

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): **November 3, 2021**

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-31812
(Commission File Number)

58-2301143
(I.R.S. Employer
Identification Number)

210 Main Street West
Baudette, Minnesota
(Address of principal executive offices)

56623
(Zip Code)

Registrant's telephone number, including area code: **(218) 634-3500**

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

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

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	ANIP	Nasdaq Stock Market

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))

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

Emerging growth company

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

Item 1.01 Entry into a Material Definitive Agreement.

Underwriting Agreement

On November 3, 2021, ANI Pharmaceuticals, Inc. (the “Company”) entered into an underwriting agreement (the “Underwriting Agreement”) with Guggenheim Securities, LLC, as representative (the “Representative”) of the several underwriters identified in Schedule I thereto (collectively with the Representative, the “Underwriters”), pursuant to which the Company has agreed to issue and sell up to 1,725,000 shares of common stock (the “Shares”), which includes 225,000 shares (the “Optional Shares”) that may be sold pursuant to an option granted to the Underwriters (the “Offering”). The Shares will be sold to the Underwriters at a public offering price of \$50.00 per share, less the underwriting discount and commissions.

The Offering is being made pursuant to the Company’s effective registration statement on Form S-3 (Registration No. 333-239771), which was previously filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the “Securities Act”). The Offering is scheduled to close on November 8, 2021, subject to customary closing conditions.

The Underwriting Agreement contains customary representations, warranties and covenants by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended, other obligations of the parties and termination provisions. The representations, warranties, and covenants contained in the Underwriting Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement and may be subject to limitations agreed upon by the contracting parties.

The foregoing description of the Underwriting Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Underwriting Agreement. A copy of the Underwriting Agreement is filed with this Current Report on Form 8-K as Exhibit 1.1 and is incorporated herein by reference.

A copy of the opinion and consent of Orrick, Herrington & Sutcliffe LLP relating to the validity of the issuance of Shares in connection with the Offering is filed herewith as Exhibit 5.1 and Exhibit 23.1, respectively.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
1.1	Underwriting Agreement, dated November 3, 2021, between ANI Pharmaceuticals, Inc. and Guggenheim Securities, LLC
5.1	Opinion of Orrick, Herrington & Sutcliffe LLP
23.1	Consent of Orrick, Herrington & Sutcliffe LLP (contained in Exhibit 5.1)
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURE

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.

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Stephen P. Carey

Senior Vice President, Finance and Chief Financial Officer

Dated: November 4, 2021

1,500,000 Shares of Common Stock

ANI PHARMACEUTICALS, INC.

UNDERWRITING AGREEMENT

November 3, 2021

Guggenheim Securities, LLC
As Representative of the
several Underwriters named in
Schedule I attached hereto

c/o Guggenheim Securities, LLC
330 Madison Avenue
New York, New York 10017

Ladies and Gentlemen:

ANI Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware (the “**Company**”), proposes, subject to the terms and conditions stated herein, to issue and sell to the several underwriters named in Schedule I hereto (the “**Underwriters**”) an aggregate of 1,500,000 shares (the “**Firm Shares**”) of its common stock, par value \$0.0001 per share (the “**Common Stock**”). The Company also proposes to issue and sell to the several Underwriters up to an additional 225,000 shares (the “**Additional Shares**”) of Common Stock at the option of the Underwriters as provided in Section 2(c) below. The Firm Shares and any Additional Shares purchased by the Underwriters are referred to herein as the “**Shares**.” Guggenheim Securities, LLC (“**Guggenheim Securities**”) is acting as representative (the “**Representative**”) of the several Underwriters in connection with the offering and sale of the Shares contemplated herein (the “**Offering**”).

As used in this underwriting agreement (the “**Agreement**”), the following defined terms shall apply:

The “**Registration Statement**” means the registration statement on Form S-3 (File No. 333-239771), including the exhibits, schedules and financial statements and any prospectus supplement relating to the Offering that is filed with the Securities and Exchange Commission (the “**Commission**”) pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the “**Securities Act**”), and the rules and regulations promulgated thereunder (the “**Rules and Regulations**”) and deemed part of such registration statement pursuant to Rule 430B under the Securities Act, as amended on each Effective Date (as defined below), and, in the event any post-effective amendment thereto or any registration statement and any amendments thereto filed pursuant to Rule 462(b) under the Securities Act (a “**Rule 462(b) Registration Statement**”) becomes effective prior to the Closing Date (as defined in Section 2(b) hereof), shall also mean such registration statement as so amended or such Rule 462(b) Registration Statement, as the case may be.

The “**Effective Date**” means, with respect to the Registration Statement, each date and time that such Registration Statement, and any post-effective amendment or amendments thereto or any Rule 462(b) Registration Statement became or becomes effective.

The “**Base Prospectus**” means the base prospectus contained in the Registration Statement at the date and time that this Agreement is executed and delivered by the parties hereto.

The “**Preliminary Prospectus**” means any preliminary prospectus supplement to the Base Prospectus which is used prior to the filing of the Prospectus (as defined below), together with the Base Prospectus.

The “**Prospectus**” means the final prospectus supplement relating to the Offering that is first filed pursuant to Rule 424(b) under the Securities Act, together with the Base Prospectus.

The “**Pricing Disclosure Package**” shall mean (i) the Base Prospectus, (ii) the Preliminary Prospectus used most recently prior to the Applicable Time (as defined below), (iii) any issuer free writing prospectus, as defined in Rule 433 under the Securities Act (an “**Issuer Free Writing Prospectus**”), identified in Schedule II hereto, (iv) the information included on Schedule III hereto, and (v) any other free writing prospectus, as defined in Rule 405 under the Securities Act (a “**Free Writing Prospectus**”), that the parties hereto shall hereafter expressly agree in writing to treat as part of the Pricing Disclosure Package.

As used herein, “**Applicable Time**” is 8:00 p.m. (New York City time) on November 3, 2021.

As used herein, “**Road Show**” means a “road show” (as defined in Rule 433 under the Securities Act) relating to the offering of the Shares contemplated hereby that is a “written communication” (as defined in Rule 405 under the Securities Act).

All references in this Agreement to the Registration Statement, any Preliminary Prospectus, the Base Prospectus and the Prospectus shall include the documents incorporated or deemed to be incorporated by reference therein. All references in this Agreement to financial statements and schedules and other information that are “**contained in**,” “**included in**,” “**filed with**,” “**stated in**” or “**part of**” the Registration Statement, the Rule 462(b) Registration Statement, any Preliminary Prospectus, the Pricing Disclosure Package or the Prospectus, and all other references of like import, shall be deemed to mean and include all such financial statements and schedules and other information that is or is deemed to be incorporated by reference in the Registration Statement, the Rule 462(b) Registration Statement, any Preliminary Prospectus, the Base Prospectus, the Pricing Disclosure Package or the Prospectus, as the case may be.

All references in this Agreement to amendments or supplements to the Registration Statement, the Rule 462(b) Registration Statement, any Preliminary Prospectus, the Pricing Disclosure Package or the Prospectus shall be deemed to mean and include the filing of any document under the 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 Rule 462(b) Registration Statement, any Preliminary Prospectus, the Pricing Disclosure Package, or the Prospectus, as the case may be. All references in this Agreement to the Registration Statement, 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**”).

1. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, each of the Underwriters as of the date hereof, the Applicable Time, the Closing Date (as hereinafter defined) and any Additional Closing Date (as hereinafter defined) that:

(a) The Registration Statement has been declared effective by the Commission under the Securities Act. The Company has complied, to the Commission's satisfaction, with all requests of the Commission for additional or supplemental information, 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 Company's knowledge, are contemplated or threatened by the Commission. At the time the Registration Statement was originally filed with the Commission, the Company met the then-applicable 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 Pricing Disclosure Package 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) Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, as of the applicable Effective Date, complied and, until such time as the Underwriters are no longer required to deliver a Prospectus in order to confirm sales of the Shares, will comply in all material respects with the Securities Act and the Rules and Regulations. The Preliminary Prospectus and the Prospectus, at the time each was filed with the Commission, complied in all material respects with the requirements of the Securities Act and the Rules and Regulations. Each Preliminary Prospectus delivered to the Underwriters for use in connection with this Offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(c) The Registration Statement, when it became effective, did not contain and, as amended or supplemented, if applicable, will not contain, as of the date of such amendment or supplement, an untrue statement of a material fact or omitted or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that this representation and warranty shall not apply to any information contained in or omitted from the Registration Statement or any amendment thereto in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of any Underwriter through the Representative specifically for use therein. The parties hereto agree that such information provided by or on behalf of any Underwriter through the Representative consists solely of the material referred to in Section 19 hereof. Each "forward-looking statement" (within the meaning of Section 27A of the Securities Act or Section 21E of the Exchange Act) contained or incorporated by reference in the Registration Statement, the Preliminary Prospectus or the Prospectus has been made or reaffirmed with a reasonable basis and has been disclosed in good faith.

(d) The Pricing Disclosure Package, as of the Applicable Time, did not contain 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 under which they were made, not misleading. The Prospectus will not, as of its date, as of the Closing Date or as of any Additional Closing Date, contain 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 under which they were made, not misleading. Each Issuer Free Writing Prospectus (i) complies in all material respects with the applicable provisions of the Securities Act and the Rules and Regulations, and (ii) does not contain 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 in which they were made, not misleading. No representation and warranty is made in this Section 1(d) with respect to any information contained in or omitted from the Pricing Disclosure Package or the Prospectus in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of any Underwriter through the Representative specifically for use therein. The parties hereto agree that such information provided by or on behalf of any Underwriter through the Representative consists solely of the material referred to in Section 19 hereof.

(e) At the earliest time (i) after the filing of the Registration Statement that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) of the Rules and Regulations) of the Shares and (ii) at the date hereof, the Company was not and is not an “ineligible issuer,” as defined in Rule 405 of the Rules and Regulations, including (but not limited to) the Company or any subsidiary in the preceding three years not having been convicted of a felony or misdemeanor or having been made the subject of a judicial or administrative decree or order as described in Rule 405 of the Rules and Regulations.

(f) Each Issuer Free Writing Prospectus conformed or will conform in all material respects to the requirements of the Securities Act and the Rules and Regulations on the date of first use, and the Company has complied with the requirements of Rule 433 under the Securities Act with respect to each Issuer Free Writing Prospectus including, without limitation, all prospectus delivery, filing, record retention and legending requirements applicable to any such Issuer Free Writing Prospectus. The Company has not (i) distributed any offering material in connection with the Offering other than any Preliminary Prospectus, the Prospectus, and any Issuer Free Writing Prospectus set forth on Schedule II hereto, or (ii) filed, referred to, approved, used or authorized the use of any “free writing prospectus” as defined in Rule 405 under the Securities Act with respect to the Offering or the Shares, except for any Issuer Free Writing Prospectus set forth in Schedule II hereto and any electronic Road Show previously approved by the Representative. The Company has retained in accordance with the Securities Act and the Rules and Regulations all Issuer Free Writing Prospectuses that were not required to be filed pursuant to the Securities Act and the Rules and Regulations.

(g) The Company (i) has not alone engaged in any oral or written communication with potential investors (“**Testing-the-Waters Communications**”), other than Testing-the-Waters Communications with the prior consent of the Representative with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone to engage in Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications (as defined below) other than those listed on Schedule V hereto. “Written Testing-the-Waters Communication” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(h) Each of EisnerAmper LLP, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement, the Pricing Disclosure Package or the Prospectus, and RAM Associates is (i) an independent registered public accounting firm as required by the Securities Act, the Exchange Act, and the rules of the Public Company Accounting Oversight Board (“**PCAOB**”), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(i) Subsequent to the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package or the Prospectus, except as disclosed therein, (i) the Company has not declared or paid any dividends, or made any other distribution of any kind, on or in respect of its capital stock, (ii) there has not been any material change in the capital stock or long-term or short-term debt, if any, of the Company or its subsidiaries listed in Exhibit A hereto (the “**Subsidiaries**”), (iii) there have been no transactions entered into by the Company or the Subsidiaries, other than in the ordinary course of business, which are material with respect to the Company and the Subsidiaries, taken as a whole, (iv) neither the Company nor any Subsidiary has sustained any material loss or interference with its business or properties from fire, explosion, flood, earthquake, hurricane, accident or other calamity, whether or not covered by insurance, or from any labor dispute or any legal or governmental proceeding, and (v) there has not been any material adverse change, or any development that would reasonably be expected to result in a prospective material adverse change, whether or not arising from transactions in the ordinary course of business, in or affecting the business, management, condition (financial or otherwise), results of operations, stockholders’ equity, properties or prospects of the Company and the Subsidiaries, taken as a whole (a “**Material Adverse Change**”). Since the date of the latest balance sheet included, or incorporated by reference, in the Registration Statement, the Pricing Disclosure Package or the Prospectus, neither the Company nor any Subsidiary has incurred or undertaken any liabilities or obligations, whether direct or indirect, liquidated or contingent, matured or unmatured, or entered into any transactions, including any acquisition or disposition of any business or asset, which are material to the Company and the Subsidiaries, taken as a whole, except for liabilities, obligations and transactions which are disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(j) The Company has an authorized capitalization as set forth in the Pricing Disclosure Package and the Prospectus, and all of the issued and outstanding shares of capital stock of the Company are fully paid and non-assessable and have been duly authorized and validly issued, in compliance with all applicable state, federal and foreign securities laws and not in violation of or subject to any preemptive or similar right that entitles any person to acquire from the Company or the Subsidiaries any Common Stock or other security of the Company or any security convertible into, or exercisable or exchangeable for, Common Stock or any other such security of the Company (any “**Relevant Security**”), except for such rights as may have been fully satisfied or waived prior to the effectiveness of the Registration Statement. All of the issued shares of capital stock of or other ownership interests in the Subsidiaries owned, directly or indirectly, by the Company have been duly authorized and validly issued and are fully paid and non-assessable and are owned directly or indirectly by the Company free and clear of any lien, charge, mortgage, pledge, security interest, claim, equity, trust or other encumbrance, preferential arrangement, defect or restriction of any kind whatsoever (any “**Lien**”).

(k) The Shares to be delivered on the Closing Date and any Additional Closing Date, if any, have been duly authorized and, when issued and delivered in accordance with this Agreement, will be validly issued, fully paid and non-assessable, will have been issued in compliance with all applicable state, federal and foreign securities laws and will not have been issued in violation of or subject to any preemptive or similar right that entitles any person to acquire any Relevant Security from the Company. The Common Stock and the Shares conform to the descriptions thereof contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has no outstanding warrants, options to purchase, or any preemptive rights or other rights to subscribe for or to purchase, or any contracts or commitments to issue or sell, any Relevant Security. No holder of any Relevant Security has any rights to require registration under the Securities Act of any Relevant Security in connection with the offer and sale of the Shares contemplated hereby, except for any such rights that have either been fully complied with by the Company or effectively waived by the holders thereof.

(l) The Company and each Subsidiary has been duly organized and validly exists as a corporation, partnership or limited liability company (as the case may be) in good standing under the laws of its jurisdiction of organization and has corporate, partnership or limited liability company power and authority (as the case may be) to own or lease its property and conduct its business as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The Company and each Subsidiary is qualified to do business and is in good standing as a foreign corporation, partnership or limited liability company (as the case may be) in each jurisdiction in which the character or location of its properties (owned, leased or licensed) or the nature or conduct of its business makes such qualification necessary, except for those failures to be so qualified or in good standing which (individually and in the aggregate) would not reasonably be expected to have a material adverse effect on (i) the business, management, condition (financial or otherwise), results of operations, stockholders' equity, properties or prospects of the Company and the Subsidiaries, taken as a whole; or (ii) the ability of the Company to consummate the Offering or any other transaction contemplated by this Agreement or the Registration Statement, the Pricing Disclosure Package and the Prospectus (a "**Material Adverse Effect**"). The certificate or articles of incorporation, by-laws, partnership agreement, limited liability company agreement or other constitutive and organizational documents (as the case may be) of the Company and the Subsidiaries comply with the requirements of applicable law and are in full force and effect. The Subsidiaries are the only "subsidiaries" of the Company (within the meaning of Rule 405 under the Securities Act.)

(m) Neither the Company nor any Subsidiary (i) is in violation of its certificate or articles of incorporation, by-laws, certificate of formation, limited liability company agreement, partnership agreement or other organizational documents, (ii) is in default under, and no event has occurred which, with notice or lapse of time or both, would constitute a default under or result in the creation or imposition of any Lien upon any property or assets of the Company or the Subsidiaries pursuant to, any indenture, mortgage, deed of trust, note, lease, loan agreement or other agreement or instrument to which it is a party or by which it is bound or to which any of its property or assets is subject, or (iii) is in violation of any statute, law, rule, regulation, ordinance, directive, judgment, writ, decree or order of any court or judicial, regulatory or other legal or governmental agency or body, foreign or domestic, having jurisdiction over the Company or the Subsidiaries except (in the case of clauses (ii) and (iii) above) for violations or defaults that would not (individually or in the aggregate) reasonably be expected to have a Material Adverse Effect.

(n) The Company and the Subsidiaries have all requisite power and authority, and all necessary consents, approvals, authorizations, orders, registrations, qualifications, licenses, filings and permits of, with and from all judicial, regulatory and other legal or governmental agencies and bodies and all third parties, foreign and domestic (collectively, the “**Consents**”), to own, lease and operate its properties and conduct its business as it is now being conducted and as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, and each such Consent is valid and in full force and effect, except in each case as would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any Subsidiary has received notice of any investigation or proceedings which, if decided adversely to the Company or the Subsidiaries, would reasonably be expected to result in the revocation of, or imposition of a materially burdensome restriction on, any such Consent.

(o) This Agreement has been duly and validly authorized, executed and delivered by the Company.

(p) The issue and sale of the Shares (including the use of proceeds from the sale of the Shares as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus), the compliance by the Company with this Agreement and the consummation of the transactions contemplated hereby and by the Registration Statement, the Pricing Disclosure Package and the Prospectus do not and will not (i) conflict with or result in a breach or violation of any of the terms and provisions of, or constitute a default (or an event which with notice or lapse of time, or both, would constitute a default) under, or result in the creation or imposition of any Lien upon any property or assets of the Company or the Subsidiaries pursuant to, any indenture, mortgage, deed of trust, note, lease, loan agreement or other agreement, instrument, franchise, license or permit to which the Company or any Subsidiary is a party or by which the Company or the Subsidiaries or their respective properties, operations or assets may be bound, (ii) violate or conflict with any provision of the certificate or articles of incorporation, by-laws, certificate of formation, limited liability company agreement, partnership agreement or other organizational documents (as the case may be) of the Company or the Subsidiaries, or (iii) violate or conflict with any statute, law, rule, regulation, ordinance, directive, judgment, writ, decree or order of any court or judicial, regulatory, administrative or other legal or governmental agency or body (including, without limitation, the U.S. Food and Drug Administration (the “**FDA**”), domestic or foreign, having jurisdiction over the Company or the Subsidiaries, except (in the case of clauses (i) and (iii) above) as would not reasonably be expected to have a Material Adverse Effect.

(q) No Consent is required for the execution, delivery and performance by the Company of this Agreement, the issue and sale of the Shares (including the use of proceeds from the sale of the Shares as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus) and the consummation by the Company of the transactions contemplated hereby and by the Registration Statement, the Pricing Disclosure Package and the Prospectus, except the registration under the Securities Act of the Shares, such Consents as may be required by the Nasdaq Stock Market LLC (“**Nasdaq**”) in regards to the listing of the Shares, FINRA (as defined below) in connection with the purchase and distribution of the Shares by the Underwriters, and under applicable state securities or blue sky laws and such other Consents as have been obtained.

(r) Except as disclosed in the Registration Statement, Pricing Disclosure Package and Prospectus, there is no judicial, regulatory, arbitral or other legal or governmental proceeding or other litigation or arbitration, domestic or foreign, pending to which the Company or any Subsidiary is a party or of which any property, operations or assets of the Company or the Subsidiaries is the subject which, individually or in the aggregate, if determined adversely to the Company or any Subsidiary, would reasonably be expected to have a Material Adverse Effect on the consummation of the transactions contemplated in this Agreement or the performance by the Company of its obligations hereunder; to the Company's knowledge, no such proceeding, litigation or arbitration is threatened or contemplated; and the defense of all such proceedings, litigation and arbitration against or involving the Company or any Subsidiary would not reasonably be expected to have a Material Adverse Effect.

(s) The financial statements, including the notes thereto, and the supporting schedules included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus present fairly in all material respects the consolidated financial position as of the dates indicated and the cash flows and results of operations for the periods specified of the Company and the Subsidiaries; said financial statements have been prepared in conformity with United States generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods involved; and the supporting schedules, if any, included in the Registration Statement, the Pricing Disclosure Package and the Prospectus present fairly in all material respects in accordance with GAAP the information required to be stated therein. The pro forma financial statements and the related notes, if any, included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus have been properly compiled and prepared in accordance with the applicable requirements of the Securities Act, the Rules and Regulations and the Exchange Act and present fairly the information shown 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. No other historical or pro forma financial statements or supporting schedules are required to be included in the Registration Statement, the Pricing Disclosure Package or the Prospectus by the Securities Act, the Exchange Act or the Rules and Regulations. The other financial and statistical information included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus present fairly in all material respects the information included therein and have been prepared on a basis consistent with that of the financial statements that are included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus and the books and records of the respective entities presented therein. All disclosures contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus, or incorporated by reference therein, 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 of the Securities Act, to the extent applicable. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package 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.

(t) There are no contracts or documents which are required to be described under the Securities Act in the Registration Statement, the Pricing Disclosure Package or the Prospectus or to be filed as exhibits to the Registration Statement which have not been so described and filed as required.

(u) The Company maintains a system of internal accounting and other controls designed to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets, (iii) access to assets is permitted only in accordance with management's general or specific authorization, (iv) the recorded accounting for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package 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.

(v) The Company maintains a system of internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) that complies with the requirements of the Exchange Act and has been designed by the Company's principal executive officer and principal financial officer, or under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. The Company's internal control over financial reporting is effective, and as of the date of the most recent balance sheet of the Company, the Company is not aware of any material weaknesses in its internal control over financial reporting. Since the date of the latest audited financial statements included or incorporated by reference in the Pricing Disclosure Package, 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.

(w) The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act) that comply with the requirements of the Exchange Act. Such disclosure controls and procedures are (i) designed to ensure that material information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to management of the Company, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure to be made and (ii) effective in all material respects to perform the functions for which they were established.

(x) There is and has been no failure on the part of the Company or, to the Company's knowledge, any of the Company's directors or executive officers, in their capacities as such, to comply in all material respects with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "**Sarbanes-Oxley Act**"), including Section 402 related to loans and Sections 302 and 906 related to certifications.

(y) The shares of Common Stock are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and have been approved for listing on the Nasdaq Capital Market, subject to completion of the issuance of the Shares pursuant to this Agreement, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Shares under the Exchange Act or delisting the Shares from the Nasdaq Capital Market. Other than as disclosed in the Registration Statement, Pricing Disclosure Package and the Prospectus, the Company has not received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of Nasdaq.

(z) To the Company's knowledge, no relationship, direct or indirect, exists between or among the Company or any affiliate of the Company, on the one hand, and any director, officer, shareholder, customer or supplier of the Company or any affiliate of the Company, on the other hand, which is required by the Securities Act or the Exchange Act to be described in the Registration Statement or the Prospectus that is not so described as required. There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of their respective family members. The Company has not, in violation of the Sarbanes-Oxley Act, directly or indirectly, including through any affiliate of the Company, extended or maintained credit, arranged for the extension of credit, or renewed an extension of credit, in the form of a personal loan to or for any director or executive officer of the Company.

(aa) Neither the Company nor any of its affiliates (within the meaning of Rule 144 under the Securities Act) has taken, directly or indirectly, any action which constitutes or is designed to cause or result in, or which would reasonably be expected to constitute, cause or result in, the stabilization or manipulation of the price of any security to facilitate the sale or resale of the Shares or to result in a violation of Regulation M under the Exchange Act.

(bb) Neither the Company nor any of its affiliates (within the meaning of Rule 144 under the Securities Act) has, prior to the date hereof, made any offer or sale of any securities which would be "integrated" (within the meaning of the Securities Act and the Rules and Regulations) with the offer and sale of the Shares pursuant to the Registration Statement.

(cc) All of the information provided to the Underwriters or to counsel for the Underwriters by the Company and, to the Company's knowledge, its officers, 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 Shares is true, complete and correct in all material respects and compliant with Financial Industry Regulatory Authority, Inc.'s ("**FINRA**") rules and, to the Company's knowledge, any letters, filings or other supplemental information provided to FINRA pursuant to FINRA rules or the conduct rules of the National Association of Securities Dealers is true, complete and correct in all material respects.

(dd) The statements set forth in the Pricing Disclosure Package and Prospectus under the caption “Description of Capital Stock”, insofar as it purports to constitute a summary of the terms of the Common Stock, and under the captions “Risk Factors”, insofar as they purport to describe the provisions of the laws and documents referred to therein, are accurate and complete in all material respects.

(ee) The Company is not and, at all times up to and including consummation of the transactions contemplated by this Agreement, and after giving effect to application of the net proceeds of the Offering as described in the Pricing Disclosure Package and the Prospectus, will not be, required to register as an “investment company” under the Investment Company Act of 1940, as amended, and is not and will not be an entity “controlled” by an “investment company” within the meaning of such act.

(ff) There are no contracts, agreements or understandings between the Company and any person that would give rise to a valid claim against the Company or any Underwriter for a brokerage commission, finder’s fee or other like payment in connection with the transactions contemplated by this Agreement or, to the Company’s knowledge, any arrangements, agreements, understandings, payments or issuance with respect to the Company or any of its officers, directors, shareholders, partners, employees, subsidiaries or affiliates that may affect the Underwriters’ compensation, as determined by FINRA Rule 5110.

(gg) The Company and each Subsidiary owns or leases all such properties as are necessary to the conduct of its business as presently operated and as proposed to be operated as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The Company and the Subsidiaries have good and marketable title to all real property and good and marketable title to all personal property owned by them that are material to the business of the Company taken as a whole, in each case free and clear of any and all Liens except such as are described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or such as do not (individually or in the aggregate) materially affect the value of such property or materially interfere with the use made or proposed to be made of such property by the Company and the Subsidiaries; and any real property and buildings held under lease or sublease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with such exceptions as are not material to, and do not materially interfere with, the use made and proposed to be made of such property and buildings by the Company and the Subsidiaries. Neither the Company nor any Subsidiary has received any notice of any claim adverse to its ownership of any real or personal property or of any claim against the continued possession of any real property, whether owned or held under lease or sublease by the Company or the Subsidiaries.

(hh) The Company and its Subsidiaries own or possess, or can acquire on reasonable terms, adequate patents, patent rights, licenses, approvals, inventions, copyrights, domain names, technology, trade secrets, know-how (including unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, trade names or other intellectual property and similar rights, including registrations and applications for registration thereof (collectively, “**Intellectual Property Rights**”) necessary or material to the conduct of the business now conducted or proposed in the Registration Statement, the Pricing Disclosure Package and the Prospectus to be conducted by them, and the failure to own, possess or acquire such Intellectual Property Rights and the expected expiration of any such Intellectual Property Rights would not, individually or in the aggregate, have a Material Adverse Effect. To the Company’s knowledge, none of the patents and patent applications owned or licensed by the Company or its Subsidiaries is invalid or unenforceable, in whole or in part. To the Company’s knowledge, none of the Intellectual Property Rights owned or licensed by the Company or its Subsidiaries, other than patents and patent applications, are invalid or unenforceable, in whole or in part. To the knowledge of the Company, there are no unreleased liens or security interests which have been filed against any of the Intellectual Property Rights owned or licensed by the Company. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (i) the Company is not obligated to pay a material royalty, grant a license or provide other material consideration to any third party in connection with the Intellectual Property Rights owned by or licensed to the Company; (ii) to the Company’s knowledge, there are no rights of third parties to any of the Intellectual Property Rights owned by or licensed to the Company or its Subsidiaries, in any field of use, other than the respective licensor to the Company of such Intellectual Property Rights; (iii) to the Company’s knowledge, there is no material infringement, misappropriation breach, default or other violation, or the occurrence of any event that with notice or the passage of time would constitute any of the foregoing, by the Company or its Subsidiaries of any third party Intellectual Property Rights or third parties of any of the Intellectual Property Rights of the Company or its Subsidiaries; (iv) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others against the Company or its Subsidiaries or, to the Company’s knowledge against any person or entity, (a) challenging the Company’s or any of its Subsidiaries’ rights in or to, or the violation of any of the terms of, any of their Intellectual Property Rights; (b) challenging the validity, enforceability or scope of any such Intellectual Property Rights; or (c) that alleges the Company or any of its Subsidiaries infringes, misappropriates or otherwise violates or conflicts with any Intellectual Property Rights or other proprietary rights of others, and, in each case, the Company is unaware of any facts which would form a reasonable basis for any such claim; (v) none of the Intellectual Property Rights owned by or licensed to the Company or its Subsidiaries in their businesses has been obtained or is being used by the Company or its Subsidiaries in violation of any contractual obligation binding on the Company or any of its Subsidiaries in violation of the rights of any persons; and (vi) to the Company’s knowledge, no employee or consultant of the Company or any of its Subsidiaries is in or has ever been in violation of any term of any employment or consulting contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer or consultant where the basis of such violation relates to such employee’s employment with or such consultant’s services to the Company or any of its Subsidiaries or actions undertaken by the employee or consultant while employed with or providing services to the Company or any of its Subsidiaries. To the knowledge of the Company and as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, (1) neither the commercial development nor the sale of any of the proposed products or processes of the Company, as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, infringes, misappropriates or otherwise violates, or would, upon the commercialization of such proposed products or processes, infringe, misappropriate or otherwise violate, any Intellectual Property Rights of any third party; and (2) each current and former employee and consultant of the Company (a) has executed an inventions assignment and confidentiality agreement with the Company, on or about the respective date of hire, and signed copies of such agreements have been made available to the Underwriters and their counsel; and (b) has signed or agreed to assign to the Company any and all Intellectual Property Rights he or she may possess or may have possessed that are related to the Company’s business, as currently conducted and as proposed to be conducted, as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus. All patents and patent applications owned by or licensed to the Company or under which the Company has rights have, to the knowledge of the Company, been duly and properly filed and maintained; to the knowledge of the Company, the parties prosecuting such applications have complied with their duty of candor and disclosure to the U.S. Patent and Trademark Office (the “**USPTO**”) and any similar office or agency in the world in connection with such applications; and the Company is not aware of any facts required to be disclosed to the USPTO or similar office or agency that were not disclosed and which would preclude the grant of a patent in connection with any such application or would form the basis of a finding of invalidity with respect to any patents that have issued with respect to such applications.

(ii) The Company's and the Subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them), and databases (collectively, "**IT Systems**") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and the Subsidiaries as currently conducted, and, to the Company's knowledge, are free from any material defects, viruses, worms, Trojan horses or similar flaws or harmful programs. To the Company's knowledge, there has been no security breach or attack or other compromise of or relating to any of the Company's or the Subsidiaries' IT Systems, including any such activity that would result in any unauthorized use, access, misappropriation or modification of Personal Data as defined below. The Company and the Subsidiaries have been and are presently in material compliance with all applicable laws, statutes, and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal or external policies and contractual obligations relating to the privacy and security of IT Systems and data (including all personal, personally identifiable, sensitive, confidential or regulated data ("**Personal Data**")) and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.

(jj) Neither the Company nor any Subsidiary has been notified in writing, or have been required by applicable Law or by any court or any other federal, state, local or foreign governmental or regulatory authority having jurisdiction over the Company, the Subsidiaries or any of their properties or assets to notify in writing, any person of any Personal Data or security-related incident. Neither the Company nor any Subsidiary has received any written notice of any claims, investigations, or alleged violations of Law with respect to Personal Data. To the Company's knowledge, no person has commenced any proceedings relating to the Company's or any Subsidiary's information privacy or data security practices.

(kk) The Company and the Subsidiaries have implemented, and required of their third-party vendors, adequate policies and commercially reasonable security controls regarding the collection, use, disclosure, retention, confidentiality, integrity, and availability of personal and business sensitive information in their possession, custody, or control, or held or processed on their behalf, and regarding the integrity and availability of the information technology the Company and the Subsidiaries own, operate, or outsource.

(ll) The Company and the Subsidiaries maintain insurance in such amounts and covering such risks as the Company reasonably considers adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses in similar industries, all of which insurance is in full force and effect, except where the failure to maintain such insurance would not reasonably be expected to have a Material Adverse Effect. There are no material claims by the Company or the Subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause. The Company reasonably believes that it will be able to renew its existing insurance as and when such coverage expires or will be able to obtain replacement insurance adequate for the conduct of the business and the value of its properties at a cost that would not have a Material Adverse Effect.

(mm) Except as would not reasonably be expected to result in a Material Adverse Effect, the Company and each Subsidiary has accurately prepared and timely filed all federal, state, foreign and other tax returns that are required to be filed by it or have been granted extensions thereof and has paid or made provision for the payment of all taxes, assessments, governmental or other similar charges, including without limitation, all sales and use taxes and all taxes which the Company or any Subsidiary is obligated to withhold from amounts owing to employees, creditors and third parties, with respect to the periods covered by such tax returns (whether or not such amounts are shown as due on any tax return). Except as would not reasonably be expected to result in a Material Adverse Effect, no deficiency assessment with respect to a proposed adjustment of the Company's or the Subsidiaries' federal, state, local or foreign taxes is pending or, to the Company's knowledge, threatened. The accruals and reserves on the books and records of the Company and the Subsidiaries in respect of tax liabilities for any taxable period not finally determined are adequate to meet any assessments and related liabilities for any such period and, since December 31, 2019, except as would not reasonably be expected to have a Material Adverse Effect, the Company and the Subsidiaries have not incurred any liability for taxes other than in the ordinary course of its business. There is no tax lien, whether imposed by any federal, state, foreign or other taxing authority, outstanding against the assets, properties or business of the Company or the Subsidiaries, other than any such tax lien arising automatically under applicable law with respect to taxes not yet due and payable or being contested in good faith.

(nn) No labor disturbance by the employees of the Company or the Subsidiaries exists or, to the Company's knowledge, is imminent, and the Company is not aware of any existing or imminent labor disturbances by the employees of any of its or the Subsidiaries' principal suppliers, manufacturers', customers or contractors, which, in either case (individually or in the aggregate), would reasonably be expected to have a Material Adverse Effect.

(oo) Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, (i) each “employee benefit plan” (within the meaning of Section 3(3) of the Employee Retirement Security Act of 1974, as amended (“**ERISA**”)) for which the Company or any member of its “Controlled Group” (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Internal Revenue Code of 1986, as amended (the “**Code**”)) would have any liability (each a “**Plan**”) has been maintained in compliance with its terms and with the requirements of all applicable statutes, rules and regulations including ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption; (iii) with respect to each Plan subject to Title IV of ERISA (A) no “reportable event” (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur, (B) no “accumulated funding deficiency” (within the meaning of Section 302 of ERISA or Section 412 of the Code), whether or not waived, has occurred or is reasonably expected to occur, (C) the fair market value of the assets under each Plan exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan), and (D) neither the Company or any member of its Controlled Group has incurred, or reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guaranty Corporation in the ordinary course and without default) in respect of a Plan (including a “multiemployer plan”, within the meaning of Section 4001(c)(3) of ERISA); and (iv) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

(pp) There has been no storage, generation, transportation, handling, use, treatment, disposal, discharge, emission, contamination, release or other activity involving any kind of hazardous, toxic or other wastes, pollutants, contaminants, petroleum products or other hazardous or toxic substances, chemicals or materials (“**Hazardous Substances**”) by, due to, on behalf of, or caused by the Company or the Subsidiaries (or, to the Company’s knowledge, any other entity for whose acts or omissions the Company is or may be liable) upon any property now or previously owned, operated, used or leased by the Company or the Subsidiaries, or upon any other property, which would be a violation of or give rise to any liability under any applicable law, rule, regulation, order, judgment, decree or permit, common law provision or other legally binding standard relating to pollution or protection of human health and the environment (“**Environmental Law**”), except for violations and liabilities which, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect. There has been no disposal, discharge, emission, contamination or other release of any kind at, onto or from any such property or into the environment surrounding any such property of any Hazardous Substances with respect to which the Company or any Subsidiary has knowledge, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Neither the Company nor any Subsidiary has agreed to assume, undertake or provide indemnification for any liability of any other person under any Environmental Law, including any obligation for cleanup or remedial action, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. There is no pending or, to the Company’s knowledge, threatened administrative, regulatory or judicial action, claim or notice of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any Subsidiary, except in each case which, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect. No property of the Company or any Subsidiary is subject to any Lien under any Environmental Law. Neither the Company nor any Subsidiary is subject to any order, decree, agreement or other individualized legal requirement related to any Environmental Law.

(qq) The Company and the Subsidiaries (i) are in material compliance with all statutes, rules and regulations applicable to the testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company or the Subsidiaries (“**Applicable Laws**”) except where such noncompliance would not reasonably be expected to have a Material Adverse Effect, (ii) have not received any Form 483 from the FDA, notice of adverse finding, warning letter, or other written correspondence or notice from the FDA, the European Medicines Agency (the “**EMA**”), the U.K. Medicines and Healthcare Products Regulatory Agency (the “**MHRA**”), the German Federal Institute for Drugs and Medical Devices (the “**BfArM**”), or any other federal, state, local or foreign governmental or regulatory authority alleging or asserting material 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**”), that would, individually or in the aggregate, result in a Material Adverse Effect; (iii) possess all material Authorizations and such Authorizations are valid and in full force and effect and neither the Company nor any Subsidiary is in material violation of any term of any such Authorizations except where such nonpossession, failure or noncompliance would not reasonably be expected to have a Material Adverse Effect; (iv) have not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA, the EMA, the MHRA, the BfArM, or any other federal, state, local or foreign governmental or regulatory authority or third party alleging that any Company product, operation or activity is in material violation of any Applicable Laws or Authorizations which noncompliance would reasonably be expected to have a Material Adverse Effect and has no knowledge that the FDA, the EMA, the MHRA, the BfArM, or any other federal, state, local or foreign governmental or regulatory authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding against the Company; (v) have not received written notice that the FDA, EMA, the MHRA, the BfArM, or any other federal, state, local or foreign governmental or regulatory authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations that would reasonably be expected to have a Material Adverse Effect and has no knowledge that the FDA, EMA, the MHRA, the BfArM, or any other federal, state, local or foreign governmental or regulatory authority is considering such action; and (vi) have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations, except whether the failure to file, obtain, maintain or submit such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments would not result in a Material Adverse Effect, and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission) except such incompleteness and incorrections as would not reasonably be expected to result in a Material Adverse Effect.

(tr) The Company and each of its Subsidiaries has operated and currently is in compliance in all material respects with all applicable Health Care Laws (as defined below), including, without limitation, the rules and regulations of the FDA, the U.S. Department of Health and Human Services Office of Inspector General, the Centers for Medicare & Medicaid Services, the Office for Civil Rights, the Department of Justice or any other governmental agency or body having jurisdiction over the Company or any of its activities, and has not engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other state or federal health care program. For purposes of this Agreement, “**Health Care Laws**” shall mean the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Act (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 Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.) (“**HIPAA**”), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the patient privacy, data security and breach notification provisions under HIPAA, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), the Public Health Service Act (42 U.S.C. §§ 262 et seq.), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), the regulations promulgated pursuant to such laws, and any other similar local, state or federal law and regulations. The Company has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence, communication or notice from the FDA or any other governmental or regulatory authority alleging or asserting noncompliance with any Health Care Laws applicable to the Company. The Company is not a party to nor has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any governmental or regulatory authority. Neither the Company, its Subsidiaries nor any of their respective employees, officers, directors or, to the Company’s knowledge, consultants has been excluded, suspended or debarred from participation in any U.S. state or federal health care program or human clinical research or, to the Company’s knowledge, is subject to a governmental inquiry, investigation, proceeding, or other similar action that would reasonably be expected to result in debarment, suspension, or exclusion. To the extent required in connection with their respective businesses, each of the Company and its Subsidiaries has the requisite provider number or other authorization to bill the Medicare program and the respective Medicaid program in the state or states in which such entity operates unless failure to maintain such provider number or other authorization could not be expected, individually or in the aggregate, to result in a Material Adverse Change; neither the Company nor any of its Subsidiaries is subject to any pending or, to the Company’s knowledge, threatened or contemplated action which could reasonably be expected to result either in a revocation of any provider number or authorization or in the Company’s or any Subsidiary’s exclusion from the Medicare or any state Medicaid programs.

(ss) The pre-clinical and clinical studies (as applicable) conducted by, on behalf of or sponsored by the Company or its Subsidiaries, or in which the Company or its Subsidiaries or their product candidates participated, were and, if still pending are being, to the Company’s knowledge, conducted in all material respects in accordance with standard medical and scientific research procedures and with all applicable local, state and federal laws, rules and regulations, including, without limitation, the Federal Food, Drug and Cosmetic Act and its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58 and 312; to the Company’s knowledge, the descriptions of the results of such studies contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus are accurate and complete in all material respects and fairly present the data derived from such studies; the Company is not aware of any studies, the results of which are inconsistent with or otherwise call into question the study results described or referred to in the Registration Statement, the Pricing Disclosure Package or the Prospectus; and neither the FDA nor any applicable foreign regulatory agency has, to the Company’s knowledge, commenced, or, to the knowledge of the Company, threatened to initiate, any action to place a hold order on, or otherwise terminate, delay or suspend, any proposed or ongoing pre-clinical studies or clinical investigations conducted or proposed to be conducted by or on behalf of the Company.

(tt) The Company has established and administers a compliance program applicable to the Company, to assist the Company and the directors, officers and employees of the Company in complying with applicable regulatory guidelines (including, without limitation, those administered by the FDA, the EMA, the MHRA, the BfArM, and any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA or EMA); except where such noncompliance would not reasonably be expected to have a Material Adverse Effect.

(uu) Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent (while acting in such capacity), employee, affiliate or other person acting on behalf of the Company or any Subsidiary, has authorized the giving of, offer or promise to give or (i) made any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any domestic governmental official, "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "**FCPA**")) or employee; (iii) violated or is in violation of any provision of the FCPA, UK Bribery Act, any applicable non-U.S. anti-bribery statute or regulation or any locally applicable corruption laws; (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment; or (v) received notice of any investigation, proceeding or inquiry by any governmental agency, authority or body regarding any of the matters in clauses (i)-(iv) above; and the Company and the Subsidiaries and, to the Company's knowledge, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(vv) The operations of the Company and the Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "**USA Patriot Act**"), and those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, and the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or the Subsidiaries with respect to the Money Laundering Laws is pending or, to the Company's knowledge, threatened.

(ww) None of the Company nor any Subsidiary nor, to the knowledge of the Company, any officer, director, agent, employee, affiliate or any person acting on behalf of the Company or any Subsidiary is or, in the past five years, has been, in violation of any applicable U.S. or non-U.S. federal, state, local or other constitution, law, statute, ordinance, rule or regulation, in any case issued, enacted, adopted, promulgated, implemented or otherwise put into legal effect by or under the authority of any governmental entity or any other Sanctions (as defined below), (A) engaged in any services (including financial services), transfers of goods, software, or technology, or any other business activity related to (i) Cuba, Iran, North Korea, Sudan, Syria or the Crimea region of Ukraine claimed by Russia (“**Sanctioned Countries**”), (ii) the government of any Sanctioned Country, (iii) any person, entity or organization located in, resident in, formed under the laws of, or owned or controlled by the government of, any Sanctioned Country, or (iv) any person, entity or organization made subject or target of any sanctions administered or enforced by the United States Government (including the US Department of Treasury, Office of Foreign Assets Control and the US Department of State), including, without limitation, the list of Specially Designated Nationals (“**SDN List**”) of the Office of Foreign Assets Control of the U.S. Treasury Department (“**OFAC**”), or by the United Nations Security Council, the European Union, Her Majesty’s Treasury-UK, or other relevant sanctions authority (collectively, “**Sanctions**”) and the Company will not, in violation of any applicable U.S. or non-U.S. federal, state, local or other constitution, law, statute, ordinance, rule or regulation, in any case issued, enacted, adopted, promulgated, implemented or otherwise put into legal effect by or under the authority of any governmental entity or any other Sanctions, directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any of its Subsidiaries, or any joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person, or in any country or territory, that currently is the subject to any U.S. sanctions administered by OFAC or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of U.S. sanctions administered by OFAC; (B) engaged in any transfers of goods, technologies or services (including financial services) that may assist the governments of Sanctioned Countries or facilitate money laundering or other activities proscribed by United States laws, rules or regulations; (C) is a person, entity or organization currently the subject of any Sanctions; or (D) located, organized or resident in any Sanctioned Country.

(xx) The Company (i) does not have any material lending or other relationship with any bank or lending affiliate of any Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Shares to repay any outstanding debt owed to any affiliate of any Underwriter.

Any certificate signed by or on behalf of the Company and delivered to the Representative or to counsel for the Underwriters shall be deemed to be a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

2. Purchase, Sale and Delivery of the Shares.

(a) On the basis of the representations, warranties, covenants and agreements herein contained, and subject to the terms and conditions herein set forth, the Company agrees to sell to each Underwriter and each Underwriter, severally and not jointly, agrees to purchase from the Company, at a purchase price per share of \$47.00, the number of Firm Shares set forth opposite their respective names on Schedule I hereto together with any additional number of Shares which such Underwriter may become obligated to purchase pursuant to the provisions of Section 10 hereof, subject, however, to such adjustments to eliminate fractional shares as the Representative in its sole discretion shall make.

(b) The closing of the issuance of the Firm Shares shall be held at the office of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (“**Underwriters’ Counsel**”), or at such other place as shall be agreed upon by the Representative and the Company, at 10:00 a.m., New York City time, on November 8, 2021, or such other time and date as the Representative and the Company may agree upon in writing (such time and date of payment and delivery being herein called the “**Closing Date**”). Payment of the purchase price for the Firm Shares shall be made by wire transfer in same day funds to the accounts specified by the Company upon delivery of the Firm Shares to the Representative through the facilities of The Depository Trust Company (“**DTC**”) for the respective accounts of the several Underwriters. The Firm Shares shall be registered in such name or names and shall be in such denominations as the Representative may request in writing not later than the business day immediately prior to the Closing Date.

(c) In addition, the Company hereby grants to the Underwriters the option to purchase up to 225,000 Additional Shares at the same purchase price per share to be paid by the Underwriters for the Firm Shares as set forth in Section 2(a) above. This option may be exercised at any time and from time to time, in whole or in part on one or more occasions, on or before the thirtieth day following the date of the Prospectus, by written notice from the Representative to the Company. Such notice shall set forth the aggregate number of Additional Shares as to which the option is being exercised and the date and time, as reasonably determined by the Representative, when the Additional Shares are to be delivered (any such date and time being herein sometimes referred to as an “**Additional Closing Date**”); *provided, however*, that no Additional Closing Date shall occur earlier than the Closing Date or earlier than the second full business day after the date on which the option shall have been exercised nor later than the eighth full business day after the date on which the option shall have been exercised. On the basis of the representations, warranties, covenants and agreements herein contained, but subject to the terms and conditions herein set forth, upon any exercise of the option as to all or any portion of the Additional Shares, each Underwriter, acting severally and not jointly, agrees to purchase from the Company the number of Additional Shares that bears the same proportion of the total number of Additional Shares then being purchased as the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I hereto (or such number increased as set forth in Section 10 hereof) bears to the total number of Firm Shares that the Underwriters have agreed to purchase hereunder, subject, however, to such adjustments to eliminate fractional shares as the Representative in its sole discretion shall make. In the event that the Underwriters exercise less than their full option to purchase Additional Shares, the number of Additional Shares to be sold by the Company shall be, as nearly as practicable, in the same proportion as the maximum number of Additional Shares to be sold by the Company and the number of Additional Shares to be sold.

(d) The closing of the issuance of the Additional Shares shall be held at the office of Underwriters’ Counsel, or at such other place as shall be agreed upon by the Representative and the Company, at 10:00 a.m., New York City time, on any Additional Closing Date, or such other time as shall be agreed upon by the Representative and the Company. Payment of the purchase price for the Additional Shares shall be made by wire transfer in same day funds to the account specified by the Company upon delivery of the Additional Shares to the Representative through the facilities of DTC for the respective accounts of the several Underwriters. The Additional Shares shall be registered in such name or names and shall be in such denominations as the Representative may request in writing not later than the business day immediately prior to the Closing Date.

3. Offering. Upon authorization of the release of the Firm Shares by the Representative, the Underwriters propose to offer the Shares for sale to the public upon the terms and conditions set forth in the Prospectus.

4. Covenants of the Company. In addition to the other covenants and agreements of the Company contained herein, the Company further covenants and agrees with each of the Underwriters that:

(a) The Company shall prepare the Prospectus in a form approved by the Representative and file such Prospectus pursuant to, and within the time period specified in, Rule 424(b) and Rule 430B under the Securities Act; prior to the last date on which an Additional Closing Date, if any, may occur, the Company shall file no further amendment to the Registration Statement or amendment or supplement to the Prospectus to which the Representative objects in writing after being furnished in advance a copy thereof and given a reasonable opportunity to review and comment thereon; the Company shall notify the Representative promptly (and, if requested by the Representative, confirm such notice in writing) (i) when the Registration Statement and any amendments thereto become effective, (ii) of any request by the Commission for any amendment of or supplement to the Registration Statement or the Prospectus, including any document incorporated by reference therein or for any additional information, (iii) of the Company's intention to file, or prepare any supplement or amendment to, the Registration Statement, any Preliminary Prospectus or the Prospectus, (iv) of the mailing or the delivery to the Commission for filing of any amendment of or supplement to the Registration Statement or the Prospectus, including but not limited to Rule 462(b) under the Securities Act, (v) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, or suspending the use of any Preliminary Prospectus or the Prospectus or, in each case, of the initiation or threatening of any proceedings therefore, (vi) of the receipt of any comments from the Commission, and (vii) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for that purpose. If the Commission shall propose or enter a stop order at any time, the Company will make every reasonable effort to prevent the issuance of any such stop order and, if issued, to obtain the lifting of such order as soon as possible.

(b) If at any time when a prospectus relating to the Shares (or, in lieu thereof, the notice referred to in Rule 173(a) under the Securities Act) is required to be delivered under the Securities Act, any event shall have occurred as a result of which the Pricing Disclosure Package (prior to the availability of the Prospectus) or the Prospectus as then amended or supplemented would, in the judgment of the Underwriters or the Company, include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances existing at the time of delivery of such Pricing Disclosure Package or Prospectus (or, in lieu thereof, the notice referred to in Rule 173(a) under the Securities Act) to the purchaser, not misleading, or if to comply with the Securities Act, the Exchange Act or the Rules and Regulations it shall be necessary at any time to amend or supplement the Pricing Disclosure Package, the Prospectus or the Registration Statement, or to file any document incorporated by reference in the Registration Statement or the Prospectus or in any amendment thereof or supplement thereto, the Company will notify the Representative promptly and prepare and file with the Commission an appropriate amendment, supplement or document (in form and substance satisfactory to the Representative) that will correct such statement or omission or effect such compliance, and will use its reasonable best efforts to have any amendment to the Registration Statement declared effective as soon as possible.

(c) The Company will not, without the prior consent of the Representative, (i) make any offer relating to the Shares that would constitute a “free writing prospectus” as defined in Rule 405 under the Securities Act, except for any Issuer Free Writing Prospectus set forth in Schedule II hereto and any electronic Road Show previously approved by the Representative, or (ii) file, refer to, approve, use or authorize the use of any “free writing prospectus” as defined in Rule 405 under the Securities Act with respect to the Offering or the Shares. If at any time any event shall have occurred as a result of which any Issuer Free Writing Prospectus as then amended or supplemented would, in the judgment of the Underwriters or the Company, conflict with the information in the Registration Statement, the Pricing Disclosure Package or the Prospectus as then amended or supplemented or would, in the judgment of the Underwriters or the Company, include an untrue statement of a material fact or omit to state any material necessary in order to make the statements therein, in the light of the circumstances existing at the time of delivery to the purchaser, not misleading, or if to comply with the Securities Act or the Rules and Regulations it shall be necessary at any time to amend or supplement any Issuer Free Writing Prospectus, the Company will notify the Representative promptly and, if requested by the Representative, prepare and furnish without charge to each Underwriter an appropriate amendment or supplement (in form and substance satisfactory to the Representative) that will correct such statement, omission or conflict or effect such compliance.

(d) The Company will comply with the requirements of Rule 433 with respect to each Issuer Free Writing Prospectus including, without limitation, all prospectus delivery, filing, record retention and legending requirements applicable to each such Issuer Free Writing Prospectus.

(e) At the request of the Representative, the Company will promptly deliver to each of the Representative and Underwriters’ Counsel a signed copy of the Registration Statement, as initially filed and all amendments thereto, including all consents and exhibits filed therewith. At the request of the Representative, the Company will promptly deliver to each of the Underwriters such number of copies of any Preliminary Prospectus, the Prospectus, the Registration Statement, all amendments of and supplements to such documents, if any, and all documents incorporated by reference in the Registration Statement and Prospectus or any amendment thereof or supplement thereto, as the Representative may reasonably request. Prior to 10:00 A.M., New York City time, on the business day next succeeding the date of this Agreement and from time to time thereafter, at the request of the Representative, the Company will furnish the Underwriters with copies of the Prospectus in New York City in such quantities as the Representative may reasonably request.

(f) Promptly from time to time, the Company will use its reasonable best efforts, in cooperation with the Representative, to qualify the Shares for offering and sale under the securities laws relating to the offering or sale of the Shares of such jurisdictions, domestic or foreign, as the Representative may reasonably request and to maintain such qualification in effect for so long as required for the distribution thereof; except that in no event shall the Company be obligated in connection therewith to qualify as a foreign corporation or to execute a general consent to service of process or subject itself to taxation in any jurisdiction where it is not otherwise so subject.

(g) The Company will make generally available to its security holders and to the Representative as soon as practicable an earnings statement of the Company and the Subsidiaries (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 (including, at the option of the Company, Rule 158).

(h) During the period of 90 days from the date of the Prospectus (the “**Lock-Up Period**”), without the prior written consent of Guggenheim Securities, the Company (i) will not, directly or indirectly, issue, offer, sell, agree to issue, offer or sell, solicit offers to purchase, grant any call option, warrant or other right to purchase, purchase any put option or other right to sell, pledge, borrow or otherwise dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, or make any public announcement of any of the foregoing, (ii) will not establish or increase any “put equivalent position” or liquidate or decrease any “call equivalent position” (in each case within the meaning of Section 16 of the Exchange Act) with respect to any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, and (iii) will not otherwise enter into any swap, derivative or other transaction or arrangement that transfers to another, in whole or in part, any economic consequence of ownership of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, whether or not such transaction is to be settled by delivery of any shares of Common Stock, securities convertible into or exercisable or exchangeable for Common Stock, other securities, cash or other consideration, other than (A) the Shares to be sold hereunder, (B) upon the exercise of an option or warrant, the vesting of restricted stock units, performance stock units or deferred stock units or the conversion or exchange of a security outstanding on the date hereof as referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (C) pursuant to the stock-based compensation plans, the employee stock purchase plan or other compensation plans of the Company and the Subsidiaries (including any amendments to such plans) or any inducement awards as referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (D) any securities issued pursuant to the Agreement and Plan of Merger dated March 8, 2021 by and among ANI Pharmaceuticals, Inc., Nile Merger Sub LLC, Novitium Pharma LLC, Esjay LLC, Chali Properties, LLC, Chad Gassert, Muthusamy Shanmugam and Thorappadi Vijayaraj and Shareholder Representative Services LLC (the “**Merger Agreement**”), (E) any securities issued pursuant to the Equity Commitment and Investment Agreement dated March 8, 2021 by and between ANI Pharmaceuticals, Inc. and Ampersand 2020 Limited Partnership (the “**PIPE Subscription Agreement**”), (F) the filing of any registration statement on Form S-8 or a successor form thereto relating to the shares of Common Stock granted pursuant to or reserved for issuance as described in clause (C), and (G) the filing of any registration statement required by the Merger Agreement or the PIPE Subscription Agreement. For the avoidance of doubt, nothing in this section 4(h) shall prohibit the Company from fulfilling its obligations under the Merger Agreement or the PIPE Subscription Agreement.

(i) During the period of two years from the Effective Date of the Registration Statement, the Company will furnish to the Representative copies of all reports or other communications (financial or other) furnished to security holders or from time to time published or publicly disseminated by the Company, and will deliver to the Representative as soon as they are available, copies of any reports, financial statements and proxy or information statements furnished to or filed with the Commission or any national securities exchange on which any class of securities of the Company is listed; provided, that the Company will be deemed to have furnished such reports, other communications, financial statements and proxy or information statements to the Representative to the extent they are filed on EDGAR.

(j) The Company will use its best efforts to maintain the listing of its Common Stock (including the Shares) on The Nasdaq Capital Market (or another Nasdaq market) following the issuance of the Shares pursuant to this Agreement, provided; however that this covenant shall not prevent a sale, merger or similar transaction involving the Company.

(k) The Company will apply the net proceeds from the sale of the Shares as set forth under the caption "Use of Proceeds" in the Pricing Disclosure Package and the Prospectus.

(l) The Company, during the period when a prospectus (or, in lieu thereof, the notice referred to in Rule 173(a) under the Securities Act) is required to be delivered under the Securities Act in connection with the offer or sale of the Shares, will file all reports and other documents required to be filed by the Company with the Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act and the Rules and Regulations within the time periods required thereby.

(m) If the Company elects to rely upon Rule 462(b) under the Securities Act, the Company shall file a Rule 462(b) Registration Statement with the Commission in compliance with Rule 462(b) by 10:00 p.m. (New York City time), on the date of this Agreement, and the Company shall at the time of filing either pay to the Commission the filing fee for the Rule 462(b) Registration Statement or give irrevocable instructions for the payment of such fee pursuant to Rule 111(b) under the Securities Act.

(n) The Company will not take, and will cause its affiliates (within the meaning of Rule 144 under the Securities Act) not to take, directly or indirectly, any action which constitutes or is designed to cause or result in, or which would reasonably be expected to constitute, cause or result in, the stabilization or manipulation of the price of any security to facilitate the sale or resale of the Shares or to result in a violation of Regulation M under the Exchange Act.

(o) The Company will do and perform all things required or necessary to be done and performed under this Agreement by it prior to each Closing Date, and to satisfy all conditions precedent to the Underwriters' obligations hereunder to purchase the Shares.

5. Covenant of the Underwriters. Each Underwriter, severally and not jointly, covenants and agrees with the Company that such Underwriter will not use or refer to any "free writing prospectus" (as defined in Rule 405 under the Securities Act) without the prior written consent of the Company if such Underwriter's use of or reference to such "free writing prospectus" would require the Company to file with the Commission any "issuer information" (as defined in Rule 433 under the Securities Act).

6. Payment of Expenses. Whether or not the transactions contemplated by this Agreement, the Registration Statement and the Prospectus are consummated or this Agreement is terminated (provided, however, the Company shall have no obligation to reimburse any defaulting Underwriter pursuant to Section 10 hereof, the Company hereby agrees to pay all costs and expenses incident to the performance of its obligations hereunder, including the following: (i) all expenses in connection with the preparation, printing and filing of the Registration Statement, any Preliminary Prospectus, any Issuer Free Writing Prospectus, the Prospectus and any and all amendments and supplements thereto and the mailing and delivering of copies thereof to the Underwriters and dealers; (ii) the fees, disbursements and expenses of the Company's counsel and accountants in connection with the registration of the Shares under the Securities Act and the Offering; (iii) the cost of producing this Agreement and any agreement among Underwriters, blue sky survey, closing documents and other instruments, agreements or documents (including any compilations thereof) in connection with the Offering; (iv) all expenses in connection with the qualification of the Shares for offering and sale under state or foreign securities or blue sky laws as provided in Section 4(f) hereof, including the reasonable and documented fees and disbursements of counsel for the Underwriters in connection with such qualification or offering and in connection with any blue sky survey; (v) all fees and expenses in connection with listing the Shares on Nasdaq and with any filings required to be made with FINRA; (vi) the costs and expenses of the Company relating to investor presentations on any Road Show undertaken in connection with the marketing of the Shares, including without limitation, expenses associated with the production and distribution (including electronic) of Road Show slides and graphics, fees and expenses of any consultants engaged in connection with the Road Show presentations, travel and lodging expenses of the representatives and officers of the Company in connection with the Road Show; (vii) any stock transfer taxes incurred in connection with this Agreement or the Offering; and (viii) the fees and expenses incident to the performance of the obligations of the Representative (including fees, disbursements and expenses of counsel for the Underwriters, which shall be inclusive of amounts paid pursuant to Sections 6(iv), 6(v)), and 12(d) in an aggregate amount not to exceed \$150,000. The Company also will pay or cause to be paid: (x) the cost of preparing stock certificates representing the Shares; (y) the cost and charges of any transfer agent or registrar for the Shares; and (z) all other reasonable and documented costs and expenses incident to the performance of its obligations hereunder which are not otherwise specifically provided for in this Section 6.

7. Conditions of Underwriters' Obligations. The several obligations of the Underwriters to purchase and pay for the Firm Shares and the Additional Shares, as provided herein, shall be subject to the accuracy of the representations and warranties of the Company herein contained, as of the date hereof and as of the applicable Closing Date (for purposes of this Section 7, "**Closing Date**" shall refer to the Closing Date for the Firm Shares and any Additional Closing Date, if different, for the Additional Shares), to the performance by the Company of all of its obligations hereunder, and to each of the following additional conditions:

(a) The Prospectus shall have been filed with the Commission in a timely fashion in accordance with Section 4(a) hereof; no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, and no stop order suspending or preventing the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus, or the Prospectus, shall have been issued by the Commission and no proceedings therefor shall have been initiated or threatened by the Commission; all requests for additional information on the part of the Commission shall have been complied with to the Representative's reasonable satisfaction; if the Company has elected to rely on Rule 462(b) under the Securities Act, the Rule 462(b) Registration Statement shall have become effective by 10:00 p.m. (New York City time) on the date of this Agreement; and all necessary regulatory or stock exchange approvals shall have been received.

(b) At the Closing Date, the Representative shall have received the written opinion and negative assurance statement of Orrick, Herrington & Sutcliffe LLP, counsel for the Company, dated the Closing Date and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representative.

(c) At the Closing Date, the Representative shall have received the written opinion and negative assurance statement of Underwriters' Counsel, dated the Closing Date and addressed to the Underwriters, in form and substance satisfactory to the Representative, with respect to the issuance and sale of the Shares, the Registration Statement, the Pricing Disclosure Package, the Prospectus and such other matters as the Representative may require, and the Company shall have furnished to Underwriters' Counsel such documents as they may reasonably request for the purpose of enabling them to pass upon such matters.

(d) At the Closing Date, the Representative shall have received a certificate of the Chief Executive Officer and principal financial officer of the Company, dated the Closing Date, in form and substance satisfactory to the Representative as to the accuracy of the representations and warranties of the Company set forth in Section 1 hereof as of the date hereof and as of the Closing Date, as to the performance by the Company of all of its obligations hereunder to be performed at or prior to the Closing Date, as to the matters set forth in subsection (a) of this Section 7, and as to such other matters as the Representative may reasonably request.

(e) At the time this Agreement is executed and at the Closing Date, the Representative shall have received comfort letters from each of EisnerAmper LLP, independent registered public auditing firm for the Company, and RAM Associates, independent registered public auditing firm for Novitium Pharma LLC, dated, respectively, as of the date of this Agreement and as of the Closing Date, addressed to the Underwriters and in form and substance satisfactory to the Underwriters and Underwriters' Counsel, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(f) Neither the Company nor any Subsidiary shall have sustained, since the date of the latest audited financial statements included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, any material loss or interference with its business or properties from fire, explosion, flood, earthquake, hurricane, accident or other calamity, whether or not covered by insurance, or from any labor dispute or any legal or governmental proceeding, other than as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus (exclusive of any supplement thereto); and (ii) subsequent to the dates as of which information is given in the Registration Statement (exclusive of any amendment thereto subsequent to the date hereof) and the Pricing Disclosure Package and the Prospectus (exclusive of any supplement thereto), there shall not have been any material change in the capital stock or long-term or short-term debt of the Company or the Subsidiaries or any change or any development involving a change, whether or not arising from transactions in the ordinary course of business, in the business, general affairs, management, condition (financial or otherwise), results of operations, stockholders' equity, properties or prospects of the Company and the Subsidiaries, individually or taken as a whole, the effect of which, in any such case described above, is, in the judgment of the Representative, so material and adverse as to make it impracticable or inadvisable to proceed with the Offering on the terms and in the manner contemplated in the Registration Statement, the Pricing Disclosure Package and the Prospectus (exclusive of any such supplement).

(g) No Underwriter shall have discovered and disclosed to the Company on or prior to such Closing Date that any of the Registration Statement, the Pricing Disclosure Package or the Prospectus, or any amendment or supplement thereto, contains an untrue statement of a fact which, in the opinion of Underwriters' Counsel, is material or omits to state a fact which, in the opinion of such counsel, is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(h) As of the date of this Agreement, the Representative shall have received a duly executed lock-up agreement substantially in the form of Exhibit B hereto (a "**Lock-Up Agreement**") from each person who is a director or executive officer of the Company and each other person or entity listed on Schedule IV hereto, in each case substantially in the form attached hereto as Exhibit B.

(i) At the Closing Date, the Shares shall have been approved for listing on the Nasdaq Capital Market, subject only to official notice of issuance.

(j) FINRA shall not have raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the Offering of the Shares.

(k) The Company shall have furnished the Underwriters and Underwriters' Counsel with such other certificates, opinions or other documents as they may have reasonably requested.

If any of the conditions specified in this Section 7 shall not have been fulfilled when and as required by this Agreement, or if any of the certificates, opinions, written statements or letters furnished to the Representative or to Underwriters' Counsel pursuant to this Section 7 shall not be satisfactory in form and substance to the Representative and to Underwriters' Counsel, all obligations of the Underwriters hereunder may be cancelled by the Representative at, or at any time prior to, the Closing Date and the obligations of the Underwriters to purchase the Additional Shares may be cancelled by the Representative at, or at any time prior to, any Additional Closing Date. Notice of such cancellation shall be given to the Company in writing or by telephone. Any such telephone notice shall be confirmed promptly thereafter in writing.

8. Indemnification.

(a) The Company shall indemnify and hold harmless each Underwriter, its affiliates, directors, officers, employees and each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any and all losses, liabilities, claims, damages and expenses whatsoever as incurred (including but not limited to reasonable attorneys' fees and any and all expenses whatsoever incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, and any and all amounts paid in settlement of any claim or litigation), joint or several, to which they or any of them may become subject under the Securities Act, the Exchange Act or otherwise, insofar as such losses, liabilities, claims, damages or expenses (or actions in respect thereof) arise out of or are based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact included (A) in any Preliminary Prospectus or the Prospectus, or in any supplement thereto or amendment thereof, or in any Issuer Free Writing Prospectus, or in any "issuer information" (as defined in Rule 433(h)(2) under the Securities Act) filed or required to be filed pursuant to Rule 433(d) under the Securities Act, or (B) in any other materials or information provided to investors by, or with the approval of, the Company in connection with the Offering, including in any Road Show for the Offering ("**Marketing Materials**"), or the omission or alleged omission to state in any Preliminary Prospectus or the Prospectus, or in any supplement thereto or amendment thereof, or in any Issuer Free Writing Prospectus, or in any "issuer information" (as defined in Rule 433(h)(2) under the Securities Act) filed or required to be filed pursuant to Rule 433(d) under the Securities Act, or in any Marketing Materials, 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 will not be liable in any such case to the extent but only to the extent that any such loss, liability, claim, damage or expense arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representative expressly for use therein. The parties agree that such information provided by or on behalf of any Underwriter through the Representative consists solely of the material referred to in Section 19 hereof. This indemnity agreement will be in addition to any liability which the Company may otherwise have, including but not limited to other liability under this Agreement.

(b) Each Underwriter, severally and not jointly, shall indemnify and hold harmless the Company, each of the directors of the Company, each of the officers of the Company who shall have signed the Registration Statement, and each other person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any losses, liabilities, claims, damages and expenses whatsoever as incurred (including but not limited to attorneys' fees and any and all expenses whatsoever incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, and any and all amounts paid in settlement of any claim or litigation), joint or several, to which they or any of them may become subject under the Securities Act, the Exchange Act or otherwise, insofar as such losses, liabilities, claims, damages or expenses (or actions in respect thereof) arise out of or are based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact contained in any related Preliminary Prospectus or the Prospectus, or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission 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, in each case to the extent, but only to the extent, that any such loss, liability, claim, damage or expense arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of any Underwriter through the Representative specifically for use therein; provided, however, that in no case shall any Underwriter be liable or responsible for any amount in excess of the underwriting discount applicable to the Shares to be purchased by such Underwriter hereunder. The parties agree that such information provided by or on behalf of any Underwriter through the Representative consists solely of the material referred to in Section 19 hereof.

(c) Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of any claims or the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify each party against whom indemnification is to be sought in writing of the claim or the commencement thereof (but the failure so to notify an indemnifying party shall not relieve the indemnifying party from any liability which it may have under this Section 8 to the extent that it is not materially prejudiced as a result thereof or otherwise has notice of any such action, and in any event shall not relieve it from any liability that such indemnifying party may have otherwise than on account of the indemnity agreement hereunder). In case any such claim or action is brought against any indemnified party, and it notifies an indemnifying party of the commencement thereof, the indemnifying party will be entitled to participate, at its own expense in the defense of such action, and to the extent it may elect by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel satisfactory to such indemnified party; provided however, that counsel to the indemnifying party shall not (except with the written consent of the indemnified party) also be counsel to the indemnified party. Notwithstanding the foregoing, the indemnified party or parties shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such indemnified party or parties unless (i) the employment of such counsel shall have been authorized in writing by one of the indemnifying parties in connection with the defense of such action, (ii) the indemnifying parties shall not have employed counsel to have charge of the defense of such action within a reasonable time after notice of commencement of the action, (iii) the indemnifying party does not diligently defend the action after assumption of the defense, or (iv) such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from or additional to those available to one or all of the indemnifying parties (in which case the indemnifying parties shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events such fees and expenses shall be borne by the indemnifying parties hereof, then, in addition to the fees and expenses of such counsel for the indemnified parties, the indemnifying party shall be liable for the reasonable fees and expenses of not more than one counsel (in addition to any local counsel) separate from its own counsel. No indemnifying party shall, without the prior written consent of the indemnified parties, effect any settlement or compromise of, or consent to the entry of judgment with respect to, any pending or threatened claim, investigation, action or proceeding in respect of which indemnity or contribution may be or could have been sought by an indemnified party under this Section 8 or Section 9 hereof (whether or not the indemnified party is an actual or potential party thereto), unless such settlement, compromise or judgment (i) includes an unconditional release of the indemnified party from all liability arising out of such claim, investigation, action or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or any failure to act, by or on behalf of the indemnified party.

9. Contribution. In order to provide for contribution in circumstances in which the indemnification provided for in Section 8 hereof is for any reason held to be unavailable from any indemnifying party or is insufficient to hold harmless a party indemnified thereunder, the Company and the Underwriters severally shall contribute to the aggregate losses, claims, damages, liabilities and expenses of the nature contemplated by such indemnification provision (including any investigation, reasonable attorneys' fees and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claims asserted, but after deducting in the case of losses, claims, damages, liabilities and expenses suffered by the Company, any contribution received by the Company from persons, other than the Underwriters, who may also be liable for contribution, including persons who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, officers of the Company who signed the Registration Statement and directors of the Company) as incurred to which the Company and one or more of the Underwriters may be subject, in such proportions as is appropriate to reflect the relative benefits received by the Company and by the Underwriters from the Offering or, if such allocation is not permitted by applicable law, in such proportions as are appropriate to reflect not only the relative benefits referred to above but also the relative fault of the Company and the Underwriters in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company and the Underwriters shall be deemed to be in the same proportion as the total proceeds from the Offering (net of underwriting discounts and commissions but before deducting expenses) received by the Company, on the one hand, and the underwriting discount and commissions received by the Underwriters, on the other hand, in each case as set forth in the table on the cover page of the Prospectus, bear to the aggregate initial public offering price of the Shares as set in the table on the cover page of the Prospectus. The relative fault of each of the Company and of the Underwriters shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters and the parties' relative intent, 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 contribution pursuant to this Section 9 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 9. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above in this Section 9 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any judicial, regulatory or other legal or governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this Section 9, (i) no Underwriter shall be required to contribute any amount in excess of the amount by which the discounts and commissions applicable to the Shares underwritten by it and distributed to the public exceeds the amount of any damages which such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission and (ii) no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9, each of the Underwriters' affiliates, directors, officers, employees and each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act shall have the same rights to contribution as such Underwriter, and 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 officer of the Company who shall have signed the Registration Statement and each director of the Company shall have the same rights to contribution as the Company, subject in each case to clauses (i) and (ii) of the immediately preceding sentence. Any party entitled to contribution will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim for contribution may be made against another party or parties, notify each party or parties from whom contribution may be sought, but the omission to so notify such party or parties shall not relieve the party or parties from whom contribution may be sought from any obligation it or they may have under this Section 9 or otherwise. The obligations of the Underwriters to contribute pursuant to this Section 9 are several in proportion to the respective number of Shares to be purchased by each of the Underwriters hereunder and not joint.

10. Underwriter Default.

(a) If any Underwriter or Underwriters shall default in its or their obligation to purchase Firm Shares or Additional Shares hereunder, and if the Firm Shares or Additional Shares with respect to which such default relates (the “**Default Shares**”) do not (after giving effect to arrangements, if any, made by the Representative pursuant to subsection (b) below) exceed in the aggregate 10% of the number of Firm Shares or Additional Shares, each non-defaulting Underwriter, acting severally and not jointly, agrees to purchase from the Company that number of Default Shares that bears the same proportion of the total number of Default Shares then being purchased as the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I hereto bears to the aggregate number of Firm Shares set forth opposite the names of the non-defaulting Underwriters, subject, however, to such adjustments to eliminate fractional shares as the Representative in its sole discretion shall make.

(b) In the event that the aggregate number of Default Shares exceeds 10% of the number of Firm Shares or Additional Shares, as the case may be, the Representative may in its discretion arrange for itself or for another party or parties (including any non-defaulting Underwriter or Underwriters who so agree) to purchase the Default Shares on the terms contained herein. In the event that within five calendar days after such a default the Representative does not arrange for the purchase of the Default Shares as provided in this Section 10, this Agreement or, in the case of a default with respect to the Additional Shares, the obligations of the Underwriters to purchase and of the Company to sell the Additional Shares shall thereupon terminate, without liability on the part of the Company with respect thereto (except in each case as provided in Sections 6, 8, 9, 11 and 12(d)) or the Underwriters, but nothing in this Agreement shall relieve a defaulting Underwriter or Underwriters of its or their liability, if any, to the other Underwriters and the Company for damages occasioned by its or their default hereunder.

(c) In the event that any Default Shares are to be purchased by the non-defaulting Underwriters, or are to be purchased by another party or parties as aforesaid, the Representative or the Company shall have the right to postpone the Closing Date or Additional Closing Date, as the case may be for a period, not exceeding five business days, in order to effect whatever changes may thereby be made necessary in the Registration Statement or the Prospectus or in any other documents and arrangements, and the Company agrees to file promptly any amendment or supplement to the Registration Statement or the Prospectus which, in the opinion of Underwriters’ Counsel, may thereby be made necessary or advisable. The term “**Underwriter**” as used in this Agreement shall include any party substituted under this Section 10 with like effect as if it had originally been a party to this Agreement with respect to such Firm Shares and Additional Shares.

11. Survival of Representations and Agreements. All representations and warranties, covenants and agreements of the Underwriters and the Company contained in this Agreement or in certificates of officers of the Company submitted pursuant hereto, including the agreements contained in Section 6, the indemnity agreements contained in Section 8 and the contribution agreements contained in Section 9, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of any Underwriter or any controlling person thereof or by or on behalf of the Company, any of its officers and directors or any controlling person thereof, and shall survive delivery of and payment for the Shares to and by the Underwriters. The representations contained in Section 1 and the agreements contained in Sections 6, 8, 9, 11, 12 and 18 hereof shall survive any termination of this Agreement, including termination pursuant to Section 10 or 12 hereof.

12. Effective Date of Agreement; Termination.

(a) This Agreement shall become effective when the parties hereto have executed and delivered this Agreement.

(b) The Representative shall have the right to terminate this Agreement at any time prior to the Closing Date or to terminate the obligations of the Underwriters to purchase the Additional Shares at any time prior to any Additional Closing Date, as the case may be, if, at or after the Applicable Time, (i) any domestic or international event or act or occurrence has materially disrupted, or in the opinion of the Representative will in the immediate future materially disrupt, the market for the Company's securities or securities in general; or (ii) trading on The New York Stock Exchange ("NYSE") or Nasdaq shall have been suspended or been made subject to material limitations, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required, on the NYSE or Nasdaq or by order of the Commission or any other governmental authority having jurisdiction; or (iii) a banking moratorium has been declared by any state or federal authority or any material disruption in commercial banking or securities settlement or clearance services shall have occurred; or (iv) (A) there shall have occurred any outbreak or escalation of hostilities or acts of terrorism involving the United States or there is a declaration of a national emergency or war by the United States or (B) there shall have been any other calamity or crisis or any change in political, financial or economic conditions if the effect of any such event in (A) or (B), in the judgment of the Representative, makes it impracticable or inadvisable to proceed with the offering, sale and delivery of the Firm Shares or the Additional Shares, as the case may be, on the terms and in the manner contemplated by the Prospectus; or (v) any of the events described in Section 7(h) shall have occurred or the Underwriters shall decline to purchase the Shares for any reason permitted under this Agreement.

(c) Any notice of termination pursuant to this Section 12 shall be in writing.

(d) If this Agreement shall be terminated pursuant to any of the provisions hereof, or if the sale of the Shares provided for herein is not consummated because any condition to the obligations of the Underwriters set forth herein is not satisfied or because of any refusal, inability or failure on the part of the Company to perform any agreement herein or comply with any provision hereof, the Company will, subject to demand by the Representative, reimburse the Underwriters for all reasonable out-of-pocket expenses incurred by the Underwriters in connection herewith (including the reasonable and documented fees and expenses of their counsel); provided, however, that the amount paid to the Underwriters pursuant to this Section 12 and Section 6 herein shall not exceed \$150,000 in the aggregate; provided, further, however, that in the event of a termination pursuant to Section 10 hereof, only the non-defaulting Underwriters shall be entitled to receive such reimbursement.

13. Research Analyst Independence. The Company acknowledges that the Underwriters' research analysts and research departments are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriters' research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the Offering that differ from the views of personnel in their respective investment banking divisions. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by personnel in such Underwriters' investment banking divisions. The Company acknowledges that each of the Underwriters is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

14. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Shares pursuant to this Agreement, including the determination of the public offering price of the 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, (b) in connection with the Offering and the process leading thereto, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, the Subsidiaries or their respective stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the Offering or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company or the Subsidiaries on other matters) and no Underwriter has any obligation to the Company with respect to the Offering except the obligations expressly set forth in this Agreement, (d) 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, (e) any duties and obligations that the Underwriters may have to the Company shall be limited to those duties and obligations specifically stated herein and (f) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the Offering and the Company has consulted its own respective legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

15. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 15:

“**BHC Act Affiliate**” has the meaning assigned to the term “affiliate” in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).

“**Covered Entity**” means any of the following: (i) a “covered entity” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a “covered bank” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a “covered FSI” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

“**Default Right**” has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

“**U.S. Special Resolution Regime**” means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

16. Notices. All communications hereunder, except as may be otherwise specifically provided herein, shall be in writing, and:

(a) if sent to any Underwriter, shall be mailed, delivered, or faxed and confirmed in writing, to such Underwriter c/o Guggenheim Securities, LLC, 330 Madison Avenue, New York, New York 10017, Fax (212) 658-9689, Attention: Head of Equity Capital Markets, with copies to the General Counsel and Underwriter’s Counsel at Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., One Financial Center, Boston, Massachusetts 02111, Attention: William Hicks, Esq.;

(b) if sent to the Company, shall be mailed, delivered, or faxed and confirmed in writing to the Company at ANI Pharmaceuticals, Inc., 210 Main Street, West Baudette, MN 56623, Attention: Chief Executive Officer, with a copy to its counsel at Orrick, Herrington, and Sutcliffe, LLP, 405 Howard Street, San Francisco, CA 94105, Attention: Karen Dempsey, Esq.; *provided, however*, that any notice to an Underwriter pursuant to Section 8 shall be delivered or sent by mail or facsimile transmission to such Underwriter at its address set forth in its acceptance facsimile to Guggenheim Securities, which address will be supplied to any other party hereto by Guggenheim Securities upon request. Any such notices and other communications shall take effect at the time of receipt thereof.

17. Parties. This Agreement shall insure solely to the benefit of, and shall be binding upon, the Underwriters and the Company and the controlling persons, affiliates, directors, officers, employees and agents referred to in Section 8 and Section 9 hereof, and their respective successors and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the parties hereto and said controlling persons and their respective successors, officers, directors, heirs and legal representatives, and it is not for the benefit of any other person, firm or corporation. The term “successors and assigns” shall not include a purchaser, in its capacity as such, of Shares from any of the Underwriters.

18. Governing Law and Jurisdiction; Waiver of Jury Trial. **This Agreement shall be governed by and construed in accordance with the laws of the State of New York.** The Company irrevocably (a) submits to the jurisdiction of any court of the State of New York located in the City and County of New York, Borough of Manhattan or any federal courts of the United States of America located in the City and County of New York, Borough of Manhattan for the purpose of any suit, action, or other proceeding arising out of this Agreement, or any of the agreements or transactions contemplated by this Agreement, the Registration Statement and the Prospectus (each, a “**Proceeding**”), (b) agrees that all claims in respect of any Proceeding may be heard and determined in any such court, (c) waives, to the fullest extent permitted by law, any immunity from jurisdiction of any such court or from any legal process therein, (d) agrees not to commence any Proceeding other than in such courts, and (e) waives, to the fullest extent permitted by law, any claim that such Proceeding is brought in an inconvenient forum. THE COMPANY (ON BEHALF OF ITSELF AND, TO THE FULLEST EXTENT PERMITTED BY LAW, ON BEHALF OF ITS RESPECTIVE EQUITY HOLDERS AND CREDITORS) HEREBY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY CLAIM BASED UPON, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, THE REGISTRATION STATEMENT AND THE PROSPECTUS.

19. The parties acknowledge and agree that, for purposes of Sections 1(c), 1(d), 1(e) and 8 hereof, the information provided by or on behalf of any Underwriter consists solely of the material included under the captions: “Underwriting—Commissions and Discounts; Expenses” (concerning the selling concession amount) in the Prospectus, the first three paragraphs under the caption “Underwriting—Price Stabilization and Short Positions” in the Prospectus and the paragraph under the caption “Underwriting—Passive Market Making” in the Prospectus.

20. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same instrument. Delivery of a signed counterpart of this Agreement by facsimile or other electronic transmission shall constitute valid and sufficient delivery thereof.

21. Headings. The headings herein are inserted for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

22. Time is of the Essence. Time shall be of the essence of this Agreement. As used herein, the term “**business day**” shall mean any day when the Commission’s office in Washington, D.C. is open for business.

[Signature page follows]

If the foregoing correctly sets forth your understanding, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among us.

Very truly yours,

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey

Name: Stephen P. Carey

Title: Senior Vice President, Finance and Chief Financial Officer

Accepted as of the date first above written

GUGGENHEIM SECURITIES, LLC

By: /s/ Ken Springer

Name: Ken Springer

Title: Senior Managing Director

On behalf of itself and the other Underwriters named in Schedule I hereto.

[Signature Page to Underwriting Agreement]

SCHEDULE I

Underwriter	Total Number of Firm Shares to be Purchased	Number of Additional Shares to be Purchased if Option is Fully Exercised
Guggenheim Securities, LLC	1,200,000	180,000
Raymond James & Associates, Inc.	225,000	33,750
H.C. Wainwright & Co., LLC	75,000	11,250
Total	1,500,000	225,000

Schedule I

SCHEDULE II

Issuer Free Writing Prospectuses included in the Pricing Disclosure Package

None.

Schedule II

SCHEDULE III

1. The Company is selling 1,500,000 shares of Common Stock.
2. The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional 225,000 shares of Common Stock.
3. The public offering price per share of Common Stock shall be \$50.00.

Schedule III

SCHEDULE IV

Signatories to Lock-Up Agreements

Robert E. Brown, Jr.
Stephen P. Carey
Chad Gassert
Ori Gutwerg
Thomas J. Haughey
James G. Marken
Christopher Mutz
Nikhil Lalwani
David B. Nash
Antonio R. Pera
Muthusamy Shanmugam
Jeanne A. Thoma
Patrick D. Walsh
Meridian Venture Partners II, L.P.

Schedule IV

SCHEDULE V

Written Testing-the-Waters Communications

None.

Schedule V

EXHIBIT A

Subsidiaries

ANIP Acquisition Company
ANI Pharmaceuticals Canada Inc.

Exhibit A

EXHIBIT B

Form of Lock-Up Agreement

Guggenheim Securities, LLC
As Representative of the several
Underwriters referred to below

c/o Guggenheim Securities, LLC
330 Madison Avenue, 14th Floor
New York, New York 10017

ANI Pharmaceuticals, Inc. - Lock-Up Agreement

Ladies and Gentlemen:

This letter agreement (this "Agreement") relates to the proposed public offering (the "Offering") by ANI Pharmaceuticals, Inc., a Delaware corporation (the "Company"), of its common stock, \$0.0001 par value (the "Stock"), pursuant to an Underwriting Agreement (the "Underwriting Agreement") to be entered into between the Company and Guggenheim Securities, LLC ("Guggenheim"), as representative of the several underwriters named therein (the "Underwriters").

In order to induce you and the other Underwriters to underwrite the Offering, the undersigned hereby agrees that, without the prior written consent of Guggenheim, during the period from the date hereof until 90 days from the date of the final prospectus supplement for the Offering (the "Lock-Up Period"), the undersigned (a) will not, directly or indirectly, offer, sell, agree to offer or sell, solicit offers to purchase, grant any call option or purchase any put option with respect to, pledge, borrow or otherwise dispose of, any Relevant Security (as defined below), and (b) will not establish or increase any "put equivalent position" or liquidate or decrease any "call equivalent position" with respect to any Relevant Security (in each case within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations promulgated thereunder), or otherwise enter into any swap, derivative or other transaction or arrangement that transfers to another, in whole or in part, any economic consequence of ownership of a Relevant Security, whether or not such transaction is to be settled by delivery of Relevant Securities, other securities, cash or other consideration. As used herein "Relevant Security" means the Stock, any other equity security of the Company or any of its subsidiaries and any security convertible into, or exercisable or exchangeable for, any Stock or other such equity security.

The foregoing restrictions in this Agreement shall not apply to:

- a) the transfer of Relevant Securities (i) as a bona fide gift or gifts, (ii) by will, other testamentary document or intestate succession, (iii) to a Family Member (as defined below), (iv) to a trust for the direct or indirect benefit of the undersigned and/or one or more Family Members, (v) by operation of law, including pursuant to a domestic order, divorce settlement, divorce decree, separation agreement or pursuant to an order of a court of competent jurisdiction enforcing such agreement, (vi) to a charitable trust, (vii) to a corporation, limited liability company, partnership, or other entity wholly owned by the undersigned and/or one or more Family Members or (viii) to the undersigned's affiliates or to any investment fund or other entity controlled or managed by, controlling or managing, or under common control with, the undersigned;

- b) the transfer of Relevant Securities (i) as forfeitures to satisfy tax withholding obligations of the undersigned in connection with the vesting or exercise of equity awards by the undersigned existing as of the date of the final prospectus supplement and described or incorporated by reference in the final prospectus supplement, (ii) pursuant to a net exercise or cashless exercise (to satisfy exercise price or related withholding obligations) by the undersigned of outstanding equity awards existing as of the date of the final prospectus supplement and described or incorporated by reference in the final prospectus supplement, provided that any shares of Stock acquired upon the net exercise or cashless exercise of equity awards described in this clause (b) shall be subject to the restrictions set forth in this Agreement;
- c) distributions of Relevant Securities to partners, members or stockholders of the undersigned;
- d) transactions relating to Relevant Securities acquired in the Offering or in open market transactions after the closing of the Offering; and
- e) the transfer of Relevant Securities pursuant to a bona fide third-party tender offer for all outstanding shares of the Company, merger, consolidation or other similar transaction made to all holders of the Company's securities involving a change of control 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 Relevant Securities in connection with such transaction, or vote any Relevant Securities in favor of any transaction), provided that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such securities held by the undersigned shall remain subject to the provisions of this Agreement.

It shall be a further condition to any transfer or distribution pursuant to the preceding clauses (a), (b), (c), or (d) that no public disclosure or filing by any party (donor, donee, transferor or transferee) under the Exchange Act, or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a filing on Form 5 made after the expiration of the Lock-Up Period or the filing of a required Schedule 13F or 13G or, with respect to clause (b), any filings required under Section 16 of the Exchange Act, provided that each such Section 16 filings shall clearly indicate in the footnotes thereto the nature of the transfer).

It shall be a condition to any transfer or distribution pursuant to each of the preceding clauses (a) or (c) that (x) any such transfer shall not involve a disposition for value and (y) each resulting transferee or donee of Relevant Securities executes and delivers to you an agreement satisfactory to you in which such transferee agrees to be bound by the terms of this Agreement for the remainder of the Lock-Up Period.

For purposes of this Agreement, the term “Family Member” shall mean any relationship by blood, domestic partnership, marriage or adoption not more remote than first cousin.

In addition, the restrictions described in this Agreement shall not apply to the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act, provided that no transfers occur under such plan during the Lock-Up Period and no public announcement or filing shall be required or voluntarily made by any person in connection therewith other than general disclosure in Company periodic reports to the effect that the Company directors and officers may enter into such trading plans from time to time.

Furthermore, the undersigned may, without the prior written consent of Guggenheim, (i) exercise any outstanding warrant, or any option to purchase shares of Common Stock granted under any stock incentive plan or stock purchase plan of the Company, provided that the underlying shares of Common Stock shall continue to be subject to the restrictions on transfer set forth in this Letter Agreement and (ii) transfer or surrender to the Company shares of Common Stock pursuant to any contractual arrangement that provides the Company with an option to repurchase such shares of Common Stock in connection with the termination of the undersigned’s employment or other service relationship with the Company, or pursuant to a right of first refusal with respect to transfers of such shares of Common Stock or other securities, provided that any filing under Section 16 of the Exchange Act shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause (ii) and no other public announcement shall be required or shall be made voluntarily in connection with such transfer or surrender.

The undersigned hereby authorizes the Company during the Lock-Up Period to cause any transfer agent for the Relevant Securities to decline to transfer, and to note stop transfer restrictions on the stock register and other records relating to, Relevant Securities for which the undersigned is the record holder and, in the case of Relevant Securities for which the undersigned is the beneficial but not the record holder, agrees during the Lock-Up Period to cause the record holder to cause the relevant transfer agent to decline to transfer, and to note stop transfer restrictions on the stock register and other records relating to, such Relevant Securities. The undersigned hereby further agrees that, without the prior written consent of Guggenheim, during the Lock-Up Period the undersigned (x) will not file or participate in the filing with the U.S. Securities and Exchange Commission (the “SEC”) of any registration statement, or circulate or participate in the circulation of any preliminary or final prospectus supplement or other disclosure document with respect to any proposed offering or sale of a Relevant Security and (y) will not exercise any rights the undersigned may have to require registration with the SEC of any proposed offering or sale of a Relevant Security; provided, however, that such restrictions shall not apply to any Relevant Securities issued pursuant to (i) Agreement and Plan of Merger dated March 8, 2021 by and among ANI Pharmaceuticals, Inc., Nile Merger Sub LLC, Novitium Pharma LLC, Esjay LLC, Chali Properties, LLC, Chad Gassert, Muthusamy Shanmugam and Thorappadi Vijayaraj and Shareholder Representative Services LLC or (ii) Equity Commitment and Investment Agreement dated March 8, 2021 by and between ANI Pharmaceuticals, Inc. and Ampersand 2020 Limited Partnership or any rights of the undersigned related thereto.

Exhibit B

It is understood that, if (i) the Company notifies the Underwriters that it does not intend to proceed with the Offering, (ii) the Underwriting Agreement does not become effective, (iii) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Stock, or (iv) the closing of the Offering pursuant to the Underwriting Agreement has not occurred by November 30, 2021, the undersigned will be released from its obligations under this Agreement.

The undersigned understands that the Company and the Underwriters will proceed with the Offering in reliance on this Agreement.

Whether or not the Offering actually occurs depends on a number of factors, including market conditions. Any Offering will only be made pursuant to the Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Agreement and that this Agreement constitutes the legal, valid and binding obligation of the undersigned, enforceable in accordance with its terms. Upon request, the undersigned will execute any additional documents necessary in connection with enforcement hereof. Any obligations of the undersigned shall be binding upon the successors and assigns of the undersigned from the date first above written.

Exhibit B

This Agreement shall be governed by and construed in accordance with the laws of the State of New York. Delivery of a signed copy of this Agreement by electronic or facsimile transmission shall be effective as delivery of the original hereof.

Very truly yours,

By: _____

Print Name: _____

Exhibit B



Orrick, Herrington & Sutcliffe LLP
The Orrick Building
405 Howard Street
San Francisco, CA 94105-2669
+1-415-773-5700
orrick.com

November 8, 2021

ANI Pharmaceuticals, Inc.
210 Main Street West
Baudette, Minnesota 56623

Re: 1,500,000 Shares of Common Stock of ANI Pharmaceuticals, Inc.

Ladies and Gentlemen:

We have acted as counsel for ANI Pharmaceuticals, Inc., a Delaware corporation (the "Company"), in connection with the offering by the Company of 1,500,000 shares of the Company's common stock, par value \$0.0001 (the "Shares"), pursuant to a registration statement on Form S-3 (Registration Statement No. 333-239771) (the "Registration Statement"), filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Act"), the prospectus dated July 17, 2020 (the "Base Prospectus"), and the prospectus supplement dated November 3, 2021, filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations of the Act (the "Prospectus Supplement"). The Base Prospectus and the Prospectus Supplement are collectively referred to as the "Prospectus." The Shares are to be sold by the Company in the manner described in the Registration Statement and the Prospectus. The Company is filing this opinion letter with the Commission on a Current Report on Form 8-K (the "Current Report").

In connection with this opinion, we have examined originals or copies, certified or otherwise identified to our satisfaction, of (i) the Restated Certificate of Incorporation of the Company, as amended through the date hereof, (ii) the Amended and Restated By-Laws of the Company, as amended through the date hereof, (iii) certain resolutions of the Board of Directors of the Company and its pricing committee relating to the issuance, sale and registration of the Shares, (iv) the Registration Statement, (v) the Prospectus, and (vi) such corporate records, agreements, documents and other instruments, and such certificates or comparable documents of public officials and of officers and representatives of the Company, and have made such inquiries of such officers and representatives, as we have deemed relevant and necessary or appropriate as a basis for the opinion set forth below.



November 8, 2021

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In our examination, we have assumed the legal capacity of all-natural persons, the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as facsimile, electronic, certified or photostatic copies, and the authenticity of the originals of such copies. In making our examination of documents executed or to be executed, we have assumed that the parties thereto, other than the Company, had or will have the power, corporate or other, to enter into and perform all obligations thereunder and have also assumed the due authorization by all requisite action, corporate or other, and the execution and delivery by such parties of such documents and the validity and binding effect thereof on such parties. As to any facts material to the opinions expressed herein that we did not independently establish or verify, we have relied upon statements and representations of officers and other representatives of the Company and others and of public officials.

Based on the foregoing and subject to the limitations, qualifications and assumptions set forth herein, we are of the opinion that the Shares have been duly authorized and, upon issuance, delivery and payment therefor in the manner contemplated by the Registration Statement and the Prospectus, will be validly issued, fully paid and non-assessable.

The opinion expressed herein is limited to the corporate laws of the State of Delaware and the federal laws of the United States of America, and we express no opinion as to the effect on the matters covered by this letter of the laws of any other jurisdictions.

We hereby consent to the filing of this opinion as an exhibit to Current Report and to reference to us under the caption "Legal Matters" in the Prospectus. In giving such consent, we do not hereby admit that we are included in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ Orrick, Herrington & Sutcliffe LLP

ORRICK, HERRINGTON & SUTCLIFFE LLP
