
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

**Current Report
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): March 15, 2018

HISTOGENICS CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36751
(Commission
File Number)

04-3522315
(I.R.S. Employer
Identification Number)

**830 Winter Street, 3rd Floor
Waltham, Massachusetts 02451
(781) 547-7900**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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

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

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

Emerging growth company

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.

Equity Distribution Agreement

On March 15, 2018, Histogenics Corporation (“Histogenics”) entered into an equity distribution agreement (the “Equity Distribution Agreement”) with Canaccord Genuity Inc. (“Canaccord”), pursuant to which Histogenics may, from time to time, sell shares of Histogenics’ common stock, par value \$0.01 per share (the “Shares”), having an aggregate offering price of up to \$10 million through Canaccord, as Histogenics’ sales agent.

The Shares will be offered and sold by Histogenics pursuant to its previously filed and currently effective Registration Statement on Form S-3 (Reg. No. 333-216741) (the “Registration Statement”). The Shares may only be offered and sold by means of a prospectus, including a prospectus supplement, forming part of the effective Registration Statement. Sales of the common stock, if any, will be made at market prices by methods deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”), including sales made directly on The Nasdaq Capital Market, on any other existing trading market for the common stock, or to or through a market maker other than on an exchange. We will pay Canaccord a commission rate of 3.0% of the gross proceeds from the sales of common stock sold pursuant to the terms of the Equity Distribution Agreement. We also have provided Canaccord with customary indemnification rights. We and Canaccord each have the right, by giving written notice as specified in the Equity Distribution Agreement, to terminate the Equity Distribution Agreement in each party’s sole discretion at any time.

The Company is not obligated to make any sales of the Shares under the Equity Distribution Agreement. The offering of Shares pursuant to the Equity Distribution Agreement will terminate upon the earlier of (i) the sale of all the Shares subject to the Equity Distribution Agreement, or (ii) termination of the Equity Distribution Agreement in accordance with its terms.

The foregoing description of the Equity Distribution Agreement does not purport to be complete and is qualified in its entirety by reference to the full Equity Distribution Agreement, a copy of which is attached hereto as Exhibit 10.1 and is incorporated by reference herein.

A copy of the opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP relating to the validity of the issuance and sale of the Shares in the offering is attached as Exhibit 5.1 hereto.

This Current Report on Form 8-K does not constitute an offer to sell the Shares or a solicitation of an offer to buy the Shares, nor shall there be any sale of the Shares in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Item 2.02. Results of Operations and Financial Condition.

On March 15, 2018, Histogenics issued a press release and is holding a conference call regarding its results of operations and financial condition for the full year and quarter ended December 31, 2017. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Various statements to be made during the conference call are “forward-looking statements” under the securities laws. Words such as, but not limited to, “anticipate,” “believe,” “can,” “could,” “expect,” “estimate,” “design,” “goal,” “intend,” “may,” “might,” “objective,” “plan,” “predict,” “project,” “target,” “likely,” “should,” “will,” and “would,” or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

Important factors that could cause actual results to differ materially from those reflected in Histogenics’ forward-looking statements include, among others: the timing and success of Histogenics’ NeoCart Phase 3 clinical trial, including, without limitation, possible delays in generating the data from the clinical trial; the ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; MEDINET’s ability to initiate NeoCart Clinical development in Japan in a timely manner; NeoCart’s regulation as a Regenerative Medical Product; the market size and potential patient population in Japan; the scope, progress, timing, expansion, and costs of developing and commercializing Histogenics’ product candidates; the ability to obtain and maintain regulatory approval regarding the comparability of critical NeoCart raw materials following our technology transfer and manufacturing location transition; the size and growth of the potential markets for Histogenics’ product candidates and the ability to serve those markets; Histogenics’ expectations regarding its expenses and revenue; and other factors that are described in the “Risk Factors” and “Management’s Discussion and

Analysis of Financial Condition and Results of Operations” sections of Histogenics’ Annual Report on Form 10-K for the year ended December 31, 2017, which is on file with the SEC and available on the SEC’s website at www.sec.gov. In addition to the risks described above and in Histogenics’ annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Histogenics’ results.

There can be no assurance that the actual results or developments anticipated by Histogenics will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Histogenics. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Histogenics or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Histogenics cautions investors not to rely too heavily on the forward-looking statements Histogenics makes or that are made on its behalf. The information conveyed on the conference call will be provided only as of the date of the call, and Histogenics undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements made during the call after the date thereof, whether as a result of new information, future events or otherwise.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
5.1	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
10.1	Equity Distribution Agreement, dated as of March 15, 2018, by and between Histogenics Corporation and Canaccord Genuity, Inc.
23.1	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (contained in Exhibit 5.1)
99.1	Press Release of Histogenics Corporation, dated March 15, 2018

SIGNATURE

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

HISTOGENICS CORPORATION

Date: March 15, 2018

By: /s/ Adam Gridley

Adam Gridley

President and Chief Executive Officer

March 15, 2018

Histogenics Corporation
830 Winter Street, 3rd Floor
Waltham, MA 02451

Ladies and Gentlemen:

We have acted as counsel to Histogenics Corporation, a Delaware corporation (the “**Company**”), and you have requested our opinion with respect to certain matters in connection with the offering by the Company of the number of authorized but unissued shares having aggregate sale proceeds of up to \$10 million (the “**Shares**”) of the Company’s common stock, par value \$0.01 (the “**Common Stock**”), registered and to be issued pursuant to the Registration Statement on Form S-3 (File No. 333-216741) originally filed with the Securities and Exchange Commission (the “**Commission**”) under the Securities Act of 1933, as amended (the “**Act**”), on March 16, 2017 (the “**Registration Statement**”), the related prospectus dated March 30, 2017, included in the Registration Statement (the “**Base Prospectus**”), and the prospectus supplement to be filed with the Commission pursuant to Rule 424(b) of the rules and regulations of the Act (the “**Prospectus Supplement**”). The Base Prospectus and the Prospectus Supplement are collectively referred to as the “**Prospectus**.” The Shares are to be sold by the Company in accordance with the Equity Distribution Agreement (the “**Sales Agreement**”), dated March 15, 2018, by and between the Company and Canaccord Genuity Inc., as described in the Prospectus Supplement.

In connection with this opinion, we have examined and relied upon the Registration Statement, the Prospectus, resolutions of the Company’s Board of Directors, the Sales Agreement, the Company’s Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as currently in effect, and the originals or copies certified to our satisfaction of such other documents, records, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. With your consent, we have relied upon certificates and other assurances of officers of the Company as to factual matters without having independently verified such factual matters. We have assumed the genuineness and authenticity of all documents submitted to us as originals, and the conformity to originals of all documents submitted to us as copies thereof and the due execution and delivery by all parties other than the Company of all documents where due execution and delivery are a prerequisite to the effectiveness thereof.

This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or the Prospectus, other than as expressly stated herein with respect to the issue of the Shares. Our opinion is limited to the matters stated herein and no opinion is implied or may be inferred beyond the matters expressly stated. Our opinion herein is expressed solely with respect to the General Corporation Law of the State of Delaware and we express no opinion with respect to any other laws. Our opinion is based on these laws as in effect on the date hereof, and we disclaim any obligation to advise you of facts, circumstances, events or developments which hereafter may be brought to our attention and which may alter, affect or modify the opinion expressed herein.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, the Shares have been duly authorized and when the Shares to be issued and sold by the Company are issued and paid for in accordance with the terms of the Sales Agreement, such Shares will be validly issued, fully paid and nonassessable.

We consent to the reference to our firm under the caption “Legal Matters” in the Prospectus Supplement and to the filing of this opinion as an exhibit to a Current Report of the Company on Form 8-K. 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 Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
GUNDERSON DETTMER STOUGH VILLENEUVE FRANKLIN & HACHIGIAN, LLP

HISTOGENICS CORPORATION
\$10,000,000
EQUITY DISTRIBUTION AGREEMENT

March 15, 2018

Canaccord Genuity Inc.
99 High Street, Suite 1200
Boston, Massachusetts 02110

Ladies and Gentlemen:

Histogenics Corporation, a Delaware corporation (the "Company"), confirms its agreement (this "Agreement") with Canaccord Genuity Inc. ("Canaccord"), as follows:

1. Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it will issue and sell through Canaccord, acting as sales agent, shares (the "Shares") of the Company's common stock, \$0.01 par value per share (the "Common Stock") having an aggregate offering price of up to \$10,000,000. The Shares will be sold on the terms set forth herein at such times and in such amounts as the Company and Canaccord shall agree from time to time. The issuance and sale of the Shares through Canaccord will be effected pursuant to the Registration Statement (as defined below) filed by the Company and declared effective by the Securities and Exchange Commission (the "Commission").

2. Placements.

- (a) Placement Notice. Each time that the Company wishes to issue and sell Shares hereunder (each, a "Placement"), it will notify Canaccord by e-mail notice (or other method mutually agreed to in writing by the parties) containing the parameters within which it desires to sell the Shares, which shall at a minimum include the number of Shares ("Placement Shares") to be issued, the time period during which sales are requested to be made, any limitation on the number of Shares that may be sold in any one day and any minimum price below which sales may not be made (a "Placement Notice"), a form of which shall be mutually agreed upon by the Company and Canaccord. The Placement Notice shall originate from any of the individuals (each an "Authorized Representative") from the Company set forth on Schedule 1 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the

individuals from Canaccord set forth on Schedule 1 attached hereto, as such Schedule 1 may be amended from time to time. The Placement Notice shall be effective upon confirmation by Canaccord unless and until (i) Canaccord declines to accept the terms contained therein for any reason, in its sole discretion, in accordance with the notice requirements set forth in Section 4, (ii) the entire amount of the Placement Shares have been sold, (iii) the Company suspends or terminates the Placement Notice in accordance with the notice requirements set forth in Section 4, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) the Agreement has been terminated under the provisions of Section 12.

- (i) Placement Fee. The amount of compensation to be paid by the Company to Canaccord with respect to each Placement (in addition to any expense reimbursement pursuant to Section 7(i)(ii)) shall be equal to 3.0% of gross proceeds from each Placement.
- (ii) No Obligation. It is expressly acknowledged and agreed that neither the Company nor Canaccord will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to Canaccord, and then only upon the terms specified therein and herein. It is also expressly acknowledged that Canaccord will be under no obligation to purchase Shares on a principal basis. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice control.

3. Sale of Placement Shares by Canaccord. Subject to the terms and conditions of this Agreement, upon the Company's issuance of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, Canaccord will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell on behalf of the Company and as agent, such Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. The Company acknowledges that Canaccord will conduct the sale of Placement Shares in compliance with applicable law including, without limitation, Regulation M under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and that such compliance may include a delay in commencement of sales efforts after receipt of a Placement Notice. Canaccord will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which they have made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to Canaccord with respect to such sales, and the Net Proceeds (as defined below) payable to the Company. Canaccord may sell Placement Shares by any method permitted by law deemed to be an "at the market" offering under Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), including without limitation sales made directly on or through The Nasdaq Capital Market (the "Principal Trading Market"), on any other existing trading market for the Common Stock, sales to or through a market maker other than on an exchange or in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices. Notwithstanding anything to the

contrary set forth in this Agreement or a Placement Notice, the Company acknowledges and agrees that (i) there can be no assurance that Canaccord will be successful in selling any Placement Shares or as to the price at which any Placement Shares are sold, if at all, and (ii) Canaccord will incur no liability or obligation to the Company or any other person or entity if they do not sell Placement Shares for any reason other than a failure by Canaccord to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell on behalf of the Company and as agent such Placement Shares as provided under this Section 3. For the purposes hereof, "Trading Day" means any day on which the Principal Trading Market is open for trading.

4. Suspension of Sales. The Company or Canaccord may, upon notice to the other party in writing, by telephone (confirmed immediately by verifiable facsimile transmission or e-mail) or by e-mail notice (or other method mutually agreed to in writing by the parties), suspend any sale of Placement Shares; provided, however, that such suspension shall not affect or impair either party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. The Company agrees that no such notice shall be effective against Canaccord unless it is made to one of the individuals named on Schedule 1 hereto, as such Schedule may be amended from time to time.

5. Settlement.

- (a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the third (3rd) Business Day (or such earlier day as is agreed by the parties to be industry practice for regular-way trading) following the date on which such sales are made (each a "Settlement Date"). The amount of proceeds to be delivered to the Company on a Settlement Date against the receipt of the Placement Shares sold ("Net Proceeds") will be equal to the aggregate sales price at which such Placement Shares were sold, after deduction for (i) the commission or other compensation for such sales payable by the Company to Canaccord, as the case may be, pursuant to Section 2 hereof, as the case may be, (ii) any other amounts due and payable by the Company to Canaccord hereunder pursuant to Section 7(i) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.
- (b) Delivery of Shares. On each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting Canaccord's accounts or its designee's account at The Depository Trust Company through its Deposit Withdrawal Agent Commission System or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Placement Shares, which in all cases shall be freely tradeable, transferable, registered shares in good deliverable form, Canaccord will, on each Settlement Date, deliver the related Net Proceeds in same day funds delivered to an account designated by the Company prior to the Settlement Date. If the Company defaults in its obligation to deliver Placement Shares on a Settlement Date, the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 10 hereto, it will (i) hold Canaccord

harmless against any loss, claim, damage, or expense (including legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to Canaccord any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, Canaccord that:

- (a) Registration Statement and Prospectus. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has filed all reports, schedules, forms, statements and other documents required to be filed by it with the Commission (the "Commission Documents") since the Company has been subject to the requirements of Section 12 of the Exchange Act, and all of such filings required to be filed within the last 12 months have been made on a timely basis. The Common Stock is currently quoted on the Principal Trading Market under the trading symbol "HSGX". The Company and the transactions contemplated hereby meet the requirements for use of Form S-3 under the Securities Act and the rules and regulations thereunder or the interpretations thereof by the Commission ("Rules and Regulations"), including but not limited to the transaction requirements for an offering made by the issuer set forth in Instruction I.B.6 to Form S-3. The Company has prepared and filed with the Commission a registration statement on Form S-3 (Registration Number 333-216741) with respect to the Shares to be offered and sold by the Company pursuant to this Agreement. Such registration statement, at any given time, including the amendments thereto at such time, the exhibits and any schedules thereto at such time, the documents incorporated by reference therein pursuant to Item 12 of Form S-3 under the Securities Act at such time and the documents otherwise deemed to be a part thereof or included therein by the Rules and Regulations, is herein called the "Registration Statement." The Registration Statement, including the base prospectus contained therein (the "Base Prospectus") was prepared by the Company in conformity with the requirements of the Securities Act and all applicable Rules and Regulations. One or more prospectus supplements relating to the Shares (the "Prospectus Supplements," and together with the Base Prospectus and any amendment thereto and all documents incorporated therein by reference, the "Prospectus") have been or will be prepared by the Company in conformity with the requirements of the Securities Act and all applicable Rules and Regulations and have been or will be filed with the Commission in the manner and time frame required by the Securities Act and the Rules and Regulations. Any amendment or supplement to the Registration Statement or Prospectus required by this Agreement will be so prepared and filed by the Company and, as applicable, the Company will use commercially reasonable efforts to cause it to become effective as soon as reasonably practicable. No stop order suspending the effectiveness of the Registration Statement has been issued, and no proceeding for that purpose has been instituted or, to the knowledge of the Company, threatened by the Commission. No order preventing or suspending the use of the Base Prospectus, the Prospectus Supplement, the Prospectus or any Issuer Free Writing Prospectus (as defined

herein) has been issued by the Commission. Copies of all filings made by the Company under the Securities Act and all Commission Documents that were filed with the Commission have either been delivered to Canaccord or made available to Canaccord on the Commission's Electronic Data Gathering, Analysis, and Retrieval system ("EDGAR"). Any reference herein to the Registration Statement, the Prospectus, or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated (or deemed to be incorporated) by reference therein pursuant to Item 12 of Form S-3 under the Securities Act, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For the purposes of this Agreement, the "Applicable Time" means, with respect to any Shares, the time of sale of such Shares pursuant to this Agreement.

- (b) No Misstatement or Omission. Each part of the Registration Statement, when such part became or becomes effective, at any deemed effective date pursuant to Rule 430B(f)(2) on the date of filing thereof with the Commission and at each Applicable Time and Settlement Date, and the Prospectus, on the date of filing thereof with the Commission and at each Applicable Time and Settlement Date, conformed or will conform in all material respects with the requirements of the Securities Act and the Rules and Regulations; each part of the Registration Statement, when such part became or becomes effective, did not or will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; and the Prospectus, on the date of filing thereof with the Commission, and the Prospectus and the applicable Issuer Free Writing Prospectus(es) issued at or prior to such Applicable Time, taken together (collectively, and with respect to any Shares, together with the public offering price of such Shares, the "Disclosure Package") and at each Applicable Time and Settlement Date, did not or will not include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; except that the foregoing shall not apply to statements or omissions in any such document made in reliance on information furnished in writing to the Company by Canaccord expressly stating that such information is intended for use in the Registration Statement, the Prospectus, or any amendment or supplement thereto, or in any Issuer Free Writing Prospectus(es).
- (c) Conformity with Securities Act and Exchange Act. The documents incorporated by reference in the Registration Statement or the Prospectus, or any amendment or supplement thereto, when they became effective under the Securities Act or were filed with the Commission under the Exchange Act, as the case may be, conformed in all material respects with the requirements of the Securities Act or the Exchange Act, as applicable, and the rules and regulations of the Commission promulgated under the Exchange Act or the interpretations thereof by the Commission (the "Exchange Act Regulations"), and none of such documents

contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein, or necessary to make the statements therein not misleading; and any further documents so filed and incorporated by reference in the Registration Statement or the Prospectus or any further amendment or supplement thereto, 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, the Rules and Regulations, the Exchange Act or the Exchange Act Regulations, as applicable, and will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, not misleading; provided however, that this representation and warranty shall not apply to any statements or omissions (a) that have been corrected in a filing that has been incorporated by reference in the Prospectus not less than 24 hours prior to the relevant Applicable Time or (b) made in reliance on information furnished in writing to the Company by Canaccord expressly stating that such information is intended for use in any such document.

- (d) Financial Information. The financial statements (including the related notes thereto and the supporting schedules) of the Company and its consolidated subsidiaries listed on Schedule 2 hereto (the “Subsidiaries”), set forth or incorporated by reference in the Registration Statement, Prospectus and Disclosure Package, have been and will be prepared in accordance with Regulation S-X under the Securities Act, in all material respects, and with United States generally accepted accounting principles (“GAAP”) consistently applied at the times and during the periods covered thereby (except (i) as may be otherwise indicated in such financial statements or the notes thereto, and (ii) in the case of unaudited interim statements, subject to normal year-end audit adjustments and the exclusion or condensing of certain footnotes), and fairly present in all material respects and will fairly present in all material respects the financial position of the Company as of the dates indicated and the results of its operations and the changes in its cash flows for the periods specified (subject, in the case of unaudited statements, to normal year-end adjustments); and the other financial information included or incorporated by reference in the Registration Statement, the Prospectus and the Disclosure Package has been derived from the accounting records of the Company and its Subsidiaries and presents fairly in all material respects the information shown thereby. The Company does not have any material liabilities or obligations, direct or contingent, which are not disclosed in the Registration Statement, Prospectus and Disclosure Package, as of the date of filing of those documents. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included in the Registration Statement, the Disclosure Package or the Prospectus under the Securities Act or the Rules and Regulations. All disclosures contained in the Registration Statement, the Disclosure Package or the Prospectus regarding “non-GAAP financial measures” (as such term is defined by the rules and regulations of the Commission) comply with Regulation G of the Exchange Act, and Item 10 of Regulation S-K of the Securities Act, to the extent applicable.

- (e) Company Not Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto and at the date hereof, the Company was not and is not an “ineligible issuer,” as defined in Rule 405 of the rules and regulations of the Commission, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.
- (f) Emerging Growth Company Status. As of the date hereof, the Company is an “emerging growth company” as defined in Section 2(a) of the Securities Act (an “Emerging Growth Company”).
- (g) Organization.
- (i) The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware with full corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement and Prospectus; and the Company is duly qualified as a foreign entity to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure, individually or in the aggregate, to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect on (i) the consolidated business, operations, assets, properties, financial condition, prospects or results of operations of the Company and its Subsidiaries taken as a whole, (ii) the transactions contemplated hereby or (iii) the ability of the Company to perform its obligations under this Agreement (collectively, a “Material Adverse Effect”).
- (ii) Each of the Subsidiaries has been duly formed and is validly existing (and in good standing, where applicable) under the laws of the jurisdiction of its formation has full power and authority to own, lease and operate its properties and conduct its business as described in the Registration Statement and their Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a Material Adverse Effect. All of the issued and outstanding share capital or other equity or ownership interests of each of the Company’s Subsidiaries has been duly authorized and validly issued, is fully paid and nonassessable (where such concept exists) and is owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim, except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus.

- (h) Subsidiaries. Except as described in the Prospectus, all of the assets described in the Prospectus as owned by the Subsidiaries of the Company are owned directly by the Subsidiaries. Except for the Subsidiaries, the Company owns no beneficial interest, directly or indirectly, in any corporation, partnership, joint venture, limited liability company or other entity.
- (i) Encumbrances. Except as described in the Registration Statement, Prospectus and Disclosure Package, each of the Company and its Subsidiaries has (i) good and marketable title to all of the properties and assets owned by it that are material to the business of the Company and the Subsidiaries taken as a whole, free and clear of all material liens, charges, claims, security interests or encumbrances (collectively, "Encumbrances"), except those that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, and (ii) possession under all material leases to which it is party as lessee. All leases and contracts to which the Company or its Subsidiaries is a party are valid and binding and no material default has occurred and is continuing thereunder, and no event or circumstance that with the passage of time or giving of notice, or both, would constitute such a material default has occurred and is continuing, and, to the knowledge of the Company, no defaults by the counterparties exist under any such leases or contracts.
- (j) No Improper Practices. (i) Neither the Company nor the Subsidiaries, nor to the knowledge of the Company, any director, officer, agent, employee or other person associated with or acting on behalf of the Company or the Subsidiaries, has, in the past five years, used any corporate funds of Company for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds of Company, violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977; or made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment; (ii) no relationship, direct or indirect, exists between or among the Company or, to the knowledge of the Company, the Subsidiaries, on the one hand, and the directors, officers and stockholders of the Company or, to the knowledge of the Company, the Subsidiaries, on the other hand, that is required by the Securities Act to be described in the Registration Statement and the Prospectus that is not so described; (iii) no relationship, direct or indirect, exists between or among the Company or the Subsidiaries or any affiliate of them, on the one hand, and the directors, officers, stockholders or directors of the Company or, to the knowledge of the Company, the Subsidiaries, on the other hand, that is required by the rules of the Financial Industry Regulatory Authority ("FINRA") to be described in the Registration Statement and the Prospectus that is not so described; and (iv) except as described in the Prospectus, there are no material outstanding loans or advances or material guarantees of indebtedness by the Company or, to the knowledge of the Company, the Subsidiaries to or for the benefit of any of their respective officers or directors or any of the members of the families of any of them.

- (k) Investment Company Act. The Company is not now and, after giving effect to the offering and sale of the Shares, will not be required to register as an “investment company” or an entity “controlled” by an “investment company,” as such terms are defined in the Investment Company Act of 1940, as amended (the “Investment Company Act”).
- (l) Capitalization. The Company has an authorized capitalization as set forth in the Registration Statement, the Disclosure Package and the Prospectus as of the date or dates set forth therein. All of the issued shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and have been issued in compliance with all applicable United States federal and state and all applicable foreign securities laws; and all of the issued shares of capital stock or other equity interests of the Subsidiaries have been duly and validly authorized and issued and are fully paid and non-assessable (except, in the case of any foreign subsidiary, for directors’ qualifying shares) and the shares of such Subsidiaries are owned directly or indirectly by the Company and are held free and clear of all Encumbrances. None of the outstanding shares of Common Stock were issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. Except as may be described in the Registration Statement and the Prospectus, and except with respect to equity awards issued under the Company’s equity incentive plans, there are no outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company.
- (m) Stock Options. With respect to the outstanding stock options (the “Stock Options”) granted pursuant to the stock-based compensation plans of the Company (the “Company Stock Plans”), (i) each Stock Option intended to qualify as an “incentive stock option” under Section 422 of the Internal Revenue Code of 1986, as amended (the “Code”), so qualified, (ii) 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, (iii) each such grant was made in accordance with the terms of the Company Stock Plans and all other applicable laws and regulatory rules or requirements, except where the failure to comply with such laws, regulatory rules or requirements would not result in a Material Adverse Effect, and (iv) each such grant was properly accounted for in accordance with GAAP in the financial statements (including the related notes) of the Company included in the Registration Statement, the Disclosure Package and the Prospectus, to the extent required under GAAP to be accounted for in such financial statements.

- (n) The Shares. The Shares have been duly authorized and, when issued, delivered and paid for pursuant to this Agreement, will be validly issued, fully paid and non-assessable, free and clear of all Encumbrances and will be issued in compliance with all applicable United States federal and state and all applicable foreign securities laws; the capital stock of the Company, including the Common Stock, conforms in all material respects to the description thereof contained in the Registration Statement and the Common Stock, including the Placement Shares, will conform to the description thereof contained in the Prospectus as amended or supplemented. Neither the stockholders of the Company, nor any other person or entity have any preemptive rights or rights of first refusal with respect to the Placement Shares, or other rights to purchase or receive any of the Placement Shares or any other securities or assets of the Company, and no person has the right, contractual or otherwise, to cause the Company to issue to it, or register pursuant to the Securities Act, any shares of capital stock or other securities or assets of the Company upon the issuance or sale of the Placement Shares, in each case except for rights that have been validly waived.
- (o) No Material Changes. Since the date of the most recent financial statements of the Company set forth or incorporated by reference in the Registration Statement, the Prospectus and the Disclosure Package, (i) neither the Company nor any of the Subsidiaries has sustained any material loss or interference with the business of the Company and its Subsidiaries, taken as a whole, including without limitation, from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, except in each case as otherwise disclosed in the Registration Statement, Prospectus and Disclosure Package; (ii) there have been no transactions entered into by the Company or the Subsidiaries which are material to the Company and its Subsidiaries, considered as a whole, (iii) there has not been any material change, on a consolidated basis, in the authorized capital stock of the Company and its Subsidiaries (other than the issuance of shares of Common Stock upon the exercise of stock options and warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Registration Statement, Prospectus and Disclosure Package), any material increase in the short-term debt or long-term debt of the Company and its Subsidiaries, on a consolidated basis, 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 Effect, or any development reasonably likely to cause or result in a Material Adverse Effect.

(p) Legal Proceedings.

- (i) Except as set forth in the Registration Statement, Prospectus and Disclosure Package, there is no legal, governmental, administrative or other claim, proceeding, investigation, action, suit or inquiry pending, or, to the knowledge of the Company, threatened against or affecting the Company or its Subsidiaries or any of their respective properties or to which the Company or its Subsidiaries is or may be a party or to which any property of the Company or its Subsidiaries is or may be the subject, or against any officer, director or employee of the Company or the Subsidiaries in connection with such person's employment therewith that, if determined adversely to the Company or the Subsidiaries or such officer, director or employee, would individually or in the aggregate have, or reasonably be expected to result in, a Material Adverse Effect. Neither the Company nor its Subsidiaries is a party to or subject to the provisions of, any order, writ, injunction, judgment or decree of any court or government agency or instrumentality which would have a Material Adverse Effect.
- (ii) There are no legal, governmental or administrative proceedings, investigations, actions, suits or inquiries or contracts or documents of the Company or its Subsidiaries that are required to be described in or filed as exhibits to the Commission Documents, Registration Statement or any of the documents incorporated by reference therein by the Securities Act or the Exchange Act or by the rules and regulations of the Commission thereunder that have not been so described or filed as required by the Securities Act or the Exchange Act and the Rules and Regulations under either of them.

(q) Authorization; Enforceability.

- (i) The Company has all requisite corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, to provide the representations, warranties and indemnities under this Agreement and all necessary action has been duly and validly taken by the Company to authorize the execution, delivery and performance of this Agreement. This Agreement has been duly and validly authorized, executed and delivered by the Company and constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as rights to indemnification and contribution hereunder may be limited by applicable law and except as enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting the enforcement of creditors' rights generally and by general equitable principles (whether applied in a proceeding in law or equity).
- (ii) Executing and delivering this Agreement and the issuance and sale of the Shares and the compliance by the Company with all of the provisions of this Agreement and the consummation of the transactions contemplated herein will not result in (i) a breach or violation of any of the terms and provisions of, or constitute a default under, any obligation, agreement, covenant or condition contained in any indenture, mortgage, deed of trust,

loan or credit agreement or other agreement or instrument to which the Company or its Subsidiaries is a party or by which either of them is bound or to which any of the property of the Company or its Subsidiaries is subject, (ii) a violation of the Company's certificate of incorporation or bylaws, (iii) a violation of any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or its Subsidiaries or any of their properties, or (iv) the creation of any material Encumbrance upon any assets of the Company or its Subsidiaries or the triggering, solely as a result of the Company's execution and delivery of this Agreement, of any preemptive or anti-dilution rights or rights of first refusal or first offer, or any similar rights (whether pursuant to a "poison pill" provision or otherwise), on the part of holders of the Company's securities or any other person, except, in the cases of (i), (iii) and (iv) above, for any such conflict, breach, violation, creation or default that would not, individually or in the aggregate, have a Material Adverse Effect. Neither the Company nor its Subsidiaries or affiliates, nor any person acting on its or their behalf, has issued or sold any shares of Common Stock or securities or instruments convertible into, exchangeable for and/or otherwise entitling the holder thereof to acquire shares of Common Stock which would be integrated with the offer and sale of the Shares hereunder.

- (r) Enforceability of Agreements. All agreements between the Company and third parties expressly referenced in the Prospectus are legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification provisions of certain agreements may be limited by federal or state securities laws or public policy considerations in respect thereof and except for any unenforceability that, individually or in the aggregate, would not reasonably be expected to result in a Material Adverse Effect.
- (s) Registration Rights. There are no persons with registration rights or other similar rights to have any securities registered for sale pursuant to the Registration Statement or otherwise registered for sale or sold by the Company under the Securities Act pursuant to this Agreement, other than those rights that have been disclosed in the Registration Statement, the Disclosure Package and the Prospectus and have been waived or satisfied
- (t) No Violations or Default. The Company and each of its Subsidiaries is not (A) in violation of its charter or by-laws or other applicable governing documents, (B) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease or other agreement or instrument to which the Company or any of its Subsidiaries is a party or by which it may be bound or to which any of the properties or assets of the Company or any of its Subsidiaries is

subject (collectively, “Agreements and Instruments”), except for such defaults that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, or (C) in violation of any law, statute, rule, regulation, judgment, order, writ or decree of any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency having jurisdiction over the Company or any of its Subsidiaries or any of their respective properties, assets or operations (each, a “Governmental Entity”), except for such violations that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the Disclosure Package and the Prospectus and compliance by the Company with its obligations hereunder have been duly authorized by all necessary corporate action and do not and will not, whether with or without the giving of notice or passage of time or both, conflict with or constitute a breach of, or default or Repayment Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or any of its Subsidiaries pursuant to, the Agreements and Instruments (except for such conflicts, breaches, defaults or Repayment Events or liens, charges or encumbrances that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect), nor will such action result in any violation of (i) the provisions of the charter or by-laws or similar organization document of the Company or any of its Subsidiaries or (ii) any law, statute, rule, regulation, judgment, order, writ or decree of any Governmental Entity, except with respect to clause (ii), such violations as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. As used herein, a “Repayment Event” means any event or condition which gives the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder’s behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its Subsidiaries.

- (u) Compliance with Laws. The Company and its Subsidiaries have not violated and are in compliance with all laws, statutes, ordinances, regulations, rules and orders of each foreign, federal, state or local government and any other governmental department or agency having jurisdiction over the Company and the Subsidiaries, and any judgment, decision, decree or order of any court or governmental agency, department or authority having jurisdiction over the Company and the Subsidiaries, except for such violations or noncompliance which, individually or in the aggregate, would not have a Material Adverse Effect.
- (v) Compliance with Healthcare Laws. Except as would not reasonably be expected to result in a Material Adverse Effect, the Company and each of its Subsidiaries is conducting its business in compliance with all applicable health care laws, rules, and regulations of each jurisdiction in which it conducts its business (collectively, the “Health Care Laws”), including, without limitation, (A) the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.), and the rules and regulations promulgated thereunder (as amended, collectively, the “FFDCA”), (B) all

applicable federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)), the Stark Law (42 U.S.C. §1395nn), the civil False Claims Act (31 U.S.C. § 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code and the regulations promulgated pursuant to such statutes, (C) the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (18 U.S.C. §§669, 1035, 1347 and 1518; 42 U.S.C. §1320d et seq.) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and the regulations promulgated thereunder, (D) the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (42 U.S.C. §1395w-101 et seq.) and the regulations promulgated thereunder, (E) the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, (F) Medicare (Title XVIII of the Social Security Act) and the regulations promulgated thereunder, and (G) Medicaid (Title XIX of the Social Security Act) and the regulations promulgated thereunder, each of such applicable laws, rules and regulations as may be amended from time to time.

- (w) Consents and Permits. The Company and each of its Subsidiaries possesses such permits, licenses, certificates, approvals, clearances, consents and other authorizations (collectively, "Governmental Licenses") issued by the appropriate Governmental Entities necessary to conduct the business now operated by them, which may include, without limitation, such Governmental Licenses required by the United States Food and Drug Administration (the "FDA"), CE marking approval in the European Union and such Governmental Licenses and approvals required in Japan, except where the failure to possess would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. The Company and each of its Subsidiaries is in compliance with the terms and conditions of all Governmental Licenses and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or result in any other material impairment of the rights of the holder of any Government License, except where the failure so to comply would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. All of the Governmental Licenses are valid and in full force and effect. Neither the Company nor any of its Subsidiaries (a) has received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any U.S. or non-U.S. Governmental Entity or third party alleging that any product, operation or activity is in violation of any Health Care Laws or Governmental Licenses and has no knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (b) has received written notice that the FDA or any other Governmental Entity has taken, is taking or intends to take regulatory action, including, without limitation, any FDA Form 483 notice of adverse finding, warning letter, untitled letter or similar correspondence or notice, and has no knowledge that the FDA or any other Governmental Entity is considering such action; (c) has, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted

or issued, any recall, safety alert, or similar notice or action relating to any alleged product defect or violation of Health Care Laws; and (d) is a party to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, or similar agreements, or has any reporting obligations pursuant to any such agreement, plan or correction or other remedial measure entered into with any Governmental Entity. Neither the Company nor any of its Subsidiaries, nor their respective officers, directors, employees, agents or contractors have been or are currently excluded from participation in the Medicare and Medicaid programs or any other state or federal health care program.

- (x) Absence of Further Requirements. No filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any Governmental Entity is necessary or required for the performance by the Company of its obligations hereunder, in connection with the offering, sale of the Shares hereunder or the consummation of the transactions contemplated by this Agreement, except such as have been already obtained or as may be required under the Securities Act, the Rules and Regulations, the rules of The Nasdaq Stock Market LLC, state securities laws or the rules of the Financial Industry Regulatory Authority, Inc. (“FINRA”)
- (y) Insurance. On the date hereof, and after the date hereof other than as set forth in the Prospectus, the Company and its Subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as is prudent, reasonable and customary for companies engaged in similar businesses in similar industries; neither the Company nor its Subsidiaries has received notice from any insurer or agent of such insurer that material capital improvements or other expenditures will have to be made in order to continue such insurance; all such insurance is outstanding and in full force and effect and neither the Company nor the Subsidiaries has received any notice of cancellation or proposed cancellation relating to such insurance.
- (z) Environmental Laws.
 - (i) Except as described in the Registration Statement, the Disclosure Package and the Prospectus or would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, (A) neither the Company nor any of Subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mold

(collectively, “Hazardous Materials”) or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, “Environmental Laws”), (B) the Company and each of its Subsidiaries has all permits, authorizations and approvals required under any applicable Environmental Laws and is in compliance with their requirements, (C) there are no pending or, to the knowledge of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its Subsidiaries and (D) to the knowledge of the Company, there are no existing events, conditions or facts that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or Governmental Entity, against or affecting the Company or any of its Subsidiaries relating to Hazardous Materials or any Environmental Laws.

- (ii) In the ordinary course of its business, the Company conducts a periodic review of the effect of Environmental Laws on the business, operations and properties of the Company and its Subsidiaries, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, individually or in the aggregate, have a Material Adverse Effect.
- (aa) Independent Public Accountants. Grant Thornton LLP, which has audited the consolidated balance sheets of the Company as of December 31, 2017 and 2016 and the consolidated statements of operations, comprehensive loss, changes in stockholders’ equity, and cash flows for the years then ended, which are all included in or incorporated by reference in the Registration Statement and the Prospectus, is a registered independent public accounting firm as required by the Securities Act, the Rules and Regulations and the Exchange Act.
- (bb) 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 Commission Documents, the Registration Statement or the Prospectus, has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.
- (cc) Title to Property. The Company and the Subsidiaries has good and marketable title to all real property owned by it and good title or valid leases to all personal property owned by it, in each case, free and clear of all mortgages, pledges, liens, security interests, claims, restrictions or encumbrances (except for customary

easements and rights of way) of any kind except such as (A) are described in the Registration Statement, the Disclosure Package and the Prospectus or (B) do not, singly or in the aggregate, materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries; and all of the leases and subleases material to the business of the Company and that of the Subsidiaries and under which the Company or any of its Subsidiaries holds properties described in the Registration Statement, the Disclosure Package or the Prospectus, are in full force and effect, and neither the Company nor any of its Subsidiaries has received any written notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any of its Subsidiaries under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or any of its Subsidiaries to the continued possession of the leased or subleased premises under any such lease or sublease

- (dd) Possession of Intellectual Property. Except as would not reasonably be expected to result in a Material Adverse Effect, (i) the Company and the Subsidiaries, owns all right, title and interest in or otherwise have the right to use all patents, inventions, copyrights, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, trade names and other intellectual property rights (collectively, “Intellectual Property”) that is necessary for, used or held for use in, or otherwise exploited in connection with, the conduct of the business now operated by them, and (ii) to the Company’s knowledge, neither the Company nor any of its Subsidiaries is infringing, misappropriating, diluting or otherwise violating the Intellectual Property of any third party. Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus or as would not reasonably be expected to result in a Material Adverse Effect, (i) no action, suit, claim, or other proceeding is pending, or to the Company’s knowledge, is threatened, alleging that the Company or any of its Subsidiaries is infringing, misappropriating, diluting, or otherwise violating the Intellectual Property of any third party in any respect, (ii) to the Company’s knowledge, no third party is infringing, misappropriating, diluting, or otherwise violating the Company or any of its Subsidiaries’ Intellectual Property in any respect, and (iii) no action, suit, claim, or other proceeding is pending, or to the Company’s knowledge, is threatened, challenging the validity, enforceability, scope, registration, ownership or use of any Intellectual Property of the Company or any of its Subsidiaries that is, singly or in the aggregate, necessary to its business (with the exception of office actions in connection with applications for the registration or issuance of such Intellectual Property).
- (ee) Taxes.
- (i) The Company was not, for the immediately preceding taxable year, treated as, will not, for the current taxable year, be treated as, and does not anticipate that, for any subsequent taxable year, it will be treated as a “passive foreign investment company,” a “foreign investment company” or a “foreign personal holding company” for United States federal income tax purposes.

- (ii) The Company has filed all United States federal and state and all applicable local and foreign income tax returns which have been required to be filed through the date hereof, except in any case in which the failure to so file would not, individually or in the aggregate, have a Material Adverse Effect.
- (iii) The Company has paid all United States federal, state and local and foreign taxes required to be paid and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing would otherwise be delinquent, except, in all cases, for any such tax, assessment, fine or penalty that is being contested in good faith and except in any case in which the failure to so pay would not, individually or in the aggregate, result in a Material Adverse Effect.
- (iv) No stamp or other issuance or transfer taxes or duties and no capital gains, income, withholding or other taxes are payable by or on behalf of Canaccord to any political subdivision or taxing authority in connection with the sale and delivery by the Company of the Placement Shares to or for the account of Canaccord or the sale and delivery by Canaccord of the Placement Shares to the purchasers thereof.
- (ff) No Reliance. The Company has not relied upon Canaccord or legal counsel for Canaccord for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.
- (gg) Underwriter Agreements. Except for this Agreement, the Company is not a party to any agreement with an agent or underwriter for any other “at the market” or continuous equity transaction or negotiated or underwritten public offering.
- (hh) Disclosure Controls.
 - (i) The Company has established and maintains disclosure controls and procedures (as such term is defined in Rule 13a-15 under the Exchange Act), which (a) are designed to ensure that material information relating to the Company, including its consolidated Subsidiaries, is made known to the Company’s principal executive officer and its principal financial officer by others within those entities, particularly during the preparation of the Registration Statement; (b) have been evaluated for effectiveness as of the date of the filing of the Registration Statement with the Commission; and (c) are effective in all material respects to perform the functions for which they were established.
 - (ii) The Company (a) makes and keeps accurate books and records and (b) maintains internal accounting controls which provide reasonable assurance that (1) transactions are executed in accordance with

management's authorization, (2) transactions are recorded as necessary to permit preparation of its financial statements and to maintain accountability for its assets, (3) access to its assets is permitted only in accordance with management's authorization and (4) the reported accountability for its assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

- (ii) Accounting Controls. Except as described in the Registration Statement, the Disclosure Package and the Prospectus, the Company maintains effective internal control over financial reporting (as defined under Rule 13a-15 and 15d-15 of the Exchange Act Regulations) and a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (E) the interactive data in eXtensible Business Reporting Language incorporated by reference in the Registration Statement, the Disclosure Package and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as described in the Registration Statement, the Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (1) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.
- (jj) Certain Market Activities. The Company has not taken, directly or indirectly, without giving effect to activities by Canaccord, any action designed to, or that might be reasonably expected to, cause or result in stabilization or manipulation of the price of the Shares.
- (kk) Broker/Dealer Relationships. Neither the Company nor the Subsidiaries or any related entities (i) is required to register as a "broker" or "dealer" in accordance with the provisions of the Exchange Act or (ii) directly or indirectly through one or more intermediaries, controls or is a "person associated with a FINRA member" or "associated person of a FINRA member" (within the meaning of Article I of the Bylaws of the FINRA).
- (ll) No Integration. The Company has not sold or issued any securities that would be integrated with the sale of the Placement Shares contemplated by this Agreement pursuant to the Securities Act or the Rules and Regulations.

- (mm) Sarbanes-Oxley. The principal executive officer and principal financial officer of the Company have made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the “Sarbanes-Oxley Act”) with respect to all reports, schedules, forms, statements and other documents required to be filed by it with the Commission, and the statements contained in any such certification are complete and correct. The Company, and to its knowledge, all of the Company’s directors or officers, in their capacities as such, are in compliance in all material respects with all applicable effective provisions of the Sarbanes-Oxley Act.
- (nn) Finder’s Fees. Neither the Company nor the Subsidiaries has incurred any liability for any brokerage commission, finder’s fees or similar payments in connection with the transactions herein contemplated, except as may otherwise exist with respect to Canaccord pursuant to this Agreement.
- (oo) Labor Disputes. No labor dispute with the employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is imminent, and the Company has no knowledge of any existing or imminent labor dispute by the employees of any of its principal suppliers, manufacturers or contractors.
- (pp) Canaccord Purchases. The Company acknowledges and agrees that Canaccord has informed the Company that Canaccord may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell the shares of Common Stock for Canaccord’s own account and for the account of its clients at the same time as sales of Placement Shares occur pursuant to this Agreement.
- (qq) No Registration Rights. Except as may be described in the Prospectus, including the documents incorporated therein by reference, neither the Company nor its Subsidiaries is party to any agreement that provides any person with the right to require the Company or 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 Placement Shares.
- (rr) Prospectus Disclosure. The statements set forth in the Prospectus under the caption “Description of Capital Stock” insofar as they purport to constitute a summary of the terms of the Shares, under the caption “Plan of Distribution,” insofar as they purport to describe the provisions of the laws and documents referred to therein and under the caption “Material United States Federal Income Tax Consequences to Non-U.S. Holders of Our Common Stock” insofar as they purport to describe the provisions of the laws and documents referred to therein, are accurate and complete.
- (ss) OFAC. Neither the Company, any of the Subsidiaries nor, to the knowledge of the Company, its or their respective directors, officers, agents, employees, affiliates or representatives (each, a “Person”) are currently the subject of sanctions administered or enforced by the United States Government, including, without limitation, the U.S. Department of the Treasury’s Office of Foreign

Assets Control (“OFAC”), the United Nations Security Council, the European Union, Her Majesty’s Treasury, or other relevant sanctions authority applicable to the Company and its Subsidiaries (collectively, “Sanctions”), nor is the Company or any of the Subsidiaries located, organized or resident in a country or territory that is the subject of Sanctions; and the Company does not intend to, directly or indirectly, use the proceeds of the sale of the Placement Shares, or lend, contribute or otherwise make available such proceeds to any Subsidiaries, joint venture partners or other Person, to fund any activities of or business with any Person, or in any country or territory, that, at the time of such funding, is the subject of Sanctions or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

- (tt) Operations. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions to which the Company and its Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “Money Laundering Laws”), except as would not reasonably be expected to result in a Material Adverse Effect; and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.
- (uu) Off-Balance Sheet Arrangements. There are no transactions, arrangements and other relationships between and/or among the Company, and/or, to the knowledge of the Company, any of its affiliates and any unconsolidated entity, including, but not limited to, any structural finance, special purpose or limited purpose entity (each, an “Off Balance Sheet Transaction”) that could reasonably be expected to affect materially the Company’s liquidity or the availability of or requirements for its capital resources, including those Off Balance Sheet Transactions described in the Commission’s Statement about Management’s Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), required to be described in the Prospectus which have not been described as required.
- (vv) ERISA. Other than as would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect and except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, (i) no “employee benefit plan” (as defined in Section 3(3) of ERISA), for which the Company would have any liability (whether absolute or contingent) (each a “Plan”) has experienced a failure to satisfy the “minimum funding standard” (as defined in Section 302 of the Employee Retirement Income Security Act of 1974, as amended, (“ERISA”) or Section 412 of the Code, or other event of the kind described in Section 4043(c) of ERISA (other than events with respect to which

the 30-day notice requirement under Section 4043 of ERISA has been waived) or any similar minimum funding failure event with respect to any Plan (other than a Plan that under applicable law is required to be funded by a trust or funding vehicle maintained exclusively by a governmental authority) that is maintained outside of the United States primarily for the benefit of persons substantially all of whom are nonresident aliens (ii) each Plan is in compliance in all respects with applicable law, including, without limitation, ERISA and the Code; (iii) other than in the ordinary course, neither the Company nor any trade or business, whether or not incorporated, that, together with the Company, would be deemed to be a “single employer” within the meaning of Section 4001(b)(1) of ERISA or Section 414(b), 414(c), 414(m) or 414(o) of the Code has incurred or reasonably expects to incur any liability with respect to any Plan (A) under Title IV of ERISA or (B) in respect of any post-employment health, medical or life insurance benefits for former, current or future employees of the Company, except as required to avoid excise tax under Section 4980B of the Code and except, on a case by case basis, limited extensions of health insurance benefits (for a period of no more than 18 months post-employment) to former employees receiving severance payments from the Company; and (iv) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or by failure to act, which could cause the loss of such qualification. The Company is not, nor at any time during the last three years has the Company been, a party to any collective bargaining agreement or other labor agreement with respect to employees of the Company. There are no pending, or, to the Company’s knowledge, threatened, activities or proceedings by any labor union or similar entity to organize any employees of the Company. No labor dispute with, or labor strike, work stoppage or other material labor disturbance by, the employees of the Company exists or to the Company’s knowledge is imminent.

- (ww) No Misstatement or Omission in an Issuer Free Writing Prospectus. Each issuer free writing prospectus, as defined in Rule 405 under the Securities Act (an “Issuer Free Writing Prospectus”), as of the Applicable Time did not or will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; provided, however, that the Company makes no representation or warranty with respect to any statement contained in any Issuer Free Writing Prospectus in reliance upon and in conformity with written information furnished to the Company by and through Canaccord for use therein.
- (xx) Conformity of Issuer Free Writing Prospectus. Each Issuer Free Writing Prospectus conformed or will conform in all material respects with the requirements of the Securities Act on the date of first use, and the Company has complied or will comply with any filing requirements applicable to such Issuer Free Writing Prospectus pursuant to the Securities Act. Each Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Placement Shares, did not, does not and will not include any information that conflicted, conflicts or will conflict with the

information contained in the Registration Statement or the Prospectus, including any document incorporated by reference therein that has not been superseded or modified. The Company has not made any offer relating to the Shares that would constitute an Issuer Free Writing Prospectus without the prior written consent of Canaccord. The Company has retained in accordance with the Securities Act all Issuer Free Writing Prospectuses that were not required to be filed pursuant to the Securities Act.

- (yy) Clinical Studies. The clinical, pre-clinical and other studies and tests conducted by or on behalf of the Company, any of its Subsidiaries or in which the Company or its products or product candidates has participated, were and, if still pending, are being conducted in material accordance with experimental protocols, procedures and controls and in material accordance with all applicable local, state, federal and foreign laws, rules, regulations and guidance, including, without limitation, the FDCA. None of the descriptions of the tests and preclinical and clinical studies, conducted by or on behalf of the Company contained in the Registration Statement, the Disclosure Package and the Prospectus contains an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Company is not aware of any studies, tests or trials the results of which the Company believes reasonably call into question the study, test or trial results described or referred to in the Registration Statement, the Disclosure Package and the Prospectus when viewed in the context in which such results are described and the clinical state of development. Except to the extent disclosed in the Registration Statement, the Disclosure Package and the Prospectus, no investigational device exemption filed by or on behalf of the Company with the FDA or a Governmental Entity has been terminated or suspended by the FDA or Governmental Entity, and neither the FDA nor any Governmental Entity has commenced, or, to the knowledge of the Company, threatened to initiate, any action to place a clinical hold order on, or otherwise terminate or suspend any ongoing studies, tests or preclinical or clinical trials or investigations conducted or proposed to be conducted by or on behalf of the Company or any of its Subsidiaries.
- (zz) Lending Relationship. Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, the Company (A) does not have any material lending or other relationship with any bank or lending affiliate of Canaccord and (B) does not intend to use any of the proceeds from the sale of the Placement Shares to repay any outstanding debt owed to any affiliate of Canaccord.
- (aaa) Statistical and Market-Related Data. Any statistical and market-related data included in the Registration Statement, the Disclosure Package or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate in all material respects and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

- (bbb) Maintenance of Rating. The Company does not have any securities rated by any “nationally recognized statistical rating organization” (as defined for purposes of Rule 436(g) under the Securities Act).
- (ccc) Related Party Transactions. There are no business relationships or related-party transactions involving the Company, any of the Subsidiaries or any other person required to be described in the Registration Statement, the Prospectus and the Disclosure Package which have not been described as required. The Disclosure Package contains in all material respects the same description of the matters set forth in the preceding sentence contained in the Prospectus.
- (ddd) Margin Rules. The application of the proceeds received by the Company from the issuance, sale and delivery of the Placement Shares as described in the Registration Statement, the 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.

7. Covenants of the Company. The Company covenants and agrees with Canaccord that:

- (a) Registration Statement Amendments. After the date of this Agreement and during the period in which a prospectus relating to the Placement Shares is required to be delivered by Canaccord under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or Rule 173(a) under the Securities Act), (i) the Company will notify Canaccord promptly of the time when any subsequent amendment to the Registration Statement has been filed with the Commission and has become effective (each, a “Registration Statement Amendment Date”) or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information; (ii) the Company will file promptly all other material required to be filed by it with the Commission pursuant to Rule 433(d) under the Securities Act; (iii) it will prepare and file with the Commission, promptly upon Canaccord’s request, any amendments or supplements to the Registration Statement or Prospectus that, in Canaccord’s reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by Canaccord (provided, however that the failure of Canaccord to make such request shall not relieve the Company of any obligation or liability hereunder, or affect Canaccord’s right to rely on the representations and warranties made by the Company in this Agreement); and (iv) the Company will submit to Canaccord a copy of any amendment or supplement to the Registration Statement or Prospectus a reasonable period of time before the filing thereof and will afford Canaccord and Canaccord’s counsel a reasonable opportunity to comment on any such proposed filing prior to such proposed filing; and the Company will cause each amendment or supplement to the Prospectus to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424 (b) of the Rules and Regulations or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed.

- (b) Notice of Commission Stop Orders. The Company will advise Canaccord, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of the Prospectus or other prospectus in respect of the Shares, of any notice of objection of the Commission to the use of the form of the Registration Statement or any post-effective amendment thereto pursuant to Rule 401(g)(2) under the Securities Act, of the suspension of the qualification of the Shares for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the form of the Registration Statement or the Prospectus or for additional information; and, in the event of the issuance of any such stop order or of any such order preventing or suspending the use of the Prospectus in respect of the Shares or suspending any such qualification, to promptly use its commercially reasonable efforts to obtain the withdrawal of such order; and in the event of any such issuance of a notice of objection, promptly to take such reasonable steps as may be necessary to permit offers and sales of the Placement Shares by Canaccord, which may include, without limitation, amending the Registration Statement or filing a new registration statement, at the Company's expense (references herein to the Registration Statement shall include any such amendment or new registration statement).
- (c) Delivery of Prospectus; Subsequent Changes. Within the time during which a prospectus relating to the Placement Shares is required to be delivered by Canaccord under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or Rule 173(a) under the Securities Act), the Company will comply with all requirements imposed upon it by the Securities Act and by the Rules and Regulations, as from time to time in force, and will file on or before their respective due dates all reports required to be filed by it with the Commission pursuant to Sections 13(a), 13(c), 15(d), if applicable, or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will immediately notify Canaccord to suspend the offering of Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance.
- (d) Nasdaq Filings. In connection with the offering and sale of the Placement Shares, the Company will file with The Nasdaq Capital Market all documents and notices, and make all certifications, required by The Nasdaq Capital Market of companies that have securities that are listed on The Nasdaq Capital Market.

- (e) Listing of Placement Shares. The Company will use commercially reasonable efforts to cause the Placement Shares to be listed on the Principal Trading Market and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as Canaccord designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; provided that the Company shall not be required in connection therewith to 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 or to file a general consent to service of process in any such jurisdiction or subject itself to taxation in any such jurisdiction if it is not otherwise so subject.
- (f) Delivery of Registration Statement and Prospectus. The Company will furnish to Canaccord and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during the period in which a prospectus relating to the Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as Canaccord may from time to time reasonably request and, at Canaccord's request, will also furnish copies of the Prospectus to each exchange or market on which sales of Placement Shares may be made.
- (g) Company Information. The Company will furnish to Canaccord for a period of one (1) year from the date of this Agreement such information as is furnished to holders of the Shares or furnished to or filed with the Commission or any national securities exchange or automatic quotation system and is reasonably requested by Canaccord regarding the Company or its Subsidiaries.
- (h) Earnings Statement. The Company will make generally available to its security holders as soon as reasonably practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) of the Securities Act and Rule 158 of the Rules and Regulations.
- (i) Expenses.
 - (i) The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, will pay or cause to be paid all expenses incident to the performance of its obligations hereunder, including but not limited to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of each Prospectus and of each amendment and supplement thereto and each

Issuer Free Writing Prospectus (as defined in Section 8 of this Agreement), (ii) the preparation, issuance and delivery of the Placement Shares, (iii) all fees and disbursements of the Company's counsel, accountants and other advisors, (iv) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(e) of this Agreement, including filing fees in connection therewith, (v) the printing and delivery to Canaccord of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (vi) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on the Exchange, and (vii) any filing fees and expenses incident to any review by the Financial Industry Regulatory Authority (including reasonable fees and disbursements of counsel to Canaccord incurred in connection therewith) of the terms of the sale of the Placement Shares.

- (ii) In addition to any fees that may be payable to Canaccord hereunder and regardless of whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, the Company shall reimburse Canaccord for all of its reasonable expenses, up to a maximum reimbursement of \$50,000, arising out of this Agreement (including travel and related expenses, the costs of document preparation, production and distribution, third party research and database services and the reasonable fees and disbursements of counsel to Canaccord) within ten (10) days of the presentation by Canaccord to the Company of a reasonably detailed statement therefor.
- (j) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus.
- (k) Other Sales. Without the prior written consent of Canaccord (which consent shall not be unreasonably withheld, conditioned or delayed), the Company will not (A) directly or indirectly, offer to sell, sell, announce the intention to sell, contract to sell, pledge, lend, grant or sell any option, right or warrant to sell or any contract to purchase, purchase any contract or option to sell or otherwise transfer or dispose of any shares of Common Stock (other than the Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock or file any registration statement under the Securities Act with respect to any of the foregoing (other than a registration statement on Form S-8), or (B) enter into any swap or other agreement or any transaction that transfers in whole or in part, directly or indirectly, any of the economic consequence of ownership of the Common Stock, or any securities convertible into or exchangeable or exercisable for or repayable with Common Stock, whether any such swap or transaction described in clause (A) or (B) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise, during the period beginning on the fifth (5th) Business Day immediately prior to the date on which any Placement Notice is delivered by the Company hereunder and

ending on the fifth (5th) Business Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice; and without the prior written consent of Canaccord (which consent shall not be unreasonably withheld), the Company will not directly or indirectly in any other “at the market” or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any shares of Common Stock (other than the Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock prior to the later of the termination of this Agreement and the thirtieth (30th) day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice; provided, however, that such restrictions will not be applicable to the Company’s issuance or sale of (i) Common Stock, options to purchase shares of Common Stock or Common Stock issuable upon the exercise of options, pursuant to any employee or director (x) stock option or benefits plan, (y) stock ownership plan or (z) dividend reinvestment plan (but not shares subject to a waiver to exceed plan limits in its dividend reinvestment plan) of the Company whether now in effect or hereafter implemented, and (ii) Common Stock issuable upon conversion of securities or the exercise of warrants, options or other rights in effect or outstanding on the date hereof, and disclosed in writing to Canaccord or otherwise disclosed in the Registration Statement, Prospectus or Disclosure Package.

- (l) Change of Circumstances. The Company will, at any time during the term of this Agreement, as supplemented from time to time, advise Canaccord immediately after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect any opinion, certificate, letter or other document provided to Canaccord pursuant to this Agreement.
- (m) Due Diligence Cooperation. The Company will cooperate with any due diligence review conducted by Canaccord or its agents, including, without limitation, providing information and making available documents and senior corporate officers, as Canaccord may reasonably request; provided, however, that the Company shall be required to make available senior corporate officers only (i) by telephone or at the Company’s principal offices and (ii) during the Company’s ordinary business hours.
- (n) Affirmation of Representations, Warranties, Covenants and Other Agreements. Upon commencement of the offering of the Placement Shares under this Agreement (and upon the recommencement of the offering of the Placement Shares under this Agreement following any termination of a suspension of sales hereunder), and at each Applicable Time, each Settlement Date, each Registration Statement Amendment Date (as defined below) and each Company Periodic Report Date (as defined below), in each case, to the extent no waiver is applicable pursuant to Section 7(p), the Company shall be deemed to have affirmed each representation, warranty, covenant and other agreement contained in this Agreement.

- (o) **Required Filings Relating to Placement of Placement Shares.** In each Annual Report on Form 10-K or Quarterly Report on Form 10-Q filed by the Company in respect of any quarter in which sales of Placement Shares were made by Canaccord under this Agreement (each date on which any such document is filed, and any date on which an amendment to any such document is filed, a “Company Periodic Report Date”), the Company shall set forth with regard to such quarter the number of Shares sold through the Canaccord under this Agreement, the Net Proceeds received by the Company and the compensation paid by the Company to Canaccord with respect to sales of Placement Shares pursuant to this Agreement.
- (p) **Representation Dates; Certificate.** During the term of this Agreement, on the date of each Placement Notice given hereunder, promptly upon each request of Canaccord, and each time the Company (i) files the Prospectus relating to the Placement Shares or amends or supplements (other than a prospectus supplement relating solely to an offering of securities other than the Placement Shares) the Registration Statement or the Prospectus relating to the Placement Shares by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) files an annual report on Form 10-K under the Exchange Act; (iii) files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) files a report on Form 8-K containing amended financial information (other than an earnings release, to “furnish” information pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassifications of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a “Representation Date”); the Company shall furnish Canaccord (but in the case of clause (iv) above only if Canaccord reasonably determines that the financial information contained in such Form 8-K is material) with a certificate, in the form attached hereto as Exhibit A. The requirement to provide a certificate under this Section 7(p) shall be waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date; provided, however, that such waiver shall not apply for any Representation Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide Canaccord with a certificate under this Section 7(p), then before the Company delivers the Placement Notice or Canaccord sells any Placement Shares, the Company shall provide Canaccord with a certificate, in the form attached hereto as Exhibit A, dated the date of the Placement Notice.

- (q) **Legal Opinions.** Upon execution of this Agreement, upon commencement of the offering of Placement Shares under this Agreement (and upon the recommencement of the offering of the Placement Shares under this Agreement following any termination of a suspension of sales hereunder), and promptly after each (i) Registration Statement Amendment Date, (ii) Company Periodic Report Date, and (iii) each reasonable request by Canaccord, in each case, to the extent no waiver is applicable pursuant to Section 7(p), the Company will furnish or cause to be furnished to Canaccord the written opinion and negative assurance letter, to the extent applicable, of (a) Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, counsel for the Company, and (b) Troutman Sanders LLP, intellectual property counsel for the Company, or other counsel reasonably satisfactory to Canaccord, dated the date of this Agreement or the date of such commencement or recommencement or the date of effectiveness of such amendment or the date of filing with the Commission of such supplement or other document, as the case may be, in a form and substance reasonably satisfactory to Canaccord and its counsel; provided, however, in lieu of such opinion and letter, counsel last furnishing such letter to Canaccord shall furnish Canaccord with a letter substantially to the effect that Canaccord may rely on such last opinion and letter to the same extent as though each were dated the date of such letter authorizing reliance (except that statements in such last letter shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented to the time of delivery of such letter authorizing reliance). As used in this paragraph, to the extent there shall be an Applicable Time on or following the date referred to in clause (i) or (ii) above, promptly shall be deemed to be on or prior to the next succeeding Applicable Time. Such opinion and negative assurance letter, to the extent applicable, shall be rendered to Canaccord at the request of the Company and shall state so therein.
- (r) **Comfort Letters.** Upon execution of this Agreement, upon commencement of the offering of Placement Shares under this Agreement (and upon the recommencement of the offering of the Shares under this Agreement following any termination of a suspension of sales hereunder), and promptly after each (i) Registration Statement Amendment Date, (ii) Company Periodic Report Date, and (iii) each reasonable request by Canaccord, in each case, to the extent no waiver is applicable pursuant to Section 7(p) the Company shall cause its independent accountants reasonably satisfactory to Canaccord, to furnish Canaccord letters dated the date of this Agreement or the date of such commencement or recommencement or the date of effectiveness of such amendment or the date of filing of such supplement or other document with the Commission, as the case may be (the “**Comfort Letters**”), in form and substance satisfactory to Canaccord, (i) confirming that they are registered independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X of the Commission, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters included in or incorporated by reference in the Registration Statement as ordinarily covered by accountants’ “comfort letters” to underwriters in connection with registered public offerings (the first such letter, the “**Initial Comfort Letter**”) and (iii) updating the Initial Comfort Letter with any information which would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

- (s) Market Activities. The Company will not, directly or indirectly, without giving effect to activities by Canaccord, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Shares or (ii) sell, bid for, or purchase the Shares, or pay anyone any compensation for soliciting purchases of the Shares other than Canaccord.
- (t) Insurance. The Company and its Subsidiaries shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for companies engaged in similar businesses in similar industries.
- (u) Compliance with Laws. The Company and its Subsidiaries shall comply with all federal, state and local or foreign law, rule, regulation, ordinance, order or decree, except where failure to so comply would not reasonably be expected to result in a Material Adverse Effect. Furthermore, the Company and its Subsidiaries shall maintain, or cause to be maintained, all material environmental permits, licenses and other material authorizations required by federal, state and local law in order to conduct their businesses as described in the Prospectus, and the Company and its Subsidiaries shall conduct their businesses, or cause their businesses to be conducted, in substantial compliance with such material permits, licenses and authorizations and with applicable environmental laws, except where the failure to maintain or be in compliance with such permits, licenses and authorizations would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.
- (v) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that it will not be or become, at any time prior to the termination of this Agreement, an “investment company,” as such term is defined in the Investment Company Act, assuming no change in the Commission’s current interpretation as to entities that are not considered an investment company.
- (w) Securities Act and Exchange Act. The Company will use commercially reasonable efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Shares as contemplated by the provisions hereof and the Prospectus.
- (x) No Offer to Sell. Other than a free writing prospectus (as defined in Rule 405 under the Securities Act) approved in advance by the Company and Canaccord in its capacity as principal or agent hereunder, neither Canaccord nor the Company (including its agents and representatives, other than Canaccord in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed by it with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Common Stock hereunder.

- (y) Sarbanes-Oxley Act. The Company and the Subsidiaries will use their commercially reasonable efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act.
- (z) Consent to Canaccord Trading. The Company consents to Canaccord trading in the shares of Common Stock of the Company for Canaccord's own account and for the account of its clients at the same time as sales of Placement Shares occur pursuant to this Agreement.
- (aa) Rescission Offers. If, to the knowledge of the Company, all filings required by Rule 424 in connection with this offering shall not have been made or the representation in Section 6 shall not be true and correct on the applicable Settlement Date, the Company will offer to any person who has agreed to purchase Placement Shares from the Company as the result of an offer to purchase solicited by Canaccord the right to refuse to purchase and pay for such Placement Shares.
- (bb) Actively Traded Security. If, at the time of execution of this Agreement, the Company's Common Stock is not an "actively traded security" exempted from the requirements of Rule 101 of Regulation M under the Exchange Act by subsection (c)(1) of such rule, the Company shall notify Canaccord at the time the Common Stock becomes an "actively traded security" under such rule. Furthermore, the Company shall notify Canaccord immediately if the Common Stock, having once qualified for such exemption, ceases to so qualify.
- (cc) Blue Sky Qualifications. The Company will use its commercially reasonable efforts, in cooperation with Canaccord, to qualify the Placement Shares for sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as Canaccord may designate and to maintain such qualifications in effect so long as required to complete the sale of the Placement Shares; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.
- (dd) Emerging Growth Company Status. The Company will promptly notify Canaccord if the Company ceases to be an Emerging Growth Company at any time prior to the termination of this Agreement.

8. Additional Representations and Covenants of the Company.

(a) Issuer Free Writing Prospectuses.

- (i) The Company represents that it has not made, and covenants that, unless it obtains the prior written consent of Canaccord, it will not make any offer relating to the Shares that would constitute a “free writing prospectus” (as defined in Rule 405 of the Securities Act) (an “Issuer Free Writing Prospectus”) required to be filed by it with the Commission or retained by the Company under Rule 433 of the Securities Act; except as set forth in a Placement Notice, no use of any Issuer Free Writing Prospectus has been consented to by Canaccord. The Company agrees that it will comply with the requirements of Rules 164 and 433 of the Securities Act applicable to any Issuer Free Writing Prospectus, including timely filing with the Commission or retention where required and legending.
- (ii) The Company agrees that no Issuer Free Writing Prospectus, if any, will include any information that conflicts with the information contained in the Registration Statement, including any document incorporated by reference therein that has not been superseded or modified, or the Prospectus. In addition, no Issuer Free Writing Prospectus, if any, will include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; provided however, the foregoing shall not apply to any statements or omissions in any Issuer Free Writing Prospectus made in reliance on information furnished in writing to the Company by Canaccord expressly stating that such information is intended for use therein.
- (iii) The Company agrees that if at any time following issuance of an Issuer Free Writing Prospectus any event occurred or occurs as a result of which such Issuer Free Writing Prospectus would conflict with the information in the Registration Statement, including any document incorporated by reference therein that has not been superseded or modified, or the Prospectus or would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, the Company will give prompt notice thereof to Canaccord and, if requested by Canaccord, will prepare and furnish without charge to Canaccord an Issuer Free Writing Prospectus or other document which will correct such conflict, statement or omission; provided, however, the foregoing shall not apply to any statements or omissions in any Issuer Free Writing Prospectus made in reliance on information furnished in writing to the Company by Canaccord expressly stating that such information is intended for use therein.

- (b) Non-Issuer Free Writing Prospectus. The Company consents to the use by Canaccord of a free writing prospectus that (a) is not an “Issuer Free Writing Prospectus” as defined in Rule 433 under the Securities Act, and (b) contains only information describing the preliminary terms of the Shares or their offering, or information permitted under Rule 134 under the Securities Act; provided that

Canaccord covenants with the Company not to take any action that would result in the Company being required to file with the Commission under Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of Canaccord that otherwise would not be required to be filed by the Company thereunder, but for the action of Canaccord.

- (c) Distribution of Offering Materials. The Company has not distributed and will not distribute, during the term of this Agreement, any offering materials in connection with the offering and sale of the Placement Shares other than the Registration Statement, Prospectus or any Issuer Free Writing Prospectus reviewed and consented to by Canaccord and included in a Placement Notice (as described in clause (a)(i) above).

9. Conditions to Canaccord's Obligations. The obligations of Canaccord hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein and in the applicable Placement Notices, to the due performance by the Company of its obligations hereunder, to the completion by Canaccord of a due diligence review satisfactory to Canaccord in its reasonable judgment, and to the continuing satisfaction (or waiver by Canaccord in its sole discretion) of the following additional conditions:

- (a) Registration Statement Effective. The Registration Statement shall have become effective and shall be available for the sale of (i) all Placement Shares issued pursuant to all prior Placements and not yet sold by Canaccord and (ii) all Placement Shares contemplated to be issued by the Placement Notice relating to such Placement.
- (b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission or any other federal or state or foreign or other governmental, administrative or self-regulatory authority during the period of effectiveness of the Registration Statement, the response to which might reasonably require any amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state or foreign or other governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; (iv) the occurrence of any event that makes any statement made in the Registration Statement or the Prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related prospectus or documents so that, in the case of the Registration Statement, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading, and in the case of the Prospectus, it will not

contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; and (v) the Company's reasonable determination that a post-effective amendment to the Registration Statement would be appropriate.

- (c) No Misstatement or Material Omission. Canaccord shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in Canaccord's opinion is material, or omits to state a fact that in Canaccord's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.
- (d) Material Changes. Except as contemplated and appropriately disclosed in the Prospectus, or disclosed in the Company's reports filed with the Commission, in each case at the time the applicable Placement Notice is delivered, there shall not have been any material change, on a consolidated basis, in the authorized capital stock of the Company and its Subsidiaries, or any Material Adverse Effect, or any development that may reasonably be expected to cause a Material Adverse Effect, or a downgrading in or withdrawal of the rating assigned to any of the Company's securities by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities, the effect of which, in the sole judgment of Canaccord (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.
- (e) Certificate. Canaccord shall have received the certificate required to be delivered pursuant to Section 7(p) on or before the date on which delivery of such certificate is required pursuant to Section 7(p).
- (f) Legal Opinions. Canaccord shall have received the opinions of counsel to the Company required to be delivered pursuant Section 7(q) on or before the date on which such delivery of such opinions are required pursuant to Section 7(q). In addition, Canaccord shall have received the opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel to Canaccord, on such dates and with respect to such matters as Canaccord may reasonably request.
- (g) Comfort Letters. Canaccord shall have received the Comfort Letter required to be delivered pursuant Section 7(r) on or before the date on which such delivery of such letter is required pursuant to Section 7(r).
- (h) Approval for Listing; No Suspension. The Placement Shares shall have either been (i) approved for listing, subject to notice of issuance, on the Principal Trading Market, or (ii) the Company shall have filed an application for listing of the Placement Shares on the Principal Trading Market at or prior to the issuance of the Placement Notice. Trading in the Common Stock shall not have been suspended on such market.

- (i) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(p), the Company shall have furnished to Canaccord such appropriate further information, certificates, opinions and documents as Canaccord may reasonably request. All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof. The Company will furnish Canaccord with such conformed copies of such opinions, certificates, letters and other documents as Canaccord shall reasonably request.
- (j) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.
- (k) No Termination Event. There shall not have occurred any event that would permit Canaccord to terminate this Agreement pursuant to Section 12(a).

10. Indemnification and Contribution.

- (a) Company Indemnification. The Company will indemnify and hold harmless Canaccord and each person, if any, who controls Canaccord against any losses, claims, damages or liabilities, joint or several, to which Canaccord or controlling person may become subject, under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Prospectus, the Disclosure Package, or any Issuer Free Writing Prospectus or any "issuer information" filed or required to be filed pursuant to Rule 433(d) under the Securities Act, or any amendment or supplement to the Registration Statement, the Prospectus or the Disclosure Package, or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Placement Shares under the securities laws thereof or filed with the Commission, or arise out of or are based upon the omission or alleged omission to state in the Registration Statement, the Prospectus, the Disclosure Package, or any Issuer Free Writing Prospectus or any "issuer information" filed or required to be filed pursuant to Rule 433(d) under the Securities Act, or any amendment or supplement to the Registration Statement, the Prospectus, or the Disclosure Package or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Placement Shares under the securities laws thereof or filed with the Commission a material fact required to be stated in it or necessary to make the statements in it not misleading, and will reimburse Canaccord for any reasonable legal expenses of counsel for Canaccord, and for other expenses reasonably incurred by Canaccord in connection with investigating

or defending any such action or claim as such expenses are incurred; provided, however, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Prospectus or the Disclosure Package, or any such amendment or supplement thereto, in reliance upon and in conformity with written information furnished to the Company by and through Canaccord expressly for use therein.

- (b) Canaccord Indemnification. Canaccord will indemnify and hold harmless the Company against any losses, claims, damages or liabilities to which the Company may become subject, under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendments thereto), the Prospectus (or any amendment or supplement thereto), the Disclosure Package or any Issuer Free Writing Prospectus, or arise out of or are based upon the omission or alleged omission to state therein a material fact, in the case of the Registration Statement or any amendment thereto, required to be stated therein or necessary to make the statements therein not misleading and, in the case of the Prospectus or any supplement thereto, the Disclosure Package or the Issuer Free Writing Prospectus, necessary to make the statements therein, in light of the circumstances in which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement (or any amendments thereto), the Prospectus (or any amendment or supplement thereto), the Disclosure Package, or any Issuer Free Writing Prospectus, in reliance upon and in conformity with written information furnished to the Company by and through Canaccord expressly for use therein; and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with investigating or defending any such action or claim as such expenses are incurred.
- (c) Procedure.
- (i) Each indemnified party shall give written notice as promptly as reasonably practicable to each indemnifying party of any action commenced against it in respect of which indemnity may be sought hereunder, but failure to so notify an indemnifying party shall not relieve such indemnifying party from any liability hereunder to the extent it is not materially prejudiced as a result thereof and in any event shall not relieve it from any liability which it may have otherwise than on account of this Section 10. In the case of parties indemnified pursuant to Section 10(a) above, counsel to the indemnified parties shall be selected by Canaccord, and, in the case of parties indemnified pursuant to Section 10(b) above, counsel to the indemnified parties shall be selected by the Company. An indemnifying party may participate at its own expense in the defense of any such action; *provided, however*, that counsel to the indemnifying party shall not

(except with the consent of the indemnified party) also be counsel to the indemnified party. In no event shall the indemnifying parties be liable for fees and expenses of more than one counsel (in addition to any relevant local counsel) separate from their own counsel for all indemnified parties in connection with any one action or separate but similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification or contribution could be sought under this Section 10 (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

- (ii) The indemnifying party 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 party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested that an indemnifying party reimburse the indemnified party for reasonable fees and expenses of counsel as contemplated by this section, the indemnifying person shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into (A) more than 60 days after receipt by the indemnifying party of such request and (B) more than 30 days after receipt by the indemnifying party of the proposed terms of such settlement and (ii) the indemnifying party shall not have reimbursed the indemnified person in accordance with such request prior to the date of such settlement.
- (d) Contribution. If the indemnification provided for in this Section 10 is unavailable to or insufficient to hold harmless an indemnified party under subsection (a) or (b) above in respect of any losses, claims, damages or liabilities (or actions in respect thereof) referred to therein, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (or actions in respect thereof) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and Canaccord on the other from the offering of the Placement Shares. If, however, the allocation provided by the immediately preceding sentence is not permitted by applicable law or if the indemnified party failed to give the notice required under subsection (c) above, then each indemnifying party shall

contribute to such amount paid or payable by such indemnified party in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and Canaccord on the other in connection with the statements or omissions which resulted in such losses, claims, damages or liabilities (or actions in respect thereof), as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and Canaccord on the other shall be deemed to be in the same proportion as the total net proceeds from the offering of the Shares (before deducting expenses) received by the Company, bear to the total underwriting discounts, commissions and other fees received by Canaccord. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company on the one hand or Canaccord on the other and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and Canaccord agree that it would not be just and equitable if contributions pursuant to this subsection (d) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to above in this subsection (d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages or liabilities (or actions in respect thereof) referred to above in this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this subsection (d), Canaccord shall not be required to contribute any amount in excess of the amount by which the total price at which the Placement Shares distributed to the public by it were offered to the public exceeds the amount of any damages which Canaccord 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.

- (e) Obligations. The obligations of the Company under this Section 10 shall be in addition to any liability which the Company may otherwise have and shall extend, upon the same terms and conditions, to each person, if any, who controls Canaccord within the meaning of the Securities Act; and the obligations of Canaccord under this Section 10 shall be in addition to any liability which Canaccord may otherwise have and shall extend, upon the same terms and conditions, to each officer and director of the Company and to each person, if any, who controls the Company within the meaning of the Securities Act.

11. Representations and Agreements to Survive Delivery. All representations and warranties of the Company herein or in certificates delivered pursuant hereto shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of Canaccord, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

12. Termination.

- (a) Canaccord shall have the right to terminate this Agreement at any time by giving notice as hereinafter specified if (i) any Material Adverse Effect has occurred, or any development that is reasonably expected to cause a Material Adverse Effect has occurred or any other event has occurred which, in the sole judgment of Canaccord, may materially impair Canaccord's ability to proceed with the offering to sell the Shares, (ii) the Company shall have failed, refused or been unable, at or prior to any Settlement Date, to perform any agreement on its part to be performed hereunder, (iii) any other condition of Canaccord's obligations hereunder is not fulfilled, or (iv) any suspension or limitation of trading in the shares of Common Stock of the Company on the Principal Trading Market shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(j) (Expenses), Section 10 (Indemnification), Section 11 (Survival of Representations), Section 12(f) (Termination), Section 17 (Applicable Law; Consent to Jurisdiction) and Section 18 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If Canaccord elects to terminate this Agreement as provided in this Section 12(a), Canaccord shall provide the required notice as specified in Section 13 (Notices).
- (b) The Company shall have the right to terminate this Agreement in its sole discretion at any time by giving ten (10) days' notice as hereinafter specified. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(j), Section 10, Section 11, Section 12(f), Section 17 and Section 18 hereof shall remain in full force and effect notwithstanding such termination.
- (c) In addition to, and without limiting Canaccord's rights under Section 12(a), Canaccord shall have the right to terminate this Agreement in its sole discretion at any time after the date of this Agreement by giving ten (10) days' notice as hereinafter specified. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(j), Section 10, Section 11, Section 12(f), Section 17 and Section 18 hereof shall remain in full force and effect notwithstanding such termination.
- (d) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 12(a), 12(b) or 12(c) above or otherwise by mutual agreement of the parties; provided that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(j), Section 10, Section 11, Section 12(f), Section 17 and Section 18 shall remain in full force and effect.

- (e) Any termination of this Agreement shall be effective on the date specified in such notice of termination; provided that such termination shall not be effective until the close of business on the date of receipt of such notice by Canaccord or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.
- (f) In the event that the Company terminates this Agreement, as permitted under Section 12(b), the Company shall be under no continuing obligation pursuant to this Agreement to utilize the services of Canaccord in connection with any sale of securities of the Company or to pay any compensation to Canaccord other than compensation with respect to sales of Placement Shares subscribed on or before the termination date and the Company shall be free to engage other placement agents and underwriters from and after the termination date with no continuing obligation to Canaccord.

13. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing and if sent to Canaccord, shall be delivered to:

Canaccord Genuity Inc.
99 High Street, Suite 1200
Boston, MA 02110
Attention: ECM, General Counsel

With a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Attention: William C. Hicks, Esq.

or if sent to the Company, shall be delivered to:

Histogenics Corporation
830 Winter Street, 3rd Floor
Waltham, Massachusetts 02451
Attention: Chief Financial Officer

With a copy to:

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
One Marina Park Drive, Suite 900
Boston, Massachusetts 02210
Attention: Albert W. Vanderlaan

Each party to this Agreement may change such address for notices by sending to the other party to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission or e-mail (with an original to follow) on or before 4:30 p.m., eastern time, on a

Business Day or, if such day is not a Business Day, on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier, (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid), and (iv) if sent by e-mail, on the Business Day on which receipt is confirmed by the individual to whom the notice is sent, other than via auto-reply. For purposes of this Agreement, "Business Day," shall mean any day on which the Principal Trading Market and commercial banks in the city of New York are open for business.

14. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and Canaccord and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 10 hereof. References to any of either of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party, provided, however, that Canaccord may assign its rights and obligations hereunder to an affiliate of Canaccord qualified to perform Canaccord's obligations under this Agreement without obtaining the Company's consent.

15. Adjustments for Stock Splits. The parties acknowledge and agree that all share related numbers contained in this Agreement shall be adjusted to take into account any stock split, stock dividend or similar event effected with respect to the Shares.

16. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and placement notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and Canaccord. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable, the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions contained herein shall not be affected or impaired thereby.

17. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

18. Waiver of Jury Trial. The Company and Canaccord hereby irrevocably waive any right either may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.

19. Absence of Fiduciary Duties. The parties acknowledge that they are sophisticated in business and financial matters and that each of them is solely responsible for making its own independent investigation and analysis of the transactions contemplated by this Agreement. They further acknowledge that Canaccord has not been engaged by the Company to provide, and has not provided, financial advisory services in connection with the terms of the offering and sale of the Shares nor has Canaccord assumed at any time a fiduciary relationship to the Company in connection with such offering and sale. The parties also acknowledge that the provisions of this Agreement fairly allocate the risks of the transactions contemplated hereby among them in light of their respective knowledge of the Company and their respective abilities to investigate its affairs and business in order to assure that full and adequate disclosure has been made in the Registration Statement and the Prospectus (and any amendments and supplements thereto). The Company hereby waives, to the fullest extent permitted by law, any claims it may have against Canaccord for breach of fiduciary duty or alleged breach of fiduciary duty and agrees Canaccord shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, employees or creditors of Company.

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

[Remainder of page left intentionally blank]

If the foregoing accurately reflects your understanding and agreement with respect to the matters described herein please indicate your agreement by countersigning this Agreement in the space provided below.

Very truly yours,

HISTOGENICS CORPORATION.

By: /s/ Adam Gridley
Name: Adam Gridley
Title: Chief Executive Officer and President

ACCEPTED as of the date first-above
written:

CANACCORD GENUITY INC.

By: /s/ Jennifer Pardi
Name: Jennifer Pardi
Title: Senior Managing Director

[Signature page to Equity Distribution Agreement]

The Authorized Representatives of the Company are as follows:

<u>Name and Office / Title</u>	<u>E-mail Address</u>	<u>Telephone Numbers</u>	<u>Fax Number</u>
Adam Gridley / Chief Executive Officer and President	agridley@gunder.com	Office: (781) 547-7991	N/A
Jonathan Lieber / Chief Financial Officer and Treasurer	jlieber@gunder.com	Office: (781) 547-7909	N/A

The Authorized Representatives of Canaccord are as follows:

<u>Name and Office / Title</u>	<u>E-mail Address</u>	<u>Telephone Numbers</u>	<u>Fax Number</u>
Jeffrey G. Barlow / President	jbarlow@canaccordgenuity.com	Office: (617) 371-3713 Cell:	(617) 371-3798
Tom Pollard / Principal	tpollard@canaccordgenuity.com	Office: (415) 229-0664 Cell:	(415) 229-7194
Jennifer Pardi / Senior Managing Director	jpardi@canaccordgenuity.com	Office: (617) 788-1554 Cell:	(617) 788-1553
Andrew Viles / Senior Managing Director and Internal Counsel	aviles@canaccordgenuity.com	Office: (617) 371-3715 Cell:	(781) 775-5295

Subsidiary
Histogenics Limited
Prochon BioTech, Ltd.
Histogenics Securities Corporation

**Jurisdiction of
Organization**
United Kingdom
Israel
Massachusetts

**Name under
which the Subsidiary conducts business**
Histogenics Limited
Prochon BioTech, Ltd.
Histogenics Securities Corporation

OFFICER'S CERTIFICATE

I, *[name of executive officer]*, the *[title of executive officer]* of Histogenics Corporation ("Company"), a Delaware corporation, do hereby certify in such capacity and on behalf of the Company pursuant to Section 7(p) of the Equity Distribution Agreement dated March 15, 2018 (the "Distribution Agreement") between the Company and Canaccord Genuity Inc., to the best of my knowledge that:

(i) The representations and warranties of the Company in Section 6 of the Distribution Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Effect, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Distribution Agreement at or prior to the date hereof.

Date:

By: _____
Name:
Title:



**HISTOGENICS CORPORATION ANNOUNCES FINANCIAL AND OPERATING RESULTS
FOR THE FOURTH QUARTER AND YEAR ENDED DECEMBER 31, 2017**

- *NeoCart® Top-line Phase 3 Clinical Trial Data and Potential Biologics License Application Filing Remain on Track for Third Quarter of 2018 –*
- *NeoCart Licensing Agreement with MEDINET Co. Ltd. Provides Important Source of Funding and Enables Development and Potential Commercialization in Japanese Market –*
- *Company to Host Conference Call and Webcast Today at 8:30 a.m. EDT –*

WALTHAM, Mass., March 15, 2018 /GLOBE NEWSWIRE/ – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a leader in the development of restorative cell therapies (RCTs) that may offer rapid-onset pain relief and restored function, announced its financial and operational results for the quarter and year ended December 31, 2017.

“We achieved multiple, significant milestones in our global development strategy for NeoCart in 2017, providing a strong foundation for additional value creation in 2018. With the completion of enrollment in the NeoCart Phase 3 clinical trial in the first half of 2017, we are on track to report top-line data from this trial and potentially submit a Biologics License Application for this novel restorative cell therapy in the third quarter of 2018. In parallel we are initiating pre-commercialization activities for the U.S. market in advance of a potential launch of NeoCart in fourth quarter of 2019, and we continue to hear positive anecdotal feedback from our investigators regarding NeoCart patients,” stated Adam Gridley, President and Chief Executive Officer of Histogenics. “We also made significant progress on the international expansion of the NeoCart platform by completing formal discussions with the Japan Pharmaceuticals and Medical Devices Agency on the development and regulatory pathway for NeoCart in Japan. Our robust historical data packages and the PMDA conclusions were instrumental in our ability to complete the licensing agreement with MEDINET for the rights to develop and commercialize NeoCart in Japan.”

2017 and Recent Milestones

NeoCart Clinical, Regulatory and Commercialization

- *Completed enrollment for NeoCart Phase 3 clinical trial:* In June 2017, Histogenics enrolled the final patient for its 249-patient Phase 3 randomized, controlled clinical trial conducted against the current standard of care, microfracture. The trial is being conducted under a Special Protocol Assessment with the United States Food and Drug Administration (the FDA).
- *Executed licensing agreement for the development and commercialization of NeoCart in Japan with MEDINET Co., Ltd. (MEDINET):* In December 2017, Histogenics entered into an agreement with MEDINET, a pioneering leader in the development and commercialization of cancer immuno-cell therapy technologies, for the development and commercialization of NeoCart for the Japanese market. The agreement included a \$10 million up-front payment, potential total payments of up to \$87 million in total milestones and tiered royalties on sales. MEDINET intends to initiate NeoCart clinical development in Japan in the second half of 2018, and may enter the Japanese market in 2021, if approved.

- *Completed formal discussions with the Japan Pharmaceuticals and Medical Devices Agency (PMDA) to establish the development/regulatory pathway for NeoCart in Japan:* Histogenics successfully concluded formal discussions with the PMDA in the second quarter of 2017. Feedback from the PMDA was positive and included the determination that a 30-patient, one-year confirmatory clinical trial with Japanese patients, comparing NeoCart to microfracture, would be sufficient for applying for full Marketing and Manufacturing Authorization in Japan in conjunction with data from Histogenics' fully enrolled U.S. Phase 3 clinical trial. Additionally, the PMDA agreed that NeoCart would be regulated as a Regenerative Medicine Product, as covered by the recently enacted laws in Japan, and that Histogenics may supply the confirmatory clinical trial from the U.S. using the current good manufacturing processes (cGMP) for NeoCart.
- *Confirmed significant unmet need in cartilage repair through U.S. and Japan NeoCart market research:* Histogenics conducted primary market research in the U.S. and Japan with approximately 200 orthopedic and sports medicine surgeons across both markets. The findings provide support for Histogenics' assumptions regarding the size of each market, the lack of satisfactory solutions, and confirm the need for a novel cartilage repair therapy. Surgeons noted a strong desire for a safe and effective alternative to microfracture that may potentially offer patients a more rapid recovery from pain and return to function as well as a durable treatment response.

NeoCart Data Publications and Presentations

- *Generated additional peer-reviewed data that may support the upcoming NeoCart regulatory submissions and highlight the potential of Histogenics' RCT platform:* The published results included analyses of the compressive properties of engineered cartilage tissue grown with chondrocytes seeded in a porous scaffold in a study titled "*In Vitro Culture Increases Mechanical Stability of Human Tissue Engineered Cartilage Constructs by Prevention of Microscale Scaffold Buckling*," which appeared in the peer-reviewed Journal of Biomechanics. In addition, a study appearing in the Journal of Orthopaedic Research entitled "*Mechanical Properties and Structure-Function Relationships of Human Chondrocyte-Seeded Cartilage Constructs After In Vitro Culture*" evaluated 3-D bioprinting of collagen and chondrocytes. These studies may support both process optimization and a potential Biologics License Application (BLA) filing for NeoCart, as well as the future development of additional product candidates based on the RCT technology platform.
- *Podium and poster presentations at Orthopedic Research Society (ORS) Annual Meeting:* Dr. Shuichi Mizuno, Ph.D., a scientific founder of NeoCart, Assistant Professor, Orthopedic Surgery, Brigham and Women's Hospital (BWH), and Harvard Medical School, delivered a podium presentation on NeoCart and Histogenics' RCT technology platform at the ORS Annual Meeting on March 10, 2018. In addition, three additional poster presentations on NeoCart were presented during the meeting. Data presented on these posters are available [here](#).

Corporate

- *Enhanced executive team ahead of potential approval and commercialization of NeoCart:* In October 2017, Histogenics promoted Stephen Kennedy from Chief Technology Officer to Executive Vice President & Chief Operating Officer. In June 2017, Donald Haut was appointed Chief Business Officer. Both individuals possess strong professional experience that will be instrumental as Histogenics prepares for potential NeoCart commercial manufacturing and launch.
- *Completed registered direct financing:* In January 2018, Histogenics raised net proceeds of \$5.9 million dollars from a registered direct offering of its common stock. The proceeds from the offering provided an important source of additional funding and flexibility in advance of a potential NeoCart BLA filing.

2018 Corporate Objectives

- *Report NeoCart top-line Phase 3 data and submit BLA:* Assuming positive results from the report of top-line superiority data from the NeoCart Phase 3 clinical trial in the third quarter of 2018, Histogenics remains positioned to submit a BLA with the FDA thereafter in the third quarter of 2018.
- *Continue advancement of NeoCart U.S. commercialization strategy:* In advance of potential FDA approval of NeoCart, Histogenics intends to continue to prepare for a potential NeoCart launch in the U.S., including the assembly of a leading Clinical Advisory Board, the further development of marketing and reimbursement strategies and the initial development of sales and medical science liaison territories.
- *Leverage collaborations to generate and publish additional data to support BLA and foreign regulatory filings and potential U.S. commercialization of NeoCart:* Histogenics expects to continue to generate data from its collaborations with BWH, Cornell University (Cornell) and Intrexon Corporation (Intrexon). Anticipated presentations and publications in 2018 include additional biomechanical and three-dimensional printing data from the collaboration with Cornell, the use of chondrocytes to develop new products to treat additional soft-tissue and musculoskeletal-related disorders from the collaboration with BWH and proof-of-concept data from studies combining Intrexon's induced Pluripotent Stem Cell (iPSC) technology and Histogenics' NeoCart platform to manufacture next generation, NeoCart restorative cell therapies using iPSC-derived chondrocytes.
- *Secure additional manufacturing capacity:* Subject to positive top-line data from the NeoCart Phase 3 clinical trial, Histogenics intends to initiate the design and buildout of additional space to support expected increased commercial manufacturing requirements in future years following the initial launch of NeoCart.
- *Support MEDINETS' Japan clinical trial and regulatory activities:* Histogenics is working closely with MEDINET on the development of NeoCart for the Japanese market. Specifically, the companies intend to work on the preparation of a clinical trial notification to support the planned NeoCart Phase 3 clinical trial in Japan in the second half of 2018. In addition, Histogenics intends to continue to explore additional licensing opportunities for NeoCart outside of North America.

Financial Results for the Year Ended December 31, 2017

Histogenics' loss from operations was \$(25.0) million for the year ended December 31, 2017, compared to \$(30.3) million for the year ended December 31, 2016. The decrease in operating loss was driven by a reduction in research and development expenses and partially offset by an increase in general and administrative expenses.

Research and development expenses were \$15.6 million for the year ended December 31, 2017, compared to \$21.6 million for the year ended December 31, 2016. The decrease was primarily due to decreases in collaboration, consulting and temporary labor expenses, clinical trial-related costs, personnel-related expenses and repairs and maintenance costs concurrent with the wind up of enrollment in our NeoCart Phase 3 clinical trial. General and administrative expenses were \$9.4 million for the year ended December 31, 2017, compared to \$8.5 million for the year ended December 31, 2016. The increase was primarily due to increased activities related to potential commercialization of NeoCart and was driven by increases in personnel-related costs, professional fees and facility-related and stock-based compensation expenses.

Basic net loss attributable to common stockholders was \$(22.5) million for the year ended December 31, 2017, or \$(0.99) per share, compared to \$(13.9) million, or \$(0.97) per share, for the year ended December 31, 2016. The increase in basic net loss attributable to common stockholders is attributable to the conversion into common stock in 2017 of a significant portion of the convertible preferred stock issued in connection with the 2016 private placement and changes in the fair value of the warrants issued in connection with the 2016 private placement, both of which were offset by a reduction in operating expenses in 2017 relative to 2016. Diluted net loss attributable to common stockholders was \$(22.5) million for the year ended December 31, 2017, or \$(0.99) per share, compared to \$(31.4) million, or \$(2.18) per share, for the year ended December 31, 2016. The difference in diluted net loss per share is primarily due to a reduction in operating expenses.

At December 31, 2017, Histogenics had cash, cash equivalents and marketable securities of \$8.0 million, compared to \$31.9 million at December 31, 2016. Cash at December 31, 2017 excludes approximately \$9.0 million net of expenses received in January 2018 in connection with the licensing agreement entered into with MEDINET in December 2017 and \$5.9 in net proceeds from the registered direct offering completed in January 2018.

Histogenics expects total operating expenses of between \$29 million and \$31 million for the year ending December 31, 2018 and believes its current cash position will be sufficient to fund its operations into the fourth quarter of 2018.

Conference Call and Webcast Information

Histogenics management will host a conference call on Thursday, March 15, 2018 at 8:30 a.m. EDT. A question-and-answer session will follow Histogenics' remarks. To participate on the live call, please dial (877) 930-8064 (domestic) or (253) 336-8040 (international) and provide the conference ID "7394538" five to ten minutes before the start of the call.



To access a live audio webcast of the presentation on the “Investor Relations” page of the Histogenics website, please click [here](#). A replay of the webcast will be archived on Histogenics’ website for approximately 45 days following the presentation.

About Histogenics Corporation

Histogenics (Nasdaq: HSGX) is a leader in the development of restorative cell therapies that may offer rapid-onset pain relief and restored function. Histogenics’ lead investigational product, NeoCart, is designed to rebuild a patient’s own knee cartilage to treat pain at the source and potentially prevent a patient’s progression to osteoarthritis. NeoCart is one of the most rigorously studied restorative cell therapies for orthopedic use. Histogenics recently completed enrollment of its NeoCart Phase 3 clinical trial and expects to report top-line, one-year superiority data in the third quarter of 2018. NeoCart is designed to perform like articular hyaline cartilage at the time of treatment, and as a result, may provide patients with more rapid pain relief and accelerated recovery as compared to the current standard of care. Histogenics’ technology platform has the potential to be used for a broad range of additional restorative cell therapy indications. For more information on Histogenics and NeoCart, please visit www.histogenics.com.

Forward-Looking Statements

Various statements in this release are “forward-looking statements” under the securities laws. Words such as, but not limited to, “anticipate,” “believe,” “can,” “could,” “expect,” “estimate,” “design,” “goal,” “intend,” “may,” “might,” “objective,” “plan,” “predict,” “project,” “target,” “likely,” “should,” “will,” and “would,” or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

Important factors that could cause actual results to differ materially from those reflected in Histogenics’ forward-looking statements include, among others: the timing and success of Histogenics’ NeoCart Phase 3 clinical trial, including, without limitation, possible delays in generating the data from the clinical trial; the ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; MEDINET’s ability to initiate NeoCart clinical development in Japan in a timely manner; NeoCart’s regulation as a Regenerative Medical Product; the market size and potential patient population in Japan; the scope, progress, timing, expansion, and costs of developing and commercializing Histogenics’ product candidates; the ability to obtain and maintain regulatory approval regarding the comparability of critical NeoCart raw materials following our technology transfer and manufacturing location transition; the size and growth of the potential markets for Histogenics’ product candidates and the ability to serve those markets; Histogenics’ expectations regarding its expenses and revenue; and other factors that are described in the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of Histogenics’ Annual Report on Form 10-K for the year ended December 31, 2016 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, which are on file with the SEC and available on the SEC’s website at www.sec.gov. Additional factors may be set forth in those sections of Histogenics’ Annual Report on Form 10-K for the year ended December 31, 2017, to be filed with the SEC in the first quarter of 2018. In addition to the risks described above and in Histogenics’ annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Histogenics’ results.



There can be no assurance that the actual results or developments anticipated by Histogenics will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Histogenics. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Histogenics or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Histogenics cautions investors not to rely too heavily on the forward-looking statements Histogenics makes or that are made on its behalf. The information in this release is provided only as of the date of this release, and Histogenics undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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HISTOGENICS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	3,366	5,317	15,566	21,577
General and administrative	2,667	2,389	9,384	8,530
Impairment of intangible asset	—	200	—	200
Total operating expenses	<u>6,033</u>	<u>7,906</u>	<u>24,950</u>	<u>30,307</u>
Loss from operations	(6,033)	(7,906)	(24,950)	(30,307)
Other income (expense):				
Interest income (expense), net	20	(5)	134	(60)
Other income (expense), net	25	50	(116)	(248)
Warrant expense	—	(44)	—	(3,100)
Change in fair value of warrant liability	(808)	16,968	(1,482)	17,507
Total other income (expense), net	<u>(763)</u>	<u>16,969</u>	<u>(1,464)</u>	<u>14,099</u>
Net Income (loss)	<u>\$ (6,796)</u>	<u>\$ 9,063</u>	<u>\$ (26,414)</u>	<u>\$ (16,208)</u>
Net Income (loss) attributable to common stockholders				
Basic:	\$ (6,129)	\$ 5,844	\$ (22,499)	\$ (13,863)
Diluted:	\$ (6,129)	\$ (11,125)	\$ (22,499)	\$ (31,370)
Net Income (loss) per common share:				
Basic:	\$ (0.26)	\$ 0.34	\$ (0.99)	\$ (0.97)
Diluted:	\$ (0.26)	\$ (0.63)	\$ (0.99)	\$ (2.18)
Weighted-average shares used to compute earnings (loss) per common share:				
Basic:	24,005,598	17,143,121	22,669,819	14,256,954
Diluted:	24,005,598	17,508,120	22,669,819	14,389,192



HISTOGENICS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except share and per share data)

	December 31, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	\$ 7,981	\$ 31,908
Prepaid expenses and other current assets	194	173
Property and equipment, net	2,723	3,860
Other assets, net	137	137
Total assets	\$ 11,035	\$ 36,078
Current liabilities	\$ 3,805	\$ 5,171
Warrant and other non-current liabilities	18,498	17,340
Total stockholders' equity (deficit)	(11,268)	13,567
Total liabilities and stockholders' equity (deficit)	\$ 11,035	\$ 36,078

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SOURCE: Histogenics Corporation