and the Prospectus are legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors’ rights generally and by general equitable principles and (ii) the indemnification provisions of certain agreements may be limited by federal or state securities laws or public policy considerations in respect thereof.

**(s) No Litigation.** Except as set forth in the Registration Statement, the Time of Sale Prospectus or the Prospectus, there are no actions, suits or proceedings by or before any Governmental Authority pending, nor, to the Company's knowledge, any audits or investigations by or before any Governmental Authority, to which the Company or a Subsidiary is a party or to which any property of the Company or any of its Subsidiaries is the subject that, individually or in the aggregate, if determined adversely to the Company or its Subsidiaries, would reasonably be expected to have a Material Adverse Effect and, to the Company's knowledge, no such actions, suits, proceedings, audits or investigations are threatened or contemplated by any Governmental Authority or threatened by others; and (i) there are no current or pending audits, investigations, actions, suits or proceedings by or before any Governmental Authority that are required under the Securities Act to be described in the Registration Statement, the Time of Sale Prospectus or Prospectus that are not so described; and (ii) there are no contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement that are not so filed.

**(t) Consents and Permits.** 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 its Subsidiaries has received any notice, warning letter or other communication from the U.S. Food and Drug Administration ("FDA") or any other governmental entity, which (i) [reserved], (ii) [reserved], (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 reasonably be expected to 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 Health Care Laws. The Company has not been informed by the FDA or any non-U.S. counterpart that the FDA or any non-U.S. counterpart will prohibit the marketing, sale, license or use in the United States or in any other territory any product proposed to be developed, produced or marketed by the Company or any Subsidiary nor has the FDA or any non-U.S. counterpart expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company or any Subsidiary. To the Company's knowledge, there are no legal or governmental proceedings relating to any Health Care Law pending or threatened to which the Company is a party, nor is it aware of any material violations of such acts or regulations by the Company, which would have a Material Adverse Effect. For purposes of this Agreement, "**Health Care Laws**" means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; (ii) all applicable federal, state, local and all applicable foreign health care related fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the U.S. Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the

health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”) (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), the statutes, regulations and directives of applicable government funded or sponsored healthcare programs, and the regulations promulgated pursuant to such statutes; (iii) the Standards for Privacy of Individually Identifiable Health Information, the Security Standards, and the Standards for Electronic Transactions and Code Sets promulgated under HIPAA, the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated thereunder and any state or non-U.S. counterpart thereof or other law or regulation the purpose of which is to protect the privacy of individuals or prescribers; (iv) Medicare (Title XVIII of the Social Security Act); (v) Medicaid (Title XIX of the Social Security Act); and (vi) any and all other applicable health care laws and regulations.

**(u) Regulatory Filings.** Except as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, neither the Company nor any of its Subsidiaries has failed to file with the applicable Governmental Authority (including the FDA or any foreign, federal, state or local Governmental Authority performing functions similar to those performed by the FDA) any required filing, declaration, listing, registration, report or submission, except for such failures that, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect; except as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, all such filings, declarations, listings, registrations, reports or submissions were in material compliance with applicable laws when filed and no deficiencies have been asserted by any applicable regulatory authority with respect to any such filings, declarations, listings, registrations, reports or submissions, except for any deficiencies that, individually or in the aggregate, would not have a Material Adverse Effect. The Company has operated and currently is, in all material respects, in compliance with all applicable Health Care Laws. The Company has no knowledge of any studies, tests or trials not described in the Registration Statement, the Time of Sale Prospectus and the Prospectus the results of which reasonably call into question in any material respect the results of the studies, tests and trials described in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

**(v) Intellectual Property.** Except as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, the Company and its Subsidiaries own, possess, license or have other rights to use, or could obtain on commercially reasonable terms, all foreign and domestic patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, Internet domain names, know-how and other intellectual property (collectively, the “**Intellectual Property**”), necessary for the conduct of their respective businesses as now conducted except to the extent that the failure to own, possess, license or otherwise hold adequate rights to use such Intellectual Property would not, individually or in the aggregate, have a Material Adverse Effect. Except as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus (i) there are no rights of third parties to any such Intellectual Property owned by the Company and its Subsidiaries, except for licenses granted in the ordinary course to third parties, or that could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect; (ii) to the Company’s knowledge, there is no infringement by third parties of any such Intellectual Property; (iii) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the Company’s and its Subsidiaries’ rights

in or to any such Intellectual Property, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim; (iv) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property; (v) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company and its Subsidiaries infringe or otherwise violate any patent, trademark, copyright, trade secret or other proprietary rights of others; (vi) to the Company's knowledge, there is no third-party U.S. patent or published U.S. patent application which contains claims for which an Interference Proceeding (as defined in 35 U.S.C. § 135), or the equivalent in any other jurisdiction, has been commenced against any patent or patent application described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as being owned by or licensed to the Company; and (vii) the Company and its Subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or such Subsidiary, and all such agreements are in full force and effect, except, in the case of any of clauses (i)-(vii) above, for any such infringement by third parties or any such pending or threatened suit, action, proceeding or claim as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

**(w) Clinical Studies.** The preclinical studies and tests and clinical trials described in the Registration Statement, the Time of Sale Prospectus and the Prospectus were, and, if still pending, are being conducted in all material respects in accordance with the experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company; the descriptions of such studies, tests and trials, and the results thereof, contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus are accurate and complete in all material respects; the Company is not aware of any tests, studies or trials not described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, the results of which reasonably call into question the results of the tests, studies and trials described in the Registration Statement, the Time of Sale Prospectus and the Prospectus; and the Company has not received any written notice or correspondence from the FDA or any foreign, state or local Governmental Authority exercising comparable authority or any institutional review board or comparable authority requiring the termination, suspension, clinical hold or material modification of any tests, studies or trials.

**(x) No Material Defaults.** Neither the Company nor any of the Subsidiaries has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect. The Company has not (i) failed to pay any dividend or sinking fund installment on preferred shares or (ii) defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases.

**(y) Certain Market Activities.** Neither the Company nor any of its Subsidiaries has taken, directly or indirectly, any action designed to or that might cause or result in stabilization or manipulation of the price of the Common Stock or of any other securities, including any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act ("**Regulation M**")) with respect to the Common Stock, whether to facilitate the sale or resale of the Offered Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M or applicable foreign securities laws and rules.

**(z) Reserved.**

**(aa) No Reliance.** The Company has not relied upon the Underwriters or legal counsel for the Underwriters for any legal, tax or accounting advice in connection with the offering and sale of the Offered Shares.

**(bb) Taxes.** The Company and each of its Subsidiaries have filed all federal, state, local and foreign tax returns which have been required to be filed and paid all taxes shown thereon through the date hereof, to the extent that such taxes have become due and are not being contested in good faith, except where the failure to so file or pay would not reasonably be expected to have a Material Adverse Effect. Except as otherwise disclosed in or contemplated by the Registration Statement, the Time of Sale Prospectus or the Prospectus, no tax deficiency has been determined adversely to the Company or any of its Subsidiaries which has had, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. The Company has no knowledge of any federal, state, or other governmental tax deficiency, penalty or assessment which has been or might be asserted or threatened against it which would reasonably be expected to have a Material Adverse Effect.

**(cc) Title to Real and Personal Property.** Except as set forth in the Registration Statement, the Time of Sale Prospectus or the Prospectus, the Company and its Subsidiaries have good and marketable title in fee simple to all items of real property owned by them, good and valid title to all personal property described in the Registration Statement, the Time of Sale Prospectus or the Prospectus as being owned by them that are material to the businesses of the Company or such Subsidiary, in each case free and clear of all mortgages, liens, encumbrances and claims, except those matters that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and any of its Subsidiaries or (ii) would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Any real or personal property described in the Registration Statement, the Time of Sale Prospectus or the Prospectus as being leased by the Company and any of its Subsidiaries is held by them under valid, existing and enforceable leases, free and clear of all mortgages, liens, encumbrances and claims, except those matters that (A) do not materially interfere with the use made or proposed to be made of such property by the Company or any of its Subsidiaries or (B) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. Each of the properties of the Company and its Subsidiaries complies with all applicable codes, laws and regulations (including, without limitation, building and zoning codes, laws and regulations and laws relating to access to such properties), except for such failures to comply that would not, individually or in the aggregate, reasonably be expected to interfere in any material respect with the use made and proposed to be made of such property by the Company and its Subsidiaries or otherwise have a Material Adverse Effect. None of the Company or its Subsidiaries has received from any Governmental Authorities any notice of any condemnation of, or zoning change affecting, the properties of the Company and its Subsidiaries, and the Company knows of no such condemnation or zoning change which is threatened, except for such that would not reasonably be expected to interfere in any material respect with the use made and proposed to be made of such property by the Company and its Subsidiaries or otherwise have a Material Adverse Effect, individually or in the aggregate.



**(dd) Environmental Laws.** Except as set forth in the Registration Statement, the Time of Sale Prospectus or the Prospectus, the Company and its Subsidiaries (i) are in compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, decisions and orders relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, “**Environmental Laws**”); (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses as described in the Registration Statement, the Time of Sale Prospectus or the Prospectus; and (iii) have not received notice of any actual or potential liability for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except, in the case of any of clauses (i), (ii) or (iii) above, for any such failure to comply or failure to receive required permits, licenses, other approvals or liability as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

**(ee) Reserved.**

**(ff) Disclosure Controls.** The Company and each of its Subsidiaries maintain systems 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 generally accepted accounting principles 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’s internal control over financial reporting is effective and the Company is not aware of any material weaknesses in its internal control over financial reporting (other than as set forth in the Registration Statement, Time of Sale Prospectus or Prospectus). Since the date of the latest audited financial statements of the Company included in the Prospectus, there has been no change in the Company’s internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting (other than as set forth in the Registration Statement, Time of Sale Prospectus or Prospectus). The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15) for the Company and designed such disclosure controls and procedures to ensure that material information relating to the Company and each of its Subsidiaries is made known to the certifying officers by others within those entities, particularly during the period in which the Company’s Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as the case may be, is being prepared. The Company’s certifying officers have evaluated the effectiveness of the Company’s disclosure controls and procedures as of a date within 90 days prior to the filing date of the Form 10-K for the fiscal year most recently ended (such date, the “**Evaluation Date**”). The Company presented in its Form 10-K for the fiscal year most recently ended the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date and the disclosure controls and procedures are effective. Since the Evaluation Date, there have been no significant changes in the Company’s internal controls (as such term is defined in Item 307(b) of Regulation S-K under the Securities Act) or, to the Company’s knowledge, in other factors that could significantly affect the Company’s internal controls.

(gg) Reserved.

(hh) Sarbanes-Oxley. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any applicable provisions of the Sarbanes-Oxley Act and the rules and regulations promulgated thereunder. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it or furnished by it to the Commission. For purposes of the preceding sentence, "principal executive officer" and "principal financial officer" shall have the meanings given to such terms in the Sarbanes-Oxley Act.

(ii) Brokers. Neither the Company nor any of the Subsidiaries has incurred any liability for any finder's fees, brokerage commissions or similar payments in connection with the transactions herein contemplated, except as may otherwise exist with respect to or pursuant to this Agreement.

(jj) Labor Disputes and Matters. Neither the Company or any of its Subsidiaries employs any person represented by a union or collective bargaining unit. No labor disturbance by or dispute with employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is threatened which would reasonably be expected to have a Material Adverse Effect.

(kk) Investment Company Act. Neither the Company nor any of the Subsidiaries is, or will be, either after receipt of payment for the Offered Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus or the Prospectus, required to register as an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended (the "**Investment Company Act**").

(ll) Operations. The operations of the Company and its Subsidiaries are and have been conducted at all times in material compliance with applicable financial record keeping and reporting requirements of applicable law, including the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions to which the Company or its Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Authority (collectively, the "**Money Laundering Laws**"); and no action, suit or proceeding by or before any Governmental Authority involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

**(mm) Off-Balance Sheet Arrangements.** There are no transactions, arrangements and other relationships between and/or among the Company, and/or any of its affiliates and any unconsolidated entity, including, but not limited to, any structural finance, special purpose or limited purpose entity (each, an “**Off-Balance Sheet Transaction**”) that would affect materially the Company’s liquidity or the availability of or requirements for its capital resources, including those Off-Balance Sheet Transactions described in the Commission’s Statement about Management’s Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus which have not been described as required.

**(nn) ERISA.** To the knowledge of the Company, each material employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended (“**ERISA**”), that is maintained, administered or contributed to by the Company or any of its affiliates for employees or former employees of the Company and any of its Subsidiaries has been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Internal Revenue Code of 1986, as amended (the “**Code**”); no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred which would result in a material liability to the Company with respect to any such plan excluding transactions effected pursuant to a statutory or administrative exemption; and for each such plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no “accumulated funding deficiency” as defined in Section 412 of the Code has been incurred, whether or not waived, and the fair market value of the assets of each such plan (excluding for these purposes accrued but unpaid contributions) exceeds the present value of all benefits accrued under such plan determined using reasonable actuarial assumptions. Each of the material employee benefit plans of the Company complies in all material respects with applicable law.

**(oo) Forward-Looking Statements.** Each financial or operational projection or other “forward-looking statement” (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act, or as defined by any other applicable securities laws) contained in the Registration Statement, the Time of Sale Prospectus or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that it was false or misleading.

**(pp) Margin Rules.** Neither the issuance, sale and delivery of the Offered Shares nor the application of the proceeds thereof by the Company as described in the Registration Statement and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

**(qq) Insurance.** The Company and each of its Subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company and each of its Subsidiaries reasonably believe are adequate for the conduct of their business and as is customary for companies engaged in similar businesses in similar industries.

**(rr) No Improper Practices.** (i) Neither the Company nor the Subsidiaries, nor any director, officer, or employee of the Company or any Subsidiary nor, to the Company's knowledge, any agent, affiliate or other person acting on behalf of the Company or any Subsidiary has, in the past five years, made any unlawful contributions to any candidate for any political office (or failed fully to disclose any contribution in violation of applicable law) or made any contribution or other payment to any official of, or candidate for, any federal, state, municipal, or foreign office or other person charged with similar public or quasi-public duty in violation of any applicable law or of the character required to be disclosed in the Prospectus; (ii) no relationship, direct or indirect, exists between or among the Company or any Subsidiary or any affiliate of any of them, on the one hand, and the directors, officers and stockholders of the Company or any Subsidiary, on the other hand, that is required by the Securities Act to be described in the Registration Statement, the Time of Sale Prospectus and the Prospectus that is not so described; (iii) no relationship, direct or indirect, exists between or among the Company or any Subsidiary or any affiliate of them, on the one hand, and the directors, officers, or stockholders of the Company or any Subsidiary, on the other hand, that is required by the rules of FINRA to be described in the Registration Statement, the Time of Sale Prospectus and the Prospectus that is not so described; (iv) there are no material outstanding loans or advances or material guarantees of indebtedness by the Company or any Subsidiary to or for the benefit of any of their respective officers or directors or any of the members of the families of any of them; and (v) the Company has not offered, or caused any placement agent to offer, Common Stock to any person with the intent to influence unlawfully (A) a customer or supplier of the Company or any Subsidiary to alter the customer's or supplier's level or type of business with the Company or any Subsidiary or (B) a trade journalist or publication to write or publish favorable information about the Company or any Subsidiary or any of their respective products or services, and, (vi) neither the Company nor any Subsidiary nor any director, officer or employee of the Company or any Subsidiary nor, to the Company's knowledge, any agent, affiliate or other person acting on behalf of the Company or any Subsidiary has (A) violated or is in violation of any applicable provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, or any other applicable anti-bribery or anti-corruption law (collectively, "**Anti-Corruption Laws**"), (B) promised, offered, provided, attempted to provide or authorized the provision of anything of value, directly or indirectly, to any person for the purpose of obtaining or retaining business, influencing any act or decision of the recipient or securing any improper advantage, or (C) made any payment of funds of the Company or any Subsidiary or received or retained any funds in violation of any Anti-Corruption Laws.

**(ss) No Conflicts.** Neither the execution of this Agreement, nor the issuance, offering or sale of the Offered Shares, nor the consummation of any of the transactions contemplated herein, nor the compliance by the Company with the terms and provisions hereof will conflict with, or will result in a breach of, any of the terms and provisions of, or has constituted or will constitute a default under, or has resulted in or will result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any contract or other agreement to which the Company may be bound or to which any of the property or assets of the Company is subject, except (i) such conflicts, breaches or defaults as may have been waived and (ii) such conflicts, breaches and defaults that would not reasonably be

expected to have a Material Adverse Effect; nor will such action result (x) in any violation of the provisions of the organizational or governing documents of the Company, or (y) in any violation of the provisions of any statute or any order, rule or regulation applicable to the Company or of any Governmental Authority having jurisdiction over the Company other than, with respect to clause (y) only, any violation that would not have a Material Adverse Effect; provided, however, that such violation shall not have any adverse effect with respect to the Underwriters.

**(tt) Sanctions.** (i) The Company represents that, neither the Company nor any of its Subsidiaries (collectively, the “**Entity**”) or, any director, officer, employee, agent, affiliate or representative of the Entity, is a government, individual, or entity (in this paragraph (tt), “**Person**”) that is, or is owned or controlled by a Person that is:

(A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury’s Office of Foreign Assets Control (“**OFAC**”), the United Nations Security Council, the European Union, Her Majesty’s Treasury, or other relevant sanctions authorities, including designation on OFAC’s Specially Designated Nationals and Blocked Persons List, OFAC’s Foreign Sanctions Evaders List or other similar applicable legislation or rules (as amended, collectively, “**Sanctions**”), nor

(B) located, organized or resident in a country or territory that is the subject of Sanctions that broadly prohibit dealings with that country or territory (including Cuba, Iran, North Korea, Sudan, Syria and the Crimea Region of the Ukraine) (the “**Sanctioned Countries**”).

(ii) The Entity represents and covenants that it will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:

(A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions or is a Sanctioned Country; or

(B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) The Entity represents and covenants that, except as detailed in the Registration Statement and the Prospectus, for the past 5 years, it has not engaged in, is not now engaging in, and will not engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions or is or was a Sanctioned Country.

**(uu) Compliance with Laws.** Each of the Company and its Subsidiaries: (i) is and at all times has been in compliance with all statutes, rules, or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company or its Subsidiaries (“**Applicable Laws**”),

except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; (ii) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any other Governmental Authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws (“**Authorizations**”); (iii) possesses all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (iv) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such Governmental Authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (v) has not received notice that any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations and has no knowledge that any such Governmental Authority is considering such action; (vi) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (vii) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, “dear healthcare provider” letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company’s knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

**(vv) Statistical and Market-Related Data.** All statistical, demographic and market-related data included in the Registration Statement, the Time of Sale Prospectus or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate or represent the Company’s good faith estimates that are made on the basis of data derived from such sources.

**(ww) Stock Exchange Listing.** The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is listed on the Nasdaq Global Select Market of the NASDAQ, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Nasdaq Global Select Market of the NASDAQ. Except as set forth in the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company has not received any notification that the Commission or the NASDAQ is contemplating terminating such registration or listing. To the Company’s knowledge, it is in compliance with all applicable listing requirements of the NASDAQ, except as disclosed in the Registration Statement, the Time of Sale Prospectus or the Prospectus.

**(xx) Related-Party Transactions.** There are no business relationships or related-party transactions involving the Company or any of its Subsidiaries or any other person required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus that have not been described as required.

(yy) FINRA Matters. All of the information provided to the Underwriters or to counsel for the Underwriters by the Company, its counsel, its officers and directors and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Offered Shares is true, complete, correct and compliant with FINRA's rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules is true, complete and correct.

(zz) Parties to Lock-Up Agreements. As of the First Closing Date, the Company has furnished to the Underwriters a letter agreement in the form attached hereto as Exhibit A (the "**Lock-up Agreement**") from each of the persons listed on Exhibit B. Such Exhibit B lists under an appropriate caption the directors and executive officers and certain other stockholders of the Company. If any additional persons shall become directors or executive officers of the Company prior to the end of the Lock-up Period (as defined below), the Company shall cause each such person, prior to or contemporaneously with their appointment or election as a director or executive officer of the Company, to execute and deliver to Wainwright a Lock-up Agreement.

(aaa) Reserved.

(bbb) No Contract Terminations. Neither the Company nor any of its Subsidiaries has sent or received any communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in the Registration Statement, the Time of Sale Prospectus or the Prospectus, and no such termination or non-renewal has been threatened by the Company or any of its Subsidiaries or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

(ccc) Integration. Neither the Company, nor any of its affiliates, nor any person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that, to the knowledge of the Company, would cause the offering of the Offered Shares to be integrated with prior offerings by the Company for purposes of the Securities Act that would require the registration of any such securities under the Securities Act.

Any certificate signed by any officer of the Company or any of its Subsidiaries and delivered to any Underwriter or to counsel for the Underwriters in connection with the offering, or the purchase and sale, of the Offered Shares shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

The Company has a reasonable basis for making each of the representations set forth in this Section 1. The Company acknowledges that the Underwriters and, for purposes of the opinions to be delivered pursuant to Section 6 hereof, counsel to the Company and counsel to the Underwriters, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

## 2. Purchase, Sale and Delivery of the Offered Shares.

(a) The Firm Shares. Upon the terms herein set forth, the Company agrees to issue and sell to the several Underwriters an aggregate of 5,125,384 Firm Shares. On the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Underwriters agree, severally and not jointly, to purchase from the Company the respective number of Firm Shares set forth opposite their names on Schedule A. The purchase price per Firm Share to be paid by the several Underwriters to the Company shall be \$1.2025 per share.

(b) The First Closing Date. Delivery of book-entry entitlements for the Firm Shares to be purchased by the Underwriters and payment therefor shall be made at the offices of Haynes and Boone, LLP, 30 Rockefeller Plaza, 26<sup>th</sup> Floor, New York, NY 10112 (or such other place as may be agreed to by the Company and the Representative) at 10:00 a.m. Eastern time, on July 30, 2020, or such other time and date not later than 1:00 p.m. Eastern time, on July 30, 2020, as the Representative shall designate by notice to the Company (the time and date of such closing are called the “**First Closing Date**”). The Company hereby acknowledges that circumstances under which the Representative may provide notice to postpone the Closing Date as originally scheduled include, but are not limited to, any determination by the Company or the Representative to recirculate to the public copies of an amended or supplemented Prospectus or a delay as contemplated by the provisions of Section 11.

(c) The Optional Shares; Option Closing Date. In addition, on the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to an aggregate of 768,807 Optional Shares from the Company at the purchase price per share to be paid by the Underwriters for the Firm Shares. The option granted hereunder may be exercised at any time and from time to time in whole or in part upon notice by the Representative to the Company, which notice may be given at any time within 30 days from the date of this Agreement. Such notice shall set forth (i) the aggregate number of Optional Shares as to which the Underwriters are exercising the option and (ii) the time, date and place at which book-entry entitlements for the Optional Shares will be delivered (which time and date may be simultaneous with, but not earlier than, the First Closing Date; and in the event that such time and date are simultaneous with the First Closing Date, the term “**First Closing Date**” shall refer to the time and date of delivery of book-entry entitlements for the Firm Shares and such Optional Shares). Any such time and date of delivery, if subsequent to the First Closing Date, is called an “**Option Closing Date**,” shall be determined by the Representative and shall not be earlier than two or later than five full business days after delivery of such notice of exercise. If any Optional Shares are to be purchased, (a) each Underwriter agrees, severally and not jointly, to purchase the number of Optional Shares (subject to such adjustments to eliminate fractional shares as the Representative may determine) that bears the same proportion to the total number of Optional Shares to be purchased as the number of Firm Shares set forth on Schedule A opposite the name of such Underwriter bears to the total number of Firm Shares and (b) the Company agrees to sell the number of Optional Shares set forth in the paragraph “Introductory” of this Agreement (subject to such adjustments to eliminate fractional shares as the Representative may determine). The Representative may cancel the option at any time prior to its expiration by giving written notice of such cancellation to the Company.



(d) Public Offering of the Offered Shares. The Representative hereby advises the Company that the Underwriters intend to offer for sale to the public, initially on the terms set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus, their respective portions of the Offered Shares as soon after this Agreement has been executed as the Representative, in its sole judgment, has determined is advisable and practicable.

(e) Payment for the Offered Shares. (i) Payment for the Offered Shares shall be made at the First Closing Date (and, if applicable, at each Option Closing Date) by wire transfer of immediately available funds to the order of the Company. (ii) It is understood that the Representative has been authorized, for their own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Shares and any Optional Shares the Underwriters have agreed to purchase. Wainwright, individually and not as the Representative of the Underwriters, may (but shall not be obligated to) make payment for any Offered Shares to be purchased by any Underwriter whose funds shall not have been received by the Representative by the First Closing Date or the applicable Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

(f) Delivery of the Offered Shares. The Company shall deliver, or cause to be delivered to the Representative for the accounts of the several Underwriters book-entry entitlements for the Firm Shares at the First Closing Date, against the irrevocable release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The Company shall also deliver, or cause to be delivered through the facilities of DTC unless the Representative shall otherwise instruct, to the Representative for the accounts of the several Underwriters, book-entry entitlements for the Optional Shares the Underwriters have agreed to purchase at the First Closing Date or the applicable Option Closing Date, as the case may be, against the release of a wire transfer of immediately available funds for the amount of the purchase price therefor. If the Representative so elects, delivery of the Offered Shares will be made by credit to the accounts designated by the Representative through The Depository Trust Company's full fast transfer or DWAC programs. Time shall be of the essence, and delivery at the time and place specified in this Agreement is a further condition to the obligations of the Underwriters.

### 3. Additional Covenants of the Company.

The Company further covenants and agrees with each Underwriter as follows:

(a) Delivery of Registration Statement, Time of Sale Prospectus and Prospectus. The Company shall furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the business day next succeeding the date of this Agreement and during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) Representative's Review of Proposed Amendments and Supplements. During the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), the Company (i) will furnish to the Representative for review, a reasonable period of time prior to the proposed time of filing of any proposed amendment or supplement to the Registration Statement, a copy of each such amendment or supplement and (ii) will not amend or supplement the Registration Statement (including any amendment or supplement through incorporation of any report filed under the Exchange Act) without the Representative's prior written consent, not to be unreasonably withheld, conditioned or delayed. Prior to amending or supplementing any preliminary prospectus, the Time of Sale Prospectus or the Prospectus (including any amendment or supplement through incorporation of any report filed under the Exchange Act), the Company shall furnish to the Representative for review, a reasonable amount of time prior to the time of filing or use of the proposed amendment or supplement, a copy of each such proposed amendment or supplement. The Company shall not file or use any such proposed amendment or supplement without the Representative's prior written consent, not to be unreasonably withheld, conditioned or delayed. The Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) Free Writing Prospectuses. The Company shall furnish to the Representative for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto prepared by or on behalf of, used by, or referred to by the Company, and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Representative's prior written consent, not to be unreasonably withheld, conditioned or delayed. The Company shall furnish to each Underwriter, without charge, as many copies of any free writing prospectus prepared by or on behalf of, used by or referred to by the Company as such Underwriter may reasonably request. If at any time when a prospectus is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares (but in any event if at any time through and including the Closing Date) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, as the case may be; *provided, however*, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Representative for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus, and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Representative's prior written consent, not to be unreasonably withheld, conditioned or delayed.

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

(e) Amendments and Supplements to Time of Sale Prospectus. If the Time of Sale Prospectus is being used to solicit offers to buy the Offered Shares at a time when the Prospectus is not yet available to prospective purchasers, and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus so that the Time of Sale Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, the Company shall (subject to Section 3(b) and Section 3(c) hereof) promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the information contained in the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) Certain Notifications and Required Actions. During the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), the Company shall promptly advise the Representative in writing of: (i) the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus; (iii) the time and date that any post-effective amendment to the Registration Statement becomes effective; and (iv) the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus or the Prospectus or of any order preventing or suspending the use of any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Stock from any securities exchange upon which it is listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order as soon as practicable. Additionally, the Company agrees that it shall comply with all applicable provisions of Rule 424(b), Rule 433 and Rule 430B under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(g) Amendments and Supplements to the Prospectus and Other Securities Act Matters. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading, or if in the opinion of the Representative or counsel for the Underwriters it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, the Company agrees (subject to Section 3(b) and Section 3(c) hereof) to promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law. Neither the Representative's consent to, nor delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 3(b) or Section 3(c).

(h) Blue Sky Compliance. The Company shall cooperate with the Representative and counsel for the Underwriters to qualify or register the Offered Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws (or other foreign laws as reasonably requested by the Underwriters and agreed to by the Company) of those jurisdictions designated by the Representative, shall comply in all material respects with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Offered Shares. The Company shall not be required to qualify as a foreign corporation or other entity or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation or other entity. The Company will advise the Representative promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Offered Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its reasonable best efforts to obtain the withdrawal thereof as soon as practicable.

(i) Use of Proceeds. The Company shall apply the net proceeds from the sale of the Offered Shares sold by it in the manner described under the caption "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(j) Transfer Agent. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Common Stock.

(k) Earnings Statement. The Company will make generally available (which may be satisfied by filing with EDGAR) to its security holders and to the Representative as soon as practicable an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company commencing after the date of this Agreement that will satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(l) Continued Compliance with Securities Laws. The Company will comply with the Securities Act and the Exchange Act so as to permit the completion of the distribution of the Offered Shares as contemplated by this Agreement, the Registration Statement, the Time of Sale Prospectus and the Prospectus. Without limiting the generality of the foregoing, the Company will, during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), file on a timely basis with the Commission and the NASDAQ all reports and documents required to be filed under the Exchange Act.

(m) Listing. The Company will use its best efforts to maintain the listing for trading of the shares of Common Stock on the Nasdaq Global Select Market of the NASDAQ.

(n) Company to Provide Copy of the Prospectus in Form That May be Downloaded from the Internet. If requested by the Representative, the Company shall cause to be prepared and delivered, at its expense, within one business day from the effective date of this Agreement, to Wainwright, an “**electronic Prospectus**” to be used by the Underwriters in connection with the offering and sale of the Offered Shares. As used herein, the term “**electronic Prospectus**” means a form of Time of Sale Prospectus, and any amendment or supplement thereto, that meets each of the following conditions: (i) it shall be encoded in an electronic format, satisfactory to Wainwright, that may be transmitted electronically by Wainwright and the other Underwriters to offerees and purchasers of the Offered Shares; (ii) it shall disclose the same information as the paper Time of Sale Prospectus, except to the extent that graphic and image material cannot be disseminated electronically, in which case such graphic and image material shall be replaced in the electronic Prospectus with a fair and accurate narrative description or tabular representation of such material, as appropriate; and (iii) it shall be in or convertible into a paper format or an electronic format, satisfactory to Wainwright, that will allow investors to store and have continuously ready access to the Time of Sale Prospectus at any future time, without charge to investors (other than any fee charged for subscription to the Internet as a whole and for on-line time). The Company hereby confirms that it has included or will include in the Prospectus filed pursuant to EDGAR or otherwise with the Commission and in the Registration Statement at the time it was declared effective an undertaking that, upon receipt of a request by an investor or his or her representative, the Company shall transmit or cause to be transmitted promptly, without charge, a paper copy of the Time of Sale Prospectus.

(o) Agreement Not to Offer or Sell Common Stock. During the period commencing on and including the date hereof and continuing through and including the 30<sup>th</sup> day following the date of the Prospectus, as extended as described below, the Company will not, without the prior written consent of Wainwright (which consent may be withheld in its sole discretion), directly or indirectly: (i) sell, offer to sell, contract to sell or lend any Common Stock or Related Securities (as defined below); (ii) effect any short sale, or establish or increase any “put equivalent position” (as defined in Rule 16a-1(h) under the Exchange Act) or liquidate or decrease any “call equivalent position “ (as defined in Rule 16a-1(b) under the Exchange Act)

of any Common Stock or Related Securities; (iii) pledge, hypothecate or grant any security interest in any Common Stock or Related Securities; (iv) in any other way transfer or dispose of any Common Stock or Related Securities; (v) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Common Stock or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise; (vi) announce the offering of any Common Stock or Related Securities; (vii) file any registration statement under the Securities Act under applicable securities laws in respect of any Common Stock or Related Securities (other than as contemplated by this Agreement with respect to the Offered Shares); or (viii) publicly announce the intention to do any of the foregoing; *provided, however*, that the Company may (A) effect the transactions contemplated hereby; (B) issue shares of Common Stock or options to purchase shares of Common Stock or restricted stock units or similar equity securities, or issue shares of Common Stock upon exercise of options, restricted stock units or similar equity securities, pursuant to any options, share bonus or other share plan or arrangement pursuant to an incentive plan in effect on the date hereof and described in the Registration Statement, the Time of Sale Prospectus and the Prospectus; (C) file a registration statement on Form S-8 in respect of the issuance, vesting, exercise or settlement of equity awards to officers or directors granted or to be granted pursuant to an incentive plan in effect on the date hereof and described in the Registration Statement Time of Sale Prospectus and the Prospectus; (D) issue any shares of Common Stock upon the exercise of an option or warrant or upon the conversion of a convertible security outstanding on the date hereof and referred to in the Registration Statement, the Time of Sale Prospectus and the Prospectus; and (E) issue any shares of capital stock of the Company or securities convertible into shares of capital stock of the Company that are issued as consideration in an acquisition, merger or similar strategic transaction approved by a majority of the disinterested directors of the Company, provided that such securities are issued as “restricted securities” (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith within thirty (30) days after the date of this Agreement, and provided that any such issuance shall only be to a person (or to the equity holders of a person) which is, itself or through its Subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities. For purposes of the foregoing, “**Related Securities**” shall mean any options or warrants or other rights to acquire Common Stock or any securities exchangeable or exercisable for or convertible into Common Stock, or to acquire other securities or rights ultimately exchangeable or exercisable for, or convertible into, Common Stock.

(p) **Future Reports to the Representative.** During the period of five years hereafter, the Company will furnish to the Representative, c/o Wainwright, at 430 Park Avenue, 4<sup>th</sup> Floor, New York, New York 10022, Attention: Head of Investment Banking, with copies to H.C. Wainwright & Co., LLC, 430 Park Avenue, 4<sup>th</sup> Floor, New York, New York 10022, Attention: General Counsel: (i) as soon as practicable after the end of each fiscal year, copies of the Annual Report of the Company containing the balance sheet of the Company as of the close of such fiscal year and statements of income, stockholders’ equity and cash flows for the year then ended and the opinion thereon of the Company’s independent public or certified public accountant; (ii) as soon as practicable after the filing thereof, copies of each proxy statement,

Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other report filed by the Company with the Commission, FINRA or any securities exchange; and (iii) as soon as available, copies of any report or communication of the Company furnished or made available generally to holders of its capital stock; *provided, however*, that the requirements of this Section 3(p) shall be satisfied to the extent that such reports, statement, communications, financial statements or other documents are available on EDGAR.

(q) Investment Limitation. The Company shall not invest or otherwise use the proceeds received by the Company from its sale of the Offered Shares in such a manner as would require the Company or any of its Subsidiaries to register as an investment company under the Investment Company Act.

(r) No Stabilization or Manipulation and Compliance with Regulation M. The Company will not take, and will use its reasonable best efforts to ensure that no affiliate of the Company will take, directly or indirectly, without giving effect to activities by the Underwriters, any action designed to or that might cause or result in stabilization or manipulation of the price of the Common Stock or any reference security with respect to the Common Stock, whether to facilitate the sale or resale of the Offered Shares or otherwise, and the Company will, and shall use its reasonable best efforts to cause each of its affiliates to, comply with all applicable provisions of Regulation M.

(s) Enforce Lock-Up Agreements. During the Lock-up Period, the Company will enforce all agreements between the Company and any of its security holders that restrict or prohibit, expressly or in operation, the offer, sale or transfer of Common Stock or Related Securities or any of the other actions restricted or prohibited under the terms of the form of Lock-up Agreement. In addition, the Company will direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such "lock-up" agreements for the duration of the periods contemplated in such agreements, including, without limitation, "lock-up" agreements entered into by the Company's officers and directors and certain other stockholders pursuant to Section 1(zz) hereof.

(t) Company to Provide Interim Financial Statements. Prior to the First Closing Date and each applicable Option Closing Date, the Company will furnish the Underwriters, as soon as they have been prepared by or are available to the Company, a copy of any unaudited interim financial statements of the Company for any period subsequent to the period covered by the most recent financial statements appearing in the Registration Statement and the Prospectus.

The Representative, on behalf of the several Underwriters, may, in its sole discretion, waive in writing the performance by the Company of any one or more of the foregoing covenants or extend the time for their performance.

4. Payment of Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Offered Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Offered Shares, (iii) all necessary

issue, transfer and other stamp taxes in connection with the issuance and sale of the Offered Shares to the Underwriters, (iv) all fees and expenses of the Company's counsel, independent public or certified public accountant and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Time of Sale Prospectus, the Prospectus, each free writing prospectus prepared by or on behalf of, used by, or referred to by the Company, and each Preliminary Prospectus, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Underwriters in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Offered Shares for offer and sale under the state securities or blue sky laws, and, if requested by the Representative, preparing and printing a "Blue Sky Survey" or memorandum, and any supplements thereto, advising the Underwriters of such qualifications, registrations and exemptions, (vii) the costs, fees and expenses incurred by the Underwriters in connection with determining their compliance with the rules and regulations of FINRA related to the Underwriters' participation in the offering and distribution of the Offered Shares, including any related filings fees and the legal fees of, and disbursements by, counsel to the Underwriters, (viii) the costs and expenses of the Company relating to investor presentations on any "road show", including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, reasonable travel and lodging expenses of the Representative approved by the Company in advance, employees and officers of the Company and any such consultants, (ix) the fees and expenses associated with listing the Offered Shares on the Nasdaq Global Select Market of the NASDAQ, (x) all other fees, costs and expenses of the nature referred to in Item 14 of Part II of the Registration Statement, (xi) all actual and documented out-of-pocket expenses and all fees of the Underwriters' legal counsel and other out-of-pocket expenses of the Underwriters reasonably incurred in connection with the transactions contemplated hereby; provided, that the amount payable pursuant to the foregoing clauses (vi), (vii) and (xi) in the aggregate shall not exceed \$100,000, (xii) the costs and fees of any escrow agent and the actual out-of-pocket costs incurred by the Underwriters in connection with clearing agent settlement and financing, which cost shall not exceed \$12,900, (xiii) \$25,000 to Wainwright for non-accountable expenses, and (xiv) a management fee to Wainwright equal to 1% of the gross proceeds raised by the Company in the offering on the Closing Date (assuming the public offering price). Any such amount payable to the Underwriters may be deducted from the purchase price for the Offered Shares.

5. Covenant of the Underwriters. Each Underwriter severally and not jointly covenants with the Company not to take any action that would result in the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not, but for such actions, be required to be filed by the Company under Rule 433(d).

6. Conditions of the Obligations of the Underwriters. The respective obligations of the several Underwriters hereunder to purchase and pay for the Offered Shares as provided herein on the First Closing Date and, with respect to the Optional Shares, each Option Closing Date, shall be subject to the accuracy of the representations and warranties on the part of the



Company set forth in Section 1 hereof as of the date hereof and as of the First Closing Date as though then made and, with respect to the Optional Shares, as of each Option Closing Date as though then made, to the timely performance by the Company of its covenants and other obligations hereunder, and to each of the following additional conditions:

(a) Comfort Letters. (i) On the date hereof, the Representative shall have received from Ernst & Young, LLP, independent registered public accountant for the Company, a letter dated the date hereof addressed to the Underwriters, in form and substance satisfactory to the Representative, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus, and each free writing prospectus, if any.

(b) Compliance with Registration Requirements; No Stop Order; No Objection from FINRA. For a period from and after the date of this Agreement and through and including the First Closing Date and, with respect to any Optional Shares purchased after the First Closing Date, each Option Closing Date:

(i) The Company shall have filed the Prospectus with the Commission (including the information required by Rule 430A under the Securities Act) in the manner and within the time period required by Rule 424(b) under the Securities Act; or the Company shall have filed a post-effective amendment to the Registration Statement containing the information required by such Rule 430A, and such post-effective amendment shall have become effective.

(ii) No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment to the Registration Statement shall be in effect, and no proceedings for such purpose shall have been instituted or threatened by the Commission.

(iii) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(c) No Material Adverse Change. For the period from and after the date of this Agreement and through and including the First Closing Date and, with respect to any Optional Shares purchased after the First Closing Date, each Option Closing Date, in the judgment of the Representative there shall not have occurred any material adverse change in the authorized capital stock of the Company or any Material Adverse Effect or any development that would cause a Material Adverse Effect.

(d) Opinion of Counsel for the Company. On each of the First Closing Date and each Option Closing Date, the Representative shall have received the opinion and negative assurance letter of Goodwin Procter LLP, counsel for the Company, dated as of such date in form and substance satisfactory to the Underwriters, dated as of such date.

(e) Opinion of Counsel for the Underwriters. On each of the First Closing Date and each Option Closing Date, the Representative shall have received the opinion of Haynes and Boone, LLP, counsel for the Underwriters in connection with the offer and sale of the Offered Shares, in form and substance satisfactory to the Underwriters, dated as of such date.

(f) Officers' Certificate. On each of the First Closing Date and each Option Closing Date, the Representative shall have received a certificate executed by the Chief Executive Officer or President of the Company and the Chief Financial Officer of the Company, dated as of such date, to the effect set forth in Section 6(b)(ii) and further to the effect that:

(i) for the period from and including the date of this Agreement through and including such date, there has not occurred any Material Adverse Effect;

(ii) the representations, warranties and covenants of the Company set forth in Section 1 of this Agreement are true and correct with the same force and effect as though expressly made on and as of such date; and

(iii) the Company has complied with all the agreements hereunder and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such date.

(g) Chief Financial Officer's Certificate. On each of the First Closing Date and each Option Closing Date, the Representative shall have received a certificate executed by the Chief Financial Officer of the Company, dated as of such date, in form and substance satisfactory to the Underwriters, dated as of such date.

(h) [Reserved].

(i) Bring-down Comfort Letter. (i) On each of the First Closing Date and each Option Closing Date the Representative shall have received from Ernst & Young, LLP, independent registered public accounts for the Company, a letter dated such date, in form and substance satisfactory to the Representative, which letter shall: (a) reaffirm the statements made in the letter furnished by them pursuant to Section 6(a), except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the First Closing Date or the applicable Option Closing Date, as the case may be.

(j) Lock-Up Agreements. On or prior to the First Closing Date, the Company shall have furnished to the Representative an agreement in the form of Exhibit A hereto from each of the directors and officers (as defined in Rule 16a-1(f) under the Exchange Act), and each such agreement shall be in full force and effect on each of the First Closing Date and each Option Closing Date.

(k) Rule 462(b) Registration Statement. In the event that a Rule 462(b) Registration Statement is filed in connection with the offering contemplated by this Agreement, such Rule 462(b) Registration Statement shall have been filed with the Commission on the date of this Agreement and shall have become effective automatically upon such filing.

(l) Nasdaq Listing. The Company shall have submitted a listing of additional shares notification form to the NASDAQ with respect to the Offered Shares and shall have received no objection thereto from the NASDAQ and shall have received a conditional listing approval that is subject only to customary listing conditions.

(m) Additional Documents. On or before each of the First Closing Date and each Option Closing Date, the Representative and counsel for the Underwriters shall have received such information, documents and opinions as they may reasonably request for the purposes of enabling them to pass upon the issuance and sale of the Offered Shares as contemplated herein, or in order to evidence the accuracy of any of the representations and warranties, or the satisfaction of any of the conditions or agreements, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Offered Shares as contemplated herein and in connection with the other transactions contemplated by this Agreement shall be satisfactory in form and substance to the Representative and counsel for the Underwriters.

If any condition specified in this Section 6 is not satisfied when and as required to be satisfied, this Agreement may be terminated by the Representative by notice from the Representative to the Company at any time on or prior to the First Closing Date and, with respect to the Optional Shares, at any time on or prior to the applicable Option Closing Date, which termination shall be without liability on the part of any party to any other party, except that Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination.

7. Reimbursement of Underwriters' Expenses. If this Agreement is terminated by the Representative pursuant to Section 6, Section 11 or Section 12, or if the sale to the Underwriters of the Offered Shares on the Closing Date is not consummated because of any refusal, inability or failure on the part of the Company to perform any agreement herein or to comply with any provision hereof, the Company agrees to reimburse the Representative and the other Underwriters (or such Underwriters as have terminated this Agreement with respect to themselves), severally, upon demand for all out-of-pocket expenses that shall have been reasonably incurred by the Representative and the Underwriters in connection with the proposed purchase and the offering and sale of the Offered Shares, including, but not limited to, fees and disbursements of counsel, printing expenses, travel expenses, postage, facsimile and telephone charges, in accordance with Section 4, up to \$100,000 in the aggregate.

8. Effectiveness of this Agreement. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

9. Indemnification.

(a) Indemnification of the Underwriters. The Company shall indemnify and hold harmless each Underwriter, its affiliates, the directors, officers, employees, counsel and agents of each Underwriter and each person, if any, who controls each Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act from and against any and all losses, claims, liabilities, expenses and damages (including any and all investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based on (i) any

untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including any information deemed to be a part thereof pursuant to Rules 430A, 430B or 430C, as applicable or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, any preliminary prospectus supplement, the Base Prospectus, any free writing prospectus, the Time of Sale Prospectus or the Prospectus (or any amendment or supplement to any of the foregoing) or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading or (iii) any untrue statement or alleged untrue statement of a material fact contained in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Offered Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically) or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided, however*, that the Company shall not be liable to the extent that such loss, claim, liability, expense or damage arises from the sale of the Offered Shares in the public offering to any person by an Underwriter and is based on an untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with Underwriter Information. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) Indemnification of the Company, its Directors and Officers. Each Underwriter shall indemnify and hold harmless the Company, its agents, each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, each director of the Company and each officer of the Company who signs the Registration Statement to the same extent as the foregoing indemnity from the Company to each Underwriter, but only insofar as losses, claims, liabilities, expenses or damages arise out of or are based on any untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with Underwriter Information. This indemnity will be in addition to any liability that each Underwriter might otherwise have. The Company hereby acknowledges that the only information that the Underwriters have furnished to the Company expressly for use in the Registration Statement, any preliminary prospectus, any preliminary prospectus supplement, the Base Prospectus, any free writing prospectus, the Time of Sale Prospectus or the Prospectus (or any amendment or supplement to any of the foregoing) are the statements set forth in the eighth and twelfth paragraphs under the caption “Underwriting” in the Preliminary Prospectus and Prospectus (the “**Underwriter Information**”). Notwithstanding any other provision of this Agreement, including this Section 9, to the contrary, in no event shall any Underwriter’s aggregate liability for indemnification hereunder exceed the underwriting discounts and commissions received by it.

(c) Notifications and Other Indemnification Procedures. Any party that proposes to assert the right to be indemnified under this Section 9 shall, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party shall not relieve the indemnifying party

from any liability that it may have to any indemnified party under the foregoing provisions of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (i) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (ii) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (iii) the indemnified party has reasonably concluded that a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party shall not have the right to direct the defense of such action on behalf of the indemnified party) or (iv) the indemnifying party has not in fact employed counsel reasonably satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel shall be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges shall be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party shall not be liable for any settlement of any action or claim effected without its written consent (which consent will not be unreasonably withheld or delayed). No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party. Notwithstanding the foregoing, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 9(a) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

10. **Contribution.** In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or the Underwriters, the Company and the Underwriters shall contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Underwriters, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and the Underwriters may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Underwriters, on the other, with respect to the statements or omissions which resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Representative on behalf of the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 10 were to be determined by pro rata allocation or by any other method of allocation (even if the Underwriters were treated as one entity for such purpose) which does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense or damage, or action in respect thereof, referred to above in this Section 10 shall be deemed to include, for purpose of this Section 10, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 10, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by it, and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligation to contribute as provided in this Section 10 are several in proportion to their respective underwriting obligations and not joint. In addition, notwithstanding anything contained herein to the contrary, no Underwriter's obligation to contribute as provided in this Section 10 shall exceed the underwriting discounts and commissions received by such Underwriter. For purposes of this Section 10, any person who

controls a party to this Agreement within the meaning of the Securities Act will have the same rights to contribution as that party, and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, and each director, officer, employee, counsel or agent of any Underwriter will have the same rights to contribution as such Underwriter, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 10, will notify any such party or parties from whom contribution may be sought, but the omission so to notify will not relieve the party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 10. No party will be liable for contribution with respect to any action or claim settled without its written consent (which consent will not be unreasonably withheld).

11. Default of One or More of the Several Underwriters. If, on the First Closing Date or any Option Closing Date any one or more of the several Underwriters shall fail or refuse to purchase Offered Shares that it or they have agreed to purchase hereunder on such date, and the aggregate number of Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase does not exceed 10% of the aggregate number of the Offered Shares to be purchased on such date, the Representative may make arrangements satisfactory to the Company for the purchase of such Offered Shares by other persons, including any of the Underwriters, but if no such arrangements are made by such date, the other Underwriters shall be obligated, severally and not jointly, in the proportions that the number of Firm Shares set forth opposite their respective names on Schedule A bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as may be specified by the Representative with the consent of the non-defaulting Underwriters, to purchase the Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date. If, on the First Closing Date or any Option Closing Date any one or more of the Underwriters shall fail or refuse to purchase Offered Shares and the aggregate number of Offered Shares with respect to which such default occurs exceeds 10% of the aggregate number of Offered Shares to be purchased on such date, and arrangements satisfactory to the Representative and the Company for the purchase of such Offered Shares are not made within 48 hours after such default, this Agreement shall terminate without liability of any party to any other party except that the provisions of Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination (except with respect to any defaulting Underwriter hereunder). In any such case either the Representative or the Company shall have the right to postpone the First Closing Date or the applicable Option Closing Date, as the case may be, but in no event for longer than seven days in order that the required changes, if any, to the Registration Statement and the Prospectus or any other documents or arrangements may be effected.

As used in this Agreement, the term “**Underwriter**” shall be deemed to include any person substituted for a defaulting Underwriter under this Section 11. Any action taken under this Section 11 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

12. Termination of this Agreement. Prior to the purchase of the Firm Shares by the Underwriters on the First Closing Date, this Agreement may be terminated by the Representative by notice given to the Company if at any time: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission, any other securities regulatory authority, or by the NASDAQ or trading in securities generally on the NASDAQ, the NYSE, or the NYSE American shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges; (ii) a general banking moratorium shall have been declared by any of U.S. federal or New York authorities or a major disruption of securities settlements or clearing services in the United States shall have occurred and be continuing; (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any substantial change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Representative is material and adverse and makes it impracticable to market the Offered Shares in the manner and on the terms described in the Time of Sale Prospectus or the Prospectus or to enforce contracts for the sale of securities; (iv) in the good faith judgment of the Representative there shall have occurred any material adverse change, or any development or event involving a prospective material adverse change, in the condition, financial or otherwise, or in the business, properties, earnings, results of operations or prospects of the Company and its Subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business; or (v) the Company shall have sustained a loss by strike, fire, flood, earthquake, accident or other calamity of such character as in the judgment of the Representative may interfere materially with the conduct of the business and operations of the Company regardless of whether or not such loss shall have been insured. Any termination pursuant to this Section 12 shall be without liability on the part of (a) the Company to any Underwriter, except that the Company shall be obligated to reimburse the expenses of the Representative and the Underwriters pursuant to Section 4 and Section 7 hereof or (b) any Underwriter to the Company; *provided, however*, that the provisions of Section 9 and Section 10 shall at all times be effective and shall survive such termination.

13. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the purchase and sale of the Offered Shares pursuant to this Agreement, including the determination of the public offering price of the Offered Shares and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (ii) in connection with the offering contemplated hereby and the process leading to such transaction, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, or its creditors, employees or any other party, (iii) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company on other matters) and no Underwriter has any obligation to the Company with respect to the offering contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.



14. **Representations and Agreements to Survive Delivery.** The respective indemnities, contributions, agreements, representations, warranties and other statements of the Company, of its officers and of the several Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of its or their partners, officers, directors or employees or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Offered Shares sold hereunder and, subject to Section 11 hereof, any termination of this Agreement.

15. **Notices.** All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Representative: H.C. Wainwright & Co., LLC  
430 Park Avenue, 4<sup>th</sup> Floor  
New York, NY 10022  
Facsimile: (212) 214-0803  
Attention: Head of Investment Banking

with a copy to: Haynes and Boone, LLP  
30 Rockefeller Plaza, 26<sup>th</sup> Floor  
New York, NY 10112  
Attention: Rick A. Werner

If to the Company: Allena Pharmaceuticals, Inc.  
One Newton Executive Park, Suite 202  
Newton, MA 02462  
Attention: Louis Brenner

with a copy to: Goodwin Procter LLP  
100 Northern Avenue  
Boston, MA 02210  
Attention: Michael H. Bison, Esq.  
Daniel A. Lang, Esq.

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day or, if such day is not a Business Day, on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which the Exchange and commercial banks in the City of New York are open for business.

An electronic communication (“**Electronic Notice**”) shall be deemed written notice for purposes of this Section 15 if sent to the electronic mail address specified by the receiving party under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives verification of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form (“**Nonelectronic Notice**”) which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

16. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Underwriters and their respective successors and the parties referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; provided, however, that an Underwriter may assign its rights and obligations hereunder to an affiliate thereof without obtaining the Company’s consent.

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

18. Entire Agreement; Amendment; Severability; Waiver. This Agreement (including all schedules and exhibits attached hereto issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Notwithstanding anything herein to the contrary, the engagement agreement dated July 24, 2020, between the Company and Wainwright, shall continue to be effective and continue to survive and be enforceable by the parties in accordance with their terms. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Underwriters. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement. No implied waiver by a party shall arise in the absence of a waiver in writing signed by such party. No failure or delay in exercising any right, power, or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any right, power, or privilege hereunder.

19. **GOVERNING LAW AND TIME; WAIVER OF JURY TRIAL.** THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. EACH PARTY 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 OR THE TRANSACTIONS CONTEMPLATED HEREBY.

20. **CONSENT TO JURISDICTION.** EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH ANY TRANSACTION CONTEMPLATED HEREBY, AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, THAT SUCH SUIT, ACTION OR PROCEEDING IS BROUGHT IN AN INCONVENIENT FORUM OR THAT THE VENUE OF SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF (CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW.

21. **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or electronic transmission.

22. **Construction.**

(a) the section and exhibit headings herein are for convenience only and shall not affect the construction hereof;

(b) words defined in the singular shall have a comparable meaning when used in the plural, and vice versa;

(c) the words “hereof,” “hereto,” “herein” and “hereunder” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement;

(d) wherever the word “include,” “includes” or “including” is used in this Agreement, it shall be deemed to be followed by the words “without limitation”;

(e) references herein to any gender shall include each other gender;

(f) references herein to any law, statute, ordinance, code, regulation, rule or other requirement of any Governmental Authority shall be deemed to refer to such law, statute, ordinance, code, regulation, rule or other requirement of any Governmental Authority as amended, reenacted, supplemented or superseded in whole or in part and in effect from time to time and also to all rules, policies, notices, instruments and regulations promulgated thereunder;

(g) if the last day for the giving of any notice or the performance of any act required or permitted under this Agreement is a day that is not a Business Day, then the time for the giving of such notice or the performance of such action shall be extended to the next succeeding Business Day; and

(h) “**knowledge**” means, as it pertains to the Company, the actual knowledge of the executive officers and directors of the Company, together with the knowledge which they would have had if they had conducted a reasonable inquiry of the relevant persons into the relevant subject matter.

(i) “**Governmental Authority**” means (i) any federal, state, local, municipal, national or international government or governmental authority, regulatory or administrative agency, governmental commission, department, board, bureau, agency or instrumentality, court, tribunal, arbitrator or arbitral body (public or private); (ii) any self-regulatory organization (including any stock exchange or quotation system); or (iii) any political subdivision of any of the foregoing.

### 23. General Provisions.

Each of the parties hereto acknowledges that it is a sophisticated business person who was adequately represented by counsel during negotiations regarding the provisions hereof, including, without limitation, the indemnification provisions of Section 9 and the contribution provisions of Section 10, and is fully informed regarding said provisions. Each of the parties hereto further acknowledges that the provisions of Section 9 and Section 10 hereof fairly allocate the risks in light of the ability of the parties to investigate the Company, its affairs and its business in order to assure that adequate disclosure has been made in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, each free writing prospectus and the Prospectus (and any amendments and supplements to the foregoing), as contemplated by the Securities Act and the Exchange Act.

**[Signature Page Follows]**

If the foregoing correctly sets forth the understanding between the Company and the Underwriters, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and the Underwriters.

Very truly yours,

ALLENA PHARMACEUTICALS, INC.

By: /s/ Edward Wholihan

Name: Edward Wholihan

Title: Chief Financial Officer

ACCEPTED as of the date first-above written:

H.C. WAINWRIGHT & CO., LLC

By: /s/ Edward D. Silvera

Name: Edward D. Silvera

Title: Chief Operating Officer

SIGNATURE PAGE  
UNDERWRITING AGREEMENT

Underwriters	Number of Firm Shares to be Purchased
H.C. Wainwright & Co., LLC	5,125,384
Total	<u>\$6,163,274.26</u>

**Free Writing Prospectuses Included in the Time of Sale Prospectus**

FWP filed with the SEC on July 27, 2020

FWP filed with the SEC on July 27, 2020

**Pricing Information**

Firm Shares: 5,125,384

Optional Shares: 768,807

Price to Public: \$1.30

Underwriters' Discount: \$0.0975



**Subsidiaries**

Allena Pharmaceuticals Security Corp.

## Form of Lock-up Agreement

July \_\_, 2020

H.C. WAINWRIGHT & CO. LLC  
As Representative of the several Underwriters  
c/o H.C. Wainwright & Co. LLC  
430 Park Avenue  
New York, New York 10022

Re: Allena Pharmaceuticals, Inc.

Dear Sirs:

This Lock-Up Agreement (this "Agreement") is being delivered to you in connection with the proposed Underwriting Agreement (the "Underwriting Agreement") between Allena Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and H.C. Wainwright & Co. LLC ("Wainwright"), as representative of a group of underwriters (collectively, the "Underwriters"), to be named therein, and the other parties thereto (if any), relating to the proposed public offering of shares of the common stock, par value \$0.001 per share (the "Common Stock"), of the Company.

In order to induce you and the other Underwriters to enter into the Underwriting Agreement, and in light of the benefits that the offering of the Common Stock will confer upon the undersigned in its capacity as a securityholder and/or an officer, director or employee of the Company, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each Underwriter that, during the period beginning on and including the earlier of the date hereof and the date of the Underwriting Agreement through and including the date that is the 30<sup>th</sup> day after the date of the Underwriting Agreement (the "Lock-Up Period"), the undersigned will not, without the prior written consent of Wainwright, directly or indirectly, (i) offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, any shares of Common Stock whether now owned or hereafter acquired by the undersigned (including, without limitation, Common Stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations promulgated under the Securities Act of 1933, as the same may be amended or supplemented from time to time (such shares, the "Beneficially Owned Shares")) or securities convertible into or exercisable or exchangeable for Common Stock, (ii) enter into any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of the Beneficially Owned Shares or securities convertible into or exercisable or exchangeable for Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition, or (iii) engage in any short selling of the Common Stock or securities convertible into or exercisable or exchangeable for Common Stock.

The restrictions set forth in the immediately preceding paragraph shall not apply to:

- (1) if the undersigned is a natural person, any transfers made by the undersigned (a) as a bona fide gift to any member of the immediate family (as defined below) of the undersigned or to a trust the beneficiaries of which are exclusively the undersigned or members of the undersigned's immediate family, (b) by will or intestate succession upon the death of the undersigned; (c) as a bona fide gift to a charity or educational institution or (d) pursuant to a qualified domestic order or in connection with a divorce settlement,
- (2) if the undersigned is a corporation, partnership, limited liability company or other business entity, any transfers to any shareholder, partner or member of, or owner of a similar equity interest in, the undersigned, as the case may be, if, in any such case, such transfer is not for value,

- (3) if the undersigned is a corporation, partnership, limited liability company or other business entity, any transfer made by the undersigned (a) in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the undersigned's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the undersigned's assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by this Agreement or (b) to another corporation, partnership, limited liability company or other business entity so long as the transferee is an affiliate (as defined below) of the undersigned and such transfer is not for value;

provided, however, that in the case of any transfer described in clause (1), (2) or (3) above, it shall be a condition to the transfer that (A) the transferee executes and delivers to Wainwright, acting on behalf of the Underwriters, not later than one business day prior to such transfer, a written agreement, in substantially the form of this Agreement and otherwise satisfactory in form and substance to Wainwright, and (B) if the undersigned is required to file a report under Section 16(a) of the Securities Exchange Act of 1934, as amended, reporting a reduction in beneficial ownership of shares of Common Stock or Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or Beneficially Owned Shares during the Lock-Up Period (as the same may be extended as described above), the undersigned shall include a statement in such report to the effect that, in the case of any transfer pursuant to clause (1) above, such transfer is being made as a gift or by will or intestate succession or, in the case of any transfer pursuant to clause (2) above, such transfer is being made to a shareholder, partner or member of, or owner of a similar equity interest in, the undersigned and is not a transfer for value or, in the case of any transfer pursuant to clause (3) above, such transfer is being made either (a) in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the undersigned's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the undersigned's assets or (b) to another corporation, partnership, limited liability company or other business entity that is an affiliate of the undersigned and such transfer is not for value.

- (4) transactions relating to shares of Common Stock or other securities acquired in the offering;
- (5) transfers or dispositions of shares of Common Stock or other securities to the Company in connection with the conversion of any convertible preferred stock into, or the exercise of any option or warrant for, shares of Common Stock; provided that (i) any such shares of Common Stock received by the undersigned shall be subject to the terms of this agreement and (ii) no filing by any party under the Exchange Act or other public announcement shall be required or shall be made voluntarily during the Restricted Period (other than a filing on a Form 4 that reports such disposition under the transaction code "F");
- (6) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, provided that (i) such plan does not provide for the transfer of common stock during the Lock-up Period and (ii) no filing by any party under the Exchange Act or other public announcement shall be required or shall be made voluntarily by or on behalf of the undersigned or the Company in connection with the establishment of such plan; or
- (7) transfers or dispositions of shares of Common Stock or such other securities pursuant to a bona fide tender offer for shares of the Company's capital stock, merger, consolidation or other similar transaction made to all holders of the Company's securities involving a Change of Control (as defined below) of the Company (including without limitation, the entering into of any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of shares of Common Stock or other securities in connection with such transaction) that has been approved by the board of directors of the Company; provided that, in the event that such Change of Control transaction is not consummated, this clause (J) shall not be applicable and the undersigned's shares and other securities shall remain subject to the restrictions contained in this agreement.

For purposes of this agreement, “immediate family” shall mean a spouse, child, grandchild or other lineal descendant (including by adoption), father, mother, brother or sister of the undersigned; and “affiliate” shall have the meaning set forth in Rule 405 under the Securities Act of 1933, as amended and “Change of Control” shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transactions or a series of related transactions, to a person or group of affiliated persons (other than an Underwriter pursuant to the offering), of the Company’s voting securities if, after such transfer, such person or group of affiliated persons would hold at least 90% of the outstanding voting securities of the Company (or the surviving entity), provided that, for the avoidance of doubt, the offering shall not constitute a Change of Control.

The undersigned further agrees that (i) it will not, during the Lock-Up Period, make any demand or request for or exercise any right with respect to the registration under the Securities Act of 1933, as amended, of any shares of Common Stock or other Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or other Beneficially Owned Shares, and (ii) the Company may, with respect to any Common Stock or other Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or other Beneficially Owned Shares owned or held (of record or beneficially) by the undersigned, cause the transfer agent or other registrar to enter stop transfer instructions and implement stop transfer procedures with respect to such securities during the Lock-Up Period (as the same may be extended as described above). In addition, the undersigned hereby waives, from the date hereof until the expiration of the 30-day period following the date of the Underwriting Agreement and any extension of such period pursuant to the terms hereof, any and all rights, if any, to request or demand registration pursuant to the Securities Act of 1933, as amended, of any shares of Common Stock that are registered in the name of the undersigned or that are Beneficially Owned Shares.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Agreement and that this Agreement has been duly authorized (if the undersigned is not a natural person), executed and delivered by the undersigned and is a valid and binding agreement of the undersigned. This Agreement and all authority herein conferred are irrevocable and shall survive the death or incapacity of the undersigned (if a natural person) and shall be binding upon the heirs, personal representatives, successors and assigns of the undersigned.

It is understood that, if (A) the Company notifies Wainwright that it does not intend to proceed with the proposed public offering of Common Stock, (B) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the shares of Common Stock to be sold thereunder, or (C) the proposed public offering of Common Stock shall not have been completed by July 31, 2020, this Agreement shall immediately be terminated and the undersigned shall be released from all obligations under this Agreement.

**[Remainder of page intentionally left blank.]**

The undersigned acknowledges and agrees that whether or not any public offering of Common Stock actually occurs depends on a number of factors, including market conditions.

Very truly yours,

\_\_\_\_\_  
(Name of Stockholder - Please Print)

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Name of Signatory if Stockholder is an entity - Please Print)

\_\_\_\_\_  
(Title of Signatory if Stockholder is an entity - Please Print)

Address: \_\_\_\_\_  
\_\_\_\_\_

**Directors, Executive Officers and Principal Stockholders Signing Lock-up Agreement**

Louis Brenner  
Edward Wholihan  
Robert Alexander  
Allene Diaz  
Andrew A.F. Hack, M.D., Ph.D  
Alexey Margolin, Ph.D.  
Gino Santini  
Robert Tepper, M.D.  
James Topper, M.D., Ph.D.



Goodwin Procter LLP  
100 Northern Avenue  
Boston, MA 02210

goodwinlaw.com  
+1 617 570 1000

July 29, 2020

Allena Pharmaceuticals, Inc.  
One Newton Executive Park  
Suite 202  
Newton, Massachusetts, 02462

Re: Securities Registered under Registration Statement on Form S-3

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-3 (File No. 333-228656) (the "Registration Statement") filed on December 3, 2018 with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the offer by Allena Pharmaceuticals, Inc., a Delaware corporation (the "Company") of up to \$200,000,000 of any combination of securities of the types specified therein. The Registration Statement was declared effective by the Commission on December 26, 2018. Reference is made to our opinion letter dated December 3, 2018 and included as Exhibit 5.1 to the Registration Statement. We are delivering this supplemental opinion letter in connection with the prospectus supplement (the "Prospectus Supplement") filed on July 29, 2020 by the Company with the Commission pursuant to Rule 424 under the Securities Act. The Prospectus Supplement relates to the offering by the Company of up to 5,125,384 shares of the Company's Common Stock, par value \$0.001 per share (the "Shares") covered by the Registration Statement. The Shares include an over-allotment option granted to the underwriters of the offering to purchase 768,807 Shares. The Shares are being sold to the several underwriters named in, and pursuant to, an underwriting agreement among the Company and such underwriters (the "Underwriting Agreement").

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinion set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinion set forth below, on certificates of officers of the Company.

The opinion set forth below is limited to the Delaware General Corporation Law.

Based on the foregoing, we are of the opinion that the Shares have been duly authorized and, upon issuance and delivery against payment therefor in accordance with the terms of the Underwriting Agreement, the Shares will be validly issued, fully paid and non-assessable.

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Allena Pharmaceuticals, Inc.

July 29, 2020

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We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption “Legal Matters” in the Registration Statement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ GOODWIN PROCTER LLP

GOODWIN PROCTER LLP





### **Allena Pharmaceuticals Announces \$5.0 Million Bought Deal Offering**

**NEWTON, Mass., July 27, 2020** — Allena Pharmaceuticals, Inc. (NASDAQ: ALNA), a late-stage, biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders, announced today that it has entered into an underwriting agreement with H.C. Wainwright & Co., LLC under which the underwriter has agreed to purchase on a firm commitment basis 3,846,154 shares of common stock of the Company, at a price to the public of \$1.30 per share, less underwriting discounts and commissions. The closing of the offering is expected to occur on or about July 30, 2020, subject to satisfaction of customary closing conditions.

H.C. Wainwright & Co. is acting as the sole book-running manager for the offering.

The Company also has granted to the underwriter a 30-day option to purchase up to an additional 576,923 shares of common stock at the public offering price, less underwriting discounts and commissions. The gross proceeds to Allena, before deducting underwriting discounts and commissions and offering expenses and assuming no exercise of the underwriter's option to purchase additional common stock, are expected to be approximately \$5.0 million. The Company intends to use the net proceeds from this offering for working capital and other general corporate purposes.

The shares of common stock are being offered by the Company pursuant to a "shelf" registration statement on Form S-3 (File No. 333-228656) previously filed with the Securities and Exchange Commission (the "SEC") on December 3, 2018, and declared effective by the SEC on December 26, 2018. The offering of the shares of common stock is made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration statement. A preliminary prospectus supplement and accompanying prospectus relating to, and describing the terms of, the offering will be filed with the SEC and will be available on the SEC's website at <http://www.sec.gov>. Electronic copies of the preliminary prospectus supplement and accompanying prospectus may also be obtained, when available, by contacting H.C. Wainwright & Co., LLC at 430 Park Avenue, 3rd Floor, New York, NY 10022, by telephone at (646) 975-6996 or e-mail at [placements@hcwco.com](mailto:placements@hcwco.com).

This press release shall not constitute an offer to sell or a solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

#### **About Allena Pharmaceuticals**

Allena Pharmaceuticals, Inc. is a late-stage biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. Allena's lead product candidate, reloxaliase, is a first-in-class, oral enzyme therapeutic candidate for the treatment of hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, chronic kidney disease and other serious kidney disorders.

### **Forward-Looking Statements**

*This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding the completion of the public offering, the satisfaction of customary closing conditions related to the public offering and the intended use of net proceeds from the public offering, statements regarding implementation of the amended trial design for URIROX-2, the timing of sample size reassessments and interim analyses during the URIROX-2 trial, Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, statements concerning the future clinical, regulatory and commercial potential of reloxaliase, statements regarding the Allena's development of ALLN-346, statements regarding Allena's financial position and need for capital. In addition, it should be noted that additional capital will*

be required to complete the planned URIROX-2 clinical trial, including the planned interim analysis at the first sample size reassessment, which capital may not be available to Allena on terms that are acceptable to it, if at all. If adequate funds are not available on a timely basis, Allena may be required to delay, limit, reduce or terminate its clinical development of reloxaliase. The impact of the COVID-19 coronavirus on Allena's business, the biotech sector generally and the broader macroeconomic environment is uncertain and could harm Allena's business by delaying regulatory review timelines, clinical development plans and our ability to raise necessary capital. Furthermore, Allena does not have sufficient cash to operate its business for the next 12 months, which raises substantial doubt about its ability to continue as a going concern. Allena will require additional capital to fund its planned operations, which may not be available to it on attractive terms or at all. If the company is unable to secure additional capital, it will be forced to delay, limit, reduce or terminate its development of reloxaliase and may not be able to continue as a going concern. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: market and other conditions, the risk that the results of the URIROX-1 clinical trial may not be replicated in the URIROX-2 or other clinical trials of reloxaliase; the risk that the reduction in 24-hour UOx excretion observed in the placebo arm of the URIROX-1 trial may be observed in the URIROX-2 or other clinical trials of reloxaliase, which may have a negative impact on Allena's ability to secure regulatory approval for this product candidate; the risk that results of earlier studies, or interim results, may not be predictive of future clinical trial results, and planned and ongoing studies may not establish an adequate safety or efficacy profile for reloxaliase to support regulatory approval or the use of the accelerated approval regulatory pathway; risks related to Allena's ability to utilize the accelerated approval pathway for reloxaliase, including the risk that available data at the time of any sample size re-estimation or interim analysis conducted during the URIROX-2 trial may not be sufficient to demonstrate an increased probability of kidney stone events in patients with enteric hyperoxaluria and increasing UOx levels; the risk that the FDA may require that Allena increase the sample size or duration of treatment following the sample size reassessments to be conducted in accordance with the adaptive design element of the trial or otherwise collect additional clinical data from the URIROX-2 or other clinical trials prior to submitting a BLA for reloxaliase; risks associated with Allena's ability to enroll a sufficient number of patients to adequately power URIROX-2 in order to achieve ultimate statistical success for kidney stone disease progression in the long-term follow-up phase of the trial; risks related to Allena's use of UOx and/or POx as surrogate endpoints in its ongoing clinical trials, neither of which it believes have been previously utilized as biomarkers to support regulatory approval of other drug candidates, and the risks related to validating that reductions in UOx and/or POx correlate with meaningful clinical benefit; risks associated with obtaining, maintaining and protecting intellectual property; risks associated with Allena's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk of competition from other companies developing products for similar uses; risk associated with Allena's financial condition and its need to obtain additional funding to support its business activities, including the future clinical development of reloxaliase and its ability to continue as a going concern; risks associated with Allena's dependence on third parties; and risks related to the COVID-19 coronavirus. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Allena's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Item 1A of Part I of Allena's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, as well as discussions of potential risks, uncertainties and other important factors in Allena's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Allena undertakes no duty to update this information unless required by law.

**Investor Contact**

Hannah Deresiewicz  
Stern Investor Relations, Inc.  
212-362-1200  
[hannah.deresiewicz@sternir.com](mailto:hannah.deresiewicz@sternir.com)

**Media Contact**

Adam Daley  
Berry & Company Public Relations  
212-253-8881  
[adaley@berrypr.com](mailto:adaley@berrypr.com)



### **Allena Pharmaceuticals Increases Previously Announced Bought Deal to \$6.7 Million**

**NEWTON, Mass., July 27, 2020** — Allena Pharmaceuticals, Inc. (NASDAQ: ALNA), a late-stage, biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders, announced today that, due to demand, the underwriter has agreed to increase the size of the previously announced public offering and purchase on a firm commitment basis 5,125,384 shares of common stock of the Company, at a price to the public of \$1.30 per share, less underwriting discounts and commissions. The closing of the offering is expected to occur on or about July 30, 2020, subject to satisfaction of customary closing conditions.

H.C. Wainwright & Co. is acting as the sole book-running manager for the offering.

The Company also has granted to the underwriter a 30-day option to purchase up to an additional 768,807 shares of common stock at the public offering price, less underwriting discounts and commissions. The gross proceeds to Allena, before deducting underwriting discounts and commissions and offering expenses and assuming no exercise of the underwriter's option to purchase additional common stock, are expected to be approximately \$6.7 million. The Company intends to use the net proceeds from this offering for working capital and other general corporate purposes.

The shares of common stock are being offered by the Company pursuant to a "shelf" registration statement on Form S-3 (File No. 333-228656) previously filed with the Securities and Exchange Commission (the "SEC") on December 3, 2018, and declared effective by the SEC on December 26, 2018. The offering of the shares of common stock is made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration statement. A preliminary prospectus supplement and accompanying prospectus relating to, the and describing the terms of, the offering have been filed with the SEC and is available on the SEC's website at <http://www.sec.gov>. A final prospectus supplement and the accompanying prospectus relating to the offering will be filed with the SEC and, upon filing, may be obtained on the SEC's website at <http://www.sec.gov> or by contacting H.C. Wainwright & Co., LLC at 430 Park Avenue, 3rd Floor, New York, NY 10022, by telephone at (646) 975-6996 or e-mail at [placements@hcwco.com](mailto:placements@hcwco.com).

This press release shall not constitute an offer to sell or a solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

**About Allena Pharmaceuticals**

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### **Forward-Looking Statements**

*This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding the completion of the public offering, the satisfaction of customary closing conditions related to the public offering and the intended use of net proceeds from the public offering, statements regarding implementation of the amended trial design for URIROX-2, the timing of sample size reassessments and interim analyses during the URIROX-2 trial, Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, statements concerning the future clinical, regulatory and*

commercial potential of reloxaliase, statements regarding the Allena's development of ALLN-346, statements regarding Allena's financial position and need for capital. In addition, it should be noted that additional capital will be required to complete the planned URIROX-2 clinical trial, including the planned interim analysis at the first sample size reassessment, which capital may not be available to Allena on terms that are acceptable to it, if at all. If adequate funds are not available on a timely basis, Allena may be required to delay, limit, reduce or terminate its clinical development of reloxaliase. The impact of the COVID-19 coronavirus on Allena's business, the biotech sector generally and the broader macroeconomic environment is uncertain and could harm Allena's business by delaying regulatory review timelines, clinical development plans and our ability to raise necessary capital. Furthermore, Allena does not have sufficient cash to operate its business for the next 12 months, which raises substantial doubt about its ability to continue as a going concern. Allena will require additional capital to fund its planned operations, which may not be available to it on attractive terms or at all. If the company is unable to secure additional capital, it will be forced to delay, limit, reduce or terminate its development of reloxaliase and may not be able to continue as a going concern. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: market and other conditions, the risk that the results of the URIROX-1 clinical trial may not be replicated in the URIROX-2 or other clinical trials of reloxaliase; the risk that the reduction in 24-hour UOx excretion observed in the placebo arm of the URIROX-1 trial may be observed in the URIROX-2 or other clinical trials of reloxaliase, which may have a negative impact on Allena's ability to secure regulatory approval for this product candidate; the risk that results of earlier studies, or interim results, may not be predictive of future clinical trial results, and planned and ongoing studies may not establish an adequate safety or efficacy profile for reloxaliase to support regulatory approval or the use of the accelerated approval regulatory pathway; risks related to Allena's ability to utilize the accelerated approval pathway for reloxaliase, including the risk that available data at the time of any sample size re-estimation or interim analysis conducted during the URIROX-2 trial may not be sufficient to demonstrate an increased probability of kidney stone events in patients with enteric hyperoxaluria and increasing UOx levels; the risk that the FDA may require that Allena increase the sample size or duration of treatment following the sample size reassessments to be conducted in accordance with the adaptive design element of the trial or otherwise collect additional clinical data from the URIROX-2 or other clinical trials prior to submitting a BLA for reloxaliase; risks associated with Allena's ability to enroll a sufficient number of patients to adequately power URIROX-2 in order to achieve ultimate statistical success for kidney stone disease progression in the long-term follow-up phase of the trial; risks related to Allena's use of UOx and/or POx as surrogate endpoints in its ongoing clinical trials, neither of which it believes have been previously utilized as biomarkers to support regulatory approval of other drug candidates, and the risks related to validating that reductions in UOx and/or POx correlate with meaningful clinical benefit; risks associated with obtaining, maintaining and protecting intellectual property; risks associated with Allena's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk of competition from other companies developing products for similar uses; risk associated with Allena's financial condition and its need to obtain additional funding to support its business activities, including the future clinical development of reloxaliase and its ability to continue as a going concern; risks associated with Allena's dependence on third parties; and risks related to the COVID-19 coronavirus. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Allena's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Item 1A of Part I of Allena's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, as well as discussions of potential risks, uncertainties and other important factors in Allena's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Allena undertakes no duty to update this information unless required by law.

**Investor Contact**

Hannah Deresiewicz  
Stern Investor Relations, Inc.  
212-362-1200  
[hannah.deresiewicz@sternir.com](mailto:hannah.deresiewicz@sternir.com)

**Media Contact**

Adam Daley  
Berry & Company Public Relations  
212-253-8881  
[adaley@berrypr.com](mailto:adaley@berrypr.com)