

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): February 16, 2021 (February 11, 2021)

Protalix BioTherapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33357
(Commission File Number)

65-0643773
(IRS Employer
Identification No.)

2 Snunit Street
Science Park, POB 455
Carmiel, Israel
(Address of principal executive offices)

2161401
(Zip Code)

Registrant's telephone number, including area code +972-4-988-9488

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value	PLX	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

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

Item 1.01 Entry into a Material Definitive Agreement.

On February 11, 2021, Protalix BioTherapeutics, Inc. (the “Company”) entered into an Underwriting Agreement (the “Underwriting Agreement”) with BofA Securities, Inc., as the representative of the several underwriters named therein (the “Underwriters”), for the issuance and sale by the Company of 7,608,695 shares of its common stock, par value \$0.001 per share (the “Common Stock”). The Underwriters agreed to purchase the shares from the Company at a price of \$4.60 per share resulting in net proceeds of approximately \$32.7 million, after deducting the underwriting discount and estimated expenses of the offering, to the Company. In addition, the Company granted the Underwriters an option for 30 days to purchase up to an additional 1,141,304 shares of Common Stock. The Company will have 44,241,527 shares issued and outstanding following the completion of the offering (or 45,382,831 shares if the underwriters exercise their option to purchase additional shares in full).

The Underwriting Agreement includes customary representations, warranties, covenants and closing conditions. It also provides for customary indemnification by the Company against certain liabilities and customary contribution provisions in respect of those liabilities. The transaction contemplated by the Underwriting Agreement is expected to close on February 17, 2021, subject to satisfaction of customary closing conditions.

The offering and sale was made pursuant to a prospectus supplement related to the Company’s effective shelf registration statement on Form S-3 (File No. 333-230604). A copy of the Underwriting Agreement is filed as Exhibit 1.1 hereto and incorporated herein by reference. The foregoing summary does not purport to be a complete description and is qualified in its entirety by reference to the Underwriting Agreement.

In connection with the filing of the Underwriting Agreement, the Company is filing as Exhibit 5.1 hereto an opinion of its counsel, Mayer Brown LLP, with respect to the legality of the shares of Common Stock.

Item 2.02 Results of Operations and Financial Condition.

As part of the public offering, the Company disclosed that it expects to report holding approximately \$38.5 million of cash, cash equivalents and short-term bank deposits as of December 31, 2020. This amount is unaudited and preliminary, and does not present all information necessary for an understanding of the Company’s financial condition as of December 31, 2020 and is subject to change upon the completion of management’s and the Company’s audit committee’s reviews and other financial closing processes as well as the completion and preparation of the Company’s consolidated financial data for the year ended December 31, 2020.

Item 8.01 Other Events.*Regulatory Update*

On August 11, 2020, the Company, together with Chiesi Farmaceutici S.p.A. (“Chiesi”), announced that the U.S. Food and Drug Administration (the “FDA”) had accepted the Biologics License Application (“BLA”) for PRX-102, and granted Priority Review designation for PRX-102, for the proposed treatment of adult patients with Fabry disease. The FDA noted in its BLA filing communication letter for PRX-102 that it is not currently planning to hold an advisory committee meeting to discuss the application. The FDA initially set an action date of January 27, 2021, under the PDUFA. However, as the Company previously announced, in November 2020, the FDA extended the PDUFA action date to April 27, 2021. As the Company publicly disclosed last year, the FDA advised the Company that it will have to inspect the Company’s manufacturing facility and the facility of a third party in Europe that performs fill and finish processes for PRX-102 as part of the FDA’s review of the BLA to ensure cGMP compliance. Due to COVID-19-related FDA travel restrictions, the FDA has advised that it may be unable to conduct the inspections prior to the PDUFA action date. The Company, together with Chiesi, is currently addressing this issue.

BRIDGE Study

On December 30, 2020, the Company announced final study results from the BRIDGE Study. The BRIDGE Study was a Phase III 12-month open-label, single arm switch-over study evaluating the safety and efficacy of PRX-102, 1 mg/kg infused every two weeks, in up to 22 Fabry patients previously treated with agalsidase alfa, marketed by Takeda Pharmaceutical Company Limited (formerly Shire Plc) as Replagal[®], for at least two years and on a stable dose for at least six months. Twenty of 22 patients completed the 12-month treatment duration. Eighteen of the patients who completed the study opted to roll over to a long-term extension study and continue to be treated with PRX-102.

As announced in May 2020, in the study, the mean annualized eGFR slope of the study participants improved from -5.90 mL/min/1.73m²/year while on agalsidase alfa to -1.19 mL/min/1.73m²/year on PRX-102 in all patients. Male patients improved from -6.36 mL/min/1.73m²/year to -1.73 mL/min/1.73m²/year and female patients improved from -5.03 mL/min/1.73m²/year to -0.21 mL/min/1.73m²/year.

Final results of the data generated in the study showed substantial improvement in renal function as measured by mean annualized eGFR slope in both male and female patients who were switched from agalsidase alfa to PRX-102. Following the switch to PRX-102, there was a decrease in patients with progressing or fast progressing kidney disease, and most patients achieved a stable status post-switch.

PRX-102 was well-tolerated in the BRIDGE Study with all adverse events being transient in nature without sequelae. Of the 22 patients enrolled in the BRIDGE Study, the majority of treatment emergent adverse events were mild or moderate in severity, with two patients (9.1%) withdrawing from the therapy due to hypersensitivity reaction that was resolved. The most common moderate treatment emergent adverse events were nasopharyngitis, headache and dyspnea. An immunogenicity assessment indicated that four out of 20 patients (20%) developed persistent antidrug antibodies over the course of the study, of which two had neutralizing activity.

Baseline characteristics of the 20 patients that completed the BRIDGE Study, ranging from ages 28 to 60 years, were as follows: mean eGFR slope of 75.87 mL/min/1.73m² in males, and 86.14 mL/min/1.73m² in females and plasma lyso-Gb₃ mean levels were 51.81 nM and 13.81 nM in males and females, respectively. While lyso-Gb₃ levels remain slightly high, particularly within the male cohort, continuous reduction in lyso-Gb₃ levels was observed of 19.55 nM (32.35%) in males and 4.57 nM (29.81%) in females.

SarcoMed License Agreement

In February 2021, the Company entered into an exclusive worldwide license agreement with SarcoMed USA Inc. ("SarcoMed") for PRX-110, a product candidate designed for use in the treatment of human respiratory disease or conditions including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases, via inhaled delivery. Under the terms of the agreement, SarcoMed will be responsible for the identification and selection of pharmaceutical candidates under the license, and the clinical research and development of such candidates. The Company is entitled to an initial cash payment of \$3.5 million, subject to certain conditions, and to additional regulatory and commercial milestone payments and tiered royalties on net sales of products that are commercialized under the license agreement. In addition, the Company and SarcoMed have agreed to commence negotiation of clinical and commercial supply agreements for PRX-110. As part of the arrangement, the Company and SarcoMed have agreed to negotiate and sign a supply agreement within 60 days of the execution of the license agreement, and SarcoMed has the right to terminate the license agreement if the parties do not successfully do so.

Offering Press Releases

On February 11, 2021, the Company issued press releases announcing the commencement and pricing of the offering. Copies of the press releases are attached as Exhibit 99.1 and Exhibit 99.2 hereto and are incorporated by reference into this Item 8.01.

Forward Looking Statements

To the extent that statements in this current report on Form 8-K are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms "expect," "anticipate," "believe," "estimate," "project," "may," "plan," "will," "would," "should" and "intend," and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. For a discussion of other risks and uncertainties which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other reports filed with the SEC. We caution readers not to place undue reliance upon any forward-looking statements as the statements in this current report on Form 8-K are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
1.1	Underwriting Agreement, dated February 11, 2021, between the Company and BofA Securities, Inc.
5.1	Opinion of Mayer Brown LLP
23.1	Consent of Mayer Brown LLP (included in Exhibit 5.1)
99.1	Press Release Announcing the Public Offering, dated February 11, 2021
99.2	Press Release Announcing the Pricing of the Offering, dated February 11, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Date: February 16, 2021

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan

Name: Dror Bashan

Title: President and Chief Executive Officer

PROTALIX BIOTHERAPEUTICS, INC.

(a Delaware corporation)

7,608,695 Shares of Common Stock

UNDERWRITING AGREEMENT

Dated: February 11, 2021

Protalix BioTherapeutics, Inc.

(a Delaware corporation)

7,608,695 Shares of Common Stock

UNDERWRITING AGREEMENT

February 11, 2021

BofA Securities, Inc.

as Representative of the several Underwriters

c/o BofA Securities, Inc.
One Bryant Park
New York, New York 10036

Ladies and Gentlemen:

Protalix BioTherapeutics, Inc., a Delaware corporation (the “Company”), confirms its agreement with BofA Securities, Inc. (“BofA”) and each of the other Underwriters named in Schedule A hereto (collectively, the “Underwriters,” which term shall also include any underwriter substituted as hereinafter provided in Section 10 hereof), for whom BofA is acting as representative (in such capacity, the “Representative”), with respect to (i) the sale by the Company and the purchase by the Underwriters, acting severally and not jointly, of the respective numbers of shares of Common Stock, par value \$0.001 per share, of the Company (“Common Stock”) set forth in Schedule A hereto and (ii) the grant by the Company to the Underwriters, acting severally and not jointly, of the option described in Section 2(b) hereof to purchase all or any part of 1,141,304 additional shares of Common Stock. The aforesaid 7,608,695 shares of Common Stock (the “Initial Securities”) to be purchased by the Underwriters and all or any part of the 1,141,304 shares of Common Stock subject to the option described in Section 2(b) hereof (the “Option Securities”) are herein called, collectively, the “Securities.”

The Company understands that the Underwriters propose to make a public offering of the Securities as soon as the Representative deems advisable after this Agreement has been executed and delivered.

The Company has prepared and filed with the Securities and Exchange Commission (the “Commission”) a shelf registration statement on Form S-3 (File No. 333-230604) covering the public offering and sale of certain securities, including the Securities, under the Securities Act of 1933, as amended (the “1933 Act”), and the rules and regulations promulgated thereunder (the “1933 Act Regulations”), which shelf registration statement has been declared effective by the Commission. Such registration statement, as of any time, means such registration statement as amended by any post-effective amendments thereto to such time, including the exhibits and any schedules thereto at such time, the documents incorporated or deemed to be incorporated by reference therein at such time pursuant to Item 12 of Form S-3 under the 1933 Act and the documents otherwise deemed to be a part thereof as of such time pursuant to Rule 430B under the 1933 Act Regulations (“Rule 430B”), is referred to herein as the “Registration Statement;” provided, however, that the “Registration Statement” without reference to a time means such registration statement as amended by any post-effective amendments thereto as of the time of the first contract of sale for the Securities, which time shall be considered the “new effective date” of such registration statement with respect to the Securities within the meaning of paragraph (f)(2) of Rule 430B, including the exhibits and schedules thereto as of such time, the documents incorporated or deemed incorporated by reference therein at such time pursuant to Item 12 of Form S-3 under the 1933 Act and the documents otherwise deemed to be a part thereof as of such time pursuant to the Rule 430B. Any registration statement filed pursuant to Rule 462 of the 1933 Act Regulations is herein called the “Rule 462(b) Registration Statement” and, after such filing, the term “Registration Statement” shall include the Rule 462(b) Registration Statement. Each preliminary prospectus used in connection with the offering of the Securities, including the documents incorporated or deemed to be incorporated by reference therein pursuant to Item 12 of Form S-3 under the 1933 Act, are collectively referred to herein as a “preliminary prospectus.” Promptly after execution and delivery of this Agreement, the Company will prepare and file a final prospectus relating to the Securities in accordance with the provisions of Rule 424(b) under the 1933 Act Regulations (“Rule 424(b)"). The final prospectus, in the form first furnished or made available to the Underwriters for use in connection with the offering of the Securities, including the documents incorporated or deemed to be incorporated by reference therein pursuant to Item 12 of Form S-3 under the 1933 Act, are collectively referred to herein as the “Prospectus.” For purposes of this Agreement, all references to the Registration Statement, any preliminary prospectus, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval system (or any successor system)(“EDGAR”).

As used in this Agreement:

“Applicable Time” means 7:00 P.M., New York City time, on February 11, 2021 or such other time as agreed by the Company and BofA.

“General Disclosure Package” means any Issuer General Use Free Writing Prospectuses issued at or prior to the Applicable Time, the most recent preliminary prospectus (including any documents incorporated therein by reference) that is distributed to investors prior to the Applicable Time and the information included on Schedule B-1 hereto, all considered together.

“Issuer Free Writing Prospectus” means any “issuer free writing prospectus,” as defined in Rule 433 of the 1933 Act Regulations (“Rule 433”), including without limitation any “free writing prospectus” (as defined in Rule 405 of the 1933 Act Regulations (“Rule 405”)) relating to the Securities that is (i) required to be filed with the Commission by the Company, (ii) a “road show that is a written communication” within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Securities or of the offering that does not reflect the final terms, in each case 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).

“Issuer General Use Free Writing Prospectus” means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors, as evidenced by its being specified in Schedule B-2 hereto.

“Issuer Limited Use Free Writing Prospectus” means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

“Testing-the-Waters Communication” means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the 1933 Act.

“Written Testing-the-Waters Communication” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the 1933 Act.

All references in this Agreement to financial statements and schedules and other information which is “contained,” “included” or “stated” (or other references of like import) in the Registration Statement, any preliminary prospectus or the Prospectus shall be deemed to include all such financial statements and schedules and other information incorporated or deemed incorporated by reference in the Registration Statement, any preliminary prospectus or the Prospectus, as the case may be, prior to the execution and delivery of this Agreement; and all references in this Agreement to amendments or supplements to the Registration Statement, any preliminary prospectus or the Prospectus shall be deemed to include the filing of any document under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the “1934 Act”), incorporated or deemed to be incorporated by reference in the Registration Statement, such preliminary prospectus or the Prospectus, as the case may be, at or after the execution and delivery of this Agreement.

SECTION 1. Representations and Warranties.

(a) Representations and Warranties by the Company. The Company represents and warrants to each Underwriter as of the date hereof, the Applicable Time, the Closing Time (as defined below) and any Date of Delivery (as defined below), and agrees with each Underwriter, as follows:

(i) Registration Statement and Prospectuses. The Company meets the requirements for use of Form S-3 under the 1933 Act for primary offerings. Each of the Registration Statement and any post-effective amendment thereto has become effective under the 1933 Act. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company’s knowledge, contemplated. The Company has complied with each request (if any) from the Commission for additional information.

Each of the Registration Statement and any post-effective amendment thereto, at the time of its effectiveness, each deemed effective date with respect to the Underwriters pursuant to Rule 430B(f)(2) under the 1933 Act Regulations complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus, the Prospectus and any amendment or supplement thereto, at the time each was filed with the Commission complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus and the Prospectus delivered to the Underwriters for use in connection with this offering was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, when they became effective or at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the 1934 Act and the rules and regulations of the Commission under the 1934 Act (the “1934 Act Regulations”).

(ii) Accurate Disclosure. Neither the Registration Statement nor any amendment thereto, at its effective time, on the date hereof, at the Closing Time or at any Date of Delivery, contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. At the Applicable Time, Closing Time and any Date of Delivery, neither of (A) the General Disclosure Package nor (B) any individual Issuer Limited Use Free Writing Prospectus, when considered together with the General Disclosure Package, when considered together with the General Disclosure Package, included, includes or will include an untrue statement of a material fact or omitted, omits 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. Neither the Prospectus nor any amendment or supplement thereto, as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Time or at any Date of Delivery, included, includes or will include an untrue statement of a material fact or omitted, omits 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. The documents incorporated or deemed to be incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus, at the time the Registration Statement became effective or when such documents incorporated by reference were filed with the Commission, as the case may be, when read together with the other information in the Registration Statement, the General Disclosure Package or the Prospectus, as the case may be, did not and will not include 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 not misleading.

The representations and warranties in this subsection shall not apply to statements in or omissions from the Registration Statement (or any amendment thereto), the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) made in reliance upon and in conformity with written information furnished to the Company by any Underwriter through BofA expressly for use therein. For purposes of this Agreement, the only information so furnished shall be the information in the first paragraph under the heading “Underwriting–Commissions and Discounts,” the information in the second, third and fourth paragraphs under the heading “Underwriting–Price Stabilization, Short Positions” and the information under the heading “Underwriting–Electronic Distribution” in each case contained in the Prospectus (collectively, the “Underwriter Information”).

(iii) Issuer Free Writing Prospectuses. No Issuer Free Writing Prospectus conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein, and any preliminary or other prospectus deemed to be a part thereof that has not been superseded or modified.

(iv) Testing-the-Waters Materials. The Company (A) has not engaged in any Testing-the-Waters Communication and (B) has not authorized anyone other than the Representative to engage in Testing-the-Waters Communications. The Company reconfirms that the Representative has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications.

(v) Company Not Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or another offering participant made a *bona fide* offer (within the meaning of Rule 164(h)(2) of the 1933 Act Regulations) of the Securities and at the date hereof, the Company was not and is not an “ineligible issuer,” as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

(vi) Independent Accountants. Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, who has certified the financial statements and supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus is an independent public accountant as required by the 1933 Act, the 1933 Act Regulations, the 1934 Act, the 1934 Act Regulations and the Public Company Accounting Oversight Board.

(vii) Financial Statements; Non-GAAP Financial Measures. The financial statements of the Company included in the Registration Statement, the General Disclosure Package and the Prospectus, together with the related schedules and notes, present fairly in all material respects the financial position of the Company and its consolidated subsidiaries at the dates indicated and the statement of operations, stockholders' equity and cash flows of the Company and its consolidated subsidiaries for the periods specified; said financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods involved. Except as included in the Registration Statement, the General Disclosure Package and the Prospectus, no historical or pro forma financial statements or supporting schedules are required to be included in the Registration Statement, any preliminary prospectus or the Prospectus under the 1933 Act or the 1933 Act Regulations. The interactive data in eXtensible Business Reporting Language incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus fairly presents in all material respects the required information and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(viii) No Material Adverse Change in Business. Except as otherwise stated therein, since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, (A) there has been no material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, (B) there have been no transactions entered into by the Company or any of its subsidiaries, other than those in the ordinary course of business, which are material with respect to the Company and its subsidiaries considered as one enterprise, and (C) there has been no dividend or distribution of any kind declared, paid or made by the Company on any class or series of its capital stock.

(ix) Good Standing of the Company. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and to enter into and perform its obligations under, and to consummate the transactions contemplated in, this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure so to qualify or to be in good standing would not, singly or in the aggregate, reasonably be expected to result in a material adverse effect in (A) the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, or (B) the ability of the Company to enter into and perform any of its obligations under, or to consummate any of the transactions contemplated in, this Agreement (collectively, a "Material Adverse Effect").

(x) Good Standing of Subsidiaries. Each "significant subsidiary" of the Company (as such term is defined in Rule 1-02 of Regulation S-X), if any (each, a "Significant Subsidiary" and, collectively, the "Significant Subsidiaries") has been duly organized and is validly existing in good standing under the laws of the jurisdiction of its incorporation or organization, has all requisite power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure so to qualify or to be in good standing would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, all of the outstanding shares of capital stock or other equity interests in each Significant Subsidiary have been duly authorized and validly issued, are fully paid and non-assessable and are owned by the Company, directly or through other subsidiaries of the Company, free and clear of any security interest, mortgage, pledge, lien, encumbrance, claim or equity. None of the outstanding shares of capital stock or other equity interests in any Significant Subsidiary were issued in violation of the preemptive or similar rights of any securityholder of such Significant Subsidiary or any other person or entity.

(xi) Capitalization. The authorized, issued and outstanding shares of capital stock of the Company are as set forth in the Registration Statement and the Prospectus (except for subsequent issuances, if any, pursuant to this Agreement, pursuant to reservations, agreements or employee benefit plans referred to in the Registration Statement, the General Disclosure Package and the Prospectus or pursuant to the exercise of convertible securities or options referred to in the Registration Statement, the General Disclosure Package and the Prospectus). The outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable. None of the outstanding shares of capital stock of the Company were issued in violation of the preemptive or other similar rights of any securityholder of the Company or any other person or entity.

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

(xiii) Authorization and Description of Securities. The Securities have been duly authorized for issuance and sale by the Company pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement against payment of the consideration set forth in this Agreement, will be validly issued, fully paid and non-assessable. The issuance of the Securities is not subject to the preemptive or other similar rights of any securityholder of the Company or any other person or entity. The Common Stock conforms to all statements relating thereto contained in the Registration Statement, the General Disclosure Package and the Prospectus and such statements conform to the rights set forth in the instruments defining the same. No holder of Securities will be subject to personal liability by reason of being such a holder.

(xiv) Registration Rights. There are no persons with registration rights or other similar rights to have any securities registered for sale pursuant to the Registration Statement or otherwise registered for sale or sold by the Company under the 1933 Act pursuant to this Agreement, other than those rights that have been disclosed in the Registration Statement, the General Disclosure Package and the Prospectus and have been waived.

(xv) Absence of Violations, Defaults and Conflicts. Neither the Company nor any of its subsidiaries are (A) in violation of its charter, by-laws or similar organizational document, (B) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease or other agreement or instrument to which the Company or any of its subsidiaries are a party or by which it or any of them may be bound or to which any of the properties, assets or operations of the Company or any of its subsidiaries are subject (collectively, "Agreements and Instruments"), except for such defaults that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, or (C) in violation of any law, statute, rule, regulation, judgment, order, writ or decree of any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency having jurisdiction over the Company or any of its subsidiaries or any of their respective properties, assets or operations (each, a "Governmental Entity"), except for such violations that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the General Disclosure Package and the Prospectus (including the issuance and sale of Securities and the use of the proceeds from the sale thereof as described therein under the caption "Use of Proceeds") and compliance by the Company with its obligations hereunder have been duly authorized by all requisite action and do not and will not, whether with or without the giving of notice or passage of time or both, conflict with or constitute a breach of, or default or Repayment Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any properties, assets or operations of the Company or any of its subsidiaries pursuant to, the Agreements and Instruments (except for such conflicts, breaches, defaults or Repayment Events or liens, charges or encumbrances that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect), nor will such action result in any violation of the provisions of (a) the charter, by-laws or similar organizational document of the Company or any of its subsidiaries or (b) any law, statute, rule, regulation, judgment, order, writ or decree of any Governmental Entity, except in the case of clause (b), as would not singly or in the aggregate, reasonably be expected to have a Material Adverse Effect. As used herein, a "Repayment Event" means any event or condition which gives the holder of any note, debenture or other financing instrument (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of the related financing by the Company or any of its subsidiaries.

(xvi) Absence of Labor Dispute. No labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is imminent, which could, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(xvii) Absence of Proceedings. Except as stated in the Registration Statement, the General Disclosure Package and the Prospectus, there is no action, suit, proceeding, inquiry or investigation before or brought by any Governmental Entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which could, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The aggregate of all pending legal or governmental proceedings to which the Company or any of its subsidiaries are a party or of which any of their respective properties, assets or operations are the subject which are not described in the Registration Statement, the General Disclosure Package and the Prospectus, including ordinary routine litigation incidental to the business, would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(xviii) Accuracy of Exhibits. There are no contracts or documents which are required to be described in all material respects in the Registration Statement, any preliminary prospectus or the Prospectus or to be filed as exhibits to the Registration Statement which have not been so described and filed as required.

(xix) Absence of Further Requirements. No filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any Governmental Entity is necessary or required for the Company's due authorization, execution and delivery of, or performance of its obligations under, this Agreement or for the offering, issuance, sale or delivery of Securities or the consummation of the transactions contemplated in this Agreement except such as have been already obtained or as may be required under the 1933 Act, the 1933 Act Regulations, the rules of the NYSE American LLC ("NYSE American"), the securities laws of any state or non-U.S. jurisdiction or the rules of Financial Industry Regulatory Authority, Inc. ("FINRA").

(xx) Possession of Licenses and Permits. The Company and its subsidiaries possess and are in compliance in all material respects with the terms of all licenses, approvals, orders, certificates, permits and other authorizations (collectively, “Licenses”) issued by all applicable authorities, including, without limitation, all such Licenses required by the U.S. Food and Drug Administration or any component thereof and/or by any other U.S. state, local or foreign government or drug regulatory agency (collectively, the “Regulatory Agencies”) necessary to conduct their respective businesses as described in the Registration Statement, the General Disclosure Package and the Prospectus, as applicable, and neither the Company nor any such subsidiary has received any notice of proceedings (or otherwise) relating to the revocation or modification of, or non-compliance with, any such License that, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a Material Adverse Effect, except as set forth or contemplated in the Registration Statement, the General Disclosure Package and the Prospectus, and all such Licenses are in full force and effect. The Company and its subsidiaries are in compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any product manufactured or distributed by them, except where such noncompliance would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(xxi) Title to Property. The Company and its subsidiaries have good and marketable title to all real property owned by them and good title to all other properties owned by them that is material to the business of the Company and its subsidiaries, in each case, free and clear of all mortgages, pledges, liens, security interests, claims, restrictions or encumbrances of any kind except such as (A) are described in the Registration Statement, the General Disclosure Package and the Prospectus or (B) do not, singly or in the aggregate, materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company or any of its subsidiaries. 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 any of its subsidiaries holds properties described in the Registration Statement, the General Disclosure Package or the Prospectus, are in full force and effect, and neither the Company nor any such subsidiary has any notice of any material claim of any sort that has been asserted by anyone adverse to its rights under any of the leases or subleases mentioned above or affecting or questioning its rights to the continued possession of the leased or subleased premises under any such lease or sublease.

(xxii) Possession of Intellectual Property. The Company and its subsidiaries own, possess, have a valid license or otherwise have adequate rights to use, on reasonable terms, all patents, trademarks, service marks, trade names, Internet domain names, copyrights and copyrightable works, licenses, inventions, trade secrets, technology, and software, data, know-how (whether or not patentable) and other intellectual property or proprietary rights (including all registrations and applications for registration and renewals of, and all goodwill associated with, the foregoing) (collectively, the “Intellectual Property”) necessary for the conduct of the Company’s and its subsidiaries’ businesses as now conducted and intended to be conducted. Except as would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect: (a) there are no rights of third parties to any such Intellectual Property; (b) to the Company’s knowledge, there is no material infringement, misappropriation or other violation by third parties of any such Intellectual Property; (c) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the Company’s or its subsidiaries’ rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (d) such Intellectual Property is subsisting and, to the knowledge of the Company, valid and enforceable, and there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (e) to the knowledge of the Company, the Company and its subsidiaries do not engage in any activity that, and there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others that the Company or any of its subsidiaries, infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, and the Company is unaware of any other fact which would form a reasonable basis for any such claim; (f) to the Company’s knowledge there is no U.S. patent or published U.S. patent application which contains claims that have (or may have) priority over or dominate (or may dominate) any Intellectual Property described in the Registration Statement, the General Disclosure Package and the Prospectus as being owned by or licensed to the Company or its subsidiaries or that interferes with the issued or pending claims of any such Intellectual Property; and (g) there is no prior art of which the Company is aware that may render any U.S. patent held by the Company or its subsidiaries invalid or any U.S. patent application held by the Company or its subsidiaries unpatentable that has not been disclosed to the U.S. Patent and Trademark Office. Each current and former employee and officer of the Company and its subsidiaries or any Affiliate has executed a valid written agreement with the Company or such subsidiary or Affiliate regarding confidentiality and the assignment of all proprietary information and inventions created by such person. Each current and former consultant to the Company and its subsidiaries or any Affiliate that may be involved in the generation of Intellectual Property has executed a valid written agreement with the Company or such subsidiary or Affiliate regarding confidentiality and the assignment of all proprietary information and inventions created by such person.

(xxiii) Environmental Laws. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus or would not, singly or in the aggregate, result in a Material Adverse Effect, neither the Company nor any of its subsidiaries (a) are in violation of any and all applicable foreign, federal, state and local laws and regulations (including common law and any binding judicial or administrative decisions) relating to the protection of human health and safety, the environment (including sustainability and the protection of habitats or ecosystems) or hazardous, toxic or radioactive substances or wastes, pollutants or contaminants (including greenhouse gases) (“Environmental Laws”); (b) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (c) have not received any notice, demand or claim alleging any actual or potential noncompliance with or liability under any Environmental Law or permit, license or approval thereunder and are not aware of any fact or circumstance that would reasonably be expected to form the basis of any such notice, demand or claim. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, neither the Company nor any of its subsidiaries has been named as a “potentially responsible party” under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended. In the ordinary course of its business, the Company periodically reviews the effect of Environmental Laws on the business, operations and properties of the Company and its subsidiaries, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license, registration or approval, any related constraints on operating activities and any potential liabilities to third parties); on the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, singly or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xxiv) Accounting Controls and Disclosure Controls. The Company maintains effective internal control over financial reporting (as defined under Rule 13-a15 and Rule 15d-15 of the 1934 Act Regulations) and a system of internal accounting controls sufficient to provide reasonable assurances that: (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (E) the interactive data in eXtensible Business Reporting Language incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus fairly presents in all material respects the required information and is prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (1) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) 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 maintains an effective system of disclosure controls and procedures (as defined in Rule 13a-15 and Rule 15d-15 of the 1934 Act Regulations) that are designed to ensure that the information required to be disclosed by the Company in the reports that it files or submits under the 1934 Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, and is accumulated and communicated to the Company's management, including its principal executive officer or officers and principal financial officer or officers, as appropriate, to allow timely decisions regarding disclosure.

(xxv) Compliance with the Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any provision of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated in connection therewith, including, without limitation, Section 402 related to loans and Sections 302 and 906 related to certifications.

(xxvi) Payment of Taxes. All United States federal, state, local and non-U.S. tax returns of the Company and its subsidiaries required by law to be filed have been filed, except where the failure to do so would not, singly or in the aggregate, reasonably be expected to have a Material Adverse Effect and all taxes shown by such returns or otherwise assessed, which are due and payable, have been paid, except assessments against which appeals have been or will be promptly taken and as to which adequate reserves have been provided in accordance with GAAP by the Company. Except as otherwise disclosed in or contemplated by the Registration Statement or the Prospectus, no tax deficiency has been determined adversely to the Company which has had, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. The Company has no knowledge of any federal, state or other governmental tax deficiency, penalty or assessment which has been or might be asserted or threatened against it which would reasonably be expected to have a Material Adverse Effect. The charges, accruals and reserves on the books of the Company in respect of any income and corporation tax liability for any years not finally determined are adequate to meet any assessments or re-assessments for additional income tax for any years not finally determined, except to the extent of any inadequacy that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(xxvii) Insurance. The Company and its subsidiaries carry or are entitled to the benefits of insurance, with financially sound and reputable insurers, in such amounts and covering such risks as is generally maintained by companies of established repute engaged in the same or similar business, and all such insurance is in full force and effect. The Company has no reason to believe that it or any of its subsidiaries will not be able (A) to renew its existing insurance coverage as and when such policies expire or (B) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Neither of the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied where such denial would or has resulted in a Material Adverse Effect.

(xxviii) Investment Company Act. The Company is not required, and upon the issuance and sale of the Securities as herein contemplated and the application of the net proceeds therefrom as described in the Registration Statement, the General Disclosure Package and the Prospectus will not be required, to register as an “investment company” under the Investment Company Act of 1940, as amended (the “1940 Act”).

(xxix) Absence of Manipulation. Neither the Company nor any affiliate of the Company has taken, nor will the Company or any affiliate take, directly or indirectly, any action which is designed, or would be expected, to cause or result in, or which constitutes, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities or to result in a violation of Regulation M under the 1934 Act.

(xxx) Foreign Corrupt Practices Act. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of either (A) the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the “FCPA”), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any “foreign official” (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA or (B) the U.K. Bribery Act 2010 (the “Bribery Act”), and the Company, its subsidiaries and, to the knowledge of the Company, its other affiliates have conducted their businesses in compliance with the FCPA and the Bribery Act and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(xxxi) Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the “Money Laundering Laws”). No action, suit or proceeding by or before any Governmental Entity involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xxxii) OFAC. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is (A) an individual or entity (“Person”) currently the subject or target of any sanctions administered or enforced by the United States Government, including, without limitation the U.S. Department of the Treasury’s Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty’s Treasury, or other relevant sanctions authority (collectively, “Sanctions”), or (B) located, organized or resident in a country or territory that is the subject of Sanctions. The Company will not, directly or indirectly, use the proceeds of the sale of the Securities, or lend, contribute or otherwise make available such proceeds to any of its subsidiaries, joint venture partners or other Persons, to fund any activities of or business with any Person, or in any country or territory, that, at the time of such funding, is the subject of Sanctions or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

(xxxiii) Lending Relationship. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of any Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Securities to repay any outstanding debt owed to any affiliate of any Underwriter.

(xxxiv) Statistical and Market-Related Data. Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included in the Registration Statement, the General Disclosure Package or the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

(xxxv) Cybersecurity and Data Protection. (A) There has been no security breach or incident, unauthorized access or disclosure, or other compromise of or relating to, the Company's or its subsidiaries' information technology and computer systems, networks, hardware, software, data and databases (including the data and information of their respective patients, customers, employees, suppliers, vendors and any third party data maintained, processed or stored by the Company or its subsidiaries, and any such data processed or stored by third parties on behalf of the Company or its subsidiaries), equipment or technology (collectively, "IT Systems and Data"), (B) neither the Company nor its subsidiaries have been notified of, and have no knowledge of any event or condition that would result in, any security breach or incident, unauthorized access or disclosure of or other compromise to their IT Systems and Data and (C) the Company and its subsidiaries have implemented appropriate controls, policies, procedures, and technological safeguards to maintain and protect the integrity, continuous operation, redundancy, disaster recovery and security of their IT Systems and Data consistent with industry standards and practices, or as required by applicable data protection laws, Healthcare Laws and regulatory standards, except with respect to clauses (A) and (B), for any such security breach or incident, unauthorized access or disclosure, or other compromises, as would not, individually or in the aggregate, have a Material Adverse Effect, or with respect to clause (C), where the failure to do so would not, individually or in the aggregate, have a Material Adverse Effect. The Company and its subsidiaries are presently in compliance in all material respects with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of the IT Systems and Data, including the collection, use, transfer, processing, disposal, disclosure, handling, storage and analysis of personally identifiable information, protected health information, consumer information and other confidential information of the Company, its subsidiaries and any third parties in their possession, and the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification.

(xxxvi) Regulatory Matters. The Company and each of its subsidiaries: (a) are and have been in material compliance with applicable health care laws, including, without limitation, the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), the Federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, the exclusion laws, Social Security Act § 1128 (42 U.S.C. § 1320a-7), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act) and the regulations promulgated pursuant to such laws, and comparable state laws, and all other local, state, federal, national, supranational and foreign laws, manual provisions, policies and administrative guidance relating to the regulation of the Company and its subsidiaries (collectively, “Health Care Laws”); (b) have not received notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Regulatory Agency or third party alleging that any product operation or activity is in material violation of any Health Care Laws and has no knowledge that any such Regulatory Agency or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; and (c) are not a party to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order or similar agreements or have any reporting obligations pursuant to any such agreement, plan or correction or other remedial measure entered into with any governmental authority. Neither the Company nor its subsidiaries or any of their officers, directors, employees, agents or contractors has been or is currently debarred, suspended or excluded from participation in the Medicare and Medicaid programs or any other state or federal health care program.

(xxxvii) Preclinical and Clinical Studies and Tests. The preclinical tests and clinical trials that are described in, or the results of which are referred to in, the Registration Statement, the General Disclosure Package and the Prospectus, as applicable, were and, if still pending, are being conducted in all material respects in accordance with protocols filed with the appropriate Regulatory Agencies for each such test or trial, as the case may be, and with standard medical and scientific research procedures and all applicable statutes, directives, rules and regulations of the Regulatory Agencies, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder; each description of such tests and trials, and the results thereof, contained in the Registration Statement, the General Disclosure Package and the Prospectus, as applicable, is accurate and complete in all material respects and fairly presents the data about and derived from such tests and trials, and the Company has no knowledge of any other studies or tests or modifications, the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the General Disclosure Package and the Prospectus, as applicable; neither the Company nor its subsidiaries has received any notices or other correspondence from any Regulatory Agency requiring the termination, suspension or modification of any clinical trials; and each of the Company and its subsidiaries has operated and currently is in compliance in all material respects with all applicable rules and regulations of the Regulatory Agencies

(xxxviii) No Safety Notices. (i) There have been no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, “dear doctor” letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company’s or its subsidiaries’ products and product candidates (“Safety Notices”), except as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, and (ii) there are no facts that would be reasonably likely to result in (x) a Safety Notice with respect to the Company’s or its subsidiaries’ products and product candidates, or (y) a termination or suspension of testing of any of the Company’s or its subsidiaries’ products and product candidates, except, in each of cases (x) or (y) such as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect

(b) *Officer's Certificates.* Any certificate signed by any officer of the Company or its Subsidiaries delivered to the Representative or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

SECTION 2. Sale and Delivery to Underwriters; Closing.

(a) *Initial Securities.* On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company agrees to sell to each Underwriter, severally and not jointly, and each Underwriter, severally and not jointly, agrees to purchase from the Company, at the price per share set forth in Schedule A, that number of Initial Securities set forth in Schedule A opposite the name of such Underwriter, plus any additional number of Initial Securities which such Underwriter may become obligated to purchase pursuant to the provisions of Section 10 hereof, bears to the total number of Initial Securities, subject, in each case, to such adjustments among the Underwriters as BofA in its sole discretion shall make to eliminate any sales or purchases of fractional shares.

(b) *Option Securities.* In addition, on the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company hereby grants an option to the Underwriters, severally and not jointly, to purchase up to an additional 1,141,304 shares of Common Stock, as set forth in Schedule B, at the price per share set forth in Schedule A, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities. The option hereby granted may be exercised for 30 days after the date hereof and may be exercised in whole or in part at any time from time to time upon notice by the Representative to the Company setting forth the number of Option Securities as to which the several Underwriters are then exercising the option and the time and date of payment and delivery for such Option Securities. Any such time and date of delivery (a "Date of Delivery") shall be determined by the Representative, but shall not be later than seven full business days after the exercise of said option, nor in any event prior to the Closing Time. If the option is exercised as to all or any portion of the Option Securities, each of the Underwriters, acting severally and not jointly, will purchase that proportion of the total number of Option Securities then being purchased which the number of Initial Securities set forth in Schedule A opposite the name of such Underwriter bears to the total number of Initial Securities, subject, in each case, to such adjustments as BofA in its sole discretion shall make to eliminate any sales or purchases of fractional shares.

(c) *Payment.* Payment of the purchase price for, and delivery of certificates or security entitlements for, the Initial Securities shall be made at the offices of Shearman & Sterling LLP, 599 Lexington Avenue, New York, New York 10022, or at such other place as shall be agreed upon by the Representative and the Company, at 9:00 A.M. (New York City time) on the second (third, if the pricing occurs after 4:30 P.M. (New York City time) on any given day) business day after the date hereof (unless postponed in accordance with the provisions of Section 10), or such other time not later than five business days after such date as shall be agreed upon by the Representative and the Company (such time and date of payment and delivery being herein called "Closing Time").

In addition, in the event that any or all of the Option Securities are purchased by the Underwriters, payment of the purchase price for, and delivery of certificates or security entitlements for, such Option Securities shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representative and the Company, on each Date of Delivery as specified in the notice from BofA to the Company.

Payment shall be made to the Company by wire transfer of immediately available funds to a bank account designated by the Company against delivery to the Representative for the respective accounts of the Underwriters of electronic book-entry security entitlements for the Securities to be purchased by them. It is understood that each Underwriter has authorized the Representative, for its account, to accept delivery of, receipt for, and make payment of the purchase price for, the Initial Securities and the Option Securities, if any, which it has agreed to purchase. BofA, individually and not as representative of the Underwriters, may (but shall not be obligated to) make payment of the purchase price for the Initial Securities or the Option Securities, if any, to be purchased by any Underwriter whose funds have not been received by the Closing Time or the relevant Date of Delivery, as the case may be, but such payment shall not relieve such Underwriter from its obligations hereunder.

SECTION 3. Covenants of the Company. The Company covenants with each Underwriter as follows:

(a) *Compliance with Securities Regulations and Commission Requests.* The Company, subject to Section 3(b), will comply with the requirements of Rule 430B, and will notify the Representative immediately, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed, (ii) of the receipt of any comments from the Commission, (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus, including any document incorporated by reference therein or for additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any preliminary prospectus or the Prospectus, or of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the 1933 Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the 1933 Act in connection with the offering of the Securities. The Company will effect all filings required under Rule 424(b), in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and will take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company will make every reasonable effort to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof as soon as reasonably practicable.

(b) *Continued Compliance with Securities Laws.* The Company will comply with the 1933 Act, the 1933 Act Regulations, the 1934 Act and the 1934 Act Regulations so as to permit the completion of the distribution of the Securities as contemplated in this Agreement and in the Registration Statement, the General Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172 of the 1933 Act Regulations ("Rule 172"), would be) required by the 1933 Act to be delivered in connection with sales of the Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include 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 not misleading, (ii) amend or supplement the General Disclosure Package or the Prospectus in order that the General Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the General Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the 1933 Act or the 1933 Act Regulations, the Company will promptly (A) give the Representative notice of such event, (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the General Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representative with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representative or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company will give the Representative notice of its intention to make any such filing from the Applicable Time to the Closing Time and will furnish the Representative with copies of any such documents a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representative or counsel for the Underwriters shall reasonably object.

(c) *Delivery of Registration Statements.* The Company has furnished or will deliver to the Representative and counsel for the Underwriters, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith or incorporated by reference therein and documents incorporated or deemed to be incorporated by reference therein) and signed copies of all consents and certificates of experts, and will also deliver to the Representative, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(d) *Delivery of Prospectuses.* The Company has delivered to each Underwriter, without charge, as many copies of each preliminary prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the 1933 Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(e) *Blue Sky Qualifications.* The Company will use its best efforts, in cooperation with the Underwriters, to qualify the Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representative may designate and to maintain such qualifications in effect so long as required to complete the distribution of the Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

(f) *Rule 158.* The Company will timely file such reports pursuant to the 1934 Act as are necessary in order to make generally available to its securityholders as soon as practicable an earnings statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, the last paragraph of Section 11(a) of the 1933 Act.

(g) *Use of Proceeds.* The Company will use the net proceeds received by it from the sale of the Securities in the manner specified in the Registration Statement, the General Disclosure Package and the Prospectus under “Use of Proceeds.”

(h) *Listing.* The Company will use its best efforts to effect and maintain the listing of the Securities on the NYSE American.

(i) *Restriction on Sale of Securities.* During a period of 90 days from the date of the Prospectus, the Company will not, without the prior written consent of BofA, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or file any registration statement under the 1933 Act with respect to any of the foregoing or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock, whether any such swap or transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise or (iii) publicly disclose the intention to do any of the foregoing described in clauses (i) or (ii). The foregoing sentence shall not apply to (A) the Securities to be sold hereunder, (B) any shares of Common Stock issued by the Company upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (C) any shares of Common Stock issued or options to purchase Common Stock granted pursuant to existing employee benefit plans of the Company referred to in the Registration Statement, the General Disclosure Package and the Prospectus or (D) any shares of Common Stock issued pursuant to any non-employee director stock plan or dividend reinvestment plan referred to in the Registration Statement, the General Disclosure Package and the Prospectus.

(j) *Reporting Requirements.* The Company, during the period when a Prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, will file all documents required to be filed with the Commission pursuant to the 1934 Act within the time periods required by the 1934 Act and 1934 Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Securities as may be required under Rule 463 under the 1933 Act.

(k) *Issuer Free Writing Prospectuses.* The Company agrees that, unless it obtains the prior written consent of the Representative, it will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a “free writing prospectus,” or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Representative will be deemed to have consented to the Issuer Free Writing Prospectuses listed on Schedule C-2 hereto and any “road show that is a written communication” within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representative. Each of the Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented to, by the Representative as an “issuer free writing prospectus,” as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement, any preliminary prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

SECTION 4. Payment of Expenses.

(a) *Expenses.* The Company will pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, printing and filing of the Registration Statement (including financial statements and exhibits) as originally filed and each amendment thereto, (ii) the preparation, printing and delivery to the Underwriters of copies of each preliminary prospectus, each Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto and any costs associated with electronic delivery of any of the foregoing by the Underwriters to investors, (iii) the preparation, issuance and delivery of the certificates or security entitlements for the Securities to the Underwriters, including any stock or other transfer taxes and any stamp or other duties payable upon the sale, issuance or delivery of the Securities to the Underwriters, (iv) the fees and disbursements of the Company's counsel, accountants and other advisors, (v) the qualification of the Securities under securities laws in accordance with the provisions of Section 3(e) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters in connection therewith and in connection with the preparation of the Blue Sky Survey and any supplement thereto, (vi) the fees and expenses of any transfer agent or registrar for the Securities, (vii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the Securities, including without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and the cost of aircraft and other transportation chartered in connection with the road show, (viii) the filing fees incident to, and the reasonable fees and disbursements of counsel to the Underwriters in connection with, the review by FINRA of the terms of the sale of the Securities in an amount not to exceed \$10,000, (ix) the fees and expenses incurred in connection with the listing of the Securities on the NYSE American and (x) the costs and expenses (including, without limitation, any damages or other amounts payable in connection with legal or contractual liability) associated with the reforming of any contracts for sale of the Securities made by the Underwriters caused by a breach of the representation contained in the third sentence of Section 1(a)(ii).

(b) *Termination of Agreement.* If this Agreement is terminated by the Representative in accordance with the provisions of Section 5, Section 9(a)(i) or (iii) or Section 10 hereof, the Company shall reimburse the Underwriters for all of their out-of-pocket expenses, including the reasonable fees and disbursements of counsel for the Underwriters.

SECTION 5. Conditions of Underwriters' Obligations. The obligations of the several Underwriters hereunder are subject to the accuracy of the representations and warranties of the Company contained herein or in certificates of any officer of the Company or any of its subsidiaries delivered pursuant to the provisions hereof, to the performance by the Company of its covenants and other obligations hereunder, and to the following further conditions:

(a) *Effectiveness of Registration Statement.* The Registration Statement, including any Rule 462(b) Registration Statement, has become effective and, at the Closing Time, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated; and the Company has complied with each request (if any) from the Commission for additional information.

(b) *Opinion of Counsel for Company.* At the Closing Time, the Representative shall have received (i) the favorable opinion and negative assurance letter, dated the Closing Time, of (i) Mayer Brown LLP, New York counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, (ii) the opinion, dated the Closing Time, of Horn & Co. Law Offices, Israeli counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, and (iii) the opinion, dated the Closing Time, of Ehrlich & Fenster, special intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriters.

(c) *Opinion of Counsel for Underwriters.* At the Closing Time, the Representative shall have received the favorable opinion, dated the Closing Time, of Shearman & Sterling LLP, counsel for the Underwriters, together with signed or reproduced copies of such letter for each of the other Underwriters with respect to the matters as the Underwriters may reasonably request. In giving such opinion such counsel may rely, as to all matters governed by the laws of jurisdictions other than the law of the State of New York, the General Corporation Law of the State of Delaware and the federal securities laws of the United States, upon the opinions of counsel satisfactory to the Representative. Such counsel may also state that, insofar as such opinion involves factual matters, they have relied, to the extent they deem proper, upon certificates of officers and other representatives of the Company and its subsidiaries and certificates of public officials.

(d) *Officers' Certificate.* At the Closing Time, there shall not have been, since the date hereof or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, and the Representative shall have received a certificate of the Chief Executive Officer or the President of the Company and of the chief financial or chief accounting officer of the Company, dated the Closing Time, to the effect that (i) there has been no such material adverse change, (ii) the representations and warranties of the Company in this Agreement are true and correct with the same force and effect as though expressly made at and as of the Closing Time, (iii) the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied at or prior to the Closing Time, and (iv) no stop order suspending the effectiveness of the Registration Statement under the 1933 Act has been issued, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to their knowledge, contemplated.

(e) *Accountant's Comfort Letter.* At the time of the execution of this Agreement, the Representative shall have received from Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, a letter, dated such date, in form and substance satisfactory to the Representative, together with signed or reproduced copies of such letter for each of the other Underwriters containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the General Disclosure Package and the Prospectus.

(f) *Bring-down Comfort Letter.* At the Closing Time, the Representative shall have received from Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, a letter, dated as of the Closing Time, to the effect that they reaffirm the statements made in the letter furnished pursuant to subsection (g) of this Section, except that the specified date referred to shall be a date not more than three business days prior to the Closing Time.

(g) *Approval of Listing.* At the Closing Time, the Securities shall have been approved for listing on the NYSE American, subject only to official notice of issuance.

(h) *No Objection.* FINRA has confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Securities.

(i) *Lock-up Agreements.* At the date of this Agreement, the Representative shall have received an agreement substantially in the form of Exhibit A hereto signed by the persons listed on Schedule C hereto.

(j) *Chief Financial Officer's Certificate.* At the time of the execution of this Agreement and at the Closing Time, the Representative shall have received from the chief financial officer of the Company a certificate in a form reasonably satisfactory to the Representative.

(k) *Conditions to Purchase of Option Securities.* In the event that the Underwriters exercise their option provided in Section 2(b) hereof to purchase all or any portion of the Option Securities, the representations and warranties of the Company contained herein and the statements in any certificates furnished by the Company and any of its subsidiaries hereunder shall be true and correct as of each Date of Delivery and, at the relevant Date of Delivery, the Representative shall have received:

(i) Officers' Certificate. A certificate, dated such Date of Delivery, of the President or a Vice President of the Company and of the chief financial or chief accounting officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(e) hereof remains true and correct as of such Date of Delivery.

(ii) Opinion of Counsel for Company. If requested by the Representative, the favorable opinion of (i) Mayer Brown LLP, New York counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, (ii) Horn & Co. Law Offices, Israeli counsel for the Company, and (iii) Ehrlich & Fenster, special intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(b) hereof.

(v) Opinion of Counsel for Underwriters. If requested by the Representative, the favorable opinion of Shearman & Sterling LLP, counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(d) hereof.

(vi) Bring-down Comfort Letter. If requested by the Representative, a letter from Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, in form and substance satisfactory to the Representative and dated such Date of Delivery, substantially in the same form and substance as the letter furnished to the Representative pursuant to Section 5(g) hereof, except that the "specified date" in the letter furnished pursuant to this paragraph shall be a date not more than three business days prior to such Date of Delivery.

(vii) Chief Financial Officer's Certificate. A certificate, dated such Date of Delivery of the Chief Financial Officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(k) hereof remains true and correct as of such Date of Delivery.

(l) *Additional Documents.* At the Closing Time and at each Date of Delivery (if any) counsel for the Underwriters shall have been furnished with such documents and opinions as they may require for the purpose of enabling them to pass upon the issuance and sale of the Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Securities as herein contemplated shall be satisfactory in form and substance to the Representative and counsel for the Underwriters.

(m) *Termination of Agreement.* If any condition specified in this Section shall not have been fulfilled when and as required to be fulfilled, this Agreement, or, in the case of any condition to the purchase of Option Securities on a Date of Delivery which is after the Closing Time, the obligations of the several Underwriters to purchase the relevant Option Securities, may be terminated by the Representative by notice to the Company at any time at or prior to Closing Time or such Date of Delivery, as the case may be, and such termination shall be without liability of any party to any other party except as provided in Section 4 and except that Sections 1, 6, 7, 8, 14, 15, 16 and 17 shall survive any such termination and remain in full force and effect.

SECTION 6. Indemnification.

(a) *Indemnification of Underwriters.* The Company agrees to indemnify and hold harmless each Underwriter, its affiliates (as such term is defined in Rule 501(b) under the 1933 Act (each, an “Affiliate”)), its selling agents and each person, if any, who controls any Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, arising out of any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including any information deemed to be a part thereof pursuant to Rule 430B, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or arising out of any untrue statement or alleged untrue statement of a material fact included (A) in any preliminary prospectus, any Issuer Free Writing Prospectus, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) or (B) in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities (“Marketing Materials”), including any roadshow or investor presentations made to investors by the Company (whether in person or electronically), or the omission or alleged omission in any preliminary prospectus, Issuer Free Writing Prospectus, Prospectus or in any Marketing Materials of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 6(d) below) any such settlement is effected with the written consent of the Company;

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel chosen by BofA), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above;

provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made in the Registration Statement (or any amendment thereto), including any information deemed to be a part thereof pursuant to Rule 430B, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(c) *Indemnification of Company, Directors and Officers.* Each Underwriter severally agrees to indemnify and hold harmless the Company, its directors, each of its officers who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act, against any and all loss, liability, claim, damage and expense described in the indemnity contained in subsection (a) of this Section, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendment thereto), including any information deemed to be a part thereof pursuant to Rule 430B, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(d) *Actions against Parties; Notification.* Each indemnified party shall give notice as promptly as reasonably practicable to each indemnifying party of any action commenced against it in respect of which indemnity may be sought hereunder, but failure to so notify an indemnifying party shall not relieve such indemnifying party from any liability hereunder to the extent it is not materially prejudiced as a result thereof and in any event shall not relieve it from any liability which it may have otherwise than on account of this indemnity agreement. In the case of parties indemnified pursuant to Section 6(a) above, counsel to the indemnified parties shall be selected by BofA, and, in the case of parties indemnified pursuant to Section 6(c) above, counsel to the indemnified parties shall be selected by the Company. An indemnifying party may participate at its own expense in the defense of any such action; provided, however, that counsel to the indemnifying party shall not (except with the consent of the indemnified party) also be counsel to the indemnified party. In no event shall the indemnifying parties be liable for fees and expenses of more than one counsel (in addition to any local counsel) separate from their own counsel for all indemnified parties in connection with any one action or separate but similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification or contribution could be sought under this Section 6 or Section 7 hereof (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 from all liability arising out of such litigation, investigation, proceeding 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.

(e) *Settlement without Consent if Failure to Reimburse.* If at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a)(ii) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

SECTION 7. Contribution. If the indemnification provided for in Section 6 hereof is for any reason unavailable to or insufficient to hold harmless an indemnified party in respect of any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount of such losses, liabilities, claims, damages and expenses incurred by such indemnified party, as incurred, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Securities pursuant to this Agreement or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and of the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, liabilities, claims, damages or expenses, 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 hand, in connection with the offering of the Securities pursuant to this Agreement shall be deemed to be in the same respective proportions as the total net proceeds from the offering of the Securities pursuant to this Agreement (before deducting expenses) received by the Company, on the one hand, and the total underwriting discount received by the Underwriters, on the other hand, in each case as set forth on the cover of the Prospectus, bear to the aggregate initial public offering price of the Securities as set forth on the cover of the Prospectus.

The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 7 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 7. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above in this Section 7 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission.

Notwithstanding the provisions of this Section 7, no Underwriter shall be required to contribute any amount in excess of the underwriting commissions received by such Underwriter in connection with the Securities underwritten by it and distributed to the public.

No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

For purposes of this Section 7, each person, if any, who controls an Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act and each Underwriter's Affiliates and selling agents shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act shall have the same rights to contribution as the Company. The Underwriters' respective obligations to contribute pursuant to this Section 7 are several in proportion to the number of Initial Securities set forth opposite their respective names in Schedule A hereto and not joint.

SECTION 8. Representations, Warranties and Agreements to Survive. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company or any of its subsidiaries submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors, any person controlling the Company and (ii) delivery of and payment for the Securities.

SECTION 9. Termination of Agreement.

(a) *Termination.* The Representative may terminate this Agreement, by notice to the Company, at any time at or prior to the Closing Time (i) if there has been, in the judgment of the Representative, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, or (ii) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Representative, impracticable or inadvisable to proceed with the completion of the offering or to enforce contracts for the sale of the Securities, or (iii) if trading in any securities of the Company has been suspended or materially limited by the Commission or the NYSE American, or (iv) if trading generally on the NYSE American or the New York Stock Exchange or in the Nasdaq Global Select Market has been suspended or materially limited, or minimum or maximum prices for trading have been fixed, or maximum ranges for prices have been required, by any of said exchanges or by order of the Commission, FINRA or any other governmental authority, or (v) a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States, or (vi) if a banking moratorium has been declared by either Federal or New York authorities.

(b) *Liabilities.* If this Agreement is terminated pursuant to this Section, such termination shall be without liability of any party to any other party except as provided in Section 4 hereof, and provided further that Sections 1, 6, 7, 8, 14, 15, 16 and 17 shall survive such termination and remain in full force and effect.

SECTION 10. Default by One or More of the Underwriters. If one or more of the Underwriters shall fail at the Closing Time or a Date of Delivery to purchase the Securities which it or they are obligated to purchase under this Agreement (the "Defaulted Securities"), the Representative shall have the right, within 24 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other underwriters, to purchase all, but not less than all, of the Defaulted Securities in such amounts as may be agreed upon and upon the terms herein set forth; if, however, the Representative shall not have completed such arrangements within such 24-hour period, then:

(i) if the number of Defaulted Securities does not exceed 10% of the number of Securities to be purchased on such date, each of the non-defaulting Underwriters shall be obligated, severally and not jointly, to purchase the full amount thereof in the proportions that their respective underwriting obligations hereunder bear to the underwriting obligations of all non-defaulting Underwriters, or

(ii) if the number of Defaulted Securities exceeds 10% of the number of Securities to be purchased on such date, this Agreement or, with respect to any Date of Delivery which occurs after the Closing Time, the obligation of the Underwriters to purchase, and the Company to sell, the Option Securities to be purchased and sold on such Date of Delivery shall terminate without liability on the part of any non-defaulting Underwriter.

No action taken pursuant to this Section shall relieve any defaulting Underwriter from liability in respect of its default.

In the event of any such default which does not result in a termination of this Agreement or, in the case of a Date of Delivery which is after the Closing Time, which does not result in a termination of the obligation of the Underwriters to purchase and the Company to sell the relevant Option Securities, as the case may be, either the (i) Representative or (ii) the Company shall have the right to postpone the Closing Time or the relevant Date of Delivery, as the case may be, for a period not exceeding seven days in order to effect any required changes in the Registration Statement, the General Disclosure Package or the Prospectus or in any other documents or arrangements. As used herein, the term "Underwriter" includes any person substituted for an Underwriter under this Section 10.

SECTION 11. Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted by any standard form of telecommunication. Notices to the Underwriters shall be directed to BofA at One Bryant Park, New York, New York 10036, attention of Syndicate Department (facsimile: (646) 855-3073), with a copy to ECM Legal (facsimile: (212) 230-8730) with a copy to Shearman & Sterling LLP at 599 Lexington Avenue, New York, NY 10022, attention of Ilir Mujalovic; notices to the Company shall be directed to it at Protalix BioTherapeutics, Inc., 2 Snunit Street, Science Park P.O.B. 455, Carmiel 20100, Israel, Attention: Dror Bashan, with a copy to Mayer Brown LLP, 1221 Avenue of the Americas, New York, New York 10020, Attention: Anna Pinedo.

SECTION 12. No Advisory or Fiduciary Relationship. Each of the Company acknowledges and agrees that (a) the purchase and sale of the Securities pursuant to this Agreement, including the determination of the public offering price of the Securities and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, and does not constitute a recommendation, investment advice, or solicitation of any action by the Underwriters, (b) in connection with the offering of the Securities and the process leading thereto, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, any of its subsidiaries, or their respective stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Securities or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company or any of its subsidiaries on other matters) and no Underwriter has any obligation to the Company with respect to the offering of the Securities except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of each of the Company, and (e) the Underwriters have not provided any legal, accounting, regulatory, investment or tax advice with respect to the offering of the Securities and the Company has consulted its own respective legal, accounting, financial, regulatory and tax advisors to the extent it deemed appropriate, and (f) none of the activities of the Underwriters in connection with the transactions contemplated herein constitutes a recommendation, investment advice or solicitation of any action by the Underwriters with respect to any entity or natural person.

SECTION 13. Recognition of the U.S. Special Resolution Regimes.

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

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

For purposes of this Section 13, a “BHC Act Affiliate” has the meaning assigned to the term “affiliate” in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). “Covered Entity” means any of the following: (i) a “covered entity” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a “covered bank” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a “covered FSI” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). “Default Right” has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable. “U.S. Special Resolution Regime” means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

SECTION 14. Parties. This Agreement shall inure to the benefit of and be binding upon the Underwriters and the Company and their respective successors. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, firm or corporation, other than the Underwriters, the Company and their respective successors and the controlling persons and officers and directors referred to in Sections 6 and 7 and their heirs and legal representatives, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the Underwriters, the Company and their respective successors, and said controlling persons and officers and directors and their heirs and legal representatives, and for the benefit of no other person, firm or corporation. No purchaser of Securities from any Underwriter shall be deemed to be a successor by reason merely of such purchase.

SECTION 15. Trial by Jury. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates), each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

SECTION 16. GOVERNING LAW. THIS AGREEMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK WITHOUT REGARD TO ITS CHOICE OF LAW PROVISIONS.

SECTION 17. Consent to Jurisdiction; Waiver of Immunity. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby (“Related Proceedings”) shall be instituted in (i) the federal courts of the United States of America located in the City and County of New York, Borough of Manhattan or (ii) the courts of the State of New York located in the City and County of New York, Borough of Manhattan (collectively, the “Specified Courts”), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a “Related Judgment”), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party’s address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

SECTION 18. TIME. TIME SHALL BE OF THE ESSENCE OF THIS AGREEMENT. EXCEPT AS OTHERWISE SET FORTH HEREIN, SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME.

SECTION 19. Counterparts and Electronic Signatures. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement. Electronic signatures complying with the New York Electronic Signatures and Records Act (N.Y. State Tech. §§ 301-309), as amended from time to time, or other applicable law will be deemed original signatures for purposes of this Agreement. Transmission by telecopy, electronic mail or other transmission method of an executed counterpart of this Agreement will constitute due and sufficient delivery of such counterpart.

SECTION 20. Effect of Headings. The Section headings herein are for convenience only and shall not affect the construction hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement among the Underwriters and the Company in accordance with its terms.

Very truly yours,

Protalix BioTherapeutics, Inc.

By /s/ Eyal Rubin

Title: Senior Vice President and Chief Financial Officer

[Signature Page to Underwriting Agreement]

CONFIRMED AND ACCEPTED,
as of the date first above written:

BOFA SECURITIES, INC.

By /s/ Aamir Mecklai
Authorized Signatory

For itself and as Representative of the other Underwriters named in Schedule A hereto.

[Signature Page to Underwriting Agreement]

SCHEDULE A

The public offering price per share for the Securities shall be \$4.60.

The purchase price per share for the Securities to be paid by the several Underwriters shall be \$4.324, being an amount equal to the initial public offering price set forth above less \$0.276 per share, subject to adjustment in accordance with Section 2(b) for dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities.

<u>Name of Underwriter</u>	<u>Number of Initial Securities</u>
BofA Securities, Inc.	6,847,826
Oppenheimer & Co. Inc.	<u>760,869</u>
Total	<u><u>7,608,695</u></u>

SCHEDULE B-1

Pricing Terms

1. The Company is selling 7,608,695 shares of Common Stock.
2. The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional 1,141,304 shares of Common Stock.
3. The public offering price per share for the Securities shall be \$4.60.

SCHEDULE B-2

Free Writing Prospectuses

None.

Sch B- 2

SCHEDULE C

List of Persons and Entities Subject to Lock-up

Amos Bar Shalev
Aharon Schwartz, Ph.D
Dror Bashan
David Granot
Einat Brill Almon ph.D
Eyal Rubin
Gwen A. Melincoff
Pol Boudes
Yael Hayon
Yaron Naos
Zeev Bronfeld

[Form of lock-up from directors, officers or other stockholders pursuant to Section 5(k)]

Exhibit A

February [●], 2021

BofA Securities, Inc,

as Representative of the several
Underwriters to be named in the
within-mentioned Underwriting Agreement

c/o BofA Securities, Inc.
One Bryant Park
New York, New York 10036

Re: Proposed Public Offering by Protalix BioTherapeutics, Inc.

Dear Sirs:

The undersigned, a stockholder, an officer and/or director, as applicable, of Protalix BioTherapeutics, Inc., a Delaware corporation (the "Company"), understands that BofA Securities, Inc. ("BofA") propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Company providing for the public offering of shares of the Company's common stock, par value \$0.001 per share (the "Common Stock"). In recognition of the benefit that such an offering will confer upon the undersigned as a stockholder, an officer and/or director, as applicable, of the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each underwriter to be named in the Underwriting Agreement that, during the period beginning on the date hereof and ending on the date that is 90 days from the date of the Underwriting Agreement (subject to extensions as discussed below), the undersigned will not, without the prior written consent of BofA, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of the Company's Common Stock or any 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 (collectively, the "Lock-Up Securities"), or exercise any right with respect to the registration of any of the Lock-up Securities, or file or cause to be filed any registration statement in connection therewith, under the Securities Act of 1933, as amended, or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Lock-Up Securities, whether any such swap or transaction is to be settled by delivery of Common Stock or other securities, in cash or otherwise or (iii) publicly disclose the intention to do any of the foregoing described in clauses (i) or (ii).

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer the Lock-Up Securities without the prior written consent of BofA, provided that (1) BofA receives a signed lock-up agreement for the balance of the lockup period from each donee, trustee, distributee, or transferee, as the case may be, (2) any such transfer shall not involve a disposition for value, (3) such transfers are not required to be reported with the Securities and Exchange Commission on Form 4 in accordance with Section 16 of the Securities Exchange Act of 1934, as amended, and (4) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers:

- (i) as a *bona fide* gift or gifts; or

- (ii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this lock-up agreement, “immediate family” shall mean any relationship by blood, marriage or adoption, not more remote than first cousin); or
- (iii) as a distribution to limited partners or stockholders of the undersigned; or
- (iv) to the undersigned’s affiliates or to any investment fund or other entity controlled or managed by the undersigned.

Furthermore, the undersigned may sell shares of Common Stock of the Company purchased by the undersigned on the open market following the Public Offering if and only if (i) such sales are not required to be reported in any public report or filing with the Securities and Exchange Commission, or otherwise and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales.

The undersigned acknowledges and agrees that the underwriters have not provided any recommendation or investment advice nor have the underwriters solicited any action from the undersigned with respect to the offering of the securities and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company’s transfer agent and registrar against the transfer of the Lock-Up Securities except in compliance with the foregoing restrictions.

This Lock-Up Agreement and any claim, controversy or dispute arising under or related to this Lock-Up Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof.

The undersigned hereby consents to receipt of this Lock-Up Agreement in electronic form and understands and agrees that this Lock-Up Agreement may be signed electronically. In the event that any signature is delivered by facsimile transmission, electronic mail, or otherwise by electronic transmission evidencing an intent to sign this Lock-Up Agreement, such facsimile transmission, electronic mail or other electronic transmission shall create a valid and binding obligation of the undersigned with the same force and effect as if such signature were an original. Execution and delivery of this Lock-Up Agreement by facsimile transmission, electronic mail or other electronic transmission is legal, valid and binding for all purposes.

[*Signature Page Follows*]

Very truly yours,

[NAME OF STOCKHOLDER/OFFICER/DIRECTOR]

Signature: _____

Print Name: _____

February 16, 2021

Protalix BioTherapeutics, Inc.
2 Snunit St., Science Park
P.O. Box 455
Carmiel, Israel 2161401

Re: Protalix BioTherapeutics, Inc.

Ladies and Gentlemen:

We have acted as counsel to Protalix BioTherapeutics, Inc., a Delaware corporation (the “**Company**”), in connection with the issuance and sale by the Company of up to 8,749,999 shares (the “**Shares**”) of its common stock, par value \$0.001 per share (the “**Common Stock**”), including up to 1,141,304 Shares that may be sold pursuant to the exercise of an option to purchase additional shares, pursuant to a Registration Statement on Form S-3, file number 333-230604 (as the same may be amended and supplemented, the “**Registration Statement**”), filed with the United States Securities and Exchange Commission (the “**Commission**”) under the Securities Act of 1933, as amended (the “**Securities Act**”), base prospectus, dated April 12, 2019 (the “**Base Prospectus**”), and a prospectus supplement, dated February 11, 2021 (together with the Base Prospectus, the “**Prospectus**”). This opinion is being furnished in accordance with the requirements of Item 601(b)(5)(i) of Regulation S-K.

In connection with this opinion, we have examined originals or copies, certified or otherwise identified to our satisfaction, of: (i) the corporate and organizational documents of the Company, including the Certificate of Incorporation, as amended through the date hereof (the “**Articles**”), and the Bylaws of the Company, as amended through the date hereof, (ii) the resolutions (the “**Resolutions**”) of the Board of Directors of the Company and a committee thereof with respect to the issuance and sale of the Shares, (iii) the Registration Statement and exhibits thereto, including the Prospectus comprising a part thereof, and (iv) an executed copy of the Underwriting Agreement, dated as of February 11, 2021, by and between the Company and BofA Securities, Inc. acting as the representative of the several underwriters listed on Schedule A thereto (the “**Underwriting Agreement**”). In addition, we have examined originals or copies, certified or otherwise identified to our satisfaction, of certain other corporate records, documents, instruments and certificates of public officials and of the Company, and we have made such inquiries of officers of the Company and public officials and considered such questions of law as we have deemed necessary for purposes of rendering the opinions set forth herein.

In connection with this opinion, we have assumed the genuineness of all signatures and the authenticity of all items submitted to us as originals and the conformity with originals of all items submitted to us as copies. In making our examination of documents executed by parties other than the Company, we have assumed that each other party has the power and authority to execute and deliver, and to perform and observe the provisions of, such documents and has duly authorized, executed and delivered such documents, and that such documents constitute the legal, valid and binding obligations of each such party. We also have assumed the integrity and completeness of the minute books of the Company presented to us for examination. With respect to certain factual matters, we have relied upon certificates of officers of the Company.

Mayer Brown is a global services provider comprising an association of legal practices that are separate entities including Mayer Brown LLP (Illinois, USA), Mayer Brown International LLP (England), Mayer Brown (a Hong Kong partnership) and Tauli & Chequer Advogados (a Brazilian partnership).

In expressing the opinion set forth below, we have assumed that the Shares will not be issued or transferred in violation of the restrictions on ownership and transfer set forth in the Articles. Further, our opinion is based upon current statutes, rules, regulations, cases and official interpretive opinions, and it covers certain items that are not directly or definitively addressed by such authorities.

Based upon, subject to and limited by the foregoing, we are of the opinion that, as of the date hereof, the Shares have been duly authorized and, when and if issued and delivered against payment therefor in accordance with the Articles, the Registration Statement, the Resolutions and the Underwriting Agreement, the Shares will be validly issued, fully paid and nonassessable.

We express no opinion as to matters governed by laws of any jurisdiction other than the State of Delaware, the State of New York, as appropriate, and the federal laws of the United States, as in effect on the date hereof.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the Company's Current Report on Form 8-K to be filed with the Commission on February 16, 2021, which will be incorporated by reference in the Registration Statement, and to the reference to us under the caption "Legal Matters" in the Prospectus, which is a part of the Registration Statement. In giving such consent, we do not hereby admit that we are acting within the category of persons whose consent is required under Section 7 of the Securities Act or the rules or regulations of the Commission thereunder.

Very truly yours,

/s/ Mayer Brown

Mayer Brown LLP



Protalix BioTherapeutics Announces Proposed Public Offering of Common Stock

CARMIEL, Israel, February 11, 2021 /PR Newswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: PLX, TASE: PLX), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx® plant cell-based protein expression system, today announced that it intends to make a public offer of 6,500,000 shares of its common stock. In connection with the offering, the Company intends to grant the underwriter a 30-day option to purchase up to an additional 975,000 shares of its common stock.

BofA Securities is acting as the book-running manager and Oppenheimer & Co. is acting as the co-manager for the offering. The Company expects to use the net proceeds from the offering to fund clinical trials for its product candidates, to fund its research and development activities and for working capital and general corporate purposes.

The offering is being made pursuant to an effective shelf registration statement. Before you invest, you should read the base prospectus in such shelf registration statement, the preliminary prospectus supplement and other documents the Company has filed with the U.S. Securities and Exchange Commission (the "SEC") for more information about the Company and the offering. The offering may be made only by means of a prospectus supplement and an accompanying prospectus, copies of which may be obtained by visiting EDGAR on the SEC's website at <http://www.sec.gov> or by sending a request to the offices of BofA Securities, NC1-004-03-43, 200 North College Street, 3rd Floor, Charlotte NC 28255-0001, Attention: Prospectus Department, or by email at dg.prospectus_requests@bofa.com.

This press release shall not constitute an offer to sell, or the solicitation of an offer to buy, any of the 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 Protalix BioTherapeutics, Inc.

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®. Protalix was the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the FDA in May 2012 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights.

Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human α -Galactosidase-A protein for the proposed treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa or PRX-110, for the treatment of various human respiratory diseases or conditions; PRX-115, a plant cell-expressed recombinant PEGylated Uricase for the treatment of gout; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa, and with SarcoMed USA, Inc. for the worldwide development and commercialization of PRX-110 for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms "expect," "anticipate," "believe," "estimate," "project," "may," "plan," "will," "would," "should" and "intend," and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. For a discussion of other risks and uncertainties which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other reports filed with the SEC. We caution readers not to place undue reliance upon any forward-looking statements as the statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Investor Contact

Chuck Padala, Managing Director
LifeSci Advisors
+1-646-627-8390
chuck@lifesciadvisors.com



Protalix BioTherapeutics Announces Pricing of its Upsized Public Offering of Common Stock

CARMIEL, Israel, February 11, 2021 /PR Newswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: PLX, TASE: PLX) (the "Company"), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx[®] plant cell-based protein expression system, today announced the pricing of its previously announced underwritten public offering of 7,608,695 shares of its common stock at a public offering price of \$4.60 per share. The Company granted the underwriters in the offering a 30-day option to purchase up to an additional 1,141,304 shares of its common stock. The offering is subject to customary closing conditions and is expected to close on February 17, 2021.

The Company estimates that the net proceeds from the offering, after deducting the underwriting discount but not other estimated offering expenses payable by the Company, will be approximately \$32.9 million.

BofA Securities is acting as the book-running manager and Oppenheimer & Co. is acting as the co-manager for the offering. The Company expects to use the net proceeds from the offering to fund clinical trials for its product candidates, to fund its research and development activities and for working capital and general corporate purposes.

The offering is being made pursuant to an effective shelf registration statement. Before you invest, you should read the base prospectus in such shelf registration statement, the preliminary prospectus supplement and other documents the Company has filed with the U.S. Securities and Exchange Commission (the "SEC") for more information about the Company and the offering. The offering may be made only by means of a prospectus supplement and an accompanying prospectus, copies of which may be obtained by visiting EDGAR on the SEC's website at <http://www.sec.gov> or by sending a request to the offices of BofA Securities, NC1-004-03-43, 200 North College Street, 3rd Floor, Charlotte NC 28255-0001, Attention: Prospectus Department, or by email at dg.prospectus_requests@bofa.com.

This press release shall not constitute an offer to sell, or the solicitation of an offer to buy, any of the 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 Protalix BioTherapeutics, Inc.

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx[®]. Protalix was the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the FDA in May 2012 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights.

Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human α -Galactosidase-A protein for the proposed treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa or PRX-110, for the treatment of various human respiratory diseases or conditions; PRX-115, a plant cell-expressed recombinant PEGylated Uricase for the treatment of gout; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa, and with SarcoMed USA, Inc. for the worldwide development and commercialization of PRX-110 for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery.

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To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms "expect," "anticipate," "believe," "estimate," "project," "may," "plan," "will," "would," "should" and "intend," and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. For a discussion of other risks and uncertainties which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other reports filed with the SEC. We caution readers not to place undue reliance upon any forward-looking statements as the statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Investor Contact

Chuck Padala, Managing Director
LifeSci Advisors
+1-646-627-8390
chuck@lifesciadvisors.com
