

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): November 9, 2023

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-39290
(Commission
File Number)

94-3171943
(I.R.S. Employer
Identification No.)

2600 Kelly Road, Suite 100, Warrington, Pennsylvania
(Address of principal executive offices)

18976
(Zip Code)

Registrant's telephone number, including area code: (215) 488-9300

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

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

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

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 \$0.001 per share	WINT	The Nasdaq Capital Market

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

Emerging growth company

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

Item 1.01 Entry into a Material Definitive Agreement.

On November 9, 2023, Windtree Therapeutics, Inc. (the “Company”), entered into an At The Market Offering Agreement (the “Sales Agreement”) with Ladenburg Thalmann & Co. Inc. (“Ladenburg”), under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value \$0.001 per share (the “Shares”), initially having an aggregate offering price of up to \$2,054,024 through Ladenburg as agent and/or principal (the “Offering”). Any shares offered and sold in the Offering will be issued pursuant to the Company’s shelf registration statement on Form S-3 (File No. 333-261878) filed with the Securities and Exchange Commission (the “Commission”) on December 23, 2021 (the “Registration Statement”), including the base prospectus contained therein, as declared effective by the Commission on January 3, 2022. The Company filed a prospectus supplement with the Commission on November 9, 2023 in connection with the Offering.

Under the Sales Agreement, Ladenburg may sell Shares by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended (the “Securities Act”), or in privately negotiated transactions. Ladenburg will use commercially reasonable efforts to sell the Shares from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay Ladenburg a commission of 3.0% of the aggregate gross sales proceeds of Shares sold through Ladenburg under the Sales Agreement, and also, has provided Ladenburg with customary indemnification and contribution rights. The Company also agreed to reimburse Ladenburg for the fees and disbursements of its counsel, payable upon execution of the Sales Agreement, in an amount not to exceed \$60,000, in addition to certain ongoing disbursements of its legal counsel up to \$3,500 per calendar quarter.

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

The description of the Sales Agreement is qualified in its entirety by reference to the complete terms and conditions of the Sales Agreement, which is attached as Exhibit 1.1 to this Current Report on Form 8-K and incorporated into this Item 1.01 by reference.

A copy of the opinion of Goodwin Procter LLP relating to the legality of the issuance and sale of the Shares in the Offering is filed as Exhibit 5.1 to this Current Report on Form 8-K.

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

Item 1.02 Termination of a Material Definitive Agreement.

On November 9, 2023, the Company and Ladenburg, in connection with entering into the Sales Agreement, jointly terminated the At The Market Offering Agreement, dated as of September 17, 2020, by and between the Company and Ladenburg (the “Prior Sales Agreement”). Pursuant to the Prior Sales Agreement, Ladenburg could sell shares of the Company’s common stock by any method permitted by law deemed to be an “at-the-market offering,” as defined in Rule 415(a)(4) under the Securities Act, or in privately negotiated transactions.

Item 2.02 Results of Operations and Financial Condition.

On November 9, 2023, the Company issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02 (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section and shall not be deemed to be incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Financial Statements and Exhibits.

On November 9, 2023, the Company updated information reflected in a slide presentation, which is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in various meetings with investors from time to time.

The information contained in this Item 7.01 (including Exhibit 99.2) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section and shall not be deemed to be incorporated by reference in any filing under the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

The following exhibits are being filed herewith:

Exhibit No.	Document
1.1	At The Market Offering Agreement, dated as of November 9, 2023, by and between Windtree Therapeutics, Inc. and Ladenburg Thalmann & Co. Inc.
5.1	Legal Opinion of Goodwin Procter LLP.
23.1	Consent of Goodwin Procter LLP (contained in Exhibit 5.1).
99.1	Press Release of Windtree Therapeutics, Inc., dated November 9, 2023, announcing financial results for the quarter ended September 30, 2023, furnished herewith.
99.2	Investor Presentation of Windtree Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Dated: November 9, 2023

Windtree Therapeutics, Inc.

By: /s/ Craig E. Fraser

Name: *Craig E. Fraser*

Title: *President and Chief Executive Officer*

AT THE MARKET OFFERING AGREEMENT

November 9, 2023

Ladenburg Thalmann & Co. Inc.
640 Fifth Avenue, 4th Floor
New York, NY 10019

Ladies and Gentlemen:

Windtree Therapeutics, Inc., a corporation organized under the laws of Delaware (the "Company"), confirms its agreement (this "Agreement") with Ladenburg Thalmann & Co. Inc. (the "Manager") as follows:

1. Definitions. The terms that follow, when used in this Agreement and any Terms Agreement, shall have the meanings indicated.

"Accountants" shall have the meaning ascribed to such term in Section 4(m).

"Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the Commission promulgated thereunder.

"Action" shall have the meaning ascribed to such term in Section 3(q).

"Affiliate" shall have the meaning ascribed to such term in Section 3(p).

"Applicable Time" shall mean, with respect to any Shares, the time of sale of such Shares pursuant to this Agreement or any relevant Terms Agreement.

"Base Prospectus" shall mean the base prospectus contained in the Registration Statement at the Execution Time.

"Board" shall have the meaning ascribed to such term in Section 2(b)(iii).

"Broker Fee" shall have the meaning ascribed to such term in Section 2(b)(v).

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

“Commission” shall mean the United States Securities and Exchange Commission.

“Common Stock” shall have the meaning ascribed to such term in Section 2.

“Common Stock Equivalents” shall have the meaning ascribed to such term in Section 3(g).

“Company Counsel” shall have the meaning ascribed to such term in Section 4(l).

“DTC” shall have the meaning ascribed to such term in Section 2(b)(vii).

“Effective Date” shall mean each date and time that the Registration Statement and any post-effective amendment or amendments thereto became or becomes effective.

“Exchange Act” shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission promulgated thereunder.

“Execution Time” shall mean the date and time that this Agreement is executed and delivered by the parties hereto.

“Free Writing Prospectus” shall mean a free writing prospectus, as defined in Rule 405.

“GAAP” shall have the meaning ascribed to such term in Section 3(n).

“Incorporated Documents” shall mean the documents or portions thereof filed with the Commission on or prior to the Effective Date that are incorporated by reference in the Registration Statement or the Prospectus and any documents or portions thereof filed with the Commission after the Effective Date that are deemed to be incorporated by reference in the Registration Statement or the Prospectus.

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3(v).

“Issuer Free Writing Prospectus” shall mean an issuer free writing prospectus, as defined in Rule 433.

“Losses” shall have the meaning ascribed to such term in Section 7(d).

“Manager Compensation” shall have the meaning ascribed to such term in Section 7(d).

“Material Adverse Effect” shall have the meaning ascribed to such term in Section 3(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3(t).

“Net Proceeds” shall have the meaning ascribed to such term in Section 2(b)(v).

“Permitted Free Writing Prospectus” shall have the meaning ascribed to such term in Section 4(g).

“Placement” shall have the meaning ascribed to such term in Section 2(c).

“Proceeding” shall have the meaning ascribed to such term in Section 3(b).

“Prospectus” shall mean the Base Prospectus, as supplemented by the most recently filed Prospectus Supplement (if any).

“Prospectus Supplement” shall mean each prospectus supplement relating to the Shares prepared and filed pursuant to Rule 424(b) from time to time.

“Registration Statement” shall mean the shelf registration statement on Form S-3 filed with the Commission that is effective as of the Execution Time, including exhibits and financial statements and the information contained in a Prospectus that is filed with the Commission pursuant to Rule 424(b) and deemed part of such registration statement pursuant to Rule 430B, as amended on each Effective Date and, in the event any post-effective amendment thereto becomes effective, shall also mean such registration statement as so amended.

“Representation Date” shall have the meaning ascribed to such term in Section 4(k).

“Required Approvals” shall have the meaning ascribed to such term in Section 3(e).

“Rule 158”, “Rule 163”, “Rule 164”, “Rule 172”, “Rule 173”, “Rule 405”, “Rule 415”, “Rule 424”, “Rule 430B” and “Rule 433” refer to such rules under the Act.

“Sales Notice” shall have the meaning ascribed to such term in Section 2(b)(i).

“SEC Reports” shall have the meaning ascribed to such term in Section 3(m).

“Settlement Date” shall have the meaning ascribed to such term in Section 2(b)(vii).

“Subsidiary” shall have the meaning ascribed to such term in Section 3(a).

“Terms Agreement” shall have the meaning ascribed to such term in Section 2(a).

“Time of Delivery” shall have the meaning ascribed to such term in Section 2(c).

“Trading Day” means a day on which the Trading Market is open for trading.

“Trading Market” means Nasdaq Capital Market.

2. Sale and Delivery of Shares. The Company proposes to issue and sell through or to the Manager, as sales agent and/or principal, from time to time during the term of this Agreement and on the terms set forth herein, up to the Maximum Amount (as defined below), which is equal to the lesser of such number or dollar amount of shares (the “Shares”) of the Company’s common stock, \$0.001 par value per share (“Common Stock”), that (a) equals the number or dollar amount of shares of Common Stock registered on the Registration Statement, pursuant to which the offering is being made, (b) equals the number or dollar amount of Shares registered on the Prospectus (as may be amended), (c) equals the number of authorized but unissued shares of Common Stock (less the number of shares of Common Stock issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company’s authorized capital stock), or (d) would cause the Company or the offering of the Shares to not satisfy the eligibility and transaction requirements for use of Form S-3, including, if applicable, General Instruction I.B.6 of Registration Statement on Form S-3 (the lesser of (a), (b), (c) and (d), the “Maximum Amount”). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 2 on the number and aggregate sales price of Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that the Manager shall have no obligation in connection with such compliance.

(a) Appointment of Manager as Selling Agent; Terms Agreement. For purposes of selling the Shares through the Manager, the Company hereby appoints the Manager as exclusive agent of the Company for the purpose of selling the Shares of the Company pursuant to this Agreement and the Manager agrees to use its commercially reasonable efforts to sell the Shares on the terms and subject to the conditions stated herein. The Company agrees that, whenever it determines to sell the Shares directly to the Manager as principal, it will enter into a separate agreement (each, a “Terms Agreement”) in substantially the form of Annex I hereto, relating to such sale in accordance with Section 2 of this Agreement.

(b) Agent Sales. Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company will issue and agrees to sell Shares from time to time through the Manager, acting as sales agent, and the Manager agrees to use its commercially reasonable efforts to sell, as sales agent for the Company, on the following terms:

(i) The Shares are to be sold on a daily basis or otherwise as shall be agreed to by the Company and the Manager on any day that (A) is a Trading Day, (B) the Company has instructed the Manager by telephone (confirmed promptly by electronic mail) to make such sales (“Sales Notice”) and (C) the Company has satisfied its obligations under Section 6 of this Agreement. The Company will designate the maximum amount of the Shares to be sold by the Manager daily (subject to the limitations set forth in Section 2(d)) and the minimum price per Share at which such Shares may be sold. Subject to the terms and conditions hereof, the Manager shall use its commercially reasonable efforts to sell on a particular day all of the Shares designated for the sale by the Company on such day. The gross sales price of the Shares sold under this Section 2(b) shall be the market price for the shares of Common Stock sold by the Manager under this Section 2(b) on the Trading Market at the time of sale of such Shares.

(ii) The Company acknowledges and agrees that (A) there can be no assurance that the Manager will be successful in selling the Shares, (B) the Manager will incur no liability or obligation to the Company or any other person or entity if it does not sell the Shares for any reason other than a failure by the Manager to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Shares as required under this Agreement, and (C) the Manager shall be under no obligation to purchase Shares on a principal basis pursuant to this Agreement, except as otherwise specifically agreed by the Manager and the Company pursuant to a Terms Agreement.

(iii) The Company shall not authorize the issuance and sale of, and the Manager shall not be obligated to use its commercially reasonable efforts to sell, any Share at a price lower than the minimum price therefor designated from time to time by the Company’s Board of Directors (the “Board”), or a duly authorized committee thereof, or such duly authorized officers of the Company, and notified to the Manager in writing. The Company or the Manager may, upon notice to the other party hereto by telephone (confirmed promptly by electronic mail), suspend the offering of the Shares for any reason and at any time; provided, however, that such suspension or termination shall not affect or impair the parties’ respective obligations with respect to the Shares sold hereunder prior to the giving of such notice.

(iv) The Manager may sell Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 under the Act, including without limitation sales made directly on the Trading Market, on any other existing trading market for the Common Stock or to or through a market maker. The Manager may also sell Shares in privately negotiated transactions, provided that the Manager receives the Company’s prior written approval for any sales in privately negotiated transactions and if so provided in the “Plan of Distribution” section of the Prospectus or a supplement to the Prospectus disclosing the terms of such privately negotiated transaction.

(v) The compensation to the Manager for sales of the Shares under this Section 2(b) shall be a placement fee of 3.0% of the gross sales price of the Shares sold pursuant to this Section 2(b) (“Broker Fee”). The foregoing rate of compensation shall not apply when the Manager acts as principal, in which case the Company may sell Shares to the Manager as principal at a price agreed upon at the relevant Applicable Time pursuant to a Terms Agreement. The remaining proceeds, after deduction of the Broker Fee and deduction of any transaction fees imposed by any clearing firm, execution broker, or governmental or self-regulatory organization in respect of such sales, shall constitute the net proceeds to the Company for such Shares (the “Net Proceeds”).

(vi) The Manager shall provide written confirmation (which may be by facsimile or electronic mail) to the Company following the close of trading on the Trading Market each day in which the Shares are sold under this Section 2(b) setting forth the number of the Shares sold on such day, the aggregate gross sales proceeds and the Net Proceeds to the Company, and the compensation payable by the Company to the Manager with respect to such sales.

(vii) Unless otherwise agreed between the Company and the Manager, settlement for sales of the Shares will occur at 10:00 a.m. (New York City time) on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "Settlement Date"). On or before the Trading Day prior to each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Shares being sold by crediting the Manager's or its designee's account (provided that the Manager shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company ("DTC") through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which Shares in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Manager will deliver the related Net Proceeds in same day funds to an account designated by the Company. The Company agrees that, if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Shares on a Settlement Date, in addition to and in no way limiting the rights and obligations set forth in Section 7 hereto, the Company will (i) hold the Manager harmless against any loss, claim, damage, or reasonable, documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company, and (ii) pay to the Manager any commission, discount or other compensation to which the Manager would otherwise have been entitled absent such default.

(viii) At each Applicable Time, Settlement Date, and Representation Date, the Company shall be deemed to have affirmed each representation and warranty contained in this Agreement as if such representation and warranty were made as of such date, modified as necessary to relate to the Registration Statement and the Prospectus as amended as of such date. Any obligation of the Manager to use its commercially reasonable efforts to sell the Shares on behalf of the Company shall be subject to the continuing accuracy of the representations and warranties of the Company herein, to the performance by the Company of its obligations hereunder and to the continuing satisfaction of the additional conditions specified in Section 6 of this Agreement.

(ix) If the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution" and the record date for the determination of stockholders entitled to receive the Distribution, the "Record Date"), the Company hereby covenants and agrees that, in connection with any sales of Shares pursuant to a Sales Notice on the Record Date, the Company shall issue and deliver such Shares to the Manager on the Record Date and the Record Date shall be the Settlement Date and the Company shall cover any additional costs of the Manager in connection with the delivery of Shares on the Record Date.

(c) Term Sales. If the Company wishes to sell the Shares pursuant to this Agreement but other than as set forth in Section 2(b) of this Agreement (each, a “Placement”), the Company will notify the Manager of the proposed terms of such Placement. If the Manager, acting as principal, wishes to accept such proposed terms (which it may decline to do for any reason in its sole discretion) or, following discussions with the Company wishes to accept amended terms, the Manager and the Company will enter into a Terms Agreement setting forth the terms of such Placement. The terms set forth in a Terms Agreement will not be binding on the Company or the Manager unless and until the Company and the Manager have each executed such Terms Agreement accepting all of the terms of such Terms Agreement. In the event of a conflict between the terms of this Agreement and the terms of a Terms Agreement, the terms of such Terms Agreement will control. A Terms Agreement may also specify certain provisions relating to the reoffering of such Shares by the Manager. The commitment of the Manager to purchase the Shares pursuant to any Terms Agreement shall be deemed to have been made on the basis of the representations and warranties of the Company herein contained and shall be subject to the terms and conditions herein set forth. Each Terms Agreement shall specify the number of the Shares to be purchased by the Manager pursuant thereto, the price to be paid to the Company for such Shares, any provisions relating to rights of, and default by, underwriters acting together with the Manager in the reoffering of the Shares, and the time and date (each such time and date being referred to herein as a “Time of Delivery”) and place of delivery of and payment for such Shares. Such Terms Agreement shall also specify any requirements for opinions of counsel, accountants’ letters and officers’ certificates pursuant to Section 6 of this Agreement and any other information or documents required by the Manager.

(d) Maximum Number of Shares. Under no circumstances shall the Company cause or request the offer or sale of any Shares if, after giving effect to the sale of such Shares, the aggregate amount of Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Shares under this Agreement, the Maximum Amount, (B) the amount available for offer and sale under the currently effective Registration Statement and (C) the amount authorized from time to time to be issued and sold under this Agreement by the Board, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Manager in writing. Under no circumstances shall the Company cause or request the offer or sale of any Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Board, a duly authorized committee thereof or a duly authorized executive officer, and notified to the Manager in writing. Further, under no circumstances shall the Company cause or permit the aggregate offering amount of Shares sold pursuant to this Agreement to exceed the Maximum Amount.

(e) Regulation M Notice. Unless the exceptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are satisfied with respect to the Shares, the Company shall give the Manager at least one Business Day's prior notice of its intent to sell any Shares in order to allow the Manager time to comply with Regulation M.

3. Representations and Warranties. The Company represents and warrants to, and agrees with, the Manager at the Execution Time and on each such time the following representations and warranties are repeated or deemed to be made pursuant to this Agreement, as set forth below:

(a) Subsidiaries. All of the direct and indirect subsidiaries (individually, a "Subsidiary") of the Company are set forth on Exhibit 21.1 to the Company's most recent Annual Report on Form 10-K filed with the Commission. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any "Liens" (which for purposes of this Agreement shall mean a lien, charge, security interest, encumbrance, right of first refusal, preemptive right or other restriction), and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of this Agreement, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under this Agreement (any of (i), (ii) or (iii), a "Material Adverse Effect") and no "Proceeding" (which for purposes of this Agreement shall mean any action, claim, suit, investigation or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition), whether commenced or threatened) has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization and Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and otherwise to carry out its obligations hereunder. The execution and delivery of this Agreement by the Company and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith other than in connection with the Required Approvals. This Agreement has been duly executed and delivered by the Company and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Shares and the consummation by it of the transactions contemplated hereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other "Person" (defined as an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind, including the Trading Market) in connection with the execution, delivery and performance by the Company of this Agreement, other than (i) the filings required by this Agreement, (ii) the filing with the Commission of the Prospectus Supplement, (iii) the filing of application(s) to and approval by the Trading Market for the listing of the Shares for trading thereon in the time and manner required thereby, and (iv) such filings as are required to be made under applicable state securities laws and the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("FINRA") (collectively, the "Required Approvals").

(f) Issuance of Shares. The Shares are duly authorized and, when issued and paid for in accordance with this Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company will reserve from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement. The Shares will be issued pursuant to the Registration Statement and the issuance of the Shares will be registered by the Company under the Act. The “Plan of Distribution” section within the Registration Statement and Prospectus permits the issuance and sale of the Shares as contemplated by this Agreement. Upon receipt of the Shares, the Shares will be freely tradable on the Trading Market.

(g) Capitalization. The capitalization of the Company is as set forth in the SEC Reports. The Company has not issued any capital stock since its most recently filed periodic or current report under the Exchange Act, other than pursuant to the exercise of employee stock options under the Company’s stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company’s employee stock purchase plan and pursuant to the conversion and/or exercise of securities exercisable, exchangeable or convertible into Common Stock (“Common Stock Equivalents”) outstanding as of the date of the most recently filed periodic report under the Exchange Act. Except as set forth in the SEC Reports, no Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by this Agreement. Except as set forth in the SEC Reports, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents. The issuance and sale of the Shares will not obligate the Company to issue shares of Common Stock or other securities to any Person. Except as set forth in the SEC Reports, there are no outstanding securities or instruments of the Company with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company. Except as set forth in the SEC Reports, there are no outstanding securities or instruments of the Company that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company is or may become bound to redeem a security of the Company. The Company does not have any stock appreciation rights or “phantom stock” plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Shares. Except as set forth in the SEC Reports, there are no stockholders agreements, voting agreements or other similar agreements with respect to the Company’s capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company’s stockholders.

(h) Registration Statement. The Company meets the requirements for use of Form S-3 under the Act and has prepared and filed with the Commission the Registration Statement, including the Base Prospectus, for registration under the Act of the offering and sale of the Shares. Such Registration Statement is effective and available for the offer and sale of the Shares as of the date hereof. As filed, the Base Prospectus and Prospectus Supplement contains all information required by the Act and the rules thereunder, and, except to the extent the Manager shall agree in writing to a modification, shall be in all substantive respects in the form furnished to the Manager prior to the Execution Time or prior to any such time this representation is repeated or deemed to be made. The Registration Statement, at the Execution Time, each such time this representation is repeated or deemed to be made, and at all times during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172, 173 or any similar rule) in connection with any offer or sale of the Shares, meets the requirements set forth in Rule 415(a)(1)(x). The initial Effective Date of the Registration Statement was not earlier than the date three years before the Execution Time.

(i) Accuracy of Incorporated Documents. The Incorporated Documents, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the rules thereunder, and none of the Incorporated Documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Registration Statement, the Base Prospectus, or the Prospectus, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the rules thereunder, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(j) Ineligible Issuer. (i) At the earliest time after the filing of the Registration Statement that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2)) of the Shares and (ii) as of the Execution Time and on each such time this representation is repeated or deemed to be made (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an Ineligible Issuer (as defined in Rule 405), without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an Ineligible Issuer.

(k) Free Writing Prospectus. The Company is eligible to use Issuer Free Writing Prospectuses. Each Issuer Free Writing Prospectus does not include any information the substance of which conflicts with the information contained in the Registration Statement, including any Incorporated Documents and any Prospectus Supplement deemed to be a part thereof that has not been superseded or modified; and each Issuer Free Writing Prospectus does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Manager specifically for use therein. Any Issuer Free Writing Prospectus that the Company is required to file pursuant to Rule 433(d) has been, or will be, filed with the Commission in accordance with the requirements of the Act and the rules thereunder. Each Issuer Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) or that was prepared by or behalf of or used by the Company complies or will comply in all material respects with the requirements of the Act and the rules thereunder. The Company will not, without the prior consent of the Manager, prepare, use or refer to, any Issuer Free Writing Prospectuses.

(l) Proceedings Related to Registration Statement. The Registration Statement is not the subject of a pending proceeding or examination under Section 8(d) or 8(e) of the Act, and the Company is not the subject of a pending proceeding under Section 8A of the Act in connection with the offering of the Shares. The Company has not received any notice that the Commission has issued or intends to issue a stop-order with respect to the Registration Statement or that the Commission otherwise has suspended or withdrawn the effectiveness of the Registration Statement, either temporarily or permanently, or intends or has threatened in writing to do so.

(m) SEC Reports. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the “SEC Reports”) on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension, except as could not have or reasonably be expected to result in a Material Adverse Effect. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (“GAAP”), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(n) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the Registration Statement and Prospectus, except as specifically disclosed in a subsequent SEC Report filed prior to the date on which this representation is being made, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any material liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company’s financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or “Affiliate” (defined as any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 144 under the Act), except pursuant to existing Company stock option plans or inducement grants under the Nasdaq inducement grant exception, and (vi) no executive officer of the Company or member of the Board has resigned from any position with the Company. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Shares contemplated by this Agreement or as set forth in the SEC Reports, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made.

(o) Litigation. Except as set forth in the SEC Reports, there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an “Action”). None of the Actions set forth in the SEC Reports, (i) adversely affects or challenges the legality, validity or enforceability of this Agreement or the Shares or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Act.

(p) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company’s or its Subsidiaries’ employees is a member of a union that relates to such employee’s relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(q) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

(r) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) are in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

(s) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(t) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to, or have valid and marketable rights to lease or otherwise use, all real property and all personal property that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP, and the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance, except where failure to be in compliance could not reasonably be expected to have a Material Adverse Effect.

(u) Intellectual Property. To their knowledge, the Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to do so could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement, with the exception of certain non-core patents in-licensed from Philip Morris USA, Inc. or Philip Morris Products S.A., which have expired or will expire within two (2) years from the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(v) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(w) Affiliate Transactions. Except as set forth in the SEC Reports, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of \$120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(x) Sarbanes Oxley Compliance. The Company and the Subsidiaries are in compliance in all material respects with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(y) Certain Fees. Other than payments to be made to the Manager, no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by this Agreement. The Manager shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section 3(y) that may be due in connection with the transactions contemplated by this Agreement.

(z) No Other Sales Agency Agreement. The Company has not entered into any other sales agency agreements or other similar arrangements with any agent or any other representative in respect of at the market offerings of the Shares.

(aa) [RESERVED]

(bb) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Other than as disclosed in the SEC Reports, the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. Other than as disclosed in the SEC Reports, the Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(cc) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the Shares.

(dd) Solvency. Based on the consolidated financial condition of the Company as of the date hereof, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the date hereof. The SEC Reports set forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed in excess of \$50,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of \$50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(ee) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed, or secured all extensions for the filing of, all applicable United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction and none of the Company or its Subsidiaries has received a written notice of an intention to audit the Company or Subsidiaries with respect to taxes.

(ff) Foreign Corrupt Practices. Neither the Company, nor to the knowledge of the Company, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA.

(gg) Accountants. The Company's accounting firm is set forth in the SEC Reports. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2023.

(hh) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Manager in connection with the Shares.

(ii) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration (“FDA”) under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder (“FDCA”) that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a “Pharmaceutical Product”), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company’s knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor, to the knowledge of the Company, has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(jj) Stock Option Plans. Each stock option granted by the Company under the Company’s stock option plan was granted (i) in accordance with the terms of the Company’s stock option plan or in accordance with Nasdaq rule 5635(c)(4), and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company’s stock option plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(kk) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company’s knowledge, any director, officer, agent or employee of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department (“OFAC”).

(ll) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon the Manager's request.

(mm) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(nn) Money Laundering. To the extent the Company and its Subsidiaries are subject to such requirements, the operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(oo) FINRA Member Shareholders. To the Company's knowledge, there are no affiliations with any FINRA member firm among the Company's officers, directors or any five percent (5%) or greater stockholder of the Company, except as set forth in the Registration Statement or the Prospectus.

4. Agreements. The Company agrees with the Manager that:

(a) Right to Review Amendments and Supplements to Registration Statement and Prospectus. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act in connection with the offering or the sale of Shares, the Company will not file any amendment to the Registration Statement or supplement (including any Prospectus Supplement) to the Base Prospectus (other than documents incorporated by reference therein) unless the Company has furnished to the Manager a copy for its review prior to filing and will not file any such proposed amendment or supplement to which the Manager reasonably objects. The Company has properly completed the Prospectus, in a form approved by the Manager, and filed such Prospectus, as amended at the Execution Time, with the Commission pursuant to the applicable paragraph of Rule 424(b) by the Execution Time and will cause any supplement to the Prospectus to be properly completed, in a form approved by the Manager, and will file such supplement with the Commission pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed thereby and will provide evidence reasonably satisfactory to the Manager of such timely filing. The Company will promptly advise the Manager (i) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the Commission pursuant to Rule 424(b), (ii) when, during any period when the delivery of a prospectus (whether physically or through compliance with Rule 172, 173 or any similar rule) is required under the Act in connection with the offering or sale of the Shares, any amendment to the Registration Statement shall have been filed or become effective (other than any annual report of the Company filed pursuant to Section 13(a) or 15(d) of the Exchange Act), (iii) of any request by the Commission or its staff for any amendment of the Registration Statement, or any Rule 462(b) Registration Statement, or for any supplement to the Prospectus or for any additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any notice objecting to its use or the institution or threatening of any proceeding for that purpose and (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the institution or threatening of any proceeding for such purpose. The Company will use its reasonable best efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain as soon as possible the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or a new registration statement and using its reasonable best efforts to have such amendment or new registration statement declared effective as soon as practicable.

(b) Subsequent Events. If, at any time on or after an Applicable Time but prior to the related Settlement Date, any event occurs as a result of which the Registration Statement or Prospectus would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Manager so that any use of the Registration Statement or Prospectus may cease until such are amended or supplemented; (ii) amend or supplement the Registration Statement or Prospectus to correct such statement or omission; and (iii) supply any amendment or supplement to the Manager in such quantities as the Manager may reasonably request.

(c) Notification of Subsequent Filings. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act, any event occurs as a result of which the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made not misleading, or if it shall be necessary to amend the Registration Statement, file a new registration statement or supplement the Prospectus to comply with the Act or the Exchange Act or the respective rules thereunder, including in connection with use or delivery of the Prospectus, the Company promptly will (i) notify the Manager of any such event, (ii) subject to Section 4(a), prepare and file with the Commission an amendment or supplement or new registration statement which will correct such statement or omission or effect such compliance, (iii) use its reasonable best efforts to have any amendment to the Registration Statement or new registration statement declared effective as soon as practicable in order to avoid any disruption in use of the Prospectus and (iv) supply any supplemented Prospectus to the Manager in such quantities as the Manager may reasonably request.

(d) Earnings Statements. As soon as practicable, the Company will make generally available to its security holders and to the Manager an earnings statement or statements of the Company and its Subsidiaries which will satisfy the provisions of Section 11(a) of the Act and Rule 158. For the avoidance of doubt, the Company's compliance with the reporting requirements of the Exchange Act shall be deemed to satisfy the requirements of this Section 4(d).

(e) Delivery of Registration Statement. Upon the request of the Manager, the Company will furnish to the Manager and counsel for the Manager, without charge, signed copies of the Registration Statement (including exhibits thereto) and, so long as delivery of a prospectus by the Manager or dealer may be required by the Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule), as many copies of the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Manager may reasonably request, provided that the Company's obligations to provide such copies shall not apply to any filing available via EDGAR. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) Qualification of Shares. The Company will arrange, if necessary, for the qualification of the Shares for sale under the laws of such jurisdictions as the Manager may designate and will maintain such qualifications in effect so long as required for the distribution of the Shares; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Shares, in any jurisdiction where it is not now so subject.

(g) Free Writing Prospectus. The Company agrees that, unless it has or shall have obtained the prior written consent of the Manager, and the Manager agrees with the Company that, unless it has or shall have obtained, as the case may be, the prior written consent of the Company, it has not made and will not make any offer relating to the Shares that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a “free writing prospectus” (as defined in Rule 405) required to be filed by the Company or the Manager, as applicable, with the Commission or retained by the Company under Rule 433. Any such free writing prospectus consented to by the Manager or the Company is hereinafter referred to as a “Permitted Free Writing Prospectus.” The Company agrees that (i) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (ii) it has complied and will comply, as the case may be, with the requirements of Rules 164 and 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping.

(h) Subsequent Equity Issuances. The Company shall not deliver any Sales Notice hereunder (and any Sales Notice previously delivered shall not apply during such three Business Days) for at least three (3) Business Days prior to any date on which the Company or any Subsidiary offers, sells, issues, contracts to sell, contracts to issue or otherwise disposes of, directly or indirectly, any Common Stock or any Common Stock Equivalents (other than the Shares), subject to the Manager’s right to waive this obligation, provided that, without compliance with the foregoing obligation, the Company may issue and sell Common Stock pursuant to any employee stock option plan, stock ownership plan or dividend reinvestment plan of the Company in effect at the Execution Time and the Company may issue Common Stock issuable upon the conversion or exercise of Common Stock Equivalents outstanding at the Execution Time.

(i) Market Manipulation. Until the termination of this Agreement, the Company will not take, directly or indirectly, any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation in violation of the Act, Exchange Act or the rules and regulations thereunder of the price of any security of the Company to facilitate the sale or resale of the Shares or otherwise violate any provision of Regulation M under the Exchange Act.

(j) Notification of Incorrect Certificate. The Company will, at any time during the term of this Agreement, as supplemented from time to time, advise the Manager as soon as practicable after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect any opinion, certificate, letter and other document provided to the Manager pursuant to Section 6 herein.

(k) Certification of Accuracy of Disclosure. Upon commencement of the offering of the Shares under this Agreement (and upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder lasting more than 30 Trading Days), and each time that (i) the Registration Statement or Prospectus shall be amended or supplemented, other than by means of Incorporated Documents or relating solely to the offering of securities other than the Shares, (ii) the Company files its Annual Report on Form 10-K under the Exchange Act, (iii) the Company files its quarterly reports on Form 10-Q under the Exchange Act, (iv) the Company files a Current Report on Form 8-K containing amended financial information (other than information that is furnished and not filed), if the Manager reasonably determines that the information in such Form 8-K is material, or (v) the Shares are delivered to the Manager as principal at the Time of Delivery pursuant to a Terms Agreement (such commencement or recommencement date and each such date referred to in (i), (ii), (iii), (iv) and (v) above, a “Representation Date”), unless waived by the Manager, the Company shall furnish or cause to be furnished to the Manager forthwith a certificate dated and delivered on the Representation Date, (or if the Representation Date is triggered by the filing of an SEC Report, then delivery shall be within three (3) Business Days of such Representation Date) in form reasonably satisfactory to the Manager to the effect that the statements contained in the certificate referred to in Section 6 of this Agreement which were last furnished to the Manager are true and correct at the Representation Date, as though made at and as of such date (except that such statements shall be deemed to relate to the Registration Statement and the Prospectus as amended and supplemented to such date) or, in lieu of such certificate, a certificate of the same tenor as the certificate referred to in said Section 6, modified as necessary to relate to the Registration Statement and the Prospectus as amended and supplemented to the date of delivery of such certificate.

(l) Bring Down Opinions; Negative Assurance. At each Representation Date (or if the Representation Date is triggered by the filing of an SEC Report, then delivery shall be within three (3) Business Days of such Representation Date) unless waived by the Manager, the Company shall furnish or cause to be furnished forthwith to the Manager and to counsel to the Manager (i) a written opinion of counsel to the Company (“Company Counsel”) addressed to the Manager and dated and delivered on such Representation Date, in form and substance reasonably satisfactory to the Manager, including a negative assurance representation and (ii) a legal opinion of counsel to the Company with respect to intellectual property matters (“Company IP Counsel”) addressed to the Manager and dated and delivered on such Representation Date, in form and substance reasonably satisfactory to the Manager, including a negative assurance representation.

(m) Auditor Bring Down “Comfort” Letter. At each Representation Date (or if the Representation Date is triggered by the filing of the Company’s Annual Report on Form 10-K, then delivery shall be within three (3) Business Days of such Form 10-K filing), unless waived by the Manager, the Company shall cause the Company’s auditors (the “Accountants”), or other independent accountants satisfactory to the Manager forthwith to furnish the Manager a letter, and, if reasonably requested by the Manager, the Company shall cause the Chief Financial Officer of the Company forthwith to furnish the Manager a certificate, in each case dated on such Representation Date, in form satisfactory to the Manager, of the same tenor as the letters and certificate referred to in Section 6 of this Agreement but modified to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letters and certificate.

(n) Due Diligence Session. Upon commencement of the offering of the Shares under this Agreement (and upon the recommencement of the offering of the Shares under this Agreement following the termination of a suspension of sales hereunder lasting more than 30 Trading Days), and at each Representation Date (or if the Representation Date is triggered by the filing of an SEC Report, then within three (3) Business Days of such Representation Date), the Company will conduct a due diligence session, in form and substance, reasonably satisfactory to the Manager, which shall include representatives of management and Accountants. The Company shall cooperate timely with any reasonable due diligence request from or review conducted by the Manager or its agents from time to time in connection with the transactions contemplated by this Agreement, including, without limitation, providing information and available documents and reasonable access to appropriate corporate officers and the Company's agents during regular business hours. The Company shall reimburse the Manager for Manager's counsel's time in each such due diligence update session, up to a maximum of \$3,500 per update, plus any incidental expense incurred by the Manager in connection therewith.

(o) Acknowledgment of Trading. The Company consents to the Manager trading in the Common Stock for the Manager's own account and for the account of its clients at the same time as sales of the Shares occur pursuant to this Agreement or pursuant to a Terms Agreement, provided such trading complies with applicable requirements of the Act, the Exchange Act and the Trading Market.

(p) Disclosure of Shares Sold. The Company will disclose in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, as applicable, the number of Shares sold through the Manager under this Agreement, the Net Proceeds to the Company and the compensation paid by the Company with respect to sales of Shares pursuant to this Agreement during the relevant quarter; and, if required by any subsequent change in Commission policy or request, more frequently by means of a Current Report on Form 8-K or a further supplement to the Prospectus.

(q) Bring Down of Representations and Warranties. Each acceptance by the Company of an offer to purchase the Shares hereunder, and each execution and delivery by the Company of a Terms Agreement, shall be deemed to be an affirmation to the Manager 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 acceptance or of such Terms Agreement as though made at and as of such date, and an undertaking that such representations and warranties will be true and correct as of the Settlement Date for the Shares relating to such acceptance or as of the Time of Delivery relating to such sale, as the case may be, as though made at and as of 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).

(r) Reservation of Shares. The Company shall ensure that there are at all times sufficient shares of Common Stock to provide for the issuance, free of any preemptive rights, out of its authorized but unissued shares of Common Stock or shares of Common Stock held in treasury, of the maximum aggregate number of Shares authorized for issuance by the Board pursuant to the terms of this Agreement. The Company will use its commercially reasonable efforts to cause the Shares to be listed for trading on the Trading Market and to maintain such listing.

(s) Obligation Under Exchange Act. During any period when the delivery of a prospectus relating to the Shares is required (including in circumstances where such requirement may be satisfied pursuant to Rule 172, 173 or any similar rule) to be delivered under the Act, the Company will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act and the regulations thereunder.

(t) DTC Facility. The Company shall cooperate with the Manager and use its reasonable efforts to permit the Shares to be eligible for clearance and settlement through the facilities of DTC.

(u) Use of Proceeds. The Company will apply the Net Proceeds from the sale of the Shares in the manner set forth in the Prospectus.

(v) Filing of Prospectus Supplement. If any material sales are made pursuant to this Agreement which are not made in “at the market” offerings as defined in Rule 415 and in connection with any Placement pursuant to a Terms Agreement, the Company shall file a supplement to the Prospectus describing the terms of such transaction, the amount of Shares sold, the price thereof, the Manager’s compensation, and such other information as may be required pursuant to Rule 424 and Rule 430B, as applicable, within the time required by Rule 424.

(w) Additional Registration Statement. To the extent that the Registration Statement is not available for the sales of the Shares as contemplated by this Agreement, the Company shall file a new registration statement with respect to any additional shares of Common Stock necessary to complete such sales of the Shares and shall cause such registration statement to become effective as promptly as practicable. After the effectiveness of any such registration statement, all references to “Registration Statement” included in this Agreement shall be deemed to include such new registration statement, including all documents incorporated by reference therein pursuant to Item 12 of Form S-3, and all references to “Prospectus” included in this Agreement shall be deemed to include the final form of prospectus relating to the Shares, including all documents incorporated therein by reference, included in any such registration statement at the time such registration statement became effective.

5. Payment of Expenses. The Company agrees to pay the costs and expenses incident to the performance of its obligations under this Agreement, whether or not the transactions contemplated hereby are consummated, including without limitation: (i) the preparation, printing or reproduction and filing with the Commission of the Registration Statement (including financial statements and exhibits thereto), the Prospectus and each Issuer Free Writing Prospectus, and each amendment or supplement to any of them; (ii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Registration Statement, the Prospectus, and each Issuer Free Writing Prospectus, and all amendments or supplements to any of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Shares; (iii) the preparation, printing, authentication, issuance and delivery of certificates for the Shares, including any stamp or transfer taxes in connection with the original issuance and sale of the Shares; (iv) the printing (or reproduction) and delivery of this Agreement, any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Shares; (v) the registration of the Shares under the Exchange Act, if applicable, and the listing of the Shares on the Trading Market; (vi) any registration or qualification of the Shares for offer and sale under the securities or blue sky laws of the several states (including filing fees and the reasonable fees and expenses of counsel for the Manager relating to such registration and qualification); (vii) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Shares; (viii) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; (ix) the filing fee under FINRA Rule 5110; (x) the reasonable fees and expenses of the Manager's counsel, not to exceed \$60,000 (excluding any periodic due diligence fees provided for under Section 4(n)), which shall be paid upon the Execution Time; and (xi) all other costs and expenses incident to the performance by the Company of its obligations hereunder.

6. Conditions to the Obligations of the Manager. The obligations of the Manager under this Agreement and any Terms Agreement shall be subject to (i) the accuracy of the representations and warranties on the part of the Company contained herein as of the Execution Time, each Representation Date, and as of each Applicable Time, Settlement Date and Time of Delivery, (ii) the performance in all material respects by the Company of its obligations hereunder and (iii) the following additional conditions:

(a) Registration Statement Effective; Filing of Prospectus. The Registration Statement shall have become effective. The Prospectus shall have been filed with the Commission in the manner and within the time period so required; each supplement to the Prospectus shall have been filed in the manner required by Rule 424(b) within the time period required hereunder and under the Act; any other material required to be filed by the Company pursuant to Rule 433(d) under the Act, shall have been filed with the Commission within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use shall have been issued and no proceedings for that purpose shall have been instituted or threatened.

(b) Delivery of Opinions. The Company, as required by Section 4(l), shall have caused the Company Counsel and the Company IP Counsel to furnish to the Manager their opinions and negative assurance statement, each dated as of such date and addressed to the Manager in form and substance acceptable to the Manager.

(c) Delivery of Officer's Certificate. The Company, as required by Section 4(k), shall have furnished or caused to be furnished to the Manager a certificate of the Company signed by the Chief Executive Officer or the President and the principal financial or accounting officer of the Company, dated as of such date, to the effect that the signers of such certificate have carefully examined the Registration Statement, the Prospectus and any documents incorporated by reference therein and any supplements or amendments thereto and this Agreement and that:

(i) the representations and warranties of the Company in this Agreement are true and correct on and as of such date with the same effect as if made on such date and the Company has complied in all material respects with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to such date;

(ii) no stop order suspending the effectiveness of the Registration Statement or any notice objecting to its use has been issued and no proceedings for that purpose have been instituted or, to the Company's knowledge, threatened; and

(iii) since the date of the most recent financial statements included in the Registration Statement, the Prospectus and the Incorporated Documents, there has been no Material Adverse Effect on the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Registration Statement and the Prospectus.

(d) Delivery of Accountants' "Comfort" Letter. The Company, as required by Section 4(m), shall have requested and caused the Accountants to have furnished to the Manager letters (which may refer to letters previously delivered to the Manager), dated as of such date the letters are delivered, in form and substance satisfactory to the Manager, (i) confirming that they are an independent public accounting firm within the meaning of the Act and the Exchange Act, (ii) stating, as of the date of such letter, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings (the first such letter, the "Initial Comfort Letter") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(e) No Material Adverse Event. Since the respective dates as of which information is disclosed in the Registration Statement, the Prospectus and the Incorporated Documents, except as otherwise stated therein, there shall not have been (i) any change or decrease in previously reported results specified in the letter or letters referred to in paragraph (d) of this Section 6 or (ii) any change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Registration Statement, the Prospectus and the Incorporated Documents (exclusive of any amendment or supplement thereto) the effect of which, in any case referred to in clause (i) or (ii) above, is, in the sole judgment of the Manager, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Registration Statement (exclusive of any amendment thereof), the Incorporated Documents and the Prospectus (exclusive of any amendment or supplement thereto).

(f) No FINRA Objections. FINRA shall not have raised any objection with respect to the fairness and reasonableness of the terms and arrangements under this Agreement.

(g) Shares Listed on Trading Market. The Shares shall have been listed and admitted and authorized for trading on the Trading Market, and satisfactory evidence of such actions shall have been provided to the Manager.

(h) Other Assurances. Prior to each Settlement Date and Time of Delivery, as applicable, the Company shall have furnished to the Manager such further information, certificates and documents as the Manager may reasonably request.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Manager and counsel for the Manager, this Agreement and all obligations of the Manager hereunder may be canceled at, or at any time prior to, any Settlement Date or Time of Delivery, as applicable, by the Manager. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 shall be delivered to the office of Ellenoff Grossman & Schole LLP, counsel for the Manager, at 1345 Avenue of the Americas, New York, New York 10105, on each such date as provided in this Agreement.

7. Indemnification and Contribution.

(a) Indemnification by Company. The Company agrees to indemnify and hold harmless the Manager, the directors, officers, employees and agents of the Manager and each person who controls the Manager within the meaning of either the Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement for the registration of the Shares as originally filed or in any amendment thereof, or in the Prospectus, any Issuer Free Writing Prospectus, or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and agrees to reimburse each such indemnified party for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by the Manager specifically for inclusion therein. This indemnity agreement will be in addition to any liability that the Company may otherwise have.

(b) Indemnification by Manager. The Manager agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signs the Registration Statement, and each person who controls the Company within the meaning of either the Act or the Exchange Act, to the same extent as the foregoing indemnity from the Company to the Manager, but only with reference to written information relating to the Manager furnished to the Company by the Manager specifically for inclusion in the documents referred to in the foregoing indemnity; provided, however, that in no case shall the Manager be responsible for any amount in excess of the Manager Compensation. This indemnity agreement will be in addition to any liability which the Manager may otherwise have.

(c) Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 7 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 7, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraph (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel retained by the indemnified party or parties except as set forth below); provided, however, that such counsel shall be reasonably satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel to represent the indemnified party in an action, the indemnified party shall have the right to employ separate counsel (including local counsel), and the indemnifying party shall bear the reasonable fees, costs and expenses of such separate counsel if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest, (ii) the actual or potential defendants in, or targets of, any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded 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, (iii) 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 the institution of such action or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding.

(d) Contribution. In the event that the indemnity provided in paragraph (a), (b) or (c) of this Section 7 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company and the Manager agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with investigating or defending the same) (collectively "Losses") to which the Company and the Manager may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and by the Manager on the other from the offering of the Shares; provided, however, that in no case shall the Manager be responsible for any amount in excess of the sum of (i) the Broker Fee applicable to the Shares sold pursuant to Section 2(b) and paid hereunder and (ii) the underwriting discounts and commissions applicable to the Shares purchased by the Manager pursuant to a Placement as contemplated by Section 2(c) and paid hereunder (collectively, the "Manager Compensation"). If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Manager severally shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and of the Manager on the other in connection with the statements or omissions which resulted in such Losses as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by it, and benefits received by the Manager shall be deemed to be equal to the Manager Compensation as determined by this Agreement. Relative fault shall be determined by reference to, among other things, whether any untrue or any alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company on the one hand or the Manager on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Manager agree that it would not be just and equitable if contribution were determined by pro rata allocation or any other method of allocation which does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (d), no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 7, each person who controls the Manager within the meaning of either the Act or the Exchange Act and each director, officer, employee and agent of the Manager shall have the same rights to contribution as the Manager, and each person who controls the Company within the meaning of either the Act or the Exchange Act, each officer of the Company who shall have signed the Registration Statement and each director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (d).

8. Termination.

(a) The Company shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time upon five (5) Business Days' prior written notice. Any such termination shall be without liability of any party to any other party except that (i) with respect to any pending sale, through the Manager for the Company, the obligations of the Company, including in respect of compensation of the Manager, shall remain in full force and effect notwithstanding the termination and (ii) the provisions of Sections 5, 7, 8, 9, 10, 12, the second sentence of 13 and 14 of this Agreement shall remain in full force and effect notwithstanding such termination.

(b) The Manager shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time upon five (5) Business Days' prior written notice. Any such termination shall be without liability of any party to any other party except that the provisions of Sections 5, 7, 8, 9, 10, 12, the second sentence of 13 and 14 of this Agreement shall remain in full force and effect notwithstanding such termination.

(c) This Agreement shall remain in full force and effect until such date that this Agreement is terminated pursuant to Sections 8(a) or (b) above or otherwise by mutual agreement of the parties, provided that any such termination by mutual agreement shall in all cases be deemed to provide that Sections 5, 7, 8, 9, 10, 12, the second sentence of 13 and 14 shall remain in full force and effect.

(d) Any termination of this Agreement shall be effective on the date specified in such notice of termination, provided that such termination shall not be effective until the close of business on the date of receipt of such notice by the Manager or the Company, as the case may be. If such termination shall occur prior to the Settlement Date or Time of Delivery for any sale of the Shares, such sale of the Shares shall settle in accordance with the provisions of Section 2(b) of this Agreement.

(e) In the case of any purchase of Shares by the Manager pursuant to a Terms Agreement, the obligations of the Manager pursuant to such Terms Agreement shall be subject to termination, in the absolute discretion of the Manager, by prompt oral notice given to the Company prior to the Time of Delivery relating to such Shares, if any, and confirmed promptly by facsimile or electronic mail, if since the time of execution of the Terms Agreement and prior to such delivery and payment, (i) trading in the Common Stock shall have been suspended by the Commission or the Trading Market or trading in securities generally on the Trading Market shall have been suspended or limited or minimum prices shall have been established on such exchange, (ii) a banking moratorium shall have been declared either by Federal or New York State authorities or (iii) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States of a national emergency or war, or other calamity or crisis the effect of which on financial markets is such as to make it, in the sole judgment of the Manager, impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Prospectus (exclusive of any amendment or supplement thereto).

9. Representations and Indemnities to Survive. The respective agreements, representations and warranties and indemnities of the Company or its officers and of the Manager set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by the Manager or the Company or any of the officers, directors, employees, agents or controlling persons referred to in Section 7, and will survive delivery of and payment for the Shares.

10. Notices. All communications hereunder will be in writing and effective only on receipt, and will be mailed, delivered, e-mailed or facsimiled to the addresses of the Company and the Manager, respectively, set forth on the signature page hereto.

11. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 7, and no other person will have any right or obligation hereunder.

12. No Fiduciary Duty. The Company hereby acknowledges that (a) the offering and sale of the Shares pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Manager and any affiliate through which it may be acting, on the other, (b) the Manager is acting solely as sales agent and/or principal in connection with the offering and sale of the Company's securities and not as a fiduciary of the Company and (c) the Company's engagement of the Manager in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether the Manager has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Manager has rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

13. Integration. This Agreement and any Terms Agreement supersede all prior agreements and understandings (whether written or oral) between the Company and the Manager with respect to the subject matter hereof. Notwithstanding anything herein to the contrary, the letter agreement, dated October 24, 2023, by and between the Company and the Manager shall continue to be effective and the terms therein shall continue to survive and be enforceable by the Manager in accordance with its terms, provided that, in the event of a conflict between the terms of the letter agreement and this Agreement, the terms of this Agreement shall prevail.

14. Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Manager. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

15. Applicable Law. This Agreement and any Terms Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York. Each of the Company and the Manager: (i) agrees that any legal suit, action or proceeding arising out of or relating to this Agreement shall be instituted exclusively in New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, (ii) waives any objection which it may have or hereafter to the venue of any such suit, action or proceeding, and (iii) irrevocably consents to the jurisdiction of the New York Supreme Court, County of New York, and the United States District Court for the Southern District of New York in any such suit, action or proceeding. Each of the Company and the Manager further agrees to accept and acknowledge service of any and all process which may be served in any such suit, action or proceeding in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York and agrees that service of process upon the Company mailed by certified mail to the Company's address shall be deemed in every respect effective service of process upon the Company, in any such suit, action or proceeding, and service of process upon the Manager mailed by certified mail to the Manager's address shall be deemed in every respect effective service process upon the Manager, in any such suit, action or proceeding. If either party shall commence an action or proceeding to enforce any provision of this Agreement, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its reasonable attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

16. Termination of Prior Sales Agreement. The Company and the Manager agree that the At The Market Offering Agreement, dated as of September 17, 2020, by and between the Company and the Manager, is hereby terminated in all respects, other than provisions that by their terms survive termination.

17. **WAIVER OF JURY TRIAL. THE COMPANY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, ANY TERMS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.**

18. Counterparts. This Agreement and any Terms Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, which may be delivered by facsimile or in .pdf file via e-mail.

19. Headings. The section headings used in this Agreement and any Terms Agreement are for convenience only and shall not affect the construction hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the Manager.

Very truly yours,

WINDTREE THERAPEUTICS, INC.

By: /s/ Craig E. Fraser

Name: Craig E. Fraser

Title: President and Chief Executive Officer

Address for Notice:

2600 Kelly Road, Suite 100
Warrington, PA 18976
Attn: Chief Financial Officer
Email: jtatory@windtreetx.com

Copy to:

Goodwin Procter LLP
620 Eighth Avenue
New York, NY 10018
Email: JPorter@goodwinlaw.com and JPlatt@goodwinlaw.com
Attn: Jennifer L. Porter and Justin S. Platt

The foregoing Agreement is hereby confirmed and accepted as of the date first written above.

LADENBURG THALMANN & CO. INC.

By: /s/ Nicholas Stergis

Name: Nicholas Stergis

Title: Managing Director

Address for Notice:

640 Fifth Avenue, 4th Floor

New York, NY 10019

Email:

Fax:

Attn: General Counsel and Head of Investment Banking

Form of Terms Agreement

ANNEX I

WINDTREE THERAPEUTICS, INC.

TERMS AGREEMENT

Dear Sirs:

Windtree Therapeutics, Inc. (the "Company") proposes, subject to the terms and conditions stated herein and in the At The Market Offering Agreement, dated November 9, 2023 (the "At The Market Offering Agreement"), between the Company and Ladenburg Thalmann & Co. Inc. ("Manager"), to issue and sell to Manager the securities specified in the Schedule I hereto (the "Purchased Shares").

Each of the provisions of the At The Market Offering Agreement not specifically related to the solicitation by the Manager, as agent of the Company, of offers to purchase securities is incorporated herein by reference in its entirety, and shall be deemed to be part of this Terms Agreement to the same extent as if such provisions had been set forth in full herein. Each of the representations and warranties set forth therein shall be deemed to have been made at and as of the date of this Terms Agreement and the Time of Delivery, except that each representation and warranty in Section 3 of the At The Market Offering Agreement which makes reference to the Prospectus (as therein defined) shall be deemed to be a representation and warranty as of the date of the At The Market Offering Agreement in relation to the Prospectus, and also a representation and warranty as of the date of this Terms Agreement and the Time of Delivery in relation to the Prospectus as amended and supplemented to relate to the Purchased Shares.

An amendment to the Registration Statement (as defined in the At The Market Offering Agreement), or a supplement to the Prospectus, as the case may be, relating to the Purchased Shares, in the form heretofore delivered to the Manager is now proposed to be filed with the Securities and Exchange Commission.

Subject to the terms and conditions set forth herein and in the At The Market Offering Agreement which are incorporated herein by reference, the Company agrees to issue and sell to the Manager and the latter agrees to purchase from the Company the number of shares of the Purchased Shares at the time and place and at the purchase price set forth in the Schedule I hereto.

If the foregoing is in accordance with your understanding, please sign and return to us a counterpart hereof, whereupon this Terms Agreement, including those provisions of the At The Market Offering Agreement incorporated herein by reference, shall constitute a binding agreement between the Manager and the Company.

WINDTREE THERAPEUTICS, INC.

By: _____
Name:
Title:

ACCEPTED as of the date first written above.

LADENBURG THALMANN & CO. INC.

By: _____
Name:
Title:



Goodwin Procter
LLP
One Commerce
Square
2005 Market Street,
32nd Floor
Philadelphia, PA
19103

goodwinlaw.com
+1 445 207 7800

November 9, 2023

Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976

Re: Securities Registered under Registration Statement on Form S-3

Reference is made to the Registration Statement on Form S-3 (File No. 333-261878) (as amended or supplemented, the "Registration Statement") filed on December 23, 2021 with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the offering by Windtree Therapeutics, Inc., a Delaware corporation (the "Company"), of up to \$100,000,000 of any combination of securities of the types specified therein. The Registration Statement was declared effective by the Commission on January 3, 2022.

We are delivering this opinion letter in connection with the prospectus supplement (the "Prospectus Supplement") filed on November 9, 2023 by the Company with the Commission pursuant to Rule 424 under the Securities Act. The Prospectus Supplement relates to the offering by the Company of up to \$2,054,024 in shares (the "Shares") of the Company's common stock, par value \$0.001 per share ("Common Stock") covered by the Registration Statement. The Shares are being offered and sold by the sales agent named in, and pursuant to, the At The Market Offering Agreement between the Company and such sales agent (the "Sales Agreement").

We have reviewed such documents and made such examination of law as we have deemed appropriate to give the opinion set forth below. We have relied, without independent verification, on certificates of public officials and, as to matters of fact material to the opinion set forth below, on certificates of officers of the Company.

For purposes of the opinion set forth below, we have assumed that the Shares are issued for a price per share equal to or greater than the minimum price authorized by the Company's board of directors prior to the date hereof (the "Minimum Price") and that no event occurs that causes the number of authorized shares of Common Stock available for issuance by the Company to be less than the number of then unissued Shares that may be issued for the Minimum Price.

For purposes of the opinion set forth below, we refer to the following as “Future Approval and Issuance”: (a) the approval by the Company’s board of directors (or a duly authorized committee of the board of directors) of the issuance of the Shares (the “Approval”) and (b) the issuance of the Shares in accordance with the Approval and the receipt by the Company of the consideration (which shall not be less than the par value of such Shares) to be paid in accordance with the Approval.

The opinion set forth below is limited to the Delaware General Corporation Law.

Based on the foregoing, we are of the opinion that the Shares have been duly authorized and, upon Future Approval and Issuance, will be validly issued, fully paid and nonassessable. This opinion letter and the opinions it contains shall be interpreted in accordance with the Core Opinion Principles as published in *74 Business Lawyer* 815 (Summer 2019).

This opinion is being furnished to you for submission to the Commission as an exhibit to the Company’s Current Report on Form 8-K relating to the Shares (the “Current Report”), which is incorporated by reference in the Registration Statement. We hereby consent to the filing of this opinion letter as an exhibit to the Current Report and its incorporation by reference and the reference to our firm in that report. In giving our consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Very truly yours,

/s/ Goodwin Procter LLP

GOODWIN PROCTER LLP



Windtree Therapeutics Reports Third Quarter 2023 Financial Results and Provides Key Business Updates

WARRINGTON, PA – November 9, 2023 – Windtree Therapeutics, Inc. (“Windtree” or “the Company”) (NasdaqCM: WINT), a biotechnology company focused on advancing late-stage interventions for cardiovascular disorders, today reported financial results for the third quarter ended September 30, 2023 and provided key business updates.

“During the third quarter, we initiated our plan to move the istaroxime program in cardiogenic shock to Phase 3 readiness by advancing two clinical trials. First, we began building upon the positive data from the SEISMic study by progressing the SEISMic Extension Study for dose optimization in U.S., Europe and Latin American countries and sites. Additionally, we continued to progress start-up activities for a study of istaroxime in more severe SCAI Stage C cardiogenic shock patients that, with adequate resourcing, we anticipate will begin enrollment in the fourth quarter,” said Craig Fraser, Chief Executive Officer of Windtree. “Additionally, this quarter noted progress with our next generation, dual mechanism SERCA2a activators, including additional research and the awarding by the U.S. Patent and Trademark Office of a new composition of matter patent. Beyond multiple development activities, we are engaged in business development discussions. This is a busy time for Windtree, and over this and the next few quarters, we expect to deliver several milestones and events.”

Key Business Updates

- Progressed study and research site startup activities and regulatory filings in the U.S., Europe, and Latin America for both the SEISMic Extension Study and the SCAI Stage C Study for istaroxime in cardiogenic shock.
 - In August 2023, the Company announced that the United States Patent and Trademark Office issued US Patent No. 11,730,746 providing patent coverage for the dual mechanism SERCA2a Activators. The new composition of matter patent, titled: “17BETA-HETEROCYCLYL-DIGITALIS LIKE COMPOUNDS FOR THE TREATMENT OF HEART FAILURE,” provides patent protection through late 2039.
 - Company management recently attended several investor conferences including the Dawson James Small Cap Growth Conference; and the ThinkEquity Conference; and participated in a panel discussion titled, “Cardiac Kids: Late-Stage Advancement for Cardiovascular Disorders,” at the Lytham Partners Fall 2023 Investor Conference.
 - Cash and cash equivalents as of September 30, 2023 were \$7.4 million.
-



Select Third Quarter 2023 Financial Results

For each of the quarters ended September 30, 2023 and 2022, the Company reported an operating loss of \$4.7 million. Included in operating loss for the third quarter of 2022 is non-cash expense of \$0.5 million related to the impairment of goodwill.

Research and development expenses were \$2.1 million for the third quarter of 2023, compared to \$1.5 million for the third quarter of 2022. The increase in research and development expenses is primarily due to (i) an increase of \$0.6 million due to the initiation of the SEISMiC Extension study during the third quarter of 2023 and planning and start-up costs for the potential study of istaroxime in more severe SCAI Stage C cardiogenic shock; and (ii) a \$0.6 million reversal of royalty expense in the third quarter of 2022 related to the KL4 surfactant platform; partially offset by (iii) a decrease of \$0.4 million in personnel costs related to reductions in headcount; (iv) a decrease of \$0.1 million related to the KL4 surfactant platform as the Company continues to focus its resources on the development of its istaroxime pipeline; and (v) a decrease of \$0.1 million in non-cash stock-based compensation expense.

General and administrative expenses for the third quarter of 2023 were \$2.6 million, compared to \$2.7 million for the third quarter of 2022. The decrease in general and administrative expenses is primarily due to (i) a decrease of \$0.3 million in non-cash stock-based compensation expense due to the timing of equity grants during 2023 compared to 2022; (ii) a decrease of \$0.2 million in personnel costs due to headcount reductions; (iii) a decrease of \$0.2 million in incentive bonus expense; and (iv) a decrease of \$0.1 million in insurance costs; partially offset by (v) an increase of \$0.4 million in severance expense related to a former executive; and (vi) an increase of \$0.3 million in professional fees.

The Company reported a net loss of \$4.4 million (\$0.86 per basic share) on 5.1 million weighted-average common shares outstanding for the quarter ended September 30, 2023, compared to a net loss of \$4.1 million (\$6.51 per basic share) on 0.6 million weighted average common shares outstanding for the comparable period in 2022.

As of September 30, 2023, the Company reported cash and cash equivalents of \$7.4 million, which is expected to be sufficient to support our development activities and fund our business operations through the first quarter of 2024.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, which will be filed with the Securities and Exchange Commission on November 9, 2023, and includes detailed discussions about the Company's business plans and operations, financial condition, and results of operations.



About Windtree Therapeutics, Inc.

Windtree Therapeutics, Inc. is advancing late-stage interventions for cardiovascular disorders to treat patients in moments of crisis. Using new scientific and clinical approaches, Windtree is developing a multi-asset franchise anchored around compounds with an ability to activate SERCA2a, with lead candidate, istaroxime, being developed as a first-in-class treatment for acute heart failure and for early cardiogenic shock. Windtree's heart failure platform includes follow-on pre-clinical SERCA2a activator assets as well. In pulmonary care, Windtree has focused on facilitating the transfer of the KL4 surfactant platform, to its licensees, Lee's Pharmaceutical (HK) Ltd. and Zhaoke Pharmaceutical (Hefei) Co. Ltd. Included in Windtree's portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The Company may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are based on information available to the Company as of the date of this press release and are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company's current expectations. Examples of such risks and uncertainties include: risks and uncertainties associated with the economic and social consequences of the COVID-19 pandemic and the evolving events in Israel and Gaza, including any adverse impact on the Company's clinical trials, clinical trial timelines or disruption in supply chain; the success and advancement of the clinical development programs for istaroxime and the Company's other product candidates; the Company's ability to secure significant additional capital as and when needed; the Company's ability to access the debt or equity markets; the Company's ability to manage costs and execute on its operational and budget plans; the results, cost and timing of the Company's clinical development programs, including any delays to such clinical trials relating to enrollment or site initiation; risks related to technology transfers to contract manufacturers and manufacturing development activities; delays encountered by the Company, contract manufacturers or suppliers in manufacturing drug products, drug substances, and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the U.S. Food and Drug Administration or other regulatory authorities may not agree with the Company on matters raised during regulatory reviews, may require significant additional activities, or may not accept or may withhold or delay consideration of applications, or may not approve or may limit approval of the Company's product candidates, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals and risks related to the Company's efforts to maintain and protect the patents and licenses related to its product candidates; risks that the Company may never realize the value of its intangible assets and have to incur future impairment charges; risks related to the size and growth potential of the markets for the Company's product candidates, and the Company's ability to service those markets; the Company's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of the Company's product candidates, if approved; and the impacts of political unrest, including as a result of geopolitical tension, including the conflict between Russia and Ukraine, the People's Republic of China and the Republic of China (Taiwan), and the evolving events in Israel and Gaza, and any sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries which could have an adverse impact on the Company's operations, including through disruption in supply chain or access to potential international clinical trial sites, and through disruption, instability and volatility in the global markets, which could have an adverse impact on the Company's ability to access the capital markets. These and other risks are described in the Company's periodic reports, including its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at www.sec.gov. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Contact Information:

Matt Epstein
Kendall Investor Relations, LLC
mepstein@kendallir.com

+++++ Tables to Follow +++++



WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(in thousands, except share and per share data)

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 7,365	\$ 6,172
Prepaid expenses and other current assets	1,543	1,205
Total current assets	<u>8,908</u>	<u>7,377</u>
Property and equipment, net	205	262
Restricted cash	150	154
Operating lease right-of-use assets	1,544	1,853
Intangible assets	25,250	25,250
Goodwill	-	3,058
Total assets	<u>\$ 36,057</u>	<u>\$ 37,954</u>
LIABILITIES, MEZZANINE EQUITY & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 944	\$ 249
Accrued expenses	1,859	1,552
Operating lease liabilities - current portion	439	404
Loans payable	467	252
Total current liabilities	<u>3,709</u>	<u>2,457</u>
Operating lease liabilities - non-current portion	1,251	1,624
Restructured debt liability - contingent milestone payments	15,000	15,000
Other liabilities	3,800	3,800
Deferred tax liabilities	4,813	5,061
Total liabilities	<u>28,573</u>	<u>27,942</u>
Mezzanine Equity:		
Series A redeemable preferred stock, \$0.001 par value; 0 and 40,000 shares authorized; 0 and 38,610.119 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	-
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 5,000,000 and 4,960,000 shares authorized; 0 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	-
Common stock, \$0.001 par value; 120,000,000 shares authorized at September 30, 2023 and December 31, 2022; 5,148,220 and 772,203 shares issued at September 30, 2023 and December 31, 2022, respectively; 5,148,219 and 772,202 shares outstanding at September 30, 2023 and December 31, 2022, respectively	5	-
Additional paid-in capital	850,202	837,598
Accumulated deficit	(839,669)	(824,532)
Treasury stock (at cost); 1 share	(3,054)	(3,054)
Total stockholders' equity	<u>7,484</u>	<u>10,012</u>
Total liabilities, mezzanine equity & stockholders' equity	<u>\$ 36,057</u>	<u>\$ 37,954</u>



WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(in thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Expenses:				
Research and development	\$ 2,110	\$ 1,543	\$ 5,288	\$ 9,883
General and administrative	2,580	2,653	7,292	8,548
Loss on impairment of goodwill	-	454	3,058	12,090
Total operating expenses	<u>4,690</u>	<u>4,650</u>	<u>15,638</u>	<u>30,521</u>
Operating loss	<u>(4,690)</u>	<u>(4,650)</u>	<u>(15,638)</u>	<u>(30,521)</u>
Other income (expense):				
Interest income	112	39	264	57
Interest expense	(13)	(14)	(38)	(40)
Other income, net	166	569	275	988
Total other income, net	<u>265</u>	<u>594</u>	<u>501</u>	<u>1,005</u>
Net loss	<u>\$ (4,425)</u>	<u>\$ (4,056)</u>	<u>\$ (15,137)</u>	<u>\$ (29,516)</u>
Net loss per common share				
Basic and diluted	\$ (0.86)	\$ (6.51)	\$ (4.50)	\$ (49.94)
Weighted average number of common shares outstanding				
Basic and diluted	5,148	623	3,363	591



Windtree Therapeutics
Company Overview

November 2023



WINDTREE
THERAPEUTICS™

(NASDAQ: WINT)

Forward-Looking Statements

This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, among other things, include statements about the Company's clinical development programs, business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development activities, or otherwise as to future events. The forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will," "should," "could," "targets," "projects," "contemplates," "predicts," "potential" or "continues" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. These risks and uncertainties are further described in the Company's periodic filings with the Securities and Exchange Commission ("SEC"), including the Company's most recent reports on Form 10-K, and any subsequent quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments thereto ("Company Filings"). Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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Investment Highlights

- ✓ Clinical stage biopharmaceutical company focused on acute cardiovascular critical conditions with advanced stage programs intended to address large markets with significant unmet needs (NASDAQ: WINT)
- ✓ First in class, novel lead asset istaroxime has demonstrated positive efficacy and an attractive profile compared to currently available rescue medications in three Phase 2 global studies, highlighted by improvements in cardiac function and increases in blood pressure with favorable renal function profile
- ✓ Attractive cardiogenic shock development pathway with potential for relatively small, rapid, low-cost clinical studies with attractive primary endpoint (blood pressure)
- ✓ Advancing pipeline to generate several planned clinical milestones and readouts over the next 12-18 months. Company expects to be Phase 3 ready in cardiogenic shock in 2H 2024
- ✓ Focus on business development activities for potential deals with global partners or other strategic opportunities
- ✓ Lean, capital efficient operation led by a highly experienced management team

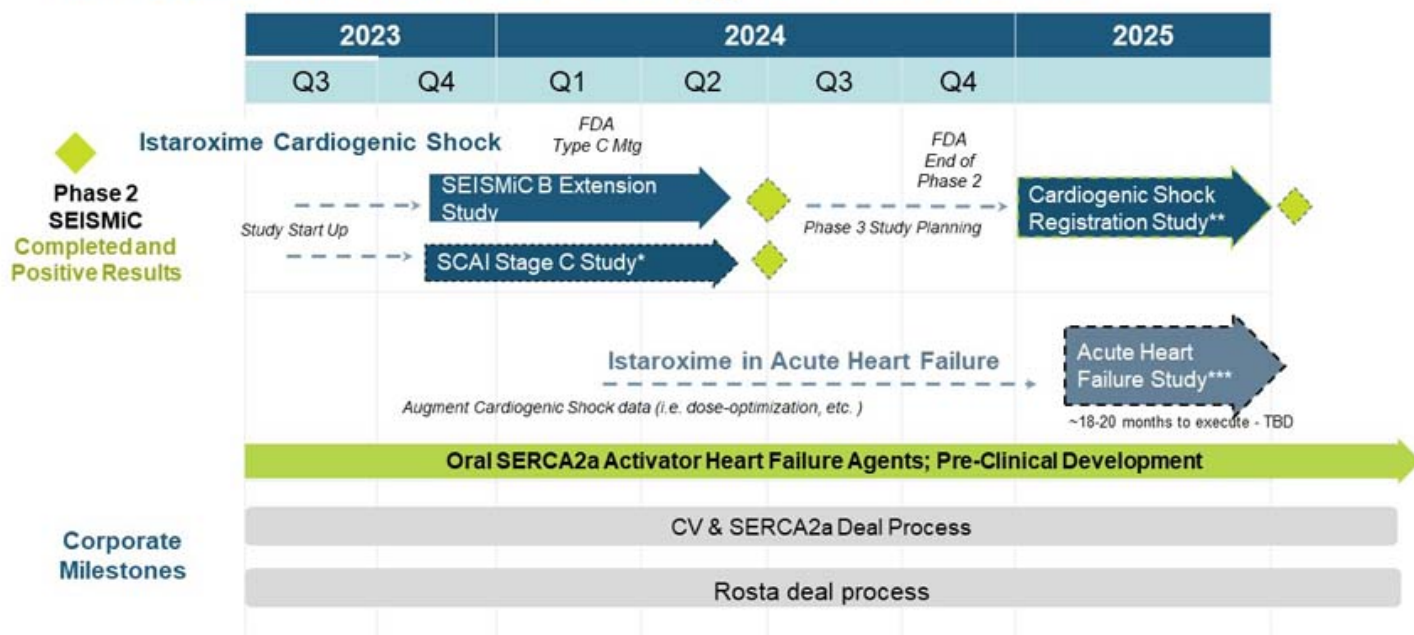
Multi-Asset / Indication Pipeline with Several Near-Term Milestones

Cardiogenic Shock with Istaroxime as Lead Program

Multi-asset
Heart Failure
platform for
partnership

Product Candidates	Indication	Phase	Development Status / Plans
<i>Priority Program</i>			
Istaroxime	Cardiogenic Shock	Phase 2	<ul style="list-style-type: none"> Lead program Positive Phase 2 study Executing small follow-on studies with planned Mid'24 read-outs intended to transition to phase 3
Istaroxime	Acute Heart Failure	Phase 2b (completed)	<ul style="list-style-type: none"> Positive 2a and 2b data Augment AHF data with cardiogenic shock data, if positive and adequate, for phase 3 for AHF with partnership
Oral SERCA2a Activators	Chronic Heart Failure, including potentially HFpEF	Preclinical	<ul style="list-style-type: none"> Chronic and Acute Heart Failure Target for collaboration/partnership
Rostafuroxin	Treatment Resistant Hypertension - Genetically Associated	Phase 2b	<ul style="list-style-type: none"> Phase 2 data in hypertension and genetically associated hypertension Company holding development to out-license and repositioned for the attractive and large Resistant Hypertension market
KL4 Surfactant and AEROSURF	KL4 surfactant Drug/Device Tx for RDS and potential other applications	Phase 2b	<ul style="list-style-type: none"> Global out-license to Lee's Pharma Lee's Pharma responsible for all costs of development

Istaroxime Milestones and Strategy for Value Creation



* Study start-up; initiation and guidance to be confirmed in Q4 2023
 ** Study and guidance pending positive EOP2 meeting and adequate funding
 *** Study and guidance pending positive EOP2 meeting and adequate funding (via partnership)

◆ Represents planned topline data available



Istaroxime

Cardiogenic Shock

Potential to transform the standard of care for critical patients



Cardiogenic Shock - A Critical Condition Caused by a Failing Heart

A severe presentation of heart failure characterized by **low blood pressure and inadequate blood flow to vital organs (hypoperfusion)** accompanied by congestion and high filling pressures of the heart. It **requires very urgent treatment.**



- Caused by severe impairment of cardiac function that results in diminished cardiac output, end-organ hypoperfusion and hypoxemia
- Most often requires pharmacological or mechanical intervention with key clinical objective to increase SBP to >90mmHg and improve tissue perfusion
- Cardiogenic shock patients typically require hospital intensive care and consume significant hospital resources
- High mortality (~30-40%) and substantial morbidity in survivors¹
- US + EU markets represent an ~\$1.0B market potential² with high unmet need

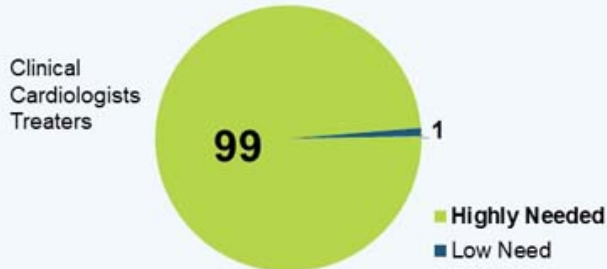
1) Kolte D. American Heart Association; 2014 Jan 13; (rates associated with classic, stage C shock)
2) Estimates from claims data and epi data September 2021, multiplied by assumed various regional prices

Significant Unmet Need and Reported Desire for Istaroxime

- **No satisfactory pharmacological intervention to reverse the conditions**
 - Available therapies have unwanted side effects such as risk for arrhythmias, decreasing blood pressure, renal dysfunction and even increases in mortality that limit their usefulness and position them as “rescue medicines”
- A therapy that can be used **earlier** to rapidly **improve blood pressure and cardiac function without unwanted side effects** is needed

Market research shows need and enthusiasm for istaroxime profile

100 U.S. Cardiologists questioned on degree of unmet need for new innovative pharmacologic treatments for ECS¹

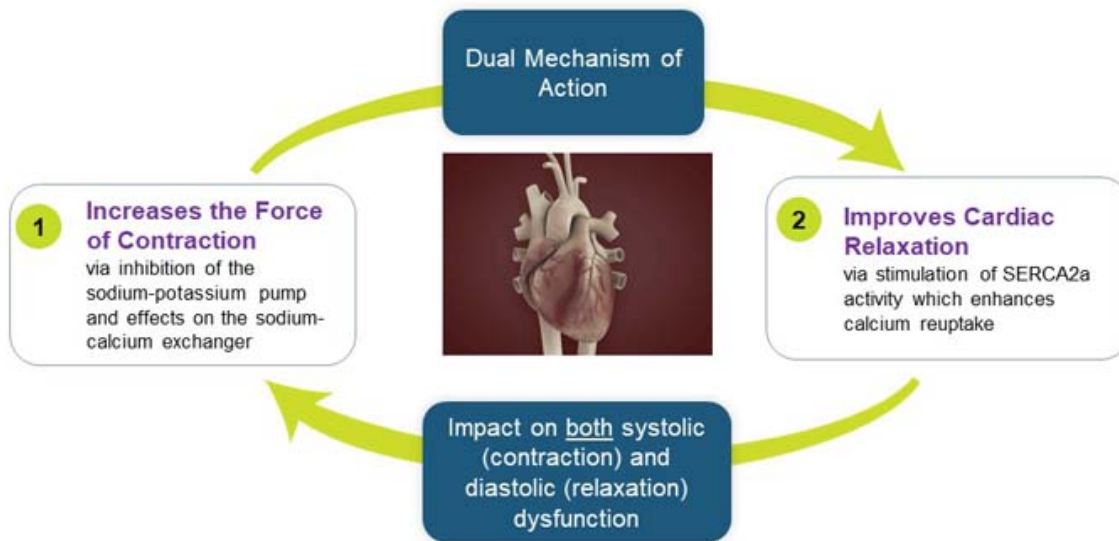


✓ 84% of the cardiologists responded they would be likely to extremely likely to use istaroxime for early cardiogenic shock patients

✓ Majority responded they would position utilization before use of other existing classes of therapies such as inotropes and vasopressors

Istaroxime – Novel First-in-Class Therapy

Novel intravenous agent designed to improve
systolic contraction and diastolic relaxation of the heart



Istaroxime Cardiogenic Shock Program Came from AHF Phase 2 Trials and the Potential Attractive Regulatory Pathway

Phase 2a and 2b data in AHF - istaroxime uniquely and significantly improved:



Cardiac Function

- increased stroke volume
- lowered cardiac filling pressures

Systolic Blood Pressure

Renal Function (eGFR)

Key Question that Windtree Decided to Answer with a Clinical Study:
Would istaroxime increase BP and improve cardiac function for early cardiogenic shock?

SEISMic Early Cardiogenic Shock Study

Clinical strategy: Start development with patients in early cardiogenic shock caused by severe heart failure



60 patients in early cardiogenic shock (SBP 75-90mmHg) with AHF



Study drug was infused for 24 hours in a 1:1 randomization to placebo or istaroxime. Two istaroxime target doses were evaluated, 1.5µg/kg/min in the first group and 1.0 µg/kg/min in the next group.



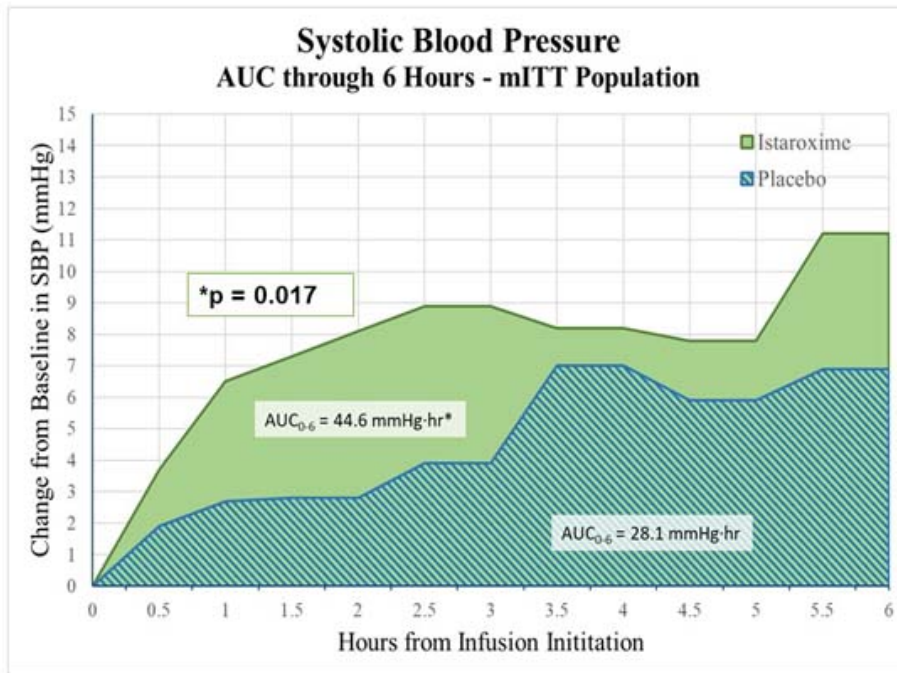
Primary endpoint was SBP AUC at 6 hours comparing istaroxime to placebo

Secondary measures included: SBP profile at 24 hours, echocardiology measures associated systolic and diastolic cardiac function, renal function, various safety and tolerability measures

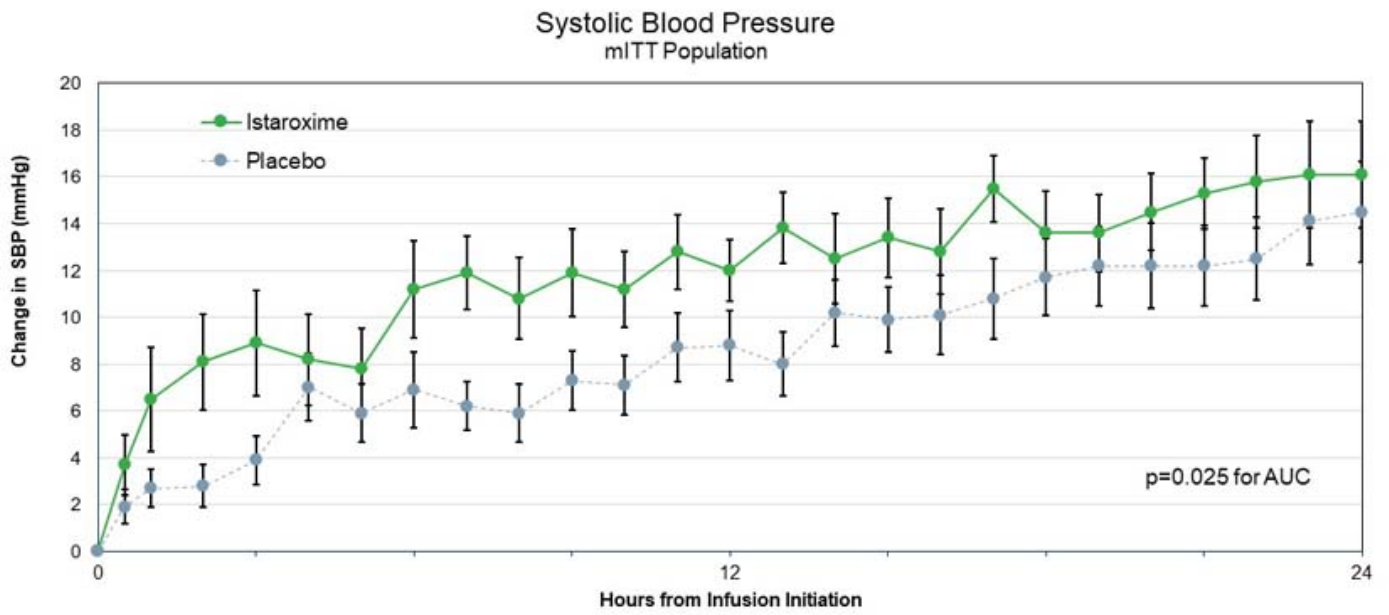


Positive Results in the Early Cardiogenic Shock Study

Istaroxime Achieved Positive Primary Endpoint



Systolic BP Improvements Persisted over 24 Hours



Cardiac Function Improvement

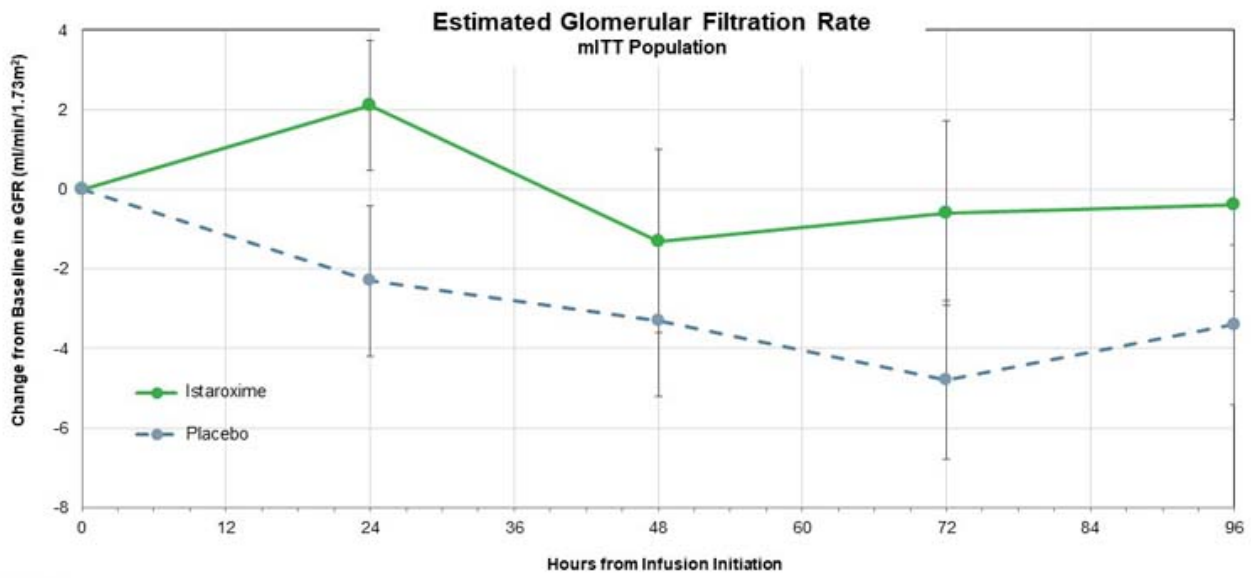
Echocardiography demonstrated improvements in key systolic and diastolic cardiac function measures including:

- ✓ **Cardiac index** (amount of output from the heart over a minute) significantly increased
- ✓ **Stroke volume** (amount of blood from the heart with each heartbeat) substantially increased
 - (4 mL/m²) approaching statistical significance
- ✓ **The strength and cardiac geometry of the heart improved including:**
 - Left atrial area was reduced
 - Left ventricular end systolic volume was reduced
 - Left ventricular end diastolic volume was reduced



Treatment was Associated with a Favorable Renal Profile

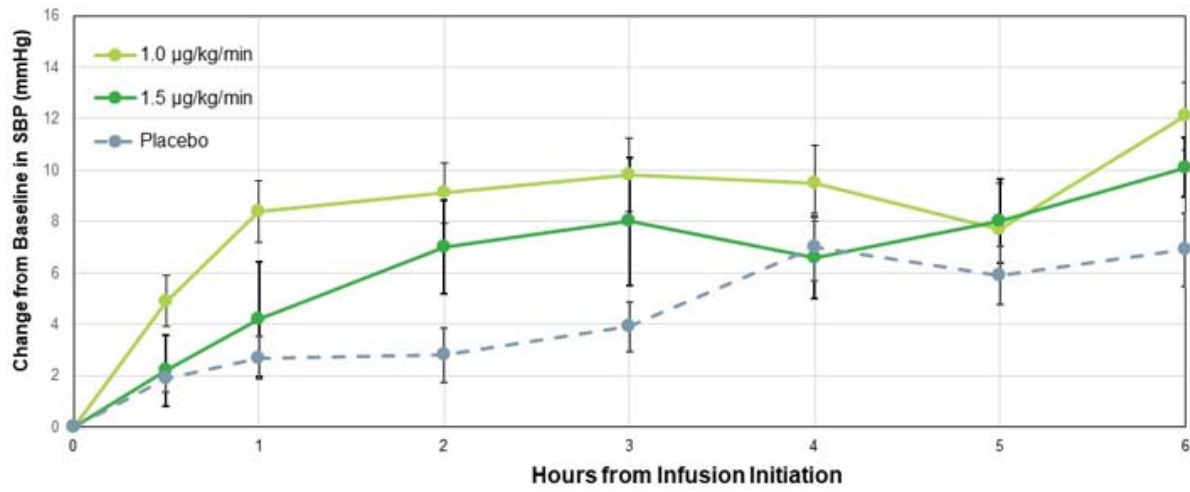
Renal function was not decreased in istaroxime treated patients



1.0 µg/kg/min Produced a Favorable Effect on SBP

1.0 µg/kg/min dosing was associated with:

- Early, rapid SBP increase and improvement in more echocardiographic assessments of cardiac function
- More favorable adverse event, serious adverse event and clinical event profile

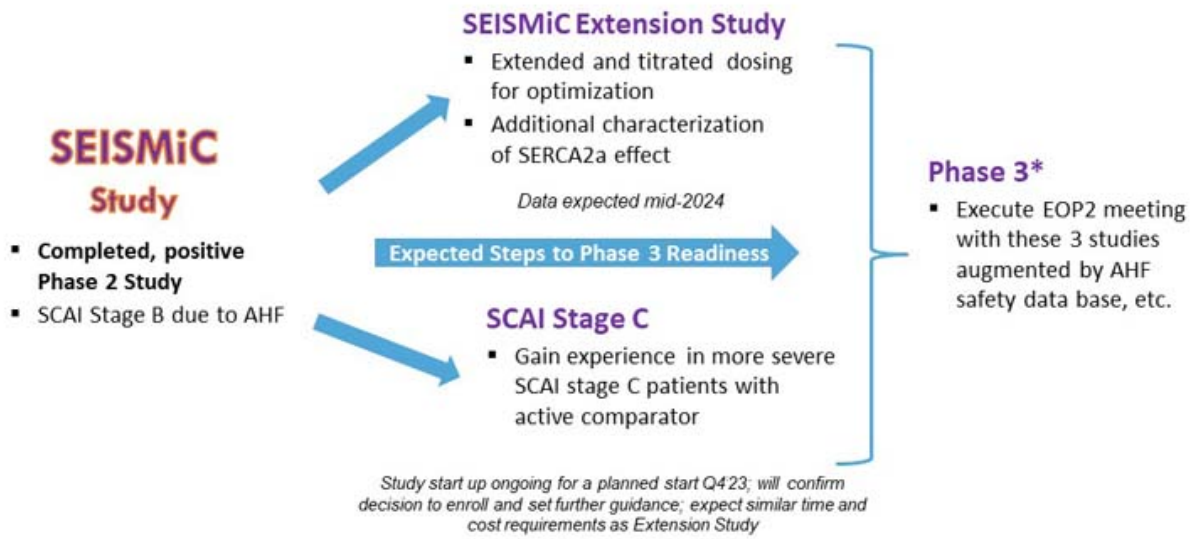


SEISMIC Study Results Summary

- ✓ Systolic blood pressure significantly increased within the first 6 hours of initiating the infusion ($p=0.017$) and the increase was maintained throughout the 24-hour infusion ($p=0.025$)
 - SBP increases were rapid within the first hour and sustained through the 96-hour post-infusion measure
- ✓ Key secondary endpoints of systolic and diastolic cardiac function and performance were improved
- ✓ Renal function was maintained
- ✓ SEISMIC provided valuable information for optimizing our dose moving forward
- ✓ These data substantiate and advance the rationale for istaroxime as a potential treatment for cardiogenic shock and align with the existing data from the program in AHF

Cardiogenic Shock Development Strategy

Focus on thoroughness, speed and relatively low cost of trials



Istaroxime Cardiogenic Shock Studies

Expected Steps to Phase 3 Readiness

Dose Optimization – Extension Study

Study Objectives:

- Advance the characterization of the physiology associated with longer istaroxime dosing as well as evaluate a dose titration
- More fully illuminate the effects and potential benefits associated with SERCA2a activation
- Support our regulatory strategy for istaroxime



Double-blind, placebo controlled in up to 30 patients with SBP between 70-100mmHg conducted in sites in the US, EU and LATAM



Two istaroxime doses versus placebo. Istaroxime dosed for up to 60-hours, decreasing the dose over time



Multiple physiologic measures associated with cardiac function, blood pressure and safety

SCAI Stage C Study

Study Objectives:

- Gain experience with istaroxime in SCAI stage C patients experiencing hypotension effects on organs
- Study istaroxime in a setting which has active background therapy (pressors) present



20 patients with SCAI Stage C shock due to ADHF: Hypotension + hypoperfusion. (Protocol will allow additional enrollment after this review)

Istaroxime or placebo will be added to initial standard of care shock therapy (blinded)



Hold shock therapies constant for 6 hours to assess the primary BP endpoint, changes are allowed if the patient's condition dictates. Thereafter, taper the initial shock therapy with istaroxime supporting the patient



Multiple physiologic measures associated with cardiac function, blood pressure and safety



Plan allows the potential for more subjects to be added to the study

Cardiogenic Shock Represents a Significant Opportunity for Istaroxime and Windtree

- ✓ Significant opportunity for Istaroxime to make a difference:
 - ~30-40% mortality in classic shock and high morbidity
 - Very long average length of hospital stay (~ 19.5 days¹) means high cost of hospital care (estimated >\$175k²) and creates opportunity for pharmacoeconomic benefits
- ✓ Currently available pharmacologic treatments have undesirable side effects and can result in poor outcomes
- ✓ Lack of competition in development or active competition in the market
- ✓ Attractive \$1.25B valuation of market potential versus time and cost of development supports potential deals



¹ US Hospital Claims Data, 2022

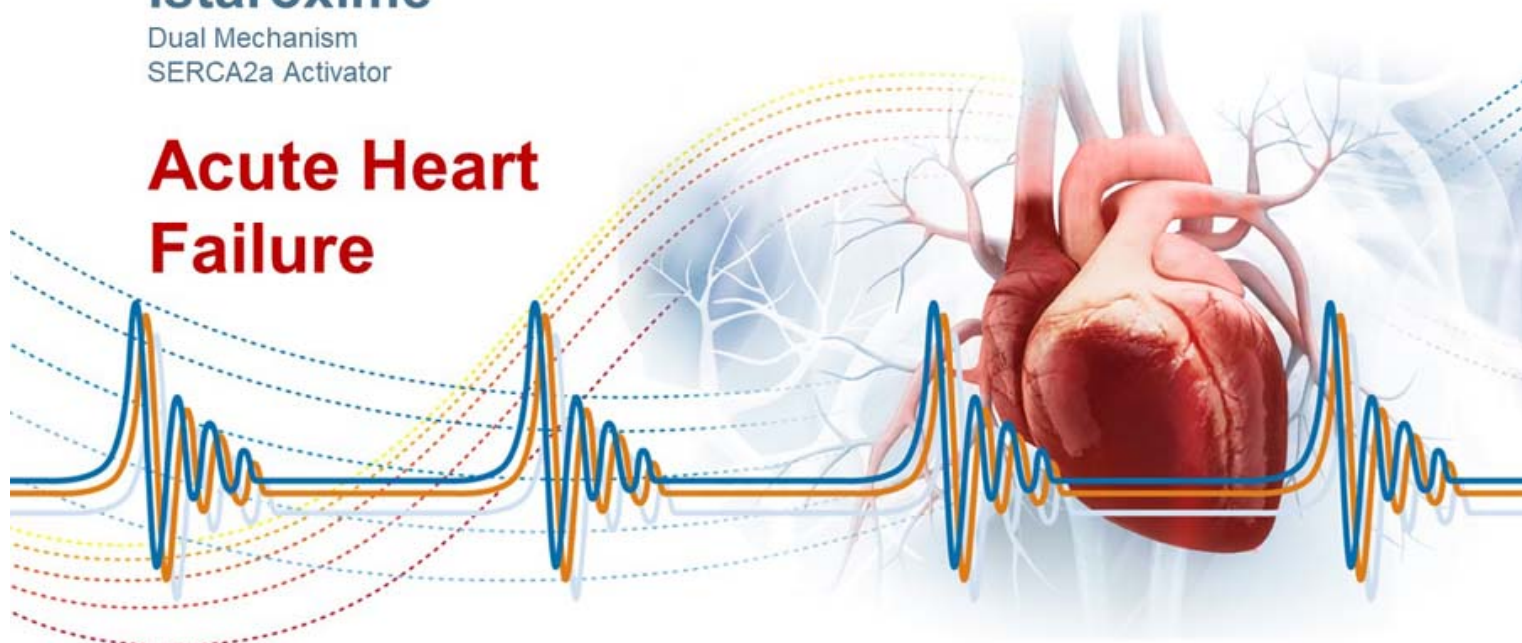
² Healthcare.gov, Department of Health & Human Services, estimated from average cost of hospital stay

³ Long et al, USC Cardiology Review, Describing and Classifying Shock: Recent Insights, Sept 2021

Istaroxime

Dual Mechanism
SERCA2a Activator

Acute Heart Failure



Heart Failure –

A Large and Growing Market with Significant Mortality and Unmet Need

#1 cause of U.S. hospitalization in patients > 65 years old

Annual Admissions
~1.3M U.S.
~1.5M E.U.



Patients
7M U.S.,
25M+ worldwide



~7%

In-patient mortality

30-day mortality can exceed 10%



>\$18B

annual U.S. hospital costs

Most expensive of the Medicare diagnoses



0

New pharmacologic advancements in acute heart failure for decades



Lack of therapeutic advances led the FDA to issue new Heart Failure Guidance in July 2019 for greater development flexibility in acceptable endpoints, specifically acknowledging mortality is not required

Acute Heart Failure – Significant Unmet Clinical Need

Patient Management Goals

- **Clinical objectives** for AHF patient management include:
 - **Relieve pulmonary congestion** and general edema (e.g., “dry out”) with IV diuretics
 - **Improve cardiac function** and peripheral/organ perfusion
 - **Achieve stable, fully compensated** clinical state
 - Transition to oral, outpatient medicines (for chronic management of heart failure)

Current Treatment Options

- **Current approaches to acutely improve cardiac function are associated with unwanted effects:**
 - Heart rhythm disturbances
 - Increased heart rate and myocardial oxygen demand
 - Decreased blood pressure
 - Potential damage to the heart muscle
 - Worsening renal function
 - Mortality
- **Patients with low blood pressure (SBP) and peripheral hypoperfusion are high risk, challenging patients who are also generally resistant to diuretic therapy and often discharged in a sub-optimal state**



- 1) ADHERE Registry, n=48,567; JAMA 2006
- 2) European Journal of Heart Failure; Voors, PRE-RELAX AHF Study; 2011; 13

Istaroxime AHF Phase 2a & 2b Studies

Phase 2a



n=120
ADHF Patients



Dosing=
0.5, 1, 1.5 µg/kg/min



6 hour
Infusion

- Primary: PCWP significantly improved
- Stroke Vol & SBP – significant increase
- Heart Rate (HR) - lowered

Phase 2b

n=120
ADHF Patients
(dyspnea plus need
for IV furosemide ≥ 40mg)

Dosing=
0.5, 1.0 µg/kg/min

24 hour
Infusion

Results

Positive Phase 2 trial results demonstrated improved cardiac function
without unwanted side effects of existing rescue therapies

Istaroxime in AHF Phase 2b – Results Summary



Cardiac Function Improved with Both Doses

- Significant increase in stroke volume (amount of blood expelled with each heartbeat)
- Lowered cardiac filling pressures



Increased in Systolic Blood Pressure



Increased Renal Function (eGFR)



Heart Rate Decreased

Favorable Heart Rhythm Profile Observed

- No increase in clinically significant arrhythmias or ventricular tachycardia

Istaroxime – Acute Heart Failure

Objective: Evaluate potential Phase 3 AHF program based on data from our cardiogenic shock program

Potential Phase 3 AHF Program



Augment our data from the positive phase 2a and phase 2b AHF studies with the efficacy, safety and dosing and characterization learnings from the extension and other studies in the severe AHF patients experiencing early cardiogenic shock. If positive and adequate, move istaroxime into phase 3 for AHF.



Our strategy is to focus on treating heart failure patients with low blood pressure, who also tend to be diuretic resistant, as a patient population that we believe could particularly benefit from the unique profile and potential ability of istaroxime to increase cardiac function and increase blood pressure while maintaining or improving renal function.

Currently seeking partnership to execute this clinical trial

Next Generation, Oral SERCA2a Activators Acute and Chronic Heart Failure Platform

The Company also has pre-clinical programs on product candidates including:

Pure SERCA2a Activators

- **Potential Oral & i.v. therapies** for chronic heart failure (CHF) and AHF
- Attractive approach for **heart failure with preserved ejection fraction (HFpEF)** - which represents nearly half of heart failure* and is underserved

Dual Mechanism, (SERCA2a & Na⁺/K⁺) Compounds

- **“Next generation istaroxime”** as oral/i.v. for **in-patient acute and out-patient chronic use**
- **Granted patent for composition of matter** from the European Patent Office and issued patent from the US Patent and Trademark Office

These next generation agents help form complete chronic and acute heart failure treatment portfolio for both licensing/partnership and potential commercialization



*American Heart Association, Circulation Research, Vol. 124, No. 11, Heart Failure with Preserved Ejection Fraction in Perspective, May 2019

Active Engagement in BD Opportunities

Goal: Non-Dilutive Resourcing and Creating Shareholder Value

Global / Regional
Licensing

COMPLETE

AEROSURF / KL4 Platform –

- Exclusive global license to Lee's Pharm and Zhaoke. Potential proceeds:
 - Up to \$78.9 million in potential milestone payments, low double-digit % royalties
 - *WINT no longer responsible for any costs for KL4 platform*

Licensing opportunities

- Istaroxime – AHF and Cardiogenic Shock
- SERCA2a Activators – Chronic and Acute Heart Failure
- Rostafuroxin – Treatment Resistant Hypertension

Strategic
Transaction

- Acquisition by a pharmaceutical company
- Merger if it creates more shareholder value

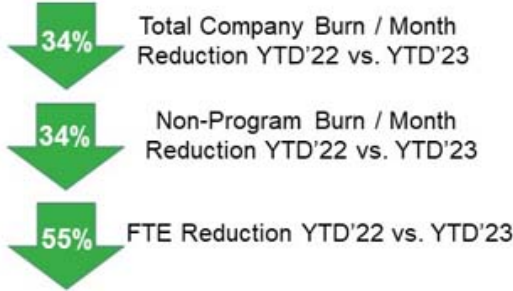
Milestones and Financial Summary

Cash

Sept 30, 2023 \$7.4M

Driving Capital Efficiency to Program Investment

Significantly reduced company expenses and cash burn via out-licensing KL4 platform, focused resources on lead priority program



In the near term, the Company plans to maintain the lower non-program cash burn that was achieved during YTD'23.

Anticipated Events / Milestones for the next 4-6 quarters

- ✓ Extension Study – first patient enrolled
- ✓ Stage C Study – first patient enrolled*
- ✓ Oral SERCA2a advancement (i.e., patent, pubs)
- ✓ **Extension Study Data**
- ✓ **Stage C Study Data***
- ✓ Regulatory interactions (i.e., End of Phase 2, etc.)
- ✓ Potential for Business Development (ongoing)

* Stage C Study start up ongoing for a planned start Q4 2023; will confirm decision to enroll and set further guidance

Strategy for Value-Creation - Focus for the Next 4-6 Quarters

Clinical Milestones

- Strong trial execution of Cardiogenic Shock Extension and SCAI Stage C
- Enable transition to EOP2/Ph3
- Execute select CMC actions

Transformative BD

- Licensing and partnership for non-dilutive value
- Strategic: Increase value, portfolio with enhanced opportunities and mitigated risk



WINDTREE
THERAPEUTICS



WINT Team

Retention, Motivation and Performance Culture

High IR/PR Communication

- Deliverables and news, dedicated media, etc.




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