

**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): December 1, 2021

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts
(State or other jurisdiction of
incorporation)

0-17999
(Commission File Number)

04-2726691
(IRS Employer
Identification No.)

830 Winter Street, Waltham, MA 02451
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 895-0600

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

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

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, \$.01 par value	IMGN	Nasdaq Global Select Market

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

Emerging growth company

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

ITEM 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On December 1, 2021, ImmunoGen, Inc. (the “Company”) entered into an underwriting agreement (the “Underwriting Agreement”) with Jefferies LLC and Cowen and Company, LLC, as representatives of the several underwriters (the “Underwriters”) named in Schedule 1 of the Underwriting Agreement, related to a public offering of 11,636,364 shares of the Company’s common stock, par value \$0.01 per share (the “Common Stock”), at a price of \$6.60 per share, less the underwriting discounts and commissions, and, to certain investors in lieu of common stock, pre-funded warrants to purchase an aggregate of 27,363,636 shares of the Company’s common stock at a price of \$6.59 (the “Pre-Funded Warrants”), which represents the per share public offering price for the common stock less the \$0.01 per share exercise price for each Pre-Funded Warrant (the “Offering”). Pursuant to the terms of the Underwriting Agreement, the Company granted the Underwriters an option, exercisable for 30 days following the date of the Underwriting Agreement, to purchase up to an additional 5,850,000 shares of Common Stock at the same price, which the Underwriters exercised on December 2, 2021. The Offering is expected to close on December 6, 2021, subject to the satisfaction of customary closing conditions.

The Pre-Funded Warrants will be exercisable at any time after the date of issuance. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage to a percentage not in excess of 19.99% by providing at least 61 days’ prior notice to the Company.

The Offering was made pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-251502), which was filed with the Securities and Exchange Commission (the “SEC”) on December 18, 2020 and became effective upon filing.

The Underwriting Agreement contains customary representations, warranties, and agreements by the Company and customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended, and termination provisions.

A copy of the Underwriting Agreement and the form of Pre-Funded Warrant are filed as Exhibits 1.1 and 4.1, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

ITEM 8.01 OTHER EVENTS

An opinion dated December 1, 2021, regarding the legality of the issuance and sale of the shares of the Common Stock and the Pre-Funded Warrants in the Offering is filed as Exhibit 5.1 to this Current Report on Form 8-K. Certain information relating to Part II, Item 14 “Other Expenses of Issuance and Distribution” of the Registration Statement is also filed as Exhibit 99.1 to this Current Report on Form 8-K.

The Company filed a preliminary prospectus supplement dated November 30, 2021 in relation to the Offering, which contained an updated summary description of the Company's business in the section entitled "Company Overview," which is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference, and additional risk factor disclosure in the section entitled "Risk Factors," which is filed as Exhibit 99.3 to this Current Report on Form 8-K and incorporated herein by reference. The information contained in Exhibits 99.2 and 99.3 supplements the information provided in the Company's previous periodic filings with the SEC in order to reflect recent business developments.

This Current Report on Form 8-K, including the exhibits hereto, shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act of 1933, nor shall there be any sale of the Company's securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Exhibit No.	Exhibit
1.1	Underwriting Agreement dated December 1, 2021 by and among ImmunoGen, Inc. and Jefferies LLC and Cowen and Company, LLC, as representatives of the several underwriters named in Schedule 1 thereto
4.1	Form of Pre-Funded Warrant
5.1	Opinion of Ropes & Gray LLP
23.1	Consent of Ropes & Gray LLP (included in the opinion filed as Exhibit 5.1)
99.1	Information relating to Item 14 of the Registration Statement on Form S-3 (File No. 333-251502)
99.2	Supplemental Description of Business
99.3	Supplemental Risk Factors
104	Cover Page Interactive Data File (embedded within the Inline XBRL (eXtensible Business Reporting Language) 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.

ImmunoGen, Inc.
(Registrant)

Date: December 3, 2021

/s/ Renee Lentini

Renee Lentini
Vice President and Chief Accounting Officer

ImmunoGen, Inc.

11,636,364 Shares of Common Stock, par value \$0.01 per share
Pre-Funded Warrants to Purchase 27,363,636 Shares of Common Stock

Underwriting Agreement

December 1, 2021

JEFFERIES LLC
COWEN AND COMPANY, LLC
As Representatives of
the several Underwriters listed in
Schedule 1 hereto

c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

c/o Cowen and Company, LLC
599 Lexington Avenue
New York, New York 10022

Ladies and Gentlemen:

ImmunoGen, Inc., a Massachusetts corporation (the "Company"), proposes to issue and sell to the several Underwriters listed in Schedule 1 hereto (the "Underwriters"), for whom you are acting as representatives (the "Representatives"), an aggregate of 11,636,364 shares (the "Underwritten Shares") of common stock, par value \$0.01 per share, of the Company (the "Common Stock"), pre-funded warrants to purchase an aggregate of 27,363,636 shares of Common Stock in the form attached as Exhibit A (the "Warrants") and, at the option of the Underwriters, up to an additional 5,850,000 shares of Common Stock (the "Option Shares"). The Underwritten Shares and the Warrants are herein referred to as the "Underwritten Securities." The Underwritten Shares and the Option Shares are herein referred to as the "Shares". The shares of Common Stock issuable upon exercise of the Warrants are herein referred to as the "Warrant Shares." The Shares and Warrants are herein referred to as the "Securities." The shares of Common Stock to be outstanding after giving effect to the sale of the Shares and the exercise of the Warrants are referred to herein as the "Stock".

The Company hereby confirms its agreement with the several Underwriters concerning the purchase and sale of the Securities, as follows:

1. Registration Statement. The Company has prepared and filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder (collectively, the "Securities Act"), a registration statement on Form S-3 (File No. 333-251502) including a prospectus, relating to the Shares, the Warrants and the Warrant Shares. Such registration statement, including the information, if any, deemed pursuant to Rule 430A, 430B or 430C under the Securities Act to be part of the registration statement at the time of its effectiveness ("Rule 430 Information"), is referred to herein as the "Registration Statement"; and as used herein, the term "Preliminary Prospectus" means each prospectus included in such registration statement (and any amendments thereto) relating to the Securities, any prospectus filed with the Commission pursuant to Rule 424(a) under the Securities Act relating to the Securities, any prospectus filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to the Securities and the prospectus included in the Registration Statement at the time of its effectiveness that omits Rule 430 Information, and the term "Prospectus" means the prospectus in the form first used (or made available upon request of purchasers pursuant to Rule 173 under the Securities Act) in connection with confirmation of sales of the Securities. If the Company has filed an abbreviated registration statement pursuant to Rule 462(b) under the Securities Act (the "Rule 462 Registration Statement"), then any reference herein to the term "Registration Statement" shall be deemed to include such Rule 462 Registration Statement. Any reference in this Agreement to the Registration Statement, the Pricing Disclosure Package, any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include the documents incorporated by reference therein pursuant to Item 12 of Form S-3 under the Securities Act, as of the effective date of the Registration Statement or the date of such Preliminary Prospectus or the Prospectus, as the case may be, and any reference to "amend", "amendment" or "supplement" with respect to the Registration Statement, any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include any documents filed after such date under the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder (collectively, the "Exchange Act") that are deemed to be incorporated by reference therein. Capitalized terms used but not defined herein shall have the meanings given to such terms in the Registration Statement and the Prospectus.

At or prior to the Applicable Time (as defined below), the Company had prepared the following information (collectively with the pricing information set forth on Annex B-1, the "Pricing Disclosure Package"): a Preliminary Prospectus dated November 30, 2021, and each "free-writing prospectus" (as defined pursuant to Rule 405 under the Securities Act) listed on Annex B-1 hereto.

"Applicable Time" means 5:20 p.m., New York City time, on December 1, 2021.

2. Purchase of the Securities.

(a) The Company agrees to issue and sell the Underwritten Securities to the several Underwriters as provided in this Agreement, and each Underwriter, on the basis of the representations, warranties and agreements set forth herein and subject to the conditions set forth herein, agrees, severally and not jointly, to purchase at a price of \$6.204 per share of Common Stock (the "Share Purchase Price") from the Company the respective number of Underwritten Shares set forth opposite such Underwriter's name in Schedule 1 hereto, and to purchase from the Company the respective number of Warrants set forth opposite such Underwriter's name in Schedule 1 hereto at a price of \$6.194 per Warrant (the "Warrant Purchase Price").

In addition, the Company agrees to issue and sell the Option Shares to the several Underwriters as provided in this Agreement, and the Underwriters, on the basis of the representations, warranties and agreements set forth herein and subject to the conditions set forth herein, shall have the option to purchase, severally and not jointly, from the Company the Option Shares at the Share Purchase Price less an amount per share equal to any dividends or distributions declared by the Company and payable on the Underwritten Shares but not payable on the Option Shares.

If any Option Shares are to be purchased, the number of Option Shares to be purchased by each Underwriter shall be the number of Option Shares which bears the same ratio to the aggregate number of Option Shares being purchased as the number of Underwritten Shares set forth opposite the name of such Underwriter in Schedule 1 hereto (or such number increased as set forth in Section 10 hereof) bears to the aggregate number of Underwritten Shares being purchased from the Company by the several Underwriters, subject, however, to such adjustments to eliminate any fractional Shares as the Representatives in their sole discretion shall make.

The Underwriters may exercise the option to purchase the Option Shares at any time in whole, or from time to time in part, on or before the thirtieth day following the date of the Prospectus, by written notice from the Representatives to the Company. Such notice shall set forth the aggregate number of Option Shares as to which the option is being exercised and the date and time when the Option Shares are to be delivered and paid for which may be the same date and time as the Closing Date (as hereinafter defined) but shall not be earlier than the Closing Date nor later than the tenth full business day (as hereinafter defined) after the date of such notice (unless such time and date are postponed in accordance with the provisions of Section 10 hereof). Any such notice shall be given at least two business days prior to the date and time of delivery specified therein.

(b) The Company understands that the Underwriters intend to make a public offering of the Securities as soon after the effectiveness of this Agreement as in the judgment of the Representatives is advisable, and initially to offer the Securities on the terms set forth in the Pricing Disclosure Package. The Company acknowledges and agrees that the Underwriters may offer and sell Securities to or through any affiliate of an Underwriter.

(c) Payment for the Securities shall be made by wire transfer in immediately available funds to the account specified by the Company to the Representatives in the case of the Underwritten Securities, at the offices of Latham & Watkins LLP, 12670 High Bluff Drive, San Diego, California 92130 at 10:00 a.m. New York City time on December 6, 2021, or at such other time or place on the same or such other date, not later than the fifth business day thereafter, as the Representatives and the Company may agree upon in writing or, in the case of the Option Shares, on the date and at the time and place specified by the Representatives in the written notice of the Underwriters' election to purchase such Option Shares. The time and date of such payment for the Underwritten Securities is referred to herein as the "Closing Date" and the time and date for any such payment for the Option Shares, if other than the Closing Date, is herein referred to as an "Additional Closing Date".

Payment for the Securities to be purchased on the Closing Date or the Additional Closing Date, as the case may be, shall be made against delivery to the Representatives for the respective accounts of the several Underwriters of the Securities to be purchased on such date, with any transfer taxes payable in connection with the sale of the Securities duly paid by the Company. Delivery of the Shares shall be made through the facilities of The Depository Trust Company ("DTC") unless the Representatives shall otherwise instruct. The Warrants shall be delivered to the Representatives in definitive form, registered in such names and in such denominations as the Representatives shall request in writing not later than the Closing Date. The Warrants and, if the Shares are certificated, the certificates for the Shares, will be made available for inspection and packaging by the Representatives at the office of DTC or its designated custodian not later than 1:00 P.M., New York City time, on the business day prior to the Closing Date or the Additional Closing Date, as the case may be.

Notwithstanding the foregoing, the Company and the Representatives shall instruct purchasers of the Warrants in the public offering to make payment for the Warrants on the Closing Date to the Company by wire transfer in immediately available funds to the account specified by the Company at a purchase price of \$6.59 per Warrant, in lieu of payment by the Underwriters for such Warrants, and the Company shall deliver such Warrants to such purchasers on the Closing Date in definitive form against such payment, in lieu of the Company's obligation to deliver such Warrants to the Underwriters; provided that, upon receipt by the Company of payment for the Warrants, the Company shall promptly (but in no event later than the Closing Date) pay \$0.396 per Warrant to the Underwriters by wire transfer in immediately available funds to the account specified by the Representatives.

In the event that the purchasers of the Warrants in the public offering fail to make payment to the Company for all or part of the Warrants on the Closing Date, the Representatives may elect, by written notice to the Company, to receive shares of Common Stock in lieu of all or a portion of such Warrants to be delivered to the Underwriters under this Agreement.

(d) The Company acknowledges and agrees that the Underwriters are acting solely in the capacity of an arm's length contractual counterparty to the Company with respect to the offering of Securities contemplated hereby (including in connection with determining the terms of the offering) and not as a financial advisor or a fiduciary to, or an agent of, the Company or any other person. The Company also acknowledges and agrees that the Underwriters may be engaged in a broad range of transactions that involve interests that differ from those of the Company. Additionally, neither the Representatives nor any other Underwriter is advising the Company or any other person as to any legal, tax, investment, accounting or regulatory matters in any jurisdiction. The Company shall consult with its own advisors concerning such matters and shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby, and the Underwriters shall have no responsibility or liability to the Company with respect thereto. No Underwriter has any obligation to the Company with respect to the offering of Securities except the obligations expressly set forth in this Agreement. Any review by the Underwriters of the Company, the transactions contemplated hereby or other matters relating to such transactions will be performed solely for the benefit of the Underwriters and shall not be on behalf of the Company.

3. Representations and Warranties of the Company. The Company represents and warrants to each Underwriter that:

(a) *Preliminary Prospectus.* No order preventing or suspending the use of any Preliminary Prospectus has been issued by the Commission, and each Preliminary Prospectus included in the Pricing Disclosure Package, at the time of filing thereof, complied in all material respects with the Securities Act, and no Preliminary Prospectus, at the time of filing thereof, contained any untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation and warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in any Preliminary Prospectus, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 7(b) hereof.

(b) *Pricing Disclosure Package.* The Pricing Disclosure Package as of the Applicable Time did not, and as of the Closing Date and as of the applicable Additional Closing Date, as the case may be, will not, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation and warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in such Pricing Disclosure Package, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 7(b) hereof. No statement of material fact included in the Prospectus has been omitted from the Pricing Disclosure Package and no statement of material fact included in the Pricing Disclosure Package that is required to be included in the Prospectus has been omitted therefrom.

(c) *Issuer Free Writing Prospectus.* Other than the Registration Statement, the Preliminary Prospectus and the Prospectus, the Company (including its agents and representatives, other than the Underwriters in their capacity as such) has not prepared, used, authorized, approved or referred to and will not prepare, use, authorize, approve or refer to any “written communication” (as defined in Rule 405 under the Securities Act) that constitutes an offer to sell or solicitation of an offer to buy the Securities (each such communication by the Company or its agents and representatives (other than a communication referred to in clause (i) below) an “Issuer Free Writing Prospectus”) other than (i) any document not constituting a prospectus pursuant to Section 2(a)(10)(a) of the Securities Act or Rule 134 under the Securities Act or (ii) the documents listed on Annex B-1 hereto, including the free writing prospectus substantially in the form of Annex B-2 hereto (the “Warrant FWP”), each electronic road show and any other written communications approved in writing in advance by the Representatives. Each such Issuer Free Writing Prospectus complied in all material respects with the Securities Act, has been or will be (within the time period specified in Rule 433) filed in accordance with the Securities Act (to the extent required thereby) and, when taken together with the Preliminary Prospectus accompanying, or delivered prior to delivery of, such Issuer Free Writing Prospectus, did not, and as of the Closing Date and as of the applicable Additional Closing Date, as the case may be, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation and warranty with respect to any statements or omissions made in each such Issuer Free Writing Prospectus or Preliminary Prospectus in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in such Issuer Free Writing Prospectus or Preliminary Prospectus, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 7(b) hereof. Each such Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Securities or until any earlier date that the Company notified or notifies the Representatives as described in Section 4(e), did not, does not and will not include any information that conflicted, 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 Prospectus deemed to be a part thereof that has not been superseded or modified.

(d) *Registration Statement and Prospectus.* At the time the Company, or any person acting on their behalf (within the meaning, for this clause only, of Rule 163(c) under the Securities Act) made any offer relating to the Underwritten Securities in reliance on the exemption of Rule 163 under the Securities Act (“Rule 163”) the Company (x) was a “well-known seasoned issuer” as defined in Rule 405 under the Securities Act (“Rule 405”) and (y) was not an “ineligible issuer,” as defined in Rule 405. The Registration Statement has become effective under the Securities Act. At the time the Registration Statement was originally filed with the Commission, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. No order suspending the effectiveness of the Registration Statement has been issued by the Commission and no proceeding for that purpose or pursuant to Section 8A of the Securities Act against the Company or related to the offering of the Securities has been initiated or, to the Company’s knowledge, threatened by the Commission; as of the applicable effective date of the Registration Statement and any post-effective amendment thereto, the Registration Statement and any such post-effective amendment complied and will comply in all material respects with the Securities Act, and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading; and as of the date of the Prospectus and any amendment or supplement thereto and as of the Closing Date and as of the applicable Additional Closing Date, as the case may be, the Prospectus will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation and warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in the Registration Statement and the Prospectus and any amendment or supplement thereto, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 7(b) hereof.

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

(f) *Financial Statements.* The financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus comply in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as applicable, and present fairly the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified, it being understood that unaudited interim financial statements are subject to normal year-end adjustments; such financial statements have been prepared in conformity with generally accepted accounting principles in the United States applied on a consistent basis throughout the periods covered thereby, except as may be otherwise specified therein or to the extent unaudited interim financial statements exclude footnotes or may be condensed or summary statements, and any supporting schedules included or incorporated by reference in the Registration Statement present fairly the information required to be stated therein; and the other financial information included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries and presents fairly the information shown thereby.

(g) *No Material Adverse Change.* Since the date of the most recent financial statements of the Company included or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (i) there has not been any change in the capital stock (other than the issuance of Stock issued pursuant to the exercise of stock options or vesting of deferred Stock units or restricted Stock units under the Company Stock Plans (as defined below), the issuance of restricted Stock under the Company Stock Plans, or the issuance of Stock under the Company's existing employee stock purchase plan), long-term debt, notes payable or current portion of long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development involving a prospective material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations or business prospects of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as otherwise disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(h) *Organization and Good Standing.* The Company and each of its subsidiaries have been duly organized and are validly existing and in good standing under the laws of their respective jurisdictions of organization, are duly qualified to do business and are in good standing in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification, and have the corporate and authority necessary to own or hold their respective properties and to conduct the businesses in which they are engaged, except where the failure to be so qualified, in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect on the business, properties, management, financial position, stockholders' equity, results of operations or business prospects of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under this Agreement (a "Material Adverse Effect"). The Company has no subsidiaries other than those listed in Exhibit 21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020, and the Company does not control, directly or indirectly, any other corporation, partnership, joint venture, association or other business organization.

(i) *Capitalization.* The Company has an authorized capitalization as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; all the outstanding shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and are not subject to any pre-emptive or similar rights; except as described in or expressly contemplated by the Pricing Disclosure Package and the Prospectus, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company or any of its subsidiaries, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any capital stock of the Company or any such subsidiary, any such convertible or exchangeable securities or any such rights, warrants or options; the capital stock of the Company conforms in all material respects to the description thereof contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus; and all the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly and validly authorized and issued, are fully paid and non-assessable and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party. None of the outstanding capital stock or equity interest in any subsidiary was issued in violation of preemptive or similar rights of any security holder of such subsidiary.

(j) *Stock Options.* With respect to the stock options (the "Stock Options") granted pursuant to the stock-based compensation plans of the Company and its subsidiaries (the "Company Stock Plans"), (i) each grant of a Stock Option was duly authorized no later than the date on which the grant of such Stock Option was by its terms to be effective (the "Grant Date") by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto, (ii) each such grant was, in all material respects, made in accordance with the terms of the Company Stock Plans, the Exchange Act and all other applicable laws and regulatory rules or requirements, including the Code, the rules of the Nasdaq Global Select Market ("Nasdaq") and any other exchange on which Company securities are traded, and (iii) each such grant was, in all material respects, properly accounted for in accordance with GAAP in the financial statements (including the related notes) of the Company and disclosed in the Company's filings with the Commission in accordance with the Exchange Act and all other applicable laws. The Company has not knowingly granted, and there is no and has been no policy or practice of the Company of granting, Stock Options prior to, or otherwise coordinating the grant of Stock Options with, the release or other public announcement of material information regarding the Company or its subsidiaries or their results of operations or prospects.

(k) *Due Authorization.* The Company has full right, power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of this Agreement and the consummation of the transactions contemplated hereby has been duly and validly taken.

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

(m) *The Securities.* (i) The Shares to be issued and sold by the Company hereunder have been duly authorized by the Company and, when issued and delivered and paid for as provided herein, will be duly and validly issued and will be fully paid and nonassessable and will conform to the descriptions thereof in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (ii) the Warrants have been duly authorized by the Company and, when executed and delivered by the Company in accordance with this Agreement, will constitute valid and legally binding agreements of the Company enforceable against the Company in accordance with their terms, except as enforceability may be limited by applicable bankruptcy, insolvency or similar laws affecting creditors' rights generally or by equitable principles relating to enforceability, and will conform to the descriptions thereof in the Pricing Disclosure Package; (iii) the Warrant Shares to be issued by the Company upon exercise of the Warrants, as provided therein, have been duly authorized and, when issued and delivered upon exercise as provided under the Warrant, will be duly and validly issued, fully paid and non-assessable and will conform in all material respects to the descriptions thereof in the Registration Statement, the Pricing Disclosure Package and the Prospectus; and (iv) the issuance of the Securities and the Warrant Shares is not subject to any preemptive or similar rights, other than those which were complied with by the Company.

(n) *Description of this Agreement.* This Agreement conforms in all material respects to the description thereof contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(o) *No Violation or Default.* Neither the Company nor any of its subsidiaries is (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.

(p) *No Conflicts.* The execution, delivery and performance by the Company of this Agreement and the Warrants, the issuance and sale of the Securities and the Warrant Shares and the consummation of the transactions contemplated by this Agreement and in the Warrants or the Pricing Disclosure Package and the Prospectus will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or any of its subsidiaries or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority except, in the case of clauses (i) and (iii) above, for any such conflict or violation that would not, individually or in the aggregate, have a Material Adverse Effect.

(q) *No Consents Required.* No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Securities and the consummation of the transactions contemplated by this Agreement, except for the registration of the Securities under the Securities Act, as may be required by the Financial Industry Regulatory Authority, Inc. (“FINRA”) and under applicable state or foreign securities laws in connection with the purchase and distribution of the Securities by the Underwriters.

(r) *Legal Proceedings.* Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company or any of its subsidiaries is or may be a party or to which any property of the Company or any of its subsidiaries is or may be the subject that, individually or in the aggregate, if determined adversely to the Company or any of its subsidiaries, would reasonably be expected to have a Material Adverse Effect; to the knowledge of the Company, no such investigations, actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others; and (i) there are no current or pending legal, governmental or regulatory actions, suits or proceedings that are required under the Securities Act to be described in the Registration Statement, the Pricing Disclosure Package or the Prospectus that are not so described in the Registration Statement, the Pricing Disclosure Package and the Prospectus and (ii) there are no statutes, regulations or contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement or described in the Registration Statement, the Pricing Disclosure Package or the Prospectus that are not so filed as exhibits to the Registration Statement or described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(s) *Independent Accountants.* Ernst & Young LLP, who have certified certain financial statements of the Company and its subsidiaries, is an independent registered public accounting firm with respect to the Company and its subsidiaries within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act.

(t) *Title to Real and Personal Property.* Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and its subsidiaries have good and marketable title in fee simple (in the case of real property) to, or have valid rights to lease or otherwise use, all items of real and personal property that are material to the respective businesses of the Company and its subsidiaries, in each case free and clear of all liens, encumbrances, claims and defects and imperfections of title except those that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(u) *Title to Intellectual Property.* Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and its subsidiaries own, or have obtained valid and enforceable licenses for, or other rights to use, the inventions, patent applications, patents, trademarks (both registered and unregistered), trade names, copyrights, trade secrets and other proprietary information (collectively, the “Intellectual Property”) described in the Registration Statement, the Pricing Disclosure Package and the Prospectus as being owned or licensed by them; to the Company’s knowledge and except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and its subsidiaries own, or have obtained valid and enforceable licenses for, or other rights to use, all Intellectual Property used in, or necessary for the conduct of, their respective businesses as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except as would not reasonably be expected to have a Material Adverse Effect; to the Company’s knowledge, there is no pending or threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any Intellectual Property rights of others, except as would not reasonably be expected to have a Material Adverse Effect, and the Company is unaware of any facts which could form a reasonable basis for any such claim; and none of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or, to the Company’s knowledge, upon any of its officers, directors or employees. To the Company’s knowledge, there are no third parties who have or will be able to establish rights to any Intellectual Property described in the Registration Statement, the Pricing Disclosure Package and the Prospectus as exclusively owned or exclusively licensed by the Company, except as would not reasonably be expected to have a Material Adverse Effect or except for licenses granted in writing by the Company or its subsidiaries to any third-parties (“Exclusive Intellectual Property”); there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the Company’s ownership or rights in or to any Exclusive Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim except as could not reasonably be expected to have a Material Adverse Effect; there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any Exclusive Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim except as could not reasonably be expected to have a Material Adverse Effect; to the Company’s knowledge, there is no patent or patent application that contains claims that interfere with the issued or pending claims of any of the Intellectual Property except as would not reasonably be expected to have a Material Adverse Effect; and to the Company’s knowledge, there is no prior art material to any patent or patent application of the Exclusive Intellectual Property that has not been disclosed to the U.S. Patent and Trademark Office, except as would not reasonably be expected to have a Material Adverse Effect.

(v) *No Undisclosed Relationships.* No relationship, direct or indirect, exists between or among the Company or any of its subsidiaries, on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company or any of its subsidiaries, on the other, that is required by the Securities Act to be described in the Registration Statement and the Prospectus and that is not so described in such documents and in the Pricing Disclosure Package.

(w) *Investment Company Act.* The Company is not and, after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, will not be required to register as an “investment company” or an entity “controlled” by an “investment company” within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder (collectively, the “Investment Company Act”).

(x) *Taxes.* The Company and its subsidiaries have paid all federal, state, local and foreign taxes and filed all tax returns required to be paid or filed through the date hereof; and except as otherwise disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there is no tax deficiency that has been, or could reasonably be expected to be, asserted against the Company or any of its subsidiaries or any of their respective properties or assets; except in each case where such failure to file or such tax deficiency would not have a Material Adverse Effect.

(y) *Licenses and Permits.* The Company and its subsidiaries possess all licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Effect; and except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, neither the Company nor any of its subsidiaries has received notice of any revocation or modification of any such license, certificate, permit or authorization or has any reason to believe that any such license, certificate, permit or authorization will not be renewed in the ordinary course.

(z) *No Labor Disputes.* No labor disturbance by or dispute with employees of the Company or any of its subsidiaries exists or, to the best knowledge of the Company, is contemplated or threatened and the Company is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, except in each case as would not have a Material Adverse Effect.

(aa) *Compliance with and Liability under Environmental Laws; Hazardous Materials.* Except, in each case set forth in this section (aa), as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, or as would not, individually or in the aggregate, have a Material Adverse Effect, (i) the Company and each of its subsidiaries and their respective properties, assets and operations are in compliance with Environmental Laws (as defined below), (ii) there are no past or present events, conditions, circumstances, activities, practices, actions, omissions or plans that could reasonably be expected to give rise to any costs or liabilities to the Company or any of its subsidiaries under, or to interfere with or prevent compliance by the Company or any of its subsidiaries with, Environmental Laws, (iii) none of the Company or any of its subsidiaries (A) to the knowledge of the Company, is the subject of any investigation, (B) has received any notice or claim, (C) is a party to any pending or, to the Company's knowledge, threatened action, suit or proceeding, (D) is bound by any judgment, decree or order or (E) has entered into any agreement, in each case relating to any alleged violation of any Environmental Law or any actual or alleged release or threatened release or cleanup at any location of any Hazardous Materials (as defined below) (as used herein, "Environmental Law" means any federal, state, local or foreign law, statute, ordinance, rule, regulation, order, decree, judgment, injunction, permit, license, authorization or other binding requirement, or common law, relating to human health or safety or the protection, cleanup or restoration of the environment or natural resources, including those relating to the distribution, processing, generation, treatment, storage, disposal, transportation, other handling or release or threatened release of Hazardous Materials, and "Hazardous Materials" means any material (including, without limitation, pollutants, contaminants, hazardous or toxic substances or wastes) that is regulated by or may give rise to liability under any Environmental Law).

(bb) *Compliance With ERISA.* (i) Each employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), for which the Company or any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Internal Revenue Code of 1986, as amended (the "Code")) would have any liability (each, a "Plan") has been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption; (iii) for each Plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no "accumulated funding deficiency" as defined in Section 412 of the Code, whether or not waived, has occurred or is reasonably expected to occur; (iv) either the fair market value of the assets of each Plan, which is required to be funded under the Code or ERISA, exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan) or each such Plan is funded in accordance with ERISA or the Code; (v) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur; (vi) neither the Company nor any member of the Controlled Group has incurred, nor reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the PBGC, in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(a)(3) of ERISA); and (vii) there is no pending audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other governmental agency or any foreign regulatory agency with respect to any Plan that could reasonably be expected to result in material liability to the Company or its subsidiaries.

(cc) *Disclosure Controls.* The Company and its subsidiaries maintain an effective system of “disclosure controls and procedures” (as defined in Rule 13a-15(e) of the Exchange Act) that complies with the requirements of the Exchange Act and that has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company’s management as appropriate to allow timely decisions regarding required disclosure. The Company and its subsidiaries have carried out evaluations of the effectiveness of their disclosure controls and procedures as required by Rule 13a-15 of the Exchange Act.

(dd) *Accounting Controls.* The Company and its subsidiaries maintain systems of “internal control over financial reporting” (as defined in Rule 13a-15(f) of the Exchange Act) that comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, the Company’s principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, including, but not limited to internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management’s general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. There are no material weaknesses in the Company’s internal controls. The Company’s auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal controls over financial reporting.

(ee) *Insurance.* The Company and its subsidiaries have insurance covering their respective properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks as the Company considers to be in accordance with customary industry practice for companies of comparable size, market capitalization and stage of business and clinical development to protect the Company and its subsidiaries and their respective businesses; and neither the Company nor any of its subsidiaries has (i) received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance or (ii) any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business.

(ff) *No Unlawful Payments.* Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, employee, agent or other person associated with or acting on behalf of the Company or any of its subsidiaries has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom, or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and its subsidiaries have instituted, maintain and enforce, and will continue to maintain and enforce, policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(gg) [Reserved]

(hh) *Compliance with 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, including those 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 agency (collectively, the “Anti-Money Laundering Laws”), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(ii) *Compliance with Sanctions Laws.* Neither the Company nor any of its subsidiaries, nor, to the knowledge of the Company, any director, officer, employee, agent, affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries is currently the subject or the target of any sanctions administered or enforced by the U.S. government, (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury (“OFAC”) or the U.S. Department of State and including, without limitation, the designation as a “specially designated national” or “blocked person”), the United Nations Security Council (“UNSC”), the European Union, Her Majesty’s Treasury (“HMT”), or other relevant sanctions authority (collectively, “Sanctions”), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or target of Sanctions, including, without limitation, Cuba, Iran, North Korea, Syria and Crimea (each, a “Sanctioned Country”); and the Company will not directly or indirectly use the proceeds of the offering of the Securities hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, initial purchaser, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(jj) *Affiliations.* To the Company's knowledge, there are no affiliations or associations between (i) the Underwriters and (ii) the Company or any of the Company's officers, directors or 5% or greater security holders or any beneficial owner of the Company's unregistered equity securities that were acquired at any time on or after the 180th day immediately preceding the date the Registration Statement was initially filed with the Commission, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(kk) *No Restrictions on Subsidiaries.* No subsidiary of the Company is currently prohibited, directly or indirectly, under any agreement or other instrument to which it is a party or is subject, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's properties or assets to the Company or any other subsidiary of the Company.

(ll) *No Broker's Fees.* Neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries or any Underwriter for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Securities.

(mm) *No Registration Rights.* No person has the right to require the Company or any of its subsidiaries to register any securities for sale under the Securities Act by reason of the filing of the Registration Statement with the Commission or the issuance and sale of the Securities.

(nn) *No Stabilization.* The Company has not taken, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Securities.

(oo) *Business With Cuba.* The Company has complied with all provisions of Section 517.075, Florida Statutes (Chapter 92-198, Laws of Florida, as amended) relating to doing business with the Government of Cuba or with any person or affiliate located in Cuba.

(pp) *Margin Rules.* The application of the proceeds received by the Company from the issuance, sale and delivery of the Securities as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus will not violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(qq) *Forward-Looking Statements.* No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(rr) *Statistical and Market 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 Pricing Disclosure Package and the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects.

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

(tt) *FDA Compliance.* Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company: (A) is and at all times has been in material compliance with all statutes, rules or regulations of the U.S. Food and Drug Administration (“FDA”) and other comparable federal, state, local or foreign governmental or regulatory authority (“Governmental Authority”) applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company (“Applicable Laws”); (B) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from the FDA or any Governmental Authority alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws (“Authorizations”), which would, individually or in the aggregate, result in a Material Adverse Effect; (C) possesses all material Authorizations and such Authorizations are valid and in full force and effect and the Company is not in material violation of any term of any such Authorizations; (D) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any Governmental Authority or third party alleging that any product operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA or any Governmental Authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) has not received written notice that the FDA or any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA or any Governmental Authority is considering such action; and (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission).

(uu) *Clinical Studies.* The nonclinical studies and clinical trials conducted by or, to the Company’s knowledge, on behalf of the Company were and, if still ongoing, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all Applicable Laws and Authorizations, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder (collectively, “FFDCA”); the descriptions of the results of such nonclinical studies and clinical trials contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus are, to the Company’s knowledge, accurate and complete in all material respects and fairly present the data derived from such nonclinical studies and clinical trials; except to the extent disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company is not aware of any nonclinical studies or clinical trials, the results of which the Company believes reasonably call into question the study or trial results described or referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus when viewed in the context in which such results are described and the clinical stage of development; and, except to the extent disclosed in the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company has not received any written notices or other correspondence from the FDA or any Governmental Authority requiring the termination, suspension or material modification of any nonclinical studies, clinical trials conducted by or on behalf of the Company.

(vv) *Compliance with Health Care Laws.* The Company is not a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any Governmental Authority. Additionally, neither the Company nor any of its employees, officers or directors has been excluded, suspended or debarred from participation in any government health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

(ww) *eXtensible Business Reporting Language.* The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Pricing Disclosure Package and the Prospectus fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(xx) *Cybersecurity.* The Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "IT Systems") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted, and to the Company's knowledge, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its subsidiaries have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR; (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA"); and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. There have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and its subsidiaries are presently in material compliance 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 IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.

(yy) *Compliance with Data Privacy Laws.* The Company and its subsidiaries are, and at all prior times within the last five years were, in material compliance with all applicable state and federal data privacy and security laws and regulations, including without limitation HIPAA, and the Company and its subsidiaries have taken commercially reasonable actions to prepare to comply with, and since May 25, 2018, have been and currently are in material compliance with, the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (collectively, the "Privacy Laws"). To ensure compliance with the Privacy Laws, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "Policies"). The Company and its subsidiaries have at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

4. Further Agreements of the Company. The Company covenants and agrees with each Underwriter that:

(a) *Required Filings.* The Company will file the final Prospectus with the Commission within the time periods specified by Rule 424(b) and Rule 430A, 430B or 430C under the Securities Act; will file any Issuer Free Writing Prospectus to the extent required by Rule 433 under the Securities Act (including the Warrant FWP); will file promptly all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of the Prospectus and for so long as the delivery of a prospectus is required in connection with the offering or sale of the Securities; and will furnish copies of the Prospectus and each Issuer Free Writing Prospectus (to the extent not previously delivered) to the Underwriters as soon as practicable after the execution of this Agreement in such quantities as the Representatives may reasonably request.

(b) *Delivery of Copies.* The Company will deliver, without charge, (i) to the Representatives, upon request, a conformed copy of the Registration Statement as originally filed and each amendment thereto, in each case including all exhibits and consents filed therewith and documents incorporated by reference therein; and (ii) to each Underwriter (A) upon request, a conformed copy of the Registration Statement as originally filed and each amendment thereto, in each case including all exhibits and consents filed therewith and (B) during the Prospectus Delivery Period (as defined below), as many copies of the Prospectus (including all amendments and supplements thereto and documents incorporated by reference therein) and each Issuer Free Writing Prospectus as the Representatives may reasonably request. As used herein, the term "Prospectus Delivery Period" means such period of time after the first date of the public offering of the Securities as in the opinion of counsel for the Underwriters a prospectus relating to the Securities is required by law to be delivered (or required to be delivered but for Rule 172 under the Securities Act) in connection with sales of the Securities by any Underwriter or dealer.

(c) *Amendments or Supplements, Issuer Free Writing Prospectuses.* Before making, preparing, using, authorizing, approving, referring to or filing any Issuer Free Writing Prospectus, and before filing any amendment or supplement to the Registration Statement (other than the filing of an Annual Report on Form 10-K that occurs after the Prospectus Delivery Period) or the Prospectus, whether before or after the time that the Registration Statement becomes effective, the Company will furnish to the Representatives and counsel for the Underwriters a copy of the proposed Issuer Free Writing Prospectus, amendment or supplement for review and will not make, prepare, use, authorize, approve, refer to or file any such Issuer Free Writing Prospectus or file any such proposed amendment or supplement to which the Representatives reasonably objects.

(d) *Notice to the Representatives.* The Company will advise the Representatives promptly, and confirm such advice in writing, (i) when any amendment to the Registration Statement has been filed and becomes effective; (ii) when any supplement to the Prospectus or any Issuer Free Writing Prospectus or any amendment to the Prospectus has been filed; (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or the receipt of any comments from the Commission relating to the Registration Statement or any other request by the Commission for any additional information; (iv) of the issuance by the Commission of any order suspending the effectiveness of the Registration Statement or preventing or suspending the use of any Preliminary Prospectus, any of the Pricing Disclosure Package or the Prospectus or the initiation or threatening of any proceeding for that purpose or pursuant to Section 8A of the Securities Act; (v) of the occurrence of any event within the Prospectus Delivery Period as a result of which the Prospectus, the Pricing Disclosure Package or any Issuer Free Writing Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Prospectus, the Pricing Disclosure Package or any such Issuer Free Writing Prospectus is delivered to a purchaser, not misleading; and (vi) of the receipt by the Company of any notice with respect to any suspension of the qualification of the Securities for offer and sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; and the Company will use its reasonable best efforts to prevent the issuance of any such order suspending the effectiveness of the Registration Statement, preventing or suspending the use of any Preliminary Prospectus, any of the Pricing Disclosure Package or the Prospectus or suspending any such qualification of the Securities and, if any such order is issued, will obtain as soon as possible the withdrawal thereof.

(e) *Ongoing Compliance.* If during the Prospectus Delivery Period (i) any event shall occur or condition shall exist as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Prospectus is delivered to a purchaser, not misleading or (ii) it is necessary to amend or supplement the Prospectus to comply with law, the Company will immediately notify the Underwriters thereof and forthwith prepare and, subject to paragraph (c) above, file with the Commission and furnish to the Underwriters and to such dealers as the Representatives may designate, such amendments or supplements to the Prospectus as may be necessary so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances existing when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus will comply with law.

(f) *Pricing Disclosure Package.* If at any time prior to the Closing Date (i) any event shall occur or condition shall exist as a result of which the Pricing Disclosure Package as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Pricing Disclosure Package is delivered to a purchaser, not misleading or (ii) it is necessary to amend or supplement the Pricing Disclosure Package to comply with law, the Company will immediately notify the Underwriters thereof and forthwith prepare and, subject to paragraph (c) above, file with the Commission (to the extent required) and furnish to the Underwriters and to such dealers as the Representatives may designate, such amendments or supplements to the Pricing Disclosure Package as may be necessary so that the statements in the Pricing Disclosure Package as so amended or supplemented will not, in the light of the circumstances existing when the Pricing Disclosure Package is delivered or purchased, be misleading or so that the Pricing Disclosure Package will comply with law.

(g) *Blue Sky Compliance.* The Company will qualify the Securities for offer and sale under the securities or Blue Sky laws of such jurisdictions as the Representatives shall reasonably request and will continue such qualifications in effect so long as required for distribution of the Securities; provided that the Company shall not be required to (i) qualify as a foreign corporation or other entity or as a dealer in securities in any such jurisdiction where it would not otherwise be required to so qualify, (ii) file any general consent to service of process in any such jurisdiction or (iii) subject itself to taxation in any such jurisdiction if it is not otherwise so subject.

(h) *Earning Statement.* The Company will make generally available to its security holders and the Representatives as soon as practicable an earning statement that satisfies the provisions of Section 11(a) of the Securities Act and Rule 158 of the Commission promulgated thereunder covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the “effective date” (as defined in Rule 158) of the Registration Statement; provided that the Company will be deemed to have satisfied such requirement to the extent such information is filed on the Commission’s Electronic Data Gathering, Analysis, and Retrieval system or any successor system (“EDGAR”).

(i) *Clear Market.* For a period of 90 days after the date of the Prospectus, the Company will not (i) offer, pledge, announce the intention to sell, 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, directly or indirectly, or file with the Commission a registration statement under the Securities Act relating to, any shares of Stock or any securities convertible into or exercisable or exchangeable for Stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Stock or any such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Stock or such other securities, in cash or otherwise, without the prior written consent of the Representatives (provided however, that with respect to offers and sales under the Company’s Open Market Sale Agreement with Jefferies LLC only the prior written consent of Jefferies LLC shall be required), or (iii) announce the offering of any shares of Stock or any securities convertible into or exercisable or exchangeable for Stock, (iv) submit or file any registration statement under the Securities Act in respect of shares of Stock or any securities convertible into or exercisable or exchangeable for Stock (other than as contemplated by this Agreement with respect to the Securities), (v) effect a reverse stock split, recapitalization, share consolidation, reclassification or similar transaction affecting the outstanding shares of Stock; or (vi) publicly announce the intention to do any of the foregoing, other than (w) the Securities to be sold hereunder and the delivery of the Warrant Shares upon exercise of the Warrants, (x) the issuance of Stock and Stock-based awards, including restricted Stock, deferred Stock units, restricted Stock units or options to acquire shares of Stock of the Company, granted under existing equity incentive plans or any shares of Stock of the Company issued upon the exercise of options, deferred Stock units or restricted Stock units granted under existing equity incentive plans or shares of Stock of the Company issued under the Company’s existing employee stock purchase plan disclosed in the Registration Statement, and the filing of one or more registration statements on Form S-8 with the Commission for the registration of such shares of Stock under the Securities Act, (y) the issuance of shares of Stock or securities convertible into or exercisable for shares of Stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options, in each case outstanding as of the date of this Agreement and described in the Prospectus, and (z) shares of Stock or securities convertible into or exercisable or exchangeable for shares of Stock representing in the aggregate no more than 5% of the Company’s issued and outstanding shares of Stock as of the date of this Agreement, which may be sold only to collaborators, vendors, manufacturers, distributors, customers or other similar parties pursuant to a collaboration, licensing agreement, strategic alliance, manufacturing or distribution arrangement or similar transaction, so long as recipients of such securities agree to be bound by a lock-up agreement in substantially the form attached as Exhibit B hereto.

(j) *Use of Proceeds.* The Company will apply the net proceeds from the sale of the Securities as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus under the heading “Use of Proceeds”.

(k) *No Stabilization.* The Company will not take, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Stock.

(l) *Exchange Listing.* The Company will use its best efforts to list the Shares and the Warrant Shares on Nasdaq.

(m) *Reports.* So long as any of the Securities or the Warrant Shares are outstanding, the Company will furnish to the Representatives, as soon as they are available, copies of all reports or other communications (financial or other) furnished to holders of the Securities or the Warrant Shares, and copies of any reports and financial statements furnished to or filed with the Commission or any national securities exchange or automatic quotation system; provided the Company will be deemed to have furnished such reports and financial statements to the Representatives to the extent they are filed on EDGAR. The Company's obligations under this paragraph (m) shall expire at the end of the Prospectus Delivery Period.

(n) *Record Retention.* The Company will, pursuant to reasonable procedures developed in good faith, retain copies of each Issuer Free Writing Prospectus that is not filed with the Commission in accordance with Rule 433 under the Securities Act.

(o) *Reserve for Warrant Shares.* The Company shall, at all times while any Warrants are outstanding, reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of such Warrants, the number of Warrant Shares that are initially issuable and deliverable upon the then-outstanding Warrants.

5. Certain Agreements of the Underwriters. Each Underwriter hereby represents and agrees that:

(a) It has not used, authorized use of, referred to or participated in the planning for use of and will not use, authorize use of, refer to, or participate in the planning for use of, any "free writing prospectus", as defined in Rule 405 under the Securities Act (which term includes use of any written information furnished to the Commission by the Company and not incorporated by reference into the Registration Statement and any press release issued by the Company) other than (i) a free writing prospectus that contains no "issuer information" (as defined in Rule 433(h)(2) under the Securities Act) that was not included (including through incorporation by reference) in the Preliminary Prospectus or a previously filed Issuer Free Writing Prospectus, (ii) any Issuer Free Writing Prospectus listed on Annex B-1 or prepared pursuant to Section 3(c) or Section 4(c) above (including any electronic road show), or (iii) any free writing prospectus prepared by such underwriter and approved by the Company in advance in writing (each such free writing prospectus referred to in clauses (i) or (iii), an "Underwriter Free Writing Prospectus").

(b) It has not and will not, without the prior written consent of the Company, use any free writing prospectus that contains the final terms of the Securities unless such terms have previously been included in a free writing prospectus filed with the Commission; provided that Underwriters may use a term sheet substantially in the form of Annex C hereto without the consent of the Company; provided further that any Underwriter using such term sheet shall notify the Company, and provide a copy of such term sheet to the Company, prior to, or substantially concurrently with, the first use of such term sheet.

(c) It is not subject to any pending proceeding under Section 8A of the Securities Act with respect to the offering (and will promptly notify the Company if any such proceeding against it is initiated during the Prospectus Delivery Period).

6. Conditions of Underwriters' Obligations. The obligation of each Underwriter to purchase the Underwritten Securities on the Closing Date or the Option Shares on an Additional Closing Date, as the case may be, as provided herein is subject to the performance by the Company of its covenants and other obligations hereunder and to the following additional conditions:

(a) *Registration Compliance; No Stop Order.* No order suspending the effectiveness of the Registration Statement shall be in effect, and no proceeding for such purpose or pursuant to Section 8A under the Securities Act shall be pending before or threatened by the Commission; the Prospectus and each Issuer Free Writing Prospectus shall have been timely filed with the Commission under the Securities Act (in the case of an Issuer Free Writing Prospectus (including the Warrant FWP), to the extent required by Rule 433 under the Securities Act) and in accordance with Section 4(a) hereof; and all requests by the Commission for additional information shall have been complied with to the reasonable satisfaction of the Representatives.

(b) *Representations and Warranties.* The representations and warranties of the Company contained herein shall be true and correct on the date hereof and on and as of the Closing Date or the applicable Additional Closing Date, as the case may be; and the statements of the Company and its officers made in any certificates delivered pursuant to this Agreement shall be true and correct on and as of the Closing Date or the applicable Additional Closing Date, as the case may be.

(c) *No Downgrade.* Subsequent to the earlier of (A) the Applicable Time and (B) the execution and delivery of this Agreement, if there are any debt securities or preferred stock of, or guaranteed by, the Company or any of its subsidiaries that are rated by a "national recognized statistical rating organization," (i) no downgrading shall have occurred in the rating accorded any securities or preferred stock of or guaranteed by the Company or any of its subsidiaries by any "nationally recognized statistical rating organization", as such term is defined by the Commission for purposes of Rule 436(g)(2) under the Securities Act and (ii) no such organization shall have publicly announced that it has under surveillance or review, or has changed its outlook with respect to, its rating of any securities or preferred stock of or guaranteed by the Company or any of its subsidiaries (other than an announcement with positive implications of a possible upgrading).

(d) *No Material Adverse Change.* No event or condition of a type described in Section 3(g) hereof shall have occurred or shall exist, which event or condition is not described in the Pricing Disclosure Package (excluding any amendment or supplement thereto) and the Prospectus (excluding any amendment or supplement thereto) and the effect of which in the judgment of the Representatives makes it impracticable or inadvisable to proceed with the offering, sale or delivery of the Securities on the Closing Date or the applicable Additional Closing Date, as the case may be, on the terms and in the manner contemplated by this Agreement, the Pricing Disclosure Package and the Prospectus.

(e) *Officer's Certificate.* The Representatives shall have received on and as of the Closing Date or the applicable Additional Closing Date, as the case may be, a certificate of the principal financial officer or principal accounting officer of the Company and one additional executive officer of the Company satisfactory to the Representatives (i) confirming that such officers have carefully reviewed the Registration Statement, the Pricing Disclosure Package and the Prospectus and, to the best knowledge of such officer, the representations set forth in Sections 3(b) and 3(d) hereof are true and correct, (ii) confirming that the other representations and warranties of the Company in this Agreement are true and correct and that the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date or the applicable Additional Closing Date, as the case may be, and (iii) to the effect set forth in paragraphs (a), (c) and (d) above.

(f) *Comfort Letters.* On the date of this Agreement and on the Closing Date or the applicable Additional Closing Date, as the case may be, Ernst & Young LLP shall have furnished to the Representatives, at the request of the Company, letters, dated the respective dates of delivery thereof and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, containing statements and information of the type customarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus; provided, that the letter delivered on the Closing Date or the applicable Additional Closing Date, as the case may be, shall use a "cut-off" date no more than three business days prior to such Closing Date or such Additional Closing Date, as the case may be.

(g) *Opinion and 10b-5 Statement of Counsel for the Company.* Ropes & Gray LLP, counsel for the Company, shall have furnished to the Representatives, at the request of the Company, their written opinion and 10b-5 Statement, dated the Closing Date or the applicable Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, to the effect set forth in Annex A-1 hereto.

(h) *Opinions of Special Intellectual Property Counsels for the Company.* Each of (i) Sterne, Kessler, Goldstein & Fox P.L.L.C., special intellectual property counsel for the Company and (ii) McCarter & English, LLP, special intellectual property counsel for the Company, shall have furnished to the Representatives, at the request of the Company, its written opinion, dated the Closing Date or the applicable Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, to the effect set forth in Annexes A-2 and A-3 hereto, respectively.

(i) *Opinion and 10b-5 Statement of Counsel for the Underwriters.* The Representatives shall have received on and as of the Closing Date or the applicable Additional Closing Date, as the case may be, an opinion and 10b-5 Statement of Latham & Watkins LLP, counsel for the Underwriters, with respect to such matters as the Representatives may reasonably request, and such counsel shall have received such documents and information as they may reasonably request to enable them to pass upon such matters.

(j) *No Legal Impediment to Issuance.* No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any federal, state or foreign governmental or regulatory authority that would, as of the Closing Date or the applicable Additional Closing Date, as the case may be, prevent the issuance or sale of the Securities; and no injunction or order of any federal, state or foreign court shall have been issued that would, as of the Closing Date or the applicable Additional Closing Date, as the case may be, prevent the issuance or sale of the Securities.

(k) *Good Standing.* The Representatives shall have received on and as of the Closing Date or the applicable Additional Closing Date, as the case may be, satisfactory evidence of the good standing of the Company and its subsidiaries in their respective jurisdictions of organization and their good standing as foreign entities in such other jurisdictions as the Representatives may reasonably request, in each case in writing or any standard form of telecommunication from the appropriate governmental authorities of such jurisdictions.

(l) *Exchange Listing.* The Shares to be delivered on the Closing Date or applicable Additional Closing Date, as the case may be, and any Warrant Shares to be delivered upon exercise of the Warrants, shall have been approved for listing on Nasdaq, subject to official notice of issuance.

(m) *Lock-up Agreements.* The “lock-up” agreements, each substantially in the form of Exhibit B hereto, between you and certain officers and directors of the Company relating to sales and certain other dispositions of shares of Stock or certain other securities, delivered to you on or before the date hereof, shall be full force and effect on the Closing Date or applicable Additional Closing Date, as the case may be.

(n) *Additional Documents.* On or prior to the Closing Date or the applicable Additional Closing Date, as the case may be, the Company shall have furnished to the Representatives such further certificates and documents as the Representatives may reasonably request.

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

7. Indemnification and Contribution.

(a) *Indemnification of the Underwriters.* The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors and officers and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any and all losses, claims, damages and liabilities (including, without limitation, reasonable legal fees and other expenses incurred in connection with any suit, action or proceeding or any claim asserted, as such fees and expenses are incurred), joint or several, that arise out of, or are based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary in order to make the statements therein, not misleading or (ii) any untrue statement or alleged untrue statement of a material fact contained in the Prospectus (or any amendment or supplement thereto), any Issuer Free Writing Prospectus, any “issuer information” filed or required to be filed pursuant to Rule 433(d) under the Securities Act or any Pricing Disclosure Package, or caused by any omission or alleged omission to state therein a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading, in each case except insofar as such losses, claims, damages or liabilities arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use therein, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in subsection (b) below.

(b) *Indemnification of the Company.* Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, its directors, its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the indemnity set forth in paragraph (a) above, but only with respect to any losses, claims, damages or liabilities that arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to such Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in the Registration Statement, the Prospectus (or any amendment or supplement thereto), any Issuer Free Writing Prospectus or any Pricing Disclosure Package, it being understood and agreed upon that the only such information furnished by any Underwriter consists of the following information in the Prospectus furnished on behalf of each Underwriter: The names and corresponding amounts of Securities set forth in the table of Underwriters, the statements in the third paragraph concerning the terms of offering by the Underwriters, the concession amount identified in the fifth paragraph, and the statements in the first sentence of the twelfth paragraph and the statements in the sixteenth paragraph concerning stabilization transactions, in each case under the caption “Underwriting” in the Prospectus.

(c) *Notice and Procedures.* If any suit, action, proceeding (including any governmental or regulatory investigation), claim or demand shall be brought or asserted against any person in respect of which indemnification may be sought pursuant to either paragraph (a) or (b) above, such person (the “Indemnified Person”) shall promptly notify the person against whom such indemnification may be sought (the “Indemnifying Person”) in writing; provided that the failure to notify the Indemnifying Person shall not relieve it from any liability that it may have under paragraph (a) or (b) above except to the extent that it has been materially prejudiced (through the forfeiture of substantive rights or defenses) by such failure; and provided, further, that the failure to notify the Indemnifying Person shall not relieve it from any liability that it may have to an Indemnified Person otherwise than under paragraph (a) or (b) above. If any such proceeding shall be brought or asserted against an Indemnified Person and it shall have notified the Indemnifying Person thereof, the Indemnifying Person shall retain counsel reasonably satisfactory to the Indemnified Person (who shall not, without the consent of the Indemnified Person, be counsel to the Indemnifying Person) to represent the Indemnified Person in such proceeding and shall pay the fees and expenses of such counsel related to such proceeding, as incurred. In any such proceeding, any Indemnified Person shall have the right to retain its own counsel, but the reasonable fees and expenses of such counsel shall be at the expense of such Indemnified Person unless (i) the Indemnifying Person and the Indemnified Person shall have mutually agreed to the contrary; (ii) the Indemnifying Person has failed within a reasonable time to retain counsel reasonably satisfactory to the Indemnified Person; (iii) the Indemnified Person shall have reasonably concluded that there may be legal defenses available to it that are different from or in addition to those available to the Indemnifying Person; or (iv) the named parties in any such proceeding (including any impleaded parties) include both the Indemnifying Person and the Indemnified Person and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interest between them. It is understood and agreed that the Indemnifying Person shall not, in connection with any proceeding or related proceeding in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all Indemnified Persons, and that all such fees and expenses shall be reimbursed as they are incurred. Any such separate firm for any Underwriter, its affiliates, directors and officers and any control persons of such Underwriter shall be designated in writing by the Representatives and any such separate firm for the Company, its directors, its officers who signed the Registration Statement and any control persons of the Company shall be designated in writing by the Company. The Indemnifying Person shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the Indemnifying Person agrees to indemnify each Indemnified Person from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an Indemnified Person shall have requested that an Indemnifying Person reimburse the Indemnified Person for fees and expenses of counsel as contemplated by this paragraph, the Indemnifying Person shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by the Indemnifying Person of such request and (ii) the Indemnifying Person shall not have reimbursed the Indemnified Person in accordance with such request prior to the date of such settlement. No Indemnifying Person shall, without the written consent of the Indemnified Person, effect any settlement of any pending or threatened proceeding in respect of which any Indemnified Person is or could have been a party and indemnification could have been sought hereunder by such Indemnified Person, unless such settlement (x) includes an unconditional release of such Indemnified Person, in form and substance reasonably satisfactory to such Indemnified Person, from all liability on claims that are the subject matter of such proceeding and (y) does not include any statement as to or any admission of fault, culpability or a failure to act by or on behalf of any Indemnified Person.

(d) *Contribution.* If the indemnification provided for in paragraphs (a) and (b) above is unavailable to an Indemnified Person or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then each Indemnifying Person under such paragraph, in lieu of indemnifying such Indemnified Person thereunder, shall contribute to the amount paid or payable by such Indemnified Person as a result of such losses, claims, damages or liabilities (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 from the offering of the Securities 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) but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, 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 shall be deemed to be in the same respective proportions as the net proceeds (before deducting expenses) received by the Company from the sale of the Securities and the total underwriting discounts and commissions received by the Underwriters in connection therewith, in each case as set forth in the table on the cover of the Prospectus, bear to the aggregate offering price of the Securities. The relative fault of the Company on the one hand and the Underwriters on the other shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

(e) *Limitation on Liability.* 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 that does not take account of the equitable considerations referred to in paragraph (d) above. The amount paid or payable by an Indemnified Person as a result of the losses, claims, damages and liabilities referred to in paragraph (d) above shall be deemed to include, subject to the limitations set forth above, any legal or other expenses incurred by such Indemnified Person in connection with any such action or claim. Notwithstanding the provisions of this Section 7, in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute pursuant to this Section 7 are several in proportion to their respective purchase obligations hereunder and not joint.

(f) *Non-Exclusive Remedies.* The remedies provided for in this Section 7 are not exclusive and shall not limit any rights or remedies which may otherwise be available to any Indemnified Person at law or in equity.

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

9. Termination. This Agreement may be terminated in the absolute discretion of the Representatives, by notice to the Company, if after the execution and delivery of this Agreement and prior to the Closing Date or, in the case of the Option Shares, prior to the applicable Additional Closing Date (i) trading generally shall have been suspended or materially limited on or by any of the New York Stock Exchange, the American Stock Exchange, Nasdaq, the Chicago Board Options Exchange, the Chicago Mercantile Exchange or the Chicago Board of Trade; (ii) trading of any securities issued or guaranteed by the Company shall have been suspended on any exchange or in any over-the-counter market; (iii) a general moratorium on commercial banking activities shall have been declared by federal or New York State authorities; or (iv) there shall have occurred any outbreak or escalation of hostilities or any change in financial markets or any calamity or crisis, either within or outside the United States, that, in the judgment of the Representatives, is material and adverse and makes it impracticable or inadvisable to proceed with the offering, sale or delivery of the Securities on the Closing Date or the applicable Additional Closing Date, as the case may be, on the terms and in the manner contemplated by this Agreement, the Pricing Disclosure Package and the Prospectus.

10. Defaulting Underwriter.

(a) If, on the Closing Date or the applicable Additional Closing Date, as the case may be, any Underwriter defaults on its obligation to purchase the Securities that it has agreed to purchase hereunder on such date, the non-defaulting Underwriters may in their discretion arrange for the purchase of such Securities by other persons satisfactory to the Company on the terms contained in this Agreement. If, within 36 hours after any such default by any Underwriter, the non-defaulting Underwriters do not arrange for the purchase of such Securities, then the Company shall be entitled to a further period of 36 hours within which to procure other persons satisfactory to the non-defaulting Underwriters to purchase such Securities on such terms. If other persons become obligated or agree to purchase the Securities of a defaulting Underwriter, either the non-defaulting Underwriters or the Company may postpone the Closing Date or the applicable Additional Closing Date, as the case may be, for up to five full business days in order to effect any changes that in the opinion of counsel for the Company or counsel for the Underwriters may be necessary in the Registration Statement and the Prospectus or in any other document or arrangement, and the Company agrees to promptly prepare any amendment or supplement to the Registration Statement and the Prospectus that effects any such changes. As used in this Agreement, the term "Underwriter" includes, for all purposes of this Agreement unless the context otherwise requires, any person not listed in Schedule 1 hereto that, pursuant to this Section 10, purchases Securities that a defaulting Underwriter agreed but failed to purchase.

(b) If, after giving effect to any arrangements for the purchase of the Securities of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company as provided in paragraph (a) above, the aggregate number of Securities that remain unpurchased on the Closing Date or the applicable Additional Closing Date, as the case may be, does not exceed one-eleventh of the aggregate number of Securities to be purchased on such date, then the Company shall have the right to require each non-defaulting Underwriter to purchase the number of Securities that such Underwriter agreed to purchase hereunder on such date plus such Underwriter's pro rata share (based on the number of Securities that such Underwriter agreed to purchase on such date) of the Securities of such defaulting Underwriter or Underwriters for which such arrangements have not been made.

(c) If, after giving effect to any arrangements for the purchase of the Securities of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company as provided in paragraph (a) above, the aggregate number of Securities that remain unpurchased on the Closing Date or the applicable Additional Closing Date, as the case may be, exceeds one-eleventh of the aggregate amount of Securities to be purchased on such date, or if the Company shall not exercise the right described in paragraph (b) above, then this Agreement or, with respect to any Additional Closing Date, the obligation of the Underwriters to purchase Securities on the Additional Closing Date, as the case may be, shall terminate without liability on the part of the non-defaulting Underwriters. Any termination of this Agreement pursuant to this Section 10 shall be without liability on the part of the Company, except that the Company will continue to be liable for the payment of expenses as set forth in Section 11 hereof and except that the provisions of Section 7 hereof shall not terminate and shall remain in effect.

(d) Nothing contained herein shall relieve a defaulting Underwriter of any liability it may have to the Company or any non-defaulting Underwriter for damages caused by its default.

11. Payment of Expenses.

(a) Whether or not the transactions contemplated by this Agreement are consummated or this Agreement is terminated, the Company will pay or cause to be paid all costs and expenses incident to the performance of its obligations hereunder, including without limitation, (i) the costs incident to the authorization, issuance, sale, preparation and delivery of the Securities and any taxes payable in that connection; (ii) the costs incident to the preparation, printing and filing under the Securities Act of the Registration Statement, the Preliminary Prospectus, any Issuer Free Writing Prospectus, any Pricing Disclosure Package and the Prospectus (including all exhibits, amendments and supplements thereto) and the distribution thereof; (iii) the costs of reproducing and distributing this Agreement; (iv) the fees and expenses of the Company's counsel and independent accountants; (v) the reasonable fees and expenses incurred in connection with the registration or qualification and determination of eligibility for investment of the Securities under the laws of such jurisdictions as the Representatives may designate and the preparation, printing and distribution of a Blue Sky Memorandum (including the related fees and expenses of counsel for the Underwriters, which fees and expenses shall not exceed \$10,000 in the aggregate); (vi) the cost of preparing stock certificates; (vii) the costs and charges of any transfer agent and any registrar; (viii) all reasonable expenses and application fees incurred in connection with any filing with, and clearance of the offering by, FINRA; (ix) all expenses incurred by the Company in connection with any "road show" presentation to potential investors; and (x) all expenses and application fees related to the listing of the Shares and the Warrant Shares on Nasdaq. It is understood that, subject to this Section 11(a) and Section 11(b) below, the Underwriters will pay all of their costs and expenses, including fees and expenses of their counsel.

(b) If (i) this Agreement is terminated pursuant to Section 9, (ii) the Company for any reason fails to tender the Securities for delivery to the Underwriters, or (iii) this Agreement is terminated as a result of the failure by the Company to satisfy the conditions in Section 6, the Company agrees to reimburse the Underwriters for all accountable out-of-pocket costs and expenses (including the reasonable fees and expenses of their counsel) reasonably incurred by the Underwriters in connection with this Agreement and the offering contemplated hereby.

12. Persons Entitled to Benefit of Agreement. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers and directors and any controlling persons referred to herein, and the affiliates of each Underwriter referred to in Section 7 hereof. Nothing in this Agreement is intended or shall be construed to give any other person any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision contained herein. No purchaser of Securities from any Underwriter shall be deemed to be a successor merely by reason of such purchase.

13. Survival. The respective indemnities, rights of contribution, representations, warranties and agreements of the Company and the Underwriters contained in this Agreement or made by or on behalf of the Company or the Underwriters pursuant to this Agreement or any certificate delivered pursuant hereto shall survive the delivery of and payment for the Securities and shall remain in full force and effect, regardless of any termination of this Agreement or any investigation made by or on behalf of the Company or the Underwriters.

14. Certain Defined Terms. For purposes of this Agreement, (a) except where otherwise expressly provided, the term “affiliate” has the meaning set forth in Rule 405 under the Securities Act; (b) the term “business day” means any day other than a day on which banks are permitted or required to be closed in New York City; and (c) the term “subsidiary” has the meaning set forth in Rule 405 under the Securities Act.

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

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

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

For purposes of this Agreement, (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); (B) “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); (C) “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; and (D) “U.S. Special Resolution Regime” means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

16. Miscellaneous.

(a) *Authority of the Representatives.* Any action by the Underwriters hereunder may be taken by the Representatives on behalf of the Underwriters, and any such action taken by the Representatives shall be binding upon the Underwriters.

(b) *Notices.* All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted and confirmed by any standard form of telecommunication. Notices to the Underwriters shall be given to the Representatives c/o Jefferies LLC, 520 Madison Avenue, New York, New York 10022, Attention: General Counsel, Facsimile: (646) 619-4437; c/o Cowen and Company, LLC, 599 Lexington Avenue, New York, New York 10022, Attention: Head of Equity Capital Markets, Facsimile: (646) 562-1249; and with a copy to Latham & Watkins LLP, 12670 High Bluff Drive, San Diego, California 92130, Facsimile: (858) 523-5450, Attention: Michael E. Sullivan, Esq. Notices to the Company shall be given to it at ImmunoGen, Inc., 830 Winter Street, Waltham, Massachusetts 02451, Facsimile: (781) 207-0265, Attention: Joseph J. Kenny.

(c) *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 applicable to agreements made and to be performed in such state.

(d) *Submission to Jurisdiction.* The Company hereby submits to the exclusive jurisdiction of the U.S. federal and New York state courts in the Borough of Manhattan in The City of New York in any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. The Company waives any objection which it may now or hereafter have to the laying of venue of any such suit or proceeding in such courts. The Company agrees that final judgment in any such suit, action or proceeding brought in such court shall be, subject to the Company's rights to appeal such judgments, binding upon the Company and may be enforced in any court to the jurisdiction of which Company is subject by a suit upon such judgment.

(e) *Counterparts.* This Agreement may be signed in counterparts (which may include counterparts delivered by any standard form of telecommunication), each of which shall be an original and all of which together shall constitute one and the same instrument. The words "execution," "signed," "signature," and words of like import in this Agreement or in any instruments, agreements, certificates, officers' certificates, Company orders, legal opinions, negative assurance letters or other documents entered into or delivered pursuant to or in connection with this Agreement or the issuance or sale of the Securities shall include images of manually executed signatures transmitted by facsimile or other electronic format (including, without limitation, "pdf", "tif" or "jpg") and electronic signatures (including, without limitation, DocuSign and AdobeSign), and this Agreement and any instruments, agreements, certificates, officers' certificates, Company orders, legal opinions, negative assurance letters or other documents entered into or delivered pursuant to or in connection with this Agreement may be executed, attested and transmitted by any of the foregoing electronic means and formats. The use of electronic signatures and electronic records (including, without limitation, any contract or other record created, generated, sent, communicated, received, or stored by electronic means) shall be of the same legal effect, validity and enforceability as a manually executed signature or use of a paper-based record-keeping system to the fullest extent permitted by applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act and any other applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act or the Uniform Commercial Code.

(f) *Amendments or Waivers.* No amendment or waiver of any provision of this Agreement, nor any consent or approval to any departure therefrom, shall in any event be effective unless the same shall be in writing and signed by the parties hereto.

(g) *Headings.* The headings herein are included for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms.

Very truly yours,

IMMUNOGEN, INC.

By: /s/ Susan Altschuller, Ph.D.

Name: Susan Altschuller, Ph.D.

Title: Senior Vice President and Chief Financial Officer

The foregoing Underwriting Agreement is hereby confirmed and accepted by the Representatives in New York, New York as of the date first above written.

JEFFERIES LLC
COWEN AND COMPANY, LLC

Acting as Representatives of the
several Underwriters named in
the attached Schedule 1

By: Jefferies LLC

By: /s/ Dustin Tyner
Name: Dustin Tyner
Title: Managing Director

By: Cowen and Company, LLC

By: /s/ Mariel A. Healy
Name: Mariel A. Healy
Title: Managing Director

Name	Number of Underwritten Shares	Number of Warrants
Jefferies LLC	4,538,182	10,671,819
Cowen and Company, LLC	3,665,455	8,619,545
Guggenheim Securities, LLC	2,385,455	5,609,545
Canaccord Genuity, LLC	1,047,272	2,462,727
Total	11,636,364	27,363,636

Form of Opinion of Counsel for the Company

Form Negative Assurance of Company Counsel

Form of Opinion of Special Intellectual Property Counsel for the Company

Form of Opinion of Special Intellectual Property Counsel for the Company

a. Issuer Free Writing Prospectus

The free writing prospectus dated as of December 1, 2021, substantially in the form set forth in Annex B-2.

b. Pricing Information Provided Orally by Underwriters

Public offering price per Share: \$6.60
Number of Shares: 11,636,364
Public offering price per Warrant: \$6.59
Warrants being offered: 27,363,636
Option to purchase additional shares: 5,850,000
Net proceeds before expenses: \$241,682,363.64

Form of Warrant FWP

Issuer Free Writing Prospectus
Filed Pursuant to Rule 433
Dated December 1, 2021
Relating to Preliminary Prospectus Supplement Dated November 30, 2021
Registration Statement No. 333-251502

\$175,000,000



ImmunoGen, Inc.

Common stock**Pre-funded warrants to purchase common stock**

This free writing prospectus relates only to the offering described below and should be read together with the preliminary prospectus supplement dated November 30, 2021 (the "Preliminary Prospectus Supplement"), including the documents incorporated by reference therein, and the accompanying base prospectus. This free writing prospectus supplements the Preliminary Prospectus Supplement primarily to reflect the addition of certain pre-funded warrants, and the shares of common stock issuable upon the exercise of such pre-funded warrants, to the securities being offered by ImmunoGen, Inc. Except as otherwise indicated, all information in this free writing prospectus and the Preliminary Prospectus Supplement assumes no exercise of outstanding options or warrants (including the pre-funded warrant in respect of 5,434,782 shares of our common stock we issued in August 2021 (the "existing pre-funded warrant")), no exercise of the underwriters' option to purchase additional shares of our common stock and no exercise of the pre-funded warrants included in this offering.

This free writing prospectus is qualified in its entirety by reference to the Preliminary Prospectus Supplement, including the documents incorporated by reference therein, and the accompanying base prospectus. Financial information and other information presented in the Preliminary Prospectus Supplement or incorporated by reference therein is deemed to have changed to the extent affected by the changes described herein. This free writing prospectus should be read together with the Preliminary Prospectus Supplement, including the documents incorporated by reference therein, and the accompanying base prospectus, before making a decision in connection with an investment in the securities. Capitalized terms used in this free writing prospectus but not defined have the meanings given to them in the Preliminary Prospectus Supplement.

Certain of our existing shareholders (or their affiliates) have indicated an interest in purchasing a portion of the securities in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer, or no securities to any of these shareholders and any of these shareholders could determine to purchase more, fewer, or no securities in this offering. The underwriters will receive the same underwriting discount on any securities purchased by these shareholders as they will on any other securities sold to the public in this offering.

Issuer: ImmunoGen, Inc.
Common stock offered by us: \$175,000,000 of shares.

Pre-funded warrants offered by us: We are also offering, in lieu of common stock to certain investors, pre-funded warrants to purchase shares of our common stock. The purchase price of each pre-funded warrant equals the price per share at which the shares of our common stock are being sold to the public in this offering, minus \$0.01, which is the exercise price of each pre-funded warrant per share. Each pre-funded warrant will be exercisable at any time after the date of issuance of such pre-funded warrant, subject to an ownership limitation. See “Description of pre-funded warrants.” This free writing prospectus and the Preliminary Prospectus Supplement also relate to the offering of the shares of our common stock issuable upon exercise of the pre-funded warrants.

The lock-up restrictions described in the Preliminary Prospectus Supplement under “Underwriting” will not apply to issuance of common stock upon the exercise of the pre-funded warrants during the 90-day period following the date of Preliminary Prospectus Supplement.

Underwriters’ option to purchase additional shares: We have granted the underwriters an option, for a period of 30 days, to purchase additional shares of our common stock. The number of shares subject to the underwriters’ option equals 15% of the total number of shares of common stock we are offering plus the shares of common stock underlying the pre-funded warrants.

Dilution: After giving effect to the issuance and sale of shares of our common stock and pre-funded warrants to purchase shares of our common stock at the public offering price of \$ per share of our common stock and \$ per pre-funded warrant (which equals the public offering price per share of the common stock less the \$0.01 per share exercise price of each such pre-funded warrant) (and excluding shares of common stock issued and any proceeds received upon exercise of the pre-funded warrants or any resulting accounting associated with the pre-funded warrants), less the underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of September 30, 2021 would have been \$ million, or \$ per share of common stock. This represents an immediate increase in the as adjusted net tangible book value of \$ per share to our existing shareholders and an immediate dilution of \$ per share to new investors participating.

Listing Shares of our common stock are listed on the Nasdaq Global Select Market, or Nasdaq, under the symbol “IMGN.” We do not intend to list the pre-funded warrants on Nasdaq, any other nationally recognized securities exchange or any other nationally recognized trading system.

Risk factors

There is no public market for the pre-funded warrants in this offering.

There is no established public trading market for the pre-funded warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the pre-funded warrants will be limited.

Any holder of the pre-funded warrants will have no rights as common stockholder until such holder exercises its pre-funded warrant and acquires our common stock.

Until the holder of each pre-funded warrants exercise its pre-funded warrant and acquires shares of our common stock, such holder will have no rights with respect to the shares of our common stock underlying such pre-funded warrant. Upon exercise of their respective pre-funded warrant, the holder will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

A significant holder or beneficial holder of our common stock may not be permitted to exercise the pre-funded warrant that it holds.

A holder of a pre-funded warrant will not be entitled to exercise any portion of the pre-funded warrant that, upon giving effect to such exercise, would cause the aggregate number of shares of our common stock beneficially owned by such holder (together with its affiliates and any other persons whose beneficial ownership of Common Stock would be aggregated with the holder for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) to exceed 9.99% of the total number of then issued and outstanding shares of common stock, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant and subject to such holder’s rights under the pre-funded warrant to increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days’ prior notice from such holder to us. As a result, you may not be able to exercise your pre-funded warrant for shares of our common stock at a time when it would be financially beneficial for you to do so. In such a circumstance, you could seek to sell your pre-funded warrant to realize value, but you may be unable to do so in the absence of an established trading market.

Use of proceeds

We estimate that the net proceeds we receive from the issuance and sale of shares of our common stock and pre-funded warrants in this offering will be approximately \$164.2 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, or approximately \$188.9 million if the underwriters exercise their option to purchase additional shares in full. We will receive nominal proceeds, if any, upon exercise of the pre-funded warrants.

We intend to use the net proceeds from this offering to fund our operations, including, but not limited to, commercialization activities, clinical trial activities, supply of drug product, business development activities, capital expenditures, and working capital.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. The amounts and timing of these expenditures will depend on a number of factors, such as whether and when we receive any regulatory approvals for our product candidates, our ability to enter into additional collaboration, licensing, or similar transactions, the timing and progress of our research and development efforts, technological advances, and the competitive environment for our product candidates. As a result, our management will have broad discretion to allocate the net proceeds from this offering. We have no current plans, commitments, or agreements with respect to any acquisitions and may not make any acquisitions. Pending application of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term, investment-grade, interest-bearing securities.

Description of pre-funded warrants

The following is a summary of the material attributes and characteristics of the pre-funded warrants. The form of pre-funded warrants will be provided to the pre-funded warrant purchasers in this offering and will be filed as an exhibit to a Current Report on Form 8-K with the Securities and Exchange Commission (the SEC) in connection with this offering. The following summary is subject in all respects to the provisions contained in the pre-funded warrants.

Each pre-funded warrant entitles the holder thereof to purchase shares of our common stock at an exercise price equal to \$0.01 per share. Each pre-funded warrant will be exercisable at any time beginning on the date of issuance. The number of shares of our common stock issuable upon exercise of pre-funded warrant is subject to adjustment upon certain corporate events, including certain stock dividends and splits, combinations, reclassifications and certain other events.

The holder of the pre-funded warrant may exercise the pre-funded warrant by delivering an exercise notice, completed and duly signed, and payment in cash of the exercise price for the number of shares of our common stock for which the pre-funded warrant is being exercised. The holder of the pre-funded warrant may also satisfy its obligation to pay the exercise price through a “cashless exercise,” in which the holder receives the net value of the pre-funded warrant in shares of common stock determined according to the formula set forth in the pre-funded warrant.

Upon a holder's exercise of the pre-funded warrant, we will issue the shares of common stock to which the holder is entitled pursuant to such exercise within three trading days after the exercise date.

A holder of the pre-funded warrant will not be entitled to exercise any portion of such pre-funded warrant that, upon giving effect to such exercise, would cause the aggregate number of shares of our common stock beneficially owned by such holder (together with its affiliates and any other persons whose beneficial ownership of common stock would be aggregated with the holder for purposes of Section 13(d) of the Exchange Act) to exceed 9.99% of the total number of then issued and outstanding shares of common stock, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant and subject to such holder's rights under the pre-funded warrant to increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from such holder to us.

Upon the consummation of a fundamental transaction (as described in the pre-funded warrants), the holders of the pre-funded warrants will be entitled to receive, upon exercise of the pre-funded warrants, the kind and amount of securities, cash, or other property that such holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction, without regard to any limitations on exercise contained in the pre-funded warrants.

There is no established public trading market for the pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the pre-funded warrants on any national securities exchange or other nationally recognized trading system.

ImmunoGen, Inc. shall initially serve as the warrant agent under the pre-funded warrants.

The pre-funded warrants do not confer upon the holder any voting or other rights as shareholders of ImmunoGen, Inc.

Underwriting

The underwriters will purchase the pre-funded warrants pursuant to the underwriting agreement described in the Preliminary Prospectus Supplement on terms generally consistent with those applicable to the shares of common stock being sold in the offering. The per share underwriting discounts and commissions for the pre-funded warrants will be equal to the per share underwriting discounts and commissions on the shares of our common stock sold in the offering.

General

Additional conforming changes are hereby made to the Preliminary Prospectus Supplement to reflect the changes described in this free writing prospectus. All terms of the Preliminary Prospectus Supplement applicable to our common stock will be applicable to the shares underlying the pre-funded warrants upon issuance.

ImmunoGen, Inc. has filed a registration statement (including a preliminary prospectus supplement dated November 30, 2021 and the accompanying base prospectus) with the SEC for the offering to which this communication relates. Before you invest, you should read the preliminary prospectus supplement and the accompanying base prospectus and other documents the Company has filed with the SEC for more complete information about the Company and the offering. You may get these documents for free by visiting EDGAR on the SEC website at www.sec.gov. Alternatively, copies may be obtained by contacting Jefferies LLC, Attention: Equity Syndicate Prospectus Department, 520 Madison Avenue, 2nd Floor, New York, NY 10022, by e-mail at prospectus_department@jefferies.com or by telephone at (877) 821-7388; Cowen and Company, LLC c/o Broadridge Financial Solutions, Attention: Prospectus Department, 1155 Long Island Avenue, Edgewood, NY, 11717, by email at PostSaleManualRequests@broadridge.com or by telephone at (833) 297-2926; or Guggenheim Securities, LLC, Attention: Equity Syndicate Department, 330 Madison Avenue, 8th Floor, New York, NY 10017, or by email at GSEquityProspectusDelivery@guggenheimpartners.com or by telephone at (212) 518-9544.

None.

FORM OF PRE-FUNDED WARRANT

FORM OF LOCK-UP AGREEMENT

_____, 2021

JEFFERIES LLC
COWEN AND COMPANY, LLC
As Representatives of
the several Underwriters listed in
Schedule 1 to the Underwriting
Agreement referred to below

c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

c/o Cowen and Company, LLC
599 Lexington Avenue
New York, NY 10022

Re: ImmunoGen, Inc. – Public Offering

Ladies and Gentlemen:

The undersigned understands that Jefferies LLC (“**Jefferies**”) and Cowen and Company, LLC (“**Cowen**”) propose to enter into an Underwriting Agreement (the “**Underwriting Agreement**”) with ImmunoGen, Inc., a Massachusetts corporation (the “**Company**”), providing for the public offering (the “**Public Offering**”) by the several Underwriters named in Schedule 1 to the Underwriting Agreement (the “**Underwriters**”), of Common Stock, \$0.01 par value per share, of the Company (the “**Securities**”). Capitalized terms used herein and not otherwise defined shall have the meanings set forth in the Underwriting Agreement.

In consideration of the Underwriters' agreement to purchase and make the Public Offering of the Securities, and for other good and valuable consideration receipt of which is hereby acknowledged, the undersigned hereby agrees that, without the prior written consents of each of Jefferies and Cowen on behalf of the Underwriters, the undersigned will not, during the period ending 90 days after the date of the prospectus (the "**Lock-Up Period**") relating to the Public Offering (the "**Prospectus**"), (1) 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, directly or indirectly, any shares of Common Stock, \$0.01 per share par value, of the Company (the "**Common Stock**") or any securities convertible into or exercisable or exchangeable for Common Stock (including without limitation, Common Stock or such other securities which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant), or publicly disclose the intention to make any offer, sale, pledge or disposition, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Common Stock or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise or (3) make any demand for or exercise any right with respect to the registration of any shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock, in each case other than (A) transfers of shares of Common Stock as a bona fide gift or gifts, (B) transfers either during the undersigned's lifetime or on death by will or intestacy to the undersigned's immediate family or to a trust, the beneficiaries of which are the undersigned and a member or members of the undersigned's immediate family and (C) distributions of shares of Common Stock to members or stockholders of the undersigned; provided that in the case of any transfer or distribution pursuant to clause (A), (B) or (C), each donee or distributee shall execute and deliver to Jefferies and Cowen a lock-up letter in the form of this paragraph; and provided, further, that in the case of any transfer or distribution pursuant to clause (A), (B) or (C), no filing by any party (donor, donee, transferor or transferee) under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a filing on a Form 5 made upon the earlier of (i) February 14, 2022 or (ii) after the expiration of the 90-day period referred to above). For the purposes of this paragraph, "immediate family" shall mean a spouse, domestic partner, lineal descendant (including adopted children), father, mother, brother or sister of the transferor. Furthermore, notwithstanding the lock-up restrictions described herein, the undersigned may, at any time after the date hereof, establish any new plan meeting the requirements of Rule 10b5-1 under the Exchange Act (a "**New Plan**"), if then permitted by the Company and applicable law; provided that the shares of Common Stock subject to such New Plan may not be sold during the Lock-Up Period and there shall be no public announcement made in connection with entering such New Plan. Additionally, notwithstanding the restrictions imposed by this letter agreement (the "**Letter Agreement**"), the undersigned may exercise a stock option issued prior to the date hereof that is due to expire during the Lock-Up Period and the foregoing restrictions shall not apply to sales or transfer of securities (A) to the Company upon the net cashless exercise of options to purchase securities that are due to expire during the Lock-Up Period or (B) in connection with the sale by the undersigned (or the Company on behalf of the undersigned) of up to such number of shares of Common Stock as necessary for the purpose of paying the exercise price of options that are due to expire during the Lock-Up Period or for paying taxes (including estimated taxes) or to satisfy the income and payroll tax withholding obligations due as a result of the exercise of such options that are due to expire during the Lock-Up Period, in each case pursuant to employee benefit plans disclosed in the Registration Statement and the Prospectus; provided however that to the extent a public announcement or filing under the Exchange Act, if any, is required or voluntarily made by or on behalf of the undersigned or the Company regarding any such sales or transfers, such announcement or filing shall include a statement to the effect that the sale or transfer was made pursuant in connection with the exercise of options that would have otherwise expired during the Lock-Up Period.

The restrictions contained herein shall not apply to any transfers, sales, tenders or other dispositions of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock pursuant to a bona fide third-party tender offer, merger, amalgamation, consolidation or other similar transaction made to or involving all holders of the Common Stock or such other securities pursuant to a change of control of the ownership of the Company (including, without limitation, the entry into any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of Common Stock or other such securities in connection with any such transaction, or vote any securities in favor of any such transaction); provided that if such tender offer, merger, amalgamation, consolidation or other similar transaction is not completed, any Common Stock or any security convertible into or exercisable or exchangeable for Common Stock subject to this Letter Agreement shall remain subject to the restrictions contained in this Letter Agreement. For purposes of this Letter Agreement, "change of control" shall mean the consummation of any bona fide third party tender offer, merger, amalgamation, consolidation or other similar transaction the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, other than the Company, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of 50% of total voting power of the voting stock of the Company.

In furtherance of the foregoing, the Company, and any duly appointed transfer agent for the registration or transfer of the securities described herein, are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this Letter Agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Letter Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

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 Public Offering of Common Stock and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate. The undersigned further acknowledges and agrees that, although the Underwriters may be required or choose to provide certain Regulation Best Interest and Form CRS disclosures to you in connection with the Public Offering, the Underwriters are not making a recommendation to you to enter into this Letter Agreement and nothing set forth in such disclosures is intended to suggest that any Underwriter is making such a recommendation.

The undersigned understands that, if the Underwriting Agreement does not become effective by December 31, 2021, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Stock to be sold thereunder, the undersigned shall be released from all obligations under this Letter Agreement. The undersigned understands that the Company and the Underwriters are entering into the Underwriting Agreement and proceeding with the Public Offering in reliance upon this Letter Agreement.

[Signature Page Follows]

This Letter Agreement and any claim, controversy or dispute arising under or related to this Letter 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.

Very truly yours,

By: _____
Name:
Title:

IMMUNOGEN, INC.

PRE-FUNDED WARRANT TO PURCHASE COMMON STOCK

Number of Shares: [●]
(subject to adjustment)

Warrant No. [●]

Original Issue Date: December 6, 2021

ImmunoGen, Inc., a Massachusetts corporation (the “*Company*”), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, [●] or its permitted registered assigns (the “*Holder*”), is entitled, subject to the terms set forth below, to purchase from the Company up to a total of [●] shares of common stock, \$0.01 par value per share (the “*Common Stock*”), of the Company (each such share, a “*Warrant Share*” and all such shares, the “*Warrant Shares*”) at an exercise price per share equal to \$0.01 per share (as adjusted from time to time as provided in Section 9 herein, the “*Exercise Price*”), upon surrender of this Pre-Funded Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the “*Warrant*”) at any time and from time to time on or after the date hereof (the “*Original Issue Date*”), and subject to the following terms and conditions:

1. **Definitions.** For purposes of this Warrant, the following terms shall have the following meanings:

- (a) “*Affiliate*” means any Person directly or indirectly controlled by, controlling, or under common control with, a Holder, but only for so long as such control shall continue. For purposes of this definition, “control” (including, with correlative meanings, “controlled by,” “controlling” and “under common control with”) means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities (whether directly or pursuant to any option, warrant, or other similar arrangement) or other comparable equity interests.
 - (b) “*Commission*” means the United States Securities and Exchange Commission.
 - (c) “*Exchange Act*” means the Securities Exchange Act of 1934, as amended.
 - (d) “*Principal Trading Market*” means the national securities exchange or other trading market on which the Common Stock is primarily listed and quoted for trading, which, as of the Original Issue Date, shall be The Nasdaq Global Select Market.
 - (e) “*Registration Statement*” means the Company’s registration statement on Form S-3 (File No. 333-251502), which was filed, and became effective, on December 18, 2020.
 - (f) “*Securities Act*” means the Securities Act of 1933, as amended.
 - (g) “*Trading Day*” means any weekday on which the Principal Trading Market is open for trading.
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- (h) “*Transfer Agent*” means Broadridge Corporate Issuer Solutions, Inc., the Company’s transfer agent and registrar for the Common Stock, and any successor appointed in such capacity.
- (i) “*VWAP*” means, for any date, the price determined by the first of the following clauses that applies: (i) if the Common Stock is then listed or quoted on a national securities exchange or other trading market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Principal Trading Market as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (ii) if the Common Stock is then listed or quoted for trading and neither OTCQB nor OTCQX is the Principal Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX, as applicable, (iii) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the “Pink Sheets” published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (iv) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.
2. Issuance of Securities; Registration of Warrants. The Warrant, as initially issued by the Company, is offered and sold pursuant to the Registration Statement. As of the Original Issue Date, the Warrant Shares are issuable under the Registration Statement. Accordingly, the Warrant and, assuming issuance pursuant to the Registration Statement or an exchange meeting the requirements of Section 3(a)(9) of the Exchange Act as in effect on the Original Issue Date, the Warrant Shares, are not “restricted securities” under Rule 144 promulgated under the Securities Act. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the “*Warrant Register*”), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder) from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.
3. Registration of Transfers. Subject to compliance with all applicable securities laws, the Company shall, or will cause its Transfer Agent to, register the transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, and payment for all applicable transfer taxes (if any). Upon any such registration or transfer, a new warrant to purchase Common Stock in substantially the form of this Warrant (any such new warrant, a “*New Warrant*”) evidencing the portion of this Warrant so transferred shall be issued to the transferee, and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Company shall, or will cause its Transfer Agent to, prepare, issue, and deliver at the Company’s own expense any New Warrant under this Section 3. Until due presentment for registration of transfer, the Company may treat the registered Holder hereof as the owner and holder of this Warrant for all purposes and the Company shall not be affected by any notice to the contrary.

4. Exercise and Duration of Warrants.

- (a) All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 of this Warrant at any time and from time to time on or after the Original Issue Date.
- (b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached as Schedule 1 hereto (the “*Exercise Notice*”), completed and duly signed, and (ii) payment of the Exercise Price for the number of Warrant Shares as to which this Warrant is being exercised (which may take the form of a “cashless exercise” if so indicated in the Exercise Notice pursuant to Section 10 below), and the date on which the last of such items is delivered to the Company (as determined in accordance with the notice provisions hereof) is an “*Exercise Date*.” The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares.

5. Delivery of Warrant Shares.

- (a) Upon exercise of this Warrant, the Company shall promptly (but in no event more than three (3) Trading Days after the Exercise Date), upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder’s or its designee’s balance account with The Depository Trust Company (“*DTC*”) through its Deposit Withdrawal Agent Commission system, or if the Transfer Agent is not participating in the Fast Automated Securities Transfer Program (the “*FAST Program*”) or if the certificates or book entry position are required to bear a legend regarding restriction on transferability, issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate or book entry position, registered in the Company’s share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. The Holder, or any natural person or legal entity (each, a “*Person*”) permissibly so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date, irrespective of the date such Warrant Shares are credited to the Holder’s DTC account or the date of delivery of the certificates or book entry position evidencing such Warrant Shares, as the case may be.
- (b) If by the close of the third Trading Day after the Exercise Date, the Company fails to credit the Holder’s balance account with DTC for such number of Warrant Shares to which the Holder is entitled, and if after such third Trading Day and prior to the receipt of such Warrant Shares, the Holder purchases (in an open market transaction, provided such purchases shall be made in a commercially reasonable manner at prevailing market prices) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a “*Buy-In*”), then the Company shall, within two Trading Days after the Holder’s request, in the Holder’s sole discretion, either (i) pay in cash to the Holder an amount equal to the Holder’s total purchase price (including commercially reasonable brokerage commissions, if any) for the shares of Common Stock so purchased, at which point the Company’s obligation to deliver such Warrant Shares shall terminate, or (ii) (A) pay in cash to the Holder the amount, if any, by which (1) the Holder’s total purchase price (including commercially reasonable brokerage commissions, if any) for the shares of Common Stock purchased in the Buy-In exceeds (2) the product of (x) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue, times (y) the price at which the sell order giving rise to such purchase obligation was executed (assuming such sale was executed on commercially reasonable terms at prevailing market prices and, if the sale was executed in multiple transactions, the volume weighted average price), and (B) at the option of the Holder, either (1) reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or (2) deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. The provisions of this Section 5(b) shall be the only remedy available to the Holder in the event the Company fails to deliver to the Holder the required number of Warrant Shares in the manner required pursuant to Section 5(a) and a Buy-In occurs. Irrespective of whether there is a Buy-In, no remedy shall be available, notwithstanding the requirements of Section 5(a), unless and until the Company fails to deliver to the Holder the required number of Warrant Shares by the close of the third Trading Day after the Exercise Date.

- (c) To the extent permitted by law and subject to Section 5(b), the Company's obligations to issue and deliver Warrant Shares in accordance with and subject to the terms hereof (including the limitations set forth in Section 11 below) are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance that might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Warrant Shares. Subject to Section 5(b), nothing herein shall limit the Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates or a book entry position representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.
6. Charges, Taxes and Expenses. Issuance and delivery of a book entry position for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense (excluding any applicable stamp duties) in respect of the issuance of such or book entry shares, all of which taxes and expenses shall be paid by the Company; provided, however, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any certificates for Warrant Shares or the Warrants in a name other than that of the Holder or an Affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.
7. Replacement of Warrant. If this Warrant is mutilated, lost, stolen, or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft, or destruction (in such case) and, in each case, a customary and reasonable indemnity and surety bond if requested by the Company. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. Reservation of Warrant Shares. The Company covenants that it will at all times while this Warrant is outstanding reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares that are then issuable and deliverable upon the exercise of this Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments and restrictions of Section 9). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid, and nonassessable. The Company will take all such action as may be reasonably necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed.
9. Certain Adjustments. The number of Warrant Shares issuable upon exercise of this Warrant is subject to adjustment from time to time as set forth in this Section 9.
- (a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock issued and outstanding on the Original Issue Date and in accordance with the terms of such stock on the Original Issue Date or as amended, that is payable in shares of Common Stock, (ii) subdivides its outstanding shares of Common Stock into a larger number of shares of Common Stock, (iii) combines its outstanding shares of Common Stock into a smaller number of shares of Common Stock or (iv) issues by reclassification of shares of capital stock any additional shares of Common Stock of the Company, then in each such case the number of Warrant Shares then underlying this Warrant shall be divided by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately before such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, provided, however, that if such record date shall have been fixed and such dividend is not fully paid on the date fixed therefor, the number of Warrant Shares shall be recomputed accordingly as of the close of business on such record date and thereafter the Warrant Shares shall be adjusted pursuant to this paragraph as of the time of actual payment of such dividends. Any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.
- (b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph), (iii) rights or warrants to subscribe for or purchase any security, or (iv) cash or any other asset (in each case, "*Distributed Property*"), then, upon any exercise of this Warrant that occurs after the record date fixed for determination of stockholders entitled to receive such distribution, the Holder shall be entitled to receive, in addition to the Warrant Shares otherwise issuable upon such exercise (if applicable), the Distributed Property that such Holder would have been entitled to receive in respect of such number of Warrant Shares had the Holder been the record holder of such Warrant Shares immediately prior to such record date without regard to any limitation on exercise contained therein.

- (c) Fundamental Transactions. If, at any time while this Warrant is outstanding (i) the Company effects any merger or consolidation of the Company with or into another Person, in which the Company is not the surviving entity or the stockholders of the Company immediately prior to such merger or consolidation do not own, directly or indirectly, at least 50% of the voting power of the surviving entity immediately after such merger or consolidation, (ii) the Company effects any sale to another Person of all or substantially all of its assets in one transaction or a series of related transactions, (iii) pursuant to any tender offer or exchange offer (whether by the Company or another Person), holders of capital stock who tender shares representing more than 50% of the voting power of the capital stock of the Company and the Company or such other Person, as applicable, accepts such tender for payment, (iv) the Company consummates a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the voting power of the capital stock of the Company (except for any such transaction in which the stockholders of the Company immediately prior to such transaction maintain, in substantially the same proportions, the voting power of such Person immediately after the transaction) or (v) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (other than as a result of a subdivision or combination of shares of Common Stock covered by Section 9(a) above) (in any such case, a “*Fundamental Transaction*”), then following such Fundamental Transaction the Holder shall have the right to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant without regard to any limitations on exercise contained herein (the “*Alternate Consideration*”). The Company shall not effect any Fundamental Transaction in which the Company is not the surviving entity or the Alternate Consideration includes securities of another Person unless (x) the Alternate Consideration is solely cash and the Company provides for the simultaneous “cashless exercise” of this Warrant pursuant to Section 10 below or (y) prior to, simultaneously with or promptly following the consummation thereof, any successor to the Company, surviving entity or other Person (including any purchaser of assets of the Company) shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to receive, and the other obligations under this Warrant. The provisions of this paragraph (c) shall similarly apply to subsequent transactions analogous of a Fundamental Transaction type.
- (d) Calculations. All calculations under this Section 9 shall be made to the nearest share.
- (e) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, at the written request of the Holder, promptly compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Transfer Agent.

(f) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital stock of the Company or any subsidiary, (ii) enters into any definitive agreement contemplating or soliciting stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least ten (10) days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction; *provided, however,* that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice. In addition, if while this Warrant is outstanding, the Company enters into any definitive agreement contemplating or solicits stockholder approval for any Fundamental Transaction contemplated by Section 9(c), other than a Fundamental Transaction under clause (iii) of Section 9(c), the Company shall deliver to the Holder a notice of such Fundamental Transaction at least ten (10) days prior to the date such Fundamental Transaction is consummated. Holder agrees to maintain any information disclosed pursuant to this Section 9(f) in confidence until such information is publicly available and shall comply with applicable law with respect to trading in the Company's securities following receipt any such information.

10. Payment of Exercise Price. Notwithstanding anything contained herein to the contrary, the Holder may, in its sole discretion, satisfy its obligation to pay the Exercise Price through a "cashless exercise," in which event the Company shall issue to the Holder the number of Warrant Shares determined as follows:

$$X = Y [(A-B)/A]$$

where:

"X" equals the number of Warrant Shares to be issued to the Holder;

"Y" equals the total number of Warrant Shares with respect to which this Warrant is then being exercised;

"A" equals the last VWAP immediately preceding the time of delivery of the Exercise Notice giving rise to the applicable "cashless exercise," as set forth in the applicable Exercise Notice (to clarify, the "last VWAP" will be the last VWAP as calculated over an entire Trading Day such that, in the event that this Warrant is exercised at a time that the Trading Market is open, the prior Trading Day's VWAP shall be used in this calculation); and

"B" equals the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood, and acknowledged that the Warrant Shares issued in a “cashless exercise” transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued (provided that the Commission continues to take the position that such treatment is proper at the time of such exercise).

Except as set forth in Section 12 (payment of cash in lieu of fractional shares), in no event will the exercise of this Warrant be settled in cash.

11. Limitations on Exercise.

- (a) Notwithstanding anything to the contrary contained in any Section herein, the Company shall not effect any exercise of this Warrant, and the Holder shall not be entitled to exercise this Warrant for a number of Warrant Shares in excess of that number of Warrant Shares which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of Common Stock beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder’s for purposes of Section 13(d) of the Exchange Act, to exceed 9.99% of the total number of issued and outstanding shares of Common Stock of the Company following such exercise, or (ii) the combined voting power of the securities of the Company beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder’s for purposes of Section 13(d) of the Exchange Act to exceed 9.99% of the combined voting power of all of the securities of the Company then outstanding following such exercise. For purposes of this Warrant, in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (x) the Company’s most recent Quarterly Report on Form 10-Q or Annual Report on Form 10-K, as the case may be, filed with the Commission prior to the date hereof, (y) a more recent public announcement by the Company or (z) any other notice by the Company or its transfer agent setting forth the number of shares of Common Stock outstanding. Upon the written request of the Holder, the Company shall within three (3) Trading Days confirm in writing or by electronic mail to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder since the date as of which such number of outstanding shares of Common Stock was reported. By written notice to the Company, the Holder may from time to time increase or decrease the Maximum Percentage to any other percentage specified not in excess of 19.99% in such notice; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. For purposes of this Section 11(a), the aggregate number of shares of Common Stock or voting securities beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder’s for purposes of Section 13(d) of the Exchange Act shall include the shares of Common Stock issuable upon the exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (x) exercise of the remaining unexercised and non-cancelled portion of this Warrant by the Holder and (y) exercise or conversion of the unexercised, non-converted or non-cancelled portion of any other securities of the Company that do not have voting power (including, without limitation, any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock), is subject to a limitation on conversion or exercise analogous to the limitation contained herein and is beneficially owned by the Holder or any of its Affiliates and other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder’s for purposes of Section 13(d) of the Exchange Act.

- (b) This Section 11 shall not restrict the number of shares of Common Stock that a Holder may receive or beneficially own in order to determine the amount of securities or other consideration that such Holder may receive in the event of a Fundamental Transaction as contemplated in Section 9 of this Warrant.
12. No Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the number of Warrant Shares to be issued shall be rounded down to the next whole number and the Company shall pay the Holder in cash the fair market value (based on the last VWAP immediately preceding the time of delivery of the applicable Exercise Notice) for any such fractional shares.
13. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via confirmed e-mail at the e-mail address specified below prior to 4:00 P.M., New York City time, on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via confirmed e-mail at the e-mail address specified below on a day that is not a Trading Day or later than 4:00 P.M., New York City time, on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next business day delivery, or (iv) upon actual receipt by the Person to whom such notice is required to be given, if by hand delivery. The e-mail address for purposes of providing notice hereunder is: legal.department@immunogen.com.
14. Warrant Agent. The Company shall initially serve as warrant agent under this Warrant. Upon ten (10) days' notice to the Holder, the Company may appoint a new warrant agent. Any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.
15. Miscellaneous.
- (a) No Rights as a Stockholder. The Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, amalgamation, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

- (b) Authorized Shares. Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation amending its articles of organization or effect any reorganization, transfer of assets, consolidation, merger, dissolution, issue, or sale of securities or any other voluntary action to avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.
- (c) Successors and Assigns. Subject to compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder except to a successor in the event of a Fundamental Transaction. This Warrant shall be binding on and inure to the benefit of the Company and the Holder and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy, or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.
- (d) Amendment and Waiver. Except as otherwise provided herein, the provisions of the Warrants may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holder.
- (e) Acceptance. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.
- (f) Governing Law; Jurisdiction. ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT, AND INTERPRETATION OF THIS WARRANT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE COMMONWEALTH OF MASSACHUSETTS WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE COMMONWEALTH OF MASSACHUSETTS, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HERewith OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN (INCLUDING WITH RESPECT TO THE ENFORCEMENT OF ANY OF THE TRANSACTION DOCUMENTS), AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF VIA REGISTERED OR CERTIFIED MAIL OR OVERNIGHT DELIVERY (WITH EVIDENCE OF DELIVERY) TO SUCH PERSON AT THE ADDRESS IN EFFECT FOR NOTICES TO IT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW. EACH OF THE COMPANY AND THE HOLDER HEREBY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

- (g) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant, and shall not be deemed to limit or affect any of the provisions hereof.
- (h) Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the Company and the Holder will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its authorized officer as of the date first indicated above.

IMMUNOGEN, INC.

By: _____
Name:
Title:

SCHEDULE 1

FORM OF EXERCISE NOTICE

[To be executed by the Holder to purchase shares of Common Stock under the Warrant]

Ladies and Gentlemen:

- (1) The undersigned is the Holder of Warrant No. _____ (the “*Warrant*”) issued by ImmunoGen, Inc., a Massachusetts corporation (the “*Company*”). Capitalized terms used herein and not otherwise defined herein have the respective meanings set forth in the Warrant.
- (2) The undersigned hereby exercises its right to purchase Warrant Shares pursuant to the Warrant.
- (3) The Holder intends that payment of the Exercise Price shall be made as (check one):
 - Cash Exercise
 - “Cashless Exercise” under Section 10 of the Warrant
- (4) If the Holder has elected a Cash Exercise, the Holder shall pay the sum of \$_____ in immediately available funds to the Company in accordance with the terms of the Warrant.
- (5) Pursuant to this Exercise Notice, the Company shall deliver to the Holder Warrant Shares determined in accordance with the terms of the Warrant.
- (6) By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended) permitted to be owned under Section 11(a) of the Warrant to which this notice relates.

Dated: _____

Name of Holder: _____

By: _____

Name: _____

Title: _____

(Signature must conform in all respects to name of Holder as specified on the face of the Warrant)



ROPES & GRAY LLP
PRUDENTIAL TOWER
800 BOYLSTON STREET
BOSTON, MA 02199-3600
WWW.ROPESGRAY.COM

December 3, 2021

ImmunoGen, Inc.
830 Winter Street
Waltham, MA 02451-1477

Re: Registration Statement on Form S-3 (File No. 333-251502)

Ladies and Gentlemen:

We have acted as counsel to ImmunoGen, Inc., a Massachusetts corporation (the "Company"), in connection with the issuance and sale of (i) 17,486,364 shares (the "Shares") of the common stock, \$.01 par value ("Common Stock"), of the Company and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase 27,363,636 shares of Common Stock (the "Warrant Shares") pursuant to the above-referenced registration statement (the "Registration Statement") filed by the Company with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"). The Shares and Pre-Funded Warrants are being sold pursuant to an underwriting agreement, dated December 1, 2021 (the "Underwriting Agreement"), among the Company and the representatives of the underwriters named therein.

In connection with this opinion letter, we have examined such certificates, documents and records and have made such investigation of fact and such examination of law as we have deemed appropriate in order to enable us to render the opinions set forth herein. In conducting such investigation, we have relied, without independent verification, upon certificates of officers of the Company, public officials and other appropriate persons.

The opinions expressed below are limited to the Massachusetts Business Corporation Act.

Based upon and subject to the foregoing, we are of the opinion that (i) the Shares have been duly authorized and, when issued and delivered pursuant to the Underwriting Agreement against payment of the consideration set forth therein, will be validly issued, fully paid and non-assessable, (ii) provided that the Pre-Funded Warrants have been duly executed and delivered by the Company and duly delivered to the purchaser thereof against payment therefor, then the Pre-Funded Warrants, when issued and sold as described in the Prospectus, assuming a sufficient number of Warrant Shares are at the time available for issuance, will be a valid and legally binding obligation of the Company, enforceable against the Company in accordance with its terms, except as enforcement thereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting creditors' rights generally and by general equitable principles (regardless of whether such enforceability is considered in a proceeding at law or in equity) and implied covenants of good faith and fair dealing, and (iii) the Warrant Shares, when issued upon exercise of the Pre-Funded Warrants in accordance with its terms, will have been duly authorized and validly issued and will be fully paid and non-assessable.

We hereby consent to your filing this opinion as an exhibit to a Current Report on Form 8-K to be incorporated by reference into the Registration Statement and to the use of our name under the caption “Legal Matters” in the Prospectus. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Ropes & Gray LLP

Ropes & Gray LLP

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth estimates of the various expenses, other than any underwriting discounts and commissions, in connection with the sale and distribution of the securities being registered.

Securities and Exchange Commission Registration Fee	\$	27,440
Printing and related expenses		10,000
Legal fees and expenses		260,000
Accounting fees and expenses		25,000
Transfer Agent and Registrar fees		4,500
Miscellaneous		3,060
Total	\$	330,000

The following is a supplement (the “Supplement”) to the description of the business of ImmunoGen, Inc. (the “Company”) included in the Company’s reports filed with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The Supplement should not be read in isolation and should be read together with the description of the Company’s business set forth in the Company’s reports filed pursuant to the Exchange Act. Unless otherwise provided in this Supplement, references to the “we,” “us,” and “our” and similar references refer to the Company.

We are a clinical-stage biotechnology company focused on developing the next generation of antibody- drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer patients more good days. We call this our commitment to “target a better now.”

An ADC with our proprietary technology comprises an antibody that binds to a target found on tumor cells and is conjugated to one of our potent anti-cancer agents as a “payload” to kill the tumor cell once the ADC has bound to its target. ADCs are an expanding approach to the treatment of cancer, with eleven approved products and the number of agents in development growing significantly in recent years.

We have established a leadership position in ADCs with a portfolio of differentiated product candidates to address both solid tumors and hematological malignancies.

Our lead program is mirvetuximab soravtansine (mirvetuximab), a first-in-class investigational ADC targeting folate receptor alpha (FR α), a cell-surface protein over-expressed in a number of epithelial tumors, including ovarian, endometrial, and non-small-cell lung cancers. Following consultation with the FDA, we initiated two trials of mirvetuximab in patients with platinum-resistant ovarian cancer whose tumors express high levels of FR α (FR α -high): SORAYA, a single-arm clinical trial that could lead to accelerated approval, pending FDA review; and MIRASOL, a randomized Phase 3 clinical trial that, if successful, could lead to full approval in this setting.

SORAYA is a single-arm study of mirvetuximab in patients with FR α -high platinum-resistant epithelial ovarian, primary peritoneal, or fallopian tube cancer and who have been treated with up to three prior regimens—at least one of which included bevacizumab. The primary endpoint for the study is confirmed objective response rate (ORR) as assessed by investigator, including complete and partial responses, and the key secondary endpoint is duration of response (DOR). ORR was also assessed by blinded independent central review (BICR). The study is designed to assess ORR as compared to a null hypothesis of a 12% ORR, based on expectations with available single agent chemotherapy from the AURELIA study in patients with platinum-resistant ovarian cancer and one to two prior lines of therapy.

SORAYA enrolled 106 patients with a median of three prior lines of therapy (range one to four; 51% had three prior lines of therapy and 48% had one to two prior lines of therapy). All patients received prior bevacizumab; 48% of patients received a prior poly ADP-ribose polymerase (PARP) inhibitor. As of the data cutoff on November 16, 2021, the median follow-up time was 8.1 months.

ORR by investigator was 32.4% (95% confidence interval (CI): 23.6%, 42.2%), including five complete responses (CRs). ORR by BICR was 31.6% (95% CI: 22.4%, 41.9%), including five CRs. Responses were observed regardless of prior PARP inhibitor or number of prior lines of therapy.

As of the November 16, 2021 cutoff date, median DOR was 5.9 months (95% CI: 5.6, 7.7). With nearly half of responders continuing on therapy, the duration of response continues to evolve and, with longer follow-up, median DOR could range from 5.7 to just above 7 months.

Mirvetuximab was observed to be well-tolerated, consistent with safety data seen in more than 700 patients treated in the broader mirvetuximab program. Treatment-related adverse events led to dose reductions in 19% of patients, dose delays in 32% of patients, and discontinuations in 7% of patients.

The most common treatment-related adverse events included blurred vision (41% all grade; 6% grade 3+), keratopathy (35% all grade; 9% grade 3+), and nausea (29% all grade; 0% grade 3+).

We plan to submit a biologics license application (BLA) to the FDA in the first quarter of 2022 for accelerated approval of mirvetuximab in second through fourth-line patients with FR α positive, platinum-resistant ovarian cancer who have been previously treated with bevacizumab. Thereafter, we plan to seek full approval on the basis of the Phase 3 MIRASOL trial, if the primary endpoint in MIRASOL is met.

Beyond FR α -high, platinum-resistant ovarian cancer in patients who had one or more prior lines of therapy, our strategy is to move mirvetuximab into earlier lines of ovarian cancer therapy. To this end, we are supporting investigator-sponsored trials of mirvetuximab in combination with carboplatin in a single-arm study in the neoadjuvant setting and in a randomized study comparing mirvetuximab combined with carboplatin to standard of care in patients with recurrent platinum-sensitive disease. We also initiated PICCOLO, a single-arm study of mirvetuximab monotherapy in later-line platinum-sensitive patients. In addition, we presented mature data from our Phase 1b FORWARD II trial of mirvetuximab plus Avastin[®] (bevacizumab) in recurrent ovarian cancer in an oral presentation at the American Society for Clinical Oncology Annual Meeting in June 2021. The combination demonstrated a 64% ORR, 11.8 month median DOR, and 10.6 month median progression free survival. Most AEs were low grade and the most common treatment related adverse events were gastrointestinal or ocular issues. We believe the combination of mirvetuximab plus bevacizumab has compelling activity in patients with high FR α recurrent ovarian cancer.

IMGN632 is an ADC comprised of a high-affinity antibody designed to target CD123 with site-specific conjugation to a DNA-alkylating payload of the novel IGN (indolinobenzodiazepine pseudodimer) class. Our IGNs are designed to alkylate DNA without cross-linking, which has provided a broad therapeutic index in preclinical models. We are advancing IMGN632 in clinical trials for patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) and acute myeloid leukemia (AML). BPDCN is a rare form of blood cancer, with an annual incidence of between 500 and 1000 patients in the US. In October 2020, the FDA granted Breakthrough Therapy designation for IMGN632 for the treatment of patients with relapsed or refractory BPDCN. Based on feedback from the FDA, we have amended our ongoing 801 Phase 2 study, known as CADENZA, to add a new cohort of up to 20 frontline patients. Due to the impact of the pandemic and the challenge of enrolling patients in the ultra-rare BPDCN patient population, accrual has been slower than anticipated. We now expect to generate top-line data for this frontline cohort in the second half of 2022. At the upcoming American Society of Hematology Annual Meeting (ASH), we will present an abstract on three frontline patients who were enrolled in Study 801 prior to opening of the pivotal frontline cohort; all three of these patients achieved clinical complete response (CRc).

Our 802 study, which is a Phase 1b/2 study designed to determine the safety, tolerability, and preliminary antileukemia activity of IMG632 when administered in combination with azacytidine (AZA) and/or venetoclax (VEN) to patients with relapsed and frontline CD123-positive AML, is in the dose-escalation phase, enrolling relapsed and refractory patients to determine the recommended Phase 2 dose of IMG632 for combination regimens. In the ASH abstract published in November 2021, responses were seen across all cohorts/doses and schedules (efficacy evaluable population, n=29). Higher intensity cohorts (n=20) were associated with higher response rates, including an ORR of 75% and a composite complete remission (CCR) rate of 40%. Significant activity was also observed in the FLT3 mutant subset (n=7), with ORR and CCR rates of 100% and 71%, respectively. The toxicity profile was manageable in this R/R AML population with multiple prior therapies. The most common treatment emergent adverse events all grades seen in >20% of patients were infusion-related reactions, febrile neutropenia, hypophosphatemia, dyspnea, pneumonia, and fatigue. One patient discontinued IMG632 due to an infusion-related reaction. Cytopenias and infections were consistent with those observed with the AZA+VEN regimen in this relapsed/refractory population. No tumor lysis syndrome, veno-occlusive disease, capillary leak or cytokine release were observed. 30-day mortality was 0%.

We look forward to sharing additional data from this study in an oral presentation at ASH 2021.

We continue to advance additional pipeline programs. IMGC936 is an ADC in co-development with MacroGenics, Inc. that is designed to target ADAM9, an enzyme over-expressed in a range of solid tumors and implicated in tumor progression and metastasis. IMGC936 incorporates a number of innovations, including antibody engineering to extend half-life, site-specific conjugation with a fixed drug-antibody ratio to enable higher dosing, and a next-generation linker and payload designed for improved stability and bystander activity. We presented preclinical data on IMGC936 at the American Association for Cancer Research Annual Meeting in April 2021, demonstrating anti-tumor activity in multiple solid tumor models, we continue to enroll patients in the Phase 1 study for this program, and expect initial data in 2022.

IMG151 is our next generation anti-FR α product candidate in preclinical development. This ADC integrates innovation in each of its components, which we believe may enable IMG151 to address patient populations with lower levels of FR α expression, including tumor types outside of ovarian cancer. We expect to submit the IND application for IMG151 by the end of 2021.

We have selectively licensed restricted access to our ADC platform technology to other companies to expand the use of our technology and to provide us with cash to fund our own programs. These agreements typically provide the licensee with rights to use our ADC platform technology with its antibodies or related targeting vehicles to a defined target in order to develop products. The licensee is generally responsible for the development, clinical testing, manufacturing, registration, and commercialization of any resulting product candidate. As part of these agreements, we generally are entitled to receive upfront fees, potential milestone payments, and potential royalties on any sales of resulting products.

Risk Factor Update

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below and discussed under the section captioned “Risk Factors” contained in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on March 1, 2021 (the Annual Report). The risks and uncertainties described below and in our Annual Report are those that we currently believe may materially affect our company and if any of these risks actually occur, our business, financial condition, results of operations, or cash flow could be seriously harmed. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial also may become important factors that affect our company and may materially impair our business. This risk factor update is focused on the specific impacts of mirvetuximab soravtansine (mirvetuximab) on our business. For more information on the risks related to our operations as a whole, please see Part I, Item 1A of our Annual Report.

Interim, top-line, or preliminary data from our clinical trials that we announce may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we have publicly disclosed, and in the future will disclose, preliminary or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Therefore, final results from the studies may differ from the top-line results initially reported, and the final results may indicate different conclusions once additional data have been evaluated. As such, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the outcomes may materially change as patient enrollment continues and more data become available. Adverse differences between top-line, preliminary, or interim data, on the one hand, and final data, on the other, could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses, or may interpret or weigh the importance of data differently, which could negatively affect the approvability or commercialization of the particular product candidate.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the final results differ from the interim, top-line, or preliminary data, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and to commercialize, our product candidates may be harmed, which may negatively affect our business, financial condition, results of operations, and prospects.

We expect to file for approval for mirvetuximab from the FDA through the use of accelerated approval pathways. If unable to obtain approval under an accelerated pathway, we may be required to conduct additional pre-clinical studies or clinical trials beyond those that we currently contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We are seeking approval for mirvetuximab for the treatment of folate receptor alpha (FR α)-high platinum-resistant epithelial ovarian, primary peritoneal, or fallopian tube cancer with one to three prior lines of therapy under the accelerated approval pathway. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act (FDCA) and the FDA's implementing regulations, the FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that demonstrates an effect on a surrogate endpoint, or intermediate clinical endpoint, that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit.

The FDA may not accept our application for accelerated approval, may not grant such approval on a timely basis, or may not grant approval at all. The FDA or foreign regulatory authorities could require us to conduct further studies prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for mirvetuximab would result in a longer time period to commercialization of mirvetuximab, would increase the cost of development of mirvetuximab, and would harm our competitive position in the marketplace.

Moreover, even if we receive accelerated approval from the FDA, we will be subject to rigorous post-marketing requirements, including the completion of confirmatory post-market clinical trial(s) to verify the clinical benefit of mirvetuximab, and submission to the FDA of all promotional materials 30-120 days prior to their dissemination. Products that receive accelerated approval may be subject to expedited withdrawal procedures if post-marketing studies fail to verify the predicted clinical benefit. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post-market study, a post-market study does not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading.

Side effects, serious adverse events, or other undesirable properties could arise from the use of mirvetuximab and, in turn, could delay or halt clinical trials, delay or prevent its regulatory approval, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approval.

Undesirable side effects or serious adverse events caused by mirvetuximab could cause us or regulatory authorities to interrupt, delay, or halt respective clinical trials and could result in a restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities.

Any related drug-side effects or serious adverse events in our clinical trials could affect clinical trial patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims.

In our Phase 3 SORAYA trial evaluating the safety and efficacy of mirvetuximab monotherapy in patients with FR α -high platinum-resistant epithelial ovarian, primary peritoneal, or fallopian tube cancer who had been previously treated with Avastin® (bevacizumab), the most commonly reported treatment-related adverse events included ocular events (blurred vision 41% all grade, 6% grade 3+; keratopathy 35% all grade, 9% grade 3+; dry eye 23% all grade, 2% grade 3+) and low grade gastrointestinal events (nausea 29% all grade, 0% grade 3+; and diarrhea 22% all grade, 2% grade 3+). Treatment-related adverse events leading to drug discontinuation occurred in 7% of patients.

In the randomized Phase 3 FORWARD I trial evaluating mirvetuximab compared to chemotherapy in women with FR α -positive, platinum-resistant epithelial ovarian, primary peritoneal, or fallopian tube cancer, the most common drug-related adverse events included nausea, blurred vision, and keratopathy.

In the Phase 1b FORWARD II study, doublet combinations of mirvetuximab with carboplatin and with bevacizumab were studied, as well as a triplet of mirvetuximab with carboplatin and bevacizumab. In these combinations, no new safety signals were seen; adverse events observed with the combinations were as expected based on the side effect profiles of each agent and duration of therapy.

Additionally, if mirvetuximab receives marketing approval, and we or others later identify undesirable side effects or serious adverse events caused by mirvetuximab, a number of potentially significant negative consequences could result, including:

- we may suspend or be forced to suspend marketing of mirvetuximab;
 - we may be obliged to conduct a product recall or product withdrawal;
 - regulatory authorities may suspend, vary, or withdraw their approvals of mirvetuximab;
 - regulatory authorities may order the seizure of mirvetuximab;
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- regulatory authorities may require additional warnings on the label or a risk evaluation and mitigation strategy (REMS) that could diminish the usage or otherwise limit the commercial success of mirvetuximab;
- we may be required to conduct post-marketing studies;
- we could be sued and held liable for harm caused to patients;
- we could be required to pay fines and face other administrative, civil, and criminal penalties; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of mirvetuximab, if approved.

While we have received orphan drug designation for mirvetuximab and other product candidates for specified indications, we may seek additional orphan drug designation for those and some of our other drug candidates. However, we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Mirvetuximab has been granted orphan drug designation by the FDA in the United States, and orphan medicinal product status by the European Medicines Agency (EMA) in the European Union for the treatment of ovarian cancer. IMG632 has been granted orphan drug designation by the FDA for the treatment of acute myeloid leukemia (AML) and for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), and by the EMA for the treatment of BPDCN. As part of our business strategy, we may seek orphan drug designation for our other drug candidates; however, we may be unsuccessful.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the U.S. Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug or biologic for that time period. Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve another product that meets the definition of a “same drug” under 21 C.F.R. 316.3 for the same condition if the FDA concludes that the later product is clinically superior by evidence that it is safer, more effective, or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we intend to seek additional orphan drug designation for our other drug candidates, we may never receive such designations. Even if we receive orphan drug designation for any of our drug candidates, there is no guarantee that we will enjoy the benefits of those designations or obtain orphan drug exclusivity.

As our business grows, we will become increasingly subject to additional healthcare regulation and enforcement by various government entities, and our failure to strictly adhere to these regulatory regimes could have a detrimental impact on our business.

In the United States, pharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, including laws intended to prevent fraud and abuse in the healthcare industry. These laws, some of which will apply only if and when we have an approved product, include:

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
 - the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
 - the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
 - FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing products prior to approval or for off-label use, and regulates the distribution of samples;
 - federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
 - the federal Open Payments (or federal “sunshine” law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
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- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers, or require pharmaceutical companies to report payments to health care providers or marketing expenditures.

Ensuring compliance is time-consuming and costly. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations, and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices are non-compliant. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.
