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): March 15, 2019

MATINAS BIOPHARMA HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38022**	**46-3011414**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

1545 Route 206 South, Suite 302 **Bedminster, New Jersey** *(Address of principal executive offices)*	**07921** *(Zip Code)*

Registrant's telephone number, including area code: **(908) 443-1860**

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

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

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

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

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

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

Emerging growth company [X]

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

Item 1.01. Entry into a Material Definitive Agreement.

On March 15, 2019, Matinas BioPharma Holdings, Inc. (the "Company") entered into an underwriting agreement (the "Underwriting Agreement") with BTIG, LLC, (the "Underwriter"), relating to the offering, issuance and sale of 27,272,727 shares (the "Shares") of the Company's common stock, par value $0.0001 (the "Common Stock"), at a price to the public of $1.10 per share (the "Offering"). The net proceeds to the Company from the Offering are expected to be approximately $27.8 million, after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. The Offering is expected to close on or about March 19, 2019, subject to customary closing conditions. Pursuant to the Underwriting Agreement, the Underwriter has a 30-day option to purchase up to 4,090,909 additional shares of Common Stock on the same terms as the Underwriters are purchasing the base number of shares.

The Offering is being made pursuant to the Company's effective registration statement on Form S-3 (File No. 333-217106) previously filed with and declared effective by the Securities and Exchange Commission (the "SEC") and a prospectus supplement and accompanying base prospectus filed with the SEC.

The Underwriting Agreement contains customary representations, warranties and agreements by the Company, 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 is not complete and is qualified in its entirety by reference to the full text of the Underwriting Agreement, a copy of which is filed as Exhibit 1.1 to this report and is incorporated by reference herein. A copy of the opinion of Lowenstein Sandler LLP relating to the legality of the issuance and sale of Shares in the Offering is attached as Exhibit 5.1 to this report.

Item 7.01. Regulation FD Disclosure.

On March 14, 2019, the Company issued a press release regarding the launch of the Offering. On March 15, 2019, the Company issued a press release announcing that it had priced the Offering. Copies of the press releases are furnished hereto as Exhibits 99.1 and 99.2, respectively, to this Current Report and incorporated herein by reference.

Item 8.01. Other Events.

The preliminary prospectus supplement used by the Company in connection with the Offering has updated business and risk factors sections, and the information in the following paragraph. The business and risk factors sections are attached hereto as Exhibits 99.3 and 99.4, respectively, and are incorporated by reference into this Item 8.01.

At December 31, 2018, the Company had approximately $13.0 million in cash and cash equivalents, including restricted cash. This amount is preliminary, unaudited and subject to the completion of the audit of the Company's consolidated financial statements as of and for the year ended December 31, 2018 (Audited 2018 Financial Statements). As a result, this amount may differ from the amount that will be reflected in the Audited 2018 Financial Statements. Additional information and disclosures are required for a more complete understanding of the Company's financial position and results of operations as of December 31, 2018.

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may involve risks and uncertainties, such as statements related to the anticipated closing of the Offering and the amount of proceeds expected from the Offering. The risks and uncertainties involved include the Company's ability to satisfy certain conditions to closing on a timely basis or at all, as well as other risks detailed from time to time in the Company's SEC filings, including in its annual filing on Form 10-K, as amended filed with the SEC on March 16, 2018, the preliminary prospectus supplement filed with the SEC on March 14, 2019, and the final prospectus supplement to be filed with the SEC.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description.
1.1	Underwriting Agreement, dated March 15, 2019, by and between Matinas BioPharma Holdings, Inc. and BTIG, LLC.
5.1	Opinion of Lowenstein Sandler LLP.
23.1	Consent of Lowenstein Sandler LLP (included in the opinion of Lowenstein Sandler LLP filed as Exhibit 5.1 hereto).
99.1	Press Release dated March 14, 2019
99.2	Press Release dated March 15, 2019
99.3	Business Section
99.4	Risk Factors Section

SIGNATURES

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

MATINAS BIOPHARMA HOLDINGS, INC.

Dated: March 15, 2019

By: */s/ Jerome D. Jabbour*
Name: Jerome D. Jabbour
Title: Chief Executive Officer

27,272,727 Shares

MATINAS BIOPHARMA HOLDINGS, INC.

Common Stock

UNDERWRITING AGREEMENT

March 15, 2019

BTIG, LLC
As Representative of the several Underwriters
600 Montgomery Street
San Francisco, California 94111

Dear Sirs:

1. *Introductory*. Matinas BioPharma Holdings, Inc., a Delaware corporation (the "Company"), proposes to sell, pursuant to the terms of this Agreement, to the several underwriters named in Schedule I hereto (the "Underwriters," or, each, an Underwriter"), an aggregate of 27,272,727 shares of the Company's common stock, $0.0001 par value per share (the "Common Stock"). The aggregate of 27,272,727 shares so proposed to be sold is hereinafter referred to as the "Firm Stock". The Company also proposes to sell to the Underwriters, upon the terms and conditions set forth in Section 3 hereof, up to an additional 4,090,909 shares of Common Stock (the "Optional Stock"). The Firm Stock and the Optional Stock are hereinafter collectively referred to as the "Stock". BTIG, LLC ("BTIG") is acting as representative of the several Underwriters and in such capacity is hereinafter referred to as the "Representative."

2. *Representations and Warranties of the Company.* The Company represents and warrants to the several Underwriters, as of the date hereof and as of each Closing Date (as defined below), and agrees with the several Underwriters, that:

(a) A registration statement of the Company on Form S-3 (File No. 333-217106) (including such amendments and supplements thereto as may have been filed before execution of this Agreement, the "Initial Registration Statement") in respect of the Stock has been filed with the Securities and Exchange Commission (the "Commission") pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"). The Company meets the requirements for use of Form S-3 under the Securities Act and the rules and regulations of the Commission thereunder (the "Rules and Regulations"). The Initial Registration Statement and any post-effective amendment thereto, excluding exhibits thereto, each in the form heretofore delivered to you as Representative of the other Underwriters, have been declared effective by the Commission in such form and meet the requirements of the Securities Act and the Rules and Regulations. The proposed offering of the Stock may be made pursuant to General Instruction I.B.1. of Form S-3. Other than (i) a registration statement, if any, increasing the size of the offering filed pursuant to Rule 462(b) under the Securities Act and the Rules and Regulations (a "Rule 462(b) Registration Statement") and (ii) the Prospectus (as defined below) contemplated by this Agreement to be filed pursuant to Rule 424(b) of the Rules and Regulations in accordance with Section 4(a) hereof and (iii) any Issuer Free Writing Prospectus (as defined below), no other document with respect to the offer and sale of the Stock has heretofore been filed with the Commission. No stop order suspending the effectiveness of the Initial Registration Statement, any post-effective amendment thereto or the Rule 462(b) Registration Statement, if any, has been issued and no proceeding for that purpose or pursuant to Section 8A of the Securities Act has been initiated or, to the knowledge of the Company, threatened by the Commission (any preliminary prospectus included in the Initial Registration Statement or filed with the Commission pursuant to Rule 424(a) of the Rules and Regulations is hereinafter called a "Preliminary Prospectus"). The various parts of the Initial Registration Statement and the Rule 462(b) Registration Statement, if any, in each case including all exhibits thereto and including the information contained in the Prospectus filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations and deemed by virtue of Rules 430A, 430B and 430C under the Securities Act to be part of the Initial Registration Statement at the time it became effective are hereinafter collectively called the "Registration Statement." The base prospectus included in the Initial Registration Statement at the time of effectiveness thereof (the "Base Prospectus"), as supplemented by the final prospectus supplement relating to the offer and sale of the Stock, in the form to be filed pursuant to and within the time limits described in Rule 424(b) under the Rules and Regulations, is hereinafter called the "Prospectus."

Any reference herein to any Registration Statement, Base Prospectus, Preliminary Prospectus or the Prospectus shall be deemed to refer to and include the documents incorporated by reference therein. Any reference to any amendment or supplement to any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include any documents filed after the date of such Preliminary Prospectus or the Prospectus under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and incorporated by reference in such Preliminary Prospectus or Prospectus, as the case may be. Any reference to any amendment to the Registration Statement shall be deemed to refer to and include any annual report of the Company filed pursuant to Section 13(a) or 15(d) of the Exchange Act after the date of this Agreement that is incorporated by reference in the Registration Statement.

(b) As of the Applicable Time (as defined below) and as of the Closing Date or the Option Closing Date (as defined below), as the case may be, neither (i) the General Use Free Writing Prospectus(es) (as defined below) issued at or prior to the Applicable Time, the Pricing Prospectus (as defined below) and the information included on Schedule II hereto, all considered together (collectively, the "General Disclosure Package"), (ii) any individual Limited Use Free Writing Prospectus (as defined below), nor (iii) any bona fide electronic road show (as defined in Rule 433(h)(5) of the Rules and Regulations that has been made available without restriction to any person), when considered together with the General Disclosure Package, included or will include any untrue statement of a material fact or omitted or will 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; *provided, however*, that the Company makes no representations or warranties as to information contained in or omitted from the Pricing Prospectus or any Issuer Free Writing Prospectus, in reliance upon, and in conformity with, written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information as defined in Section 17. As used in this paragraph (b) and elsewhere in this Agreement:

"Applicable Time" means 8:00 a.m., New York time, on the date of this Agreement or such other time as agreed to by the Company and the Representative.

"Pricing Prospectus" means the Preliminary Prospectus, if any, and the Base Prospectus, each as amended and supplemented immediately prior to the Applicable Time, including any document incorporated by reference therein and any prospectus supplement deemed to be a part thereof.

"Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 of the Rules and Regulations relating to the Stock in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) of the Rules and Regulations.

"General Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is identified on Schedule III to this Agreement.

"Limited Use Free Writing Prospectuses" means any Issuer Free Writing Prospectus that is not a General Use Free Writing Prospectus.

(c) No order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus relating to the proposed offering of the Stock has been issued by the Commission, and no proceeding for that purpose or pursuant to Section 8A of the Securities Act has been instituted or, to the knowledge of the Company, threatened by the Commission, and each Preliminary Prospectus, at the time of filing thereof, conformed in all material respects to the requirements of the Securities Act and the Rules and Regulations, and did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided, however*, that the Company makes no representations or warranties as to information contained in or omitted from any Preliminary Prospectus, in reliance upon, and in conformity with, written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information as defined in Section 17.

(d) At the respective time the Registration Statement and any amendments thereto became or become effective as to the Underwriters, at the date of this Agreement and at each Closing Date, each Registration Statement and any amendments thereto conformed and will conform in all material respects to the requirements of the Securities Act and the Rules and Regulations and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading; and the Prospectus and any amendments or supplements thereto, at the time the Prospectus or any amendment or supplement thereto was issued and at each Closing Date, conformed and will conform in all material respects to the requirements of the Securities Act and the Rules and Regulations and did not and will 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 light of the circumstances under which they were made, not misleading; *provided*, *however*, that the foregoing representations and warranties in this paragraph (d) shall not apply to information contained in or omitted from the Registration Statement or the Prospectus, or any amendment or supplement thereto, in reliance upon, and in conformity with, written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information (as defined in Section 17).

(e) Each Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Stock or until any earlier date that the Company notified or notifies the Representative as described in Section 4(f), did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, Pricing Prospectus or the Prospectus, including any document incorporated by reference therein and any prospectus supplement deemed to be a part thereof that has not been superseded or modified, or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus in reliance upon, and in conformity with, written information furnished to the Company by the Representative by or on behalf of the Underwriters specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information.

(f) The documents incorporated by reference in the Prospectus, when they became effective or were filed with the Commission, as the case may be, conformed in all material respects to the requirements of the Securities Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder and none of such documents contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; and any further documents so filed and incorporated by reference in the Prospectus, when such documents are filed with Commission, will conform in all material respects to the requirements of the Securities Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(g) The Company has not, directly or indirectly, distributed and will not distribute any offering material in connection with the proposed offering and sale of the Stock other than any Preliminary Prospectus, the Prospectus and other materials, if any, permitted under the Securities Act and consistent with Section 4(b) below. The Company will file with the Commission all Issuer Free Writing Prospectuses (other than a "road show," as described in Rule 433(d)(8) of the Rules and Regulations) in the time and manner required under Rules 163(b)(2) and 433(d) of the Rules and Regulations.

(h) At the time of filing the Initial Registration Statement and any post-effective amendments thereto, and at the date hereof, the Company was not, and the Company currently is not, an "ineligible issuer," as defined in Rule 405 of the Rules and Regulations.

(i) Each of the Company and its subsidiaries (as defined in Section 15) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation or other entity, as applicable, in good standing (to the extent such concept is recognized in the applicable jurisdiction) under the laws of their respective jurisdictions of incorporation, are duly qualified to do business and are in good standing (to the extent such concept is recognized in the applicable jurisdiction) as foreign corporations in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification, and have all power and authority necessary to own or hold their respective properties and to conduct the businesses in which they are engaged, except where the failure to so qualify or have such power or authority would not have, singularly or in the aggregate, a material adverse effect on the condition (financial or otherwise), results of operations, assets, business or prospects of the Company and its subsidiaries taken as a whole (a "Material Adverse Effect"). The Company owns or controls, directly or indirectly, only the following corporations, partnerships, limited liability partnerships, limited liability companies, associations or other entities: Matinas BioPharma, Inc. and Matinas BioPharma Nanotechnologies, Inc.

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

(k) The Stock to be issued and sold by the Company to the Underwriters hereunder has been duly and validly authorized and, when issued and delivered by the Company against payment therefor as provided herein, will be duly and validly issued, fully paid and nonassessable and free of any preemptive or similar rights and will conform to the description thereof contained in the General Disclosure Package and the Prospectus.

(l) The Company has an authorized capitalization as set forth under the heading "Description of Capital Stock" in the Prospectus, and all of the issued shares of capital stock of the Company have been duly and validly authorized and issued, are fully paid and non-assessable, have been issued in compliance with applicable federal and state securities laws, and conform in all material respects to the description thereof contained in the General Disclosure Package and the Prospectus. All of the Company's options, warrants and other rights to purchase or exchange any securities for shares of the Company's capital stock have been duly authorized and validly issued and were issued in compliance with applicable federal and state securities laws. None of the outstanding shares of Common Stock was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. As of the date set forth in the General Disclosure Package, there were no authorized or outstanding shares of capital stock, options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or its subsidiaries other than those described above or accurately described in the General Disclosure Package. Since such date, except as described in the General Disclosure Package, the Company has not issued any securities other than Common Stock issued pursuant to the exercise of warrants or upon the exercise of stock options or other awards outstanding under the Company's stock option plans, options or other securities granted or issued pursuant to the Company's existing equity compensation plans or other plans, and the issuance of Common Stock pursuant to employee stock purchase plans. The description of the Company's equity compensation plans, employee stock purchase plan and other stock plans or arrangements, and the options or other rights granted thereunder, as described in the General Disclosure Package and the Prospectus, accurately and fairly present in all material respects the information required to be shown with respect to the equity compensation plans, employee stock purchase plan and such other plans and arrangements, and the options and rights granted thereunder.

(m) All the outstanding shares of capital stock of the subsidiaries of the Company have been duly authorized and validly issued, are fully paid and nonassessable and, except to the extent set forth in the General Disclosure Package or the Prospectus, are owned by the Company directly or indirectly through one or more wholly-owned subsidiaries, free and clear of any claim, lien, encumbrance, security interest, restriction upon voting or transfer or any other claim of any third party.

(n) The execution, delivery and performance of this Agreement by the Company, the issuance and sale of the Stock by the Company and the consummation of the transactions contemplated hereby will not (with or without notice or lapse of time or both) (i) conflict with or result in a breach or violation of any of the terms or provisions of, constitute a default or a Debt Repayment Triggering Event (as defined below) under, give rise to any right of termination or other right or the cancellation or acceleration of any right or obligation or loss of a benefit under, or give rise to the creation or imposition of any lien, encumbrance, security interest, claim or charge upon any property or assets of the Company or its subsidiaries pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, (ii) result in any violation of the provisions of the certificate of incorporation or by-laws (or analogous governing instruments, as applicable) of the Company or its subsidiaries, or (iii) result in a violation of any law, statute, rule, regulation, judgment, order or decree of any court or governmental agency or body, domestic or foreign, having jurisdiction over the Company or its subsidiaries or any of their properties or assets"). A "Debt Repayment Triggering Event" means any event or condition that gives, or with the giving of notice or lapse of time would give the holder of any note, debenture or other evidence of material indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or its subsidiaries.

(o) Except for the registration of the Stock under the Securities Act and such consents, approvals, authorizations, registrations or qualifications as may be required under the Exchange Act and applicable state or foreign securities laws, the Financial Industry Regulatory Authority ("FINRA") and the NYSE American LLC in connection with the purchase and distribution of the Stock by the Underwriters and the listing of the Stock on the NYSE American LLC or those otherwise obtained, no consent, approval, authorization or order of, or filing, qualification or registration (each an "Authorization") with, any court, governmental or non-governmental agency or body, foreign or domestic having jurisdiction over the Company or any of its properties or assets which has not been made, obtained or taken and is not in full force and effect, is required for the execution, delivery and performance of this Agreement by the Company, the offer or sale of the Stock or the consummation of the transactions contemplated hereby. All corporate approvals necessary for the Company to consummate the transactions contemplated by this Agreement have been obtained and are in effect.

(p) EisnerAmper LLP, who have audited certain financial statements included or incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus, and have audited the Company's internal control over financial reporting, is an independent registered public accounting firm within the meaning of Article 2-01 of Regulation S-X and the Public Company Accounting Oversight Board (United States) (the "PCAOB").

(q) The financial statements, together with the related notes, included or incorporated by reference in the General Disclosure Package, the Prospectus and in each Registration Statement fairly present in all material respects the financial position and the results of operations and changes in financial position of the Company and its consolidated subsidiaries at the respective dates or for the respective periods therein specified. Such statements and related notes have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") applied on a consistent basis throughout the periods involved except as may be set forth in the related notes included or incorporated by reference in the General Disclosure Package. The financial statements, together with the related notes included or incorporated by reference in the General Disclosure Package and the Prospectus comply as to form in all material respects with Regulation S-X. No other financial statements or exhibits are required by Regulation S-X to be described, included or incorporated by reference in the Registration Statement, the General Disclosure Package or the Prospectus. There is no pro forma or as adjusted financial information which is required to be included in the Registration Statement, the General Disclosure Package, and the Prospectus or a document incorporated by reference therein in accordance with Regulation S-X that is not so included.

(r) Neither the Company nor its subsidiaries has sustained, since the date of the latest audited financial statements included or incorporated by reference in the General Disclosure Package, any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth or contemplated in the General Disclosure Package; and, since such date, there has not been any change in the capital stock (other than option and other securities grants in the ordinary course of business pursuant to the Company's current plans and stock option and warrant exercises and stock repurchases) or long-term debt of the Company or its subsidiaries, or any material adverse changes, or any development involving a prospective material adverse change, in or affecting the business, assets, management, financial position, prospects, stockholders' equity or results of operations of the Company and its subsidiaries taken as a whole, in each case other than as set forth or contemplated in the General Disclosure Package.

(s) Except as set forth in the General Disclosure Package, there is no legal or governmental proceeding to which the Company or any of its subsidiaries is a party or of which any property or assets of the Company or any of its subsidiaries is the subject, including any proceeding before the United States Food and Drug Administration of the U.S. Department of Health and Human Services ("FDA") or comparable federal, state, local or foreign governmental bodies (it being understood that the interactions between the Company and the FDA and such comparable governmental bodies relating to the testing, clinical development, manufacture and product approval process for its products shall not be deemed proceedings for purposes of this representation), which is required to be described in the Registration Statement, the General Disclosure Package or the Prospectus or a document incorporated by reference therein and is not described therein, or which, singularly or in the aggregate, if determined adversely to the Company or its subsidiaries, would reasonably be expected to have a Material Adverse Effect; and to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or threatened by others. The Company is in compliance with all applicable federal, state, local and foreign laws, regulations, orders and decrees governing its business as currently conducted, or any other federal, state or foreign agencies or bodies engaged in the regulation of medical devices, except where noncompliance would not, singly or in the aggregate, reasonably be expected to have a Material Adverse Effect. All preclinical and clinical studies conducted by or on behalf of the Company and submitted to regulatory authorities to support approval for commercialization of the Company's products have been conducted by the Company, or to the Company's knowledge by third parties, in compliance with all applicable federal, state or foreign laws, rules, orders and regulations, except for such failure or failures to be in compliance as would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect.

(t) Neither the Company nor any of its subsidiaries is in (i) violation of its charter or by-laws (or analogous governing instrument, as applicable), (ii) default in any respect, and no event has occurred which, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement, lease 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) violation in any respect of any law, ordinance, governmental rule, regulation or court order, decree or judgment to which it or its property or assets may be subject (including, without limitation, those administrated by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) except, in the case of clauses (ii) and (iii) of this paragraph (r), for any violations or defaults which, singularly or in the aggregate, would not reasonably be expected to have a Material Adverse Effect.

(u) The Company and its subsidiaries possess all licenses, certificates, authorizations and permits issued by, and have made all declarations and filings with, the appropriate local, state, federal or foreign regulatory agencies or bodies (including, without limitation, those administered by the FDA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA) which are required for the ownership of their respective properties or the conduct of their respective businesses as described in the General Disclosure Package and the Prospectus (collectively, the "Governmental Permits") except where any failures to possess or make the same, singularly or in the aggregate, would not reasonably be expected to have a Material Adverse Effect. The Company and its subsidiaries are in compliance with all such Governmental Permits; all such Governmental Permits are valid and in full force and effect, except where the validity or failure to be in full force and effect would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. Neither the Company nor its subsidiaries has received written notification of any revocation, suspension, termination or invalidation (or proceedings related thereto) of any such Governmental Permit and to the knowledge of the Company, no event has occurred that allows or results in, or after notice or lapse of time or both would allow or result in, revocation, suspension, termination or invalidation (or proceedings related thereto) of any such Governmental Permit. The studies, tests and preclinical or clinical trials conducted by or on behalf of the Company that are described in the General Disclosure Package and the Prospectus (the "Company Studies and Trials") were and, if still pending, are being, conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional scientific standards; the descriptions of the results of the Company Studies and Trials contained in the General Disclosure Package and Prospectus are accurate in all material respects; and the Company has not received any written notices or correspondence from the FDA or any foreign, state or local governmental body exercising comparable authority requiring the termination or suspension of any Company Studies or Trials which termination or suspension would reasonably be expected to have a Material Adverse Effect.

(v) Neither the Company nor any of its subsidiaries is, and, after giving effect to the proposed offering of the Stock and the application of the proceeds thereof as described in the General Disclosure Package and the Prospectus, will be required to register as an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder.

(w) Neither the Company nor, to the knowledge of the Company, any of its officers, directors or affiliates has taken or will take, directly or indirectly, any action designed or intended to stabilize or manipulate the price of any security of the Company, or which caused or resulted in, or which might in the future reasonably be expected to cause or result in, stabilization or manipulation of the price of any security of the Company.

(x) Except as described in the General Disclosure Package and the Prospectus, the Company and its subsidiaries own or possess the right to use, or has a reasonable basis to believe that it can acquire on reasonable terms the right to use, all (i) patents, trademarks, service marks, service mark registrations, Internet domain name registrations, copyrights, licenses, trade secret rights ("Intellectual Property Rights") and (ii) inventions, software, works of authorships, trade marks, service marks, trade names, databases, formulae, know how, Internet domain names and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or procedures) (collectively, "Intellectual Property Assets") necessary to conduct its businesses as currently conducted and described in the General Disclosure Package and the Prospectus, and which the failure to own or have such rights would, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any opinion from its legal counsel concluding that any activities of their respective businesses infringe, misappropriate, or otherwise violate, valid and enforceable Intellectual Property Rights of any other person, and except as described in the General Disclosure Package and the Prospectus, have not received written notice of any challenge, which is to their knowledge still pending, by any other person to the rights of the Company and its subsidiaries with respect to any Intellectual Property Rights or Intellectual Property Assets owned or used by the Company and its subsidiaries, which if determined adversely against the Company would, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Except as described in the General Disclosure Package and the Prospectus, to the knowledge of the Company, the business of the Company and its subsidiaries as now conducted does not give rise to any infringement of, any misappropriation of, or other violation of, any valid and enforceable Intellectual Property Rights of any other person. To the knowledge of the Company, all licenses for the use of the Intellectual Property Rights described in the General Disclosure Package and the Prospectus are valid, binding upon, and enforceable by or against the parties thereto in accordance to its terms. The Company and its subsidiaries have complied in all material respects with, and are not in breach nor have received any written notice of any asserted or threatened claim of breach of any Intellectual Property license, and the Company has no knowledge of any breach by any other person to any Intellectual Property license. Except as described in the General Disclosure Package, no claim has been made against the Company nor its subsidiaries alleging the infringement by the Company or its subsidiaries of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person, except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The Company and its subsidiaries have taken reasonable steps to protect, maintain and safeguard its Intellectual Property Rights, including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require any further consent of any other person in respect of, the right of the Company and its subsidiaries to own, use, or hold for use any of the Intellectual Property Rights as owned, used or held for use in the conduct of the business as currently conducted. The Company and its subsidiaries have taken reasonable actions to obtain ownership of works of authorship and inventions made by its employees, consultants and contractors during the time they were employed by or under contract with the Company and its subsidiaries and which relate to the business of the Company, or licenses to use such works of authorship or inventions.

(y) The Company and its subsidiaries have valid title to, or have valid rights to lease or otherwise use, all items of real or personal property which are material to the business of the Company and its subsidiaries taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that do not, singularly or in the aggregate, materially affect the value of such property and do not materially interfere with the use made of such property by the Company and its subsidiaries; and all of the leases and subleases material to the business of the Company and its subsidiaries, considered as one enterprise, and under which the Company or its subsidiaries holds properties described in the General Disclosure Package and the Prospectus, are in full force and effect, and neither the Company nor its subsidiaries has received any written notice of any claim (i) adverse to the rights of the Company or any of its subsidiaries under any of the leases or subleases mentioned above, or (ii) affecting or questioning the rights of the Company or its subsidiaries to the continued possession of the leased or subleased premises under any such lease or sublease, which in each of clauses (i) and (ii) would reasonably be expected to result in a Material Adverse Effect.

(z) There is (A) no significant unfair labor practice complaint pending against the Company or its subsidiaries, nor to the knowledge of the Company, threatened against it or its subsidiaries, before the National Labor Relations Board, any state or local labor relation board or any foreign labor relations board, and no significant grievance or significant arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company or its subsidiaries, or, to the knowledge of the Company, threatened against the Company and (B) no labor disturbance by the employees of the Company or its subsidiaries exists or, to the Company's knowledge, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or its subsidiaries's principal suppliers, manufacturers, customers or contractors, that would reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company or any subsidiaries plans to terminate employment with the Company or any such subsidiaries.

(aa) No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("ERISA"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "Code")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur with respect to any employee benefit plan of the Company or its subsidiaries which would, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. Each employee benefit plan of the Company or its subsidiaries is in compliance in all material respects with applicable law, including ERISA and the Code. The Company and its subsidiaries have not incurred and would not reasonably be expected to incur liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company or its subsidiaries would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified in all material respects, and nothing has occurred, whether by action or by failure to act, which could, singularly or in the aggregate, cause the loss of such qualification.

(bb) The Company and its subsidiaries are in compliance with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to the Company's business ("Environmental Laws"), except where the failure to comply would not, singularly or in the aggregate, have a Material Adverse Effect. There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company or its subsidiaries (or, to the Company's knowledge, any other entity for whose acts or omissions the Company or any of its subsidiaries is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company or its subsidiaries, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability except for any violation or liability which would not reasonably be expected to have, singularly or in the aggregate with all such violations and liabilities, a Material Adverse Effect; and there has been no disposal, discharge, emission or other release of any kind onto such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances with respect to which the Company or its subsidiaries has knowledge, except for any such disposal, discharge, emission, or other release of any kind that would not reasonably be expected to have, singularly or in the aggregate with all such discharges and other releases, a Material Adverse Effect.

(cc) The Company and its subsidiaries each (i) have timely filed all necessary federal, state, local and foreign tax returns (or timely filed applicable extensions therefor) that have been required to be filed, (ii) have paid all federal, state, local and foreign taxes, assessments, governmental or other charges due and payable for which it is liable, including, without limitation, all sales and use taxes and all taxes which the Company or its any of its subsidiaries is obligated to withhold from amounts owing to employees, creditors and third parties, and (iii) do not have any tax deficiency or claims outstanding or assessed or, to its knowledge, proposed against any of them, except those, in each of the cases described in clauses (i), (ii) and (iii) of this paragraph (cc), that would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(dd) The Company and its subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as is customary for companies engaged in similar businesses in similar industries. Neither the Company nor its subsidiaries has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect. All policies of insurance owned by the Company or its subsidiaries are, to the Company's knowledge, in full force and effect and the Company and its subsidiaries are in compliance in all material respects with the terms of such policies. Neither the Company nor its subsidiaries has received written notice from any insurer, agent of such insurer or the broker of the Company or its subsidiaries that any material capital improvements or any other material expenditures (other than premium payments) are required or necessary to be made in order to continue such insurance.

(ee) The Company maintains a system of internal control over financial reporting (as such term is defined in Rule 13a-15 of the General Rules and Regulations under the Exchange Act (the "Exchange Act Rules")) 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 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; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company maintains effective internal control over financial reporting (as such term is defined in Rule 13a-15 of the Exchange Act Rules). Except as described in the General Disclosure Package, since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (B) 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. The Company's internal control over financial reporting is, or upon consummation of the offering of the Stock will be, overseen by the Audit Committee of the Board of Directors of the Company (the "Audit Committee") in accordance with the applicable Exchange Act Rules. The Company maintains disclosure controls and procedures (as such is defined in Rule 13a-15 of the Exchange Act Rules) that comply with the applicable requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company and its subsidiaries is accumulated and communicated to the Company's management, including the Company's principal executive officer and principal financial officer by others within those entities, and such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established.

(ff) The minute books of the Company and its subsidiaries that would be a "significant subsidiaries" within the meaning of Rule 1-02(w) of Regulation S-X have been made available to the Underwriters and counsel for the Underwriters, and such books (i) contain a summary of all meetings and actions of the board of directors (including each board committee) and stockholders of the Company and its subsidiaries (or analogous governing bodies and interest holders, as applicable) since January 1, 2016 through the date of the latest meeting and action, and (ii) accurately in all material respects reflect all transactions authorized in such minutes.

(gg) There is no franchise agreement, lease, contract, or other agreement or document required by the Securities Act or by the Rules and Regulations to be described in the General Disclosure Package and in the Prospectus or any document incorporated by reference therein or to be filed as an exhibit to the Registration Statement or a document incorporated by reference therein which is not so described or filed therein as required, except where the failure to timely file any such franchise, agreement, lease, contract, or other agreement or document as an exhibit to the Registration Statement or a document incorporated by reference therein would not reasonably be expected to result in a Material Adverse Effect; and all descriptions of any such franchise agreements, leases, contracts, or other agreements or documents contained in the General Disclosure Package and in the Prospectus or in a document incorporated by reference therein are accurate and complete descriptions of such documents in all material respects to the extent required by the Securities Act and by the Rules and Regulations. Other than as described in the General Disclosure Package and the Prospectus, no such franchise agreement, lease, contract or other agreement has been suspended or terminated for convenience or default by the Company, its subsidiaries or any of the other parties thereto, and neither the Company nor its subsidiaries has received notice of and the Company does not have knowledge of any such pending or threatened suspension or termination except for such suspensions or terminations or pending or threatened suspensions or terminations that would not reasonably be expected to, singularly or in the aggregate, have a Material Adverse Effect.

(hh) No relationship, direct or indirect, exists between or among the Company or its subsidiaries on the one hand, and the directors, officers, stockholders (or analogous interest holders), customers or suppliers of the Company and its subsidiaries or any of their affiliates on the other hand, which is required to be described in the General Disclosure Package and the Prospectus or a document incorporated by reference therein and which is not so described.

(ii) No person or entity has the right to require registration of shares of Common Stock or other securities of the Company or its subsidiaries because of the filing or effectiveness of the Registration Statement or otherwise, except for persons and entities who have expressly waived such right in writing or who have been given timely and proper written notice and have failed to exercise such right within the time or times required under the terms and conditions of such right.

(jj) The Company does not own any "margin securities" as that term is defined in Regulation U of the Board of Governors of the Federal Reserve System (the "Federal Reserve Board"), and none of the proceeds of the sale of the Stock will be used, directly or indirectly, for the purpose of purchasing or carrying any margin security, for the purpose of reducing or retiring any indebtedness which was originally incurred to purchase or carry any margin security or for any other purpose which might cause any of the Stock to be considered a "purpose credit" within the meanings of Regulation T, U or X of the Federal Reserve Board.

(kk) The Company is not a party to any contract, agreement or understanding with any person that would give rise to a valid claim against the Company or the Underwriters for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Stock or any transaction contemplated by this Agreement, the Registration Statement, the General Disclosure Package or the Prospectus, other than any fee due to any financial advisor retained by the Company in connection with the transactions contemplated by this Agreement.

(ll) No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in either the General Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(mm) The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act and is listed on the NYSE American LLC, and except as described in the General Disclosure Package, the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the NYSE American LLC, nor has the Company received any notification that the Commission or FINRA is contemplating terminating such registration or listing. The Company has filed with the NYSE American LLC a notification of the listing of the Stock on the NYSE American LLC.

(nn) The Company is in compliance in all material respects with all applicable provisions of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof (the "Sarbanes-Oxley Act").

(oo) The Company is in compliance in all material respects with all applicable corporate governance requirements set forth in the rules and regulations of the NYSE American LLC.

(pp) Neither the Company nor its subsidiaries nor, to the Company's knowledge, any employee or agent of the Company or its subsidiaries, has (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to foreign or domestic political parties or campaigns from corporate funds, (iii) violated any provision of the Foreign Corrupt Practices Act of 1977, as amended or (iv) made any other unlawful payment.

(qq) There are no transactions, arrangements or other relationships between and/or among the Company, any of its affiliates (as such term is defined in Rule 405 of the Rules and Regulations) and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity that could reasonably be expected to materially affect the Company's liquidity or the availability of or requirements for its capital resources, which transaction, arrangement or other relationship is required to be described in the General Disclosure Package and the Prospectus or a document incorporated by reference therein and that has not been described as required.

(rr) There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees of indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of their respective immediate family members, except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus.

(ss) The statistical and market related data included in the Registration Statement, the General Disclosure Package and the Prospectus, if any, are based on or derived from sources that the Company believes to be reliable and accurate in all material respects, and such data agree in all material respects with the sources from which they are derived.

(tt) The operations of the Company and its subsidiaries are and have been conducted at all times in compliance in all material respects with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (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 its subsidiaries with respect to the Money Laundering Laws is pending, or to the Company's knowledge, threatened.

(uu) Neither the Company nor its subsidiaries nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and, to the Company's knowledge, the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiaries, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(vv) Neither the Company nor, to the Company's knowledge, any of its affiliates (within the meaning of FINRA Rule 5121(f) directly or indirectly controls, is controlled by, or is under common control with, or is an associated person (within the meaning of Article I, Section 1(ee) of the By-laws of FINRA) of, any member firm of FINRA.

3. *Purchase, Sale and Delivery of Offered Securities*. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to sell to the Underwriters, and the Underwriters agree, severally and not jointly, to purchase from the Company the respective number of shares of Firm Stock set forth opposite the names of the Underwriters in Schedule I hereto.

The purchase price per share to be paid by the Underwriters to the Company for the Firm Stock will be $1.034 per share (the "Purchase Price").

The Company will deliver the Firm Stock to the Representative for the respective accounts of the several Underwriters through the facilities of The Depository Trust Company, issued in such names and in such denominations as the Representative may direct by notice in writing to the Company given at or prior to 12:00 Noon, New York time, on the second (2nd) full business day preceding the Closing Date, against payment of the aggregate purchase price therefor, as determined pursuant to the immediately preceding paragraph, by wire transfer in federal (same day) funds to an account at a bank acceptable to the Representative payable to the order of the Company at the offices of Goodwin Procter LLP, The New York Times Building, 620 Eighth Avenue, New York, New York. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligations of each Underwriter hereunder. The time and date of the delivery and closing shall be at 10:00 A.M., New York time, on March 19, 2019, in accordance with Rule 15c6-1 of the Exchange Act. The time and date of such payment and delivery are herein referred to as the "Closing Date". The Closing Date and the location of delivery of, and the form of payment for, the Firm Stock may be varied by agreement between the Company and the Representative.

For the purpose of covering any over-allotments in connection with the distribution and sale of the Firm Stock as contemplated by the Prospectus, the Underwriters may purchase all or less than all of the Optional Stock, provided that such shares of Optional Stock shall be purchased from the Company for the account of each Underwriter in the same proportion as the number of shares of Firm Stock set forth opposite such Underwriter's name on Schedule I bears to the total number of shares of Firm Stock (subject to adjustment by the Representative to eliminate fractions). The price per share to be paid for the Optional Stock shall be the Purchase Price. The Company agrees to sell to the Underwriters the number of shares of Optional Stock specified in the written notice delivered by the Representative to the Company described below and the Underwriters agree, severally and not jointly, to purchase such shares of Optional Stock. The option granted hereby may be exercised as to all or any part of the Optional Stock (subject to the proviso in the first sentence of this paragraph) at any time, and from time to time, not more than thirty (30) days subsequent to the date of this Agreement. No Optional Stock shall be sold and delivered unless the Firm Stock previously has been, or simultaneously is, sold and delivered. The right to purchase the Optional Stock or any portion thereof may be surrendered and terminated at any time prior to the exercise of such right upon notice by the Representative to the Company.

The option granted hereby may be exercised by written notice being given to the Company by the Representative setting forth the number of shares of the Optional Stock to be purchased by the Underwriters and the date and time for delivery of and payment for the Optional Stock. Each date and time for delivery of and payment for the Optional Stock (which may be the Closing Date, but not earlier) is herein called the "Option Closing Date" and, with respect to any Optional Stock delivered pursuant to a written notice given after the Closing Date, shall in no event be earlier than three (3) business days nor later than five (5) business days after such written notice is given. The Option Closing Date and the Closing Date are herein called the "Closing Dates."

The Company will deliver the Optional Stock to the Representative for the respective accounts of the several Underwriters through the facilities of The Depository Trust Company or, at the election of the Representative, issued in such names and in such denominations as the Representative may direct by notice in writing to the Company given at or prior to 12:00 Noon, New York time, on the second (2nd) full business day preceding the Option Closing Date against payment of the aggregate Purchase Price therefor by wire transfer in federal (same day) funds to an account at a bank acceptable to the Representative payable to the order of the Company at the offices of Goodwin Procter LLP, The New York Times Building, 620 Eighth Avenue, New York, New York. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligations of each Underwriter hereunder. The Option Closing Date and the location of delivery of, and the form of payment for, the Optional Stock may be varied by agreement between the Company and the Representative.

The several Underwriters propose to offer the Stock for sale upon the terms and conditions set forth in the Prospectus.

4. Further Agreements Of The Company. The Company agrees with the several Underwriters:

(a) To prepare the Rule 462(b) Registration Statement, if necessary, in a form approved by the Representative and file such Rule 462(b) Registration Statement with the Commission by 10:00 P.M., New York time, on the date hereof, 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 Rules and Regulations; to prepare the Prospectus in a form approved by the Representative containing information previously omitted at the time of effectiveness of the Registration Statement in reliance on Rules 430A, 430B or 430C of the Rules and Regulations and to file such Prospectus pursuant to Rule 424(b) of the Rules and Regulations not later than the second business (2^{nd}) day following the execution and delivery of this Agreement or, if applicable, such earlier time as may be required by Rule 430A of the Rules and Regulations; to notify the Representative promptly of the Company's intention to file or prepare any supplement or amendment to any Registration Statement or to the Prospectus and to make no amendment or supplement to the Registration Statement, the General Disclosure Package or to the Prospectus to which the Representative shall reasonably object by notice to the Company after a reasonable period to review; to advise the Representative, promptly after it receives notice thereof, of the time when any amendment to any Registration Statement has been filed or becomes effective or any supplement to the General Disclosure Package or the Prospectus or any amended Prospectus has been filed and to furnish the Representative with copies thereof; to file promptly all material required to be filed by the Company with the Commission pursuant to Rules 433(d) or 163(b)(2) of the Rules and Regulations, as the case may be; to file promptly all reports and any definitive proxy or information statements 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 subsequent to the date of the Prospectus and for so long as the delivery of a prospectus (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations) is required in connection with the offering or sale of the Stock; to advise the Representative, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus, of the suspension of the qualification of the Stock for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the Registration Statement, the General Disclosure Package or the Prospectus or for additional information; and, in the event of the issuance of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus or suspending any such qualification, and promptly to use its best efforts to obtain the withdrawal of such order.

(b) The Company represents and agrees that, unless it obtains the prior written consent of the Representative, and each Underwriter represents and agrees that, unless it obtains the prior written consent of the Company and the Representative, it has not made and will not, other than the Final Term Sheet (defined below), if any, prepared and filed pursuant to Section 4(c) hereof, make any offer relating to the Stock that would constitute a "free writing prospectus" as defined in Rule 405 of the Rules and Regulations (each, a "Permitted Free Writing Prospectus"); *provided* that the prior written consent of the Representative hereto shall be deemed to have been given in respect of the Issuer Free Writing Prospectuses included in Schedule III hereto. The Company represents that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus, comply with the requirements of Rules 164 and 433 of the Rules and Regulations applicable to any Issuer Free Writing Prospectus, including the requirements relating to timely filing with the Commission, legending and record keeping and will not take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) of the Rules and Regulations a free writing prospectus prepared by or on behalf of such Underwriter that such Underwriter otherwise would not have been required to file thereunder. The Company consents to the use by any Underwriter of a free writing prospectus that (a) is not an "issuer free writing prospectus" as defined in Rule 433 of the Rules and Regulations, and (b) contains only (i) information describing the preliminary terms of the Stock or its offering and (ii) information that described the final terms of the Stock or its offering and that is included in the Final Term Sheet, if any, contemplated in Section 4(c) below.

(c) At the request of the Representative, the Company will prepare a final term sheet (the " Final Term Sheet ") reflecting the final terms of the Stock, in form and substance reasonably satisfactory to the Representative, and shall file such Final Term Sheet as an Issuer Free Writing Prospectus pursuant to Rule 433 of the Rules and Regulations prior to the close of business two (2) business days after the date hereof; *provided* that the Company shall provide the Representative with copies of any such Final Term Sheet within a reasonable amount of time prior to such proposed filing and will not use or file any such document to which the Representative or counsel to the Underwriters shall reasonably object.

(d) If at any time prior to the date when a prospectus relating to the Stock is required to be delivered (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations) any event occurs or condition exists as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact, or omit to state any material fact necessary to make the statements therein, in light of the circumstances under which they were made when the Prospectus is delivered (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations), not misleading, or if it is necessary at any time to amend or supplement any Registration Statement or the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus to comply with the Securities Act or the Exchange Act, the Company will promptly notify the Representative thereof and upon its request will prepare an appropriate amendment or supplement or upon its request make an appropriate filing pursuant to Section 13 or 14 of the Exchange Act in form and substance reasonably satisfactory to the Representative which will correct such statement or omission or effect such compliance and will use its reasonable best efforts to have any amendment to any Registration Statement promptly declared effective. The Company will furnish without charge to each Underwriter and to any dealer in securities as many copies as the Representative may from time to time reasonably request of such amendment or supplement. In case any Underwriter is required to deliver a prospectus (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations) relating to the Stock, the Company upon the request of the Representative and at the expense of such Underwriter will prepare promptly an amended or supplemented Prospectus as may be necessary to permit compliance with the requirements of Section 10(a)(3) of the Securities Act and deliver to such Underwriter as many copies as such Underwriter may reasonably request of such amended or supplemented Prospectus complying with Section 10(a)(3) of the Securities Act.

(e) If the General Disclosure Package is being used to solicit offers to buy the Stock at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur as a result of which, in the judgment of the Company or in the reasonable opinion of the Underwriters, it becomes necessary to amend or supplement the General Disclosure Package in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, or to make the statements therein not conflict with the information contained or incorporated by reference in the Registration Statement then on file and not superseded or modified, or if it is necessary at any time to amend or supplement the General Disclosure Package to comply with any law, the Company promptly will either (i) prepare, file with the Commission (if required) and furnish to the Underwriters and any dealers an appropriate amendment or supplement to the General Disclosure Package or (ii) prepare and file with the Commission an appropriate filing under the Exchange Act which shall be incorporated by reference in the General Disclosure Package so that the General Disclosure Package as so amended or supplemented will not, in the light of the circumstances under which they were made, be misleading or conflict with the Registration Statement then on file, or so that the General Disclosure Package will comply with law.

(f) If at any time following issuance of an Issuer Free Writing Prospectus in connection with the proposed offering there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or will conflict with the information contained in the Registration Statement, Pricing Prospectus or Prospectus, including any document incorporated by reference therein and any prospectus supplement deemed to be a part thereof and not superseded or modified or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, the Company has promptly notified or will promptly notify the Representative so that any use of the Issuer Free Writing Prospectus may cease until it is amended or supplemented and has promptly amended or will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission. The foregoing sentence does not apply to statement in or omissions from any free writing prospectus in reliance upon, and in conformity with, written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information (as defined in Section 17).

(g) To the extent not available on the Commission's Electronic Data Gathering, Analysis and Retrieval system or any successor system ("EDGAR"), upon the request of the Representative, to furnish promptly to the Representative and to counsel for the Underwriters a signed copy of each of the Registration Statement as originally filed with the Commission, and of each amendment thereto filed with the Commission, including all consents and exhibits filed therewith.

(h) Upon the request of the Representative, to the extent not available on EDGAR, to deliver promptly to the Representative in New York City such number of the following documents as the Representative shall reasonably request: (i) conformed copies of the Registration Statement as originally filed with the Commission (in each case excluding exhibits), (ii) each Preliminary Prospectus, (iii) any Issuer Free Writing Prospectus, (iv) the Prospectus (the delivery of the documents referred to in clauses (i), (ii), (iii) and (iv) of this paragraph (h) to be made not later than 10:00 A.M., New York time, on the business day following the execution and delivery of this Agreement), (v) conformed copies of any amendment to the Registration Statement (excluding exhibits), (vi) any amendment or supplement to the General Disclosure Package or the Prospectus (the delivery of the documents referred to in clauses (v) and (vi) of this paragraph (h) to be made not later than 10:00 A.M., New York City time, on the business day following the date of such amendment or supplement) and (vii) any document incorporated by reference in the General Disclosure Package or the Prospectus (excluding exhibits thereto) (the delivery of the documents referred to in clause (vii) of this paragraph (h) to be made not later than 10:00 A.M., New York City time, on the business day following the date of such document).

(i) To make generally available to its stockholders as soon as practicable, but in any event not later than sixteen (16) months after the effective date of the Registration Statement (as defined in Rule 158(c) of the Rules and Regulations), an earnings statement of the Company and its subsidiaries (which need not be audited) complying with Section 11(a) of the Securities Act and the Rules and Regulations (including, at the option of the Company, Rule 158).

(j) To take promptly from time to time such actions as the Representative may reasonably request to qualify the Stock for offering and sale under the securities or Blue Sky laws of such jurisdictions (domestic or foreign) as the Representative may designate and to continue such qualifications in effect, and to comply with such laws, for so long as required to permit the offer and sale of Stock in such jurisdictions; *provided* that the Company and its subsidiaries shall not be obligated to qualify as foreign corporations in any jurisdiction in which they are not so qualified or to file a general consent to service of process in any jurisdiction.

(k) Upon request, during the period of three (3) years from the date hereof, to the extent not available on EDGAR, to deliver to each of the Underwriters, (i) as soon as they are available, copies of all reports or other communications furnished to stockholders generally, and (ii) as soon as they are available, copies of any reports and financial statements furnished or filed with the Commission or any national securities exchange on which the Common Stock is listed. However, so long as the Company is subject to the reporting requirements of either Section 13 or Section 15(d) of the Exchange Act and is timely filing reports with the Commission on EDGAR, it is not required to furnish such reports or statements to the Underwriters.

(l) That the Company will not, for a period of ninety (90) days from the date of this Agreement, (the "Lock-Up Period") without the prior written consent of BTIG, directly or indirectly offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, other than the Company's sale of the Stock hereunder or pursuant to or in connection with (i) employee benefit plans, equity compensation plans or other compensation plans as in existence on the date hereof and as described in the General Disclosure Package, (ii) currently outstanding shares of preferred stock, options, warrants or rights, and (iii) the consummation by the Company of a strategic partnership, joint venture, collaboration or acquisition or license of any business products or technology, provided that (A) the aggregate number of shares of Common Stock that may be issued pursuant to this clause (iii) shall not exceed five percent (5%) of the number of shares of Common Stock outstanding immediately after the closing of the sale of the Stock to the Underwriters pursuant to this Agreement, and (B) this clause (iii) shall not be available unless each recipient of such Common Stock shall have, prior to, or concurrently with, the entry of a definitive agreement in connection with the applicable partnership, joint venture, collaboration, acquisition or license, agreed in writing not to sell, offer, dispose of or otherwise transfer any such Common Stock (or engage in any short sales of Common Stock prior to the issuance of such Common Stock) during the remainder, if any, of the Lock-Up Period without the prior written consent of BTIG (which consent may be withheld at BTIG's sole discretion). The Company will cause each person and entity listed in Exhibit B to furnish to BTIG, prior to the Closing Date, a letter, substantially in the form of Exhibit A hereto. The Company also agrees that during such period, other than for the sale of the Stock hereunder, the Company will not file any registration statement, preliminary prospectus or prospectus, or any amendment or supplement thereto, under the Securities Act for any such transaction or which registers, or offers for sale, Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock; provided, however, the foregoing limitation shall not apply to filing of any registration statement on Form S-8 in respect of any equity compensation plans or arrangements maintained by the Company. Notwithstanding anything to the contrary contained in this paragraph, the Company shall be permitted to keep in effect the Controlled Equity Offering^{SM} Sales Agreement, dated as of April 28, 2017, by and between the Company and Cantor Fitzgerald & Co. (the "Cantor Agreement"); provided that pursuant to the terms of this paragraph, no sales under the Cantor Agreement may be made during the Lock-Up Period.

(m) To supply the Representative with copies of all correspondence to and from, and all documents issued to and by, the Commission in connection with the registration of the Stock under the Securities Act or any of the Registration Statement, any Preliminary Prospectus or the Prospectus, or any amendment or supplement thereto or document incorporated by reference therein.

(n) Prior to the Closing Date, not to issue any press release or other communication directly or indirectly or hold any press conference with respect to the Company, its condition, financial or otherwise, or earnings, business affairs or business prospects (except for routine oral marketing communications in the ordinary course of business and consistent with the past practices of the Company and of which the Representative is notified), without the prior consent of the Representative, which consent shall not be unreasonably withheld, delayed or conditioned, unless in the judgment of the Company and its counsel, and after notification to the Representative, such press release or communication is required by law.

(o) Until BTIG shall have notified the Company of the completion of the resale of the Stock, that the Company will not, and will use its reasonable best efforts to cause its affiliated purchasers (as defined in Regulation M under the Exchange Act) not to, either alone or with one or more other persons, bid for or purchase, for any account in which it or any of its affiliated purchasers has a beneficial interest, any Stock, or attempt to induce any person to purchase any Stock; and not to, and to use its reasonable best efforts to cause its affiliated purchasers not to, make bids or purchase for the purpose of creating actual, or apparent, active trading in or of raising the price of the Stock.

(p) To at all times comply in all material respects with applicable provisions of the Sarbanes-Oxley Act in effect from time to time.

(q) To maintain, at its expense, a registrar and transfer agent for the Stock.

(r) To apply the net proceeds from the sale of the Stock as set forth in the Registration Statement, the General Disclosure Package and the Prospectus under the heading "Use of Proceeds," and, except as disclosed in the General Disclosure Package, the Company does not intend to use any of the proceeds from the sale of the Stock hereunder to repay any outstanding debt owed to any affiliate of any Underwriter.

(s) To use its reasonable efforts to list, subject to notice of issuance, and to maintain the listing of the Stock on the NYSE American LLC.

(t) To use its reasonable efforts to do and perform all things required to be done or performed under this Agreement by the Company prior to each Closing Date and to satisfy all conditions precedent to the delivery of the Stock.

5 . *Payment of Expenses*. The Company agrees to pay, or reimburse if paid by the Underwriters, whether or not the transactions contemplated hereby are consummated or this Agreement is terminated: (a) the costs incident to the authorization, issuance, sale, preparation and delivery of the Stock and any taxes payable in that connection; (b) the costs incident to the registration of the Stock under the Securities Act; (c) the costs incident to the preparation, printing and distribution of the Registration Statement, the Base Prospectus, any Preliminary Prospectus, any Issuer Free Writing Prospectus, the General Disclosure Package, the Prospectus, any amendments, supplements and exhibits thereto or any document incorporated by reference therein and the costs of printing, reproducing and distributing this Agreement and any closing documents by mail, telex or other means of communications; (d) the reasonable and documented fees and expenses (including related fees and expenses of counsel for the Underwriters) incurred in connection with securing any required review by FINRA of the terms of the sale of the Stock and any filings made with FINRA, if applicable (such fees and expenses not to exceed $15,000); (e) any applicable listing or other fees; (f) the reasonable and documented fees and expenses (including related fees and expenses of counsel to the Underwriters) of qualifying the Stock under the securities laws of the several jurisdictions as provided in Section 4(j) and of preparing, printing and distributing wrappers, Blue Sky Memoranda and Legal Investment Surveys (such fees and expenses not to exceed $10,000); (g) the cost of preparing and printing stock certificates; (h) all fees and expenses of the registrar and transfer agent of the Stock; (i) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Stock, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics; and (j) all other costs and expenses of the Company incident to the offering of the Stock or the performance of the obligations of the Company under this Agreement (including, without limitation, the fees and expenses of the Company's counsel and the Company's independent accountants). Except to the extent otherwise provided in this Section 5 and in Sections 9 and 10, the Underwriters shall pay their own costs and expenses, including the fees and expenses of their counsel and any transfer taxes on the resale of any Stock by them.

6. *Conditions of Underwriters' Obligations.* The respective obligations of the several Underwriters hereunder are subject to the accuracy, when made and as of the Applicable Time and on the Closing Date, of the representations and warranties of the Company contained herein, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations hereunder, and to each of the following additional terms and conditions:

(a) The Registration Statement has become effective under the Securities Act, and no stop order suspending the effectiveness of any Registration Statement or any part thereof, preventing or suspending the use of any Base Prospectus, any Preliminary Prospectus, the Prospectus or any Permitted Free Writing Prospectus or any part thereof shall have been issued and no proceedings for that purpose or pursuant to Section 8A under the Securities Act shall have been initiated or threatened by the Commission, and all requests for additional information on the part of the Commission (to be included or incorporated by reference in the Registration Statement or the Prospectus or otherwise) shall have been complied with to the reasonable satisfaction of the Representative; the Rule 462(b) Registration Statement, if any, each Issuer Free Writing Prospectus and the Prospectus shall have been filed with, the Commission within the applicable time period prescribed for such filing by, and in compliance with, the Rules and Regulations and in accordance with Section 4(a), and the Rule 462(b) Registration Statement, if any, shall have become effective immediately upon its filing with the Commission; and FINRA shall have raised no objection to the fairness and reasonableness of the terms of this Agreement or the transactions contemplated hereby.

(b) None of the Underwriters shall have discovered and disclosed to the Company on or prior to the Closing Date that any Registration Statement or any amendment or supplement thereto contains an untrue statement of a fact that, in the opinion of counsel for the Underwriters, is material or omits to state any fact that, 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, or that the General Disclosure Package, any Issuer Free Writing Prospectus or the Prospectus or any amendment or supplement thereto contains an untrue statement of fact that, in the opinion of such counsel, is material or omits to state any fact which, in the opinion of such counsel, is material and is necessary in order to make the statements, in the light of the circumstances in which they were made, not misleading.

(c) All corporate proceedings incident to the authorization, form and validity of each of this Agreement, the Stock, the Registration Statement, the General Disclosure Package, each Issuer Free Writing Prospectus and the Prospectus and the transactions contemplated hereby shall be reasonably satisfactory in all material respects to counsel for the Underwriters, and the Company shall have furnished to such counsel all documents and information that they may reasonably request to enable them to pass upon such matters.

(d) Lowenstein Sandler LLP, counsel to the Company, shall have furnished to the Representative such counsel's written opinion and negative assurance statement, each addressed to the Representative and dated the Closing Date, each in form and substance reasonably satisfactory to the Representative.

(e) Each of MH2 Technology Law Group LLP and Arent Fox LLP, counsel for the Company with respect to intellectual property matters, shall have furnished to the Representative such counsel's written opinion, in form and substance reasonably satisfactory to the Representative.

(f) The Representative shall have received from Goodwin Procter LLP, counsel for the Underwriters, such counsel's written opinion and negative assurance statement, dated the Closing Date, with respect to such matters as the Underwriters may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

(g) At the time of the execution of this Agreement, the Representative shall have received from EisnerAmper LLP a letter, addressed to the Underwriters, executed and dated such date, in form and substance satisfactory to the Representative (i) confirming that they are an independent registered accounting firm with respect to the Company within the meaning of the Securities Act and the Rules and Regulations and PCAOB and (ii) stating the conclusions and findings of such firm, of the type ordinarily included in accountants' "comfort letters" to underwriters, with respect to the financial statements and certain financial information contained or incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus.

(h) On the effective date of any post-effective amendment to any Registration Statement and on the Closing Date, the Representative shall have received a letter (the "bring-down letter") from EisnerAmper LLP addressed to the Underwriters and dated the Closing Date confirming, as of the date of the bring-down letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the General Disclosure Package and the Prospectus, as the case may be, as of a date not more than three (3) business days prior to the date of the bring-down letter), the conclusions and findings of such firm, of the type ordinarily included in accountants' "comfort letters" to underwriters, with respect to the financial information and other matters covered by its letter delivered to the Representative concurrently with the execution of this Agreement pursuant to paragraph (f) of this Section 6.

(i) The Company shall have furnished to the Representative a certificate, dated the Closing Date, of its Chief Executive Officer or President and its Chief Financial Officer stating in their respective capacities as officers of the Company on behalf of the Company that (i) no stop order suspending the effectiveness of the Registration Statement (including, for avoidance of doubt, any Rule 462(b) Registration Statement), or any post-effective amendment thereto, shall be in effect and no proceedings for such purpose shall have been instituted or, to their knowledge, threatened by the Commission, (ii) for the period from and including the date of this Agreement through and including such Closing Date, there has not occurred any Material Adverse Change, (iii) to their knowledge, as of the Closing Date, the representations and warranties of the Company in this Agreement are true and correct in all material respects and the Company has complied in all material respects with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date, and (iv) there has not been, subsequent to the date of the most recent audited financial statements included or incorporated by reference in the General Disclosure Package, any material adverse change in the financial position or results of operations of the Company and its subsidiaries taken as a whole, or any change or development that, singularly or in the aggregate, would reasonably be expected to involve a material adverse change in or affecting the condition (financial or otherwise), results of operations, business, assets or prospects of the Company and its subsidiaries taken as a whole, except as set forth in the Prospectus.

(j) Since the date of the latest audited financial statements included in the General Disclosure Package or incorporated by reference in the General Disclosure Package as of the date hereof, (i) neither the Company nor its subsidiaries shall have sustained any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth in the General Disclosure Package, and (ii) there shall not have been any change in the capital stock (other than issuance of options or other securities in the ordinary course of business and pursuant to the Company's equity incentive or stock purchase plans described in the General Disclosure Package and the Prospectus or Common Stock issued pursuant to the exercise of warrants or upon the exercise of stock options previously outstanding under the Company's stock option plans and the issuance of Common Stock pursuant to employee stock purchase plans) or long-term debt of the Company or its subsidiaries, or any change, or any development involving a prospective change, in or affecting the business, general affairs, management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries, otherwise than as set forth in the General Disclosure Package, the effect of which, in any such case described in clause (i) or (ii) of this paragraph (i) is, in the judgment of the Representative, so material and adverse as to make it impracticable or inadvisable to proceed with the sale or delivery of the Stock on the terms and in the manner contemplated in the General Disclosure Package.

(k) No action shall have been taken and no law, statute, rule, regulation or order shall have been enacted, adopted or issued by any governmental agency or body which would prevent the issuance or sale of the Stock or materially and adversely affect or potentially materially and adversely affect the business or operations of the Company or its subsidiaries; and no injunction, restraining order or order of any other nature by any federal or state court of competent jurisdiction shall have been issued which would prevent the issuance or sale of the Stock or materially and adversely affect or potentially materially and adversely affect the business or operations of the Company and its subsidiaries.

(l) Subsequent to the execution and delivery of this Agreement there shall not have occurred any of the following: (i) trading in securities generally on the New York Stock Exchange, Nasdaq Global Market or the NYSE American LLC or in the over-the-counter market, or trading in any securities of the Company on any exchange or in the over-the-counter market, shall have been suspended or materially limited, or minimum or maximum prices or maximum range for prices shall have been established on any such exchange or such market by the Commission, by such exchange or market or by any other regulatory body or governmental authority having jurisdiction, (ii) a banking moratorium shall have been declared by Federal or state authorities or a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States, (iii) the United States shall have become engaged in hostilities, or the subject of an act of terrorism, or there shall have been an outbreak of or escalation in hostilities involving the United States, or there shall have been a declaration of a national emergency or war by the United States or (iv) there shall have occurred such a material adverse change in general economic, political or financial conditions (or the effect of international conditions on the financial markets in the United States shall be such) as to make it, in the judgment of the Representative, impracticable or inadvisable to proceed with the sale or delivery of the Stock on the terms and in the manner contemplated in the General Disclosure Package and the Prospectus.

(m) The Company shall have filed an Additional Listing Application with the NYSE American LLC and shall have received no objection thereto from the NYSE American LLC.

(n) The Representative shall have received on and as of the Closing Date satisfactory evidence of the good standing of the Company in the State of Delaware, in writing or any standard form of telecommunication from the appropriate Governmental Authorities of such jurisdiction.

(o) The Representative shall have received the written agreements, substantially in the form of Exhibit A hereto, of the persons listed in Exhibit B to this Agreement.

(p) The Company shall have furnished to the Underwriters a Secretary's Certificate of the Company, in form and substance reasonably satisfactory to counsel for the Underwriters and customary for the type of offering contemplated by this Agreement.

(q) The Company shall have furnished to the Representative a Certificate of the Chief Financial Officer of the Company, in form and substance reasonably satisfactory to counsel for the Underwriters.

(r) On or prior to the Closing Date, the Company shall have furnished to the Representative such further certificates and documents as the Representative may reasonably request.

All opinions, letters, evidence and certificates mentioned above or elsewhere in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in form and substance reasonably satisfactory to counsel for the Underwriters.

7. *Indemnification and Contribution.*

(a) The Company shall indemnify and hold harmless each Underwriter, its directors, officers, managers, members, employees, representatives and agents 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 (collectively the "Underwriter Indemnified Parties," and each an "Underwriter Indemnified Party") against any loss, claim, damage, expense or liability whatsoever (or any action, investigation or proceeding in respect thereof), joint or several, to which such Underwriter Indemnified Party may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, expense, liability, action, investigation or proceeding arises out of or is based upon (A) any untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" that is used in connection with the offering and sale of the Stock by, or with the approval of, the Company filed or required to be filed pursuant to Rule 433(d) of the Rules and Regulations, any Registration Statement or the Prospectus, or in any amendment or supplement thereto or document incorporated by reference therein, or (B) the omission or alleged omission to state in any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" that is used in connection with the offering and sale of the Stock by, or with the approval of, the Company filed or required to be filed pursuant to Rule 433(d) of the Rules and Regulations, any Registration Statement or the Prospectus, or in any amendment or supplement thereto or document incorporated by reference therein, a material fact required to be stated therein or necessary to make the statements therein in light of (other than in the case of any Registration Statement) the circumstances under which they are made not misleading, or (C) any breach of the representations and warranties of the Company contained herein or the failure of the Company to perform its obligations hereunder or pursuant to any law, and shall reimburse each Underwriter Indemnified Party promptly upon demand for any legal fees or other expenses reasonably incurred by that Underwriter Indemnified Party in connection with investigating, or preparing to defend, or defending against, or appearing as a third party witness in respect of, or otherwise incurred in connection with, any such loss, claim, damage, expense, liability, action, investigation or proceeding, as such fees and expenses are incurred; *provided*, *however*, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage, expense or liability arises out of or is based upon an untrue statement or alleged untrue statement in, or omission or alleged omission from any Preliminary Prospectus, any Registration Statement or the Prospectus, or any such amendment or supplement thereto, or any Issuer Free Writing Prospectus made in reliance upon and in conformity with written information furnished to the Company through the Representative by or on behalf of any Underwriter specifically for use therein, which information the parties hereto agree is limited to the Underwriters' Information (as defined in Section 17).

The indemnity agreement in this Section 7(a) is not exclusive and is in addition to each other liability which the Company might have under this Agreement or otherwise, and shall not limit any rights or remedies which may otherwise be available under this Agreement, at law or in equity to any Underwriter Indemnified Party.

(b) Each Underwriter, severally and not jointly, shall indemnify and hold harmless the Company and its directors, its officers who signed the Registration Statement 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 (collectively the "Company Indemnified Parties" and each a "Company Indemnified Party") against any loss, claim, damage, expense or liability whatsoever (or any action, investigation or proceeding in respect thereof), joint or several, to which such Company Indemnified Party may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, expense, liability, action, investigation or proceeding arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" filed or required to be filed pursuant to Rule 433(d) of the Rules and Regulations, any Registration Statement or the Prospectus, or in any amendment or supplement thereto, or (ii) the omission or alleged omission to state in any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" filed or required to be filed pursuant to Rule 433(d) of the Rules and Regulations, any Registration Statement or the Prospectus, or in any amendment or supplement thereto, a material fact required to be stated therein or necessary to make the statements therein in light of (other than in the case of any Registration Statement) the circumstances under which they are made not misleading, but in each case only to the extent that the untrue statement or alleged untrue statement or omission or alleged omission was made in reliance upon and in conformity with written information furnished to the Company through the Representative by or on behalf of that Underwriter specifically for use therein, which information the parties hereto agree is limited to the Underwriters' Information as defined in Section 17, and shall reimburse the Company Indemnified Parties promptly on demand for any legal or other expenses reasonably incurred by such party in connection with investigating or preparing to defend or defending against or appearing as third party witness in connection with any such loss, claim, damage, liability, action, investigation or proceeding, as such fees and expenses are incurred. This indemnity agreement is not exclusive and is in addition to each other liability which the Underwriters might otherwise have and shall not limit any rights or remedies which may otherwise be available under this Agreement, at law or in equity to the Company Indemnified Parties.

(c) Promptly after receipt by an indemnified party under this Section 7 of notice of the commencement of any action, the indemnified party shall, if a claim in respect thereof is to be made against an indemnifying party under this Section 7, notify such indemnifying party in writing of the commencement of that action; *provided, however,* that the failure to notify the indemnifying party shall not relieve it from any liability which it may have under this Section 7 except to the extent it has been materially prejudiced by such failure; and, *provided, further,* that the failure to notify an indemnifying party shall not relieve it from any liability which it may have to an indemnified party otherwise than under this Section 7. If any such action shall be brought against an indemnified party, and it shall notify the indemnifying party thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it wishes, jointly with any other similarly notified indemnifying party, to assume the defense of such action with counsel reasonably satisfactory to the indemnified party (which counsel shall not, except with the written consent of the indemnified party, be counsel to the indemnifying party). After notice from the indemnifying party to the indemnified party of its election to assume the defense of such action, except as provided herein, the indemnifying party shall not be liable to the indemnified party under Section 7 for any legal or other expenses subsequently incurred by the indemnified party in connection with the defense of such action other than reasonable costs of investigation; *provided, however,* that any indemnified party shall have the right to employ separate counsel in any such action and to participate in the defense of such action but the fees and expenses of such counsel (other than reasonable costs of investigation) shall be at the expense of such indemnified party unless (i) the employment thereof has been specifically authorized in writing by the Company in the case of a claim for indemnification under Section 7(a) or the Representative in the case of a claim for indemnification under Section 7(b), (ii) such indemnified party shall have been advised by its counsel that there may be one or more legal defenses available to it which are different from or additional to those available to the indemnifying party, or (iii) the indemnifying party has failed to assume the defense of such action and employ counsel reasonably satisfactory to the indemnified party within a reasonable period of time after notice of the commencement of the action or the indemnifying party does not diligently defend the action after assumption of the defense, in which case, if such indemnified party notifies the indemnifying party in writing that it elects to employ separate counsel at the expense of the indemnifying party, the indemnifying party shall not have the right to assume the defense of (or, in the case of a failure to diligently defend the action after assumption of the defense, to continue to defend) such action on behalf of such indemnified party and the indemnifying party shall be responsible for legal or other expenses subsequently incurred by such indemnified party in connection with the defense of such action; *provided*, *however*, that the indemnifying party shall not, in connection with any one such action or separate but substantially similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances, be liable for the reasonable fees and expenses of more than one separate firm of attorneys at any time for all such indemnified parties (in addition to any local counsel), which firm shall be designated in writing by the Representative if the indemnified parties under this Section 7 consist of any Underwriter Indemnified Party or by the Company if the indemnified parties under this Section 7 consist of any Company Indemnified Parties. Subject to this Section 7(c), the amount payable by an indemnifying party under Section 7 shall include, but not be limited to, (x) reasonable legal fees and expenses of counsel to the indemnified party and any other expenses in investigating, or preparing to defend or defending against, or appearing as a third party witness in respect of, or otherwise incurred in connection with, any action, investigation, proceeding or claim, and (y) all amounts paid in settlement of any of the foregoing. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of judgment with respect to any pending or threatened action or any claim whatsoever, in respect of which indemnification or contribution could be sought under this Section 7 (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party in form and substance reasonably satisfactory to such indemnified party from all liability arising out of such action or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party. Subject to the provisions of the following sentence, no indemnifying party shall be liable for settlement of any pending or threatened action or any claim whatsoever that is effected without its written consent (which consent shall not be unreasonably withheld or delayed), but if settled with its written consent, if its consent has been unreasonably withheld or delayed or if there be a judgment for the plaintiff in any such matter, the indemnifying party agrees to indemnify and hold harmless any indemnified party from and against any loss or liability by reason of such settlement or judgment. In addition, if at any time an indemnified party shall have requested that an indemnifying party reimburse the indemnified party for reasonable fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 8(a) effected without its written consent if (i) such settlement is entered into more than forty-five (45) days after receipt by such indemnifying party of the request for reimbursement, (ii) such indemnifying party shall have received notice of the terms of such settlement at least thirty (30) days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(d) If the indemnification provided for in this Section 7 is unavailable or insufficient to hold harmless an indemnified party under Section 7(a) or 7(b), then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid, payable or otherwise incurred by such indemnified party as a result of such loss, claim, damage, expense or liability (or any action, investigation or proceeding in respect thereof), as incurred, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering of the Stock, or (ii) if the allocation provided by clause (i) of this Section 7(d) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) of this Section 7(d) but also the relative fault of the Company on the one hand and the Underwriters on the other with respect to the statements, omissions, acts or failures to act which resulted in such loss, claim, damage, expense or liability (or any action, investigation or proceeding in respect thereof) as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other with respect to such offering shall be deemed to be in the same proportion as the total net proceeds from the offering of the Stock purchased under this Agreement (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters with respect to the Stock purchased under this Agreement, in each case as set forth in the table on the cover page of the Prospectus. The relative fault of the Company on the one hand and the Underwriters on the other 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 on the one hand or the Underwriters on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement, omission, act or failure to act; *provided* that the parties hereto agree that the written information furnished to the Company through the Representative by or on behalf of the Underwriters for use in the Preliminary Prospectus, any Registration Statement or the Prospectus, or in any amendment or supplement thereto, consists solely of the Underwriters' Information as defined in Section 17.

(e) The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to Section 7(d) above were to be determined by pro rata allocation or by any other method of allocation which does not take into account the equitable considerations referred to Section 7(d) above. The amount paid or payable by an indemnified party as a result of the loss, claim, damage, expense, liability, action, investigation or proceeding referred to in Section 7(d) above shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating, preparing to defend or defending against or appearing as a third party witness in respect of, or otherwise incurred in connection with, any such loss, claim, damage, expense, liability, action, investigation or proceeding. Notwithstanding the provisions of this Section 7, no Underwriters shall be required to contribute any amount in excess of the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Stock to the extent that the total underwriting discounts and commissions received by such Underwriter exceeds the amount of any damages which such Underwriter has otherwise paid or become liable to pay by reason of any untrue or alleged untrue statement, omission or alleged omission, act or alleged act or failure to act or alleged failure to act. 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. The Underwriters' obligations to contribute as provided in this Section 7 are several in proportion to their respective underwriting obligations and not joint.

8. *Termination*. The obligations of the Underwriters hereunder may be terminated by the Representative, in its absolute discretion by notice given to the Company prior to delivery of and payment for the Firm Stock if, prior to that time, any of the events described in Sections 6(j) or 6(l) have occurred, or if the Underwriters shall decline to purchase the Stock for any reason permitted under this Agreement.

9. *Reimbursement of Underwriters' Expenses* . Notwithstanding anything to the contrary in this Agreement, if (a) this Agreement shall have been terminated pursuant to Section 8, (b) the Company shall fail to tender the Stock for delivery to the Underwriters for any reason not permitted under this Agreement, (c) the Underwriters shall decline to purchase the Stock for any reason permitted under this Agreement, or (d) the sale of the Stock is not consummated (i) because any condition to the obligations of the Underwriters set forth herein is not satisfied or (ii) because of the refusal, inability or failure on the part of the Company to perform any agreement herein or satisfy any condition or to comply with the provisions hereof (A) prior to the Closing Date, then in addition to the payment of amounts in accordance with Section 5, the Company shall reimburse the Underwriters for the reasonable and documented fees and expenses of Underwriters' counsel and for such other out-of-pocket expenses as shall have been reasonably and actually incurred by them in connection with this Agreement and the proposed purchase of the Stock, including, without limitation, travel and lodging expenses of the Underwriters, and upon demand the Company shall pay the full amount thereof to BTIG and (B) after the Closing Date but prior to any Option Closing Date with respect to the purchase of any Optional Stock pursuant to a notice delivered by BTIG to the Company under Section 3 hereof, the Company shall reimburse the Underwriters for the reasonable and documented fees and expenses of Underwriters' counsel and for such other out-of-pocket expenses as shall have been reasonably and actually incurred by them following the Closing Date pursuant to this Agreement in connection with the proposed purchase of such Optional Stock, and upon demand the Company shall pay the full amount thereof to BTIG, *provided* that, in no event shall the Company be obligated to reimburse the Underwriters pursuant to clauses (a), (c) or (d)(i) above in an amount in excess of $100,000 in the aggregate. If this Agreement is terminated pursuant to Section 10 by reason of the default of one or more Underwriters, the Company shall not be obligated to reimburse any defaulting Underwriter on account of expenses to the extent incurred by such defaulting Underwriter *provided* that the foregoing shall not limit any reimbursement obligation of the Company to any non-defaulting Underwriter under this Section 9.

10. *Substitution of Underwriters*. If any Underwriter or Underwriters shall default in its or their obligations to purchase shares of Stock hereunder on the Closing Date and the aggregate number of shares which such defaulting Underwriter or Underwriters agreed but failed to purchase does not exceed ten percent (10%) of the total number of shares to be purchased by all Underwriters on the Closing Date, the other Underwriters shall be obligated severally, in proportion to their respective commitments set forth on Schedule I hereto, to purchase the shares which such defaulting Underwriter or Underwriters agreed but failed to purchase on the Closing Date. If any Underwriter or Underwriters shall so default and the aggregate number of shares with respect to which such default or defaults occur is more than ten percent (10%) of the total number of shares to be purchased by all Underwriters on the Closing Date and arrangements satisfactory to the Representative and the Company for the purchase of such shares by other persons are not made within forty-eight (48) hours after such default, this Agreement shall terminate.

If the remaining Underwriters or substituted Underwriters are required hereby or agree to take up all or part of the shares of Stock of a defaulting Underwriter or Underwriters on the Closing Date as provided in this Section 10, (i) the Company shall have the right to postpone the Closing Date for a period of not more than five (5) full business days in order that the Company may effect whatever changes may thereby be made necessary in the Registration Statement or the Prospectus, or in any other documents or arrangements, and the Company agrees promptly to file any amendments to the Registration Statement or supplements to the Prospectus which may thereby be made necessary, and (ii) the respective numbers of shares to be purchased by the remaining Underwriters or substituted Underwriters shall be taken as the basis of their underwriting obligation for all purposes of this Agreement. Nothing herein contained shall relieve any defaulting Underwriter of its liability to the Company or the other Underwriters for damages occasioned by its default hereunder. Any termination of this Agreement pursuant to this Section 10 shall be without liability on the part of any non-defaulting Underwriter or the Company, except that the representations, warranties, covenants, indemnities, agreements and other statements set forth in Section 2, the obligations with respect to expenses to be paid or reimbursed to non-defaulting Underwrtiers pursuant to Sections 5 and 9 and the provisions of Section 7 and Sections 11 through 21, inclusive, shall not terminate and shall remain in full force and effect, and provided that any such termination shall not relieve a defaulting Underwriter from liability for its default.

11. *Absence of Fiduciary Relationship.* The Company acknowledges and agrees that:

(a) each Underwriter's responsibility to the Company is solely contractual in nature, the Representative has been retained solely to act as an underwriter in connection with the sale of the Stock and no fiduciary, advisory or agency relationship between the Company and the Representative has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Representative has advised or is advising the Company on other matters;

(b) the price of the Stock set forth in this Agreement was established by the Company following discussions and arms-length negotiations with the Representative, and the Company is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) it has been advised that the Representative and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Representative has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) it waives, to the fullest extent permitted by law, any claims it may have against the Representative for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that the Representative shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, employees or creditors of the Company.

12. *Successors; Persons Entitled to Benefit of Agreement*. This Agreement shall inure to the benefit of and be binding upon the several Underwriters, the Company and their respective successors and assigns. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, other than the persons mentioned in the preceding sentence, any legal or equitable right, remedy or claim under or in respect of this Agreement, or any provisions herein contained, this Agreement and all conditions and provisions hereof being intended to be and being for the sole and exclusive benefit of such persons and for the benefit of no other person; except that the representations, warranties, covenants, agreements and indemnities of the Company contained in this Agreement shall also be for the benefit of the Underwriter Indemnified Parties, and the indemnities of the several Underwriters shall be for the benefit of the Company Indemnified Parties. It is understood that each Underwriter's responsibility to the Company is solely contractual in nature and the Underwriters do not owe the Company, or any other party, any fiduciary duty as a result of this Agreement. No purchaser of any of the Stock from any Underwriter shall be deemed to be a successor or assign by reason merely of such purchase.

13. *Survival of Indemnities, Representations, Warranties, etc.* The respective indemnities, covenants, agreements, representations, warranties and other statements of the Company and the several Underwriters, as set forth in this Agreement or made by them respectively, pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter, the Company or any person controlling any of them and shall survive delivery of and payment for the Stock. Notwithstanding any termination of this Agreement, including without limitation any termination pursuant to Section 8 or Section 10, the indemnities, contribution, covenants, agreements, representations, warranties and other statements forth in Sections 2, 5, 7 and 9 and Sections 11 through 21, inclusive, of this Agreement shall not terminate and shall remain in full force and effect at all times.

14. *Notices*. All statements, requests, notices and agreements hereunder shall be in writing, and:

(a) if to the Underwriters, shall be delivered or sent by mail, telex, email or facsimile transmission to BTIG, LLC, 600 Montgomery Street, San Francisco, California 94111, Attention: Steven Druskin, Fax: 212-588-6554, with a copy (which shall not constitute notice hereunder) to Goodwin Procter LLP, The New York Times Building, 620 Eighth Avenue, New York, New York 10018, Attention: Michael D. Maline, Esq., Fax: 212-355-3333; and

(b) if to the Company, shall be delivered or sent by mail, telex, facsimile transmission or email to Matinas Biopharma Holdings, Inc., 1545 Route 206 South, Suite 302, Bedminster, NJ 07921, Attention: Jerry Jabbour, with a copy (which shall not constitute notice hereunder) to Lowenstein Sandler LLP, 1251 Avenue of the Americas, New York, New York 10021, Attention: Steve Skolnick, Fax: 973-597-2477;

provided, however, that any notice to an Underwriter pursuant to Section 7 shall be delivered or sent by mail, or facsimile transmission to such Underwriter at its address set forth in its acceptance telex to the Representative, which address will be supplied to any other party hereto by the Representative upon request. Any such statements, requests, notices or agreements shall take effect at the time of receipt thereof, except that any such statement, request, notice or agreement delivered or sent by email shall take effect at the time of confirmation of receipt thereof by the recipient thereof.

15. *Definition of Certain Terms*. For purposes of this Agreement, (a) "business day" means any day on which the NYSE American LLC is open for trading and (b) "subsidiaries" has the meaning set forth in Rule 405 of the Rules and Regulations.

16. *Governing Law and Jurisdiction.* **This Agreement shall be governed by and construed in accordance with the laws of the State of New York, including without limitation Section 5-1401 of the New York General Obligations.** The Company irrevocably (a) submits to the non-exclusive jurisdiction of the Federal and state courts in the Borough of Manhattan in The City of New York for the purpose of any suit, action or other proceeding arising out of this Agreement or the transactions contemplated by this Agreement, the Registration Statement and any Preliminary Prospectus or the Prospectus, (b) agrees that all claims in respect of any such suit, action or proceeding may be heard and determined by any such court, (c) waives to the fullest extent permitted by applicable law, any immunity from the jurisdiction of any such court or from any legal process, (d) agrees not to commence any such suit, action or proceeding other than in such courts, and (e) waives, to the fullest extent permitted by applicable law, any claim that any such suit, action or proceeding is brought in an inconvenient forum.

17. *Underwriters' Information*. The parties hereto acknowledge and agree that, for all purposes of this Agreement, the "Underwriters' Information" consists solely of the information in the paragraphs under the caption "Market Making, Stabilization and Other Transactions" under the heading "Underwriting".

18. *Authority of the Representative.* In connection with this Agreement, the Representative will act for and on behalf of the several Underwriters, and any action taken under this Agreement by the Representative, will be binding on all the Underwriters.

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

20. *General.* This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. In this Agreement, the masculine, feminine and neuter genders and the singular and the plural include one another. The section headings in this Agreement are for the convenience of the parties only and will not affect the construction or interpretation of this Agreement. This Agreement may be amended or modified, and the observance of any term of this Agreement may be waived, only by a writing signed by the Company and the Representative.

21. *Counterparts*. This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument and such signatures may be delivered by facsimile or by e-mail delivery of a ".pdf" format data file.

[*Signature page follows.*]

If the foregoing is in accordance with your understanding of the agreement between the Company and the several Underwriters, kindly indicate your acceptance in the space provided for that purpose below.

Very truly yours,

MATINAS BIOPHARMA HOLDINGS, INC.

By: */s/ Jerome D. Jabbour*
Name: Jerome D. Jabbour
Title: Chief Executive Officer

Accepted as of
the date first above written:

BTIG, LLC

Acting on its own behalf
and as Representative of the several
Underwriters referred to in the
foregoing Agreement.

By: */s/ K.C. Stone*
Name: K.C. Stone
Title: As Managing Director

SCHEDULE I

Underwriters

Name	Number of Shares of Firm Stock to be Purchased	Number of Shares of Optional Stock to be Purchased
BTIG, LLC	27,272,727	4,090,909
Total	27,272,727	4,090,909

SCHEDULE II

Pricing Information

Firm Stock to be Sold: 27,272,727 shares

Offering Price: $1.100 per share

Underwriting Discounts and Commissions: $0.066 per share

Estimated Net Proceeds to the Company (after underwriting discounts and commissions, but before transaction expenses): $28,199,999.70

SCHEDULE III

General Use Free Writing Prospectuses

None.

EXHIBIT A

Form of Lock-Up Agreement

March ___, 2019

BTIG, LLC
As Representative of the several Underwriters
600 Montgomery Street
San Francisco, California 94111

Re: Matinas BioPharma Holdings, Inc.

Dear Sirs:

This lock-up agreement (the "Agreement") is being delivered to you in connection with the proposed Underwriting Agreement (the "Underwriting Agreement") between Matinas BioPharma Holdings, Inc., a Delaware corporation (the "Company"), and BTIG, LLC ("BTIG"), as representative of a group of underwriters (collectively, the "Underwriters") to be named therein, relating to the proposed public offering (the "Offering") of shares of common stock, par value $0.0001 per share (the "Common Stock"), of the Company.

In order to induce you to enter into the Underwriting Agreement, and in light of the benefits that the Offering of the Common Stock will confer upon the undersigned in his or her capacity as a security holder and/or an officer, director or employee of the Company, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each Underwriter that, during the period beginning on and including the date of the Underwriting Agreement through and including the date that is the 90th day after the date of the Underwriting Agreement (the "Lock-Up Period"), the undersigned will not, without the prior written consent of BTIG, directly or indirectly, (i) offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, any Common Stock (including, without limitation, Common Stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations promulgated under the Securities Act of 1933, as amended (the "Securities Act") (such shares, the "Beneficially Owned Shares")) or securities convertible into or exercisable or exchangeable for Common Stock; (ii) enter into any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of the Beneficially Owned Shares or securities convertible into or exercisable or exchangeable for Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition, or (iii) engage in any short selling of the Common Stock or securities convertible into or exercisable or exchangeable for Common Stock.

The restrictions set forth in the immediately preceding paragraph shall not apply to any transfers made by the undersigned (i) as a bona fide gift to any member of the immediate family (as defined below) of the undersigned or to a trust the beneficiaries of which are exclusively the undersigned or members of the undersigned's immediate family, (ii) by will or intestate succession upon the death of the undersigned, (iii) as forfeitures of Common Stock to satisfy tax withholding obligations of the undersigned in connection with the vesting or exercise of equity awards by the undersigned pursuant to the Company's equity plans, (iv) pursuant to a net exercise or cashless exercise by the undersigned of outstanding equity awards pursuant to the Company's equity plans, provided that that any Common Stock acquired upon the net exercise or cashless exercise of equity awards described in this clause (iv) above shall be subject to the restrictions set forth in the immediately preceding paragraph, (v) pursuant to the conversion or sale of, or an offer to purchase, all or substantially all of the outstanding Common Stock, whether pursuant to a merger, tender offer or otherwise, or (vi) as a bona fide gift to a charity or educational institution; provided, however, that in the case of any transfer described in clauses (i) and (ii) above, it shall be a condition to the transfer that (x) the transferee executes and delivers to BTIG, not later than one business day prior to such transfer, a written agreement, in substantially the form of this Agreement (it being understood that any references to "immediate family" in the agreement executed by such transferee shall expressly refer only to the immediate family of the undersigned and not to the immediate family of the transferee) and otherwise reasonably satisfactory in form and substance to BTIG, and (y) if the undersigned is required to file a report under Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") reporting a reduction in beneficial ownership of Common Stock or Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or Beneficially Owned Shares during the Lock-Up Period (as the same may be extended as described above), the undersigned shall include a statement in such report to the effect that such transfer is being made as a gift or by will or intestate succession, as applicable. In addition, in the case of any transfer described in clauses (iii) and (iv) above, it shall be a condition to the transfer that if the undersigned is required to file a report under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of Common Stock or Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or Beneficially Owned Shares during the Lock-Up Period (as the same may be extended as described above), the undersigned shall include a statement in such report to the effect that such transfer is being made for tax withholding obligations or for net exercise or cashless exercise purposes, as applicable. For purposes of this paragraph, "immediate family" shall mean a spouse, child, grandchild or other lineal descendant (including by adoption), father, father-in-law, mother, mother-in-law, brother or sister of the undersigned.

Any Common Stock or Beneficially Owned Shares acquired by the undersigned in the open market after the date of this Agreement will not be subject to the restrictions set forth in this Agreement. After the date of this Agreement, the undersigned may at any time enter into a written plan meeting the requirements of Rule 10b5-1 under the Exchange Act relating to the sale of Common Stock or Beneficially Owned Shares, if then permitted by the Company, provided that the shares subject to such plan shall be subject to the restrictions set forth in this Agreement during the Lock-Up Period.

In order to enable this covenant to be enforced, the undersigned hereby consents to the placing of legends or stop transfer instructions with the Company's transfer agent with respect to any Common Stock or securities convertible into or exercisable or exchangeable for Common Stock.

The undersigned further agrees that (i) it will not, during the Lock-Up Period (as the same may be extended as described above), make any demand or request for or exercise any right with respect to the registration under the Securities Act of any Common Stock or other Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or other Beneficially Owned Shares, and (ii) the Company may, with respect to any Common Stock or other Beneficially Owned Shares or any securities convertible into or exercisable or exchangeable for Common Stock or other Beneficially Owned Shares owned or held (of record or beneficially) by the undersigned, cause the transfer agent or other registrar to enter stop transfer instructions and implement stop transfer procedures with respect to such securities during the Lock-Up Period (as the same may be extended as described above).

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Agreement and that this Agreement has been duly executed and delivered by the undersigned and is a valid and binding Agreement of the undersigned. This Agreement and all authority herein conferred are irrevocable and shall survive the death or incapacity of the undersigned and shall be binding upon the undersigned and upon the heirs, personal representatives, successors and assigns of the undersigned.

The undersigned acknowledges and agrees that whether or not any public offering of Common Stock actually occurs depends on a number of factors, including market conditions. It is understood and agreed that if (i) the Underwriting Agreement is not executed by June 30, 2019, (ii) the Company notifies you in writing that it does not intend to proceed with the offering of Common Stock, (iii) the undersigned ceases to serve as an officer or director of the Company, or (iv) the Underwriting Agreement shall be terminated (other than the provisions that survive termination thereof) prior to payment for and delivery of the securities to be sold pursuant thereto, the undersigned shall be released from his or her obligations under the provisions of this Agreement.

This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

[*Signature Page Follows*]

Very truly yours,

_____

(Name of Stockholder – Please Print)

_____

(Signature)

Address:

Exhibit A

EXHIBIT B

Officers, Directors, and Stockholders Executing Lock-Up Agreements

Jerome D. Jabbour
Theresa Matkovits
Raphael J. Mannino
Keith A. Kucinksi
James J. Ferguson
Herbert Conrad
Patrick LePore
Eric J. Ende
Matthew A. Wikler
Adam K. Stern
James S. Scibetta

Exhibit 5.1

March 15, 2019

Matinas BioPharma Holdings, Inc.
1545 Route 206 South, Suite 302
Bedminster, New Jersey 07921

Ladies and Gentlemen:

We have acted as counsel to Matinas BioPharma Holdings, Inc., a Delaware corporation (the "**Company**"), in connection with (i) the preparation and filing of the Registration Statement on Form S-3 (Registration No. 333-217106) filed with the Securities and Exchange Commission (the "**Commission**") under the Securities Act of 1933, as amended (the "**Securities Act**"), (as so filed and as amended, the "**Registration Statement**") and the related prospectus contained in the Registration Statement (the "**Base Prospectus**") and (ii) the preparation and filing of the prospectus supplement, dated March 14, 2019 (the "**Prospectus Supplement**") relating to the issuance and sale by the Company of up to 31,363,636 shares of common stock, par value $0.0001 per share (the "**Common Stock**") of the Company (the "**Shares**") (including 4,090,909 shares of Common Stock issuable by the Company upon exercise of an option to purchase additional shares granted by the Company to the underwriters).

The Shares are to be issued and sold by the Company pursuant to the Underwriting Agreement, dated as of March 15, 2019 (the "Underwriting Agreement"), between the Company and BTIG, LLC, as underwriter, the form of which is being filed with the Commission as Exhibit 1.1 to the Company's Current Report on Form 8-K, filed on the date hereof.

In connection with this opinion, we have (i) investigated such questions of law, (ii) examined originals or certified, conformed or reproduction copies of such agreements, instruments, documents and records of the Company, such certificates of public officials and such other documents and (iii) received such information from officers and representatives of the Company as we have deemed necessary or appropriate for the purposes of this opinion

In all such examinations, we have assumed the legal capacity of all natural persons, the genuineness of all signatures, the authenticity of original and certified documents and the conformity to original or certified documents of all copies submitted to us as conformed or reproduction copies. As to various questions of fact relevant to the opinion expressed herein, we have relied upon, and assume the accuracy of, the representations and warranties set forth in the Underwriting Agreement, and certificates and oral or written statements and other information of or from public officials and officers and representatives of the Company.

Based upon 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 for issuance, and when issued and paid for in accordance with the terms and conditions of the Underwriting Agreement, the Shares will be validly issued, fully paid and non-assessable.

The opinion expressed herein is limited to the applicable provisions of the General Corporation Law of the State of Delaware (the "**DGCL**"), as currently in effect, and reported judicial decisions interpreting such provisions of the DGCL.

The opinion expressed herein is limited to the matters stated herein and no opinion is implied or may be inferred beyond the matters expressly stated herein. We undertake no obligation to supplement this letter if any applicable laws change after the date hereof or if we become aware of any facts that might change the opinion expressed herein after that date or for any other reason.

We hereby consent to the inclusion of this opinion as an exhibit to a Current Report on Form 8-K to be filed by the Company with the Commission on the date hereof, which Current Report on Form 8-K will be incorporated by reference into the Registration Statement, and to the references to our firm under the caption "Legal Matters" in the Prospectus Supplement. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ Lowenstein Sandler LLP

Matinas BioPharma Announces Proposed Public Offering of Common Stock

BEDMINSTER, N.J., March 14, 2019 (BUSINESS WIRE) Matinas BioPharma Holdings, Inc. ("Matinas BioPharma" or the "Company") — (NYSE AMER:MTNB), a clinical-stage biopharmaceutical company, today announced that it has commenced an underwritten public offering of its common stock. All of the shares to be sold in the offering are to be sold by Matinas BioPharma. In connection with the offering, Matinas BioPharma intends to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of its common stock offered in the public offering.

BTIG, LLC is acting as sole book-running manager for the offering.

Matinas BioPharma anticipates using the net proceeds from the offering primarily for ongoing development activities for its product candidates, namely MAT9001, and its lipid-nano-crystal ("LNC") platform delivery technology and for working capital and other general corporate purposes.

A shelf registration statement on Form S-3 relating to the public offering of the shares of common stock described above was declared effective by the Securities and Exchange Commission (the "SEC") on April 12, 2017. A preliminary prospectus supplement and accompanying base prospectus relating to and describing the terms of the offering will be filed with the SEC. Before you invest, you should read the preliminary prospectus supplement and accompanying base prospectus for more complete information about Matinas BioPharma and this offering. An electronic copy of the preliminary prospectus supplement and accompanying base prospectus relating to the offering, when filed, will be available on the SEC's website at www.sec.gov and may also be obtained, when available, by contacting BTIG, LLC, at 825 Third Avenue, 6th Floor, New York, NY, 10022, or by telephone at (212) 593-7555 or by e-mail at equitycapitalmarkets@btig.com.

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

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on creating value through the streamlined development of MAT9001 for the treatment of cardiovascular and metabolic conditions and the application of its LNC platform technology to solve complex challenges relating to the safe and effective delivery of small molecules, gene therapies, proteins, peptides and vaccines.

Forward Looking Statements: *This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the completion, timing and size of its public offering and the anticipated use of proceeds. All statements other than statements of historical fact are statements that could be forward-looking statements. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to obtain additional capital to meet our liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; our ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this release. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.*

Investor and Media Contact
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Source: Matinas BioPharma Holdings, Inc.

Matinas BioPharma Announces Pricing of Public Offering of Common Stock

BEDMINSTER, N.J., March 15, 2019 (BUSINESS WIRE) Matinas BioPharma Holdings, Inc. ("Matinas BioPharma" or the "Company") — (NYSE AMER:MTNB), a clinical-stage biopharmaceutical company, today announced the pricing of its underwritten registered public offering of 27,272,727 shares of its common stock, offered at a price to the public of $1.10 per share for expected gross proceeds of $30.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses. In addition, Matinas BioPharma has granted the underwriters a 30-day option to purchase up to an additional 4,090,909 shares of its common stock on the same terms and conditions. All of the shares in the offering are being sold by Matinas BioPharma. The offering is expected to close on or about March 19, 2019, subject to customary closing conditions.

BTIG, LLC is acting as sole book-running manager for the offering.

Matinas BioPharma anticipates using the net proceeds from the offering primarily for ongoing development activities for its product candidates, namely MAT9001, and its lipid nano-crystal ("LNC") platform delivery technology and for working capital and other general corporate purposes.

A shelf registration statement on Form S-3 relating to the public offering of the shares of common stock described above was declared effective by the Securities and Exchange Commission (the "SEC") on April 12, 2017. A prospectus supplement and accompanying base prospectus relating to and describing the terms of the offering has been filed with the SEC and is available on the SEC's website at www.sec.gov. An electronic copy of the final prospectus supplement and accompanying base prospectus relating to the offering, when filed, will be available on the SEC's website at www.sec.gov and may also be obtained by contacting BTIG, LLC, at 825 Third Avenue, 6th Floor, New York, NY, 10022, or by telephone at (212) 593-7555 or by e-mail at equitycapitalmarkets@btig.com.

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

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on creating value through the streamlined development of MAT9001 for the treatment of cardiovascular and metabolic conditions and the application of its LNC platform technology to solve complex challenges relating to the safe and effective delivery of small molecules, gene therapies, proteins, peptides and vaccines.

Forward Looking Statements: *This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the completion, timing and size of its public offering and the anticipated use of proceeds. All statements other than statements of historical fact are statements that could be forward-looking statements. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to obtain additional capital to meet our liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; our ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this release. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.*

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Source: Matinas BioPharma Holdings, Inc.

Our Company

We are a clinical-stage biopharmaceutical company focused on creating value through (i) the streamlined development under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA of our lead product candidate, MAT9001, a highly purified, prescription-only omega-3 free fatty acid formulation specifically designed for the treatment of cardiovascular and metabolic conditions and (ii) the application of our lipid nano-crystal (LNC) platform delivery technology to solve complex challenges relating to the delivery of small molecules, gene therapies, vaccines, proteins and peptides. In general, the development timeline for a 505(b)(2) New Drug Application, or NDA, is shorter and less expensive than an NDA developed under Section 505(b)(1) for new chemical entities that have never been approved in the United States. Based upon MAT9001's unique mixture of highly purified omega-3 free fatty acids and our observations of MAT9001's enhanced bioavailability and potency as compared to Amarin Corporation's Vascepa® (icosapent ethyl) in our initial head-to-head pharmacokinetic (PK) and pharmacodynamic (PD), or PK/PD, clinical study, we believe that the results of our forthcoming targeted clinical development activities and related clinical investigations may yield an improved therapeutic profile compared to currently-existing therapies.

MAT9001 is a soft gelatin capsule containing a complex mixture of polyunsaturated free fatty acids, including multiple long-chain omega-3 fatty acids, including primarily eicosapentanoic acid (EPA) and docosapentanoic acid (DPA). Amongst other properties, omega-3 fatty acids, which are also found in FDA-approved drugs in varying amounts, such as Vascepa®, have extensive clinical evidence of safety and efficacy in lowering triglycerides (TG) in patients with hypertriglyceridemia (HTG). We believe that based upon MAT9001's unique composition, which includes more DPA than other known omega-3 fatty acids, it will prove to be differentiated from other existing therapies for the treatment of very high triglycerides, or severe hypertriglyceridemia (SHTG), and dyslipidemia.

Triglycerides are fats that are carried in the blood, together with cholesterol, within lipoproteins. High levels of triglyceride-rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease and in the case of severe hypertriglyceridemia, acute pancreatitis. High levels of triglycerides are due to both genetic and environmental factors and are associated with comorbid conditions such as diabetes, chronic renal failure, and nephrotic syndrome. Unlike the currently approved products in this category, many of which have been repurposed following clinical failures in their originally intended indications, we have specifically designed and developed MAT9001 to treat SHTG, dyslipidemia and other cardiovascular and metabolic conditions.

In 2015, we announced results from our head-to-head PK/PD clinical study against Vascepa, a prescription-only ethyl ester formulation of EPA. This was an open-label, cross-over design study conducted in 42 patients with elevated triglyceride levels. Patients were treated for 14 days with MAT9001 or Vascepa, (4 grams/day for both treatment arms), followed by a five-week wash-out period, then crossed over to the other treatment. The main objectives of the study were to measure the relative bioavailability of MAT9001 versus Vascepa as well as effects on triglyceride levels. In this study, we observed statistical superiority of MAT90001 in reducing serum triglycerides, total- and non-HDL-cholesterol, apolipoprotein CIII and PCSK9 levels. MAT9001 was observed to significantly reduce PCSK9 in patients. In this trial, MAT9001 achieved greater median percentage reduction in four of six lipid measures, including total cholesterol, when compared to Vascepa.

We are focusing our initial efforts on developing MAT9001 with an initial indication for the treatment of severe hypertriglyceridemia. If we receive U.S. Food and Drug Administration (FDA) approval for severe hypertriglyceridemia, we may seek approval for use of MAT9001 in additional indications, including the treatment of patients with mixed dyslipidemia who are already undergoing treatment with a statin, a commonly used class of cholesterol-lowering medications.

Consistent with our strategy first put in place when we filed the investigational new drug (IND) application for MAT9001 in 2014, we intend to pursue a 505(b)(2) regulatory pathway towards NDA approval in the United States. Pursuant to this streamlined development approach, we are permitted to rely, at least in part, on FDA findings of safety and/or effectiveness for a previously approved drug. Based upon written feedback received from the FDA in 2014, we believe this approach will create the opportunity for us to leverage existing data developed with certain existing omega-3 fatty acids to create a streamlined approach to potential approval for MAT9001 for the treatment of severe hypertriglyceridemia (≥500 mg/dL). Simultaneously with those preclinical and clinical studies necessary for approval of this initial indication, we intend to conduct two additional studies designed to highlight the differentiated profile of MAT9001 vs. market leading omega-3 fatty acids and potentially yielding superior data in similar patient populations to those data generated by already-approved omega-3 fatty acids. We believe this dual development strategy will best position MAT9001 to secure an approval to treat severe hypertriglyceridemia as quickly as possible while also positioning MAT9001 as the best-in-class prescription omega-3 therapy as this market and regulatory requirements evolve.

While we advance MAT9001 toward pivotal trials in the cardiovascular space, we are also determined to maximize the value associated with our unique and potentially disruptive lipid nano-crystal (LNC) platform delivery technology. Our proprietary LNC platform delivery technology, licensed from Rutgers University on an exclusive worldwide basis, nano-encapsulates molecules and is designed to render these molecules orally bioavailable, well-tolerated and safe via fusogenic intracellular delivery. We believe the ability of our drug delivery technology to efficiently deliver drugs intracellularly may result in the targeted and safe delivery of pharmaceuticals directly to the site of infection or inflammation as well as the potential to treat a variety of cell-based pathogens, diseases and conditions. We believe our cochleate technology provides us with a highly stable, efficient and broadly applicable drug delivery platform, that has the potential to deliver a broad range of therapies, including small molecules, vaccines, peptides and proteins, as well as nucleic acid polymers in the gene therapy space (e.g., siRNA, mRNA, and CRISPR/Cas-9) in diseases and conditions exhibited by inflammation (e.g., CNS and infectious diseases) as well as intracellular diseases (e.g., intracellular pathogen-related, genetic disorders, and cancer).

Our lead drug candidate based on the LNC platform is MAT2203, an oral formulation of amphotericin B, a well-known and highly-effective, antifungal drug (though traditionally highly-toxic and currently only available in an intravenous formulation) currently used and approved used to treat a variety of invasive, and potentially deadly, fungal infections. MAT2203 has been developed to date with the assistance and financial support of the National Institutes of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH). MAT2203 has been designated as a Qualified Infectious Disease Product (QIDP) with Fast Track Status for the treatment of invasive candidiasis, the treatment of aspergillosis and the prevention of invasive fungal infections in patients who are on immunosuppressive therapy. We have completed two Phase 2 studies of MAT2203 since 2015 and, leading up to and following a meeting with the Office of Antimicrobial Products (OAP) in January 2018, we had been positioning MAT2203 for an initial indication for the prophylaxis, or prevention, of invasive infections in patients who are suffering from acute lymphoblastic leukemia (ALL) who are rendered immunosuppressed due to the therapies being utilized to treat these patients' leukemia.

While we continue to believe that MAT2203 could become an important solution to the significant unmet medical need to prevent invasive fungal infections in immunosuppressed patients, we believe there are opportunities for a potentially more rapid approval of MAT2203 for the treatment of certain invasive fungal infections in areas of high unmet medical need which can be substantially supported by non-dilutive government funds. In partnership with the NIH, we have conducted numerous preclinical studies of MAT2203 for the treatment of cryptococcal meningitis. In such studies, we observed the potential for MAT2203, utilizing our LNC platform delivery technology, to (a) cross the blood-brain barrier, (b) treat this infection and (c) eliminate the toxicity normally associated with liposomal delivery of amphotericin B intravenously.

This data attracted the attention of several organizations, including the NIH, interested in finding a better treatment option for cryptococcal meningitis. The NIH recently approved and fully funded a grant submission from the University of Minnesota to conduct a clinical study of MAT2203 on patients with cryptococcal meningitis located in Uganda, Africa where this disease is very prevalent among the HIV-positive community. In consultation with the NIH and the University of Minnesota we are finalizing a protocol to commence this study during 2019. We believe that this clinical trial could become a registration-quality trial for an indication for MAT2203 to treat cryptococcal meningitis. We intend to finalize this protocol in the near term and then engage with the FDA to outline a potential pathway for approval of MAT2203 based upon this trial. Given the significant challenge associated with treating cryptococcal meningitis, we believe this indication could position MAT2203 with physicians to become the antifungal of choice for the treatment of all invasive fungal infections given the broad-spectrum nature of amphotericin B. Combined with the oral and targeted delivery and safety profile we believe the LNC platform delivery affords, we believe MAT2203 is well positioned to become a best-in-class antifungal drug. In addition, we believe that a demonstration that MAT2203 can effectively cross the blood-brain barrier in humans in this study could potentially position our LNC platform delivery technology to be utilized with molecules designed to treat diseases of the central nervous system exhibited by inflammation. Developing MAT2203 utilizing non-dilutive, government-sponsored, financing allows us to focus our internal cash resources on MAT9001 while advancing MAT2203 and our LNC platform technology into areas of significant unmet medical need and innovative medicine.

We have been engaged in discussions with various large, well-established and well-financed biotech and global pharmaceutical companies on potential applications of our LNC platform technology in the gene therapy space. Though early stage, these discussions have been based on existing data utilizing our LNC platform technology with complex nucleic acid polymers such as antisense oligonucleotides, mRNA, siRNA, and DNA plasmids. Our success in nano-encapsulating larger nucleic acids such as DNA plasmids, which can be as large as 11 kilobases in length, has also pushed us toward discussions with the NIH and others about utilizing our LNC platform delivery technology in the CRISPR-Cas9 space.

In July 2018, we announced a research collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH), focused on the development of a novel therapy for the treatment of human immunodeficiency virus (HIV) combining targeted antisense oligonucleotides (ASO) and Matinas' LNC delivery technology. In January 2019 we announced a research evaluation with a top global pharmaceutical company in which our LNC platform technology would be explored in delivering certain nucleic acid polymers, and we continue to pursue additional strategic collaborations with other interested biotech and pharmaceutical partners.

We believe these early stage, proof-of-concept evaluations could provide a more efficient, less expensive pathway to create numerous strategic verticals in areas of innovative medicine relying upon the development expertise and financial resources of well-established pharmaceutical and biotech companies. Our belief is that data from these evaluations could position us to become a licensor of our LNC platform delivery technology to numerous strategic partners better positioned to absorb the risks and costs of drug development while allowing our company to become a royalty aggregator with the potential to generate upfront license, milestone and royalty payments in order to utilize our LNC delivery platform technology.

Strategy

We are focused on creating value through the streamlined and strategic development of MAT9001 for the treatment of cardiovascular and metabolic conditions and the application of our LNC platform delivery technology to solve complex challenges relating to the delivery of small molecules, gene therapies, proteins/peptides, and vaccines. Key elements of our strategy include:

- Strategically advancing MAT9001 into clinical development toward an initial indication for the treatment of severe hypertriglyceridemia (≥500 mg/dL) (SHTG) with the goal of creating additional data further demonstrating the differentiation of MAT9001 from other prescription omega-3 drugs being used to treat a mixed dyslipidemic patient population in a rapidly emerging and expanding omega-3 market.

- Expanding application of our lipid nano-crystal (LNC) delivery platform into the gene therapy space through collaborations with sophisticated and well-resourced biotech and pharmaceutical companies in innovative areas of medicine.

- Driving MAT2203 to efficacy data in the treatment of cryptococcal meningitis, an area of significant unmet medical need, with the non-dilutive financial support of the NIH.

MAT9001

Our lead cardiovascular product candidate, MAT9001, is a proprietary prescription-only omega-3 fatty acid composition, comprised of a complex mixture of omega-3 fatty acids, including eicosapentaenoic acid, or EPA, docosapentaenoic acid, or DPA, several other omega-3 fatty acids, and relatively nominal amounts of docosahexaenoic acid, or DHA, and non-omega-3 fatty acids. We believe that based upon MAT9001's unique composition, which includes more DPA than other known omega-3 fatty acids, it will prove to be differentiated from other existing therapies for the treatment of very high triglycerides, or severe hypertriglyceridemia, and dyslipidemia. Triglycerides are fats that are carried in the blood, together with cholesterol, within lipoproteins. High levels of triglyceride rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease and in the case of severe hypertriglyceridemia, acute pancreatitis. High levels of triglycerides are due to both genetic and environmental factors and are associated with comorbid conditions such as diabetes, chronic renal failure and nephrotic syndrome. Unlike the current approved therapies in this product category, many of which have been repurposed following clinical failures in their originally intended indications, we have specifically designed and developed MAT9001 to treat severe hypertriglyceridemia and dyslipidemia. We believe that the results of these targeted development activities and related clinical investigations may yield an improved therapeutic profile compared to the currently-existing therapies, characterized most importantly by MAT9001's differentiating mechanistic features associated with its unique high DPA composition and enhanced potency as observed in our head to head clinical trial versus Vescepa.

We are primarily focused on developing MAT9001 through approval by the FDA, with an initial indication for the treatment of severe hypertriglyceridemia. Severe hypertriglyceridemia refers to a condition in which patients have high blood levels of triglycerides (TG ≥ 500 mg/dl) and is recognized as an independent risk factor for pancreatitis and cardiovascular disease. If we receive FDA approval for severe hypertriglyceridemia, we may seek approval for use of MAT9001 in additional indications, including the treatment of patients with mixed dyslipidemia who are already undergoing treatment with a statin, a commonly used class of cholesterol lowering medications. Mixed dyslipidemia refers to a condition in which patients have a combination of both elevated triglycerides (≥200mg/dl), and elevated cholesterol levels. According to the NCEP Guidelines, we estimate that approximately 30 to 35 million Americans have mixed dyslipidemia.

Hypertriglyceridemia and Cardiovascular Disease Market Overview

Hypertriglyceridemia refers to a condition in which patients have levels of triglycerides in their blood above 200 mg/dL. Severe hypertriglyceridemia refers to a condition involving levels of triglycerides equal or above 500 mg/dL. Triglycerides (TG) are fats that are carried in the blood, together with cholesterol and lipoproteins. High levels of triglyceride-rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease. Hypertriglyceridemia is due to both genetic and environmental factors. Environmental factors include obesity, sedentary lifestyle, and high caloric diets. Hypertriglyceridemia is also associated with comorbid conditions such as diabetes, chronic renal failure, and nephrotic syndrome.

The prevalence of hypertriglyceridemia is rapidly increasing in the United States and throughout the world, correlating with the increasing incidence of obesity. Severe hypertriglyceridemia is also associated with markedly increased risk for cardiovascular disease and recent studies have demonstrated that elevated triglyceride levels can be regarded as an independent risk factor for cardiovascular disease-related events such as myocardial infarction, ischemic heart disease, and ischemic stroke.

Heart attacks, strokes and other cardiovascular events represent the leading cause of death and disability among men and women in western societies. More than 1 out of every 3 adults in the United States (approximately 92 million) currently lives with one or more types of cardiovascular disease; an estimated 800,000 new or recurrent coronary events and 795,000 new or recurrent strokes occur each year; an estimated 29 million adults ≥20 years of age have high total serum cholesterol levels (≥240 mg/dL), and an estimated 71 million adults ≥20 years of age have borderline high or high low-density lipoprotein ("bad") cholesterol, or LDL-C, levels (≥130 mg/dL).

In addition to cholesterol, lipoproteins such as LDL also carry fats in the form of triglycerides. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream and has been reported to be an independent risk factor for cardiovascular disease. Triglyceride levels provide important information as a marker associated with the risk for heart disease and stroke.

Guidelines for the management of very high triglyceride levels (≥500 mg/dL) suggest that reducing triglyceride levels is the primary treatment goal in these patients to reduce the risk of acute pancreatitis. Treating LDL-C remains an important secondary goal. Other important parameters to consider in patients with very high triglycerides include levels of apolipoprotein B (apo B), non-HDL-C, and very low-density lipoprotein cholesterol (VLDL-C).

It is estimated that over 25 million adults in the United States have elevated triglyceride levels ≥200 mg/dL and that more than 50 million adults in the United States have elevated triglyceride levels ≥150 mg/dL. Additionally, approximately 4 million adults in the United States have very high triglyceride levels (≥500 mg/dL).

Mixed dyslipidemia refers to a condition in which patients have a combination of two or more lipid abnormalities including elevated triglycerides, low HDL-C, and/or elevated LDL-C. Both hypertriglyceridemia and mixed dyslipidemia are components of a range of lipid disorders collectively referred to as dyslipidemia. Dyslipidemia has been linked to atherosclerosis, commonly referred to as hardening of the arteries.

Limitations of Current Therapies

Hypertriglyceridemia (HTG) is a prevalent lipid disorder in approximately 25% of the U.S. adult population. Both epidemiological and genetic data have shown associations between HTG and coronary heart disease. Many of those patients are taking statin therapy directed at lowering the risk of cardiovascular disease (CVD) by lowering their LDL-C levels, primarily. Recently, real world administrative database analyses have reported an increased CVD risk as well as direct healthcare costs associated with HTG despite statin therapy and controlled LDL-C compared to those with TG<150 mg/dL.

There is currently no approved prescription omega-3 to lower TG levels in statin-treated patients with mixed dyslipidemia and persistent high (≥200 mg/dL and <500 mg/dL) TG levels due to uncertainty raised by FDA in 2013 regarding the benefit, if any, of drug-induced changes in lipid/lipoprotein parameters beyond statin-lowered LDL-C on cardiovascular risk among statin-treated patients with residually high TG.

Additionally, recent cardiovascular (CV) outcomes trials and meta-analyses with low dose omega-3 fatty acid mixtures containing DHA have not shown substantial benefit in patients receiving contemporary medical therapy, including statins. Due to these failed low dose omega-3 CV outcomes trials, the European regulatory authorities have concluded that omega-3 fatty acid medicines at a dose of 1-gram per day are not effective in preventing further events for patients who have had a heart attack.

TG levels provide important information as a marker associate with the risk for heart disease and stroke, especially when an individual also has low levels of high-density lipoprotein cholesterol (HDL-C) and elevated levels of low-density lipoprotein cholesterol (LDL-C). Multiple epidemiological, clinical, and genetic studies suggest that patients with elevated TG levels (>=200 mg/dL) are at a greater risk of coronary artery disease (CAD) and pancreatitis, a life-threatening condition, as compared to those with normal TG levels. The genes regulating TGs and LDL-C are equally strong predictors of CAD, unlike HDL-C which is not. Other studies suggest that managing and lowering TG levels may reduce these risks. <

Currently Available Treatment Options and Market Opportunity

The dramatic rise in obesity over the last few decades has led to a concomitant increase in cholesterol and triglyceride levels among the population. The collective term for high blood lipid levels such as high cholesterol and high triglyceride levels often used is "dyslipidemia." Observational studies have resulted in an increased awareness of the critical role that high cholesterol and high triglyceride levels have as a predictor of cardiovascular events. Accordingly, the introduction of new drugs and novel mechanisms of action to lower the risk of cardiovascular events has become a priority. The initial treatment recommendation for patients with dyslipidemia is typically a low-fat diet. If that is not effective, dyslipidemia is then often treated with statins, which account for approximately 80% of all dyslipidemia prescriptions. Statins became a highly successful class of medications for the treatment of dyslipidemia due to their ability to reduce cardiovascular risk in patients at high risk for heart attacks, strokes, and other adverse cardiovascular events. Because of these outcome benefits, the statin utilization rate as compared to the incidence and prevalence of dyslipidemia in the general population, which we refer to as the epidemiology, has risen to almost 40% in the United States. However, the primary activity of statins is in the reduction of LDL-cholesterol levels and they have only modest effects on triglyceride levels. Recognizing that statins alone are not very effective triglyceride lowering drugs, the National Cholesterol Education Program panel recommends the use of more focused therapies to lower triglyceride levels in patients with severe hypertriglyceridemia. Fibrates (a class of amphipathic carboxylic acids), omega-3 fatty acid-based medications and niacin have all been utilized to lower triglycerides levels. In patients with severe hypertriglyceridemia, first-line drug therapy is often a prescription omega-3 or fibrate. Prescription omega-3 based products have been shown to reduce triglyceride levels in the range of 20%-45%.

The treatment rate of hypertriglyceridemia has remained relatively low – below ten percent - compared to the adult population with hypertriglyceridemia. Historically, fibrates such as gemfibrozil (Lopid) and fenofibrate (Tricor or Trilipix) have led the class of treatments of hypertriglyceridemia. However, due to their inability to establish clinical outcome benefits and their limited compatibility with statin therapy, the fibrate utilization rate has remained relatively low and is currently declining. Other products used to treat severe hypertriglyceridemia incorporating niacin as the active pharmaceutical ingredient have not been able to establish additional outcome benefits as compared to statin treatment alone, and are also encountering declining utilization. Because of their lack of outcome benefits, fibrate and niacin use has been mostly concentrated in severe hypertriglyceridemia.

Many omega-3 fatty acid based products have anti-thrombotic and anti-inflammatory effects that suggest effectiveness in inhibiting atherosclerosis in animal models as well as reducing the rate of adverse cardiovascular events in humans at high risk for such events as demonstrated in the JELIS Trial and the GISSI Prevenzione trial in Italy. Furthermore, omega-3 fatty acid based products, either concentrates of both EPA and DHA or EPA alone, have been demonstrated in multiple clinical trials to lower serum concentrations in patients with hypertriglyceridemia. In a recent third-party study, increased levels of EPA and DHA in red blood cells directly correlated with significant reductions in cardiovascular health risks. However, omega-3 fatty acid based medications with significant levels of DHA have been shown to increase LDL-cholesterol levels, which is a negative side effect.

The global prescription omega-3 market has been growing steadily over the last two decades and we estimate the market currently is approaching $2 billion in global sales. The leading omega-3 prescription pharmaceutical products currently approved for the treatment of hypertriglyceridemia are Glaxo Smith Kline's Lovaza (omega-3-acid ethyl esters, an omega-3 mixture containing mostly EPA and DHA, branded as Omacor in the rest of the world), Omacor and Seacor, very similar to Lovaza and marketed in Europe; and Mochida Pharmaceutical Co., Ltd's ("Mochida") Epadel (98% ethyl eicosapentaenoate), the leading Japanese omega-3 product. Recently, a new omega-3 based medication, Amarin's Vascepa (97% ethyl eicosapentaenoate), was approved and launched in the United States. In addition, Astra Zeneca has an FDA-approved product, Epanova, which has not yet been launched.

MAT9001 Differentiation Strategy

In contrast to certain other omega-3 based prescription products, MAT9001 is not a product repurposed from a previous development program for another disease or condition, as it was specifically designed for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Specifically, we are pursuing two avenues of differentiation from existing products, including Vascepa and Lovaza:

1. MAT9001 has unique mechanistic features due to its proprietary composition of omega-3 fatty acids, including DPA, which we believe is a key differentiating omega-3 fatty acid component (*i.e.* , a component that is neither EPA nor DHA); and
2. MAT9001 is designed to have a highly concentrated potency versus other omega-3 products due to its free fatty acid formulation and potentially improved bioavailability relative to other omega-3 fatty acid pharmaceutical products, as demonstrated in our head to head study against Vascepa. Unlike ethyl-ester omega-3 fatty acid formulations, MAT9001 does not require enzymatic breakdown in the small intestine before it can be adequately absorbed. These enzymes are secreted in the intestine in response to dietary fats. Therefore, ethyl-ester omega-3 fatty acids are not optimally absorbed unless they are taken with a high-fat meal, which is contraindicated in patients with hypertriglyceridemia. Because MAT9001 is less reliant on meal-fat content for optimal absorption, it has significantly greater bioavailability than the ethyl-ester form under the recommended low-fat diet conditions.

We believe that based upon both publicly available preclinical and human data generated with MAT9001, as well as independent data associated with one of the key omega-3 components contained in MAT9001, our product has the potential to:

1. Better control cholesterol, and may decrease low-density lipoproteins, or LDL, cholesterol levels;
2. Demonstrate superior reduction across numerous lipid biomarkers, including triglycerides, VLDL, non-HDL and Apo-C3 levels; and
3. Produce certain gene regulatory effects, such as the down regulation of HMG-CoA reductase and PCSK9.

In addition, MAT9001 contains a much lower concentration of DHA than certain competitive omega-3 products, such as Lovaza or Epanova (products with mixtures of mostly EPA and DHA). As described above, these products reduce triglycerides as the main desired effect but also have the negative side effect of increasing LDL-cholesterol levels. This side effect is observed with the use of Lovaza and Epanova in patients with severe hypertriglyceredemia as well as in patients with mixed dyslipidemia. In contrast, products with very low concentrations of DHA, such as Vascepa, have not shown the increase in LDL-cholesterol levels relative to placebo in either the severe hypertriglyceridemia or mixed dyslipedemia patient populations. Omega-3 products containing low DHA levels have also demonstrated reductions in LDL-cholesterol and non-HDL-cholesterol levels. We believe MAT9001's unique composition will produce differentiating results in reducing both cholesterol and triglyceride levels. Further, based on our product design, we believe that MAT9001 is well-positioned to become a leading treatment for severe hypertriglyceridemia if approved by the FDA.

MAT9001's free fatty acid form of omega-3 differentiates it from competitors and we believe this distinction leads to numerous clinical advantages. In a head to head study vs. Vascepa, as detailed further below, improved absorption characteristics and bioavailability were observed for MAT9001 as compared to Vascepa. Our PK/PD head-to-head trial compared the bioavailability of MAT9001 and Vascepa and it was observed that MAT9001's free fatty acid form was less reliant on meal-fat content for optimal absorption than Vascepa's ethyl-ester omega-3 form, which requires a high-fat meal for optimal absorption. It was also observed that patients on a low-fat diet exhibited five times higher blood plasma levels of EPA relative to Vascepa. Additional benefits of MAT9001's improved bioavailability may include once-a-day dosing, reduced pill burden and accompanying heightened patient compliance. All adverse events (AEs) reported in this study (whether related or unrelated to study drugs) were mild or moderate in severity. The most commonly reported AEs judged as possibly related to the study drug were dry skin and rhinorrhea. No serious adverse events (SAEs) were reported during the conduct of this study. The study medications were well-tolerated by patients in this study as well.

We believe that MAT9001, with its unique ratios of omega-3 free fatty acids, increased plasma concentrations of EPA compared to Vascepa, potential once-a-day dosing convenience, and observed degree of bioavailability and potential to reduce triglyceride levels as observed in our studies to date, is well-positioned to address significant unmet medical need and become a standard of care in the treatment of hypertriglyceridemia. Furthermore, we believe that MAT9001, due to the gene regulatory effects of DPA, in combination with statins, if approved by FDA, could become a standard of care in patients with mixed dyslipidemia with a prescribing and commercial advantage favoring products with a once per day dosing convenience similar to statins.

Development History

We believe we have optimized the manufacturing process for the active pharmaceutical ingredient of MAT9001 and have completed various preclinical studies and one human clinical trial with the MAT9001 active ingredient. We completed the first preclinical studies of MAT9001 in 2013 with others completed during 2014. In 2015, we announced results from our Head-to-Head PK/PD Trial against Vascepa in which we observed statistical superiority in reducing serum triglycerides, total- and non-HDL-cholesterol, apolipoprotein CIII and PCSK9 levels. The study was a pharmacokinetic and pharmacodynamic, open-label crossover study designed to compare the bioavailability and effects of MAT9001 versus Vascepa on serum triglyceride levels. Forty-two patients were treated with 4 grams/day of MAT9001 or Vacsepa for 14 days, followed by a wash-out period and crossed over to the other treatment arm. Study subjects had fasting TG levels of 200-400 mg/dl without lipid altering therapy, or fasting TG levels of 200 to 350 mg/dL if they were on stable-dose statin monotherapy. MAT9001 was observed to significantly reduce PCSK9 in patients. In this trial, MAT9001 achieved greater median percentage reduction in four of six lipid measures, including total cholesterol, when compared to Vascepa:

- MAT9001 significantly reduced median TG levels by 33.2 percent compared to 10.5 percent for Vascepa (p-value <0.001);
- MAT9001 significantly reduced median very low-density lipoprotein cholesterol (VLDL-C) levels by 32.5 percent compared to 8.1 percent for Vascepa (p-value <0.001);
- MAT9001 significantly reduced median non-HDL-C levels by 8.8 percent compared to 4.6 percent for Vascepa (p-value=0.027);
- MAT9001reduced median HDL-C levels by 11.3 percent compared to 11.1 percent for Vascepa (p-value= 0.337)
- MAT9001 reduced median LDL-C levels by 2.4 percent compared to 4.3 percent for Vascepa (p-value=0.116)
- MAT9001 significantly reduced median total cholesterol levels by 9 percent compared to 6.2 percent for Vascepa (p-value=0.013).

MAT9001 also outperformed Vascepa in reductions in apolipoproteins (apo) and PCSK9 as compared to baseline:

- MAT9001 reduced median apolipoprotein B levels by 3.8 percent compared to 0.7 percent for Vascepa (p-value=0.058);
- MAT9001 significantly reduced median apolipoprotein AI levels by 15.3 percent compared to 10.2 percent for Vascepa (p-value=0.003);
- MAT9001 significantly reduced median apolipoprotein CIII levels by 25.5 percent compared to 5 percent for Vascepa (p-value=0.006);
- MAT9001 significantly reduced median PCSK9 levels by 12.3 percent compared to an 8.8 percent increase in PCSK9 levels for Vascepa (p-value <0.001).

Pre-treatment median values for lipids, triglycerides, apolipoproteins, and PCSK9 levels were measured. Patients were randomized and put on MAT9001 or Vascepa for 14 days. Following the initial treatment period, there was a 5-week washout period, following which patients were put on the other therapy for 14 days. Forty patients completed the trial. MAT9001 met its primary PK endpoint for bioavailability of omega-3 for MAT9001 relative to Vascepa in this study. Statistical analysis demonstrated superiority of MAT9001 over Vascepa for omega-3 bioavailability (baseline adjusted AUC and C_{max}, approximately 6-fold higher with MAT9001 on Day 14, with very high statistical significance).

MAT9001 Development Plan

Following announcement of our head to head study vs. Vascepa in 2015, due primarily to cardiovascular regulatory and commercial market conditions, as well as limited financial resources, we determined to slow down development of MAT9001 until such time as data became available from Amarin's cardiovascular outcomes trial, REDUCE-IT™.

Following the release of data from the Amarin REDUCE-IT trial, we have re-initiated our development efforts and activities for MAT9001. With the support of a world-class team of key opinion leaders, clinicians and regulatory experts we have designed a development program for MAT9001 designed to (a) potentially streamline our path to approval for MAT9001 in its initial indication to treat severe hypertriglyceridemia and, (b) create additional data both head to head vs. Vascepa and in a mixed dyslipidemic patient population in order to position MAT9001 to become the potential best-in-class omega-3 prescription product for the treatment and prevention of cardiovascular conditions. Our regulatory strategy with FDA will include leveraging a 505(b)(2) registration pathway, consistent with the feedback we received from FDA during 2014. We are in the process of reactivating our IND and expect to complete this activity in the second quarter of 2019.

Pursuant to our development strategy, we intend to advance MAT9001 into a series of clinical trials designed to (a) complete those studies required for approval of an initial indication to treat severe hypertriglyceridemia (≥500mg/dL) and, (b) complete additional trials to demonstrate the differentiation of MAT9001 vs. competitive approved omega-3 products and also create the potential for label enhancement in a mixed dyslipidemic patient population (patients with triglyceride levels 200-499 mg/dL).

During 2019 we intend to initiate and complete the following studies (a) a 28-day comparative bridging toxicology study, and (b)subject to any feedback from FDA, a comparative clinical bioavailability study (36 healthy volunteers) with key endpoints and assessments to include PK parameters (e.g., AUC, C_{max}, T_{max}, $t_{1/2}$) for total EPA, DHA and DPA and comparison of PK parameters for MAT9001 after a high fat meal and also fasting vs. fed.

Following completion of these studies, we intend to request an End-of-Phase 2 Meeting with FDA to review the data from the completed studies and to gain a Special Protocol Assessment (SPA) on our pivotal study protocol for the treatment of severe hypertriglyceridemia. During this meeting, we intend to present the design of a Phase 3 registration study in SHTG patients. We anticipate, subject to feedback from FDA, that the study will be a placebo-controlled study with two dose groups of MAT9001: 2 gram and 4 gram/day. We anticipate that approximately 270 patients will be randomized 1:1:1. It is planned that MAT9001 will be dosed either once or twice daily without regard to meals. The primary endpoint of the study is anticipated to be change in TG levels at Week 12.

In addition to the studies required for approval to treat SHTG, we intend to conduct additional trials, including a comparative PK/PD study vs. Vascepa and a second Phase 3 trial of MAT9001 as an add-on to statin therapy in patients with high triglycerides (200-499 mg/dL) at risk for cardiovascular disease. We anticipate that our second head to head study vs. Vascepa will generate topline data during the second half of 2020.

MAT2203 - Our Lead Product Using our LNC Delivery Platform Technology

We have leveraged our platform lipid nano-crystal (LNC) platform delivery technology to develop two clinical-stage products that we believe have the potential to become best-in-class drug. Our lead LNC platform product candidate, MAT2203, is an orally-administered LNC formulation of a broad spectrum anti-fungal drug called amphotericin B. We previously had been planning to conduct a Phase 2/3 adaptive-design study of MAT2203 in patients with Acute Lymphoblastic Leukemia (ALL) for the prevention of invasive fungal infections (IFI) due to immunosuppressive therapy. While we continue to believe that MAT2203 could become an important solution to the significant unmet medical need to prevent invasive fungal infections in immunosuppressed patients, we believe there are opportunities for a potentially more rapid approval of MAT2203 for the treatment of certain invasive fungal infections in areas of high unmet medical need which can be substantially supported by non-dilutive government funds. In partnership with the NIH, we have conducted numerous preclinical studies of MAT2203 for the treatment of cryptococcal meningitis. In such studies, we observed the potential for MAT2203, utilizing our LNC platform delivery technology, to (a) cross the blood-brain barrier, (b) treat this infection and (c) eliminate the toxicity normally associated with liposomal delivery of amphotericin B intravenously.

We now plan to initially develop MAT2203 for the treatment of cryptococcal meningitis, one of the most frequent and opportunistic infections in Human Immuno-Deficiency Virus (HIV) patients. Given the high morbidity associated with cryptococcal meningitis in HIV patients, the clinical unmet need is globally very high with the global burden estimated at 1 million cases annually. We believe MAT2203, if approved, to have the potential to become the drug of choice for physicians in the treatment of other invasive fungal infections. We plan to leverage the 505(b)(2) regulatory pathway for MAT2203, in part relying upon FDA's findings ofthe efficacy of amphotericin B, and anticipate meeting with the FDA in the first half of 2019 to discuss our development plans for MAT2203. We also plan to seek accelerated approval for this indication. We are in the final planning stages for a Phase 2 clinical trial, fully funded by the NIH and conducted by the University of Minnesota at their clinic in Uganda. We believe that this study may have the potential to become a pivotal study to support approval of MAT2203 for the treatment of cryptococcal meningitis, and we also plan to submit an application for Orphan Designation and QIDP Designation during the first half of 2019.

Our second clinical stage LNC-based product candidate is MAT2501, an orally administered, cochleate formulation of the broad-spectrum aminoglycoside antibiotic amikacin which may be used to treat different types of multidrug-resistant bacteria, including non-tuberculous mycobacterium infections (NTM), as well as various multidrug-resistant gram negative and intracellular bacterial infections. In May 2017, we completed and announced topline results from a Phase 1 single escalating dose clinical trial of MAT2501 in healthy volunteers in which no serious adverse events were reported and where oral administration of MAT2501 at all tested doses yielded blood levels that were well below the safety levels recommended for injected amikacin, supporting further development of MAT2501 for the treatment of NTM infections. We have decided to temporarily halt clinical development of MAT2501, in order to prioritize and accelerate the development of MAT9001 and MAT2203 and explore utilization of our LNC platform delivery technology in the gene therapy space.

MAT2203 - ***Product Profile***

MAT2203 is an orally-administered, LNC formulation of amphotericin B (a broad-spectrum fungicidal agent). Little to no clinical resistance has been reported to date with amphotericin B as compared to the rapidly emerging drug resistance seen in other antifungal therapies. Currently, IV-only administered amphotericin B is the only broad spectrum fungicidal; however, it has significant treatment-limiting side effects, most notably nephrotoxicity. The ability to provide amphotericin B orally using our proprietary and novel oral formulation comprising our LNC platform delivery technology, may offer a new and promising alternative for patients and doctors. In a clinical Phase 1 single-dose, double-blind, dose-escalating, pharmacokinetic study of 48 healthy volunteers, oral MAT2203 was observed to be well tolerated with no serious adverse events reported, and without any observed nephrotoxicity. The most commonly reported AEs were nausea and abdominal pain. None of the AEs were related to abnormal laboratory evaluations. All treatment emergent adverse events (TEAEs) were mild except 1 instance of "upper respiratory tract infection" which was moderate in a subject following 800 mg MAT2203. No AEs led to withdrawal. There were no serious AEs. There was one pregnancy (subsequently determined that the conception date was 1 to 2 days prior to dosing) resulting in elective termination from the study. More recently, in our Phase 2 trial of MAT2203 conducted by the National Institutes of Health, four out of four enrolled patients met their primary efficacy endpoint, three patients continue on treatment of which two have been successfully taking MAT2203 for more than two years as part of a long term safety extension, with no evidence of kidney or other toxicity frequently associated with the use of amphotericin B.

Antifungal Market Opportunity

The overall global antifungal market accounted for $10.7 billion in 2015 with estimated annual worldwide sales of prescription systemic antifungal drugs reaching approximately $4 billion. This includes therapies used as active treatment or prophylaxis (preventative) in the inpatient and outpatient setting, therapies used for the treatment of hospitalized patients and therapies used for the treatment of patients who are being discharged from the hospital. We estimate that, each year, there are over 1.5 million cases of invasive fungal infections caused by various species of *Candida, Aspergillus* and *Cryptococcus,* the three most common invasive fungal pathogens, globally. The estimated incidence in the U.S. for these conditions is approximately 46,000 for invasive candidiasis, 6,000 for invasive aspergillosis, and 3,000 for cryptococcal meningitis. The rapid progression of disease and high mortality rates (20% - 50%) associated with documented invasive fungal infections often result in antifungal therapy being administered in suspected (unconfirmed) cases or as a preventative measure in patients at high risk. Also, the increasingly widespread use of immune suppressive drugs as cancer chemotherapy or for organ transplantation or treatment of autoimmune disease has resulted in an increasing population of patients at risk for invasive fungal infections. Furthermore, the limited number of systemic antifungal drug classes, consisting of azoles, echinocandins and polyenes, and their extensive use, has led to increased numbers of infections with drug-resistant strains. The Centers for Disease Control and Prevention (CDC) has listed fluconazole-resistant *Candida* as a serious threat requiring prompt and sustained action and has also identified a rise in echinocandin resistance, especially among *Candida glabrata.* In June 2016, the CDC issued an extraordinary alert for healthcare facilities and providers to be on the lookout for patients with *Candida auris*, a multidrug resistant strain with high mortality (approximately 60%). Almost half of *C. auris* isolates are multidrug resistant to two or more antifungal classes (large majority resistant to fluconazole, 40% resistant to echinocandins). We believe this underscores the urgent need for new agents with demonstrated activity against resistant strains and that can be administered with significantly less toxicity and the potential to discharge patients earlier to reduce hospital stays and associated costs.

Physicians' options for the treatment of fungal infections are limited by a lack of innovative therapies. Several factors have contributed to the low rate of antifungal drug development, including a previously challenging regulatory environment that necessitated large and costly clinical trials. As a result of this regulatory environment and other factors, the number of antifungals in development has decreased, while anti-microbial resistance has increased.

Our Solution – MAT2203

Our lead anti-infective product candidate, MAT2203, is an application of our LNC platform delivery technology to a broad spectrum anti-fungal drug called amphotericin B. Amphotericin B is an IV administered drug used as a last resort for treatment of systemic fungal infections resistant to triazoles and echinocandins, including resistant candidiasis, cryptococcal meningoencephalitis, and aspergillosis. To date, there have been little to no reports of clinically observed drug-resistance to amphotericin B, further bolstering the use of this compound as the most likely last resort treatment for fungal infections in the foreseeable future. However, the use of amphotericin B is relatively limited because it is currently only available as an IV-administered product and has documented history of severe toxicity (most notably nephrotoxicity). By utilizing our LNC platform delivery technology to nano-encapsulate amphotericin B, there is now an opportunity for the drug to be administered orally with targeted delivery to infected cells, which we believe may have fewer side effects than the currently available IV-formulations of amphotericin B. Our LNC delivery of amphotericin B changes the bio-distribution, resulting in a higher level of the drug at the site of infection and a lower level of circulating amphotericin B. By reducing the amount of circulating drug, our LNC may reduce overall toxicity. Importantly, drug concentrations will be high only in tissues due to the migratory nature of macrophages to inflammatory regions. Based upon our studies to date, we believe MAT2203 has the potential to offer improved safety and reduced toxicity and, as a result, we believe MAT2203 will be able to offer a categorically different formulation that delivers orally administered amphotericin B, directly to the target cell at the site of infection. In collaboration with the NIH, in multiple studies, we have demonstrated in cryptococcal meningitis mouse models that our LNC-delivered amphotericin b, following oral administration, has the ability to successfully cross the blood brain barrier to the site of infection in mice. This demonstration provides important data indicating that our LNC platform delivery technology could become an important delivery solution for a variety of CNS-based disorders and diseases.

We believe that MAT2203 has the potential to become a best-in-class induction, consolidation, and maintenance therapy for the treatment of cryptococcal meningitis in HIV patients by offering the following key benefits.

- **Potential to treat resistant pathogens**. We believe that MAT2203 has the potential to prevent and treat fungal infections caused by drug resistant fungi, including those resistant to existing azoles and echinocandins, due to amphotericin B's fungicidal (i.e. killing the fungi) nature and potency against resistant strains and the potential for our cochleate drug delivery platform to provide higher drug exposure early in the course of therapy.

- **Enabling an all-oral therapy.** Cryptococcal meningitis has become the most common cause of adult meningitis in many parts of Africa, where cryptococcosis now rivals tuberculosis in all-case mortality. While long-term survival has improved with widespread use of antiretroviral therapy in high income countries, early mortality remains high. Early mortality rates are often ~ 70% in routine practice where access to diagnostics or medications is limited or unavailable, intracranial pressure is uncontrolled, or in settings where other barriers to the management of cryptococcal meningitis exist. IV administration of amphotericin B deoxycholate is not often possible in resource-limited settings, even when it is available.

- **Shorter and less costly hospital stays and lower outpatient costs**. By providing physicians and patients with access to an orally available, broad spectrum fungicidal agent in MAT2203, there is the potential to reduce hospital costs, which account for over 70% of the overall treatment cost of invasive fungal infections

The FDA has granted MAT2203 designations for Qualified Infectious Disease Product, or QIDP, and Fast Track for the treatment of invasive candidiasis and aspergillosis and for the prevention of IFIs in patients on immunosuppressive therapy. We are in the process of applying for a fourth QIDP for the treatment of cryptococcal meningitis. We will also apply for Orphan Drug Designation for MAT2203 for the treatment of cryptococcal meningitis. The FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. The orphan drug designation provides eligibility for orphan drug exclusivity in the United States upon FDA approval if a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation. For a product that obtains orphan drug designation on the basis of a plausible hypothesis that it is clinically superior to the same drug that is already approved for the same indication, in order to obtain orphan drug exclusivity upon approval, clinical superiority of such product to this same drug that is already approved for the same orphan indication must be demonstrated. Orphan drug exclusivity means that the FDA may not approved any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, a waiver from payment of user fees, an exemption from performing clinical studies in pediatric patients unless the FDA requires otherwise by regulation, and tax credits for the cost of the clinical research. The QIDP designation, provided under the Generating Antibiotic Incentives Now Act, or the GAIN Act, offers certain incentives for the development of new antibacterial or antifungal drugs, including eligibility for Fast Track designation, priority review and, if approved by the FDA, eligibility for an additional five years of marketing exclusivity. Fast Track designation enables more frequent interactions with FDA to expedite drug development and review. Fast Track designation does not change the standards for approval and we can provide no assurances that we can maintain Fast Track designation for MAT2203 or that such designation will result in faster regulatory review. The seven-year period of marketing exclusivity provided through orphan designation, if granted, combined with an additional five years of marketing exclusivity provided by the QIDP designation positions MAT2203 with a potential for a total of 12 years of marketing exclusivity to be granted at the time of FDA approval. Our plan is to further secure QIDP/Fast Track/Orphan Designation for the initial development target indication of cryptococcal meningitis.

Development History of MAT2203 and Initial Target Indication

MAT2203 was studied in animal model studies of various fungal infections including invasive candidiasis, aspergillosis and cryptococcal meningitis.

The data from animal studies for MAT2203 indicate a side-effect advantage over other amphotericin B formulations, which we believe is based on two phenomena:

- The lipid-crystal nano-particle is a solid particle that does not significantly "leak" its drug content while circulating. The particle releases its medication pay-load only when inside the target cells, and thus appears that the use of MAT2203 does not result in toxicities normally seen in the kidneys when using current formulations of amphotericin B.
- Because of this targeted approach, we have been able to increase the therapeutic window on a mg/kg basis as compared to IV amphotericin B formulations. We have observed equivalent efficacy at lower doses as well as been able to use oral doses of up to 10x the highest tolerable IV dose in animal model studies.

NIH-Conducted Study

In early 2017, we reported interim data from the NIH-Conducted Phase 2a Clinical Study of Orally-Administered MAT2203 for the Treatment of Chronic Refractory Mucocutaneous Candidiasis. At that time, two out of the two patients with long-standing azole resistant mucocutaneous candidiasis met the primary endpoint of the Phase 2a study, achieving ≥ 50% clinical response with treatment of MAT2203. Patient #01 achieved a 57% reduction in clinical symptoms after 8 weeks on therapy while patient #02 achieved an 85% reduction in such clinical symptoms after 6 weeks of treatment. MAT2203 was well tolerated with majority of adverse events observed being mild in severity and mostly unrelated to study drug. Importantly, for both patients renal and liver function parameters remained well within normal ranges during the core study as well as during the first 6-month extension of this study. In July 2017, the NIH/NIAID institutional review board approved continuation of treatment of patients in the study-extension for an additional 6 months, for total extension of up to one year.

In January 2018, the National Institutes of Health ("NIH") reported positive data from a third patient enrolled in this study. This third patient, with long-standing azole resistant mucocutaneous candidiasis, met the primary endpoint of the Phase 2a study in achieving ≥ 50% clinical response with treatment of MAT2203. MAT2203 was well tolerated with any adverse events observed being mild in severity and unrelated to study drug. With this third positive response, the study has met its statistical hurdle for success. In June of 2018, the NIH reported that a fourth patient had enrolled in the study and had met the primary endpoint in achieving ≥ 50% clinical response with treatment of MAT2203. All four patients had been enrolled in a long-term study extension and the initial two patients have now shown no signs of kidney or liver toxicity over the approximately twenty-four months of being administered MAT2203. The third patient was required to drop out of the long-term safety portion of the study due to the development of an infection that does not respond to amphotericin B. The fourth patient continues in the long-term safety extension for the study. The clinical response to MAT2203 seen in all three patients continuing on drug has been maintained and/or improved during the extension period in addition to patients reporting meaningful quality-of-life improvements.

VVC Study

In late 2017, we announced the topline data from our Phase 2 study in Vulvovaginal Candidiasis (VVC) using MAT2203. In the context of our overall program for MAT2203 with the aim to develop our lead product initially for the prevention of invasive fungal infections in patients who are immunocompromised due to immunosuppressive therapy, our goal was, in addition to further establishing the safety and tolerability of MAT2203, to demonstrate efficacy of MAT2203 through a mechanism involving systemic absorption in a non-life threatening fungal infection. This study concept was consistent with early human efficacy studies in the development of other anti-fungal therapies. This Phase 2 study was not designed or powered to support an indication for the treatment of VVC and therefore supplant fluconazole as the standard of care. The key data generated from this study included additional safety and tolerability data.

In this VVC study, the primary endpoint of safety was met, and it was demonstrated that oral delivery of encochleated amphotericin B is safe and well tolerated without the renal and hepatic toxicities that can be seen with administration of intravenous amphotericin B. Drug-related treatment emergent adverse events in this study were mostly of mild and gastro-intestinal nature and were seen at a rate of 20%, 18% and 2% respectively for MAT2203 200mg, MAT2203 400mg, and fluconazole. Consistent with the safety observations in the NIH study, in this VVC study no drug-related effects on liver function were observed and kidney function parameters stayed within normal ranges during the entire study for all 91 patients treated with MAT2203 for 5 days.

Development Plan

In February 2019, the NIH approved the funding of a planned clinical trial related to a grant application submitted by The University of Minnesota to study MAT2203 for the treatment of cryptococcal meningitis. The clinical study will be conducted in Uganda and has already received the approval of all necessary regulatory authorities. The protocol is in the process of being finalized and the trial is anticipated to consist of two parts with the following design. The initial portion of the trial will be a Phase 1 Study conducted in HIV patients in Uganda without active neurological infection. Subjects in this initial phase of the study will involve a determination of the maximal tolerated dose to arrive at an optimal dose for the second part of the study. A Data Monitoring Committee (DMC) will review the data from the initial phase prior to commencing the efficacy portion of the trial. Upon review of the data, the DMC will make a recommendation to the Ethics Committee/IRB as to the dose to be used in the efficacy portion of the study in patients with active neurological infection. The efficacy portion of the study has been designed as an open-label trial to evaluate the safety, tolerability, and microbiologic efficacy of oral MAT2203 as part of induction and consolidation treatment of HIV-infected patients with cryptococcal meningitis compared with standard intravenously delivered amphotericin B. Participants in the study will be enrolled in sequential cohorts designed to mitigate the risk associated with these very sick patients. Induction treatment in each cohort will start with IV amphoterticin and flucytosine treatment with oral MAT2203 administered as step-down treatment for the initial two cohorts (with earlier step-down to MAT2203 in each subsequent cohort.) The next two cohorts will test the induction of treatment with our MAT2203 product, with step-down treatment to IV amphotericin. The final cohort of patients will have a MAT2203 induction treatment (plus flucytosine) without IV administered amphotericin b. The primary endpoint for this trial will be the rate of cerebrospinal fluid (CSF) Cryptococcus clearance as measured by serial quantitative CSF fungal cultures. This study is planned to commence in the second half of 2019. The trial design is expected to be finalized during 2019 following a meeting with FDA.

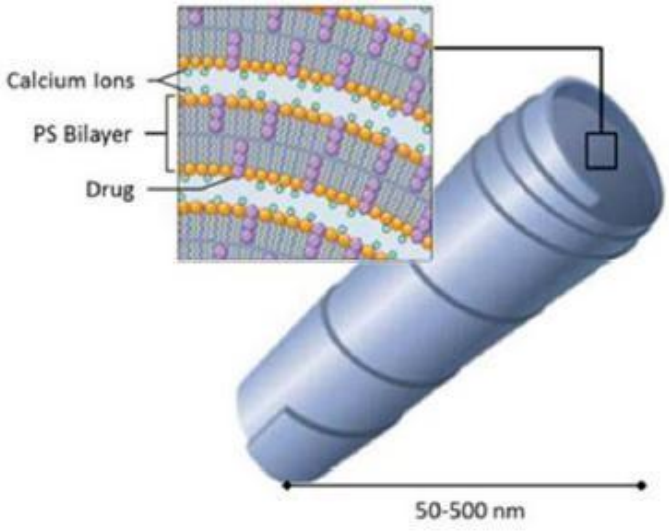
We are currently completing a 90-day rat toxicology study to support dosing with MAT2203 beyond the current 28-day tox coverage. The in-life portion of the study has been completed. There have been no signs of toxicity noted to date.

Our plan is to meet with FDA to review our development plan and study design as we intend to conduct this Phase 2 study in patients with cryptococcal meningitis under a US IND. We additionally will discuss with FDA our plans to leverage a 505(b)(2) Pathway, relying, in part, upon FDA's findings of safety and efficacy of I.V. amphotericin B.

Our Cochleate Platform Delivery Technology

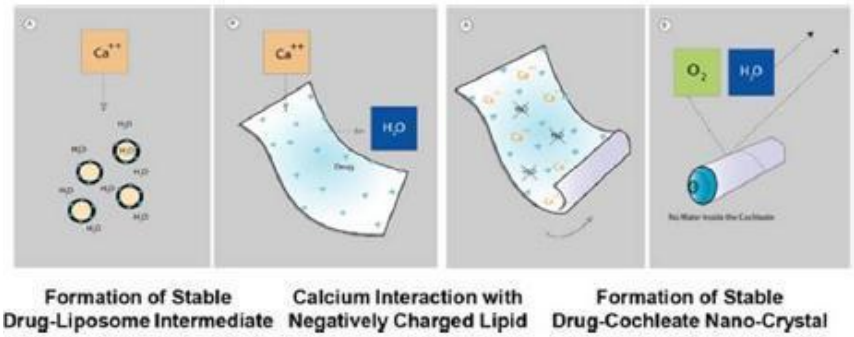
Cochleate lipid-crystal nano-particles are composed of simple, naturally occurring materials: phosphatidylserine (PS) and calcium. They are stable and have a unique multilayered structure consisting of a large, continuous, solid, lipid bilayer sheet rolled up in a spiral or as stacked sheets, with no internal aqueous space (Figure 1). This unique structure provides protection from degradation for "encochleated" molecules. Components within the interior of the cochleate remain intact, even though the outer layers of the cochleate may be exposed to harsh environmental conditions or enzymes.

Figure 1 Cochleate Formulation



The structure is formed when a series of solid lipid sheets engulf drug molecules, a process referred to as "encochleation." Encochleation, developed by Matinas and Rutgers New Jersey Medical School, involves combining calcium and soy-derived PS, two naturally occurring materials classified as GRAS (generally recognized as safe), through a stirring process to envelop the active pharmacological ingredient. The result is a nano-size encochleated drug formulation (Figure 2).

Figure 2 Formation of Cochleate



Cochleates have been shown to improve existing drugs by providing 1) cell-targeted delivery; 2) reduced blood levels thereby reducing toxicity; and 3) oral delivery of drugs now only available intravenously. Cochleates work by encapsulating molecules of drugs in a solid, anhydrous, crystalline structure, protecting them as they pass through the gastrointestinal (GI) tract where they cross the mucous membrane. Once the cochleates have crossed the mucosal barrier of the GI tract into the lymphatic system, they are picked up by particle scavenging cells of the mononuclear phagocytic system, such as macrophages and dendritic cells. (Figure 3). Activated macrophages, with drug-cochleate inside, migrate to the site of infection or to the target organ and deliver amphotericin B.

Cells in the mononuclear phagocytic system are immune cells that have the capacity to engulf and destroy numerous potentially pathogenic materials and organisms within the body. These cells are found in almost every site of the body, save a few 'immune privileged' sites (e.g. eyes, fetus, and testes). Such cells help with non-specific (innate) immune defenses as well as help initiate specific (adaptive) immune responses, thus they play a critical role bridging the gap between innate and adaptive immune responses. Our core capabilities combine the use of lipids as active pharmaceutical ingredients (API) and the use of lipids in "cochleate-shaped" lipid-crystal nano-particle drug delivery vehicles. Therapeutic applications of our proprietary delivery technology were initially focused on the delivery of several potent and highly efficacious anti-fungal and anti-bacterial agents which are currently still associated with serious side effects, including irreversible toxic effects on kidney and hearing function. We believe our technology has the potential for targeted delivery of these agents, which positions us to be at the forefront of dealing with these very serious problems. We have now also expanded our research and development efforts for our LNC Platform to focus on the delivery of a wide range of therapeutic treatments, in particular those in the oligonucleotide space (siRNA, DNA, antisense DNA, mRNA, and CRISPR-Cas9). We continue to push forward our business development efforts to further expand our collaborations across pharma and biotech companies who have innovative therapies with delivery challenges which may be addressable with our LNC platform delivery technology.

Our LNC technology is currently being used to encapsulate potent anti-infective drugs in tiny lipid-crystals which are selectively picked up by cells in the mononuclear phagocytic system, such as macrophages, and transported to infected cells. These tiny lipid crystals are referred to as "cochleates." Cochleates have a multilayer crystalline, spiral structure with no internal aqueous space. The structure is formed when a series of solid lipid sheets roll up and engulf drug molecules in between the sheets, a proprietary process referred to as "encochleation". The result is a lipid-crystal encochleated drug formulation made up of nano-sized particles. We believe our cochleate delivery technology provides an effective delivery mechanism without chemically bonding or otherwise altering the drug. Because the medications are locked in the particles, we believe the exposure to sensitive organs will be reduced, potentially resulting in reduced toxic effects. In summary, we believe this unique technology offers (1) targeted delivery, (2) decreased toxic effects, and (3) oral formulation (even for IV-only medications).

Multi-organ Protection: The key innovation of our cochleate delivery technology is our ability to package medication inside lipid-crystal particles without leaking. Because of their crystal nature, these particles are truly solid and hold on tightly to their medication pay-load. This is where the cochleate delivery technology differs markedly from other lipid-based delivery technology, such as liposomal delivery. Liposomes are liquid delivery systems which typically leak some of their drug content into the circulatory system, thus still exposing vulnerable organs and tissues to potential toxic effects. Keeping potentially organ-toxic medications inside the lipid-crystal particles strongly differentiates our cochleate delivery technology from other drug-delivery approaches.

Targeted Delivery: The size of our individual cochleate lipid-crystals is typically in the range of 50-500 nm. This is very small and by comparison close to the size of a large virus or a small bacteria. Our body produces several cell-types that are designed to remove viruses and bacteria from our system. These cell types, such as macrophages, are part of our immune system and "swallow" the bacteria and viruses they encounter in order to protect us from infections. Because of the size our lipid-crystal cochleate particles and the phospholipid surface structure (the cell membranes of bacteria are also made up from phospholipids), macrophages tend to absorb these cochleate particles very well.

Oral Formulation: Many drugs that are currently on the market are only effective in treating diseases when administered via IV. For example, many anti-infective drugs must be administered via IV in order to be effective. IV administration presents several challenges to care, such as risk of infection, patient discomfort from injections, and higher cost of care than anti-infective drugs that can be taken orally (IV delivery must be performed by a doctor or nurse, often within a very expensive hospital setting). Although several technologies have been used to attempt to convert IV drugs to orally delivered medications, success has been limited due to the difficulty in achieving adequate bioavailability (i.e., the amount of drug that is absorbed into the body) with oral formulation. We believe that the unique cochleate crystal-structure in our platform technology protects the drug from degradation when it passes through the gastrointestinal (GI) tract and that its lipid surface features facilitate the particle to be absorbed into the blood stream. The potential application of our cochleate delivery technology for the delivery of injectable medications offers significant clinical and commercial value if successfully demonstrated in human clinical trials. It is our intent to further validate the LNC Platform technology in our planned cryptococcal meningitis study.

Our cochleate lipid-crystal nano-particle technology changes the delivery of medicines in a unique manner and alters the bio-distribution of these medications by targeting tissues and organs that are affected by infection and inflammation. Besides IV-only anti-infectives such as amphotericin B and amikacin, we have orally delivered in animal studies the influenza vaccine, siRNA, NSAIDs, other anti-infectives such as atovaquone, and many other compounds across multiple therapeutic areas, demonstrating the potential broad application of our technology. We have observed rapid local accumulation in infected tissues, which appear be the result of transport of our drug-loaded cochleates by macrophages and other immune-cells. For example, in a mouse model of invasive candidiasis, comparing orally administered MAT2203 to injected amphotericin B deoxycholate (original drug Fungizone), we observed amphotericin B levels above the minimal inhibitory concentration inside infected organs on day 1 with MAT2203 treatment while such levels were not reached with the injected original amphotericin-deoxycholate product until 3-4 days of treatment. Such kinetics have been seen before with other medications, such as macrolide antibiotics (e.g. azithromycin). It appears from our data that the kinetics of cochleate delivery has similarities to the kinetics of macrolide antibiotics. We expect that additional preclinical and clinical work on the kinetics of our cochleate products will further elucidate the mechanism of cochleate delivery to the site of infection or inflammation.

Strategic Collaborations Using LNC Technology

We believe our LNC platform delivery technology can be used to reformulate a wide variety of molecules and drugs which, (i) require delivery technology to effectively protect molecules and drugs in the body and could benefit from efficient delivery and cellular uptake by target cells, and (ii) are currently only available in IV formulations or, (iii) otherwise experience significant toxicity-related adverse events. Leveraging our cochleate delivery technology, we believe we can develop a robust pipeline of product candidates, either internally or through robust strategic partnerships with pharmaceutical and biotech companies. We have tested a range of pharmaceutical compounds reformulated by our cochleate delivery technology in proof-of-concept animal studies, including oligonucleotides (mRNA, siRNA, DNA plasmids), vaccines, anti-inflammatory agents, NSAIDs and atovaquone. By way of example, in 2016 we received a patent issuance related to LNC compositions directed against expressions of proteins. The allowed patent claims cover our proprietary methods related to the composition and the formation of encochleated siRNA for potential use as therapy for regulating gene expression. We intend to pursue opportunities to develop products, either alone or in partnership with other pharmaceutical or biotech companies, related to this technology and this remains a key part of our strategy to maximize the value of this unique and disruptive lipid-crystal nanoparticle delivery technology.

We continue to actively collaborate with the NIH on a number of therapeutic fronts to further expand the generation of data to support broad use of our LNC platform technology across broad therapeutic treatment modalities. In July 2018, we announced a research collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH) focused on the development of a novel therapy for the treatment of human immunodeficiency virus (HIV) combining targeted antisense oligonucleotides (ASO) and our LNC delivery technology. The goal of this collaboration is to leverage the unique attributes of our LNC technology to safely, effectively and efficiently deliver ASO intracellularly to inhibit Trans-Activator of Transcription (Tat)/viral mRNA translation. Tat is a contributing factor in three major aspects of HIV infection post treatment with antiretroviral therapy (ART): viral replication/latency, chronic inflammation and neurological complications. Tat is a key regulatory protein not specifically targeted by currently available ART. *In vitro* and *in vivo* studies will be conducted to determine optimal structures for incorporating ASOs into the LNC technology platform, delivery into target cells and the effective inhibition of Tat and/or viral replication while monitoring Tat-induced cytotoxicity.

In January 2019 we announced a research evaluation with an undisclosed top global pharmaceutical company aimed to evaluate synergistic effects of our lipid-nano-crystal (“LNC”) platform delivery technology with our partner’s nucleic acid polymer technology. Formulations will be developed using our LNC delivery technology which enables the development of a wide range of difficult-to-deliver molecules. Promising formulations will be tested in *in vitro* and *in vivo* preclinical studies. For competitive reasons, the agreement stipulates certain confidential provisions, including the pharmaceutical company’s identity, the therapeutic molecule(s), the intended targets and the financial terms of the agreement.

Exclusive License Agreement with Rutgers University

Through our acquisition of Aquarius Biotechnologies Inc., we acquired a license from Rutgers University for the cochleate delivery technology. The Amended and Restated Exclusive License Agreement between Aquarius and Rutgers, The State University of New Jersey (successor in interest to the University of Medicine and Dentistry of New Jersey) provides for, among other things, (1) a license issue fee of $25,000 paid upon execution, (2) an increased equity interest in the company from 5% to 7.5% of Aquarius (prior to our acquisition of Aquarius in the Aquarius Merger), (3) royalties on a tiered basis between low single digits and the mid-single digits of net sales of products using such licensed technology, (4) a one-time sales milestone fee of $100,000 when and if sales of products using the licensed technology reach the specified sales threshold and (5) an annual license fee of initially $10,000, increasing to $50,000 over the term of the license agreement. We also agreed to assume the responsibility to pay required patent prosecution and maintenance fees covering the technology.

Unless otherwise terminated by either party, the term of the license, on a country by country basis, shall be the longer of 7-1/2 years from the date of first commercial sale of a product in a country using the licensed technology or until the expiration of the last-to-expire patent rights licensed under the agreement, whichever is longer. Rutgers has the right to terminate the license agreement if we have not commenced commercial sales of at least one product using the licensed technology within nine years of the effective date of the license agreement.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We will seek to protect our products and associated technologies for their manufacturing and development through a combination of patents, trade secrets, proprietary know-how, FDA exclusivity and contractual restrictions on disclosure. Our policy is to pursue, maintain and defend patent rights and to protect the technology, inventions and improvements that are commercially important to the development of our business. Our success will significantly depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology and inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely heavily on know-how and continuing technological innovation to develop and maintain our proprietary position.

Matinas-Owned Intellectual Property Relating to MAT9001

We have sought patent protection in the United States and internationally for our MAT9001 discovery program, and any other inventions to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business.

Our current patent portfolio relating to MAT9001 and MAT8800 is comprised of two issued patent U.S. patents and one issued foreign patent in Australia. The issued patents claim cover the Company's proprietary methods relating to triglyceride levels, total cholesterol, VLDL-cholesterol or apolipoprotein C-III by administering a pharmaceutical composition comprising omega-3 fatty acids including eicosapentaenoic acid (EPA) and docosapentaenoic acid (DPA). These patents provide important protection to MAT9001 through 2033. In addition, we have nineteen additional patent applications across four patent families covering the oil composition for MAT9001, other omega-3 fatty acid compositions, as well as formulations of MAT9001 and similar formulations. All of these filed patent applications also comprise methods of use of such oil compositions and formulations. Any patents that may issue from these filed United States patent applications and their counterpart international application covering the MAT9001 drug substance, formulation, and methods for use in treatment would extend protection until at least 2033.

Exclusively Licensed and Matinas-Owned Intellectual Property Relating to Our Proprietary Cochleate Delivery Technology Platform and MAT2203

The patents and patent applications that we exclusively license from Rutgers University provide patent protection for the proprietary chemistry technology used in our process to make our lipid nano-crystal and geodate cochleates and formulate the active pharmaceutical ingredients delivered inside this delivery technology, as in MAT2203, our lead product comprising the LNC platform delivery technology. Pursuant to our license agreement, we acquired rights to a portfolio that currently includes 11 pending applications and 22 issued U.S. and foreign patents, including 15 patents issued within the last 3 years, which extends patent protection until at least 2033. In addition, we have 28 Matinas-owned pending patent applications filed both in the United States and in foreign jurisdictions within the past 3 years. We have chosen to file these patent applications in selected foreign markets that we consider important for our product candidates. These international markets generally include Europe, China, India, Brazil, Russia, Canada, Japan, Korea, Australia and Mexico. These pending patent applications can extend patent protection through 2037. This patent portfolio covers our cochleate delivery system which covers a broad spectrum of technology, including amphotericin B cochleates, geodate cochleates, methods of delivering nutrients or biologically relevant molecules to a host using cochleates, cochleate vaccine compositions and protein-lipid vesicles, small interfering RNA cochleates, mRNA cochleates methods of enhancing the encochleation of hydrophilic molecules and cochleates made with low purity soy phosphatidylserine.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Relating to Our Intellectual Property and Regulatory Exclusivity."

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our proprietary LNC technology platform as well as the manufacture of certain intermediates utilized in MAT9001, as well as our soft gelatin capsule formulation, are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also plan to seek trademark protection in the United States and outside of the United States where available and when appropriate. We intend to use these registered marks in connection with our pharmaceutical research and development as well as our product candidates.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Many of these companies have far greater human and financial resources and may have product candidates in more advanced stages of development and many will reach the market before our product candidates. Competitors may also develop products that are more effective, safer or less expensive or that have better tolerability or convenience.

MAT9001

Our competitors both in the United States and abroad include large, well-established pharmaceutical and generic companies, specialty and generic pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc currently sells Lovaza®, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, which was approved by FDA in 2004 and has been on the market in the United States since 2005. Multiple generic versions of Lovaza are available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently sells Tricor® and Trilipix® for the treatment of severe hypertriglyceridemia and Niaspan®, which is primarily used to raise high-density lipoprotein cholesterol, or HDL-C, but is also used to lower triglycerides. Multiple generic versions of Tricor, Trilipix and Niaspan are also available in the United States.In 2012, Amarin Corporation received an approval to market its prescription-only omega-3 ethyl ester called Vascepa® for the treatment of severe hypertriglyceridemia

In addition, in May 2014, Epanova® (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. Neither Epanova nor Omtryg have been commercially launched, but could launch at any time. Each of these competitors, other than Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with MAT9001. Acasti Pharma, or Acasti, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2015 that it intends to pursue a regulatory pathway under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, for its omega-3 prescription drug candidate, CaPre® (omega-3 phospholipid), derived from krill oil, for the treatment of hypertriglyceridemia.

Akcea Therapeutics/Ionis Pharmaceuticals (formerly Isis Pharmaceuticals), or Akcea/Ionis, in August 2018 announced the receipt of a complete response letter from the FDA for WAYLIVRA™ (volanesorsen), a drug candidate administered through weekly subcutaneous injections, for the treatment of familial chylomicronemia syndrome (FCS). Akcea will continue to work with the FDA on the path forward for Waylivra for the treatment of FCS. Waylivra continues to be developed for the treatment of familial partial lipodystrophy (FPL).

In June 2018, Gemphire Therapeutics announced positive topline results from a Phase 2b trial (INDIGO-1) of its drug candidate, gemcabene, in patients with severe hypertriglyceridemia. Gemcabene is an oral, once-daily pill for a number of hypercholesterolemic populations and severe hypertriglyceridemia.

Zydus Cadila has a Phase 2 development program for its lead molecule, Saroglitazar, in various indications, including severe hypertriglyceridemia in the United States. In August 2018, the Company announced that it had suspended the Phase 2 trial in the severe hypertriglyceridemia indication due to study enrollment issues, while it continues development activities in other indications. The product is approved in India under the name Lipaglyn® for the treatment of hypertriglyceridemia and diabetic dyslipidemia. We are also aware that bezafibrate has been licensed by Intercept Pharmaceuticals to be further developed and potentially launched in the United States market.

MAT2203

Although we believe that our proprietary LNC platform delivery technology, experience and knowledge in our areas of focus provide us with competitive advantages, these potential competitors could reduce our commercial opportunities. For many of our product candidates, we anticipate facing competition from other products that are available on a generic basis and offered at low prices. Many of these generic products have been marketed by third parties for many years and are well accepted by physicians, patients and payers.

We believe that MAT2203 and any other development candidate we may pursue in the future using our proprietary cochleate drug delivery technology platform, paralleled with our scientific and development expertise in the field of drug delivery, provide us with competitive advantages over our peers. However, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical, and biotechnology companies, as well as from generic drug manufacturers, academic institutions, governmental agencies and public and private research institutions.

MAT2203 will primarily compete with antifungal classes approved for the treatment of candidemia and mold infections, which include polyenes, azoles and echinocandins. The approved branded therapies for these indications include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.), Mycamine (micafungin, marketed by Astellas Pharma US, Inc.), Diflucan (fluconazole, marketed by Pfizer, Inc.), Noxafil (posaconazole, marketed by Merck & Co.), Vfend (voriconazole, marketed by Pfizer, Inc.), Sporanox (itraconazole, marketed by Jansen Pharmaceuticals, Inc.), Cresemba (isavuconazole, marketed by Astellas Pharma US, Inc.), Ambisome (liposomal amphothericin B, marketed by Astellas Pharma US, Inc.) Abelcet (lipid complex amphothericin B, marketed by Sigma Tau Phrmaceuticals Inc.) and amphothericin B deoxycholate (marketed by X-Gen Pharmaceuticals, Inc.). There currently are and may be more generic versions of these products available at the time of MAT2203 market approval, which will create added competition. In addition to approved therapies, we expect that MAT2203 may compete with product candidates that we are aware of in clinical development by third parties, such as SCY-078 (being developed by Scynexis, Inc.), CD101 (being developed by Cidara Therapeutics, Inc.) and certain products being developed by Viamet Pharmaceuticals Holdings, LLC, Vical Incorporated and F2G, Ltd.

Manufacturing

We currently contract with one third party manufacturer to supply us with certain of the intermediates used in MAT9001 and a second manufacturer to formulate a third intermediate and supply us with the final drug form. We have a third manufacturer which fills and provides our final MAT9001 capsules. If any of these manufacturers should become unavailable to us for any reason, we have identified a number of potential replacements, although we might incur some delay in qualifying such replacements. We expect to add additional suppliers and manufacturers for both the intermediates and final MAT9001 drug product as we advance MAT9001 further into clinical development.

We currently lease and operate in-house manufacturing capabilities for our lead LNC platform delivery technology product candidate, MAT2203, and for our LNC platform discovery programs in the gene therapy and vaccine spaces. While sufficient to produce the clinical supplies of product necessary to conduct our ongoing clinical trials and potentially early commercialization of MAT2203, we may need to expand our internal manufacturing capabilities in the future. If we are not able to retain our current manufacturing facilities and if we do not develop additional in-house manufacturing capability for our MAT2203 and product candidates sufficient to produce product for commercialization of these products, we will need to develop relationships with third-party manufacturers for the manufacture of our product candidates which could be time consuming and expensive.

There are a number of potential third-party suppliers for amphotericin B, the generic active pharmaceutical ingredients in our lead clinical stage product candidate – MAT2203. Although to date we have not entered into formal supply agreements to secure sufficient supply of amphotericin B to support our clinical programs for MAT2203, we believe we will be able to secure supply of amphotericin B to support our clinical programs for MAT2203 and from one or more third-party suppliers. As we move through development for our product candidate, we expect to enter into long term supply arrangements for key active pharmaceutical ingredients.

Sales and Marketing

We currently do not have any sales and marketing infrastructure. We plan to retain U.S. marketing and sales rights or co-promotion rights for our product candidates for which we receive marketing approvals, particularly in situations where it is possible to access the market through a focused, specialized sales force. For situations in which a large sales force is required to access the market, and with respect to markets outside the United States, we generally plan to commercialize our product candidates through collaborative arrangements with leading pharmaceutical and biotechnology companies.

Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until December 31, 2019, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

For as long as we remain an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. We will take advantage of these reporting exemptions until we are no longer an "emerging growth company."

Corporate Information

We were incorporated in Delaware under the name Matinas BioPharma Holdings, Inc. in May 2013. We have two operating subsidiaries: Matinas BioPharma, Inc., a Delaware corporation, and Matinas BioPharma Nanotechnologies, Inc., a Delaware corporation. Nereus BioPharma LLC, a Delaware limited liability company (and Matinas BioPharma's predecessor) was formed on August 12, 2011. On February 29, 2012, Nereus BioPharma LLC converted from a limited liability company to a corporation and changed its name to Matinas BioPharma, Inc. In July 2013, Matinas BioPharma, Inc. merged with and into a wholly-owned subsidiary of ours, thereby becoming a wholly owned subsidiary of ours. On January 29, 2015, we acquired Aquarius Biotechnologies Inc. which was subsequently renamed Matinas BioPharma Nanotechnologies, Inc.

Our principal executive offices are located at 1545 Route 206 South, Suite 302, Bedminster, New Jersey 07921, and our telephone number is (908) 443-1860. Our website address is www.matinasbiopharma.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our securities.

Recent Results

At December 31, 2018, the Company had approximately $13.0 million in cash and cash equivalents, including restricted cash. This amount is preliminary, unaudited and subject to the completion of the audit of the Company's consolidated financial statements as of and for the year ended December 31, 2018 (Audited 2018 Financial Statements). As a result, this amount may differ from the amount that will be reflected in the Audited 2018 Financial Statements. Additional information and disclosures are required for a more complete understanding of the Company's financial position and results of operations as of December 31, 2018.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described under "Risk Factors" in the accompanying prospectus and our Annual Report on Form 10-K for the year ended December 31, 2017 and any subsequent updates described in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, all of which are incorporated herein by reference, and as updated by any other document that we subsequently file with the Securities and Exchange Commission and that is incorporated by reference into this prospectus supplement and the accompanying prospectus, as well as the risks described below and all of the other information contained in this prospectus supplement and the accompanying prospectus, and incorporated by reference into this prospectus supplement and the accompanying prospectus, including our financial statements and related notes, before investing in our securities. These risks and uncertainties are not the only ones facing us and there may be additional matters that we are unaware of or that we currently consider immaterial. All of these could adversely affect our business, business prospects, cash flow, results of operations and financial condition. In such case, the trading price of our common stock could decline, and you could lose all or part of your investment in our common stock.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We have incurred significant operating losses in every year since inception and expect to incur net operating losses for the foreseeable future. Our net loss was $15.5 million, $7.6 million and $ 9.1 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of September 30, 2018, we had an accumulated deficit of $62.3 million. We do not know whether or when we will become profitable. To date, we have not generated any revenues from product sales and have financed our operations primarily through private placements of our equity securities and, to a lesser extent, through funding from the National Institutes of Health, or the NIH. We have devoted substantially all of our financial resources and efforts to the research and development of potential product candidates. We are still in the early stages of development of our product candidates, and we have not completed development of any product candidate. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital. We anticipate that our expenses will increase substantially if and as we:

- conduct further preclinical and clinical studies of MAT9001, our lead product candidate;
- support the conduct of further clinical studies of MAT2203, even if such studies are primarily financed with non-dilutive funding from the NIH;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- require the manufacture of larger quantities of product candidates for clinical development and potentially commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts and personnel and infrastructure necessary to help us comply with our obligations as a public company.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. We are only in the preliminary stages of most of these activities and have not yet commenced other of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or the FDA, or comparable non-U.S. regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2017 with respect to this uncertainty. This going concern opinion, and any future going concern opinion, could materially limit our ability to raise additional capital. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. To date, we have devoted our resources to developing MAT9001 and our lead anti-infective product candidates, MAT2203 and MAT2501 and other product candidates developed from our cochleate drug delivery platform technology, but none of these product candidates can be marketed until regulatory approval has been obtained. Meaningful revenues will likely not be available until, and unless, MAT9001, MAT2203 or any of our other product candidates are approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us, or a partner. The perception that we may not be able to continue as a going concern may cause potential partners or investors to choose not to deal with us due to concerns about our ability to meet our contractual and financial obligations.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct additional preclinical and clinical studies of MAT9001, our lead product candidate, as well as the anticipated Phase 2 clinical trial of MAT2203 in cryptococcal meningitis, conduct additional preclinical and clinical trials to further validate and expand our LNC platform delivery technology, continue research and development, initiate clinical trials and, if development succeeds, seek regulatory approval of our product candidates. Our expenses could further increase if we initiate new research and preclinical development efforts for other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to incur significant additional costs associated with operating as a public company, particularly as we cease to qualify as an "emerging growth company." Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our existing cash and cash equivalents, including restricted cash, of approximately $13.0 million as of December 31, 2018, will enable us to fund our operating expenses and capital expenditure requirements into January of 2020. We have based this estimate on assumptions that may prove to be wrong in the future, and we could use our capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. Our future capital requirements, both short-term and long-term, will depend on many factors, including:

- the progress, timing, costs and results of our ongoing and planned clinical trials of MAT9001;
- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, other product candidates, including MAT2203, any future product candidates based upon our cochleate delivery technology platform, and any preclinical or clinical work done to further validate our cochleate platform delivery technology, generally;
- our ability to enter into and the terms and timing of any collaborations, licensing or other arrangements that we may establish;
- the number and development requirements of other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates by the FDA and comparable non-U.S. regulatory authorities;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies;
- the costs of operating as a public company; and
- the effect of competing technological and market developments.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, government or other third party funding, collaborations and licensing arrangements. We do not have any committed external source of funds other than limited grant funding from the NIH. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be materially diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. Securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our stockholders may be subject to substantial dilution by exercises of outstanding options and warrants, conversion of preferred shares and by the future issuance of common stock to the former stockholders of Aquarius pursuant to the terms of the merger agreement.

As of September 30, 2018, we had outstanding options to purchase an aggregate of 11,455,029 shares of our common stock at a weighted average exercise price of $1.21 per share and warrants to purchase an aggregate of 5,802,256 shares of our common stock at a weighted average exercise price of $0.61 per share. In addition, as of September 30, 2018, we had 1,467,858 million shares of Series A Preferred Stock outstanding and 7,003 shares of Series B Preferred Stock outstanding. Each share of Series A Preferred Stock may be converted into 10 shares of common stock upon the request of the holder and each share of Series B Preferred Stock may be converted into 2,000 shares of common stock upon the request of the holder. The conversion of preferred shares and the exercise of such outstanding options and the warrants, will result in dilution of the value of our shares. In addition, pursuant to the terms of the merger agreement with Matinas BioPharma Nanotechnologies, Inc. (f/k/a Aquarius Biotechnologies, Inc.), we will be required to issue up to an additional 3,000,000 shares of our common stock upon the achievement of certain milestones. The milestone consideration consists of (i) 1,500,000 shares issuable upon the dosing of the first patient in a phase III trial sponsored by us for a product utilizing the cochleate delivery technology and (ii) 1,500,000 shares issuable upon FDA approval of the first NDA submitted by us for a product utilizing the cochleate delivery technology.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced active operations in 2013 and have a limited operating history. Our product candidates are in early stages of clinical development. We have not yet demonstrated our ability to successfully obtain regulatory approvals for any of our product candidates, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Even if we obtain regulatory approval, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

U.S. federal income tax reform could materially affect our tax obligations and effective tax rate.

On December 22, 2017, the Tax Cuts and Jobs Act, or the Tax Act, was signed into law, significantly reforming the tax code. The Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, limits net operating loss (NOL) deductions, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a territorial system and modifies or repeals many business deductions and credits. The estimated impact of the Tax Act is based on our management's current knowledge and assumptions, and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. We have revalued our net deferred tax assets and liabilities at the newly enacted U.S. federal rate, and we recognized a tax benefit of $.4 million during the year ended December 31, 2017 related to the TCJA.

We continue to examine the impact this tax reform legislation may have on our business. The Tax Act requires complex computations not previously provided in U.S. tax law. As such, the application of accounting guidance for such items is currently uncertain. Further, compliance with the Tax Act and the accounting for such provisions require accumulation of information not previously required or regularly produced. As additional regulatory guidance is issued by the applicable taxing authorities, as accounting treatment is clarified, as we perform additional analysis on the application of the law, and as we refine estimates in calculating the effect, our final analysis, which will be recorded in the period completed, may be different from our current provisional amounts, which could materially affect our tax obligations and effective tax rate.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We are early in our development efforts, which may not be successful.

We completed a PK/PD study of MAT9001 head to head vs. Vascepa in 2015. We recently completed two separate Phase 2 clinical trials of MAT2203. Because of the early stage of our development efforts, we are still in the process of determining the overall clinical development path for our current and future product candidates. As a result, the timing and costs of the regulatory paths we will follow and marketing approvals remain uncertain. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our early-stage product candidates. The success of MAT9001, MAT2203, and any other product candidates we may develop will depend on many factors, including the following:

- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials;
- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and technologies;
- launching commercial sales of the product candidates, if and when approved, whether alone or selectively in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payers;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not accomplish one or more of these goals in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

We cannot be certain that MAT9001, MAT2203 or any other product candidates that we may develop will receive regulatory approval, and without regulatory approval we will not be able to market any of our product candidates. Any delay in the regulatory review or approval of any of our product candidates will materially or adversely harm our business.

We expect to invest most of our capital in the development of MAT9001. Our ability to generate revenue related to product sales, which we do not expect will occur for at least the next several years, if ever, will depend on the successful development and regulatory approval of one or more of our product candidates. All of our product candidates require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our product candidates would delay market launch, increase our cash requirements and result in additional operating losses. This failure to obtain regulatory approvals would prevent our product candidate from being marketed and would have a material and adverse effect on our business.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain. We may be unable to submit any new drug application, or an NDA, in the United States or any marketing approval application in foreign jurisdictions for any of our products. If we submit an NDA including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our product candidates, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that the marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we will be able to respond to any regulatory requests during the review period in a timely manner, or at all, without delaying potential regulatory action. We also cannot be certain that any of our product candidates will receive favorable recommendations from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding such product candidates.

Data obtained from preclinical studies and clinical trials are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our product candidates. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, policy changes and agency funding, staffing and leadership. We do not know whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for NDAs have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. Review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes. Moreover, in light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of REMS measures that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or may result in approval for a more limited indication than originally sought.

We depend in part on technology owned or licensed to us by third parties, and the loss of access to this technology would terminate or delay the further development of our product candidates, injure our reputation or force us to pay higher royalties.

We rely partially on the LNC platform delivery technology that we have licensed from Rutgers. The loss of access to this technology could materially impair our business and future viability, and could result in delays in developing, introducing or maintaining our product candidates and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the technology we license could prevent the implementation or impair the functionality of our product candidates or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes that may lead to delayed timelines and increased cost, and may prevent us from being able to complete clinical trials.

Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. The results of preclinical and clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in Phase 2 clinical studies for MAT9001 do not ensure that our Phase 3 clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

We cannot be certain that future clinical trials for MAT9001, MAT2203 or any of our other product candidates, will begin on time, not need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all, or that any interim analyses with respect to such trials will be completed on schedule or support continued clinical development of the associated product candidate.

We could also encounter delays if a clinical trial is suspended or terminated by us upon recommendation of the data monitoring committee for such trial, by the IRBs of the institutions in which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenue from the sale of any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval processes, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects significantly.

Delays in the commencement, enrollment and completion of our clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for MAT9001 and our other product candidates.

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. The commencement, enrollment and completion of clinical trials can be delayed for a variety of reasons, including:

- inability to reach agreements on acceptable terms with prospective contract research organizations (CROs) and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability to maintain necessary supplies of study drug and comparator to maintain predicted enrollment rates at clinical trial sites;
- regulatory objections to commencing a clinical trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- inability to obtain institutional review board approval, including that within the NIH, to conduct a clinical trial;
- difficulty recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates;
- inability to retain subjects in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy; and
- difficulty in importing and exporting clinical trial materials and study samples.

We may not have or be able to obtain sufficient quantities of our products to meet our supply and clinical studies obligations and our business, financial condition and results of operation may be adversely affected.

To date, we have only developed limited in-house manufacturing capabilities for the LNC technology needed for the clinical development our MAT2203 product candidate and rely exclusively on third party manufacturers for the manufacture of MAT9001. If we do not develop a long term in-house manufacturing capability for the cochleates needed for our product candidates sufficient to produce product for continued development and, if regulatory approval is obtained, then commercialization of these products, we will be dependent on a small number of third-party manufacturers for the manufacture of our product candidates. We may not have long-term agreements with any of these third parties, and if they are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our products in a timely manner from these third parties could delay clinical trials and prevent us from developing our products in a cost-effective manner or on a timely basis. In addition, manufacturers of our product candidates are subject to cGMP and similar foreign standards and we would not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval or post-approval plant inspection, the FDA will not grant approval and may institute restrictions on the marketing or sale of our products.

We may be reliant on third party manufactures and suppliers to meet the demands of our clinical supplies. Delays in receipt of materials, scheduling, release, custom's control, and regulatory compliance issues may adversely impact our ability to initiate, maintain, or complete clinical trials that we are sponsoring. Commercial manufacturing and supply agreements have not been established. Issues arising from scale-up, environmental controls, equipment requirements, or other factors, may have an adverse impact on our ability to manufacture our product candidates.

Even if we obtain regulatory approval for our product candidates, if we are unable to successfully commercialize our products, it will limit our ability to generate revenue and will materially adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approval for our product candidates, our long-term viability and growth depend on the successful commercialization of products which lead to revenue and profits. Pharmaceutical product development is an expensive, high risk, lengthy, complicated, resource intensive process. In order to succeed, among other things, we must be able to:

- identify potential drug product candidates;
- design and conduct appropriate laboratory, preclinical and other research;
- submit for and receive regulatory approval to perform clinical studies;
- design and conduct appropriate preclinical and clinical studies according to good laboratory and good clinical practices;
- select and recruit clinical investigators;
- select and recruit subjects for our studies;
- collect, analyze and correctly interpret the data from our studies;
- submit for and receive regulatory approvals for marketing; and
- manufacture the drug product candidates according to cGMP.

The development program with respect to any given product will take many years and thus delay our ability to generate profits. In addition, potential products that appear promising at early stages of development may fail for a number of reasons, including the possibility that the products may require significant additional testing or turn out to be unsafe, ineffective, too difficult or expensive to develop or manufacture, too difficult to administer, or unstable. Failure to successfully commercialize our products will adversely affect our business, financial condition and results of operations.

If our preclinical and clinical studies do not produce positive results, if our clinical trials are delayed or if serious side effects are identified during such studies or trials, we may experience delays, incur additional costs and ultimately be unable to commercialize our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, generally at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals, and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement and can take many years to complete. A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to obtain regulatory approval or commercialize our product candidates, including:

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect to be promising;
- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- conditions imposed on us by the FDA or any non-U.S. regulatory authority regarding the scope or design of our clinical trials may require us to resubmit our clinical trial protocols to institutional review boards for re-inspection due to changes in the regulatory environment;
- the number of patients required for our clinical trials may be larger than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate one or more of our clinical trials if we, the regulators or the institutional review boards determine that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate or we may not be able to reach agreements on acceptable terms with prospective clinical research organizations; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.
- In addition, if we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:
- be delayed in obtaining, or may not be able to obtain, marketing approval for one or more of our product candidates;
- obtain approval for indications that are not as broad as intended or entirely different than those indications for which we sought approval; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any preclinical tests or clinical trials will be initiated as planned, will need to be restructured or will be completed on schedule, if at all. Significant preclinical or clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Such delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

If we cannot enroll enough patients to complete our clinical trials, such failure may adversely affect our business, financial condition and results of operations.

The completion rate of clinical studies of our products is dependent on, among other factors, the patient enrollment rate. Patient enrollment is a function of many factors, including:

- investigator identification and recruitment;
- regulatory approvals to initiate study sites;
- patient population size;
- the nature of the protocol to be used in the trial;
- patient proximity to clinical sites;
- eligibility criteria for the study;
- competition from other companies' clinical studies for the same patient population; and
- ability to obtain comparator drug/device.

We believe our procedures for enrolling patients have been appropriate; however, delays in patient enrollment would increase costs and delay ultimate commercialization and sales, if any, of our products. Such delays could materially adversely affect our business, financial condition and results of operations.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired.

Even if we receive regulatory approval for MAT9001, MAT2203 or any other product candidates we may develop, we still may not be able to successfully commercialize such products and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of MAT9001, MAT2203 or any other product candidates we may develop will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of MAT9001, MAT2203 or such other product candidate will depend on a number of factors, including:

- demonstration of clinical safety and efficacy of such product candidate;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe such product candidates and of the target patient population to try new therapies;
- pricing and cost-effectiveness;
- the inclusion or omission of such product candidate in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If MAT9001, MAT2203, or any other product candidates we may develop is approved, but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of such product candidate may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize such product candidate successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render such product candidate not commercially viable. For example, regulatory authorities may approve such product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for such product candidate, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve such product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA may place conditions on approvals including potential requirements or risk management plans and the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of such product candidate. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of such product candidate.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities, we may not successfully commercialize any of our product candidates, if regulatory approval is obtained.

At present, we have no sales or marketing personnel. In order to commercialize products that are approved for commercial sales, we must either develop a sales and marketing infrastructure or collaborate with third parties that have such commercial infrastructure. If we elect to develop our own sales and marketing organization, we do not intend to begin to hire sales and marketing personnel until the time of NDA submission to the FDA at the earliest, and we do not intend to establish our own sales organization in the United States until shortly prior to FDA approval of MAT9001, MAT2203 or any of our other product candidates.

We may not be able to establish a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize MAT9001, MAT2203 or any of our other product candidates in the United States without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty successfully commercializing MAT9001, MAT2203 or any other product candidates we may develop, which would adversely affect our business, operating results and financial condition. Outside the United States, we may commercialize our product candidates by entering into collaboration agreements with pharmaceutical partners. We may not be able to enter into such agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties

If we are unable to file for approval of MAT9001 or MAT2203 under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to safety and efficacy in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing the NDAs for MAT9001 and MAT2203 include efforts to minimize the data we will be required to generate in order to obtain marketing approval for this product candidate and therefore reduce the development time. Based upon written feedback received from the FDA in 2014, we believe this approach will create the opportunity for us to leverage existing data developed with certain existing omega-3 fatty acids to create a streamlined approach to potential approval for MAT9001 for the treatment of severe hypertriglyceridemia. Although our interactions with the FDA have encouraged our efforts to continue to develop MAT9001 for severe hypertriglyceridemia, there is no assurance that we will satisfy the FDA's requirements for approval in this indication. Likewise, we intend to rely on the history of efficacy of amphotericin B, and anticipate meeting with the FDA in the first half of 2019 to discuss our development plans for MAT2203.The timelines for filing and review of our NDAs for MAT9001 and MAT2203 are based on our plan to submit these NDAs under Section 505(b)(2) of the FDCA, which would enable us to rely in part on data in the public domain or elsewhere. We have not yet filed an NDA under Section 505(b)(2) for any product candidate. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third-party would have 45 days from notification of our certification to initiate an action against us.

In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of our product candidates. Even if no exclusivity periods apply to our applications under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for any of our product candidates, to conduct substantial new research and development activities beyond those we currently plan to engage in order to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We may not be able to realize a shortened development timeline for MAT9001 for severe hypertriglyceridemia, and the FDA may not approve our NDA based on their review of the submitted data. If omega-3 fatty acids-containing products are withdrawn from the market by the FDA for any safety reason, we may not be able to reference such products to support a 505(b)(2) NDA for Tonmya, and we may need to fulfill the more extensive requirements of Section 505(b)(1). If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of our lead product candidate.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Established competitors may invest heavily to quickly discover and develop novel compounds that could make MAT9001, MAT2203 or any other product candidates we may develop obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, which could force us to lower prices or result in reduced sales, particularly those products that have been marketed by third parties for many years and are well accepted by physicians, patients and payers. In addition, new products developed by others could emerge as competitors to MAT9001, MAT2203 or any of our other product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Further, although we believe that our proprietary LNC platform delivery technology, experience and knowledge in our areas of focus provide us with competitive advantages, potential competitors for MAT2203 could reduce our commercial opportunities.

Even if we obtain marketing approval for MAT9001, MAT2203 or any other product candidates that we may develop, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our future products.

Even if we obtain United States regulatory approval of MAT9001, MAT2203 or any other product candidates that we may develop, FDA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, and post-market surveillance to monitor safety and efficacy. Our future products will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continuous review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

FDA has the authority to require a REMS, as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by FDA as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize MAT9001, MAT2203 or any of our other product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Future legislation, and/or regulations and policies adopted by the FDA may increase the time and cost required for us to conduct and complete clinical trials of MAT9001, MAT2203 and any other product candidates that we may develop.

FDA has established regulations to govern the drug development and approval process, as have foreign regulatory authorities. The policies of FDA and other regulatory authorities may change and additional laws or government regulations may be promulgated that could prevent, limit, delay but also accelerate regulatory review of our product candidates. For example, in December 2016, the Cures Act was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but all of its provisions have yet to be implemented. Among other things, the Cures Act provides a new "limited population" pathway for certain antibacterial and antifungal drugs, or LPAD, but FDA has not issued final guidance regarding the LPAD yet. Additionally, in August 2017, FDA issued final guidance setting forth its current thinking with respect to development programs and clinical trial designs for antibacterial drugs to treat serous bacterial diseases in patients with an unmet medical need. We cannot predict what if any effect the Cures Act or any existing or future guidance from FDA will have on development of our product candidates.

Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost-containment initiatives, may have a material adverse effect on us.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delay regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

For example, in the United States, the Patient Protection and Affordable Care Act of 2010 ("ACA") substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. There is continued uncertainty about the implementation of ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize MAT9001, MAT2203 or any other product candidates that we may develop in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market our product candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We have been and expect to be significantly dependent on our collaborative agreements for the development of MAT2203, which exposes us to the risk of reliance on the performance of third parties.

In conducting our research and development activities for MAT2203, we currently rely, and expect to continue to rely, on collaborative agreements with universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements is our collaboration agreements with the NIH for the development of MAT2203. The loss of, or failure to perform by us or our partners under any applicable agreements or arrangements, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our research and development activities, including our in-process and anticipated clinical trials. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

We expect that we will rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize MAT9001, MAT2203 or any other product candidates that we may develop and our business could be substantially harmed.

We expect to enter into agreements with third-party CROs, or governmental entities like the NIH, to conduct and manage our clinical programs. We rely heavily on these parties for execution of clinical studies for MAT9001, and MAT2203 and our other product candidates and can control only certain and very limited aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the NIH or CROs would not relieve us of our regulatory responsibilities. We, the NIH and our CROs would be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or the NIH or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of the NIH or our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the NIH or the CROs may not perform all of their obligations under their arrangements with us or in compliance with regulatory requirements. If NIH or the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of MAT2203, MAT9001 or any other product candidates that we may develop may be delayed or our development program may be materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs would devote to our program or our product candidates. If we are unable to rely on the clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. As a result of the foregoing, our financial results and the commercial prospects for MAT9001, MAT2203 and our other product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of MAT9001, MAT2203 or any other product candidates that we may develop. If there is not sufficient reimbursement for our future products, it is less likely that such products will be widely used.

Market acceptance and sales of MAT9001, MAT2203 or any other product candidates for which we obtain regulatory approval will depend on reimbursement policies and may be affected by future healthcare reform measures in both the United States and foreign jurisdictions. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will cover and establish payment levels. In addition, government authorities and these third-party payors are increasingly attempting to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of products that they will cover and the amounts that they will pay for these products. In addition, we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources.

Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs. Such legislation, or similar regulatory changes or relaxation of laws that restrict imports of products from other countries, could reduce the net price we receive for any future marketed products. As a result, our future products might not ultimately be considered cost-effective. We cannot be certain that reimbursement will be available for MAT9001, MAT2203 or any other product candidates that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize MAT9001, MAT2203 or any other product candidates that we develop.

MAT9001 is designed to be a prescription-only omega-3 fatty acid based medication. Omega-3 fatty acid based products are also marketed by other companies as dietary supplements, which, unlike drugs, are not subject to FDA approval and therefore do not require a prescription and are not subject to pharmaceutical manufacturing standards. As a result, MAT9001, if approved, would be subject to competition from products for which no prescription is required.

If approved by the regulatory authorities, MAT9001 will be a prescription-only omega-3 fatty acid-based medication. Mixtures of omega-3 fatty acids are naturally occurring substances in various foods, including fatty fish. Omega-3 fatty acids are also marketed as dietary supplements, which may generally be marketed without a lengthy FDA premarket review and approval process and are not subject to prescription. However, unlike prescription drug products, manufacturers of dietary supplements may not make therapeutic claims for their products; dietary supplements may be marketed with claims describing how the product affects the structure or function of the body without premarket approval, but may not expressly or implicitly represent that the dietary supplement will diagnose, cure, mitigate, treat, or prevent disease. We believe the exact omega-3 fatty acid composition and pharmaceutical-grade purity of MAT9001 has a superior therapeutic profile to the omega-3 compositions in commercially available dietary supplements. However, we cannot be sure that physicians or consumers will view MAT9001 as superior. To the extent the price of MAT9001 is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements, physicians may recommend these commercial alternatives instead of MAT9001 or patients may elect on their own to take commercially available non-prescription omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting product sales and how we price our product, thereby limiting the revenue we receive from sales of MAT9001

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business.

There is increasing pressure on biotechnology companies to reduce healthcare costs. In the U.S., these pressures come from a variety of sources, such as managed care groups, institutional, government purchasers and government leaders. For example, President Trump has indicated support for possible new measures related to drug pricing. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The biotechnology industry will likely face greater regulation and political and legal action in the future.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country.

Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval. Adverse pricing limitations prior to approval will also adversely affect us by reducing our commercial potential. Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We are, and will be, completely dependent on third parties to manufacture MAT9001, and our commercialization of MAT9001 could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of MAT9001 or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in MAT9001 for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate MAT9001 as a finished drug product for commercial distribution. As a result, we will rely on contract manufacturers throughout the development process and then if and when MAT9001 is approved for commercialization. We have not entered into any agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of MAT9001 on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture MAT9001 must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to MAT9001. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of MAT9001 or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market MAT9001, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We do not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market MAT9001, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market MAT9001.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished MAT9001 product or should cease doing business with us, we could experience significant interruptions in the supply of MAT9001 or may not be able to create a supply of MAT9001 at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of MAT9001 might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply MAT9001 at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of MAT9001 if we decided to transfer the manufacture of MAT9001 to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of MAT9001, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of MAT9001 over time. If the commercial-scale manufacturing costs of MAT9001 are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

Risks Relating to Our Intellectual Property Rights and Regulatory Exclusivity

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from discovering, developing and commercializing our product candidates.

We rely partially upon our LNC platform delivery technology which is licensed to us by Rutgers. We do not own the patents that underlie this technology. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of our license agreement with Rutgers. Pursuant to the terms of our license agreement with Rutgers, we control the prosecution, maintenance, or filing of the patents to which we hold licenses, as well as the enforcement of these patents against third parties. However, some of our patents and patent applications were either acquired from another company who acquired those patents and patent applications from yet another company, or are licensed from a third party. Thus, these patents and patent applications were not written by us or our attorneys, and we did not have control over the drafting and prosecution of certain of these patents. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Our rights to use the technology we license are subject to the validity of the owner's intellectual property rights. Enforcement of our licensed patents or defense or any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. Legal action could be initiated against the owners of the intellectual property that we license and an adverse outcome in such legal action could harm our business because it might prevent such companies or institutions from continuing to license intellectual property that we may need to operate our business. In addition, such licensors may resolve such litigation in a way that benefits them but adversely affects our ability to use the licensed technology for our products.

Certain of our licenses contained in our agreement with Rutgers contain provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination, (ii) we or any of our affiliates, licensees or sub licensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents or (iii) we declare bankruptcy or dissolve. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of these licenses would prevent us from discovering, developing and commercializing product candidates based on the cochleate delivery technology, including our lead anti-infective product candidate, MAT2203. Determining the scope of the license and related royalty obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties' payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from discovering, developing and commercializing product candidates based on the cochleate delivery technology, including our lead anti-infective product candidate.

If we discontinue development of the cochleate delivery technology, we would be required to return such technology to the former stockholders of Aquarius and we would lose the rights to our lead product candidates.

Under certain circumstances, we will be required to transfer Aquarius' cochleate delivery technology back to the former shareholders of Aquarius. This transfer would be required under the Merger Agreement in the event the following conditions are met: (i) no milestone events have occurred on or before the two-year anniversary of the effective time of the Aquarius Merger (the "Transfer Date"), (ii) during such period we shall have discontinued efforts to develop or commercialize the cochleate delivery technology (as conclusively demonstrated by our omission of the cochleate delivery technology in at least two consecutive royalty, progress and payment reports delivered to Rutgers pursuant to the license agreement entered into between Aquarius and Rutgers) and (iii) as of the Transfer Date, no unresolved indemnification claims for us and our indemnified parties are pending. If the foregoing conditions are met, we would transfer the cochleate delivery technology to the stockholder representative or to a newly formed entity as directed by the stockholder representative (in either case for the benefit of the former Aquarius stockholders) following receipt of any necessary third party consents required for the transfer, which we shall use its commercially reasonable efforts to obtain. If we are required to transfer the cochleate delivery technology back to the former shareholders of Aquarius, we would lose our rights to our lead product candidates, which would have a material and adverse effect on our business.

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents (including patents owned and licensed by us). We currently own or have rights to 22 issued patents relating to our cochleate delivery technology, as well as pending patent applications for our cochleate delivery technology that may never be approved by the United States or foreign patent offices. Furthermore, any patents which may eventually be issued from existing patent applications for any of our technologies, may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before the United States or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent protection or trade secret protection for our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also develop trademarks to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of MAT9001, MAT2203 or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize MAT9001 or MAT2203 and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties against us would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent MAT9001 or MAT2203 from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to MAT9001 or MAT2203 or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market our current product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign, MAT9001, MAT2203, or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing MAT9001, MAT2203 or a future product candidate, which could harm our business, financial condition and operating results.

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approval. Competitors may seek to oppose our patent applications to delay the approval process or to challenge our granted patents, for example, by requesting a reexamination of our patent at the United States Patent and Trademark Office, or the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. Such proceedings are generally highly technical, expensive and time consuming, and there can be no assurance that such a challenge would not result in the narrowing or complete revocation of any patent of ours that was so challenged.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at or retained by other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our anti-infective product candidates.

We may seek orphan drug designation for MAT2203 in the United States and may seek additional orphan drug designation for other product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. For a product that obtains orphan drug designation on the basis of a plausible hypothesis that it is clinically superior to the same drug that is already approved for the same indication, in order to obtain orphan drug exclusivity upon approval, clinical superiority of such product to this same drug that is already approved for the same orphan indication must be demonstrated. The exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that the application for orphan drug designation of MAT2203, or any future application with respect to any other product candidate, will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for MAT2203 for the treatment of invasive candidiasis, the treatment of aspergillosis and the prevention of invasive fungal infections due to immunosuppressive therapy and may seek fast track designation for some of our other product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Any breakthrough therapy designation granted by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Designation of our product candidates as qualified infectious disease products is not assured and, in any event, even if granted, may not actually lead to a faster development or regulatory review, and would not assure FDA approval of our product candidates.

We have received a qualified infectious disease product, or QIDP, designation for MAT2203 for certain indications and we may be eligible for designation of certain of our product candidates as QIDPs. A QIDP is "an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or certain "qualifying pathogens." A product designated as a QIDP will be granted priority review by the FDA and may qualify for "fast track" status. Upon the approval of an NDA for a drug product designated by the FDA as a QIDP, the product is granted a period of five years of regulatory exclusivity in addition to any other period of regulatory exclusivity for which the product is eligible. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for such designation or status, the FDA could decide not to grant it. Moreover, even if we do receive such a designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures and there is no assurance that our product candidate, even if determined to be a QIDP, will be approved by the FDA.

General Company-Related Risks

We will need to increase the size of our organization to grow our business, and we may experience difficulties in managing this growth.

We currently have only fifteen employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, development, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees would adversely impact our business prospects.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Jerome D. Jabbour, our Chief Executive Officer and President, would adversely impact our business prospects.

Our ability to compete in the highly competitive pharmaceutical industry depends in large part upon our ability to attract highly qualified managerial, scientific and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face a potential risk of product liability as a result of the clinical testing of MAT9001, MAT2203 or any future product candidates and will face an even greater risk if we commercialize MAT9001, MAT2203 or any other future product. For example, we may be sued if any product we develop or any material that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of MAT9001 or MAT2203. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for MAT9001, MAT2203 or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We have obtained product liability insurance covering our clinical trials in the amount of greater than or equal to $5 million in the aggregate. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage or disruption from computer viruses, software bugs, unauthorized access, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures. While we have not, to our knowledge, experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed, our competitive position could be compromised, or our business reputation could be harmed.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks related to our Securities

Pursuant to the terms of our outstanding Series A Preferred Stock, we may be obligated to pay significant royalties.

Pursuant to the terms of the Certificate of Designations of Preferences, Rights and Limitations (the "Certificate of Designations") for our outstanding Series A Preferred Stock, we may be required to pay royalties of up to $35 million per year. If and when we obtain FDA or EMA approval of MAT2203 and/or MAT2501, which we do not expect to occur before 2020, if ever, and/or if we generate sales of such products, or we receive any proceeds from the licensing or other disposition of MAT2203 or MAT2501, we are required to pay to the holders of our Series A Preferred Stock, subject to certain vesting requirements, in aggregate, a royalty equal to (i) 4.5% of Net Sales (as defined in the Certificate of Designations), subject in all cases to a cap of $25 million per calendar year, and (ii) 7.5% of Licensing Proceeds (as defined in the Certificate of Designations), subject in all cases to a cap of $10 million per calendar year. The Royalty Payment Rights will expire when the patents covering the applicable product expire, which is currently expected to be in 2033.

We are obligated to pay dividends on outstanding shares of our preferred stock.

Holders of Series A Preferred Stock are entitled to receive cumulative dividends at the rate per share of 8% per annum, payable in shares of our common stock, which annual dividend will accumulate until such time as the shares of Series A Preferred Stock are converted, at which time the accumulated dividend will be satisfied by delivery of shares of common stock at a price per share of common stock equal to the conversion price of the Series A Preferred Stock then in effect (currently $0.50 per share). The Series A Preferred Stock will automatically convert at the conversion price in effect on July 29, 2019, unless such shares are converted earlier in accordance with the terms of the Certificate of Designations for the Series A Preferred Stock.

Holders of our Series B Preferred Stock will be entitled to receive dividends payable as follows: (i) a number of shares of common stock equal to 10% of the shares of common stock underlying the Series B Preferred Stock then held by the holder on June 19, 2019, (ii) a number of shares of common stock equal to 15% of the shares of common stock underlying the Series B Preferred then held by such holder on June 19, 2020 and (iii) a number of shares of common stock equal to 20% of the shares of common stock underlying the Series B Preferred then held by such holder on June 19, 2021.

The payment of such dividends will result in additional dilution to our holders of our common stock.

Our outstanding shares of preferred stock have certain preference rights upon any liquidation, dissolution or winding up.

Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series A Preferred Stock will be entitled to (i) first receive distributions out of our assets in an amount per share equal to $5.00, or the stated value, plus all accrued and unpaid dividends, whether capital or surplus before any distributions shall be made on any shares of common stock and (ii) second, receive distributions out of our assets on an as-converted basis alongside the common stock.

The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

Our articles of incorporation give our board of directors the ability to designate and issue preferred stock in one or more series. As a result, the board of directors may, without stockholder approval, issue new series of preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the relative voting power and equity interest of the holders of common stock. Additional issuances of preferred stock, which could be issued with the right to more than one vote per share, could have the effect of discouraging, delaying or preventing a change of control of us. The possible impact on takeover attempts could adversely affect the price of our common stock. Although we have no present intention to designate any new series, or issue any shares, of preferred stock, we may do so in the future.

We do not intend to pay dividends on our common stock in the foreseeable future.

The Board of Directors will determine, in its sole discretion, our dividend policy after considering our financial condition, results of operations and capital requirements, as well as other factors. No dividends may be declared or paid on our common stock, unless a dividend, payable in the same consideration or manner, is simultaneously declared or paid, as the case may be, on the shares of Series A Preferred Stock. We do not anticipate paying cash dividends on our common stock in the foreseeable future and you should not invest in us with the anticipation of receiving dividend income.

An active public trading market for our common stock may not be sustained.

Our common stock was listed on the NYSE American under the symbol “MTNB” on March 2, 2017. Prior to March 2, 2017, our common stock was available for quotation on the OTCQB under the symbol “MTNB.” We cannot assure you that an active trading market will be sustained. A lack of an active market may impair your ability to sell shares of our common stock at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the price of shares of our common stock. An inactive market may also impair our ability to raise capital by selling shares of capital stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

Our share price has been and could remain volatile.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 1, 2016 through March 11, 2018, the market price of our common stock has fluctuated from a high of $3.99 per share in the first quarter of 2017 to a low of $0.32 per share in the second quarter of 2018. Our progress in developing our product candidates, the impact of government regulations on our products and industry, the potential sale of a large volume of our common stock by stockholders, our quarterly operating results, changes in general conditions in the economy or the financial markets and other developments affecting us or our competitors could cause the market price of our common stock to fluctuate substantially with significant market losses. If our stockholders sell a substantial number of shares of common stock, especially if those sales are made during a short period of time, those sales could adversely affect the market price of our common stock and could impair our ability to raise capital. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies for reasons unrelated to their operating performance and may adversely affect the price of our common stock. In addition, we could be subject to a securities class action litigation as a result of volatility in the price of our stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

An active trading market for our common stock may not be sustained.

Although our common stock is listed on the NYSE, the market for our shares has demonstrated varying levels of trading activity. Furthermore, the current level of trading may not be sustained in the future. The lack of an active market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company," and we intend to take advantage of reduced disclosure requirements applicable to "emerging growth companies," which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, for as long as we continue to be an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" until December 31, 2019, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. We cannot predict if investors will find our common stock less attractive if we choose to continue to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

We are incurring significantly increased costs and devote substantial management time as a result of operating as a public company, which costs may increase after we are no longer an "emerging growth company."

As a public company, we are incurring significant legal, accounting and other expenses. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Compliance with these requirements have resulted in increased legal and financial compliance costs. In addition, our management and other personnel must divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we are incurring significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act.

However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We intend to take advantage of these reporting exemptions until we are no longer an "emerging growth company."

Under the JOBS Act, "emerging growth companies" can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

After we are no longer an "emerging growth company" we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

We identified a material weakness in our internal control over financial reporting. If we are not able to remediate the material weakness and otherwise maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of SOX, or Section 404, requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

In connection with the audits of fiscal year 2017 financial statement, we identified a material weakness in our internal control over financial reporting related to our controls over accounting for stock-based compensation, which allowed for the misinterpretation and historical misapplication of Accounting Standards Codification ("ASC") 718, Compensation – Stock compensation, regarding the modification of stock option awards issued to employees. To remediate the material weakness described above, we have initiated compensating controls in the near term and are enhancing and revising the design of existing controls and procedures to properly apply ASC 718 to the cancellation and replacement of stock-based compensation awards.

If our steps are insufficient to successfully remediate the material weakness and otherwise establish and maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be materially and adversely affected. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. For as long as we are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an "emerging growth company" until December 31, 2019, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal control requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with applicable provisions of the Sarbanes-Oxley Act, and the related rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We rely on consultants to perform certain of our accounting and financial reporting functions. We will need to hire additional finance personnel and build our financial infrastructure as we comply with public company reporting requirements, including complying with the applicable requirements of Section 404 of the Sarbanes-Oxley Act. We may be unable to do so on a timely basis.

Upon dissolution of our company, you may not recoup all or any portion of your investment.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed first to the holders of our Series A Preferred Stock and thereafter to the stockholders of common stock (including the holders of our Series A Preferred Stock on an "as converted" basis) on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

Our certificate of incorporation allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. We anticipate that our board of directors will have the authority to issue up to 8,392,000 additional shares of our preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your Shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- they provide that special meetings of stockholders may be called only by the board of directors, President or our Chairman of the Board of Directors, or at the request in writing by stockholders of record owning at least fifty (50%) percent of the issued and outstanding voting shares of common stock;
- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our board of directors; and
- they allow us to issue, without stockholder approval, up to 10,000,000 shares of preferred stock (of which up to 8,392,000 shares remain available for issuance) that could adversely affect the rights and powers of the holders of our common stock.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As a result of our merger with Aquarius Biotechnologies, Inc., our ability to utilize our U.S. federal net operating loss, carryforwards and U.S. federal tax credits may be limited under Sections 382 of the Internal Revenue Code of 1986, as amended. The limitations apply if an "ownership change," as defined by Section 382 and Section 383, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 and Section 383 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. The Tax Act, among other things, imposes significant additional limitations on the deductibility of interest and limits net operating loss (NOL) deductions.

Risks Related to this Offering

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Because we have not designated the amount of net proceeds received by us from this offering to be used for any particular purpose, our management will have broad discretion as to the application of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of the offering. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of shares offered in this offering at an assumed public offering price of $ per share of common stock, and after deducting underwriting discounts and commissions and expenses and other estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of approximately $ per share. See "Dilution" below for a more detailed discussion of the dilution you will incur if you purchase our common stock in the offering.

You may experience future dilution as a result of future equity offerings.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering (on a fully-converted basis). Furthermore, sales of a substantial number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

You may be subject to substantial dilution by exercises of outstanding options and warrants, conversion of preferred shares and by the future issuance of common stock to the former stockholders of Aquarius pursuant to the terms of the merger agreement.

As of March 4, 2019, we had outstanding options to purchase an aggregate of 16,251,796 shares of our common stock at a weighted average exercise price of $1.12 per share and warrants to purchase an aggregate of 5,802,256 shares of our common stock at a weighted average exercise price of $0.61 per share. In addition, as of March 4, 2019, we had 1,467,858 shares of Series A Preferred Stock outstanding and 4,819 shares of Series B Preferred Stock outstanding. Each share of Series A Preferred Stock may be converted into 10 shares of common stock upon the request of the holder and each share of Series B Preferred Stock may be converted into 2,000 shares of common stock upon the request of the holder. In addition, pursuant to the terms of the merger agreement with Aquarius Biotechnologies, Inc., we will be required to issue up to an additional 3,000,000 shares of our common stock upon the achievement of certain milestones. The milestone consideration consists of (i) 1,500,000 shares issuable upon the dosing of the first patient in a Phase 3 trial sponsored by us for a product utilizing the lipid nano-crystal (LNC) delivery technology platform and (ii) 1,500,000 shares issuable upon FDA approval of the first NDA submitted by us for a product utilizing the lipid nano-crystal (LNC) delivery technology platform. The issuance of additional shares of common stock upon the conversion of outstanding Series A Preferred Stock, Series B Preferred Stock or exercise of outstanding options and warrants or pursuant to the terms of the merger agreement will result in further dilution of the value of our shares.

- our lack of a sales and marketing organization and our ability to commercialize products, if we obtain regulatory approval, whether alone or through potential future collaborators;

- our ability to successfully commercialize, and our expectations regarding future therapeutic and commercial potential with respect to, our product candidates;

- the accuracy of our estimates regarding expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;

- developments and projections relating to our competitors or our industry; and

- our ability to adequately support growth.

You should also consider carefully the statements set forth in the section entitled "Risk Factors" in this prospectus supplement and in our Annual Report on Form 10-K for the year ended December 31, 2017, respectively, as updated by any other document that we subsequently filed with the Securities and Exchange Commission and that is incorporated by reference into this prospectus supplement, which address various factors that could cause results or events to differ from those described in the forward-looking statements. All subsequent written and oral forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the applicable cautionary statements. We have no plans to update these forward-looking statements.