

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 12, 2024

ORCHESTRA BIOMED HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39421
(Commission
File Number)

92-2038755
(IRS Employer
Identification No.)

150 Union Square Drive
New Hope, Pennsylvania 18938
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (215) 862-5797

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	OBIO	The Nasdaq Global Market

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

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

Item 8.01 Other Events.

Entry into Sales Agreement

On August 12, 2024, Orchestra BioMed Holdings, Inc., a Delaware corporation (the “Company”), entered into a sales agreement (the “Sales Agreement”) with TD Securities (USA) LLC, as agent (“TD Cowen”), pursuant to which the Company may offer and sell shares of its common stock, par value \$0.0001 per share (the “Shares”), having an aggregate offering price of up to \$100,000,000 from time to time through TD Cowen (the “Offering”).

Sales of Shares, if any, will be made by any method that is deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, including, but not limited to, sales made by means of ordinary brokers’ transactions on the Nasdaq Global Market at market prices, in block transactions or by any other method permitted by law, at prices related to the prevailing market prices or at negotiated prices, or as otherwise agreed by the Company and TD Cowen. Actual sales of Shares pursuant to the Sales Agreement will depend on a variety of factors to be determined by the Company from time to time, including (among others) market conditions, the trading price of the Company’s common stock, capital needs and determinations by the Company of the appropriate sources of funding for the Company.

Subject to the terms and conditions of the Sales Agreement, the Agent will use its commercially reasonable efforts to sell the Shares from time to time, as sales agent, based upon the Company’s instructions.

The Company has no obligation to sell any of the Shares and may at any time suspend offers under the Sales Agreement, and either the Company or the Agent may terminate the Sales Agreement at any time. The Sales Agreement contains customary representations, warranties and covenants of the Company, indemnification rights and obligations of the parties and termination provisions. The representations, warranties and covenants contained in the Sales Agreement were made only for purposes of the Sales Agreement and as of specific dates, were solely for the benefit of the parties to the Sales Agreement and are subject to certain limitations contained in the Sales Agreement. Accordingly, investors and security holders should not rely on the representations and warranties in the Sales Agreement as characterizations of the actual state of facts.

The Offering is being made pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-279430), filed with the Securities and Exchange Commission (the “SEC”) on May 15, 2024 and declared effective on May 24, 2024 (the “Registration Statement”), a base prospectus, dated May 24, 2024, included as part of the Registration Statement, and a prospectus supplement, dated August 12, 2024 filed with the SEC pursuant to Rule 424(b)(5) on August 12, 2024.

This Current Report on Form 8-K (this “Current Report”) shall not constitute an offer to sell or the 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 offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

The foregoing description of the Sales Agreement is not complete and is qualified in its entirety by reference to the full text of the Sales Agreement, a copy of which is attached as Exhibit 1.1 to this Current Report and is incorporated by reference herein.

The legal opinion of Paul Hastings LLP relating to the Shares being offered pursuant to the Sales Agreement is filed as Exhibit 5.1 to this Current Report.

Termination of Sale Agreement

In connection with the entry into the Sales Agreement, on August 12, 2024, the Company terminated its prior Open Market Sale AgreementSM, dated as of May 15, 2024 (the “Prior Agreement”), by and between the Company and Jefferies LLC (“Jefferies”), in accordance with its terms (the “Termination”) and with the mutual agreement of Jefferies. The purpose of the Termination is to eliminate restrictions under certain SEC rules relating to the publication or dissemination of new research reports on the Company’s business by Jefferies in light of its role as sales agent under the Prior Agreement. The Prior Agreement provided for Jefferies to sell shares of the Company’s common stock having an aggregate offering price of up to \$100,000,000 million by any method deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act. Prior to the Termination, \$15.5 million of shares of the Company’s common stock had been sold under the Prior Agreement, with \$84.5 million remaining available under the Prior Agreement. The Company cannot make any further sales of its common stock pursuant to the Prior Agreement.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
1.1	Sales Agreement, dated as of August 12, 2024, by and among Orchestra BioMed Holdings, Inc. and TD Securities (USA) LLC.
5.1	Opinion of Paul Hastings LLP
23.1	Consent of Paul Hastings LLP (included in Exhibit 5.1)
104	Cover Page Interactive Data File (formatted in Inline XBRL document)

SIGNATURES

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

ORCHESTRA BIOMED HOLDINGS, INC.

By: /s/ Andrew Taylor

Name: Andrew Taylor

Title: Chief Financial Officer

Date: August 12, 2024

ORCHESTRA BIOMED HOLDINGS, INC.

\$100,000,000

SALES AGREEMENT

August 12, 2024

TD Securities (USA) LLC
1 Vanderbilt Avenue
New York, New York 10017

Ladies and Gentlemen:

Orchestra BioMed Holdings, Inc., a Delaware corporation (the “**Company**”), proposes, subject to the terms and conditions stated herein, to issue and sell from time to time through TD Securities (USA) LLC, as sales agent and/or principal (the “**Agent**”), shares of the Company’s common stock, par value \$0.0001 per share (the “**Common Shares**”), having an aggregate offering price of up to \$100,000,000 on the terms set forth in this agreement (this “**Agreement**”).

Section 1. DEFINITIONS

(a) Certain Definitions. For purposes of this Agreement, capitalized terms used herein and not otherwise defined shall have the following respective meanings:

“**Affiliate**” of a Person means another Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first- mentioned Person. The term “control” (including the terms “controlling,” “controlled by” and “under common control with”) means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

“**Agency Period**” means the period commencing on the date of this Agreement and expiring on the earliest to occur of (x) the date on which the Agent shall have placed the Maximum Program Amount pursuant to this Agreement and (y) the date this Agreement is terminated pursuant to Section 7.

“**Commission**” means the U.S. Securities and Exchange Commission.

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission thereunder.

“**Floor Price Limitation**” means the minimum price set by the Company in the Issuance Notice below which the Agent shall not sell Shares during the applicable period set forth in the Issuance Notice, which may be adjusted by the Company at any time during the period set forth in the Issuance Notice by delivering written notice of such change to the Agent and which in no event shall be less than \$1.00 without the prior written consent of the Agent, which may be withheld in the Agent’s sole discretion.

“**Issuance Amount**” means the aggregate Sales Price of the Shares to be sold by the Agent pursuant to any Issuance Notice.

“**Issuance Notice**” means a written notice delivered to the Agent by the Company in accordance with this Agreement in the form attached hereto as Exhibit A that is executed by its Chief Executive Officer, President or Chief Financial Officer.

“**Issuance Notice Date**” means any Trading Day during the Agency Period that an Issuance Notice is delivered pursuant to Section 3(b)(i).

“**Issuance Price**” means the Sales Price less the Selling Commission.

“**Maximum Program Amount**” means Common Shares with an aggregate Sales Price of the lesser of (a) the number or dollar amount of Common Shares registered under the effective Registration Statement (defined below) pursuant to which the offering is being made, (b) the number of authorized but unissued Common Shares (less Common Shares issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company’s authorized capital stock), (c) the number or dollar amount of Common Shares permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable), or (d) the number or dollar amount of Common Shares for which the Company has filed a Prospectus (defined below).

“**Person**” means an individual or a corporation, partnership, limited liability company, trust, incorporated or unincorporated association, joint venture, joint stock company, governmental authority or other entity of any kind.

“**Principal Market**” means the Nasdaq Global Market or such other national securities exchange on which the Common Shares, including any Shares, are then listed.

“**Rule 462(b)**” means Rule 462(b) promulgated under the Securities Act.

“**Sales Price**” means the actual sale execution price of each Share placed by the Agent pursuant to this Agreement.

“**Securities Act**” means the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder.

“**Selling Commission**” means up to three percent (3%) of the gross proceeds of Shares sold pursuant to this Agreement, or as otherwise agreed between the Company and the Agent with respect to any Shares sold pursuant to this Agreement.

“**Settlement Date**” means the first business day following each Trading Day during the period set forth in the Issuance Notice on which Shares are sold pursuant to this Agreement, when the Company shall deliver to the Agent the amount of Shares sold on such Trading Day and the Agent shall deliver to the Company the Issuance Price received on such sales.

“**Shares**” shall mean the Company’s Common Shares issued or issuable pursuant to this Agreement.

“**Trading Day**” means any day on which the Principal Market is open for trading.

Section 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to, and agrees with, the Agent that as of (1) the date of this Agreement, (2) each Issuance Notice Date, (3) each Settlement Date, (4) each Triggering Event Date and (5) as of each Time of Sale (each of the times referenced above is referred to herein as a “**Representation Date**”), except as may be disclosed in the Registration Statement or Prospectus (each as defined below) (including any documents incorporated by reference therein and any supplements thereto) on or before a Representation Date:

(a) Registration Statement. The Company has prepared and filed with the Commission a shelf registration statement on Form S-3 (File No. 333-279430) that contains a base prospectus. Such registration statement registers the issuance and sale by the Company of the Shares under the Securities Act. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable, with respect to the Shares. Except where the context otherwise requires, such registration statement(s), including all amendments thereto, any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, including all financial statements, exhibits and schedules thereto and all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act as from time to time amended or supplemented, is herein referred to as the “**Registration Statement**,” and the prospectus constituting a part of such registration statement(s), together with any prospectus supplement filed with the Commission pursuant to Rule 424(b) under the Securities Act relating to a particular issuance of the Shares, including all documents incorporated or deemed to be incorporated therein by reference pursuant to Item 12 of Form S-3 under the Securities Act, in each case, as from time to time amended or supplemented, is referred to herein as the “**Prospectus**,” except that if any revised prospectus is provided to the Agent by the Company for use in connection with the offering of the Shares that is not required to be filed by the Company pursuant to Rule 424(b) under the Securities Act, the term “**Prospectus**” shall refer to such revised prospectus from and after the time it is first provided to the Agent for such use. The Registration Statement at the time it originally became effective is herein called the “**Original Registration Statement**.” As used in this Agreement, the terms “amendment” or “supplement” when applied to the Registration Statement or the Prospectus shall be deemed to include the filing by the Company with the Commission of any document under the Exchange Act after the date hereof that is or is deemed to be incorporated therein by reference.

All references in this Agreement to financial statements and schedules and other information which is “contained,” “included” or “stated” in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date; and all references in this Agreement to amendments or supplements to the Registration Statement or the Prospectus shall be deemed to mean and include, without limitation, the filing of any document under the Exchange Act which is or is deemed to be incorporated by reference in or otherwise deemed under the Securities Act to be a part of or included in the Registration Statement or the Prospectus, as the case may be, as of any specified date.

At the time the Registration Statement was or will be originally declared effective and at the time the Company's most recent annual report on Form 10-K was filed with the Commission, if later, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. During the Agency Period, each time the Company files an annual report on Form 10-K the Company will meet the then-applicable requirements for use of Form S-3 under the Securities Act.

(b) Compliance with Registration Requirements. The Original Registration Statement has been declared effective by the Commission under the Securities Act, and any Rule 462(b) Registration Statement filed after the date hereof that relates to the Shares will be effective prior to the delivery of any Issuance Notice related to the Shares registered thereby. The Company has complied to the Commission's satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission.

The Prospectus when filed complied in all material respects with the Securities Act and, if filed with the Commission through its Electronic Data Gathering, Analysis and Retrieval system ("**EDGAR**") (except as may be permitted by Regulation S-T under the Securities Act), was identical to the copy thereof delivered to the Agent for use in connection with the issuance and sale of the Shares. Each of the Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendment thereto, at the time it became effective and as of each Representation Date, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the date of this Agreement, the information in the Prospectus did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus, as amended or supplemented, as of its date and as of each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein, it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information described in Section 6 below. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. The Registration Statement and the offer and sale of the Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said rule.

(c) Ineligible Issuer Status. The Company is an “ineligible issuer” in connection with the offering of the Shares pursuant to Rules 164, 405 and 433 under the Securities Act.

(d) Incorporated Documents. The documents incorporated or deemed to be incorporated by reference in the Registration Statement and the Prospectus, at the time they were filed with the Commission, complied in all material respects with the requirements of the Exchange Act, as applicable, and, when read together with the other information in the Prospectus, do 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.

(e) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the time the Registration Statement and any amendments thereto become effective and at each Time of Sale (as defined below), as the case may be, 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 the light of the circumstances under which they were made, not misleading.

(f) Statistical and Market-Related Data. All statistical, demographic and market-related data included in the Registration Statement or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects. To the extent required, the Company has obtained the written consent for the use of such data from such sources.

(g) Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting. The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which (i) 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 periods in which the periodic reports required under the Exchange Act are being prepared; (ii) have been evaluated by management of the Company for effectiveness as of the end of the Company’s most recent fiscal quarter; and (iii) are effective in all material respects to perform the functions for which they were established. Since the end of the Company’s most recent audited fiscal year, there have been no significant deficiencies or material weaknesses in the Company’s internal control over financial reporting (whether or not remediated) (other than with respect to the significant deficiency that has been disclosed to the Agent) and no change in the Company’s internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

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

(i) Authorization of the Shares. The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Shares.

(j) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(k) No Material Adverse Change. Except as otherwise disclosed in the Registration Statement and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus: (i) there has been no material adverse change, or any development that would reasonably be expected to result in a material adverse change, in (A) the condition, financial or otherwise, or in the earnings, business, operations, operating results, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity or (B) the ability of the Company to consummate the transactions contemplated by this Agreement or perform its obligations hereunder (any such change being referred to herein as a “**Material Adverse Change**”); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and its subsidiaries, considered as one entity, and have not entered into any material transactions whether or not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company or its subsidiaries and there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for dividends paid to the Company or its subsidiaries, by the Company’s subsidiaries on any class of capital stock, or any repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

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

(m) Financial Statements. The financial statements filed with the Commission as a part of the Registration Statement and the Prospectus present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of the dates indicated and the results of their operations, changes in stockholders' equity and cash flows for the periods specified. Such financial statements have been prepared, in all material respects, in conformity with U.S. generally accepted accounting principles applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto and except in the case of unaudited financial statements, which are subject to normal and recurring year-end adjustments and do not contain certain footnotes as permitted by the applicable rules of the Commission. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto. No other financial statements or supporting schedules are required to be included in the Registration Statement or the Prospectus. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement and the Prospectus.

(n) Company's Accounting System. The Company and each of its subsidiaries make and keep books and records that are accurate in all material respects and maintain a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with U.S. generally accepted accounting principles and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement 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.

(o) Incorporation and Good Standing of the Company. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the State of Delaware and each other 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 be in good standing would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

(p) Subsidiaries. Each of the Company's "subsidiaries" (for purposes of this Agreement, as defined in Rule 405 under the Securities Act) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation, partnership or limited liability company, as applicable, in good standing under the laws of the jurisdiction of its incorporation or organization and has the power and authority (corporate or other) to own, lease and operate its properties and to conduct its business as described in the Registration Statement and the Prospectus. Each of the Company's subsidiaries is duly qualified as a foreign corporation, partnership or limited liability company, as applicable, 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 be in good standing would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. All of the issued and outstanding capital stock or other equity or ownership interests of each of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. None of the outstanding capital stock or equity interest in any subsidiary was issued in violation of preemptive or similar rights of any security holder of such subsidiary. The constitutive or organizational documents of each of the subsidiaries comply in all material respects with the requirements of applicable laws of its jurisdiction of incorporation or organization and are in full force and effect. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

(q) Capitalization and Other Capital Stock Matters. The authorized, issued and outstanding capital stock of the Company is as set forth in the Registration Statement and the Prospectus (other than for subsequent issuances, if any, pursuant to this Agreement and employee benefit plans described in the Prospectus or upon the exercise of outstanding options or warrants, in each case described in the Registration Statement and the Prospectus). The Common Shares (including the Shares) conform in all material respects to the description thereof contained in the Prospectus. All of the issued and outstanding Common Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all applicable federal and state securities laws. None of the outstanding Common Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or 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 or any of its subsidiaries other than those described in the Registration Statement and the Prospectus and other than options and other equity incentive awards issued by the Company subsequent to the date of such description in the Registration Statement and Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement and the Prospectus accurately and fairly presents, in all material respects, the information required to be shown with respect to such plans, arrangements, options and rights.

(r) Stock Exchange Listing. The Common Shares are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and are listed on the Principal Market, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Shares under the Exchange Act or delisting the Common Shares from the Principal Market, nor has the Company received any notification that the Commission or the Principal Market is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the Principal Market.

(s) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) (“**Default**”) under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of their respective properties or assets are subject (each, an “**Existing Instrument**”), except for such Defaults as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. The Company’s execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Registration Statement and the Prospectus and the issuance and sale of the Shares (including the use of proceeds from the sale of the Shares as described in the Registration Statement and the Prospectus under the caption “Use of Proceeds”) (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, of the Company or any subsidiary (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries, except for such conflicts, breaches, Defaults, liens, charges, encumbrances or violations specified in subsections (ii) and (iii) above that would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company’s execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Registration Statement and the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or the applicable rules, regulations and interpretations of FINRA (as defined below). As used herein, a “**Debt Repayment Triggering Event**” means any event or condition which gives, or with the giving of notice or lapse of time would give, 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.

(t) No Material Actions or Proceedings. There is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which if determined adversely to the Company or such subsidiary would reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company or any of its subsidiaries, would not reasonably be expected to result in a Material Adverse Change. No material labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is threatened or imminent, in each case, except as would not reasonably be expected, individually or in the aggregate, to result in Material Adverse Change.

(u) Intellectual Property Rights. The Company and its subsidiaries own, or have obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property described in the Registration Statement and the Prospectus as being owned or licensed by them and which are necessary for the conduct of their respective businesses as currently conducted (collectively, “**Intellectual Property**”) and the conduct of their respective business does not infringe, misappropriate or otherwise conflict in any material respect with any such rights of others. The Intellectual Property that is registered and owned by the Company or its subsidiaries has not been adjudged by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part, and the Company is unaware of any facts which would form a reasonable basis for any such adjudication. To the Company’s knowledge: (i) there are no third parties who have rights to any Intellectual Property owned by the Company or its subsidiaries, except for customary licenses granted by the Company or its subsidiaries in the ordinary course of business, and such Intellectual Property is owned by the Company or its Affiliates free and clear of all material liens, security interests, or encumbrances; (ii) there is no infringement, misappropriation or dilution by third parties of any Intellectual Property owned by the Company or its subsidiaries; (iii) the Company is not currently infringing, misappropriating, diluting or otherwise violating the intellectual property rights of third parties; and (iv) neither the Company nor any of its subsidiaries has received any notice of infringement of or conflict with asserted rights of others with respect to any Intellectual Property, (v) the Company or its subsidiary is the owner or co-owner of the Intellectual Property that it owns and has the valid right to use the Intellectual Property; (vi) there are no material defects in any of the patents or patent applications included in the Intellectual Property, (vii) the duties of candor and good faith required by the U.S. Patent and Trademark Office (“USPTO”) during the prosecution of the United States patents and patent applications included in the Intellectual Property have been complied with, and all such requirements in foreign offices having similar requirements applicable to the Company and its subsidiaries have been complied with, and (viii) no employee of the Company or its subsidiaries is in or has been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee’s employment with the Company or its subsidiaries, except in each case covered by clauses (i) through (viii) such as would not, if determined adversely to the Company or any of its subsidiaries, individually or in the aggregate, be reasonably expected to result in a Material Adverse Change. There is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company’s rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property that is registered and owned by the Company or any of its subsidiaries, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company or any of its subsidiaries infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement or the Prospectus as under development, infringe or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim, except in each case covered by clauses (A) through (C) such as would not, if determined adversely to the Company or any of its subsidiaries, individually or in the aggregate, be reasonably expected to result in a Material Adverse Change. To the Company’s knowledge, the Company and its subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property material to the conduct of their businesses has been licensed to the Company or any subsidiary, and all such agreements are in full force and effect. The Company and its subsidiaries have taken reasonable steps to protect, maintain and safeguard the Intellectual Property owned by the Company or its subsidiaries and material to the conduct of their businesses. The product candidates BackBeat CNT (AVIM Therapy) for hypertension and CNT-HF for heart failure described in the Registration Statement and the Prospectus as under development by the Company or any subsidiary fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company or any subsidiary. The product candidates Virtue SAB for artery disease and SirolimusEFR for local inflammation in multiple indications described in the Registration Statement and the Prospectus as under development by the Company or any subsidiary fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company or any subsidiary or are otherwise covered by trade secrets.

(v) All Necessary Permits, etc. The Company and its subsidiaries possess, or qualify for applicable exemptions from, such valid and current certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described in the Registration Statement or the Prospectus (collectively, “**Permits**”), except where the failure to possess or obtain the same or so qualify would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. Neither the Company nor any of its subsidiaries is in violation of, or in default under, any of the Permits or has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any of the Permits, except for any such violations, defaults or proceedings relating to the revocation or modification of, or non-compliance with, any such Permits that would not reasonably be expected, individually or in the aggregate, if the subject of an unfavorable decision, ruling or finding, to result in a Material Adverse Change.

(w) Title to Properties. Neither the Company nor any of its subsidiaries own any real property. The Company and its subsidiaries have good and marketable title to all of the personal property and other assets reflected as owned in the financial statements referred to in Section 2(m) above (or elsewhere in the Registration Statement or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except such as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. The real property, improvements, equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or such subsidiary.

(x) Tax Law Compliance. The Company and its subsidiaries have filed all necessary U.S. federal, state and foreign income and franchise tax returns or have properly requested extensions thereof and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings or where the failure to file such tax returns or to pay such taxes would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 2(m) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company or any of its subsidiaries has not been finally determined, except to the extent of any inadequacy that would not reasonably be expected to result in a Material Adverse Change.

(y) Company Not an “Investment Company.” The Company is not, and will not be, either after receipt of payment for the Shares or after the application of the proceeds therefrom as described under “Use of Proceeds” in the Registration Statement or the Prospectus, required to register as an “investment company” under the Investment Company Act of 1940, as amended (the “**Investment Company Act**”).

(z) Insurance. Each of the Company and its subsidiaries are insured by recognized and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are generally deemed adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company and its subsidiaries for product liability claims and clinical trial liability claims. The Company has no reason to believe that it or any of its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(aa) No Price Stabilization or Manipulation; Compliance with Regulation M. Neither the Company nor any of its subsidiaries has taken, directly or indirectly, without giving effect to activities by the Agent, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Shares or of any “reference security” (as defined in Rule 100 of Regulation M under the Exchange Act (“**Regulation M**”)) with respect to the Common Shares, whether to facilitate the sale or resale of the Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(bb) Related Party Transactions. There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the Registration Statement or the Prospectus which have not been described as required.

(cc) FINRA Matters. All of the information provided to the Agent or to counsel for the Agent by the Company, its officers and directors and, to the knowledge of the Company, its counsel and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Shares is true, complete, correct and compliant with Financial Industry Regulatory Authority, Inc.’s (“**FINRA**”) rules and any letters, filings or other supplemental information provided by the Company to FINRA pursuant to FINRA Rules is true, complete and correct.

(dd) No Unlawful Contributions or Other Payments. Except as otherwise disclosed in the Prospectus, neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any employee or agent of the Company or any of its subsidiaries, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any applicable law or of the character required to be disclosed in the Registration Statement and the Prospectus.

(ee) Compliance with Environmental Laws. Except as would not be reasonably expected, individually or in the aggregate, to result in a Material Adverse Change; (i) neither the Company nor any of its subsidiaries is in violation of any applicable federal, state, local or foreign statute, law, rule, regulation, ordinance, code 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 as related to exposure to Hazardous Materials (as defined below), 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, to the knowledge of the Company, threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, “**Hazardous Materials**”) or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, “**Environmental Laws**”), (ii) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (iii) 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, in each case in writing, relating to any Environmental Law against the Company or any of its subsidiaries and (iv) to the knowledge of the Company, there are no events or circumstances that might reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding in writing by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(ff) ERISA Compliance. The Company and its subsidiaries and any “employee benefit plan” (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, “**ERISA**”)) established or maintained by the Company, its subsidiaries or their “ERISA Affiliates” (as defined below) are in compliance in all material respects with ERISA. “ERISA Affiliate” means, with respect to the Company or any of its subsidiaries, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the “**Code**”) of which the Company or such subsidiary is a member. Except as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change, (i) no “reportable event” (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any “employee benefit plan” established or maintained by the Company, its subsidiaries or, to the knowledge of the Company, any of their ERISA Affiliates, (ii) no “employee benefit plan” established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates, if such “employee benefit plan” were terminated, would have any “amount of unfunded benefit liabilities” (as defined under ERISA), (iii) neither the Company, its subsidiaries nor any of their ERISA Affiliates has incurred or reasonably expects to incur any liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any employee benefit plan and (iv) each employee benefit plan established or maintained by the Company or its subsidiaries or, to the knowledge of the Company, any of their ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code has received a current favorable determination or opinion letter from the Internal Revenue Service on which it is entitled to rely as to its qualified status and to the knowledge of the Company, nothing has occurred, whether by action or failure to act by the Company or its subsidiaries, which would cause the loss of such qualification.

(gg) Brokers. Except as otherwise disclosed in the Prospectus, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(hh) No Outstanding Loans or Other Extensions of Credit. The Company does not have any outstanding extension of credit, in the form of a personal loan, to or for any director or executive officer (or equivalent thereof) of the Company except for such extensions of credit as are expressly permitted by Section 13(k) of the Exchange Act.

(ii) Compliance with Laws. The Company and its subsidiaries have been and are in compliance in all material respects with all applicable laws, rules and regulations, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

(jj) Dividend Restrictions. Except as disclosed in the Prospectus, no subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or to any other subsidiary.

(kk) Anti-Corruption and Anti-Bribery Laws. Neither the Company nor any of its subsidiaries nor any director, officer, or employee of the Company or any of its subsidiaries, nor to the knowledge of the Company, any agent, Affiliate or other person acting on behalf of the Company or any of its subsidiaries has, in the course of its actions for, or on behalf of, the Company or any of its subsidiaries (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made or taken any act in furtherance of an offer, promise, or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or public international organization, or any political party, party official, or candidate for political office; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), the UK Bribery Act 2010, or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, authorized, requested, or taken an act in furtherance of any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment or benefit. The Company and its subsidiaries and, to the knowledge of the Company, the Company's Affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(ll) Money Laundering Laws. The operations of the Company and its subsidiaries are, and have been conducted at all times during the past ten (10) years, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “**Money Laundering Laws**”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(mm) Clinical Data and Regulatory Compliance. The preclinical tests and clinical trials, and other studies (collectively, “studies”) that are described in, or the results of which are referred to in, the Registration Statement or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company and its subsidiaries have no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement or the Prospectus; the Company and its subsidiaries have made all such filings and obtained all such approvals as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the “**Regulatory Agencies**”); neither the Company nor any of its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency requiring the termination or suspension or modification of any clinical trials that are described or referred to in the Registration Statement or the Prospectus; and the Company and its subsidiaries have each operated and currently are in compliance in all material respects with all applicable rules, regulations and policies of the Regulatory Agencies.

(nn) Sanctions. Neither the Company nor any of its subsidiaries, directors, officers or employees, nor, to the knowledge of the Company, any agent, or affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries is currently the subject or the target of any sanctions administered or enforced by the U.S. Government, (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State and including, without limitation, the designation as a “specially designated national” or “blocked person”), the United Nations Security Council, the European Union, His Majesty’s Treasury, or other relevant sanctions authority (collectively, “**Sanctions**”), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or the target of Sanctions, including, without limitation, Cuba, Iran, North Korea, Syria, the so-called Donetsk People’s Republic, the so-called Luhansk People’s Republic or any other Covered Region of Ukraine identified pursuant to Executive Order 14065, the Crimea region and the non-government controlled areas of Zaporizhzhia and Kherson Regions of Ukraine (each, a “**Sanctioned Country**”); and the Company will not directly or indirectly use the proceeds of the Placement Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or the target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. Since April 24, 2019, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(oo) Sarbanes-Oxley. The Company is in compliance, in all material respects, with all applicable provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder.

(pp) Duties, Transfer Taxes, Etc. No stamp or other issuance or transfer taxes or duties and no capital gains, income, withholding or other taxes are payable by the Agent in the United States or any political subdivision or taxing authority thereof or therein in connection with the execution, delivery or performance of this Agreement by the Company or the sale and delivery by the Company of the Shares.

(qq) Cybersecurity. Except as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change, the Company and its subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "**IT Systems**") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiaries as currently conducted, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its subsidiaries have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect "Personal Data" in its possession, and the integrity, continuous operation and security of all IT Systems and data used in connection with their businesses. "**Personal Data**" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by the European Union General Data Protection Regulation ("**GDPR**"); (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "**HIPAA**"); and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. Except as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change, there have been no breaches, violations, outages or unauthorized uses of or accesses to the Company's IT Systems, except for those that have been remedied without material cost or liability or the duty to notify any regulator, nor any incidents under internal review or investigations relating to the same. The Company and its subsidiaries are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.

(rr) Compliance with Data Privacy Laws. The Company and its subsidiaries are, and at all prior times were, in material compliance with all applicable state and federal data privacy and security laws and regulations, including without limitation HIPAA, and the Company and its subsidiaries have taken commercially reasonable actions to prepare to comply with, and since May 25, 2018, have been and currently are in compliance with, the European Union General Data Protection Regulation (“GDPR”) (EU 2016/679) (collectively, the “**Privacy Laws**”). To ensure compliance with the Privacy Laws, the Company and its subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the “**Policies**”). The Company and its subsidiaries have, except as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change, at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements, except as would not individually or in the aggregate be reasonably expected to result in a Material Adverse Change. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, its subsidiaries of any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any material order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(ss) Other Underwriting Agreements. The Company is not a party to any agreement with an agent or underwriter for any other “at the market” or continuous equity transaction.

(tt) Compliance with Health Care Laws. The Company and its subsidiaries are, and at all times have been, in compliance with all Health Care Laws applicable to the Company or any of its subsidiaries, except where the failure to do so would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change. For purposes of this Agreement, “Health Care Laws” means: (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), the Public Health Service Act (42 U.S.C. Section 201 et seq.), and the regulations promulgated thereunder; (ii) all applicable federal, state, local and foreign health care fraud and abuse laws, including, without limitation, the Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal false statements law (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286, 287, 1035, 1347 and 1349, the health care fraud criminal provisions under HIPAA (18 U.S.C. Section 1347), the civil monetary penalties law (42 U.S.C. Section 1320a-7a), the exclusion law (42 U.S.C. Section 1320a-7), the Physician Payments Sunshine Act (42 U.S.C. Section 1320-7h), the Medicare statute (Title XVIII of the Social Security Act), the Medicaid statute (Title XIX of the Social Security Act) and applicable laws governing government funded or sponsored healthcare programs; (iii) the EU Medical Devices Directive (Directive 93/42), the EU Active Implantable Medical Devices Directive (Directive 90/385), the EU Code of Medicinal Products (Directive 2001/83/EC), the EU Clinical Trials Directive (Directive 2001/20) and the EEA Member State laws implementing the provisions of each of those directives; (iv) the EU Medical Devices Regulation (Regulation 2017/745), the EU Regulation on the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Regulation 726/2004), and the EU Clinical Trials Regulation (Regulation 536/2014); (v) licensure, quality, safety and accreditation requirements under applicable federal, state, local or European Union, or foreign laws or regulatory bodies; (vi) all other local, state, federal, national, supranational, European Union, and foreign laws, relating to the regulation of the Company or its subsidiaries; and (vii) the directives and regulations promulgated pursuant to such statutes and any state or non-U.S. counterpart thereof. Neither the Company nor any of its subsidiaries, nor to the Company’s knowledge, their officers, directors, employees, agents, have engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other state or federal healthcare program. Neither the Company nor any of its subsidiaries has received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Health Care Laws nor, to the Company’s knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened. The Company and its subsidiaries have filed, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission). Neither the Company nor any of its subsidiaries is a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company nor any of its subsidiaries nor any of their respective employees, officers, directors, or agents has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

(uu) Product Manufacturing. The manufacture of the Company’s products, whether by or on behalf of the Company or any of its subsidiaries, is to the Company’s knowledge being conducted in compliance in all material respects with all applicable Health Care Laws, including, without limitation, the FDA’s current good manufacturing practice regulations for products prepared for clinical trials or sold in the United States, and the respective counterparts thereof promulgated by governmental authorities in countries outside the United States. Except as would not reasonably be expected to be material to the Company, neither the Company nor any of its subsidiaries has had any product or manufacturing site (whether Company-owned or that of a contract manufacturer for the Company’s products) subject to a governmental authority (including FDA) shutdown or import or export prohibition, nor received any FDA Form-483 or other governmental authority notice of inspectional observations, “warning letters,” “untitled letters,” requests to make changes to the Company’s products, processes or operations, or similar correspondence or notice from the FDA or other governmental authority alleging or asserting material noncompliance with any applicable Health Care Laws. To the Company’s knowledge, neither the FDA nor any other governmental authority is considering such action.

(vv) Safety Notices. There have been no material recalls, field notifications, field corrections, market withdrawals or replacements, warnings, “dear doctor” letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company’s products (collectively, “Safety Notices”), such Safety Notices, if any, were resolved or closed, and, to the Company’s knowledge, there are no material complaints with respect to the Company’s products that are currently unresolved. To the Company’s knowledge, there are no facts that would be reasonably likely to result in (i) a material Safety Notice with respect to the Company’s products, (ii) a material change in labeling of any the Company’s products, or (iii) a termination or suspension of marketing or testing of any of the Company’s products.

(ww) No Rights to Purchase Preferred Stock. The issuance and sale of the Shares as contemplated hereby will not cause any holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company to have any right to acquire any shares of preferred stock of the Company.

(xx) No Contract Terminations. Neither the Company nor any of its subsidiaries has sent or received any communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in any preliminary prospectus or the Prospectus, or referred to or described in, or filed as an exhibit to, the Registration Statement, and no such termination or non-renewal has been threatened by the Company or any of its subsidiaries or, to the Company’s knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

(yy) No Rated Debt. There are no debt securities or preferred stock issued, or guaranteed, by the Company that are rated by a “nationally recognized statistical rating organization,” as such term is defined in Section 3(a)(62) of the Exchange Act.

Any certificate signed by any officer or representative of the Company and delivered to the Agent or counsel for the Agent in connection with an issuance of Shares shall be deemed a representation and warranty by the Company (and not by such officer in his or her personal capacity) to the Agent as to the matters covered thereby on the date of such certificate.

The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to Section 4(n) hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 3. ISSUANCE AND SALE OF COMMON SHARES

(a) Sale of Securities. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company and the Agent agree that the Company may from time to time seek to sell Shares through the Agent, acting as sales agent, or directly to the Agent, acting as principal, as follows, with an aggregate Sales Price of up to the Maximum Program Amount, based on and in accordance with Issuance Notices as the Company may deliver, during the Agency Period. The Company acknowledges and agrees that sales of Shares under this Agreement may be made through Affiliates of the Agent and that the Agent may otherwise fulfill its obligations pursuant to this Agreement to or through an affiliated broker-dealer.

(b) Mechanics of Issuances.

(i) Issuance Notice. Upon the terms and subject to the conditions set forth herein, on any Trading Day during the Agency Period on which the conditions set forth in Section 5(a) and Section 5(b) shall have been satisfied, the Company may exercise its right to request an issuance of Shares by delivering to the Agent an Issuance Notice; *provided, however*, that (A) in no event may the Company deliver an Issuance Notice to the extent that (I) the sum of (x) the aggregate Sales Price of the requested Issuance Amount, plus (y) the aggregate Sales Price of all Shares issued under all previous Issuance Notices effected pursuant to this Agreement, would exceed the Maximum Program Amount; and (B) prior to delivery of any Issuance Notice, the period set forth for any previous Issuance Notice shall have expired or been terminated. An Issuance Notice shall be considered delivered on the Trading Day that it is received by e-mail to the persons set forth in Schedule A hereto and confirmed by the Company by telephone (including a voicemail message to the persons so identified), with the understanding that, with adequate prior written notice, the Agent may modify the list of such persons from time to time.

(ii) Agent Efforts. Upon the terms and subject to the conditions set forth in this Agreement, upon the receipt of an Issuance Notice, the Agent will use its commercially reasonable efforts consistent with its normal sales and trading practices to place the Shares with respect to which the Agent has agreed to act as sales agent, subject to, and in accordance with the information specified in, the Issuance Notice, unless the sale of the Shares described therein has been suspended, cancelled or otherwise terminated in accordance with the terms of this Agreement. For the avoidance of doubt, the parties to this Agreement may modify an Issuance Notice at any time provided they both agree in writing to any such modification.

(iii) Method of Offer and Sale. The Shares may be offered and sold (A) in privately negotiated transactions with the consent of the Company; (B) as a Block Sale (as defined below); or (C) by any other method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act, including sales made directly on the Principal Market or sales made into any other existing trading market of the Common Shares. In the event the Company engages the Agent for a sale of Shares in an agency transaction that would constitute a “block” within the meaning of Rule 10b-18(a)(5) under the Exchange Act (each, a “**Block Sale**”), notwithstanding anything stated to the contrary in this Agreement, the Company will provide the Agent, at the Agent’s request and upon reasonable advance notice to the Company, on or prior to the Settlement Date, the opinions of counsel, accountant’s letter and officers’ certificates as described in Section 4 hereof, each dated the Settlement Date, and such other documents and information as the Agent shall reasonably request. Nothing in this Agreement shall be deemed to require either party to agree to the method of offer and sale specified in the preceding sentence, and (except as specified in clauses (A) and (B) above) the method of placement of any Shares by the Agent shall be at the Agent’s discretion.

(iv) Confirmation to the Company. If acting as sales agent hereunder, the Agent will provide written confirmation to the Company no later than the opening of the Trading Day next following the Trading Day on which it has placed Shares hereunder setting forth the number of shares sold on such Trading Day, the corresponding Sales Price and the Issuance Price payable to the Company in respect thereof.

(v) Settlement. Each issuance of Shares will be settled on the applicable Settlement Date for such issuance of Shares and, subject to the provisions of Section 5, on or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Agent or its designee's account at The Depository Trust Company through its Deposit/Withdrawal At Custodian (DWAC) System, or by such other means of delivery as may be mutually agreed upon by the parties hereto and, upon receipt of such Shares, which in all cases shall be freely tradable, transferable, registered shares in good deliverable form, the Agent will deliver, by wire transfer of immediately available funds, the related Issuance Price in same day funds delivered to an account designated by the Company prior to the Settlement Date. The Company may sell Shares to the Agent as principal at a price agreed upon at each relevant time Shares are sold pursuant to this Agreement (each, a "Time of Sale").

(vi) Suspension or Termination of Sales. Consistent with standard market settlement practices, the Company or the Agent may, upon notice to the other party hereto in writing or by telephone (confirmed immediately by verifiable email), suspend any sale of Shares, and the period set forth in an Issuance Notice shall immediately terminate; *provided, however*, that (A) such suspension and termination shall not affect or impair either party's obligations with respect to any Shares placed or sold hereunder prior to the receipt of such notice; (B) if the Company suspends or terminates any sale of Shares after the Agent confirms such sale to the Company, the Company shall still be obligated to comply with Section 3(b)(v) with respect to such Shares; and (C) if the Company defaults in its obligation to deliver Shares on a Settlement Date, the Company agrees that it will hold the Agent harmless against any loss, claim, damage or expense (including, without limitation, penalties, interest and reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company. The parties hereto acknowledge and agree that, in performing its obligations under this Agreement, the Agent may borrow Common Shares from stock lenders in the event that the Company has not delivered Shares to settle sales as required by subsection (v) above, and may use the Shares to settle or close out such borrowings. The Company agrees that no such notice shall be effective against the Agent unless it is made to the persons identified in writing by the Agent pursuant to Section 3(b)(i).

(vii) No Guarantee of Placement, Etc. The Company acknowledges and agrees that (A) there can be no assurance that the Agent will be successful in placing Shares; (B) the Agent will incur no liability or obligation to the Company or any other Person if it does not sell Shares; and (C) the Agent shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Agent and the Company.

(viii) Material Non-Public Information. Notwithstanding any other provision of this Agreement, the Company shall not offer, sell or deliver, or request the offer or sale, of any Shares pursuant to this Agreement and, by notice to the Agent given by telephone (confirmed promptly by email), shall cancel any instructions for the placement, offer or sale of any Shares, and the Agent shall not be obligated to place any Shares, (i) during any period in which the Company is in possession of material non-public information, or (ii) at any time from and including the date on which the Company shall issue a press release containing, or shall otherwise publicly announce, its earnings, revenues or other results of operations (an "Earnings Announcement") through and including the date that the Company files a Quarterly Report on Form 10-Q or an Annual Report on Form 10-K that includes consolidated financial statements as of and for the same period or periods, as the case may be, covered by such Earnings Announcement unless the Company has filed a Form 8-K in a manner such that the information in the Earnings Announcement is incorporated by reference into the Registration Statement and the Prospectus.

(c) Fees. As compensation for services rendered, the Company shall pay to the Agent, on the applicable Settlement Date, the Selling Commission for the applicable Issuance Amount (including with respect to any suspended or terminated sale pursuant to Section 3(b)(vi)) by the Agent deducting the Selling Commission from the applicable Issuance Amount.

(d) Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Shares (including all printing and engraving costs); (ii) all fees and expenses of the registrar and transfer agent of the Shares; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Shares; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Prospectus, and all amendments and supplements thereto, and this Agreement; (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Agent in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Agent, preparing and printing a "**Blue Sky Survey**" or memorandum and a "Canadian wrapper," and any supplements thereto, advising the Agent of such qualifications, registrations, determinations and exemptions; (vii) the reasonable fees and disbursements of the Agent's counsel, including the reasonable fees and expenses of counsel for the Agent in connection with, FINRA review, if any, and approval of the Agent's participation in the offering and distribution of the Shares; (viii) the filing fees incident to FINRA review, if any; (ix) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives, employees and officers of the Company and of the Agent and any such consultants, and the cost of any aircraft chartered in connection with the road show; and (x) the fees and expenses associated with listing the Shares on the Principal Market. The fees and disbursements of Agent's counsel pursuant to subsections (vi) and (vii) above shall not exceed (A) \$75,000 in connection with execution of this Agreement and (B) \$25,000 in connection with each Triggering Event Date (as defined below) on which the Company files with the Commission an annual report on Form 10-K (including any Form 10-K/A containing amended financial information or a material amendment to the previously filed annual report on Form 10-K) and is required to provide a certificate pursuant to Section 4(m) and (C) \$15,000 in connection with each other Triggering Event Date on which the Company is required to provide a certificate pursuant to Section 4(m).

Section 4. ADDITIONAL COVENANTS

The Company covenants and agrees with the Agent as follows, in addition to any other covenants and agreements made elsewhere in this Agreement:

(a) Exchange Act Compliance. During the Agency Period, the Company shall (i) file, on a timely basis, with the Commission all reports and documents required to be filed under Section 13, 14 or 15 of the Exchange Act in the manner and within the time periods required by the Exchange Act; and (ii) either (A) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, for the relevant reporting period, (1) the number of Shares sold through the Agent pursuant to this Agreement and (2) the net proceeds received by the Company from such sales or (B) prepare a prospectus supplement containing, or include in such other filing permitted by the Securities Act or Exchange Act (each an “**Interim Prospectus Supplement**”), such summary information and, at least once a quarter and subject to this Section 4, file such Interim Prospectus Supplement pursuant to Rule 424(b) under the Securities Act (and within the time periods required by Rule 424(b) and Rule 430B under the Securities Act)).

(b) Securities Act Compliance. After the date of this Agreement, the Company shall promptly advise the Agent in writing (i) of the receipt of any comments of, or requests for additional or supplemental information from, the Commission in relation to the Registration Statement or the Prospectus; (ii) of the time and date of any filing of any post-effective amendment to the Registration Statement, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus; (iii) of the time and date that any post-effective amendment to the Registration Statement or any Rule 462(b) Registration Statement becomes effective; and (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto, any Rule 462(b) Registration Statement or any amendment or supplement to the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Common Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order as soon as practicable. Additionally, the Company agrees that it shall comply with the provisions of Rule 424(b) and Rule 433, as applicable, under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under such Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(c) Amendments and Supplements to the Prospectus and Other Securities Act Matters. During any period in which an Issuance Notice is pending, if any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, not misleading, or if in the opinion of the Agent or counsel for the Agent it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, including the Securities Act, the Company agrees (subject to Section 4(d) and 4(f)) to promptly prepare, file with the Commission and furnish at its own expense to the Agent, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law including the Securities Act. Neither the Agent’s consent to, or delivery of, any such amendment or supplement shall constitute a waiver of any of the Company’s obligations under Sections 4(d) and 4(f).

(d) Agent's Review of Proposed Amendments and Supplements. Prior to amending or supplementing the Registration Statement (including any Rule 462(b) Registration Statement) or the Prospectus (excluding any amendment or supplement through incorporation of any report filed under the Exchange Act), the Company shall furnish to the Agent for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each such proposed amendment or supplement insofar as such proposed amendment or supplement relates to the transactions contemplated in this Agreement, and the Company shall not file or use any such proposed amendment or supplement without the Agent's prior consent, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(e) Free Writing Prospectus. As of the determination date reference in Rule 164(h) under the Securities Act, the Company was an "ineligible issuer" in connection with the offering pursuant to Rules 164, 405 and 433 under the Securities Act. Neither the Company nor the Agent has prepared, used, referred to or distributed, or will prepare, use, refer to or distribute, without the other party's prior written consent, any "written communication" that constitutes a "free writing prospectus" as such terms are defined in Rule 405 under the Securities Act with respect to the offering contemplated by this Agreement.

(f) Copies of Registration Statement and Prospectus. After the date of this Agreement through the last time that a prospectus is required by the Securities Act (including, without limitation, pursuant to Rule 173(d)) to be delivered in connection with sales of the Shares, the Company agrees to furnish the Agent with copies (which may be electronic copies) of the Registration Statement and each amendment thereto, and with copies of the Prospectus and each amendment or supplement thereto in the form in which it is filed with the Commission pursuant to the Securities Act or Rule 424(b) under the Securities Act, both in such quantities as the Agent may reasonably request from time to time; and, if the delivery of a prospectus is required under the Securities Act or under the blue sky or securities laws of any jurisdiction at any time on or prior to the applicable Settlement Date for any period set forth in an Issuance Notice in connection with the offering or sale of the Shares and if at such time any event has occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it is necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Securities Act or the Exchange Act, to notify the Agent and to request that the Agent suspend offers to sell Shares (and, if so notified, the Agent shall cease such offers as soon as practicable); and if the Company decides to amend or supplement the Registration Statement or the Prospectus as then amended or supplemented, to advise the Agent promptly by telephone (with confirmation in writing) and to prepare and cause to be filed promptly with the Commission an amendment or supplement to the Registration Statement or the Prospectus as then amended or supplemented that will correct such statement or omission or effect such compliance; provided, however, that if during such same period the Agent is required to deliver a prospectus in respect of transactions in the Shares, the Company shall promptly prepare and file with the Commission such an amendment or supplement.

(g) Blue Sky Compliance. The Company shall cooperate with the Agent and counsel for the Agent to qualify or register the Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Agent, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Agent promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof as soon as practicable.

(h) Earnings Statement. As soon as practicable, the Company will make generally available to its security holders and to the Agent an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act; *provided* that the Company shall be deemed to have furnished such statements to its security holders and the Agent to the extent they are filed on the Commission's EDGAR system or any successor to such system.

(i) Listing; Reservation of Shares. (a) The Company will use commercially reasonable efforts to maintain the listing of the Shares on the Principal Market; and (b) the Company will reserve and keep available at all times, free of preemptive rights, Shares for the purpose of enabling the Company to satisfy its obligations under this Agreement.

(j) Transfer Agent. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(k) Due Diligence. During the term of this Agreement, the Company will reasonably cooperate with any reasonable due diligence review conducted by the Agent in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during normal business hours and at the Company's principal offices, or virtually, as the Agent may reasonably request from time to time.

(l) Representations and Warranties. The Company acknowledges that each delivery of an Issuance Notice and each delivery of Shares on a Settlement Date shall be deemed to be (i) an affirmation to the Agent that the representations and warranties of the Company contained in or made pursuant to this Agreement are true and correct as of the date of such Issuance Notice or of such Settlement Date, as the case may be, as though made at and as of each such date, except as may be disclosed in the Prospectus (including any documents incorporated by reference therein and any supplements thereto); and (ii) an undertaking that the Company will advise the Agent if any of such representations and warranties will not be true and correct as of the Settlement Date for the Shares relating to such Issuance Notice, as though made at and as of each such date (except that such representations and warranties shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented relating to such Shares).

(m) Deliverables at Triggering Event Dates; Certificates. The Company agrees that on or prior to the date of the first Issuance Notice and, during the term of this Agreement after the date of the first Issuance Notice, upon:

(A) the filing of the Prospectus or the amendment or supplement of any Registration Statement or Prospectus (other than a prospectus supplement relating solely to an offering of securities other than the Shares or a prospectus filed pursuant to Section 4(a)(ii)(B)), by means of a post-effective amendment, sticker or supplement, but not by means of incorporation of documents by reference into the Registration Statement or Prospectus;

(B) the filing with the Commission of an annual report on Form 10-K or a quarterly report on Form 10-Q (including any Form 10-K/A or Form 10-Q/A containing amended financial information or a material amendment to the previously filed annual report on Form 10-K or quarterly report on Form 10-Q), in each case, of the Company; or

(C) the filing with the Commission of a current report on Form 8-K of the Company containing amended financial information (other than information “furnished” pursuant to Item 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) that is material to the offering of securities of the Company in the Agent’s reasonable discretion;

(any such event, a “**Triggering Event Date**”), the Company shall furnish the Agent (but in the case of clause (C) above only if the Agent reasonably determines that the information contained in such current report on Form 8-K of the Company is material) with a certificate as of the Triggering Event Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented, (A) confirming that the representations and warranties of the Company contained in this Agreement are true and correct, (B) that the Company has performed all of its obligations hereunder to be performed on or prior to the date of such certificate and as to the matters set forth in Section 5(a)(iii) hereof, and (C) containing any other certification that the Agent shall reasonably request. The requirement to provide a certificate under this Section 4(m) shall be waived for any Triggering Event Date occurring at a time when no Issuance Notice is pending or a suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Shares hereunder (which for such calendar quarter shall be considered a Triggering Event Date) and the next occurring Triggering Event Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Triggering Event Date when a suspension was in effect and did not provide the Agent with a certificate under this Section 4(m), then before the Company delivers the instructions for the sale of Shares or the Agent sells any Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 4(m) dated as of the date that the instructions for the sale of Shares are issued.

(n) Legal Opinions. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(m) for which no waiver is applicable and excluding the date of this Agreement, a negative assurance letter and the written legal opinion of Paul Hastings LLP, counsel to the Company, Latham & Watkins LLP, counsel to the Agent, and Plumsea Law Group, LLC and Crockett and Crockett, each as intellectual property counsel to the Company, or such applicable intellectual property counsel to the Company from time to time, each dated the date of delivery, in form and substance reasonably satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented. In lieu of such opinions for subsequent periodic filings, in the discretion of the Agent, the Company may furnish a reliance letter from such counsel to the Agent, permitting the Agent to rely on a previously delivered opinion letter, modified as appropriate for any passage of time or Triggering Event Date (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of such Triggering Event Date).

(o) Comfort Letter. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(m) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause Ernst & Young LLP, the independent registered public accounting firm who has audited the financial statements included or incorporated by reference in the Registration Statement, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letter will only be required on the Triggering Event Date specified to the extent that it contains financial statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. If requested by the Agent, the Company shall also cause a comfort letter to be furnished to the Agent on the date of occurrence of any material transaction or event requiring the filing of a current report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements; provided, that, such comfort letter shall not be required to be delivered to the Agent unless and until the Company delivers an Issuance Notice that is effective on or after the date of occurrence of such material transaction or event. Subject to the preceding sentence, the Company shall be required to furnish no more than one comfort letter hereunder per calendar quarter.

(p) Secretary's Certificate. On or prior to the date of the first Issuance Notice and on or prior to each Triggering Event Date on which the Company is required to provide a certificate pursuant to Section 4(m) for which no waiver is applicable and excluding the date of this Agreement, the Company shall furnish the Agent a certificate executed by the Secretary of the Company, signing in such capacity, dated the date of delivery (i) certifying that attached thereto are true and complete copies of the resolutions duly adopted by the Board of Directors of the Company authorizing the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby (including, without limitation, the issuance of the Shares pursuant to this Agreement), which authorization shall be in full force and effect on and as of the date of such certificate, (ii) certifying and attesting to the office, incumbency, due authority and specimen signatures of each Person who executed this Agreement for or on behalf of the Company, and (iii) containing any other certification that the Agent shall reasonably request.

(q) Agent's Own Account; Clients' Account. The Company consents to the Agent trading, in compliance with applicable law, in the Common Shares for the Agent's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

(r) Investment Limitation. The Company shall not invest, or otherwise use the proceeds received by the Company from its sale of the Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

(s) Market Activities. The Company will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of the Shares or any other security, whether to facilitate the sale or resale of the Shares or otherwise, and the Company will, and shall cause each of its Affiliates to, comply with all applicable provisions of Regulation M.

(t) Notice of Other Sale. Without the written consent of the Agent, during the period beginning on the third Trading Day immediately prior to the date on which any Issuance Notice is delivered to the Agent hereunder and ending on the third Trading Day immediately following the Settlement Date with respect to Shares sold pursuant to such Issuance Notice, the Company will not: (i) directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Shares or securities convertible into or exchangeable for Common Shares (other than Shares hereunder), warrants or any rights to purchase or acquire Common Shares, and (ii) directly or indirectly enter into 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 Common Shares (other than the Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Shares, warrants or any rights to purchase or acquire, Common Shares prior to the termination of this Agreement; provided, however, that, in each case, such restrictions will not be required in connection with the Company's (i) issuance or sale of Common Shares, options to purchase Common Shares or Common Shares issuable upon the exercise of options or other equity awards pursuant to any employee or director share option, incentive or benefit plan, share purchase or ownership plan, long-term incentive plan, dividend reinvestment plan, inducement award under Nasdaq rules or other compensation plan of the Company or its subsidiaries, as in effect on the date of this Agreement or subsequently disclosed in the filings by the Company available on EDGAR or otherwise publicly disclosed or disclosed in writing to the Agent, (ii) issuance or sale of Common Shares issuable upon exchange, conversion or redemption of securities or the exercise or vesting of warrants, options or other equity awards, (iii) issuance or sale of Common Shares or securities convertible into or exchangeable for Common Shares as consideration for mergers, acquisitions, other business combinations or strategic alliances, joint ventures, marketing or distribution arrangements, collaboration agreements, co-promotion agreements, or intellectual property license agreements occurring after the date of this Agreement, which are not used for capital raising purposes and which aggregate number of Common Shares issued or sold under this subsection (iii), on an as-converted basis, if applicable, shall not exceed 7.5% of the number of Common Shares outstanding immediately prior to giving effect to such sale or issuance and (iv) modification of any outstanding options, warrants of any rights to purchase or acquire Common Shares.

Section 5. CONDITIONS TO DELIVERY OF ISSUANCE NOTICES AND TO SETTLEMENT

(a) Conditions Precedent to the Right of the Company to Deliver an Issuance Notice and the Obligation of the Agent to Sell Shares. The right of the Company to deliver an Issuance Notice hereunder is subject to the satisfaction, on the date of delivery of such Issuance Notice, and the obligation of the Agent to use its commercially reasonable efforts to place Shares during the applicable period set forth in the Issuance Notice is subject to the satisfaction, on each Trading Day during the applicable period set forth in the Issuance Notice, of each of the following conditions:

- (i) Accuracy of the Company's Representations and Warranties; Performance by the Company. The Company shall have delivered the certificate required to be delivered pursuant to Section 4(m) on or before the date on which delivery of such certificate is required pursuant to Section 4(m). The Company shall have performed, satisfied and complied with all covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to such date, including, but not limited to, the covenants contained in Section 4(n), Section 4(o) and Section 4(k).
- (ii) No Injunction. No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction or any self-regulatory organization having authority over the matters contemplated hereby that prohibits or directly and materially adversely affects any of the transactions contemplated by this Agreement, and no proceeding shall have been commenced that may have the effect of prohibiting or materially adversely affecting any of the transactions contemplated by this Agreement.
- (iii) Material Adverse Changes. Except as disclosed in the Prospectus, (a) in the judgment of the Agent there shall not have occurred any Material Adverse Change; and (b) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization" as such term is defined for purposes of Section 3(a)(62) of the Exchange Act.

(iv) No Suspension of Trading in or Delisting of Common Shares; Other Events. The trading of the Common Shares (including without limitation the Shares) shall not have been suspended by the Commission, the Principal Market or FINRA and the Common Shares (including without limitation the Shares) shall have been approved for listing or quotation on and shall not have been delisted from the Nasdaq Stock Market, the New York Stock Exchange or any of their constituent markets. There shall not have occurred (and be continuing in the case of occurrences under clauses (i) and (ii) below) any of the following: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by the Principal Market or trading in securities generally on either the Principal Market shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges by the Commission or the FINRA; (ii) a general banking moratorium shall have been declared by any of federal or New York, authorities; or (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Agent is material and adverse and makes it impracticable to market the Shares in the manner and on the terms described in the Prospectus or to enforce contracts for the sale of securities.

(b) Documents Required to be Delivered on each Issuance Notice Date. The Agent's obligation to use its commercially reasonable efforts to place Shares hereunder shall additionally be conditioned upon the delivery to the Agent on or before the Issuance Notice Date of a certificate in form and substance reasonably satisfactory to the Agent, executed by the Chief Executive Officer, President or Chief Financial Officer of the Company, to the effect that all conditions to the delivery of such Issuance Notice shall have been satisfied as at the date of such certificate (which certificate shall not be required if the foregoing representations shall be set forth in the Issuance Notice).

(c) No Misstatement or Material Omission. Agent shall not have advised the Company that the Registration Statement, the Prospectus or the Times of Sales Information, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

Section 6. INDEMNIFICATION AND CONTRIBUTION

(a) Indemnification of the Agent. The Company agrees to indemnify and hold harmless the Agent, its affiliates, directors, officers, employees and agents, and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Agent or such affiliate, director, officer, employee, agent or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained in the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, and to reimburse the Agent and each such affiliate, director, officer, employee, agent and controlling person for any and all expenses (including the reasonable and documented fees and disbursements of counsel chosen by the Agent) as such expenses are reasonably incurred by the Agent or such affiliate, director, officer, employee, agent or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement, the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in Section 6(b) below. The indemnity agreement set forth in this Section 6(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) Indemnification of the Company, its Directors and Officers. The Agent agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which the Company or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation), arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, including any information deemed to be a part thereof pursuant to Rule 430B under the Securities Act, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact contained the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; but, for each of (i) and (ii) above, only to the extent arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information furnished by the Agent to the Company consists of the information set forth in the ninth paragraph under the caption "Plan of Distribution" in the Prospectus, and to reimburse the Company and each such director, officer and controlling person for any and all documented expenses (including the reasonable and documented fees and disbursements of one counsel chosen by the Company) as such expenses are reasonably incurred by the Company or such officer, director or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The indemnity agreement set forth in this Section 6(b) shall be in addition to any liabilities that the Agent or the Company may otherwise have.

(c) Notifications and Other Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 6 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 6, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve it from any liability which it may have to any indemnified party for contribution or otherwise than under the indemnity agreement contained in this Section 6 to the extent it is not prejudiced as a proximate result of such failure. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 6 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (a) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the indemnified party (in the case of counsel for the indemnified parties referred to in Section 6(a) and Section 6(b) above), (b) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) Settlements. The indemnifying party under this Section 6 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 party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by Section 6(c) hereof, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request; and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and does not include an admission of fault or culpability or a failure to act by or on behalf of such indemnified party.

(e) Contribution. If the indemnification provided for in this Section 6 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Agent, on the other hand, from the offering of the Shares pursuant to this Agreement; or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Agent, on the other hand, in connection with the offering of the Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total gross proceeds from the offering of the Shares pursuant to this Agreement (after deducting commissions received by the Agent but before deducting expenses) received by the Company, and the total commissions received by the Agent. The relative fault of the Company, on the one hand, and the Agent, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Agent, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 6(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 6(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 6(e); provided, however, that no additional notice shall be required with respect to any action for which notice has been given under Section 6(c) for purposes of indemnification.

The Company and the Agent agree that it would not be just and equitable if contribution pursuant to this Section 6(e) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 6(e).

Notwithstanding the provisions of this Section 6(e), the Agent shall not be required to contribute any amount in excess of the agent fees received by the Agent in connection with the offering contemplated hereby. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6(e), each officer and employee of the Agent and each person, if any, who controls the Agent within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as the Agent, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 7. TERMINATION & SURVIVAL

(a) Term. Subject to the provisions of this Section 7, the term of this Agreement shall continue from the date of this Agreement until the end of the Agency Period, unless earlier terminated by the parties to this Agreement pursuant to this Section 7.

(b) Termination; Survival Following Termination.

- (i) Either party may terminate this Agreement prior to the end of the Agency Period, by giving written notice as required by this Agreement, upon ten (10) Trading Days' notice to the other party; provided that, (A) if the Company terminates this Agreement after the Agent confirms to the Company any sale of Shares, the Company shall remain obligated to comply with Section 3(b)(v) with respect to such Shares and (B) Section 2, Section 6, Section 7 and Section 8 shall survive termination of this Agreement. If termination shall occur prior to the Settlement Date for any sale of Shares, such sale shall nevertheless settle in accordance with the terms of this Agreement.
- (ii) In addition to the survival provision of Section 7(b)(i), the respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the Agent set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of the Agent or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Shares sold hereunder and any termination of this Agreement.

Section 8. RECOGNITION OF THE U.S. SPECIAL RESOLUTION REGIMES

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

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

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

Section 9. MISCELLANEOUS

(a) Press Releases and Disclosure. The Company may issue a press release describing the material terms of the transactions contemplated hereby as soon as practicable following the date of this Agreement, and may file with the Commission a Current Report on Form 8-K, with this Agreement attached as an exhibit thereto, describing the material terms of the transactions contemplated hereby, and the Company shall consult with the Agent prior to making such disclosures, and the parties hereto shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosures that is reasonably satisfactory to all parties hereto. No party hereto shall issue thereafter any press release or like public statement (including, without limitation, any disclosure required in reports filed with the Commission pursuant to the Exchange Act) related to this Agreement or any of the transactions contemplated hereby without the prior written approval of the other party hereto, except as may be necessary or appropriate in the reasonable opinion of the party seeking to make disclosure to comply with the requirements of applicable law or stock exchange rules. If any such press release or like public statement is so required, the party making such disclosure shall consult with the other party prior to making such disclosure, and the parties shall use all commercially reasonable efforts, acting in good faith, to agree upon a text for such disclosure that is reasonably satisfactory to all parties hereto.

(b) No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (i) the transactions contemplated by this Agreement, including the determination of any fees, are arm's-length commercial transactions between the Company and the Agent, (ii) when acting as a principal under this Agreement, the Agent is and has been acting solely as a principal is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (iii) the Agent has not assumed nor will assume an advisory or fiduciary responsibility in favor of the Company with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Agent has advised or is currently advising the Company on other matters) and the Agent does not have any obligation to the Company with respect to the transactions contemplated hereby except the obligations expressly set forth in this Agreement, (iv) the Agent and its respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Agent has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

(c) Research Analyst Independence. The Company acknowledges that the Agent's research analysts and research departments are required to and should be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and as such the Agent's research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company or the offering that differ from the views of their respective investment banking divisions. The Company understands that the Agent is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.

(d) Notices. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Agent:

TD Securities (USA) LLC
1 Vanderbilt Avenue
New York, NY 10017
Attention: General Counsel
Email: CIBLegal@tdsecurities.com

with a copy (which shall not constitute notice) to:

Latham & Watkins LLP
1271 Avenue of the Americas
New York, NY 10020
Attention: Nathan Ajiashvili, Esq.

If to the Company:

Orchestra BioMed Holdings, Inc.
150 Union Square Drive
New Hope, PA 18938
Attention: Chief Financial Officer

with a copy (which shall not constitute notice) to:

Paul Hastings LLP
200 Park Avenue
New York, NY 10166
Attention: Samuel Waxman, Esq.

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 9(d).

(e) Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in Section 6, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term “successors” shall not include any purchaser of the Shares as such from the Agent merely by reason of such purchase.

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

(g) Governing Law Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the “**Specified Courts**”), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party’s address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

(h) General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The Article and Section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

Each of the parties hereto acknowledges that it is a sophisticated business person who was adequately represented by counsel during negotiations regarding the provisions hereof, including, without limitation, the indemnification provisions of Section 6 and the contribution provisions of Section 6, and is fully informed regarding said provisions. Each of the parties hereto further acknowledges that the provisions of Section 6 hereof fairly allocate the risks in light of the ability of the parties to investigate the Company, its affairs and its business in order to assure that adequate disclosure has been made in the Registration Statement and the Prospectus (and any amendments and supplements to the foregoing), as contemplated by the Securities Act and the Exchange Act.

This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[Signature Page Immediately Follows]

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

Very truly yours,

ORCHESTRA BIOMED HOLDINGS, INC.

By: /s/ David P. Hochmann

Name: David P. Hochman

Title: Chief Executive Officer and Chairman of the Board of Directors

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

TD SECURITIES (USA) LLC

By: /s/ Michael Murphy

Name: Michael Murphy

Title: Managing Director

EXHIBIT A

ISSUANCE NOTICE

[Date]

TD Securities (USA) LLC
1 Vanderbilt Avenue
New York, New York 10017

Attn: [_____]

Reference is made to the Open Market Sale Agreement between Orchestra BioMed Holdings, Inc., a Delaware corporation (the “**Company**”) and TD Securities (USA) LLC (the “**Agent**”) dated as of August [•], 2024 (the “**Sales Agreement**”). The Company confirms that all conditions to the delivery of this Issuance Notice are satisfied as of the date hereof. Capitalized terms used herein shall have the meanings ascribed to them in the Sales Agreement.

Date of Delivery of Issuance Notice (determined pursuant to Section 3(b)(i)): _____

Issuance Amount (equal to the total Sales Price for such Shares):

\$ _____

Number of days in selling period: _____

First date of selling period: _____

Last date of selling period: _____

Settlement Date(s) if other than standard T+1 settlement:

Floor Price Limitation (in no event less than \$1.00 without the prior written consent of the Agent, which consent may be withheld in the Agent’s sole discretion): \$ ____ per share

Comments: _____

ORCHESTRA BIOMED HOLDINGS, INC.

By: _____
Name:
Title:

Schedule A

Notice Parties

The Company

David Hochman Chief Executive Officer

Darren Sherman President

Andrew Taylor Chief Financial Officer

The Agent

Michael Murphy Managing Director

Adriano Pierroz Director

Megan Sanford Analyst

PAUL HASTINGS

August 12, 2024

Orchestra BioMed Holdings, Inc.
150 Union Square Drive
New Hope, Pennsylvania 18938

Re: Orchestra BioMed Holdings, Inc. Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to Orchestra BioMed Holdings, Inc., a Delaware corporation (the “*Company*”), in connection with the proposed issuance and sale of up to \$100,000,000 of shares (the “*ATM Shares*”) of the Company’s common stock, par value \$0.0001 per share (the “*Common Stock*”), that may be issued and sold from time to time pursuant to that certain Sales Agreement, dated as of August 12, 2024 (the “*Sales Agreement*”), by and between the Company and TD Securities (USA) LLC, as sales agent. The ATM Shares are covered by the Registration Statement on Form S-3 (File No. 333-279430) filed by the Company with the U.S. Securities and Exchange Commission (the “*Commission*”) under the Securities Act of 1933, as amended (the “*Act*”) on May 15, 2024, and declared effective on May 24, 2024 (the “*Registration Statement*”), including the base prospectus dated May 24, 2024 included therein (the “*Base Prospectus*”) as supplemented by the prospectus supplement dated August 12, 2024, filed with the Commission pursuant to Rule 424(b) (5) under the Act on August 12, 2024 (the “*Prospectus Supplement*” and, together with the Base Prospectus, the “*Prospectus*”).

This opinion letter is being furnished in accordance 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 issuance of the ATM Shares.

As such counsel and for purposes of our opinion set forth herein, we have examined and relied upon originals or copies, certified or otherwise identified to our satisfaction, of such documents, resolutions, certificates and other instruments of the Company and corporate records furnished to us by the Company, and have reviewed certificates of public officials, statutes, records and such other instruments and documents as we have deemed necessary or appropriate as a basis for the opinion set forth below, including, without limitation:

- (i) the Registration Statement;
- (ii) the Base Prospectus;
- (iii) the Prospectus Supplement;
- (iv) the Sales Agreement;
- (v) the Company’s Certificate of Incorporation, certified as of August 9, 2024 by the Secretary of State of the State of Delaware and certified by an officer of the Company as of the date hereof (the “*Certificate of Incorporation*”), and the Amended and Restated Bylaws of the Company as presently in effect, certified by an officer of the Company as of the date hereof (together, the “*Charter Documents*”);
- (vi) resolutions adopted by the board of directors of the Company (the “*Board*”) of the Company, or a committee thereof, certified by an officer of the Company as of the date hereof (the “*Resolutions*”);

Paul Hastings LLP | 200 Park Avenue | New York, NY 10166
t: +1.212.318.6000 | www.paulhastings.com

Orchestra BioMed Holdings, Inc.
August 12, 2024
Page 2

- (vii) a certificate of the Secretary of State of the State of Delaware certifying as to the formation and good standing of the Company under the laws of the State of Delaware as of August 9, 2024 (the “*Good Standing Certificate*”); and
- (viii) certificates of officers and representatives of the Company.

In addition to the foregoing, we have made such investigations of law as we have deemed necessary or appropriate as a basis for the opinion set forth herein.

In such examination and in rendering the opinion expressed below, we have assumed, without independent investigation or verification: (i) the genuineness of all signatures on all agreements, instruments, corporate records, certificates and other documents submitted to us; (ii) the legal capacity, competency and authority of all individuals executing all agreements, instruments, corporate records, certificates and other documents submitted to us; (iii) the authenticity and completeness of all agreements, instruments, corporate records, certificates and other documents submitted to us as originals; (iv) that all agreements, instruments, corporate records, certificates and other documents submitted to us as certified, electronic, facsimile, conformed, photostatic or other copies conform to the originals thereof, and that such originals are authentic and complete; (v) the due authorization, execution and delivery of all agreements, instruments, corporate records, certificates and other documents by all parties thereto (other than the Company); (vi) that no documents submitted to us have been amended or terminated orally or in writing, except as has been disclosed to us in writing; (vii) that the statements contained in the certificates and comparable documents of public officials, officers and representatives of the Company and other persons on which we have relied for the purposes of this opinion letter are true and correct on and as of the date hereof; (viii) that there has not been nor will there be any change in the good standing status of the Company from that which was reported in the Good Standing Certificate; and (ix) that each of the officers and directors of the Company has properly exercised his or her fiduciary duties. As to all questions of fact material to this opinion letter and as to the materiality of any fact or other matter referred to herein, we have relied (without independent investigation or verification) upon representations and certificates or comparable documents of officers and representatives of the Company.

We have further assumed that the Registration Statement and any amendments thereto will be effective under the Act (and such effectiveness shall not have been terminated or rescinded) and comply with all applicable laws at the time the ATM Shares are offered and issued as contemplated by the Registration Statement and the Prospectus.

We have also assumed that (i) upon the issuance of any of the ATM Shares, the total number of shares of Common Stock issued and outstanding will not exceed the total number of shares of Common Stock that the Company is then authorized to issue under the Certificate of Incorporation, (ii) the Company will comply with all applicable notice requirements regarding uncertificated shares provided under the Delaware General Corporation Law (the “*DGCL*”), and (iii) the issue and sale of the ATM Shares to be issued by the Company from time to time will be authorized and approved by the Board or a committee thereof established by the Board with the authority to issue and sell the ATM Shares pursuant to the Sales Agreement in accordance with the DGCL, the Charter Documents and the Resolutions (with such approvals referred to herein as the “*Corporate Proceedings*”) prior to the issuance thereof.

Based upon the foregoing, and in reliance thereon, and subject to the assumptions, exceptions, qualifications and limitations set forth herein, we are of the opinion that, as of the date hereof, with respect to any ATM Shares to be offered by the Company pursuant to the Prospectus, upon the completion of all Corporate Proceedings relating to such ATM Shares, the issuance and sale of such ATM Shares will be duly authorized by all necessary corporate action of the Company and, when the ATM Shares have been duly issued and delivered against payment of the consideration therefor (not less than the par value of the ATM Shares) in accordance with the Corporate Proceedings and as contemplated by the Sales Agreement and the Prospectus, such ATM Shares will be validly issued, fully paid and nonassessable.

Orchestra BioMed Holdings, Inc.
August 12, 2024
Page 3

Without limiting any of the other limitations, exceptions, assumptions and qualifications stated elsewhere herein, we express no opinion with regard to the applicability or effect of the laws of any jurisdiction other than the DGCL as in effect on the date hereof. We are not rendering any opinion as to compliance with any federal or state antifraud law, rule or regulation relating to securities, or to the sale or issuance thereof.

This opinion letter deals only with the specified legal issues expressly addressed herein, and you should not infer any opinion that is not explicitly stated herein from any matter addressed in this opinion letter. This opinion letter is rendered solely in connection with the offering of the ATM Shares as described in the Prospectus and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. This opinion letter is rendered as of the date hereof, and we assume no obligation to advise you or any other person with regard to any change after the date hereof in the circumstances or the law that may bear on the matters set forth herein even if the change may affect the legal analysis or a legal conclusion or other matters in this opinion letter.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to a Current Report on Form 8-K of the Company for incorporation by reference in the Registration Statement and to the reference to our firm under the heading "Legal Matters" in the Prospectus Supplement. In giving such consent, we do not hereby admit that we are within the category of persons whose consent is required under Section 7 of the Act or the rules or regulations of the Commission thereunder.

Very truly yours,

/s/ Paul Hastings LLP
