As filed with the Securities and Exchange Commission on April 6, 2023.

Registration No. 333-269775

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1
to
FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

WINDTREE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**2836**	**94-3171943**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(215) 488-9300

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Craig E. Fraser
President and Chief Executive Officer
Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(215) 488-9300

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Rachael M. Bushey **Jennifer L. Porter** **Goodwin Procter LLP** **2929 Arch Street Suite #1700** **Philadelphia, Pennsylvania 19104** **(445) 207-7800**	**Diane Carman** **Senior Vice President, General Counsel** **Windtree Therapeutics, Inc.** **2600 Kelly Road, Suite 100** **Warrington, Pennsylvania 18976** **(215) 488-9300**	**Michael Nertney** **Ellenoff Grossman & Schole LLP** **1345 Avenue of the Americas** **New York, New York 10105** **(212) 370-1300**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 6, 2023

PRELIMINARY PROSPECTUS

1,948,051 Shares of Common Stock and Accompanying
Common Warrants to Purchase up to 1,948,051 Shares of Common Stock
Pre-Funded Warrants to Purchase up to 1,948,051 Shares of Common Stock and Accompanying
Common Warrants to Purchase up to 1,948,051 Shares of Common Stock

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We are offering 1,948,051 shares of our common stock, par value $0.001, or common stock, and warrants to purchase up to 1,948,051 shares of common stock, or the common warrants, pursuant to this prospectus. The combined public offering price for each share of our common stock, together with a common warrant to purchase one share of common stock, is $. Each common warrant will have an exercise price of $ per share, will be exercisable immediately and will expire on the fifth anniversary of the date of issuance. The shares of our common stock and the common warrants are immediately separable and will be issued separately, but will be purchased together in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.

We are also offering pre-funded warrants to purchase up to an aggregate of 1,948,051 shares of common stock, or the pre-funded warrants, in lieu of shares of common stock to those purchasers whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock following the consummation of this offering. A holder of pre-funded warrants will not have the right to exercise any portion of its pre-funded warrants if the holder, together with its affiliates and certain related parties, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each pre-funded warrant is exercisable for one share of our common stock. Each pre-funded warrant is being issued together with the same common warrant described above being issued with each share of common stock. For each pre-funded warrant that we sell, the number of shares of common stock that we are selling will be decreased on a one-for-one basis. The combined public offering price of each pre-funded warrant, together with the accompanying common warrant, is $. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The pre-funded warrants and the common warrants are immediately separable and will be issued separately, but will be purchased together in this offering. In this prospectus, we refer to the common warrants and pre-funded warrants together as the "warrants". This prospectus also relates to the offering of common stock issuable upon exercise of such warrants. We collectively refer to the shares of common stock and warrants offered hereby and the shares of common stock underlying the warrants as the "securities."

There is no established public trading market for the warrants, and we do not expect a market to develop. We do not intend to apply for listing of the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be limited. Our common stock is listed on the Nasdaq Capital Market under the symbol "WINT". On April 4, 2023, the last reported sale price of our common stock on the Nasdaq Capital Market was $4.62 per share. We have assumed a public offering price of $4.62 per share of common stock together with a common warrant to purchase one share of common stock, which represents the last reported sale price of our common stock as reported on the Nasdaq Capital Market on April 4, 2023. The final public offering price will be determined through negotiation between us and the underwriters in the offering and may be at a discount to the current market price. Therefore, the recent market price used throughout this prospectus may not be indicative of the final public offering price. The price of our common stock on the Nasdaq Capital Market during recent periods will only be one of many factors in determining the final public offering price. Other factors to be considered in determining the final public offering price include our history, our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers and directors, the general condition of the securities markets at the time of this offering and discussions between the underwriters and prospective investors.

We are a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and the documents incorporated by reference herein and may elect to comply with reduced public company reporting requirements in future filings. See "*Prospectus Summary——Implications of Being a Smaller Reporting Company*."

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks that we have described beginning on page 10 of this prospectus under the caption "*Risk Factors*", and under similar headings in any amendment or supplement to this prospectus or in any other documents incorporated by reference into this prospectus.

	Per Share and Accompanying Common Warrant	Per Pre-Funded Warrant and Accompanying Common Warrant	Total
Public offering price	$	$	$
Underwriting discounts and commissions(1)	$	$	$
Proceeds to us, before expenses(2)	$	$	$

(1) We have agreed to reimburse the underwriters for certain expenses. See "*Underwriting*" on page 86 for additional information regarding underwriting compensation.
(2) The above summary of offering proceeds does not give effect to any proceeds from the exercise of the warrants being issued in this offering.

We have granted the underwriters an option for a period of up to 45 days from the date of this prospectus to purchase up to 292,207 additional shares of our common stock at the public offering price of $ per share, and/or common warrants to purchase up to 292,207 shares of our common stock at the public offering price of $ per common warrant, or any combination thereof, as determined by the underwriters, less underwriting discounts and commissions, in each case solely to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the securities against payment in New York, NY on or about , 2023.

Ladenburg Thalmann

Prospectus dated , 2023

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ABOUT THIS PROSPECTUS

The registration statement we filed with the Securities and Exchange Commission, or the SEC, includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein or any amendment thereto.

You should not assume that the information contained in this prospectus or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference herein or therein is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus or any related free writing prospectus is delivered, or securities are sold, on a later date. This prospectus contains or incorporates by reference summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been or will be filed or have been or will be incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under the heading "*Where You Can Find More Information*."

You should rely only on the information that we have included or incorporated by reference in this prospectus and any related free writing prospectus that we may authorize to be provided to you. We have not, and the underwriters have not, authorized anyone to give any information or to make any representation other than those contained or incorporated by reference in this prospectus or any related free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or any related free writing prospectus. This prospectus and any related free writing prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus or any related free writing prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

In addition, while we believe the industry, market and competitive position data included in this prospectus, including the information incorporated by reference herein is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors. These factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

Unless the context otherwise requires, references in this prospectus to "Windtree," "Windtree Therapeutics," "the Company," "we," "our," and "us" refer to Windtree Therapeutics, Inc., a Delaware corporation, and our consolidated subsidiaries.

We use "Windtree Therapeutics," as our trademark, and we have been granted a trademark or have a trademark application on file with the United States Patent and Trademark Office. All trademarks or trade names referred to in this prospectus and the documents incorporated by reference herein are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus and the documents incorporated by reference herein are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us, by any other companies.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should carefully read the entire prospectus, including the risks of investing in our securities discussed under the heading "Risk Factors" and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part. Unless the context otherwise requires, the terms "Windtree", "the Company," "we," "us," "our" and similar references in this prospectus refer to Windtree Therapeutics, Inc. and its consolidated subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel therapeutics intended to address significant unmet medical needs in important cardiovascular care markets. Our development programs are primarily focused on the treatment of cardiovascular diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to improve cardiac function in patients with acute heart failure, or AHF, with a potentially differentiated safety profile from existing treatments. Istaroxime demonstrated significant improvement in both diastolic and systolic aspects of cardiac function and was generally well tolerated in three Phase 2 clinical trials. Istaroxime has been granted Fast Track designation for the treatment of AHF by the U.S. Food and Drug Administration, or FDA. Based on the profile observed in our Phase 2 clinical studies in AHF, where istaroxime significantly improved cardiac function and systolic blood pressure, or SBP, in acute decompensated heart failure patients, we initiated a Phase 2 global clinical study to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs and mortality. We completed this Phase 2 global clinical study and, in April 2022, announced positive topline results. Istaroxime rapidly and significantly increased SBP while also improving cardiac function and preserving renal function. In May 2022, we presented the study results at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain and, in September 2022, the results were published in the European Journal of Heart Failure. We believe that istaroxime has the potential to fulfill an unmet need in early and potentially more severe cardiogenic shock. We further believe that the data from our recently completed Phase 2 global clinical study in early cardiogenic shock not only supports that program's continued development but also supports the continued development of our AHF program as well.

Our heart failure cardiovascular portfolio also includes sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, activators. This research program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds. These candidates would potentially be developed for both acute decompensated and chronic out-patient heart failure. In addition, our cardiovascular drug product candidates include rostafuroxin, a novel product candidate for the treatment of hypertension in patients with a specific genetic profile. We are pursuing potential licensing arrangements and/or other strategic partnerships and do not intend to advance this product candidate without securing such an arrangement or partnership.

Previously, we were developing our KL4 surfactant platform, including AEROSURF (lucinactant for inhalation), to address a range of serious respiratory conditions in children and adults. In order to focus our resources on the development of our istaroxime pipeline, we suspended internal AEROSURF clinical activities in November 2020, and, in January 2022 we began to reduce all other costs related to the KL4 surfactant platform that were not already being performed by our licensee, Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), and its affiliate, Zhaoke Pharmaceutical (Hefei) Co. Ltd., or Zhaoke, under the terms of our License, Development and Commercialization Agreement between us and Lee's (HK) dated as of June 12, 2017, as amended, or the Original License Agreement.

On August 17, 2022, we entered into an Amended and Restated License, Development and Commercialization Agreement, or the A&R License Agreement, with Lee's (HK) and Zhaoke effective as of August 9, 2022. We refer to Zhaoke and Lee's (HK) together as the "Licensee." The A&R License Agreement amends, restates, and supersedes the Original License Agreement.

Under the A&R License Agreement, we granted to Licensee an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute, and otherwise commercialize our KL4 surfactant products, including SURFAXIN®, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant, in each case for the prevention, mitigation, and/or treatment of any respiratory disease, disorder, or condition in humans worldwide, except for Andorra, Greece, and Italy (including the Republic of San Marino and Vatican City), Portugal, and Spain, or the Licensed Territory, which countries are currently exclusively licensed to Laboratorios Del Dr. Esteve, S.A., or Esteve.

Under the Original License Agreement, Lee's (HK) previously made an upfront payment to us of $1.0 million. Pursuant to the terms of the A&R License Agreement, we may also receive up to $78.9 million in potential clinical, regulatory, and commercial milestone payments. We are also entitled to receive a low double-digit percentage of Licensee's non-royalty sublicense income.

Further, under the A&R License Agreement, Licensee is solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval, and commercialization of licensed products in the Licensed Territory, including all royalties payable in respect of third-party intellectual property rights sublicensed by us to Licensee and all intellectual property prosecution, maintenance and defense activities and costs.

Our ability to advance our development programs is dependent upon our ability to secure additional capital in both the near and long-term, through public or private securities offerings; convertible debt financings; and/or potential strategic opportunities, including licensing agreements, drug product development, and marketing collaboration arrangements, pharmaceutical research cooperation arrangements, and/or other similar transactions in geographic markets, including the U.S., and/or through potential grants and other funding commitments from U.S. government agencies, in each case, if available. We have engaged with potential counterparties in various markets and will continue to pursue non-dilutive sources of capital as well as potential private and public securities offerings. There can be no assurance, however, that we will be able to identify and enter into public or private securities offerings on acceptable terms and in amounts sufficient to meet our needs or qualify for non-dilutive funding opportunities under any grant programs sponsored by U.S. government agencies, private foundations, and/or leading academic institutions, or identify and enter into any strategic transactions that will provide the additional capital that we will require. If none of these alternatives is available, or if available and we are unable to raise sufficient capital through such transactions, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business, financial condition, and results of operations.

Business and Program Updates

The reader is referred to, and encouraged to read in its entirety, "*Item 1. Business*" *in our Annual Report on Form 10-K for the year ended December 31, 2022 that we filed with the SEC on March 31, 2023, or our 2022 Annual Report, which contains a discussion of our business and business plans, as well as information concerning our proprietary technologies and our current and planned development programs.*

Istaroxime (Early Cardiogenic Shock)

We are evaluating istaroxime for the treatment of early cardiogenic shock, a severe presentation of heart failure characterized by very low blood pressure and risk for hypoperfusion to critical organs which is associated with high mortality and morbidity and is not well treated with current therapies.

In September 2020, we initiated a Phase 2 clinical study of istaroxime for the acute treatment of cardiogenic shock in more severe heart failure patients than previously studied to evaluate the potential to improve blood pressure (primary measure) and cardiac function (secondary measure). The study also evaluated the safety and side effect profile of istaroxime in this patient population. In April 2022, we announced positive topline results with istaroxime in rapidly and significantly raising SBP. In May 2022, we presented data from our positive Phase 2 study of istaroxime in early cardiogenic shock in a late-breaker presentation at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain and, in September 2022, the results were published in the European Journal of Heart Failure. There is a significant unmet medical need in the area of early cardiogenic shock and severe heart failure. Istaroxime demonstrated a meaningful increase in blood pressure while simultaneously increasing cardiac output and preserving renal function in clinical trials of this condition.

In order to continue our development of istaroxime for the acute treatment of cardiogenic shock, subject to adequate resources, we are planning to extend enrollment in this clinical trial by up to 30 patients. We believe that this extension will advance the characterization of the physiology associated with longer dosing as well as additional dose optimization. We also believe that this extension will further characterize the effects associated with SERCA2a activation and will support our clinical and regulatory strategy for istaroxime. We currently do not have sufficient capital to fully execute the extension of this clinical trial.

Using cardiogenic shock patient U.S. hospital claims and worldwide prevalence data, we estimate the worldwide total market value of cardiogenic shock to be $1.25 billion. This estimate is calculated by multiplying the patient numbers from the largest markets, by the assumed various regional prices of drug treatment in the acute care market. The addressable market for istaroxime will be a subset of the total market value of $1.25 billion.

Istaroxime (AHF)

In 2019, we announced topline results of a successful Phase 2b clinical trial of istaroxime in which the primary endpoint of cardiac function, E/e' ratio (echocardiographic assessment reflecting changes in pulmonary capillary wedge pressure, or PCWP, or left ventricular filing pressure) as well as other important parameters were significantly improved. Istaroxime has been granted Fast Track designation by the FDA for the treatment of AHF. In April 2020, at the American College of Cardiology 2020 meeting, a new subset analysis from a Phase 2b study of istaroxime in patients hospitalized with AHF was presented. This post-hoc analysis characterized the responses to istaroxime between Caucasian and Asian patients. The analysis demonstrated that the dose of 0.5 µg/kg/min produced a similar response on E/e' and stroke volume index in the two regions studied.

Istaroxime represents a novel approach to the treatment of AHF. It has a dual mechanism of action to improve cardiovascular physiology. Current therapy for heart failure in the hospital typically includes intravenous diuretics and, if the blood pressure is low, supportive therapy with inotropes. Inotropes are often associated with adverse effects such as hypotension, arrhythmias and, in some cases, increased mortality. These drugs are used only if needed to support blood pressure and cardiac function. We believe that istaroxime, if approved, may have the potential to address unmet medical needs of these patients by improving cardiac function and management of fluid accumulation that contributes to heart failure symptoms with a potentially differentiated safety profile from current AHF therapies, including a potential reduction in complications and improvement of other clinical outcomes.

There is substantial potential synergy between our clinical trial program in early cardiogenic shock and our development program in acute decompensated heart failure. Both programs are focused on treating heart failure patients with acute congestion and low blood pressure requiring hospitalization. We believe that this category of heart failure patients (whether they are in shock or not) could particularly benefit from the unique profile and potential ability of istaroxime to improve cardiac function and increase blood pressure while maintaining or improving renal function. Our strategy is to advance istaroxime in cardiogenic shock as the lead indication and utilize this data and experience, along with the positive Phase 2a and 2b AHF studies, to potentially enter Phase 3 for acute decompensated heart failure in the normal to low SBP population. We currently do not have sufficient capital to execute our clinical trial in AHF and are seeking partnership opportunities to advance the program.

Rostafuroxin

Rostafuroxin is a novel investigational drug product candidate being developed for the treatment of hypertension in patients with a specific genetic profile, which is found in approximately 20% to 25% of the adult hypertensive population. Rostafuroxin has been studied in three Phase 2 clinical trials assessing reduction in blood pressure in a hypertensive population selected in accordance with the specified genetic profile. After positive Phase 2a results, a Phase 2b study was initiated. In this most recent Phase 2b clinical trial, rostafuroxin demonstrated efficacy in Caucasian patients in treatment of naïve hypertension. During the second quarter of 2021, we concluded a process to explore the industry's interest in investing in our drug product candidate. We currently have not been able to secure a licensing transaction or other strategic opportunity. As a result, we recorded an impairment of the related intangible asset during the year ended December 31, 2021. Based on feedback received from potential licensing partners, we have determined that there is a need for an additional Phase 2 clinical trial to demonstrate efficacy in patients with treatment resistant hypertension. We are continuing to pursue licensing arrangements, other strategic partnerships, and/or grant funding for rostafuroxin. We do not intend to conduct the additional Phase 2 clinical trial without securing such an arrangement, partnership, or grant funding.

SERCA2a Activators – Preclinical Oral, Chronic and AHF Product Candidates

We are conducting early exploratory research to assess potential product candidates, including oral and intravenous SERCA2a activator heart failure compounds, and believe that we can add value to our cardiovascular portfolio by advancing these SERCA2a activator candidates through preclinical studies. These preclinical programs build upon our expertise in the SERCA2a mechanism, that led to the development of istaroxime, the first-in-class dual mechanism agent that acts by: (i) partially inhibiting the Na+/K+ pump resulting in an inotropic effect and (ii) stimulating the SERCA2a pump activity on sarcoplasmic reticulum strengthening contraction but importantly improving relaxation and diastolic function.

Istaroxime is the first example of a dual acting agent with SERCA2a activation. We also have two families of follow-on compounds in early development. The first are those endowed with the same dual-acting mechanism of action as istaroxime, which may include potential oral bioavailability for chronic use, and the second family are those with only SERCA2a stimulatory activity. We believe that these programs represent a heart failure platform that has already provided new, novel intellectual property and additional potential opportunities that may extend into the out-patient, chronic heart failure market.

To further advance these product candidates, we are actively exploring potential licensing transactions, research partnership arrangements, or other strategic opportunities.

Going Concern

Our management has concluded that substantial doubt exists about our ability to continue as a going concern for one year from the date of this prospectus. We do not expect that the net proceeds from this offering will be sufficient to allow us to continue as a going concern for one year from the date of this prospectus. If we were to receive net proceeds of approximately $7.7 million from this offering, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will meet our capital needs through the first quarter of 2024 and support our continued development of istaroxime for the acute treatment of both early and more severe cardiogenic shock and for working capital and general corporate purposes.

Risk Factor Summary

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section titled "*Risk Factors*" immediately following this Prospectus Summary. These risks include, among others:

Risks Related to Our Financial Condition

- Our current cash position, losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings;
- We have incurred significant operating losses since inception, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability; and
- If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Risks Related to our Development Activities and Regulatory Approval of our Product Candidates

- We are substantially dependent on the success of our lead product candidate, istaroxime. To the extent that our clinical development of istaroxime is not successful, our business, financial condition, and results of operations may be materially adversely affected and the price of our common stock may decline;
- Although we have multiple product candidates or potential indications of those candidates in our clinical pipeline, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success; and
- The successful commercialization of our product candidates, if approved, will depend in part on the extent to which hospitals and hospital systems, governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those product candidates and decrease our ability to generate revenue.

Risks Related to Our Reliance on Third Parties

- We rely on third parties, primarily outside of the U.S., to conduct many of our preclinical studies and clinical trials. Any failure by a third party to conduct the clinical trials according to good clinical practices and other requirements and in a timely and quality manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates; and

- We plan to rely on third parties, some of which are located outside the U.S., to manufacture our drug product candidates, which exposes us to risks that may affect our ability to maintain supplies of our clinical materials, and subject us to uncertainty associated with the international political climate, and could potentially delay or cease our research and development activities, as well as eventual regulatory approval and commercialization of our drug product candidates.

Risks Related to our Business and Operations

- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide;

- We may seek to enter into licensing transactions, collaboration arrangements, and other similar transactions and strategic opportunities, and may not be successful in doing so, and even if we are, we may not realize the benefits of such relationships; and

- We could be adversely affected by any interruption, including from breaches in cybersecurity, in our ability to conduct business at our current location.

Risks Related to Government Regulation

- Our activities are subject to various and complex laws and regulations, and we are susceptible to a changing regulatory environment;

- We face risks related to our collection and use of data, including personal information, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices;

- Healthcare reform measures in the U.S., as well as the general tightening of drug reimbursement pathways and levels of reimbursement globally, are expected to add additional pressure to achieve financial expectations for our product candidates, if approved; and

- Our international operations subject us to additional regulatory oversight in foreign jurisdictions, as well as economic, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results.

Risks Related to Intellectual Property Matters

- If we cannot protect our intellectual property, others could use our technology in competitive products. Even if we obtain patents to protect our product candidates, those patents may not be sufficiently broad, or they may expire and others could then compete with us; and

- Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our product candidates or affect our stock price.

Risks Related to the Ownership of our Securities

- Our common stock is listed on the Nasdaq Capital Market, or Nasdaq. We can provide no assurance that we will be able to comply with the continued listing requirements over time and that our common stock will continue to be listed on Nasdaq;

- We effected a reverse stock split on February 24, 2023 which may adversely impact the market price of our common stock;

- The market price of our common stock may be highly volatile, and investors may not be able to resell their shares at or above the price at which they purchased them; and

- A small group of our investors, including Lee's Pharmaceutical Holdings Limited and Panacea Venture Management Company Ltd., may be able to exercise significant influence over our business strategy and operations.

Risks Related to this Offering

- Purchasers of common stock in this offering will experience immediate and substantial dilution in the net tangible book value of their investment. You may experience further dilution upon exercise of options;

- A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock;

- We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock;
- There is no public market for the warrants being offered in this offering;
- Holders of warrants purchased in this offering will have no rights as a common stockholder until such holder exercises its warrants and acquires our common stock, except as set forth in such warrants; and
- The warrants are speculative in nature.

Corporate Information

We were incorporated in Delaware on November 6, 1992. Our principal executive offices are located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, and our telephone number is (215) 488-9300. Our website address is *www.windtreetx.com.* The information on, or that can be accessed through, our website is not part of this prospectus and is not incorporated by reference herein and you should not consider it part of this prospectus. We have included our website address as an inactive textual reference only.

Implications of Being a Smaller Reporting Company

We are a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, as long as we are a smaller reporting company with less than $100 million in annual revenue, we are not required to obtain an attestation report on internal control over financial reporting from our independent registered public accounting firm.

Recent Developments — Preliminary First Quarter Results

Based on information currently available, we estimate that as of March 31, 2023, cash and cash equivalents were approximately $4.2 million and net cash used before financing activities for the first quarter of 2023 was $2.9 million.

Our estimate of our cash and cash equivalents as of March 31, 2023 and net cash used before financing activities for the first quarter of 2023 are preliminary and actual results may differ from these estimates due to the completion of our closing procedures with respect to the three months ended March 31, 2023, final adjustments and other developments that may arise between now and the time the financial results for the three months ended March 31, 2023 are finalized. As such, these estimates should not be viewed as a substitute for our unaudited financial statements for the three months ended March 31, 2023 prepared in accordance with U.S. generally accepted accounting principles. Our expected results could change materially and are not necessarily indicative of the results to be achieved for three months ended March 31, 2023 or any future period. As a result of the foregoing considerations and the other limitations described herein, investors are cautioned not to place undue reliance on this preliminary financial information. We do not undertake any obligation to publicly update or revise these estimates, except as required by law.

The Offering

The following summary contains basic information about this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus.

Common stock to be offered	1,948,051 shares of common stock or 2,240,258 shares if the underwriters exercise their option to purchase additional shares in full.
Common warrants	We are also offering common warrants to purchase up to 1,948,051 shares of common stock. The exercise price of each common warrant will be $ per share. Each common warrant will be immediately exercisable upon issuance for a five-year period after the date of issuance. This prospectus also relates to the offering of the common stock issuable upon exercise of such common warrants. See "*Description of the Securities We are Offering*" on page 83 of this prospectus. You should also read the form of common warrant, which is filed as an exhibit to the registration statement that includes this prospectus.
Pre-funded warrants	We are also offering pre-funded warrants to purchase up to 1,948,051 shares of common stock. The purchase price of each pre-funded warrant is equal to the price at which the share of common stock is being sold to the public in this offering, minus $0.001, and the exercise price of each pre-funded warrant is $0.001 per share. The pre-funded warrants are exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of the pre-funded warrants sold in this offering. See "*Description of the Securities We are Offering*" on page 83 of this prospectus. You should also read the form of pre-funded warrant, which is filed as an exhibit to the registration statement that includes this prospectus.
Common stock to be outstanding after this offering	2,857,064 shares, or 3,149,271 shares if the underwriters exercise their option to purchase additional shares in full.
Option to purchase additional shares of common stock and common warrants	We have granted the underwriters an option for a period of up to 45 days from the date of this prospectus to purchase up to additional shares of our common stock and/or common warrants to purchase up to shares of our common stock, in any combination thereof, from us at the public offering price per share and per common warrant, less underwriting discounts and commissions, in each case solely to cover over-allotments, if any.

Use of proceeds	We intend to use the net proceeds from this offering for the clinical development of istaroxime in cardiogenic shock and for working capital and general corporate purposes. See "*Use of Proceeds*" on page 60 of this prospectus.
Lock-up restrictions	We, each of our directors and officers, and certain of our affiliated stockholders are subject to certain lock-up restrictions as identified in the section titled "*Underwriting*."
Risk factors	You should read the section entitled "*Risk Factors*" beginning on page 10 and the documents incorporated by reference in this prospectus for a discussion of factors to consider carefully before deciding to invest in our securities.
Nasdaq Capital Market symbol	Our shares of common stock are traded on The Nasdaq Capital Market under the symbol "WINT". There is no established public trading market for the warrants, and we do not expect a market to develop. We do not intend to apply for listing of the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be limited.
Transfer Agent and Registrar	Continental Stock Transfer and Trust Company

The number of shares of our common stock to be outstanding after this offering is based on 909,013 shares of common stock outstanding as of March 31, 2023, assumes no exercise of any warrants offered hereby, and excludes:

- 449,345 shares of our common stock issuable upon the exercise of outstanding warrants as of March 31, 2023, with a weighted-average exercise price of $179.56 per share;
- 70,972 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2023, with a weighted-average exercise price of $376.68 per share;
- 6,524 shares of our common stock issuable upon the exercise of outstanding restricted stock units as of March 31, 2023, with a weighted-average grant date fair value of $49.31 per share; and
- 44,232 shares of our common stock reserved for future issuance under our 2020 Equity Incentive Plan, as amended, or 2020 Plan, plus any future increases in the number of shares of common stock reserved for issuance.

Except otherwise indicated, the information in this prospectus assumes no exercise of the outstanding options or warrants described above or sold in this offering, and no exercise by the underwriters of their option to purchase additional shares of our common stock and/or common warrants.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, and those discussed under the section entitled "Risk Factors" contained in our 2022 Annual Report and our subsequent Quarterly Reports, together with other information in this prospectus, the information and documents incorporated by reference herein, and in any free writing prospectus that we have authorized for use in connection with this offering. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment.

Risks Related to Our Financial Condition

Our current cash position, losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.

The auditor's opinion on our audited financial statements for the year ended December 31, 2022 includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern. Management has also concluded that substantial doubt exists about our ability to continue as a going concern. As of December 31, 2022, we had cash and cash equivalents of $6.2 million and current liabilities of $2.5 million. As of the date of this prospectus, we believe that, prior to this offering, we have sufficient resources available to support our development activities and fund our business operations and satisfy our obligations into the second quarter of 2023. However, we do not have sufficient cash and cash equivalents as of the date of this prospectus to support our operations for at least 12 months. We believe, that based on the anticipated net proceeds of approximately $7.7 million that we will receive from this offering, together with our existing cash and cash equivalents, we will meet our capital needs through the first quarter of 2024 and support our continued development of istaroxime for the acute treatment of both early and more severe cardiogenic shock and for working capital and general corporate purposes.

To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to secure additional capital, potentially through a combination of public or private securities offerings; convertible debt financings; and/or strategic transactions, including potential licensing arrangements, alliances and drug product collaborations focused on specified geographic markets; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If none of these alternatives is available, or if available, we are unable to raise sufficient capital through such transactions, we will not have sufficient cash resources and liquidity to fund our business operations for at least the next 12 months following the date of this prospectus. In addition, we may be unable to pay our vendors and other service partners on time, or at all. If any of our key vendors and service providers were to cease working with us or subject the delivery of products or services to timing or payment preconditions, our development activities may be adversely affected, which could have a material adverse effect on our business and operations. The failure to obtain sufficient capital on acceptable terms when needed may require us to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives and our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. In addition, market instability, including as a result of geopolitical instability, may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "*Risk Factors*" section. We have based this estimate on a number of assumptions that may prove to be wrong and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. Our inability to obtain additional funding when we need it could seriously harm our business.

We have incurred significant operating losses since inception, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability.

We have incurred operating losses since our incorporation on November 6, 1992. For the years ended December 31, 2022 and 2021, we had operating losses of $41.3 million and $77.3 million, respectively. As of December 31, 2022, we had an accumulated deficit of $824.5 million. To date, we have financed our operations primarily through private placements and public offerings of our common and preferred stock and borrowings from investors and financial institutions. As of December 31, 2022, we had cash and cash equivalents of $6.2 million and believe that we have sufficient resources available to support our development activities and fund our business operations into the second quarter of 2023.

We expect to continue to incur significant research and clinical development, regulatory and other expenses as we (i) develop product candidates; (ii) seek regulatory clearances or approvals for our planned or future product candidates; (iii) conduct clinical trials on our planned or future product candidates; and (iv) manufacture, market and sell any product candidates for which we may obtain regulatory approval. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and may cause the market price of our common stock to decline.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our planned clinical trials under our key clinical development programs, continue research and development and potentially initiate clinical trials under our other development programs and seek regulatory approval for any product candidates we may develop. In addition, as our product candidates progress through development and toward commercialization, we may need to make milestone payments to licensors and other third parties from whom we have in-licensed or acquired our product candidates. Furthermore, if and to the extent we seek to acquire or in-license additional product candidates in the future, we may be required to make significant upfront payments, milestone payments, and/or licensing payments. If we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Moreover, a small group of investors that hold a significant portion of our issued and outstanding common stock may be in a position to influence the terms of a funding transaction, potentially making it more difficult to reach agreement on terms that are acceptable to investors participating in the financing, in a timely manner, if at all. If we are unable to raise sufficient capital to fund our activities when needed and on acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or, if our product candidates are approved, any future commercialization efforts.

We have based estimates included in our operating plan on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of our clinical trials and preclinical studies of our product candidates, which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in-licensed or acquired our product candidates;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- the costs, terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- costs associated with any product candidates or technologies that we may in-license or acquire; and
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from payors and adequate market share and revenue for any approved products.

Conducting clinical trials and preclinical studies is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us at any time on acceptable terms, or at all.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until we can generate substantial product revenues to support our operations, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition, and stock price.

Global financial markets have recently, and may continue to, experience extreme volatility and disruptions, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability as a result of geopolitical unrest, liquidity constraints, failures and instability in U.S. and international financial banking systems, inflation, and other factors beyond control. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy and ability to raise capital may be adversely affected by any such economic downturn, volatile business environment, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers, and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including in connection with the ongoing coronavirus pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. For additional information regarding the impact of the coronavirus pandemic, please see "*Risk Factors—The coronavirus pandemic has negatively impacted, and may continue to negatively impact our ability to develop our product candidates.*"

Further, the impacts of political unrest, including as a result geopolitical tension, such as a deterioration in the relationship between the U.S. and China or continued conflict between Russia and Ukraine, including any additional sanctions, export controls or other restrictive actions that may be imposed by the U.S. and/or other countries against governmental or other entities in, for example, China or Russia, also could lead to disruption, instability, and volatility in the global markets, which may have an adverse impact on our business or ability to access the capital markets. Broad market and industry factors, including potentially worsening economic conditions, inflationary pressures, and other adverse effects, political, regulatory, and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition or results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Most recently, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations.

Due to the significant resources required to develop our product candidates, we must prioritize development of certain product candidates and/or certain disease indications. We may be delayed in advancing a product candidate or potential indication if our plan does not include sufficient funding to execute a clinical program. If we expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success, such failure could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We are currently focused on developing product candidates to address unmet medical needs in acute cardiovascular diseases. We seek to allocate our limited capital among our programs in an efficient manner and to advance our cardiovascular product candidate. However, due to the significant resources required to advance the development of our product candidates, we also must focus on specific indications and disease pathways and decide which product candidates and indications to pursue and the amount of resources to allocate to each such product candidate.

Our ability to advance a product candidate depends on our ability to secure the additional capital required to execute each phase of product development. In developing our plan, we were aware of the size and projected costs of our planned late stage development of istaroxime to improve cardiac function and clinical outcomes in patients with AHF. We have allocated our limited resources initially toward cardiogenic shock as we believe this may be a less resource intensive and faster development program. Such decisions concerning the allocation of research and development funds towards, or away from, particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any decision to delay, terminate or engage with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. In that event, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

We have a significant amount of intangible assets, including goodwill, recorded on our consolidated balance sheets which may lead to potentially significant impairment charges.

As a result of the acquisition of CVie Therapeutics Ltd, or CVie Therapeutics, in December 2018, we have recorded significant intangible assets and goodwill on our consolidated balance sheets, which could become impaired and lead to material charges in the future. The identifiable intangible assets resulting from the CVie Therapeutics acquisition relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin, which, as of December 31, 2022, were $22.3 million and $2.9 million, respectively, recorded in aggregate on our consolidated balance sheets as intangible assets of $25.3 million. As of December 31, 2022, goodwill recorded on our consolidated balance sheets was $3.1 million.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that intangible assets or goodwill may be impaired. If an impairment exists, we would be required to take an impairment charge with respect to the impaired asset. Events giving rise to impairment are difficult to predict, including the uncertainties associated with the development of product candidates and the success of business development activities, and are an inherent risk in the pharmaceutical industry.

As part of our annual quantitative impairment assessment of indefinite-lived IPR&D intangible assets, we reassessed certain assumptions related to our rostafuroxin drug candidate due to the current macroeconomic conditions which have made it harder to secure the funding needed to conduct the additional phase 2 clinical trial and have therefore delayed our intended development of rostafuroxin. As a result, we concluded that the fair value of the IPR&D related to our rostafuroxin drug candidate was less than its carrying value and recorded a loss on impairment of intangible assets of $6.8 million during the fourth quarter of 2022. We also reassessed the assumptions related to the fair value of the IPR&D related to our istaroxime drug candidate. As a result, the estimated fair value decreased from December 1, 2021 to December 1, 2022, but still exceeded the carrying value of that asset. As a result, no impairment charge was recognized related to the IPR&D of our istaroxime drug candidate. We are continuing to pursue licensing arrangements and/or other strategic partnerships for rostafuroxin. However, if we are unable to secure such an arrangement or partnership, or if we secure an arrangement for an amount less than anticipated, we may have to record additional impairments related to rostafuroxin in the future, which may materially adversely affect our results of operations and financial condition.

We have experienced a declining trend in the closing share price of our common stock on a split-adjusted basis, since April 2022. During each of the second and third quarters of 2022, the continued declining trend in the closing share price of our common stock, on a split-adjusted basis, suggested that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, in each quarter since that time we performed the required interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment, including the use of the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium based on transactions completed by comparable companies. Based on the annual goodwill quantitative test performed as of December 1, 2022, we determined that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, we recorded a loss on impairment of goodwill of $0.5 million in the fourth quarter of 2022. When combined with the loss on impairment of goodwill recorded during the second and third quarters, we recorded a loss on impairment of intangible assets totaling $12.6 million within operating expenses in our consolidated statements of operations during the year ended December 31, 2022.

The closing share price of our common stock, on a split-adjusted basis, has continued to decline subsequent to the end of 2022. If our share price continues to decline, we may be at risk for future impairment to goodwill in the near term.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, we are required to furnish a report by our management on our internal control over financial reporting. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our financial statements are not accurate, investors may not have a complete understanding of our operations. If we do not file our financial statements on a timely basis as required by the Securities and Exchange Commission, or the SEC, we could face severe consequences. If we are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Stock Market LLC, or Nasdaq, the SEC or other regulatory authorities. Moreover, responding to such investigations, are likely to consume a significant amount of our management resources and cause us to incur significant legal and accounting expenses. Failure to remedy any material weakness in our internal control over financial reporting, or to maintain effective control systems, could also restrict our future access to the capital markets. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Risks Related to our Development Activities and Regulatory Approval of our Product Candidates

We are substantially dependent on the success of our lead product candidate, istaroxime. To the extent that our clinical development of istaroxime is not successful, our business, financial condition, and results of operations may be materially adversely affected and the price of our common stock may decline.

We currently have no product candidates approved for sale, and we may never be able to develop marketable products. We are focusing a significant portion of our activities and resources on our lead product candidate, istaroxime, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully obtain regulatory approval for istaroxime. We currently do not have sufficient capital to fully execute clinical trials with respect to istaroxime. Furthermore, the clinical development and regulatory approval of istaroxime is subject to many risks, including the risks discussed in other risk factors, and istaroxime may not receive marketing approval from any regulatory agency. If we are unable to continue to advance istaroxime through clinical development, or if the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to istaroxime do not meet our or others' expectations, the market price of our common stock could decline significantly. Should the results of our clinical development program be insufficient to support regulatory approval, we may be forced to rely on our other product candidates, which will require additional time and resources to potentially obtain regulatory approval. There can be no assurance that we will be able to successfully develop istaroxime.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of preclinical studies and early clinical trials are not necessarily predictive of future results. In addition, our assumptions about why certain of our product candidates are worthy of future development and potential approval are based on data primarily collected by other companies. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval on a timely basis, if at all.

Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process as a result of inadequate study design, inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. For example, conducting a toxicology study as part of a preclinical program, to be included in a required regulatory submission, could result in unanticipated findings that could potentially negatively impact the clinical program. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

Product candidates in later stages of clinical trials may fail to achieve the desired safety and efficacy outcomes despite having progressed through earlier clinical trials. As a result, data we obtain from our phase 2 clinical trials may not accurately predict phase 3 trial results, whether due to differences in sample size, study arms, duration, endpoints, or other factors. If any of our product candidates should fail to perform as designed in their respective phase 3 clinical programs, such failures could adversely affect the results of our clinical development program despite promising results in earlier trials. If clinical trials for any of our product candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA or the equivalent regulatory authorities in other countries, the FDA or the equivalent regulatory authorities in other countries will not approve that drug and we would not be able to commercialize it, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if we are required to cease development activities on any of our recently acquired product candidates due to adverse clinical results or otherwise, it could result in impairment of related intangible assets and goodwill on our consolidated balance sheets.

Even if later stage clinical trials are successful, regulatory authorities may question the trial design or sufficiency for approval of the endpoints we select for our clinical trials or add new requirements, such as the completion of additional studies, as conditions for obtaining approval or obtaining an indication. For the foregoing reasons, we cannot be certain that our planned clinical trials and preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations, and result in significant additional costs and expenses, require additional time and have an adverse effect on our business, including our financial condition and results of operations.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to continue development activities, including our ability to obtain trial results, regulatory approval and commence product sales or allow for competition to emerge.

We may experience delays in clinical trials of our product candidates, or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including, but not limited to:

- our inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial or reaching a consensus with regulatory authorities on trial design or product standards;
- delays in reaching an agreement with the FDA or the equivalent foreign regulatory authorities in other countries on final trial design or the scope of the development program;
- inability to develop studies that are acceptable in all markets of interest;
- inability to come to an agreement on clinical trial design or execution factors with potential development partners;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or the equivalent regulatory authorities in other countries;
- failures or delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays associated with severe acute respiratory syndrome coronavirus 2, the causative agent in a novel strain of coronavirus, which have and may continue to impact our healthcare systems and our trial sites ability to conduct trials to varied degrees and times. Coronavirus creates risk of interrupting availability of necessary clinical supplies, local regulatory reviews, hospital ethics committee reviews, professional staff, site monitors and other necessary travel;
- delays in obtaining contracts with clinical sites and required IRB approval at each site;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- competition with other studies for study patients;
- changes to clinical trial protocol;
- delays in recruiting suitable patients to participate in a trial;

- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial to the detriment of enrollment;
- subjects experiencing severe or unexpected adverse events;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCPs, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors lacking adequate certification to provide services in all regions where we conduct our business activities;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications;
- manufacturing timing and/or obtaining sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials or changes in the manufacturing process or inability to meet analytical standards for product release or use that may be necessary or desired;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver a sufficient supply of clinical trial materials or being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process.

In addition, we may not reach agreement with the FDA, or a foreign regulator on the extent of our phase 3 programs, the design of any one or more of the clinical trials necessary for approval, or we may be unable to reach agreement on a single design that would permit us to conduct a common pivotal phase 3 clinical development program in all markets of interest. For example, we may not be able to design a study that is acceptable to both the FDA and the European Medicines Agency, or EMA, regulators, which would cause us to limit the scope of our geographical activities or greatly increase our investment. Even if we complete the clinical trial within our anticipated time, if our results are inconclusive or non-compelling or otherwise insufficient to support a strategic or financing transaction, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business.

We have conducted, and may in the future conduct, clinical trials for our product candidates at clinical sites located in the U.S. and outside of the U.S. If the FDA and other foreign equivalents raise concerns about certain of the clinical sites based on location and regulatory environment, they may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We have conducted and are expecting in the future to conduct one or more of our clinical trials for our product candidates at clinical sites located in the U.S. and outside of the U.S., including the EU, China, Russia, Israel and South America. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data may be subject to certain conditions imposed by the FDA. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless those data are considered applicable to the U.S. patient population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an onsite inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an onsite inspection or other appropriate means. There can be no assurance the FDA will accept data from clinical trials conducted outside of the U.S. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

For example, we have previously conducted clinical trials in Russia. The February 2022 invasion of Ukraine by Russia and the resulting imposition of economic and other sanctions by the U.S., EU, and many other nations on Russia, individuals in Russia, Russian businesses, and the Russian central bank, has impacted the way we executed certain trial procedures as we completed the first part of our trial in early cardiogenic shock. This geopolitical disruption could also disrupt or delay our ability to conduct clinical trial activities in Russia in the future. Although the length and impact of any military action are highly unpredictable, making them unavailable for follow-up could result in increased costs and could delay our anticipated timeline for the completion of our future clinical trials.

The coronavirus pandemic has negatively impacted, and may continue to negatively impact our ability to develop our product candidates.

The impact of the ongoing coronavirus pandemic has resulted in, and will likely continue to result in, significant disruptions to the global economy, as well as businesses and capital markets around the world. Efforts to contain the spread of coronavirus have intensified at times to manage surges in the infection rate and deaths, and many countries have at times implemented severe travel restrictions, social distancing, and delays or cancellations of elective surgeries at different times. Notwithstanding the introduction of effective vaccines, coronavirus is expected to continue affecting our ability and the ability of our employees, contractors, suppliers, and other partners in the U.S. and abroad to conduct normal business activities from time to time, including due to shutdowns that may be requested or mandated by governmental authorities.

The continued spread of coronavirus globally has previously adversely impacted trial conduct and operations and may do so again in the future. We have, in the past, initiated several clinical trials for istaroxime in the European Union, or the EU, and other worldwide locations impacted by the coronavirus outbreak. Our clinical trials have suffered delays and interruptions and our previous decision to cease enrollment in the AEROSURF clinical trial was partially due to such delays and escalating expenses. Our efforts to conduct trials could be materially delayed in the future by governmental restrictions and enrollment difficulties as hospitals reduce and divert staffing, divert resources to patients suffering from the infectious disease and limit hospital access for nonpatients.

Similarly, there is a risk that clinical supplies of our product candidates may be significantly delayed or may become unavailable as a result of coronavirus and the resulting impact on our suppliers' labor forces and operations, including as a result of governmental restrictions on business operations and the movement of people and goods in an effort to curtail the spread of the virus. There can be no assurance that we would be able to timely implement any mitigation plans. Disruptions in our supply chain, whether as a result of restricted travel, quarantine requirements or otherwise, could negatively impact clinical supplies of our product candidates, which could materially adversely impact our clinical trial and development timelines.

The continued spread of coronavirus, including potential new variants, has also led to periodic disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets in the future. It is possible that the continued spread of coronavirus could cause an economic slowdown or recession or cause other unpredictable events, each of which could adversely affect our business, results of operations or financial condition.

The extent to which coronavirus impacts our financial results going forward will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus outbreak, the rise of variants, which may be more contagious and potentially more lethal, and the actions recommended to contain the outbreak or treat its impact, among others. Moreover, the coronavirus outbreak has had indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that coronavirus or any other pandemic harms the global economy generally.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

As is the case with pharmaceuticals generally, there may be adverse events in patients treated with our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Adverse events could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many compounds that initially show promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as the use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication;

- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly, or the product could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of investigational new drugs and approved new drugs are subject to extensive regulation by the FDA in the U.S. and by comparable foreign regulatory authorities in foreign markets. In the U.S., the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. We are not permitted to market any of our product candidates in the U.S. until we receive approval of a New Drug Application, or NDA, from the FDA.

Prior to obtaining approval to commercialize a product candidate, if approved, in the U.S. or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support approval;

- serious and unexpected adverse events may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care or patient characteristics are potentially different from that of the U.S.;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks or the safety data base may not be large enough;
- such authorities may not accept the submission of an NDA or other submission to obtain regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of our third-party manufacturers with which we contract for clinical and, if approved, commercial supplies; or the approval policies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

We may conduct clinical development in the U.S., Canada, the EU, Eastern Europe, Latin America, and Asia Pacific regions and sell our products, if approved, in the U.S. and potentially in other major markets. To accomplish this objective, we must obtain and maintain regulatory approvals and comply with regulatory requirements in each jurisdiction. To avoid the significant expense and lengthy time required to complete multiple regional clinical development programs, we expect to meet with relevant regulatory authorities. While we would prefer to design a single, global clinical development program that would satisfy the regulators in all of our target markets, there can be no assurance that our efforts will be successful. If we are unable to reach agreement with the various regulatory authorities, we may not be able to pursue regulatory approval of our product candidates in all of our selected markets.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates. In addition, delays associated with coronavirus may impact local regulatory reviews occurring in a timely manner and result in delays for trial and site initiations.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Although we have multiple product candidates or potential indications of those candidates in our clinical pipeline, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we may focus on specific product candidates, indications and development programs at any time. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, license agreements and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital, management and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

Even though some of our product candidates have Fast Track designation, the FDA may not approve them at all or any sooner than other product candidates that do not have Fast Track designation.

We have received Fast Track designation from the FDA for istaroxime for the treatment of AHF. Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development, regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. Additionally, the FDA may withdraw Fast Track designation, for reasons such as it comes to believe a drug candidate no longer adequately addresses an unmet medical need. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures. If we seek Fast Track designation for other product candidates, we may not receive such a designation from the FDA.

Although we may pursue expedited regulatory programs for a product candidate or an indication, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process.

Although we have received Fast Track designation for certain of our product candidates, we believe there may be an opportunity to expedite the development of other product candidates or indications through one or more of the FDA's expedited programs, such as Fast Track, Breakthrough Therapy or priority review, we cannot be assured that any of our product candidates or indications will qualify for such programs.

For example, a product candidate may be eligible for designation as a Breakthrough Therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Although Breakthrough Therapy designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for Breakthrough Therapy designation or any other expedited program for our product candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. For example, we believe that istaroxime may fulfill an unmet medical need in early and more severe cardiogenic shock based on the profile observed in prior phase 2 clinical studies in AHF and early cardiogenic shock, in which increases in SBP as well as improvements in cardiac function were observed suggesting that istaroxime could potentially contribute to the clinical improvement of select patients in cardiogenic shock due to heart failure. However, the FDA may not agree with our assessment, and we may not be able to obtain Breakthrough Therapy designation.

Even if we are successful in obtaining a Breakthrough Therapy designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited program does not ensure that we will ultimately obtain regulatory approval for such product candidate.

We may not be able to obtain or maintain Orphan Drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as Orphan Drugs. In the U.S., Orphan Drug designation entitles a party to financial incentives such as tax advantages and user-fee waivers. In addition, if a product candidate that has Orphan Drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is clinically superior to the approved drug. A drug is clinically superior if it is safer, more effective, or makes a major contribution to patient care. The FDA has granted Orphan Drug designation for our (i) KL4 surfactant (lucinactant) for the treatment of RDS in premature infants, (ii) our KL4 surfactant for the prevention and treatment of BPD in premature infants, (iii) our KL4 surfactant for the treatment of ARDS in adults, and (iv) our KL4 surfactant for the treatment of cystic fibrosis.

If we obtain Orphan Drug exclusivity, we may lose such exclusivity if the FDA or the European Commission, or EC, determines that the request for designation was materially defective or if we are unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Moreover, Orphan Drug exclusivity may not effectively protect our product candidates from competition because different drugs can be approved for the same condition. Even after an Orphan Drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

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

From time to time, we may publicly disclose preliminary or topline or data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Even if we receive regulatory approval for any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Following potential approval of any our product candidates, the FDA may impose significant restrictions on a product's indicated uses or other aspects of the directions for use or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters, Form 483s, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

If we fail to obtain and maintain regulatory approval in foreign jurisdictions, our market opportunities will be limited.

In order to market our product candidates in the EU or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance or approval. Foreign regulatory approval processes include many of the risks associated with obtaining FDA clearance or approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance or approval does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our product candidates in markets outside the U.S., it would negatively affect our overall market penetration.

If the FDA or other applicable regulatory authorities approve generic products with claims that compete with our product candidates, it could reduce our sales of our product candidates if approved.

In the U.S., after an NDA is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated NDA, or ANDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredients, dosage form, strength, route of administration, and conditions of use, or product labeling, as our product candidates and that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidates. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of our product candidates will depend upon the acceptance of each product by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our product candidates, if approved, will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- efficacy of our product candidates compared to competing products;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, if approved, and the target patient population to try new therapies;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, global government payors, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics;

- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals;
- government health care payor imposed mandatory pricing discounting and reductions;
- delays in achieving hospital formulary acceptance or limitations of use that are more restrictive than the approved label;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates, if approved, may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates, if approved, in applicable therapeutic guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies; and
- limitations or warnings contained in approved labeling from regulatory authorities.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization for that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a REMS to assure the safe use of the drug. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates, if approved. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates, if approved.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found or alleged to have improperly promoted any of our products, if approved, for off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as our product candidates would be, if approved. In general, a product may not be promoted for uses that are not approved by the FDA or in ways that may not be consistent with the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA and other regulatory agencies have also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities or secure a sales and marketing partner, we may not successfully commercialize any of our product candidates.

We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure, we may not realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates, if approved, without strategic partners or licensees include:

- the inability of sales personnel to obtain access to or educate and appropriately persuade adequate numbers of physicians to prescribe any of our product candidates, if approved;
- inability to obtain a competitive share of voice and frequency of meeting with physicians against multiple, larger competitors;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to control or influence partner sales and marketing personnel or their prioritization of promotion of our product candidates, if approved.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which hospitals and hospital systems, governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those product candidates and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our product candidates by third-party payors will have an effect on our ability to successfully commercialize our product candidates, if approved. Even if we obtain coverage for a given product candidate, if approved, by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the U.S., the EU or elsewhere will be available for any product candidate that we may develop and for which we receive approval, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates, if approved, as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our product candidates, if approved, pricing of existing drugs may limit the amount we will be able to charge for our product candidates, if approved. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved and may not be able to obtain a satisfactory financial return on products that we may develop.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates, if approved, to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our product candidates, if approved. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Additional foreign price controls, discounts or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the U.S., the reimbursement for product candidates for which we receive approval may be reduced and experience continual mandatory price reductions compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates, if approved. We expect to experience pricing pressures in connection with the sale of any of our product, candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Risks Related to Our Reliance on Third Parties

We rely on third parties, primarily outside of the U.S., to conduct many of our preclinical studies and clinical trials. Any failure by a third party to conduct the clinical trials according to GCPs and other requirements and in a timely and quality manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

We are dependent on third parties to conduct our clinical trials and preclinical studies for our development programs. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and any third-party that we rely upon are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any third-party that we rely on or trial sites fail to comply with applicable GCPs or to provide adequate data with respect to such trials, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP and/or Quality System Regulation, or QSR requirements. Our failure or our vendors' failure to comply with these regulations may require us to delay or to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates, if approved.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional costs and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Our agreement with Universita Degli Studi di Milano-Bicocca, the institution that has performed many preclinical studies with istaroxime and our preclinical families of compounds, expired on July 31, 2022. If additional preclinical work is required for any reason, we will need to re-engage with Bicocca University or find another vendor to provide those services.

We currently do not have a back-up facility for our CMO for our drug product candidates, or our suppliers of API. If the parties we depend on for supplying our APIs and manufacturing our drug product candidates do not supply these products in a timely and quality manner, it may delay or impair our ability to execute our development plans for our current and potential pipeline products. Such delays could adversely impact our operations and financial condition.

In most cases, we are dependent upon a single supplier to provide all of our requirements for each of our APIs. We rely on a single CMO, located in China, to manufacture each of our drug product candidates that meets appropriate content, quality and stability standards for use in preclinical programs and clinical trials. In most cases, we submit purchase orders to our CMO and API suppliers as needed and do not have contractual commitments to manufacture for us in the future. If we do not maintain these manufacturing and service relationships that are important to us and are not able to identify replacement suppliers, vendors and laboratories, our ability to obtain regulatory approval for our product candidates could be impaired or delayed and our costs could substantially increase.

We may be unable to identify additional manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all, because the number of potential CMOs is limited. Even if we are able to find replacement manufacturers, suppliers, vendors and service providers when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. A new manufacturer currently not qualified with the FDA would have to be educated in, or develop substantially equivalent processes for, production of our approved products after receipt of FDA approval. To qualify and receive regulatory approval for a new manufacturer could take as long as two years. The process of changing a supplier could have an adverse impact on our current clinical development programs if supplies of drug substances or materials on hand are insufficient to satisfy demand. Such delays could have a material adverse effect on our development activities and our business.

Our product candidates are temperature sensitive and may have other attributes that lead to limited shelf life. These attributes may pose risks to supply, inventory and waste management and increased cost of goods.

Our product candidates may prove to have a stability profile that leads to a lower than desired shelf life. This poses risk in supply requirements, wasted stock, and higher cost of goods.

Our product candidates are temperature sensitive, and we may learn that any or all of our product candidates are less stable than desired. It is also possible that we may find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our product candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions.

We have established a number of analytical testing strategies, and may have to establish several more, to assess the quality of our product candidates. We may identify gaps in our analyses that might prevent release of product or could require product withdrawal or recall. For example, new or existing impurities that have an impact on product safety, efficacy, or stability may be discovered. This may lead to an inability to release or use our product candidates until the manufacturing or testing process is rectified or specifications are changed. This could potentially result in delays to our key program.

We plan to rely on third parties, some of which are located outside the U.S., to manufacture our drug product candidates, which exposes us to risks that may affect our ability to maintain supplies of our clinical materials, and subject us to uncertainty associated with the international political climate, and could potentially delay or cease our research and development activities, as well as eventual regulatory approval and commercialization of our drug product candidates.

Our manufacturing strategy involves manufacturing our drug product candidates using a CMO. We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our drug product candidates and related raw materials for clinical and preclinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other government regulations and corresponding international standards. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency compounds, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities.

Istaroxime and rostafuroxin are currently manufactured by an affiliate of Lee's (HK) in Hefei, China. We expect that Lee's (HK) will manufacture KL4 surfactant drug product candidate at an affiliate of Lee's (HK) in Hefei, China. The APIs for istaroxime and rostafuroxin are manufactured in China. If the FDA is unable to inspect the manufacturing site in China or if it is able to inspect the site but finds it deficient in any way, to secure marketing approval for our product candidates in the U.S., and potentially other markets, we may be required to designate a different manufacturer for each of our drug product candidates. A technology transfer of a manufacturing process from one CMO to another can be time consuming and expensive and there can be no assurance that such a transfer will be successful or that a new manufacturer will be able to manufacture our drug product candidates successfully. Moreover, a technology transfer from one country to another may be subject to changing international legal and regulatory requirements in a potential difficult political climate. In addition, we have limited control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel and the third-party manufacturers may fail to manufacture our product candidate according to our schedule or at all. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third-party manufacturer cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.

A third party's failure to execute on our manufacturing requirements, technology transfers of our manufacturing and our planned future reliance on CMOs exposes us, among other things, to the following risks:

- an inability to initiate or continue clinical trials of istaroxime or any future product candidates under development;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- we may implement a plan to execute a technology transfer of our manufacturing process to a CMO and, after investing significant time and resources, learn that the CMO we chose is unable to successfully complete the technology transfer and thereafter manufacture our product candidates in accordance with our plan;
- CMOs might be unable to manufacture our product candidates in the volume and to our specifications to meet our clinical and commercial needs, or we may have difficulty scheduling the production of drug product in a timely manner to meet our timing requirements;
- if we desire to make our drug product candidates available outside the U.S. for clinical or commercial purposes, our CMOs would become subject to, and may not be able to comply with, corresponding manufacturing and quality system regulations or standards of the various foreign regulators having jurisdiction over our activities abroad. Such failures (such as in-country quality testing) could result in not only a loss of approved supply to that country, but a total loss of a lot (or lots) of materials globally and could restrict our ability to execute our business strategies;
- we may have difficulty implementing changes or necessary modifications to our manufacturing processes that may be required by the FDA or foreign regulator or our CMO, if, for example, such changes would burden our CMO or otherwise disrupt operations, or our CMO could impose significant financial terms to implement any such change that could adversely affect our business. We may fail to adequately develop new manufacturing processes. Failure to achieve such required changes or modifications could delay or prevent our gaining regulatory approval for our product candidates or prevent us from continuing to market our approved products, which would have a material adverse effect on our business, financial condition and operations;
- we may fail to adequately scale manufacturing to achieve our objectives for cost of goods and profit margins;
- we may be subject to disputes arising with respect to the ownership of rights to any technology developed with third parties; and
- we may be subject to the misappropriation of our proprietary information, including our trade secrets and know-how.

Each of the foregoing risks and others could delay our development programs and, if approved, commercial manufacturing plans, limit our ability to maintain continuity of supply for our approved products, delay or impair the approval, if any, of our product candidates by the FDA, or result in higher costs or deprive us of potential product revenues.

In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products, if approved, may adversely affect our future profit margin and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Our ability to manufacture our product candidates depends upon receiving adequate supplies and related services, which may be difficult or uneconomical to procure.

Supply chain or manufacturing interruptions could negatively impact our operations and financial performance. We do not have fully redundant systems and equipment to respond promptly in the event of a significant loss at a CMO's manufacturing operations. Under certain conditions, we may be unable to produce our drug product candidates at the required volumes or to appropriate standards, if at all. The supply of any of our manufacturing materials may be interrupted because of supply shortages, poor vendor performance or other events outside our control, which may require us, among other things, to identify alternate vendors, which could involve a lengthy process, and result in increased expenses.

We are dependent on Lee's (HK) and Zhaoke for the successful development and commercialization of our KL4 surfactant products. If Lee's (HK) and Zhaoke do not devote sufficient resources to the development of those product candidates, are unsuccessful in their efforts, or chooses to terminate their agreement with us, the potential licensing revenue will not materialize.

On August 17, 2022, we entered into the A&R License Agreement with Lee's (HK) and Zhaoke effective as of August 9, 2022. The A&R License Agreement amends restates and supersedes the Original License Agreement.

Under the A&R License Agreement, Lee's is solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval and commercialization of KL4 surfactant products, including SURFAXIN®, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant. Lee's (HK) and Zhaoke may determine however, that it is commercially reasonable to de-prioritize or discontinue the development of the KL4 surfactant products. These decisions may occur for many reasons, including internal business reasons, results from clinical trials or because of unfavorable regulatory feedback.

Further, on review of the safety and efficacy data, the FDA may impose requirements on the programs that render them commercially nonviable. In addition, under the A&R License Agreement, Lee's (HK) and Zhaoke have certain decision-making rights in determining the development and commercialization plans and activities for the programs. We may disagree with Lee's (HK) and Zhaoke about the development strategy they employ, but we will have limited rights to impose our development strategy on Lee's (HK) and Zhaoke. Similarly, they may decide to seek marketing approval for, and limit commercialization of, the KL4 surfactant products to narrower indications than we would pursue. More broadly, if Lee's (HK) and Zhaoke elect to discontinue the development of the KL4 surfactant products, we may be unable to advance the product candidate ourselves.

Risks Related to our Business and Operations

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results.

These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, including manufacturing development regulatory approval and commercialization activities relating to our product candidates, which may change from period to period;
- the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the level of investment funding we are able to achieve and apply to our development operations;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- the potential for our identifiable intangible assets to become impaired, and the timing of such impairments, if any;
- the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in-licensed our acquired our product candidates;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- our allocation of resources and ability to raise additional capital;
- future changes in requirements to achieve regulatory approval;
- future accounting pronouncements or changes in our accounting policies.
- the capital markets stability and openness to investing;
- delays associated with coronavirus which will impact the ability of our healthcare systems and trial sites to conduct trials to varied degrees and times;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for any approved products, which may vary significantly.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We are continually evaluating our business strategy and may modify this strategy to respond to developments in our business and other factors, and any such modification, if not successful, could have a material adverse effect on our business, financial condition, and results of operations.

We plan to continually evaluate our business strategy and will modify our plans as necessary to achieve our objectives. As part of our shift in priorities, we entered into the A&R License Agreement in 2022 (See "*Item 1. Business*" in our 2022 Annual Report for additional information on the A&R License Agreement) to support the development of our KL4 surfactant platform and were able to eliminate the remaining costs associated with the KL4 surfactant platform. If for any reason, our licensee does not proceed with development of the KL4 surfactant platform, such action could have a material adverse effect on our potential to realize licensing revenue.

Similarly, our strategy currently contemplates that we will seek to out-license rostafuroxin and invest the proceeds in our other core programs. If we are not successful in our efforts, we may be forced to accept a significant write down of our rostafuroxin asset on our balance sheet and reassess our strategy. This action also could have a material adverse effect on our business, financial condition and results of operations.

The execution of a clinical program is complex and involves the cooperation of many individuals and entities, including third parties that we may not be able to control, and require the coordination of a number of components, any one of which could experience delays or unforeseen events or circumstances that may require the development of alternative strategies. If we encounter such events or circumstances, if we believe that certain changes would be in our best interest, we will consider adjusting our strategy and planning. If we conclude that an alternative approach may improve our ability to achieve our objectives, we will consider adopting such other approach. Similarly, if a third party were to share observations or make recommendations concerning the focus, sequence or approach of any or all of our research and development programs, we may consider taking such recommendations into account in our planning process and future activities.

There can be no assurance, whether or not we alter our strategy or plans, that we will be successful, or that we will secure regulatory approval for our product candidates and execute any product launches effectively and on time, if at all, in all markets that we may identify. Our ability to discover and/or develop new product candidates depends in part on our internal research capabilities and whether we have the resources required to conduct a development program or to acquire new product candidates. Our limited resources may not be sufficient to discover and develop or to acquire new product candidates. To support our efforts to develop our product candidates and, if approved, commercialize our products in the world markets, including the U.S., we continue to evaluate potential licensing transactions, collaboration arrangements and other strategic transactions. However, there can be no assurance that our efforts will be successful or that, even if we identify and enter into any strategic transactions, that such transactions will be successfully implemented, if at all, within our expected time frames.

We plan to continue evaluating our business strategy and may modify our strategy again in the future. To respond to changing circumstances, we may expand or alter our research and development activities from time to time and allocate resources to work on development of different product candidates or may pace, delay or halt the development of potential product development programs. As a result of changes in our strategy, we may also change or refocus our existing drug development and manufacturing activities or our plans for commercialization of our product candidates, if approved. These decisions could require changes in our facilities and personnel and restructuring various financial arrangements. There can be no assurances that any product development or other changes that we implement will be successful or that, after implementation of any such changes, that we will not refocus our efforts on new or different objectives.

Our industry is highly competitive, and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our product candidates obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies in many ways. We need to successfully introduce new products to achieve our strategic business objectives. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers' requirements, our product candidates may become obsolete and our business could suffer.

Many of our competitors' companies have substantially greater research and development, manufacturing, marketing, financial, and technology personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in developing products, preclinical testing and human clinical trials management, obtaining FDA approval and other regulatory approvals, and manufacturing and marketing products. Accordingly, our competitors may succeed in receiving FDA or foreign regulatory approval or commercializing products and obtaining patent protection before us. Our competitors may successfully secure regulatory exclusivities in various markets, which could have the effect of barring us or limiting our ability to market our product candidates, if approved, in such markets. In addition, developments by our competitors may render our drug product candidates obsolete or noncompetitive.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitive forces frequently and aggressively seek patent protection and licensing arrangements to collect royalties for technologies that they develop. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel.

The political and healthcare policy and reimbursement environment is becoming more challenging for pharmaceutical companies and manufacturers and may adversely affect our business.

Political, economic and regulatory influences globally are subjecting the healthcare industry to potential fundamental challenges that could substantially affect our business and results of operations. Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements, are continuing to arise in many countries where we potentially may seek to do business, including the U.S. There is increasing pressure on pricing, reimbursement and demands for value-based data to gain access to patients and healthcare funds globally. This may increase the costs of development, risks of commercialization and overall value of the opportunity. The Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our product candidates, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known. We also cannot predict the likelihood, nature or extent of additional government regulation that may arise from future legislation, administrative, judicial, or executive action, either in the U.S. or abroad. In addition, we rely on our CMO located in China to manufacture drug product and APIs for us, such that the supply lines for our drug product, and APIs may be affected by trade and political considerations.

Given the increasing uncertainty in the healthcare and pharmaceutical industries as well as increased regulatory scrutiny on foreign investment, capital investment in our industry and our ability to attract capital investment is becoming more challenging. This trend, if continued, may restrict or impair our ability to gain necessary funding for continued development and, if approved, commercialization of our product candidates.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we or our strategic partners or collaborators are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our product candidates.

We have assembled a team of qualified personnel to advance the development programs for our product candidates. We have competed and will continue to compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is significant and attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us.

We are highly dependent upon the members of our executive management team and certain employees and consultants who are subject matter experts. Many of these individuals have been involved with us for many years, have played integral roles in our progress and we believe that they continue to provide value to us. We have over the last few years lost long-term members of our executive team and certain professional, scientific and management personnel, due to retirement, shifts in our focus and other causes. The loss of such personnel potentially exposes us to a lack of ready recall and knowledge of past corporate events, risks previously identified and related learnings. As such, the loss of any of our remaining key personnel may further increase the associated risk and may have a material adverse effect on aspects of our business and clinical development and regulatory programs. The loss of services from any of our executives could significantly adversely affect our ability to develop and market our product candidates and obtain necessary regulatory approvals. Further, we do not maintain key man life insurance.

Our future success also will depend on the continued service of our key professional, scientific and management personnel and our ability to recruit and retain additional personnel. While we attempt to provide competitive compensation packages to attract and retain key personnel at all levels in our organization, many of our competitors have greater resources and more experience than we do, making it difficult for us to compete successfully for key personnel. We may experience intense competition for qualified personnel and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to lawsuits brought by their former employers.

If our business development activities are unsuccessful, our business could suffer, and our financial performance could be adversely affected.

As part of our long-term growth strategy, we engage in business development activities intended to identify strategic opportunities, including potential strategic alliances, joint development opportunities, acquisitions, technology licensing arrangements and other similar opportunities. Such opportunities may result in substantial investments in our business. Our success in developing product candidates or expanding into new markets from such activities will depend on a number of factors, including our ability to find suitable opportunities for investment, alliance or acquisition; whether we are able to complete an investment, alliance or acquisition on terms that are satisfactory to us; the strength of our underlying technology, product candidates and our ability to execute our business strategies; any intellectual property and litigation related to these product candidates or technology; and our ability to successfully integrate the investment, alliance or acquisition into our existing operations, including to fund our share of any IPR&D projects. If we are unsuccessful in our business development activities, we may be unable to secure needed capital and expertise to support our development programs and our financial condition could be adversely affected.

We may seek to enter into licensing transactions, collaboration arrangements, and other similar transactions and strategic opportunities, and may not be successful in doing so, and even if we are, we may not realize the benefits of such relationships.

We may seek to enter into licensing transactions, collaboration arrangements, and other similar transactions and strategic opportunities for the development or commercialization of our product candidates, or to secure the capital required to develop or commercialize a product candidate or address manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or licensing agreement, we will achieve an economic benefit that justifies such a transaction.

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

We could be adversely affected by any interruption, including from breaches in cybersecurity, in our ability to conduct business at our current location.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Despite our implementation of security measures, our information systems, like those of other companies, are vulnerable to damages from computer viruses, natural disasters, unauthorized access, cyber-attack, including ransomware, and other similar disruptions. Any system failure, accident or security breach could result in disruptions to our operations. For example, third parties may attempt to hack into systems and may obtain our proprietary information or other sensitive information, which could cause significant damage to our reputation, lead to claims against the Company and ultimately harm our business.

We do not have redundant facilities. We perform substantially all of our research and development and back office activity in a small number of locations, including our headquarters in Warrington, Pennsylvania, and a research laboratory at Chang Gung University in Taiwan under a separate collaboration agreement. We also depend upon third-party manufacturers and laboratories to manufacture our drug product candidates, APIs and perform important API and drug product release testing and stability work.

Our facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. Our facilities and those of our third-party manufacturers and laboratories may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, tornadoes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we have insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

The failure to prevail in litigation or the costs of litigation, including securities class actions, product liability claims and patent infringement claims, could harm our financial performance and business operations.

We are potentially susceptible to litigation. For example, as a public company, we may be subject to claims asserting violations of securities laws. Even if such actions are found to be without merit, the potential impact of such actions, which generally seek unquantifiable damages and attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

Our business activities, including development, manufacture and, if our product candidates are approved, marketing of our drug products also exposes us to liability risks. Using our drug product candidates, including in clinical trials, may expose us to product liability claims. Even if approved, our products may be subject to claims resulting from unintended effects that result in injury or death. Product liability claims alleging inadequate disclosure and warnings in our package inserts also may arise.

We presently carry comprehensive general liability, property damage, product liability, workers' compensation, health benefits and other insurance coverage in amounts that we believe to be adequate for the protection of our assets and operations and customary for companies in our industry of comparable size and level of activity. However, our insurance policies contain various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. There can be no assurance that the insurance coverage we maintain is sufficient or will be available in adequate amounts or at a reasonable cost. A successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation.

Product liability claims may be brought by individuals or by groups seeking to represent a class. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, and the magnitude of the potential loss relating to such lawsuits may remain unknown for substantial periods of time.

We face a potential risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any of our product candidates, if approved, or any other future product. For example, we may be sued if any product we develop, including any of our product candidates, or any materials that we use in our product candidates allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. In the U.S., claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our product candidates, if approved, or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time, attention and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize some or all of our product candidates, if approved; and
- a decline in the value of our stock.

There can be no assurance that the insurance coverage we maintain is sufficient or will be available in adequate amounts or at a reasonable cost. A successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation.

We may be required to obtain additional product liability insurance coverage. However, such insurance is expensive and may not be available when we need it. In the future, we may not be able to obtain adequate insurance, with acceptable limits and retentions, at an acceptable cost. Any product, general liability or product liability claim, even if such claim is within the limits of our insurance coverage or meritless and/or unsuccessful, could adversely affect the availability or cost of insurance generally and our cash available for other purposes, such as research and development. In addition, such claims could result in:

- uninsured expenses related to defense or payment of substantial monetary awards to claimants;

- a decrease in demand for our drug product candidates, if approved;
- damage to our reputation; and
- an inability to complete clinical trial programs or to commercialize our drug product candidates, if approved.

Risks Related to Government Regulation

Our activities are subject to various and complex laws and regulations, and we are susceptible to a changing regulatory environment. Violations or allegations of violations of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have a material adverse effect on our business, financial condition and results of operations.

Our product candidates and our operations are regulated by numerous government agencies, both inside and outside the U.S. Our drug product candidates must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. Our facilities and those of our third-party providers must pass inspection and/or be approved or licensed prior to production and remain subject to inspection at any time thereafter. Failure to comply with the requirements of the FDA or other regulatory authorities could result in warning or untitled letters, Form 483s, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of our product candidates, if approved, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could damage our reputation and have a material adverse effect on our sales.

If our product candidates are approved for commercial sale, we will be required to comply with not only the requirements of applicable regulators, but also will become subject to various laws regulating the sales, marketing, and distribution of healthcare-related products. The sales and marketing of products and relationships that pharmaceutical companies have with healthcare providers are under increasing scrutiny by federal, state and foreign government agencies. The FDA and other federal regulators have increased their enforcement activities with respect to the Anti-Kickback Statute, False Claims Act, off-label promotion of products, and other healthcare related laws, antitrust and other competition laws. Foreign governments have also increased their scrutiny of pharmaceutical companies' sales and marketing activities and relationships with healthcare providers.

Of particular importance, federal and state anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. These laws can be complicated, are subject to frequent change and may be violated unknowingly. In addition, a number of states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. Sanctions under these laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs (including Medicare and Medicaid), criminal fines, and imprisonment. Companies that have chosen to settle these alleged violations have typically paid multi-million-dollar fines to the government and agreed to abide by corporate integrity agreements, which often include significant and costly burdens.

There has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals and entities. For example, the Physician Payment Sunshine Act imposes annual reporting requirements on certain manufacturers of drugs, biologics and medical supplies with respect to payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as with respect to certain ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information regarding all payments, transfers of value or ownership or investment interests may result in civil monetary penalties. Certain states also mandate implementation of commercial compliance programs, impose restrictions on manufacturers' marketing practices, and require the tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities under certain circumstances.

We are continually evaluating our compliance programs, including policies, training and various forms of monitoring, designed to address the requirements outlined above. However, no compliance program can mitigate risk in its entirety. Violations or allegations of violations of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have a material adverse effect on our business, financial condition and results of operations.

Failure in our information technology systems could disrupt our operations and cause the loss of confidential information and business opportunities.

In the ordinary course of our business, we and our third-party contractors maintain sensitive data on our and their respective networks, including our intellectual property and proprietary or confidential business information relating to our business and that of our clinical trial participants and business partners and electronically stored work product, including clinical data, analyses, research, communications and other materials necessary to gain regulatory approval of our product candidates. The secure maintenance of this sensitive information is critical to our business and reputation. Despite the implementation of security measures, our internal computer systems and those of our third-party contractors are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, unintended loss, human error, natural disasters, terrorism, war and telecommunication and electrical failures. For information stored with our third-party contractors, we rely upon, and the integrity and confidentiality of such information is dependent upon, the risk mitigation and data preservation efforts such third-party contractors have in place. Our and our third-party contractors' respective network and storage applications and policies may not be sufficient to protect our sensitive business information and may be subject to loss, unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. Such incidents could compromise our intellectual property, expose sensitive business information, result in loss of data necessary to secure regulatory approval of our product candidates, cause interruptions in our operations, result in a material disruption of our operations, or require substantial expenditures of resources to remedy.

We face risks related to our collection and use of data, including personal information, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices.

Our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to users' accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain users' personal data or prevent use of their accounts. Data breaches could subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the U.S. and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed.

Our business requires that we and our third-party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about patients, credit card information, and our proprietary business and financial information. As a covered entity, we must comply with the HIPAA privacy and security regulations, which may increase our operational costs. Furthermore, the privacy and security regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, or PHI, including potential civil and criminal fines and penalties. We face a number of risks relative to our protection of, and our service providers' protection of, this critical information, including loss of access, fraudulent modifications, inappropriate disclosure and inappropriate access, as well as risks associated with our ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. If such event would occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, modified without our knowledge, lost or stolen.

Additionally, we share PHI with third-party contractors who are contractually obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-party contractors' computer networks. Any wrongful use or disclosure of PHI by us or our third-party contractors, including disclosure due to data theft or unauthorized access to our or our third-party contractors' computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we also could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information by us or our third-party contractors. Unauthorized access, loss, modification or dissemination could disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our solution and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business. In addition, the interpretation and application of consumer, health-related and data protection laws in the U.S. are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities, including various domestic and international privacy and security regulations. The legislative and regulatory landscape for privacy and data protection continues to evolve. In the U.S., certain states may adopt privacy and security laws and regulations that may be more stringent than applicable federal law.

A number of US states have proposed new privacy laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Our international operations are subject to international laws and regulations, regulatory guidance, and industry standards relating to data protection, privacy, and information security. This includes the EU General Data Protection Regulation, or GDPR, as well as other national data protection legislation in force in relevant EU member states (including the GDPR in such form as incorporated into the law of England and Wales, Scotland and Northern Ireland by virtue of the European Union (Withdrawal) Act 2018 and any regulations thereunder and the UK Data Protection Act 2018, or UK GDPR.

The GDPR and UK GDPR are wide-ranging in scope and impose numerous additional requirements on companies that process personal data, including imposing special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, creating mandatory data breach notification requirements in certain circumstances, requiring data protection impact assessments for high risk processing and requiring that certain measures (including contractual requirements) are put in place when engaging third-party processors. The GDPR and the UK GDPR also provide individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection.

The GDPR and UK GDPR impose strict rules on the transfer of personal data to countries outside the European Economic Area, including the U.S. The UK and Switzerland have adopted similar restrictions. Although the UK is regarded as a third country under the EU's GDPR, the EC has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the EC's new standard contractual clauses but has published a draft version of a UK-specific transfer mechanism, which, once finalized, will enable transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so will require significant effort and cost.

The GDPR and UK GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR and UK GDPR. Implementing legislation in applicable EU member states and the UK, including by seeking to establish appropriate lawful bases for the various processing activities we carry out as a controller or joint controller, reviewing security procedures and those of our vendors and collaborators, and entering into data processing agreements with relevant vendors and collaborators, we cannot be certain that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful. Given the breadth and depth of changes in data protection obligations, preparing for and complying with the GDPR and UK GDPR and similar laws' requirements are rigorous and time intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data.

Other countries around the world in which we conduct business have also enacted strict privacy and data protection laws. Further, in addition to general privacy and data protection requirements, many jurisdictions around the world have adopted legislation that regulates how businesses operate online and enforces information security, including measures relating to privacy, data security and data breaches. Many of these laws require businesses to notify data breaches to the regulators and/or to data subjects. These laws are not consistent, and compliance in the event of a widespread data breach is costly and burdensome.

In many jurisdictions, enforcement actions and consequences for non-compliance with protection, privacy and information security laws and regulations are rising. In the EU and the UK, data protection authorities may impose large penalties for violations of the data protection laws, including potential fines of up to €20 million (£17.5 million in the UK) or 4% of annual global revenue, whichever is greater. The authorities have shown a willingness to impose significant fines and issue orders preventing the processing of personal data on non-compliant businesses. Data subjects also have a private right of action, as do consumer associations, to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of applicable data protection laws.

The risk of our being found in violation of these laws is increased by the fact that the interpretation and enforcement of them is not entirely clear. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. It could also require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Failure by us or our collaborators and third-party providers to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties and orders preventing us from processing personal data), private litigation and result in significant fines and penalties against us. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

Healthcare reform measures in the U.S., as well as the general tightening of drug reimbursement pathways and levels of reimbursement globally, are expected to add additional pressure to achieve financial expectations for our product candidates, if approved.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product candidates, if approved. The U.S. government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Further changes to and under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved. The Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our product candidates, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

Our international operations subject us to additional regulatory oversight in foreign jurisdictions, as well as economic, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results.

We are subject to certain risks associated with having assets, both physical and intangible, and operations located in Taiwan. Our activity in Taiwan is subject to regulatory agencies, such as the Taiwan Food and Drug Administration. Our operations in foreign jurisdictions are conducted by our subsidiary, CVie Therapeutics, Taiwan, which also owns a substantial portion of our intellectual property. Our international operations may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results. In addition, the impacts of political unrest, including as a result geopolitical tension, such as a deterioration in the relationship between the U.S. and China, including any potential resulting sanctions, export controls, or other restrictive actions that may be imposed by the U.S. and/or other countries against governmental or other entities in, for example, China or Taiwan, also could have an adverse impact on our international operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates, if approved.

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates if we receive approval. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our product candidates, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates, if approved;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time, attention and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our product candidates, if approved; and
- a decline in our stock price.

We currently hold product liability insurance coverage at a level we believe to be consistent with our activities. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates, if approved. Insurance coverage is increasingly expensive.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates, if approved. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, in which violations of these laws could result in substantial penalties and prosecution.

We are exposed to trade and economic sanctions and other restrictions imposed by the U.S. and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U.S. Foreign Corrupt Practices Act, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control. The Department of Justice, or DOJ, also has increased its focus on the enforcement of the FCPA, particularly as it relates to the conduct of pharmaceutical companies.

In addition, the U.K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that "fails to prevent bribery" by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented "adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our third-party manufacturers or suppliers will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We carry a limited amount of specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies offer limited coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

We maintain a limited amount of insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Intellectual Property Matters

If we cannot protect our intellectual property, others could use our technology in competitive products. Even if we obtain patents to protect our product candidates, those patents may not be sufficiently broad, or they may expire and others could then compete with us.

The patent position of biotechnology companies is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the U.S. Patent and Trademark Office, or USPTO, has not adopted a consistent policy regarding the breadth of claims that is accorded in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not secure proprietary rights to products or processes that appear to be patentable.

The parties who licensed technologies to us and we have filed various U.S. and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, as well as those we may file in the future or those we may license from third parties, may not result in the USPTO or foreign patent office issuing patents. In addition, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. For example, the core composition of matter patents covering istaroxime have expired. As such, istaroxime relies on data and market exclusivity, as well as method-of-use patents, which may offer a lesser scope of protection than the original core patents. Furthermore, even if the USPTO or foreign patent offices were to issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from third parties may not provide us any protection against competitors.

The patents that we own or in-license have a limited life. Patents related to our cardiovascular drug products issued in the U.S., Europe and elsewhere have expired or will expire on various dates between 2028 and 2039. Further, we cannot guarantee that all patent applications related to our cardiovascular drug products that are still pending in U.S., Europe and elsewhere will be granted as patents.

Intellectual property rights of third parties could limit our ability to develop and market our product candidates.

Our success also depends upon our ability to operate our business without infringing the patents or violating the proprietary rights of others. Patent applications in most jurisdictions are not published until 18 months after filing. In certain cases, the USPTO keeps U.S. patent applications confidential for the entire time the applications are pending. As a result, we cannot determine in advance what inventions third parties may claim in their pending patent applications. We may need to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others through legal proceedings, which would be costly, unpredictable and time consuming. Even in proceedings where the outcome is favorable to us, they would likely divert substantial resources, including management time, from our other activities. Moreover, any adverse determination could subject us to significant liability or require us to seek licenses that third parties might not grant to us or might only grant at rates that diminish or deplete the profitability of our products. An adverse determination could also require us to alter our products or processes or cease altogether any product sales or related research and development activities.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates in the absence of such a license. The licensing and acquisition of third-party intellectual property rights is a competitive practice and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

We rely on agreements containing obligations regarding intellectual property, confidentiality and noncompetition provisions that could be breached and may be difficult to enforce.

Although we take what we believe to be reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of our confidential and proprietary information and trade secrets to third parties, as well as agreements that provide for disclosure and assignment to us of all rights to the ideas, developments, improvements, discoveries and inventions of our employees, consultants, advisors and research collaborators while we employ them, such agreements can be difficult and costly to enforce. We generally seek to enter into these types of agreements with consultants, advisors and research collaborators; however, to the extent that such parties apply or independently develop intellectual property in connection with any of our projects, disputes may arise concerning allocation of the related proprietary rights. Such disputes often involve significant expense and yield unpredictable results.

Moreover, although all employees enter into agreements with us that include non-compete covenants, and our senior executive officers have agreements that include broader non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, such non-compete provisions can be difficult and costly to monitor and enforce, such that, if any should resign, we may not be successful in enforcing our noncompetition agreements with them.

Despite the protective measures we employ, we still face the risk that:

- agreements may be breached;
- agreements may not provide adequate remedies for the applicable type of breach;
- our trade secrets or proprietary know-how may otherwise become known;
- our competitors may independently develop similar technology; or
- our competitors may independently discover our proprietary information and trade secrets.

Patents covering our product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad.

Although an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar product candidates. Competitors could attempt to replicate the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around the relevant patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some non-U.S. countries do not protect our proprietary rights to the same extent as the laws of the U.S., and we may encounter significant problems in protecting our proprietary rights in these countries.

In addition, proceedings to enforce or defend our patents, or patents to which we have ownership rights through licensing agreements, could put those patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of those patents are invalid or otherwise unenforceable. If any of the patents covering our product candidates are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in such intellectual property. Either outcome could harm our business and competitive position.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our product candidates or affect our stock price.

Our commercial success will depend in part on not infringing the patents or violating other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the U.S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. Patent applications in the U.S., the EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to develop and market our product candidates. Third parties may assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect.

As we attempt to commercialize our product candidates in their current or updated forms, launch new product candidates and enter new markets, we expect competitors may claim that one or more of our product candidates infringe their intellectual property rights as a strategy to impede our commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved, and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation. We may in the future receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents.

Moreover, we may become party to adversarial proceedings regarding our or third-party patent portfolios. Such proceedings could include supplemental examination or contested post-grant proceedings such as review, reexamination, inter parties review, interference or derivation proceedings before the USPTO and challenges in U.S. District Courts. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and/ or invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using product candidates or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments;
- incur significant legal expenses, including, in some cases, the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- pay substantial damages (possibly treble damages) or royalties to the party whose intellectual property rights on which we may be found to be infringing;

- redesign product candidates that contain the allegedly infringing intellectual property; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our product candidates unless we obtain a license or are able to redesign our product candidates to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our product candidates in a technically feasible way that would not infringe the intellectual property rights of others. We could encounter delays while we attempt to develop alternative methods or product candidates. If we fail to obtain any required licenses or make any necessary changes to our product candidates or technologies, we may be unable to commercialize one or more of our product candidates.

Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our product candidates, services and technology. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

We also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product candidates that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome of any such claim is unpredictable. Trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed or reverse engineered by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our business and competitive position could be harmed.

We may be unable to enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Additionally, in the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe on our trademarks, and we may not have adequate resources to enforce our trademarks.

Proceedings to enforce our patent or trademark rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

In the future, we may employ individuals who previously worked with other companies, including our competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal data, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.

In 2011, the U.S. enacted and later implemented wide ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases since that time, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the U.S. federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and other patent agencies over the lifetime of the patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates.

We may be unable to obtain a patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation.

In the U.S., a patent that covers a drug product approved by the FDA may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, it is possible, though unlikely, that one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended, and only one patent may be extended. In the EU, it is possible, though unlikely, that our product candidates may be eligible for term extensions based on similar legislation. However, in either jurisdiction, if we were eligible to apply for patent term extension, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such an extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable product candidates could be substantial.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our product candidates that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we may not be able to successfully commercialize our product candidates before our relevant patents we may have, or to which we have ownership rights through licensing agreements, expire;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to the Ownership of our Securities

Our common stock is listed on the Nasdaq Capital Market, or Nasdaq. We can provide no assurance that we will be able to comply with the continued listing requirements over time and that our common stock will continue to be listed on Nasdaq.

In May 2020, we successfully listed our common stock on the Nasdaq Capital Market. However, we can give no assurance that we will be able to satisfy the continued listing requirements of Nasdaq in the future, including but not limited to the corporate governance requirements and the minimum closing bid price requirement or the minimum equity requirement.

On June 3, 2022, we received a deficiency letter from the Nasdaq Listing Qualifications Department, or the Staff, of Nasdaq notifying us that, for 30 consecutive business days, the closing bid price for our common stock was below the minimum $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or Rule 5550(a)(2). The Nasdaq deficiency letter had no immediate effect on the listing of our common stock, and our common stock continued to trade on the Nasdaq Capital Market under the symbol "WINT". We were initially given 180 calendar days, or until November 30, 2022, to regain compliance with Rule 5550(a)(2), which was extended by an additional 180 calendar days, or May 29, 2023.

On February 24, 2023, we effected a reverse stock split of our issued and outstanding shares of common stock, par value $0.001 per share, at a ratio of 1 post-split share for every 50 pre-split shares. On March 10, 2023, we received written confirmation from Nasdaq notifying us that we had regained compliance with Nasdaq Listing Rule 5550(a)(2).

There can be no assurance that we will be able to maintain compliance with the continued listing requirements for Nasdaq. If we fail to maintain compliance with any such continued listing requirement, there can also be no assurance that we will be able to regain compliance with any such continued listing requirement in the future or that our common stock will not be delisted from Nasdaq Stock Market in the future. If we fail to maintain compliance, Nasdaq may take steps to delist our common stock. If such delisting should occur, it would likely have a negative effect on the price of our common stock and would impair an investor's ability to sell or purchase our common stock when desired. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement, or prevent future non-compliance with Nasdaq's listing requirements.

We effected a reverse stock split on February 24, 2023 which may adversely impact the market price of our common stock.

We effected a reverse stock split of our outstanding common stock at a ratio of 1-for-50 shares, which was effected at 12:01 a.m. Eastern Time on February 24, 2023. The effect of the reverse stock split upon the market price of our common stock cannot be predicted with certainty and there is no assurance that our common stock will trade at a price consistent with such a reverse stock split. Accordingly, it is possible that the market price of our common stock following the reverse stock split will decline, possibly more than would occur in the absence of a reverse stock split.

The effective increase in the number of shares of our common stock available for issuance as a result of our reverse stock split could result in further dilution to our existing stockholders and have antitakeover implications.

The reverse stock split alone had no effect on our authorized capital stock, and the total number of authorized shares remains the same as before the reverse stock split. The reverse stock split of our issued and outstanding shares increased the number of shares of our common stock (or securities convertible or exchangeable for our common stock) available for issuance by decreasing the number of shares of our common stock issued and outstanding. The additional available shares are available for issuance from time to time at the discretion of our Board of Directors when opportunities arise, without further stockholder action or the related delays and expenses, except as may be required for a particular transaction by law, the rules of any exchange on which our securities may then be listed, or other agreements or restrictions. Any issuance of additional shares of our common stock would increase the number of outstanding shares of our common stock and (unless such issuance was pro-rata among existing stockholders) the percentage ownership of existing stockholders would be diluted accordingly. In addition, any such issuance of additional shares of our common stock could have the effect of diluting the earnings per share and book value per share of outstanding shares of our common stock.

Additionally, the effective increase in the number of shares available for issuance could, under certain circumstances, have anti-takeover implications. For example, the additional shares of common stock that have become available for issuance could be used by us to oppose a hostile takeover attempt or to delay or prevent changes in control or our management. Although our reverse stock split is prompted by other considerations and not by the threat of any hostile takeover attempt, stockholders should be aware that our reverse stock split could facilitate future efforts by us to deter or prevent changes in control, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices.

The market price of our common stock may be highly volatile, and investors may not be able to resell their shares at or above the price at which they purchased them.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- our ability to execute our planned clinical trials on a timely basis consistent with timelines established;
- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;

- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the U.S. and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, along with any product modifications and improvements;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates;
- the implementation of our business model and strategic plans for our business and technology;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders;
- general economic, industry and market conditions other events or factors, including as a result of inflation, liquidity constraints or banking stability, many of which are beyond our control;
- our commercialization, marketing and manufacturing prospects and capabilities;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

In addition, the stock markets in general, and the markets for biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the market price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

The sale and issuance of our common stock or rights to purchase our common stock, stock incentive plans and upon the exercise of outstanding securities exercisable for shares of our common stock, including our AEROSURF warrants, which are exercisable in the future for no consideration, could result in substantial additional dilution of our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

We will require additional capital to continue to execute our business plan and advance our research and development efforts. To the extent that we raise additional capital through the issuance of additional equity securities and through the exercise of outstanding warrants, our stockholders may experience substantial dilution. We may sell shares of preferred stock or common stock in one or more transactions at prices that may be at a discount to the then-current market value of our common stock and on such other terms and conditions as we may determine from time to time. Any such transaction could result in substantial dilution of our existing stockholders. If we sell shares of our common stock in more than one transaction, stockholders who purchase our common stock may be materially diluted by subsequent sales. Such sales could also cause a drop in the market price of our common stock. The issuance of shares of our common stock in connection with a public or private financing, in connection with our compensation programs, and upon exercise of outstanding warrants will have a dilutive impact on our other stockholders and the issuance, or even potential issuance, of such shares could have a negative effect on the market price of our common stock.

The exercise of stock options and other securities could also cause our stockholders to experience substantial dilution. Moreover, holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

A small group of our investors, including Lee's Holdings and Panacea Venture Management Company Ltd., may be able to exercise significant influence over our business strategy and operations.

As of March 31, 2023, Lee's Holdings beneficially owns directly and through its affiliates, approximately 12% of our issued and outstanding shares of common stock, and Panacea Venture Management Company Ltd., affiliates of our Chairman, James Huang, beneficially owns directly and through affiliates approximately 8% of our issued and outstanding common stock. These investors could influence the outcome of corporate actions by us requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders also may exert influence in delaying or preventing a change in control, even if such a change in control would benefit our other stockholders.

In addition, affiliates of Lee's Holdings in China serve as CMO for istaroxime, rostafuroxin and potentially lyophilized KL4 surfactant. As such, we are highly dependent upon their performance to maintain our operational timelines and achieve planned milestones, and as a result, they may be in a position to exert leverage over our planning processes.

Provisions of our Amended and Restated Certificate of Incorporation, or Certificate of Incorporation, our Amended and Restated By-Laws, or By-Laws, and Delaware law could deter a change of our management and thereby discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation, our By-Laws and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management and might discourage a third party from offering to acquire us, even if a change of control or in management would be beneficial to our stockholders. Such provisions may make it costlier for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to file in a different judicial forum to resolve disputes with us or our directors, officers or employees.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Certificate of Incorporation or our By-Laws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies, which include, among other things, audited financial statements and Management Discussion and Analysis for two years instead of three years, an update of the general development of the business for such period that is material to an understanding of the company, simplified executive compensation disclosures, and exemption from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered accounting firm provide an attestation report on the effectiveness of internal control over financial reporting. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to this Offering

Purchasers of common stock in this offering will experience immediate and substantial dilution in the net tangible book value of their investment. You may experience further dilution upon exercise of options.

The public offering price per share of common stock in this offering is substantially higher than the net tangible book value per share of our common stock before giving effect to this offering. Based on a public offering price of $4.62 per share, if you purchase common stock in this offering, you will incur immediate substantial dilution of approximately $8.52 per share, representing the difference between the public offering price per share of common stock and our as adjusted net tangible book value as of December 31, 2022. Furthermore, if outstanding options or warrants are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section in this prospectus entitled "*Dilution*."

A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act.

Upon completion of this offering, based on our shares outstanding as of March 31, 2023, we will have 2,857,064 shares of common stock outstanding, which (along with the shares purchased in this offering) may be resold into the public market immediately without restriction, unless owned or purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act.

As of March 31, 2023, there were approximately 70,972 shares subject to outstanding options or otherwise issuable under our equity compensation plans, or subject to certain outstanding inducement grants, and 6,524 shares subject to outstanding restricted stock units or otherwise issuable under our equity compensation plans. We have registered the shares of common stock available for issuance under the Company's 2011 Long-Term Incentive Plan and 2020 Equity Incentive Plan under the Securities Act on Registration Statements on Form S-8. The registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above, to the extent applicable.

As of March 31, 2023, we had outstanding warrants exercisable for 449,345 shares with a weighted-average exercise price of $179.56 per share. The shares of our common stock underlying such warrants will, upon issuance, be freely tradeable without restriction or further registration under the Securities Act.

We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of net proceeds from this offering, and we could spend the net proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds from this offering for the clinical development of istaroxime in cardiogenic shock and for working capital and other general corporate purposes, including costs and expenses associated with being a public company. However, our use of these net proceeds may differ substantially from our current plans. If we do not invest or apply the net proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

There is no public market for the warrants being offered in this offering.

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

Holders of warrants purchased in this offering will have no rights as a common stockholder until such holder exercises its warrants and acquires our common stock, except as set forth in such warrants.

Until holders of warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying the warrants. Upon exercise of the warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The warrants are speculative in nature.

The warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, holders of the common warrants may exercise their right to acquire the common stock and pay an exercise price of $ per share, subject to certain adjustments, commencing immediately until expiration on the fifth anniversary of the date of issuance, after which period any unexercised common warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants, if any, is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their imputed offering price. The warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, it may not ever be profitable for holders of the warrants to exercise the warrants.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- our estimates regarding future results of operations, financial position, research and development costs, capital requirements, and our needs for additional financing;
- how long we can continue to fund our operations with our existing cash and cash equivalents;
- changes in market conditions, general economic conditions, and the banking sector, and potential constraints in accessing capital or credit if and when needed with favorable terms, if at all;
- the potential impairment of our intangible assets and goodwill on our consolidated balance sheet, which could lead to material impairment charges in the future;
- potential delays and uncertainties in our anticipated timelines and milestones and additional costs associated with the impact of the residual effects of the coronavirus pandemic on our clinical trial operations;
- the costs, timing, and results, of our preclinical studies and clinical trials, as well as the number of required trials for regulatory approval and the criteria for success in such trials;
- legal and regulatory developments in the United States, or U.S., and foreign countries, including any actions or advice that may affect the design, initiation, timing, continuation, progress or outcome of clinical trials or result in the need for additional clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates, and the indication and labeling under any such approval;
- risks related to manufacturing active pharmaceutical ingredients, drug product, and other materials we need;
- delays, interruptions or failures in the manufacture and supply of our product candidates;
- the plans of our AEROSURF and KL4 licensee, Lee's (HK) and Zhaoke, and their ability to successfully execute necessary clinical and business development activities in a timely manner, if at all, to support development and commercialize the licensed product candidates;
- the performance of third parties, both foreign and domestic, upon which we depend, including contract research organizations, contract manufacturing organizations, contract laboratories, and independent contractors;
- the size and growth of the potential markets for our product candidates, the regulatory requirements in such markets, the rate and degree of market acceptance of our product candidates, and our ability to serve those markets;
- the success of competing therapies and products that are or may become available;

- our ability to limit our exposure under product liability lawsuits;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- recently enacted and future legislation, including but not limited to, the Inflation Reduction Act of 2022, regarding the healthcare system in the U.S. or the healthcare systems in foreign jurisdictions;
- our ability to recruit or retain key scientific, commercial or management personnel or to retain our executive officers;
- our ability to secure electronically stored work product, including clinical data, analyses, research, communications, and other materials necessary to gain regulatory approval of our product candidates, including those acquired from third parties, and assure the integrity, proper functionality, and security of our internal computer and information systems and prevent or avoid cyber-attacks, malicious intrusion, breakdown, destruction, security incidents, data privacy violations, or other significant disruption;
- economic uncertainty resulting from inflation and the rapid increase in interest rates, including concerns involving liquidity, defaults or other non-performance by financial institutions;
- economic uncertainty resulting from geopolitical instability, including the ongoing military conflict between Russia and Ukraine, the People's Republic of China and the Republic of China (Taiwan); and
- other risks and uncertainties, including those described or incorporated by reference under the caption "Risk Factors" in this prospectus.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts, and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section entitled "Risk Factors" in this prospectus and the risk factors set forth in the documents incorporated by reference in this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus and the documents incorporated by reference in this prospectus completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Trademark Notice

AEROSURF®, **AFECTAIR®**, **SURFAXIN®**, **SURFAXIN LS™**, **WINDTREE THERAPEUTICS® (logo)**, **WINDTREE THERAPEUTICS™**, and **WINDTREE™** are registered and common law trademarks of Windtree Therapeutics, Inc. (Warrington, PA).

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $7.7 million, or approximately $8.9 million if the underwriters exercise their option to purchase additional shares of common stock and/or common warrants from us in full, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering and assuming no sale of the pre-funded warrants. In addition, if all of the common warrants offered pursuant to this prospectus are exercised in full for cash, we will receive approximately an additional $ in cash. We cannot predict when or if these common warrants will be exercised. It is possible that these common warrants may expire and may never be exercised.

We intend to use the net proceeds of this offering for the clinical development of istaroxime in cardiogenic shock and for working capital and other general corporate purposes. We may also use a portion of the net proceeds from this offering to in-license, acquire or invest in complementary businesses, technologies, products or assets. Although we currently have no agreements, commitments or obligations to do so, we evaluate such opportunities and engage in related discussions with third parties from time to time.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of our preclinical, clinical and future development activities may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from our planned clinical trials, our ability to take advantage of expedited programs or to obtain regulatory approval for product candidates, the timing and costs associated with the manufacture and supply of product candidates for clinical development or commercialization and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments or other securities.

DIVIDEND POLICY

We have not paid any cash dividends and we do not anticipate paying any cash dividends in the foreseeable future and we intend to retain all of our earnings, if any, to finance our growth and operations and to fund the expansion of our business. Payment of any dividends, if any, will be made in the discretion of our board of directors, or Board, after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and accompanying common warrants in this offering and the as adjusted net tangible book value per share of our common stock after the closing of this offering.

Our historical net tangible book value as of December 31, 2022 was $(18.3) million, or $(23.69) per share of our common stock, based on 772,202 shares of common stock outstanding as of December 31, 2022 (giving effect to the one-for-fifty (1-50) reverse stock split). Our historical net tangible book value represents our total tangible assets less total liabilities. Historical net tangible book value per share is our historical net tangible book value divided by the number of shares of our common stock outstanding as of December 31, 2022.

After giving effect to the sale of 1,948,051 shares of our common stock and common warrants to purchase up to 1,948,051 shares of our common stock in this offering at an assumed public offering price of $4.62 per share (which was the last reported sale price of our common stock on the Nasdaq Capital Market on April 4, 2023) and accompanying common warrant, assuming no sale of any pre-funded warrants, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2022 would have been $(10.6) million, or $(3.90) per share. This represents an immediate increase in as adjusted net tangible book value of $19.79 per share to our existing stockholders and an immediate dilution of $8.52 per share to investors purchasing our common stock and common warrants in this offering at the assumed combined public offering price. The final public offering price will be determined through negotiation between us and the underwriters in the offering and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price.

The following table illustrates this dilution on a per share basis:

Assumed combined public offering price per share of common stock and accompanying common warrant		$ 4.62
Historical net tangible book value per share as of December 31, 2022	$ (23.69)	
Increase in net tangible book value per share as of December 31, 2022 attributable to investors purchasing shares in this offering	19.79	
As adjusted net tangible book value per share as of December 31, 2022 after giving effect to this offering		(3.90)
Dilution per share to investors participating in this offering		$ 8.52

Each $1.00 increase or decrease in the assumed public offering price of $4.62 per share, the last reported sale price of our common stock on the Nasdaq Capital Market on April 4, 2023, would increase or decrease our as adjusted net tangible book value per share after this offering by $0.66 per share. For each $1.00 increase or decrease in the assumed public offering price, the dilution per share to investors participating in this offering would increase or decrease by $0.34 per share, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase of 200,000 shares of common stock offered by us would increase the as adjusted net tangible book value after this offering by $0.56 per share and decrease the dilution per share to investors participating in this offering by $0.56 per share, and a decrease of 200,000 shares of common stock offered by us would decrease the as adjusted net tangible book value by $0.64 per share and increase the dilution per share to investors in this offering by $0.64 per share, assuming that the assumed public offering price remains the same, and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise in full their option to purchase additional shares and/or common warrants, our as adjusted net tangible book value per share after this offering would be $(3.11) per share, representing an immediate increase in as adjusted net tangible book value per share of $20.58 to existing stockholders and immediate dilution of $7.73 in as adjusted net tangible book value per share to investors purchasing common stock in this offering.

The foregoing discussion and tables above are based on 772,202 shares of common stock outstanding as of December 31, 2022, assume no exercise of any warrants and no exercise by the underwriters of their option to purchase additional shares of our common stock and/or common warrants, and excludes:

- 330,927 shares of our common stock issuable upon the exercise of outstanding warrants as of December 31, 2022, with a weighted-average price of $332.02 per share;

- 77,559 shares of our common stock issuable upon the exercise of outstanding stock options as of December 31, 2022, with a weighted-average exercise price of $381.24 per share;

- 11,162 shares of our common stock issuable upon the exercise of outstanding restricted stock units as of December 31, 2022, with a weighted-average grant date fair value of $49.68 per share; and

- 11,786 shares of our common stock reserved for future issuance under our 2020 Plan, as amended, plus any future increases in the number of shares of common stock reserved for issuance.

To the extent that any outstanding warrants or options are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares in the future, there will be further dilution to new investors participating in this offering. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or equity-based securities, the issuance of these securities could result in further dilution to our stockholders.

EXECUTIVE AND DIRECTOR COMPENSATION

NAMED EXECUTIVE OFFICERS

Our named executive officers, or NEOs, for the year ended December 31, 2022, which consists of our principal executive officer and our two other most highly compensated executive officers, are:

- Craig E. Fraser, our President and CEO;
- John P. Hamill, our former Senior Vice President, CFO, and Corporate Secretary; and
- Steven G. Simonson, M.D., our Senior Vice President and CMO.

This section discusses the material components of the executive compensation program for our NEOs.

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our NEOs for services rendered during the years ended December 31, 2021 and 2022.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Craig E. Fraser	2022	544,600	—	170,238	216,922	9,150	940,910
President and CEO	2021	479,931	95,986	-	1,292,545	8,700	1,877,162
John P. Hamill	2022	398,017	—	67,626	86,283	9,150	561,076
Former Senior VP, CFO, and Corporate Secretary	2021	380,175	83,639	-	270,690	8,700	743,204
Steven G. Simonson, M.D.	2022	434,952	—	67,626	86,283	11,150	600,011
Senior VP and CMO	2021	418,193	85,311	-	507,995	10,800	1,022,299

(1) Represents the aggregate grant date fair value of restricted stock unit awards, or RSUs, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718, Stock Compensation, or ASC Topic 718, and does not take into account estimated forfeitures related to service-based vesting conditions, if any. The valuation assumptions used in calculating these values are discussed in Note 11 of the Audited Consolidated Financial Statements of our Annual Report on Form 10-K for the year ended December 31, 2022. These amounts do not represent actual amounts paid or to be realized. Amounts shown are not necessarily indicative of values to be achieved, which may be more or less than the amounts shown as awards are subject to time-based vesting.

(2) Represents the aggregate grant date fair value of option awards computed in accordance with ASC Topic 718 and does not take into account estimated forfeitures related to service-based vesting conditions, if any. The valuation assumptions used in calculating these values are discussed in Note 11 of the Audited Consolidated Financial Statements of our Annual Report on Form 10-K for the year ended December 31, 2022. These amounts do not represent actual amounts paid or to be realized. Amounts shown are not necessarily indicative of values to be achieved, which may be more or less than the amounts shown as awards are subject to time-based vesting.

(3) Reflects matching contributions under our 401(k) Plan, and, with respect to Dr. Simonson, includes $2,000 for the Company's funding of a health savings account in 2022 and $2,100 for a car allowance in 2021.

Narrative Disclosure to Summary Compensation Table

Elements of Compensation

The compensation of our NEOs generally consists of base salary, annual cash bonus opportunities, long term incentive compensation in the form of equity awards and other benefits, as described below.

Base Salary

The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the NEO's skill set, experience, role, responsibilities, and contributions.

Annual Cash Bonus Opportunities

The performance-based cash bonus opportunity for each of our NEOs is expressed as a percentage of the applicable NEO's base salary that can be achieved at a target level by meeting predetermined corporate and individual performance objectives. Each executive's target bonus for the year is set forth in their employment agreements, as may be amended by the compensation committee from time to time. For 2022, our compensation committee and Board determined that each NEO's performance bonus should be based principally on contribution towards the achievement of corporate goals. These goals primarily included research and development, financial, and positioning and awareness objectives. The compensation committee established that the 2022 annual target bonus amount for Mr. Fraser be targeted at 50% of his base salary and for Dr. Simonson and Mr. Hamill be targeted at 40% of their respective base salaries. No bonus payments will be made for the 2022 performance year.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our NEOs. Our Board or compensation committee approves equity grants in its discretion, which have historically been in the form of stock options or restricted stock units, or RSUs.

On March 4, 2022, the compensation committee approved grants of stock options to Messrs. Fraser and Hamill and Dr. Simonson to purchase 5,008, 1,992, and 1,992 shares of our common stock, respectively, each with a per share exercise price of $51.00. All options vest in equal annual installments on each of the first three anniversaries of the date of grant, subject to the NEO's continuous service through the relevant vesting dates; provided, however, that such stock options may be eligible to fully accelerate in vesting in connection with a termination of employment as further described in the section titled "*Executive Employment Agreements*" below. See "*Executive Compensation—Outstanding Equity Awards at Fiscal Year-End*" for more information regarding equity awards made to our NEOs.

Other Benefits

We currently provide health and welfare benefits that are available to all of our employees, including our NEOs, including health, dental, life, vision and disability insurance.

In addition, we maintain, and the NEOs participate in, our 401(k) Plan that is intended to be qualified under Section 401(a) of the Code and that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis and under which we are permitted to make discretionary employer contributions. The 401(k) Plan also includes a discretionary company match in an amount per participant equal to 50% of each participant's contribution (up to a maximum of 6% of the participant's base salary). Matching contributions were made in 2021 and 2022.

We do not maintain any defined benefit pension plans or nonqualified deferred compensation plans.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each NEO as of December 31, 2022:

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options - Exercisable (#)(1)	Number of Securities Underlying Unexercised Options - Unexercisable (#)(1)	Option Exercise Price ($)	Option Expiration Date	Number of Units of Stock That Have Not Vested (#) (2)	Market Value of Units of Stock That Have Not Vested ($)
Craig E. Fraser	02/02/16	68		6,990.00	02/02/26		
	07/28/16	13		5,310.00	07/28/26		
	03/01/17	33		3,690.00	03/01/27		
	12/24/18	8,438		633.00	12/24/28		
	03/19/19	667		645.00	03/19/29		
	01/22/21	2,865	2,865	272.00	01/22/31		
	03/04/22	1,252	3,756	51.00	03/04/32	3,338	28,373
John P. Hamill	07/20/20	2,813	1,407	349.00	07/20/30		
	01/22/21	400	800	272.00	01/22/31		
	03/04/22	498	1,494	51.00	03/04/32	1,326	11,271
Steven G. Simonson, M.D.	05/19/14	3		71,400.00	05/19/24		
	03/27/15	7		49,140.00	03/27/25		
	02/02/16	12		6,990.00	02/02/26		
	07/28/16	8		5,310.00	07/28/26		
	03/01/17	18		3,690.00	03/01/27		
	12/24/18	4,922		633.00	12/24/28		
	03/19/19	333		645.00	03/19/29		
	01/22/21	1,101	1,151	272.00	01/22/31		
	03/04/22	498	1,494	51.00	03/04/32	1,326	11,271

(1) Options granted prior to 2022 vest and become exercisable in equal installments on each of the first three anniversaries of the applicable grant date, assuming that the NEO continues to be employed with us through each vesting date. Options granted in 2022 vest and become exercisable with respect to one-twelfth of the total number of shares subject to the options on a quarterly basis (every three months) provided that the NEO remains in continuous service on each vesting date.

(2) The RSUs represent a contingent right to receive the equivalent number of shares of common stock. These RSUs shall vest with respect to one-third of the total number of shares subject to the RSUs on an annual basis (every 12 months) provided that the NEO remains in continuous service on each vesting date.

EXECUTIVE EMPLOYMENT AGREEMENTS

We are party to executive employment agreements, or the Executive Agreements, as amended from time to time, with each of our NEOs, the key terms of which are described below.

Mr. Fraser's Employment Agreement

We entered into an employment agreement with Mr. Fraser, effective February 1, 2016 and subsequently amended. Mr. Fraser's employment agreement provides for an annual base salary, which in 2022 was $557,300, and eligibility to receive an annual incentive-based cash bonus, which may be awarded at the discretion of the compensation committee, with a target amount equal to 50% of his base salary.

If Mr. Fraser's employment is terminated due to death or Disability (as such term is defined in the employment agreement), all equity awards held by Mr. Fraser shall become fully vested and all stock options shall continue to be exercisable for the remainder of their stated term.

If Mr. Fraser's employment is terminated by us without Cause or by Mr. Fraser for Good Reason prior to a Change of Control (as such terms are defined in the employment agreement) or after the 2nd anniversary of a Change of Control, Mr. Fraser will be eligible to receive the following, in addition to any amounts or benefits that are due under any of our vested plans or other policies, and on the condition that he enters into a separation agreement containing a final and effective plenary release of claims in a form acceptable to us, provided that all of our obligations shall cease if Mr. Fraser engages in a material breach of the employment agreement, or his restrictive covenant obligations, and fails to cure such breach within five business days after receipt from us of notice of such breach:

- A pro rata bonus equal to a percentage of Mr. Fraser's target bonus amount determined by dividing the total actual bonuses paid to other contract executives for the year in which the termination occurs by the aggregate of such other contract executives' total target bonuses for that year, and further prorated for the number of days Mr. Fraser was employed in the year of termination, payable at the time that other contract executives are paid bonuses with respect to the year of termination;

- A severance amount equal to the sum of Mr. Fraser's base salary then in effect (determined without regard to any reduction constituting Good Reason) and the target bonus amount, payable in equal installments in accordance with our regular payroll schedule from the date of termination to the date that is 12 months after the date of termination, or the Severance Period;

- All vested stock options and other similar equity awards held by Mr. Fraser shall continue to be exercisable during the Severance Period; and

- During the Severance Period, if Mr. Fraser elects to continue medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985, or COBRA, we will continue to pay our costs of Mr. Fraser's and his dependents' benefits as in effect on the date of termination as such benefits are provided to active employees.

If Mr. Fraser's employment is terminated by us without Cause or by Mr. Fraser for Good Reason prior to but in connection with a Change of Control or prior to the 2nd anniversary of a Change of Control, Mr. Fraser will be eligible to receive the following, in addition to any amounts or benefits that are due under any of our vested plans or other policies, and on the condition that he enters into a separation agreement containing a final and effective plenary release of claims in a form acceptable to us, provided that all of our obligations shall cease if Mr. Fraser engages in a material breach of the employment agreement, or his restrictive covenant obligations, and fails to cure such breach within five business days after receipt from us of notice of such breach:

- A pro rata bonus equal to Mr. Fraser's target bonus amount and prorated for the number of days Mr. Fraser was employed in the year of termination, payable in a lump sum within 10 days after the date of termination;

- A severance amount equal to 1.5 times the sum of Mr. Fraser's base salary then in effect (determined without regard to any reduction constituting Good Reason) and the target bonus amount, payable in a lump sum within 10 days after the date of termination except in certain limited circumstances;

- All equity awards held by Mr. Fraser shall accelerate and become fully vested and all stock options shall continue to be exercisable for the remainder of their stated terms; and

- For a period of 18 months following the termination date, if Mr. Fraser elects to continue medical benefits through COBRA, we will continue to pay our costs of Mr. Fraser and his dependents' benefits as in effect on the date of termination as such benefits are provided to active employees.

In addition, upon a Change of Control, for a period of 24 months after the date of the Change of Control and provided that Mr. Fraser is employed on the last day of a fiscal year ending in that period, Mr. Fraser will be entitled to an annual bonus at least equal to Mr. Fraser's target bonus amount, payable no later than March 15 in the next succeeding fiscal year.

Mr. Fraser's employment agreement includes 12-month post-employment non-competition and non-solicitation covenants and provides for confidentiality and the assignment to us of all intellectual property.

Mr. Hamill's Employment Agreement

We are a party to an employment agreement with Mr. Hamill, which was effective July 20, 2020. Mr. Hamill's employment agreement provides for an annual base salary, which in 2022 was $401,400, and an annual incentive-based cash bonus, which may be awarded at the discretion of the compensation committee, with a target amount equal to 40% of his annual base salary.

The employment agreement provides for Mr. Hamill to receive severance upon termination without Cause or by Mr. Hamill with Good Reason (as such terms are defined in the employment agreement) of (a) continued payment of base salary and subsidized COBRA benefits for 12 months following termination, (b) any earned but unpaid annual bonus for the fiscal year preceding Mr. Hamill's date of termination and a pro rata bonus equal to the annual bonus Mr. Hamill would have earned absent his separation (as defined in the employment agreement) which amount shall be paid when our other executives are paid, and (c) during the 12-month period following termination, all vested stock options and similar equity awards held by Mr. Hamill shall continue to be exercisable (such benefits the Hamill Severance Benefits).

If Mr. Hamill is terminated by us without Cause or Mr. Hamill terminates his employment with Good Reason within 24 months after a Change of Control (as defined in the employment agreement), the employment agreement further provides Mr. Hamill with severance, or the Hamill Change of Control Severance Benefits, consisting of any earned but unpaid annual bonus for the fiscal year preceding the date of Mr. Hamill's termination, a lump sum equal to one and one-half times Mr. Hamill's base salary and annual bonus amount paid in a lump sum within 10 days after the date of termination, 18 months of COBRA benefits, full vesting and acceleration of Mr. Hamill's equity awards upon the date of Mr. Hamill's termination and the continued exercisability of Mr. Hamill's equity awards for the remainder of their stated terms.

Mr. Hamill's receipt of the Hamill Severance Benefits or the Hamill Change of Control Severance Benefits, as applicable, is conditioned on his execution of a separation and release agreement in a form acceptable to us. The employment agreement further provides that in the event of a Change of Control transaction, all of Mr. Hamill's outstanding equity incentive awards will become fully vested so long as Mr. Hamill is actively employed by us at the time of such transaction. In the case of a termination of Mr. Hamill's employment due to death or disability, all shares of stock and all options shall become fully vested and any earned but unpaid annual bonus for the fiscal year preceding the termination date would be paid.

In January 2023, Mr. Hamill resigned as Chief Financial Officer. Pursuant to the terms of Mr. Hamill's employment agreement, upon his resignation, Mr. Hamill was eligible to receive all salary payable to him through the date of his resignation, as well as any other benefits as set forth in his employment agreement.

Dr. Simonson's Employment Agreement

We are a party to an employment agreement with Dr. Simonson, which was effective December 19, 2014, as subsequently amended on December 29, 2014 and March 13, 2018. Dr. Simonson's employment agreement provides for an annual base salary, which in 2022 was $438,100, and an annual incentive-based cash bonus, which may be awarded at the discretion of the compensation committee, with a target amount equal to 40% of his annual base salary.

The employment agreement provides for Dr. Simonson to receive severance (upon termination without Cause or by Dr. Simonson with Good Reason (as such terms are defined in the employment agreement)) of (a) continued payment of base salary and subsidized COBRA benefits for 12 months following termination, (b) a pro rata bonus equal to a percentage of Dr. Simonson's target bonus amount determined by dividing the total actual bonuses paid to other contract executives for the year in which the termination occurs by the aggregate of such other contract executives' total target bonuses for that year, and further prorated for the number of days Dr. Simonson was employed in the year of termination, payable at the time that other contract executives are paid bonuses with respect to the year of termination, and, (d) during the 12-month period following termination, all vested stock options and similar equity awards held by Dr. Simonson shall continue to be exercisable (such benefits, the Simonson Severance Benefits).

If Dr. Simonson is terminated by us without Cause or Dr. Simonson terminates his employment with Good Reason within 24 months of a Change of Control (as defined in the employment agreement), the employment agreement further provides Dr. Simonson with severance, or the Simonson Change of Control Severance Benefits, consisting of a lump sum equal to one and one-half times Dr. Simonson's base salary and annual bonus amount paid in a lump sum within 10 days after the date of termination, a pro rata bonus equal to Dr. Simonson's target bonus amount prorated for the number of days Dr. Simonson was employed in the year of termination, payable in a lump sum within 10 days after the date of termination, 18 months of COBRA benefits, full vesting and acceleration of Dr. Simonson's equity awards upon the date of Dr. Simonson's termination and the continued exercisability of Dr. Simonson's equity awards for the remainder of their stated terms.

Dr. Simonson's receipt of the Simonson Severance Benefits or the Simonson Change of Control Severance Benefits, as applicable, is conditioned on his execution of a separation and release agreement in a form acceptable to us. In the case of a termination of Dr. Simonson's employment due to death or disability, all shares of stock and all options shall become fully vested and any earned but unpaid annual bonus for the fiscal year preceding the termination date would be paid.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table describes as of December 31, 2022 the number of shares of our common stock issuable upon exercise of outstanding awards under our 2020 and 2011 Plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)(1)	Number of securities available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders			
2020 Long-Term Incentive Plan	50,293	$ 135.02	11,786
2011 Long-Term Incentive Plan (2)	29,140	683.94	—
Equity compensation plans not approved by security holders (3)			
Inducement Grants (4)	9,288	306.50	—
Total	**88,721**	**$ 333.26**	**11,786**

(1) Represents the weighted-average exercise price of outstanding stock options and does not include RSUs.
(2) The 2011 Plan terminated on the effective date of the 2020 Plan. All shares that were available under the 2011 Plan, including any that are expired, forfeited or otherwise returnable to the 2011 Plan are transferred to and become available for grant under the 2020 Plan. All awards granted under the 2011 Plan continue to be governed by the terms of the 2011 Plan and the award agreements.
(3) Our board of directors has not established any specific number of shares that could be issued without stockholder approval. Inducement grants to new key employees are determined on a case-by-case basis. Other than possible inducement grants, we expect that all equity awards will be made under stockholder-approved plans.
(4) Reflects grants of stock options to purchase 9,288 shares of common stock that were "inducement grants" as defined under Nasdaq Listing Rule 5635(c)(4).

DIRECTOR COMPENSATION

We have designed and implemented our compensation program for our non-employee directors to attract, motivate and retain individuals who are committed to our values and goals and who have the expertise and experience that we need to achieve those goals.

Directors who are also employees are not compensated separately for serving on the Board or any of its committees. Each of our non-employee directors receives cash compensation for his or her services. The compensation committee periodically conducts reviews of peer company director compensation practices, including before considering changes to our director compensation policy and amounts. In addition, to better align the interests of our Board with our stockholders, the compensation committee considers and recommends to the Board long-term equity compensation.

Non-Employee Director Compensation Policy

Pursuant to our Non-Employee Director Compensation Policy in place during 2022, our directors received annual cash retainers, paid on a quarterly basis. Each non-employee director received a quarterly retainer of $10,000. The Chairman of the Board received an additional $6,250 per quarter, in addition to the $10,000 quarterly retainer for all non-employee directors. Non-employee directors serving on committees of our Board also received additional cash retainers as set forth in the table below.

Non-Employee Director Compensation Policy

		Cash Retainer ($)
Board Member		10,000
Board Chair		6,250
Audit Committee		
Chair		3,750
Member		1,750
Compensation Committee		
Chair		2,500
Member		1,250
Nominating and Corporate Governance Committee		
Chair		1,875
Member		1,000
	Equity Retainer	
Initial Equity Grant	Option to purchase 600 shares of common stock, vesting in three equal annual installments, beginning on the first anniversary of the grant date and subject to the director's continued service on the Board	
Annual Equity Grant	Option to purchase 300 shares of common stock, vesting in three equal annual installments, beginning on the first anniversary of the grant date and subject to the director's continued service on the Board	

Cash fees are paid quarterly and are typically pro-rated for non-employee directors who do not serve a full quarter. Our non-employee directors are also reimbursed for their business-related expenses incurred in connection with attendance at Board and Committee meetings and related activities. Our only employee director, Mr. Fraser, receives no separate compensation for his service in such capacity.

2022 Director Compensation

The following table summarizes information concerning the compensation awarded to, earned by, or paid for services rendered in all capacities by our non-employee directors during the year ended December 31, 2022.

Name of Non-Employee Director	Fee Earned or Paid in Cash ($) (*)	Stock Awards ($)(1)	Option Awards ($)(2)	Total ($)
James Huang	65,000	2,350	2,994	70,344
Daniel E. Geffken	60,000	2,350	2,994	65,344
Evan Loh, M.D. (3)	28,500	—	—	28,500
Leslie Williams	54,500	2,350	2,994	59,844
Robert Scott, M.D.	55,000	2,350	2,994	60,344

(1) Represents the aggregate grant date fair value of RSUs computed in accordance with ASC Topic 718 and does not take into account estimated forfeitures related to service-based vesting conditions, if any. The valuation assumptions used in calculating these values are discussed in Note 11 of the Audited Consolidated Financial Statements of our Annual Report on Form 10-K for the year ended December 31, 2022. These amounts do not represent actual amounts paid or to be realized. Amounts shown are not necessarily indicative of values to be achieved, which may be more or less than the amounts shown as awards are subject to time-based vesting. As of December 31, 2022, Messrs. Huang and Geffken, Dr. Scott, and Ms. Williams each held RSUs to receive 100 shares of our common stock.

(2) Represents the aggregate grant date fair value of option awards computed in accordance with ASC Topic 718 and does not take into account estimated forfeitures related to service-based vesting conditions, if any. The valuation assumptions used in calculating these values are discussed in Note 11 of the Audited Consolidated Financial Statements of our Annual Report on Form 10-K for the year ended December 31, 2022. These amounts do not represent actual amounts paid or to be realized. Amounts shown are not necessarily indicative of values to be achieved, which may be more or less than the amounts shown as awards are subject to time-based vesting. As of December 31, 2022, Messrs. Huang and Geffken each held options to purchase 1,150 shares of our common stock; (ii) Dr. Scott and Ms. Williams each held options to purchase 750 shares of our common stock; and (iii) Dr. Loh held options to purchase 600 shares of our common stock.

(3) On May 9, 2022, Dr. Loh resigned from our Board.

(*) Due to cash resource constraints, we suspended payments of director fees in the fourth quarter of 2022. We plan to pay the accrued but unpaid director fees when cash resources become available. The amounts related to 2022 that are payable to our directors as of December 31, 2022 are as follows: Mr. Huang – $16,250, Mr. Geffken – $15,000, Ms. Williams – $13,625, and Dr. Scott – $15,520.

RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions, since January 1, 2021 or currently proposed, to which we were a party or will be a party, in which:

- the amounts involved exceeded $120,000; and
- any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions meeting this criteria to which we have been or will be a party other than compensation arrangements, which are described where required under the sections titled "*Management—Board Leadership Structure*" and "*Executive Compensation*" of Amendment No. 1 to our Annual Form 10-K/A, as filed with the SEC on April 29, 2022, as well the section titled "*Executive and Director Compensation*" included in this prospectus.

Our Board has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy covers any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest. Our management is responsible for determining whether a transaction is a related party transaction subject to our policy, and upon subject determination, is responsible for disclosing the material facts concerning the transaction and the related party's interest in our transaction to our Audit Committee. In reviewing and approving any such transactions, our Audit Committee is tasked to consider all relevant facts and circumstances with respect to the transaction and shall evaluate all available options, including ratification, revision or termination of the transaction. All of the transactions described above either were approved or ratified in compliance with this policy.

Since January 1, 2021, we have engaged in the following transactions with our directors, executive officers, holders of more than 5% of our voting securities, and affiliates or immediate family members of our directors, executive officers, and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Lee's Pharmaceutical Holdings Limited and Affiliates

We have received substantial support from Lee's Holdings, our largest stockholder. Lee's Holdings is a company incorporated in the Cayman Islands with limited liability, whose common stock is listed on the Hong Kong Stock Exchange. As of December 31, 2022 and 2021, Lee's Holdings' beneficial ownership of our issued and outstanding shares of common stock was 13% and 17%, respectively.

Asia License Agreement

In June 2017, we entered into a License, Development and Commercialization Agreement, or the Asia License Agreement, with Lee's (HK), an affiliate of Lee's Holdings, and thereafter amended it, effective August 2017. Under the Asia License Agreement, as amended, we granted to Lee's (HK) an exclusive license with a right to sublicense (i) to develop, manufacture, and commercialize our KL4 surfactant products, including SURFAXIN, which was approved by the FDA in 2012 for respiratory distress syndrome, or RDS, in premature infants, SURFAXIN LS™, the lyophilized dosage form of SURFAXIN, and AEROSURF, including the Aerosol Delivery System, or ADS, and (ii) to register and manufacture SURFAXIN and SURFAXIN LS for use in the licensed territory, which includes the People's Republic of China, Hong Kong, Thailand, Taiwan, and 12 other countries.

Under the Asia License Agreement, Lee's (HK) made an upfront payment to us of $1.0 million. We were also eligible to receive up to $35.8 million in potential clinical, regulatory and commercial milestone payments and would have shared in any sublicense income Lee's (HK) may receive at a rate equal to low double digits. In addition, Lee's (HK) was responsible for all costs and expenses in and for the licensed territory related to development activities, including a planned AEROSURF Phase 3 clinical program, regulatory activities, and commercialization activities.

On August 17, 2022, we entered into an Amended and Restated License, Development and Commercialization Agreement, or the A&R License Agreement, with Lee's (HK) and Zhaoke Pharmaceutical (Hefei) Co. Ltd., a company organized under the laws of the People's Republic of China, effective as of August 9, 2022. We refer to Zhaoke and Lee's (HK) together as the "Licensee." The A&R License Agreement amends, restates, and supersedes the Asia License Agreement.

Under the A&R License Agreement, we granted to Licensee an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute, and otherwise commercialize our KL4 surfactant products, including SURFAXIN®, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant, in each case for the prevention, mitigation and/or treatment of any respiratory disease, disorder, or condition in humans worldwide, except for Andorra, Greece, and Italy (including the Republic of San Marino and Vatican City), Portugal, and Spain, or the Licensed Territory, which countries are currently exclusively licensed to Laboratorios Del Dr. Esteve, S.A.

We may receive up to $78.9 million in potential clinical, regulatory, and commercial milestone payments under the A&R License Agreement. We are also entitled to receive a low double-digit percentage of Licensee's non-royalty sublicense income. Further, Licensee is solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval, and commercialization of licensed products in the Licensed Territory, including all royalties payable in respect of third-party intellectual property rights sublicensed by us to Licensee and all intellectual property prosecution, maintenance and defense activities and costs.

Project Financing Agreement

In August 2020, we entered into a Project Financing Agreement with Lee's (HK), or the PF Agreement, dated and effective as of August 12, 2020, under which we received payments totaling $2.8 million through October 2020. Pursuant to the PF Agreement, Lee's (HK) agreed to pay additional amounts to be set forth in an updated development budget to be agreed between the parties by September 1, 2020 and updated every six months thereafter, to fund the continued development of AEROSURF and to be paid with the payment schedule to be set forth in each updated development budget. In partial satisfaction of our obligations under the PF Agreement, we agreed to pay Lee's (HK) 50% of any Commercialization Net Revenues (as defined in the PF Agreement) up to an amount that is equal to 125% of the Project Expenses (as defined in the PF Agreement) funded by Lee's (HK). On November 12, 2020, Lee's (HK) provided notice of termination of additional funding under the PF Agreement, and we and Lee's (HK) revised our plans for the continued development of AEROSURF. Lee's (HK) agreed to continue the development of AEROSURF in Asia at its own cost. Lee's (HK) agreed to fund an additional $1.0 million to us in 2021 for certain transition and analytical services to be provided by us with respect to the development of AEROSURF, which will be considered "Project Expenses" under the terms of the PF Agreement. In 2021, we received payments totaling $1.0 million from Lee's (HK) and no further amounts are due under the PF Agreement as of December 31, 2021.

With the termination of the PF Agreement in November 2020, we ceased enrollment in our Phase 2b bridging study at the EU, clinical sites and transferred AEROSURF development activities to Lee's (HK) to be implemented under the terms of the A&R License Agreement.

Panacea Venture Management Company Ltd.

As of December 31, 2022 and 2021, Panacea Venture Management Company Ltd.'s, or Panacea's, beneficial ownership of our issued and outstanding shares of common stock was 9% and 8%, respectively. James Huang, who in connection with the CVie Acquisition in December 2018 was appointed as a director and Chairman of our Board, is a founding and Managing Partner to Panacea.

February 2023 Warrant Exercise Inducement Offer Letter

On February 21, 2023, we entered into a warrant exercise inducement offer letter with Panacea Venture Healthcare Fund I, L.P., a holder of certain of our: (i) warrants issued in July 2018 to purchase 1,250 shares of common stock with an exercise price of $600.00 per share; (ii) warrants issued in December 2018 to purchase 9,960 shares of common stock with an exercise price of $607.50 per share; (iii) warrants issued in December 2019 to purchase 5,519 shares of common stock with an exercise price of $604.50 per share; and (iv) warrants issued in May 2020 to purchase 5,517 shares of common stock with an exercise price of $398.75 per share (collectively, the February 2023 Existing Warrants).

Pursuant to the terms of the inducement letter, we agreed to amend the February 2023 Existing Warrants by lowering the exercise price of the February 2023 Existing Warrants to $7.06 per share. Additionally, the exercising holder agreed to exercise for cash all of their February 2023 Existing Warrants to purchase an aggregate of 22,246 shares of common stock in exchange for our agreement to issue to such exercising holder new warrants, or the February 2023 New Warrants, to purchase up to an aggregate of 44,492 shares of common stock. We received aggregate gross proceeds of approximately $157,000 from the exercise of the February 2023 Existing Warrants by the exercising holders.

Other Transactions

We have granted stock options to our NEOs and certain of our directors. See "*Item 11. Executive Compensation—Outstanding Equity Awards at Fiscal Year-End*" of our Definitive Proxy Statement on Schedule 14A, filed with the SEC on May 11, 2022, for a description of these grants.

We have entered into change of control and severance agreements with certain of our executive officers that provide for certain severance and change in control benefits. See "*Item 11. Executive Compensation—Executive Employment Agreements*" of our Definitive Proxy Statement on Schedule 14A, filed with the SEC on May 11, 2022 for more information.

During 2022, we incurred $0.4 million in research and development expenses for services provided by an affiliate of Lee's Holdings to our wholly owned subsidiary, CVie Therapeutics.

On December 31, 2021, we entered into a Master Manufacturing and Supply Agreement with an affiliate of Lee's Holdings for the manufacture of our istaroxime drug product candidate.

Control by Officers and Directors

Our officers and directors and their affiliates beneficially own, in the aggregate, approximately 16.60% of our outstanding common stock as of March 31, 2023. As a result, in certain circumstances, these stockholders acting together may be able to determine matters requiring approval of our stockholders, including the election of our directors, or they may delay, defer or prevent a change in control.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. These indemnification agreements, our amended and restated Certificate of Incorporation, as amended, or our Amended and Restated Certificate of Incorporation, and our By-Laws, require us to indemnify directors to the fullest extent permitted by Delaware law.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Based solely upon information made available to us, the following table sets forth information as of March 31, 2023, regarding the beneficial ownership of our common stock by:

- each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock;
- each of our NEOs and directors; and
- all of our executive officers as a group.

The percentage of common stock outstanding is based on 909,013 shares of our common stock outstanding as of March 31, 2023. For purposes of the table below, and in accordance with the rules of the SEC, we deem shares of common stock subject to options that are currently exercisable or exercisable within sixty days of March 31, 2023 to be outstanding and to be beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise noted, each of the persons or entities in this table has sole voting and investing power with respect to all of the shares of common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise noted below, the street address of each beneficial owner is c/o Windtree Therapeutics, Inc. 2600 Kelly Road, Suite 100, Warrington, PA 18976.

Name Of Beneficial Owner	Number Of Shares Of Common Stock	Percentage Of Common Stock
5% or Greater Stockholders		
Lee's Pharmaceutical Holdings Limited(1) 1/F, Building 20E, Phase 3, Hong Kong Science Park, Shatin, Hong Kong	107,189	11.65%
Panacea Venture Healthcare Fund I L.P.(2) #6 Lane 1350 Middle Fuxing Rd., Xuhui District, Shanghai, China 200319	68,983	7.59%
NEOs and Directors		
James Huang(3)	75,609	8.31%
Daniel Geffken(4)	882	*
Robert Scott, M.D.(5)	400	*
Leslie J. Williams(5)	400	*
Craig E. Fraser(6)	17,715	1.92%
Steven G. Simonson, M.D.(7)	8,559	*
All executive officers and directors as a group (8 persons)	110,152	12.07%

* Less than 1%

(1) Includes 96,337 shares of common stock and 446 Series A-1 Warrants to purchase 446 shares of common stock held directly by Lee's Holdings exercisable within 60 days of March 31, 2023, 903 Series C warrants to purchase 903 shares of common stock exercisable within 60 days of March 31, 2023, 3,984 Series G Warrants to purchase 3,984 shares of common stock exercisable within 60 days of March 31, 2023 and 5,519 Series I Warrants to purchase 5,519 shares of common stock exercisable within 60 days of March 31, 2023, held by LPH II Investments Limited, or LPH II. Lee's Holdings may be deemed to have beneficial ownership of the shares held by LPH II due to its ownership of 100% of LPH II. LPH II is currently unable to exercise the Series C and G warrants due to an ownership cap restriction, and Lee's Holdings Series A-1 Warrants are subject to a 9.99% ownership cap. The Series I Warrants are subject to a 4.99% ownership cap (or such other percentage as designated by each holder not to exceed 19.99%). Other than for purposes of Rule 13d-3 of the Act, Lee's Holdings disclaims beneficial ownership of the shares of common stock and warrants, as applicable, except to the extent of its pecuniary interest therein, as applicable. Mses. Lee Siu Fong and Leelalertsuphakun Wanee are executive directors, Dr. Li Xiaoyi is an executive director and the Chief Executive Officer, Mr. Simon Miles Ball is a non-executive director, and Drs. Chan Yau Ching (Bob) and Tsim Wah Keung (Carl) and Mr. Lam Yat Cheong are the independent directors, of Lee's Holdings, or the Lee's Holdings Directors. The Lee's Holdings Directors and the shareholders of Lee's Holdings have shared voting and investment power over the shares held by Lee's Holdings. The address for Lee's Holdings and LPH II is 1/F, Building 20E, Phase 3, Hong Kong Science Park, Shatin, Hong Kong.

(2) Includes 68,983 shares of common stock held by Panacea Venture Healthcare Fund I, L.P., or the Panacea Fund. Panacea Venture Healthcare Fund GP I, L.P. or the Immediate GP, is the general partner of the Panacea Fund, Panacea Venture Healthcare Fund GP Company, Ltd., or the Parent GP, is the general partner of the Immediate GP, and Panacea Venture Management Company Ltd., or the Management Company, is the management company of the Immediate GP. The Management Company, the Panacea Fund, the Immediate GP and the Parent GP are collectively referred to as the Panacea Entities. The Management Company together with the Parent GP and the Immediate GP may be deemed to have beneficial ownership over the shares of common stock held by the Panacea Fund. The Panacea Entities may be deemed to constitute a "group" within the meaning of Section 13(d)(3) of the Exchange Act. James Huang and Hai Mi serve as directors of the Parent GP and the Management Company. Mr. Huang, Hai Mi, and the shareholders of the Parent GP and Management Company have shared voting and investment power over the shares held by the Panacea Fund. Mr. Huang expressly disclaims beneficial ownership of the securities reported herein, except to the extent of his pecuniary interest therein, if any. The address of the Panacea Fund, Immediate GP, Parent GP and the Management Company is #6 Lane 1350 Middle Fuxing Rd., Xuhui District, Shanghai, China 200319.

(3) Includes 5,826 shares of common stock and options to purchase 800 shares of common stock exercisable within 60 days of March 31, 2023 held directly by Mr. Huang, and 68,983 shares of common stock held by Panacea Venture Healthcare Fund I, L.P., or the Panacea Fund. Panacea Venture Healthcare Fund GP I, L.P., or the Immediate GP, is the general partner of the Panacea Fund, Panacea Venture Healthcare Fund GP Company, Ltd., or the Parent GP, is the general partner of the Immediate GP, and Panacea Venture Management Company Ltd., or the Management Company, is the management company of the Immediate GP. The Management Company, the Panacea Fund, the Immediate GP and the Parent GP are collectively referred to as the Panacea Entities. The Management Company together with the Parent GP and the Immediate GP may be deemed to have beneficial ownership over the shares of common stock held by the Panacea Fund. The Panacea Entities may be deemed to constitute a "group" within the meaning of Section 13(d)(3) of the Exchange Act. Mr. Huang serves as a director of the Parent GP and the Management Company. Mr. Huang, Hai Mi, and the shareholders of the Parent GP and Management Company have shared voting and investment power over the shares held by the Panacea Fund. Mr. Huang serves as a director of the Immediate GP and may be deemed to beneficially own the shares held by the Panacea Fund. Mr. Huang expressly disclaims beneficial ownership of the securities reported herein of the Panacea Entities, except to the extent of his pecuniary interest therein, if any. The address of Mr. Huang is #6 Lane 1350 Middle Fuxing Rd., Xuhui District, Shanghai, China 200319.

(4) Includes 41 shares of common stock, 41 May 2020 Warrants to purchase 41 shares of common stock exercisable within 60 days of March 31, 2023 and options to purchase 800 shares of common stock exercisable within 60 days of March 31, 2023. The May 2020 Warrants are subject to a 4.99% ownership cap (or, at the election of each holder prior to the date of issuance, 9.99%), except that upon at least sixty-one (61) days' prior notice to us, each holder may increase the ownership cap after exercising such holder's May 2020 Warrants up to 9.99% (or up to 19.99% upon prior written approval by us).

(5) Includes options to purchase 400 shares of common stock exercisable within 60 days of March 31, 2023

(6) Includes 1,976 shares of common stock, 2 Series A-1 Warrants to purchase 2 shares of common stock exercisable within 60 days of March 31, 2023, 41 May 2020 Warrants to purchase 41 shares of common stock exercisable within 60 days of March 31, 2023, 30 March 2021 Warrants to purchase 30 shares of common stock exercisable within 60 days of March 31, 2023, and options to purchase 15,666 shares of common stock exercisable within 60 days of March 31, 2023. The May 2020 Warrants are subject to a 4.99% ownership cap (or, at the election of each holder prior to the date of issuance, 9.99%), except that upon at least sixty-one (61) days' prior notice to us, each holder may increase the ownership cap after exercising such holder's May 2020 Warrants up to 9.99% (or up to 19.99% upon prior written approval by us).

(7) Includes 695 shares of common stock, 1 Series A-1 Warrant to purchase 1 share of common stock exercisable within 60 days of March 31, 2023, 10 May 2020 Warrants to purchase 10 shares of common stock exercisable within 60 days of March 31, 2023, 30 March 2021 Warrants to purchase 30 shares of common stock exercisable within 60 days of March 31, 2023, and options to purchase 7,823 shares of common stock exercisable within 60 days of March 31, 2023. The May 2020 Warrants are subject to a 4.99% ownership cap (or, at the election of each holder prior to the date of issuance, 9.99%), except that upon at least sixty-one (61) days' prior notice to us, each holder may increase the ownership cap after exercising such holder's May 2020 Warrants up to 9.99% (or up to 19.99% upon prior written approval by us).

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation, which has been publicly filed with the SEC. See "Where You Can Find Additional Information and Incorporation of Certain Information by Reference."

Capital Stock

Our authorized capital stock consists of 120,000,000 shares of common stock, par value $0.001 per share and 5,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. The affirmative vote of the voting power of the outstanding shares of capital stock entitled to vote, voting as a single class, will be required to amend certain provisions of our Amended and Restated Certificate of Incorporation, including the provisions relating to amending our By-Laws, procedures for our stockholder meetings, director liability, and exclusive forum for proceedings.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our Board out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. In the event of a liquidation, dissolution or winding up of us, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Number of Holders

There are approximately 38 holders of our common stock as of March 31, 2023.

Preferred Stock

Our Board currently has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock by us could adversely affect the voting power of holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon a liquidation of us. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of us or other corporate action.

Anti-takeover provisions

Amended and Restated Certificate of Incorporation and By-Laws

Among other things, our Amended and Restated Certificate of Incorporation and By-Laws:

- permit our Board to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our Board;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may be removed for cause or without cause, which removal may be effected, by the affirmative vote of a majority of the votes of the issued and outstanding shares of stock entitled to vote for the election of the stockholders called and held for that purpose, or by a majority vote of the Board at a meeting called for such purpose, and the vacancy in the Board caused by any such removal may be filled by such stockholders or directors, as the case may be, at such meeting, and if the stockholders shall fail to fill such vacancy, such vacancy shall be filled in the manner as provided by the By-Laws;
- provide that all vacancies, including newly created directorships, may be filled by the decision of majority of the directors then in office, including those who have so resigned, and shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this Section for the filling of other vacancies;
- provides that stockholders may act via a consent of stockholders in lieu of a meeting without prior notice and without a vote, if a consent or consents in writing, set forth the action so taken, and is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Company by delivery to its registered office in this State, its principal place of business, or an officer or agent of the Company having custody of the book in which proceedings of meetings of stockholders are recorded;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- provide that special meetings of our stockholders may be called only by the Board, the Chairman of the Board, or the Chief Executive Officer; and
- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The amendment of any of these provisions would require the affirmative vote of the majority of voting power of the outstanding shares of capital stock entitled to vote.

The combination of these provisions makes it more difficult for our stockholders to replace our Board as well as for another party to obtain control of us by replacing our Board. Because our Board has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our Board and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our Company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the Board of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the Board and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 662⁄3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

A Delaware corporation may "opt out" of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Choice of Forum

Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for the following claims or causes of action brought under Delaware statutory or common law: (1) any derivative claim or action brought on our behalf; (2) any claim or cause of action asserting a breach of fiduciary duty by any of our directors or officers; (3) any claim or cause of action asserting a claim against us arising out of, or pursuant to, the DGCL, our Amended and Restated Certificate of Incorporation or our By-Laws; or (4) any action asserting a claim against the Company governed by the internal affairs doctrine.

Limitations of Liability and Indemnification

Our Amended and Restated Certificate of Incorporation and our By-Laws limit our directors' liability and may indemnify our directors and officers to the fullest extent permitted under the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payment of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper benefit.

The DGCL and our By-Laws provide that we will, in certain situations, indemnify our directors and officers, to the fullest extent permitted by law.

We have entered into indemnification agreements with our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. Subject to certain limitations, our indemnification agreements also require us to advance expenses incurred by our directors and officers for the defense of any action for which indemnification is required or permitted.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our Amended and Restated Certificate of Incorporation, our By-Laws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our Amended and Restated Certificate of Incorporation and By-Laws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

At present, there is no material pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened material litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act, and is therefore unenforceable.

Listing

Our common stock is listed on the Nasdaq Capital Market under the trading symbol "WINT".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

DESCRIPTION OF THE SECURITIES WE ARE OFFERING

Common Stock to be Issued as Part of this Offering

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described above under the sections "*Description of Capital Stock—Common Stock*," and "*Description of Capital Stock—Preferred Stock*" of this prospectus.

Warrants to be Issued as Part of this Offering

Common warrants

The common warrants will be issued in a form filed as an exhibit to the registration statement of which this prospectus is a part. You should review a copy of the form of common warrant for a complete description of the terms and conditions applicable to the common warrants.

Pursuant to a warrant agency agreement between us and Continental Stock Transfer and Trust Company, as warrant agent, the common warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. The following is a brief summary of the common warrants and is still subject in all respect to the provisions contained in the form of common warrant.

Duration and Exercise Price

Each whole common warrant will have an exercise price of $ per share, will be immediately exercisable upon issuance and will expire on the fifth anniversary of the date of issuance. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

The common warrants will be issued separately from the common stock and pre-funded warrants included in this offering. Each share of our common stock or pre-funded warrant purchased in this offering will include one common warrant to purchase one share of our common stock.

Exercisability

The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below in "——*Certain Adjustments*"). A holder may not exercise any portion of the common warrant to the extent that the holder would beneficially own more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the outstanding common stock after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants.

Certain Adjustments

The exercise price and the number of shares issuable upon exercise of the common warrants is subject to appropriate adjustment in the event of stock splits, stock dividends, recapitalizations, reorganizations, schemes, arrangements or similar events affecting our common stock. The common warrant holders must pay the exercise price in cash or wire transfer of immediately available funds upon exercise of the common warrants, unless such holders are utilizing the cashless exercise provision of the common warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. We intend to use commercially reasonable best efforts to have the registration statement of which this prospectus forms a part, effective when the common warrants are exercised.

Fundamental Transactions

In the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common stock is converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the common warrants. Additionally, as more fully described in the common warrant, in the event of certain fundamental transactions, the holders of the common warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the common warrants on the date of consummation of such transaction.

Transferability

Subject to applicable laws and the restriction on transfer set forth in the common warrant, the common warrant may be transferred at the option of the holder upon surrender of the common warrant to us together with the appropriate instruments of transfer.

Exchange Listing

There is no established trading market for the common warrants. In addition, we do not intend to apply for the listing of the common warrants on any national securities exchange. Without an active trading market, the liquidity of the common warrants will be limited.

Right as a Stockholder

Except as otherwise provided in the common warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

Waivers and Adjustments

Subject to certain exceptions, any terms of the common warrants may be amended or waived with our written consent and the written consent of the holder.

Pre-Funded warrants

The pre-funded warrants will be issued in a form filed as an exhibit to the registration statement of which this prospectus is a part. You should review a copy of the form of pre-funded warrant for a complete description of the terms and conditions applicable to the pre-funded warrants.

Duration and Exercise Price

The pre-funded warrants offered hereby will have an exercise price of $0.001 per share. The pre-funded warrants will be immediately exercisable upon issuance and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise prices and numbers of shares of common stock issuable upon exercise are subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The pre-funded warrants will be issued in certificated form only.

Exercisability

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise. A holder (together with its affiliates) may not exercise any portion of such holder's pre-funded warrants to the extent that the holder would own more than 4.99% (or 9.99%, at the holder's election) of our outstanding common stock immediately after exercise, except that upon notice from the holder to us, the holder may decrease or increase the limitation of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants, provided that any increase in such limitation shall not be effective until 61 days following notice to us.

Fundamental Transactions

In the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common stock is converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the pre-funded warrants.

Transferability

Subject to applicable laws and the restriction on transfer set forth in the pre-funded warrant, the pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Exchange Listing

There is no established trading market for the pre-funded warrants. In addition, we do not intend to apply for the listing of the pre-funded warrants on any national securities exchange. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Right as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Waivers and Adjustments

Subject to certain exceptions, any terms of the pre-funded warrants may be amended or waived with our written consent and the written consent of the holder.

UNDERWRITING

We are offering the securities described in this prospectus through the underwriters named below. We have entered into an underwriting agreement dated , 2023 with Ladenburg Thalmann & Co. Inc., as the representative of the underwriters in this offering. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase the number of our securities set forth opposite its name below.

Underwriters	Number of Shares	Number of Pre-Funded Warrants	Number of Common Warrants
Ladenburg Thalmann & Co. Inc.			
Total			

A copy of the underwriting agreement will be filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriters that they propose to offer the shares of common stock, pre-funded warrants, if any, and common warrants directly to the public at the public offering price set forth on the cover page of this prospectus. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of $ per share of common stock (or per pre-funded warrant) and $ per common warrant to purchase shares of common stock.

The underwriting agreement provides that the underwriters' obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriters that would permit a public offering of the securities in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

	Per Share and Accompanying Common Warrant (1)	Per Pre-Funded Warrant and Accompanying Common Warrant (1)	Total Without Over-Allotment	Total With Full Over-Allotment
Public offering price	$	$	$	$
Underwriting discounts and commissions(2)(3)	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

(1) The public offering price and underwriting discount corresponds, in respect of the securities of (i) a public offering price per share of common stock (or pre-funded warrant) of $ ($ net of the underwriting discount) and (ii) a public offering price per common warrant of $ ($ net of the underwriting discount).

(2) We have also agreed to pay the representative a management fee equal to 1.0% of the aggregate gross proceeds received from the sale of the securities in the transaction and reimburse the accountable expenses of the representative, including a pre-closing expense allowance of up to a maximum of $15,000 and an additional closing expense allowance up to a maximum of $95,000.
(3) We have granted a 45-day option to the underwriters to purchase up to 292,207 additional shares of common stock and/or additional common warrants exercisable for up to an additional 292,207 shares of common stock at the assumed public offering price per share of common stock and the assumed public offering price per common warrant set forth above less the underwriting discounts and commissions solely to cover over- allotments, if any.

We estimate the total expenses payable by us for this offering to be approximately $1.3 million, which amount includes (i) the underwriting discount of $720,000, (ii) the management fee of $90,000, (iii) reimbursement of the accountable expenses of the underwriters, including the legal fees of the representative, in an amount not to exceed $110,000 and (iv) other estimated company expenses of approximately $380,000, which includes legal, accounting, printing costs and various fees associated with the registration and listing of our securities.

The securities we are offering are being offered by the underwriters subject to certain conditions specified in the underwriting agreement.

Over-allotment Option

We have granted to the underwriters an option exercisable not later than 45 days after the date of this prospectus to purchase up to an additional 292,207 shares of common stock and/or 292,207 common warrants at the assumed public offering price per share of common stock and the public offering price per common warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover overallotments, if any, made in connection with this offering. If any additional shares of common stock and/or common warrants are purchased, the underwriters will offer these shares and/or common warrants on the same terms as those on which the other securities are being offered.

Right of First Refusal

We have granted to Ladenburg Thalmann & Co. Inc. the right of first refusal for a period of twelve months following the closing of this offering to act as sole bookrunner, exclusive placement agent or exclusive sales agent in connection with any financing of the Company, subject to certain conditions.

Tail Financing Payments

We have also agreed to pay the representative a tail fee equal to 8% of the total gross proceeds received by us from any investor who was contacted by the representative during the term of its engagement, if such investor provides us with capital in any public or private offering or other financing or capital raising transaction for a period of twelve months after expiration or termination of the engagement with the representative; provided however, we shall not be required to pay any such tail fee in respect of proceeds received by us from certain excluded investors agreed upon between us and the representative.

Listing

Our shares of common stock are listed on The Nasdaq Capital Market under the symbol “WINT.”

The last reported sale price of our shares of common stock on April 4, 2023 was $4.62 per share. The final public offering price will be determined between us, the underwriters and the investors in the offering, and may be at a discount to the current market price of our common stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price. There is no established public trading market for the warrants, and we do not expect such a market to develop. In addition, we do not intend to apply for a listing of the warrants on any national securities exchange or other nationally recognized trading system.

Lock-up Agreements

Each of our officers, directors and each of their respective affiliates and associated partners, and certain affiliated stockholders have agreed with the underwriters to be subject to a lock-up period of 75 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities from the date of this prospectus for a period of 75 days following the date of this prospectus, subject to certain exceptions. Ladenburg Thalmann & Co. Inc. may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

Determination of Offering Price

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "WINT." On April 4, 2023 the closing price of our common stock was $4.62 per share. We do not intend to apply for listing of the warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriters. Among the factors that will be considered in determining the public offering price:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The public offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares of common stock or warrants sold in this offering. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the shares of common stock and warrants sold in this offering can be resold at or above the public offering price.

Stabilization, Short Positions and Penalty Bids

The underwriters may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

Other Relationships

From time to time, certain of the underwriters and their affiliates may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they will receive customary fees and commissions. The representative has received compensation in connection with advisory services provided to the company and may receive additional compensation in connection with such advisory services. The representative also acted as book-running manager in connection with our public offerings that we consummated in May 2020 and March 2021, and as warrant solicitation agent in connection with a warrant inducement transaction that we consummated in January 2023 for which it received compensation.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriters may be required to make for these liabilities.

Electronic Distribution

A prospectus in electronic format may be made available on the websites maintained by the underwriters, if any, participating in this offering and the underwriters may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the underwriters, and should not be relied upon by investors.

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Goodwin Procter LLP, Philadelphia, Pennsylvania. Certain legal matters in connection with this offering will be passed upon for the underwriters by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated balance sheet of Windtree Therapeutics, Inc. and Subsidiaries as of December 31, 2022, and the related consolidated statements of operations, changes in mezzanine equity and stockholders' equity, and cash flows for the year then ended have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference, which report includes an explanatory paragraph about the existence of substantial doubt concerning our ability to continue as a going concern. Such financial statements have been incorporated herein by reference in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated financial statements of Windtree Therapeutics, Inc. at December 31, 2021, and for the year then ended, appearing in Windtree Therapeutics, Inc.'s 2022 Annual Report (Form 10-K) for the year ended December 31, 2022 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 3 to the consolidated financial statements), included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus forms part of a registration statement on Form S-1 that we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement or the documents incorporated by reference herein and therein. For further information with respect to us and the securities that we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement and the documents incorporated by reference herein and therein. You should rely only on the information contained in this prospectus or incorporated by reference herein or therein. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered hereby. We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including Windtree. The address of the SEC website is *www.sec.gov*.

We also maintain a website at *https://ir.windtreetx.com/filings/sec-filings*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus. We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023;
- our Definitive Proxy Statements on Form DEF 14A filed with the SEC on May 11, 2022 and January 10, 2023;
- our Current Reports on Form 8-K, filed with the SEC on January 19, 2023, January 26, 2023, February 8, 2023, February 22, 2023, and February 23, 2023; and
- the description of our common stock contained in Exhibit 4.18 our 2022 Annual Report on Form 10-K, including any amendments or reports filed for the purposes of updating this description.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have "furnished" to the SEC pursuant to the Exchange Act shall be incorporated by reference into this prospectus.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus but prior to the termination of the offering. These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements on Schedule 14A.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits that are specifically incorporated by reference into such documents. You should direct any requests for documents to Windtree Therapeutics, Inc., 2600 Kelly Road, Suite 100., Warrington, Pennsylvania 18976, Attn: Corporate Secretary.

You also may access these filings on our website at https://ir.windtreetx.com/filings/sec-filings. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus). You may also access these filings at the SEC's website at www.sec.gov.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

1,948,051 Shares of Common Stock and Accompanying
Common Warrants to Purchase up to 1,948,051 Shares of Common Stock
Pre-Funded Warrants to Purchase up to 1,948,051 Shares of Common Stock and
Accompanying Common Warrants to Purchase up to 1,948,051 Shares of Common Stock

Preliminary Prospectus
April 6, 2023

Ladenburg Thalmann

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses in connection with the issuance and distribution of the securities being registered (excluding the underwriting discount and management fee). Except for the SEC registration fee and the FINRA filing fee, all amounts are estimates.

Item	Amount
SEC registration fee	$ 2,282
FINRA filing fee	3,605
Legal fees and expenses	250,000
Accounting fees and expenses	100,000
Miscellaneous expenses	140,000
Total	$ 495,887

Item 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the DGCL, we have adopted provisions in our Amended and Restated Certificate of Incorporation and By-Laws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our By-Laws also authorizes us to indemnify any and all persons whom it shall have power to indemnify to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the DGCL, our By-Laws provide that:

- we may indemnify any and all persons whom it shall have power to indemnify to the fullest extent permitted by the DGCL, subject to limited exceptions;
- the rights provided in our By-Laws are not exclusive.

Our Amended and Restated Certificate of Incorporation and our By-Laws provide for the indemnification provisions described above and elsewhere herein. We have entered or will enter into, and intend to continue to enter into, separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

We have purchased and currently intend to maintain insurance on behalf of each and every person who is or was a director or officer of the Company against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

Item 15. Recent Sales of Unregistered Securities.

On February 2, 2021, we issued 3,400 warrants to a service provider as compensation for certain financial advisory services. The warrants were immediately exercisable for shares of common stock at a price of $412.50 per share and expire three years from the date of issuance. The issuance of these securities was exempt from registration under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, in that the transactions were by an issuer not involving any public offering.

Item 16. Exhibits and financial statement schedules.

(a) Exhibits.

The exhibits listed below are filed as part of this registration statement.

Exhibit No.	Description
1.1*	Form of Underwriting Agreement
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 10.23 to Windtree's Annual Report on Form 10-K, as filed with the SEC on March 31, 2023).
3.2	Amended and Restated By-Laws, as amended (incorporated by reference to Exhibit 3.1 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on August 11, 2022).
4.1	Form of Warrant dated October 10, 2014 (incorporated by reference to Exhibit 4.11 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014).
4.2	Form of Series A Warrant dated July 22, 2015 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 17, 2015).
4.3	Form of Series B Warrant dated July 22, 2015 (incorporated by reference to Exhibit 4.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 17, 2015).
4.4	Form of Series A-1 Warrant dated February 13, 2017 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 15, 2017).
4.5	Form of Series C Warrant dated April 4, 2018 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 4, 2018).

4.6	Form of Series D Warrant dated July 2, 2018 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 6, 2018).
4.7	Form of Series E Warrant dated December 11, 2018 (incorporated by reference to Exhibit 4.7 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).
4.8	Form of Series F Warrant dated December 24, 2018 (incorporated by reference to Exhibit 4.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018).
4.9	Form of Series G Warrant dated December 24, 2018 (incorporated by reference to Exhibit 4.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018).
4.10	Form of Series H Warrant dated February 14, 2019 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018).
4.11	Form of Series I Warrant dated December 6, 2019 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 9, 2019).
4.12	Form of Series F Warrant Amendment No. 1 dated April 24, 2020 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 29, 2020).
4.13	Form of Series I Warrant Amendment dated May 6, 2020, to the Series I Warrant dated December 6, 2019 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 7, 2020).
4.14	Form of Warrant issued in Windtree's May 2020 underwritten public offering of securities (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 22, 2020).
4.15	Form of Warrant issued in Windtree's March 2021 underwritten public offering of securities (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 24, 2021.
4.16	Form of Common Stock Purchase Warrant dated January 24, 2023 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 26, 2023).
4.17	Form of Common Stock Purchase Warrant dated February 21, 2023 (incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 22, 2023).
4.18	Description of Securities (incorporated by reference to Exhibit 4.16 to Windtree's Annual Report on Form 10-K, as filed with the SEC on March 29, 2021).
4.19*	Form of Common Warrant
4.20*	Form of Pre-Funded Warrant
4.21*	Form of Warrant Agency Agreement
5.1*	Opinion of Goodwin Procter LLP
10.1†	Sublicense Agreement dated October 28, 1996 between Johnson & Johnson, Ortho Pharmaceutical Corporation and Acute Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 to Windtree's Registration Statement on Form SB-2/A, as filed with the SEC on April 18, 1997 (Commission File Number 333-19375)).
10.2†	Amended and Restated License Agreement dated March 28, 2008, between Windtree and Philip Morris USA Inc. (incorporated by reference to Exhibit 10.4 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008).

10.3†	License Agreement dated March 28, 2008, between Windtree and Philip Morris Products S.A. (incorporated by reference to Exhibit 10.5 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as filed with the SEC on May 9, 2008).
10.4††	Amended and Restated Sublicense and Collaboration Agreement dated December 3, 2004, by and between Discovery Laboratories, Inc. (predecessor-in-interest to Windtree) and Laboratorios del Dr. Esteve, S.A. (incorporated by reference to Exhibit 10.3 to Windtree's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as filed with the SEC on November 16, 2020).
10.5††	Amended and Restated Supply Agreement dated December 3, 2004, by and between Discovery Laboratories, Inc. (predecessor-in-interest to Windtree) and Laboratorios del Dr. Esteve, S.A. (incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as filed with the SEC on November 16, 2020).
10.6†	License, Development and Commercialization Agreement dated June 12, 2017, between Windtree and Lee's Pharmaceutical (HK) Ltd. (incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, as filed with the SEC on August 21, 2017).
10.7†	Amendment No. 1 dated August 14, 2017 to the License Development and Commercialization Agreement between Windtree and Lee's Pharmaceutical (HK) Ltd. dated June 12, 2017 (incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, as filed with the SEC on November 14, 2017).
10.8	Amended and Restated License, Development and Commercialization Agreement, by and among Lee's Pharmaceutical (HK) Ltd., Zhaoke Pharmaceutical (Hefei) Co. Ltd., and Windtree Therapeutics, Inc., effective as of August 9, 2022 (incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as filed with the SEC on November 14, 2022).
10.9#	Windtree's 2011 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 31, 2018).
10.10#	Windtree's 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 31, 2020).
10.11#	Form of Restricted Stock Unit Grant for Employees under Windtree's 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.5 To Windtree's Registration Statement on Form S-8, as filed with the SEC on February 12, 2021).
10.12#	Form of Stock Option Grant for Employees under Windtree's 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.6 To Windtree's Registration Statement on Form S-8, as filed with the SEC on February 12, 2021).
10.13#	Form of Inducement Award Agreement (incorporated by reference to Exhibit 4.4 to Windtree's Registration Statement on Form S-8 (File No. 333-253067), as filed with the SEC on February 12, 2021).
10.14#	Form of Employee Option Agreement under Windtree's 2011 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as filed with the SEC on May 15, 2012).
10.15#	Form of Non-Employee Director Option Agreement under Windtree's 2011 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.10 to Windtree's Form 10-K, as filed with the SEC on April 3, 2020).

10.16#	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under Windtree's 2011 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.11 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 16, 2015).
10.17#	Form of Restricted Stock Unit Award Agreement for Employees under Windtree's 2011 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.14 to Windtree's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on April 17, 2018).
10.18#	Employment Agreement dated February 1, 2016, between Windtree and Craig Fraser (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016).
10.19#	Inducement Stock Option Award Agreement dated February 1, 2016, between Windtree and Craig Fraser (incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016).
10.20#	Amendment dated March 13, 2018, to Employment Agreement dated February 1, 2016, between Windtree and Craig Fraser (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 16, 2018).
10.21#	Employment Agreement dated December 19, 2014, between Windtree and Steven G. Simonson, M.D. (incorporated by reference to Exhibit 10.4 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 2015).
10.22#	Amendment dated December 29, 2014 to Employment Agreement dated December 19, 2014, effective as of April 1, 2015, between Windtree and Steven G. Simonson, M.D. (incorporated by reference to Exhibit 10.5 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 2015).
10.23#	Amendment dated March 13, 2018, to Employment Agreement dated December 19, 2014 between Windtree and Steven G. Simonson, M.D. (incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 16, 2018).
10.24#	At The Market Offering Agreement, dated as of September 17, 2020, by and between Windtree Therapeutics, Inc. and Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 1.2 to the Windtree's Registration Statement on Form S-3, as filed with the SEC on September 17, 2020).
10.25#	Form of Indemnification Agreement between Windtree and certain named executive officers and directors (incorporated by reference to Exhibit 10.4 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 3, 2016).
10.26	Form of Indemnification Agreement between Windtree and certain named directors (incorporated by reference to Exhibit 10.23 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).
10.27	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, between TR Stone Manor Corp. and Windtree (incorporated by reference to Exhibits 10.1 and 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 6, 2007).
10.28	Second Amendment to Lease Agreement dated January 3, 2013 between TR Stone Manor Corp. and Windtree (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 8, 2013).
10.29	Third Amendment to Lease Agreement dated November 24, 2014 between TR Stone Manor Corp. and Windtree (incorporated by reference to Exhibit 10.29 to Windtree's Annual Report on Form 10-K, as filed with the SEC on March 31, 2023).

10.30	Fourth Amendment to Lease Agreement dated April 29, 2016, between PH Stone Manor LP and Windtree (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 31, 2016).
10.31	Fifth Amendment to Lease Agreement dated February 23, 2018, between PH Stone Manor LP and Windtree (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on March 1, 2018).
10.32†	Supply Agreement dated December 22, 2010 between Corden Pharma (formerly Genzyme Pharmaceuticals LLC, now known as Corden Pharma) and Windtree (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 29, 2010).
10.33	Exchange and Termination Agreement dated October 27, 2017, between Windtree and Deerfield (incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on November 1, 2017).
10.34	Registration Rights Agreement dated October 27, 2017, between Windtree and LPH Investments Limited (incorporated by reference to Exhibit 99.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on November 1, 2017).
10.35	Registration Rights Agreement dated March 30, 2018, between Windtree and LPH II Investments Limited (incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 4, 2018).
10.36††	Collaboration Agreement dated as of October 14, 2014, by and between Battelle Memorial Institute and Discovery Laboratories, Inc. (predecessor-in-interest to Windtree) (incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, as filed with the SEC on November 16, 2020).
10.37	Payment Restructuring Agreement effective December 7, 2018, between Windtree and Battelle Memorial Institute (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 7, 2018).
10.38	Amendment No. 1 dated March 30, 2020 to Payment Restructuring Agreement, effective December 7, 2018, between Windtree and Lee's Pharmaceutical (HK) LTD (incorporated by reference to Exhibit 10.48 to Windtree's Registration Statement on Form S-1/A (File No. 333-236085), as filed with the SEC on May 6, 2020).
10.39	Loan Agreement dated October 25, 2018, between CVie Therapeutics, Lee's Pharmaceutical Holdings Limited, and O-Bank Co., Ltd. (incorporated by reference to Exhibit 10.34 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).
10.40	Shareholder Loan Agreement dated April 24, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics (incorporated by reference to Exhibit 10.35 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).
10.41	Shareholder Loan Agreement dated September 20, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics (incorporated by reference to Exhibit 10.36 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).
10.42	Shareholder Loan Agreement dated October 26, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics (incorporated by reference to Exhibit 10.37 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).

10.43	Shareholder Loan Agreement dated November 16, 2018, between Lee's Pharmaceutical International Limited and CVie Therapeutics (incorporated by reference to Exhibit 10.38 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).
10.44	Merger Agreement dated December 21, 2018, between Windtree, WT Acquisition Corp., and CVie Investments Limited (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018).
10.45	Indemnification Letter Agreement dated December 21, 2018, between Windtree and Lee's Pharmaceutical Holdings Limited (incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018).
10.46	Securities Purchase Agreement dated December 21, 2018 between Windtree and certain purchasers party thereto (incorporated by reference to Exhibit 10.3 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018).
10.47	Registration Rights Agreement dated December 21, 2018 between Windtree and certain purchasers party thereto (incorporated by reference to Exhibit 10.4 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 21, 2018).
10.48	Loan Agreement dated October 24, 2019 between Windtree and LPH II Investments Ltd. (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on October 28, 2019).
10.49	Form of Securities Purchase Agreement dated December 6, 2019 by and among Windtree and the purchasers party thereto (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 9, 2019).
10.50	Form of Registration Rights Agreement dated December 6, 2019 by and among Windtree and the purchasers party thereto (incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on December 9, 2019).
10.51#	Employment Agreement dated March 1, 2020, between Windtree and Eric Curtis (incorporated by reference to Exhibit 10.46 to Windtree's Form 10-K, as filed with the SEC on April 3, 2020).
10.52	Amendment to No. 1 dated February 20, 2020 to the Securities Purchase Agreement dated December 6, 2019 by and among Windtree and the purchasers party thereto (incorporated by reference to Exhibit 10.47 to Windtree's Form 10-K, as filed with the SEC on April 3, 2020).
10.53	Project Financing Agreement, dated August 12, 2020, by and between Windtree and Lee's Pharmaceutical (HK) Ltd. (incorporated by reference to Exhibit 10.4 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on November 16, 2020).
10.54#	Employment Agreement by and between Windtree and John Hamill, dated as of July 20, 2020 (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 23, 2020).
10.55#	Employment Agreement by and between Windtree and Diane Carman, dated as of July 1, 2021 (incorporated by reference to Exhibit 10.54 to Windtree's Annual Report on Form 10-K, as filed with the SEC on March 31, 2022).
10.56	Form of Inducement Letter dated January 20, 2023 (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on January 26, 2023).

10.57	Form of Inducement Letter dated February 21, 2023 (incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on February 22, 2023).
16.1	Letter from Ernst & Young LLP (incorporated by reference to Exhibit 16.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on May 11, 2022).
21.1	Subsidiaries of Windtree (incorporated by reference to Exhibit 21.1 to Windtree's Annual Report on Form 10-K, as filed with the SEC on April 16, 2019).
23.1*	Consent of EisnerAmper LLP, independent registered public accounting firm.
23.2*	Consent of Ernst & Young LLP, independent registered public accounting firm.
23.3*	Consent of Goodwin Procter LLP (included in exhibit 5.1).
24.1*	Power of Attorney (included on the signature page to this registration statement).
104	Cover Page Interactive Data File (formatted as Inline XBRL)
107*	Filing Fee Table.

* Filed herewith.
# Compensation Related Contract.
†Confidential treatment received for certain portions of this exhibit.
††Certain confidential portions have been omitted from this exhibit pursuant to Item 601(b)(10)(iv) of Regulation S-K.
(1) These Interactive Data Files shall not be deemed filed for purposes of Section 11 or 12 of the Securities Act, or Section 18 of the Exchange Act, or otherwise subject to liability under those sections.

(b)

Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(a)(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act, that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at the time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(5) That, for purposes of determining any liability under the Securities Act:

(i) the information omitted from the form of prospectus filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective; and

(ii) each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(h) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the indemnification provisions described herein, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Township of Warrington, Commonwealth of Pennsylvania, on April 6, 2023.

WINDTREE THERAPEUTICS, INC.

By: /s/ Craig E. Fraser
Name: *Craig E. Fraser*
Title: *President and Chief Executive Officer*

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Craig E. Fraser Craig E. Fraser	Director, President, and Chief Executive Officer *(Principal Executive Officer)*	April 6, 2023
* John Tattory	Interim Chief Financial Officer *(Principal Financial and Accounting Officer)*	April 6, 2023
* James Huang	Director (Chairman of the Board)	April 6, 2023
* Daniel E. Geffken	Director	April 6, 2023
* Robert A. Scott, M.D.	Director	April 6, 2023
* Leslie J. Williams	Director	April 6, 2023

*By: /s/ Craig E. Fraser
Craig E. Fraser
Attorney-In-Fact

_____ SHARES OF COMMON STOCK,

PRE-FUNDED WARRANTS EXERCISABLE INTO _____ SHARES OF COMMON STOCK AND

COMMON WARRANTS EXERCISABLE INTO _____ SHARES OF COMMON STOCK OF

WINDTREE THERAPEUTICS, INC.

UNDERWRITING AGREEMENT

_____, 2023

Ladenburg Thalmann & Co. Inc.,
as the Representative of the
several Underwriters, if any, named in Schedule I hereto
c/o Ladenburg Thalmann & Co. Inc.
640 Fifth Avenue, 4th Floor
New York, NY 10019

Ladies and Gentlemen:

The undersigned, Windtree Therapeutics, Inc., a company incorporated under the laws of Delaware (the "Company"), hereby confirms its agreement (this "Agreement") with the several underwriters (such underwriters, including the Representative (as defined below), the "Underwriters" and each an "Underwriter") named in Schedule I hereto for which Ladenburg Thalmann & Co. Inc. is acting as representative to the several Underwriters (the "Representative" and if there are no Underwriters other than the Representative, references to multiple Underwriters shall be disregarded and the term Representative as used herein shall have the same meaning as Underwriter) on the terms and conditions set forth herein.

It is understood that the several Underwriters are to make a public offering of the Public Securities as soon as the Representative deems it advisable to do so. The Public Securities are to be initially offered to the public at the public offering price set forth in the Prospectus.

It is further understood that you will act as the Representative for the other Underwriters, if any, in the offering and sale of the Closing Securities and, if any, the Option Securities in accordance with this Agreement.

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(k).

"Affiliate" means with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with such Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Board of Directors" means the board of directors of the Company.

"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 are generally open for use by customers on such day.

"Closing" means the closing of the purchase and sale of the Closing Securities pursuant to Section 2.1.

"Closing Date" means the hour and the date on the Trading Day on which all conditions precedent to (i) the Underwriters' obligations to pay the Closing Purchase Price and (ii) the Company's obligations to deliver the Closing Securities, in each case, have been satisfied or waived, but in no event later than 10:00 a.m. (New York City time) on the second (2nd) Trading Day following the date hereof or at such earlier time as shall be agreed upon by the Representative and the Company.

"Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

"Closing Securities" shall have the meaning ascribed to such term in Section 2.1(a)(ii).

"Closing Shares" shall have the meaning ascribed to such term in Section 2.1(a)(i).

"Closing Warrants" shall have the meaning ascribed to such term in Section 2.1(a)(iii).

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Common Warrants" means, collectively, the Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a)(ii) and Section 2.2, which Common Warrants shall be exercisable immediately and have a term of exercise equal to five (5) years, in the form of Exhibit E attached hereto.

"Company Auditors" means Ernst & Young LLP (with respect to the financial statements as of and for the years ended December 31, 2021), with offices located at One Commerce Square, 2005 Market Street, Suite 700, Philadelphia, Pennsylvania 19103, and EisnerAmper LLP (with respect to the financial statements as of and for the year ended December 31, 2022), with offices located at One Logan Square, 2130 North 18th Street, Suite 3000, Philadelphia, Pennsylvania 19103.

"Company Counsel" means Goodwin Procter LLP, with offices located at 2929 Arch Street, Suite 1700, Philadelphia, Pennsylvania 19104.

"Effective Date" shall have the meaning ascribed to such term in Section 3.1(f).

"EGS" means Ellenoff Grossman & Schole LLP, with offices located at 1345 Avenue of the Americas, New York, New York 10105.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Execution Date" shall mean the date on which the parties execute and enter into this Agreement.

"Exempt Issuance" means the issuance of (a) shares of Common Stock, options, restricted stock units or other equity awards to employees, officers, directors or consultants of the Company pursuant to the Company's benefit plans existing on the date hereof, as such plans may be amended, or pursuant to any other stock or option plan duly adopted for such purpose by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company (provided such issuances to consultants shall not exceed $500,000 of shares per annum and further provided, that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith within 75 days following the Closing Date), (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities or to extend the term of such securities, (c) securities issued pursuant to acquisitions or strategic transactions, including without limitation, joint venture, co-marketing, co-development or other collaboration arrangements, which issuances are approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith within 75 days following the Closing Date, and provided that any such issuance shall only be to a Person (or to the equity holders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities, (d) securities issued as inducement grants under the Nasdaq inducement grant exception, and (e) shares of Common Stock issued in connection with any merger or consolidation of the Company or any subsidiary of the Company with or into another entity or other similar business combination involving the Company or any subsidiary of the Company, in each case, which is approved by a majority of the disinterested directors of the Company.

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended.

"FINRA" means the Financial Industry Regulatory Authority.

"GAAP" shall have the meaning ascribed to such term in Section 3.1(i).

"Indebtedness" means (a) 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), (b) 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 (c) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP.

"IP Company Counsel" means Potter Anderson & Corroon LLP, with offices located at 1313 N. Market Street, 6th Floor, Wilmington, DE 19801-6108.

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Lock-Up Agreements" means the lock-up agreements that are delivered on the date hereof by each of the Company's officers and directors and each holder of Common Stock and Common Stock Equivalents holding, on a fully diluted basis, more than 5% of the Company's issued and outstanding Common Stock, in the form of Exhibit A attached hereto.

"Material Adverse Effect" means (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (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 any Transaction Document.

"Offering" shall have the meaning ascribed to such term in Section 2.1(c).

"Option" shall have the meaning ascribed to such term in Section 2.2.

"Option Closing Date" shall have the meaning ascribed to such term in Section 2.2(c).

"Option Closing Purchase Price" shall have the meaning ascribed to such term in Section 2.2(b), which aggregate purchase price shall be net of the underwriting discounts and commissions.

"Option Securities" shall have the meaning ascribed to such term in Section 2.2(a).

"Option Shares" shall have the meaning ascribed to such term in Section 2.2(a)(i).

"Option Warrants" shall have the meaning ascribed to such term in Section 2.2(a).

"Person" means 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.

"Pre-Funded Warrants" means, collectively, the Pre-Funded Common Stock purchase warrants delivered to the Underwriters in accordance with Section 2.1(a)(ii) and Section 2.2, which Pre-Funded Warrants shall be exercisable immediately and shall be exercisable until exercised in full, in the form of Exhibit F attached hereto.

"Preliminary Prospectus" means, if any, any preliminary prospectus relating to the Securities included in the Registration Statement or filed with the Commission pursuant to Rule 424(b).

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or, to the Company's knowledge, threatened.

"Prospectus" means the final prospectus filed for the Registration Statement.

"Prospectus Supplement" means, if any, any supplement to the Prospectus complying with Rule 424(b) of the Securities Act that is filed with the Commission.

"Public Securities" means, collectively, the Closing Securities and, if any, the Option Securities.

"Registration Statement" means, collectively, the various parts of the registration statement prepared by the Company on Form S-1 (File No. 333-269775) with respect to the Securities, each as amended as of the date hereof, including the Prospectus and Prospectus Supplement, if any, the Preliminary Prospectus, if any, and all exhibits filed with or incorporated by reference into such registration statement, and includes any Rule 462(b) Registration Statement.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Rule 424" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 462(b) Registration Statement" means any registration statement prepared by the Company registering additional Public Securities, which was filed with the Commission on or prior to the date hereof and became automatically effective pursuant to Rule 462(b) promulgated by the Commission pursuant to the Securities Act.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(i).

"Securities" means the Closing Securities, the Option Securities and the Warrant Shares.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Share Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Shares" means, collectively, the shares of Common Stock delivered to the Underwriters in accordance with Section 2.1(a)(i) and Section 2.2(a).

"Subsidiary" means any significant subsidiary (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission) of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

"Transaction Documents" means this Agreement, the Warrants, the Warrant Agency Agreement, the Lock-Up Agreements, and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means Continental Stock Transfer and Trust Company, the current transfer agent of the Company, with offices located at 1 State Street, 30 Floor, New York, NY 10004-1561 and any successor transfer agent of the Company.

"Warrant Agency Agreement" means the warrant agency agreement dated on or about the Closing Date, among the Company and the Transfer Agent pursuant to which the Transfer Agent will act as warrant agent for the Common Warrants, substantially in the form of Exhibit D attached hereto.

"Warrant Purchase Price" shall have the meaning ascribed to such term in Section 2.1(b).

"Warrant Shares" means the shares of Common Stock issuable upon exercise of the Warrants.

"Warrants" means, collectively, the Common Warrants and the Pre-Funded Warrants.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing.

(a) Upon the terms and subject to the conditions set forth herein, the Company agrees to sell (i) in the aggregate _____ shares of Common Stock, (ii) Pre-Funded Warrants exercisable for an aggregate of ____ shares of Common Stock and (iii) Common Warrants exercisable for an aggregate of _____ shares of Common Stock, and each Underwriter agrees to purchase, severally and not jointly, at the Closing, the following securities of the Company:

(i) the number of shares of Common Stock (the "Closing Shares") set forth opposite the name of such Underwriter on Schedule I hereof; and

(ii) Pre-Funded Warrants to purchase up to the number of shares of Common Stock set forth opposite the name of such Underwriter on Schedule I hereof (the "Pre-Funded Warrants"), which Pre-Funded Warrants shall have an exercise price of $0.001, subject to adjustment therein.

(iii) Common Warrants to purchase up to [100%] of the sum of the number of Closing Shares and Pre-Funded Warrants set forth opposite the name of such Underwriter on Schedule I hereof (the "Closing Warrants" and, collectively with the Closing Shares and Pre-Funded Warrants, the "Closing Securities"), which Common Warrants shall have an exercise price of $____, subject to adjustment therein.

(b) The aggregate purchase price for the Closing Securities shall equal the amount set forth opposite the name of such Underwriter on Schedule I hereto (the "Closing Purchase Price"). The combined purchase price for one Share and one Common Warrant to purchase one Warrant Share shall be $_____, which shall be allocated as $_____ per Share (the "Share Purchase Price") and $____ per Common Warrant (the "Warrant Purchase Price"). The combined purchase price for one Pre-Funded Warrant to purchase one Warrant Share and one Common Warrant to purchase one Warrant Share shall be $_____, which shall be allocated as $_____ per Pre-Funded Warrant and $____ per Common Warrant.

(c) On the Closing Date, each Underwriter shall deliver or cause to be delivered to the Company, via wire transfer, immediately available funds equal to such Underwriter's Closing Purchase Price and the Company shall deliver to, or as directed by, such Underwriter its respective Closing Securities and the Company shall deliver the other items required pursuant to Section 2.3 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3 and 2.4, the Closing shall occur at the offices of EGS or such other location as the Company and Representative shall mutually agree. The Public Securities are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (the "Offering").

(d) The Company acknowledges and agrees that, with respect to any Notice(s) of Exercise (as defined in the Pre-Funded Warrants) delivered by a Holder (as defined in the Pre-Funded Warrants) on or prior to 12:00 p.m. (New York City time) on the Closing Date, which Notice(s) of Exercise may be delivered at any time after the time of execution of this Agreement, the Company shall deliver the Warrant Shares (as defined in the Pre-Funded Warrants) subject to such notice(s) to the Holder by 4:00 p.m. (New York City time) on the Closing Date and the Closing Date shall be the Warrant Share Delivery Date (as defined in the Pre-Funded Warrants); provided that, the Company has received payment of the applicable exercise price prior to delivery of the Pre-Funded Warrants. The Company acknowledges and agrees that the Holders are third-party beneficiaries of this covenant of the Company.

2.2 Option to Purchase Additional Securities.

(a) For the purposes of covering any over-allotments in connection with the distribution and sale of the Closing Securities, the Representative is hereby granted an option (the "Option") to purchase, in the aggregate, up to _____ shares of Common Stock (the "Option Shares") and/or Common Warrants to purchase up to ____ shares of Common Stock (the "Option Warrants" and, collectively with the Option Shares, the "Option Securities")[1] which may be purchased in any combination of Option Shares and/or Option Warrants at the Share Purchase Price and/or Warrant Purchase Price, respectively.

[1] 15% of the Closing Shares and/or Pre-Funded Warrants and the Closing Warrants.

(b) In connection with an exercise of the Option, (a) the purchase price to be paid for the Option Shares is equal to the product of the Share Purchase Price multiplied by the number of Option Shares to be purchased and (b) the purchase price to be paid for the Option Warrants is equal to the product of the Warrant Purchase Price multiplied by the number of Option Warrants to be purchased (the aggregate purchase price to be paid on an Option Closing Date, the "Option Closing Purchase Price").

(c) The Option granted pursuant to this Section 2.2 may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Securities within 45 days after the Execution Date. An Underwriter will not be under any obligation to purchase any Option Securities prior to the exercise of the Option by the Representative. The Option granted hereby may be exercised by the giving of oral notice to the Company from the Representative, which must be confirmed in writing by overnight mail or electronic transmission setting forth the number of Option Shares and/or Option Warrants to be purchased and the date and time for delivery of and payment for the Option Securities (each, an "Option Closing Date"), which will not be later than two (2) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of EGS or at such other place (including remotely by other electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Securities does not occur on the Closing Date, each Option Closing Date will be as set forth in the notice. Upon exercise of the Option, the Company will become obligated to convey to the Underwriters, and, subject to the terms and conditions set forth herein, the Underwriters will become obligated to purchase, the number of Option Shares and/or Option Warrants specified in such notice. The Representative may cancel the Option at any time prior to the expiration of the Option by written notice to the Company.

2.3 Deliveries. The Company shall deliver or cause to be delivered to each Underwriter (if applicable) the following:

(i) At the Closing Date, the Closing Shares and, as to each Option Closing Date, if any, the applicable Option Shares, which shares shall be delivered via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(ii) At the Closing Date, the Pre-Funded Warrants in certificated form registered in the name or names and in such authorized denominations as the applicable Underwriter may request in writing at least one Business Day prior to the Closing Date;

(iii) At the Closing Date, the Closing Warrants and, as to each Option Closing Date, if any, the applicable Option Warrants via The Depository Trust Company Deposit or Withdrawal at Custodian system for the accounts of the several Underwriters;

(iv) At the Closing Date, the Warrant Agency Agreement duly executed by the parties thereto;

(v) At the Closing Date and at each Option Closing Date, if any, (i) a legal opinion of Company Counsel addressed to the Underwriters, including, without limitation, a negative assurance letter, in form and substance reasonably satisfactory to the Representative and (ii) a legal opinion of IP Company Counsel including, without limitation, a negative assurance letter, in form and substance reasonably satisfactory to the Representative;

(vi) Contemporaneously herewith, a cold comfort letter, addressed to the Underwriters and in form and substance satisfactory in all respects to the Representative from the Company Auditors dated, respectively, as of the date of this Agreement and a bring-down letter dated as of the Closing Date and each Option Closing Date, if any;

(vii) At the Closing Date and on each Option Closing Date, the duly executed and delivered Officer's Certificate, substantially in the form required by Exhibit B attached hereto;

(viii) At the Closing Date and on each Option Closing Date, the duly executed and delivered Secretary's Certificate, substantially in the form required by Exhibit C attached hereto;

(ix) Contemporaneously herewith, the duly executed and delivered Chief Financial Officer's Certificate, substantially in the form required by Exhibit G attached hereto, and a bring-down Chief Financial Officer's Certificate dated as of the Closing Date and each Option Closing Date, if any; and

(x) Contemporaneously herewith, the duly executed and delivered Lock-Up Agreements.

2.4 Closing Conditions. The respective obligations of each Underwriter hereunder in connection with the Closing and each Option Closing Date are subject to the following conditions being met:

(i) the accuracy in all material respects when made and on the date in question (other than representations and warranties of the Company already qualified by materiality, which shall be true and correct in all respects) of the representations and warranties of the Company contained herein (unless as of a specific date therein);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the date in question shall have been performed in all material respects;

(iii) the delivery by the Company of the items set forth in Section 2.3 of this Agreement;

(iv) the Registration Statement shall be effective on the date of this Agreement and at each of the Closing Date and each Option Closing Date, if any, no stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall have been instituted or shall, to the Company's knowledge, be pending or contemplated by the Commission and any request on the part of the Commission for additional information shall have been complied with to the reasonable satisfaction of the Representative;

(v) by the Execution Date, if required by FINRA, the Underwriters shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement;

(vi) the Closing Shares, the Option Shares and the Warrant Shares have been approved for listing on the Trading Market; and

(vii) prior to and on each of the Closing Date and each Option Closing Date, if any: (i) there shall have been no material adverse change or development involving a prospective material adverse change in the condition or prospects or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement and Prospectus; (ii) no action suit or proceeding, at law or in equity, shall have been pending or threatened against the Company or any Affiliate of the Company before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding may materially adversely affect the business, operations, prospects or financial condition or income of the Company, except as set forth in the Registration Statement and Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; and (iv) the Registration Statement and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the rules and regulations thereunder and shall conform in all material respects to the requirements of the Securities Act and the rules and regulations thereunder, and neither the Registration Statement nor the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. The Company represents and warrants to the Underwriters as of the Execution Date, as of the Closing Date and as of each Option Closing Date, if any, as follows:

(a) Subsidiaries. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, 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. If the Company has no Subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded. The Company does not own or control, directly or indirectly, any subsidiary other than the subsidiaries listed in the SEC Reports.

(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 a Material Adverse Effect and no Proceeding 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; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents to which the Company is a party and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby 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 or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which the Company is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, 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 and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby 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 in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filing with the Commission of the Prospectus, (ii) the authorization for the listing of the Shares, the Option Shares, if applicable, and the Warrant Shares on the Trading Market and (iii) such filings as are required to be made under applicable state securities laws or blue sky laws or the rules of FINRA (collectively, the "Required Approvals").

(f) Registration Statement. The Company has filed with the Commission the Registration Statement, including any related Prospectus or Prospectuses, for the registration of the Securities under the Securities Act, which Registration Statement has been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act. The Registration Statement has been declared effective by the Commission on _____, 2023 (the "Effective Date"). Any reference in this Agreement to the Registration Statement, the Prospectus or the Prospectus Supplement shall be deemed to refer to and include the documents incorporated by reference therein, if any, which were filed under the Exchange Act, on or before the date of this Agreement, or the issue date of the Prospectus or the Prospectus Supplement, as the case may be; and any reference in this Agreement to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement, the Prospectus or the Prospectus Supplement shall be deemed to refer to and include the filing of any document under the Exchange Act after the date of this Agreement, or the issue date of the Prospectus or the Prospectus Supplement, as the case may be, deemed to be incorporated therein by reference. All references in this Agreement to financial statements and schedules and other information which is "contained," "included," "described," "referenced," "set forth" or "stated" in the Registration Statement, the Prospectus or the Prospectus Supplement (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Prospectus or the Prospectus Supplement, as the case may be. No stop order suspending the effectiveness of the Registration Statement or the use of the Prospectus or the Prospectus Supplement has been issued, and no proceeding for any such purpose is pending or has been initiated or, to the Company's knowledge, is threatened by the Commission. For purposes of this Agreement, "free writing prospectus" has the meaning set forth in Rule 405 under the Securities Act. The Company will not, without the prior consent of the Representative, prepare, use or refer to, any free writing prospectus.

(g) Issuance of Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Warrant Shares, when issued in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement and the Warrants. The holder of the Securities will not be subject to personal liability by reason of being such holders. The Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. All corporate action required to be taken for the authorization, issuance and sale of the Securities has been duly and validly taken. The Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement.

(h) Capitalization. The capitalization of the Company is as set forth in the SEC Reports as further updated by the Prospectus. The Company has not issued any capital stock since its most recently filed periodic or current report under the Exchange Act that is not described in the Prospectus, other than pursuant to the exercise of employee stock options under the Company's equity compensation or stock option plans or inducement grants under the Nasdaq inducement grant exception, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of 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 the Transaction Documents. Except as a result of the purchase and sale of the Securities, or as set forth in the Registration Statement or the Prospectus, 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 Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Underwriters). Except as a result of the purchase and sale of the Securities, or as set forth in the Registration Statement or the Prospectus, 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 a result of the purchase and sale of the Securities, or as set forth in the Registration Statement or the Prospectus, 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. The authorized shares of the Company conform in all material respects to all statements relating thereto contained in the SEC Reports. The offers and sales of the Company's securities were at all relevant times either registered under the Securities Act and the applicable state securities or Blue Sky laws or, based in part on the representations and warranties of the purchasers, exempt from such registration requirements. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. 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.

(i) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the twelve months 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 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 light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the Registration Statement, the Prospectus and 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. The agreements and documents described in the Registration Statement, the Prospectus, the Prospectus Supplement and the SEC Reports conform to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the rules and regulations thereunder to be described in the Registration Statement, the Prospectus, the Prospectus Supplement or the SEC Reports or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Prospectus, the Prospectus Supplement or the SEC Reports, or (ii) is material to the Company's business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefore may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the best of the Company's knowledge, any other party is in default thereunder and, to the best of the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder. To the best of the Company's knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses, including, without limitation, those relating to environmental laws and regulations.

(j) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in a subsequent SEC Report filed prior to the date hereof, (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, (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company equity compensation or stock option plans or inducement grants under the Nasdaq inducement grant exception and (vi) no officer or director of the Company 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 Securities contemplated by this Agreement, 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. Unless otherwise disclosed in an SEC Report filed prior to the date hereof, the Company has not: (i) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

(k) Litigation. Other than as disclosed to the Representative, 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") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities 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 Securities Act.

(l) 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.

(m) 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.

(n) 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 (each, a "Material Permit"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit. The disclosures in the Registration Statement concerning the effects of Federal, State, local and all foreign regulation on the Company's business as currently contemplated are correct in all material respects.

(o) 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.

(p) 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 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.

(q) 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.

(r) Transactions With Affiliates and Employees. 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, bonus 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.

(s) Sarbanes-Oxley; Internal Accounting Controls. 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 and as of the Closing Date. 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.

(t) Certain Fees. Except as set forth in the Prospectus, no brokerage or finder's fees or commissions are or will be payable by the Company, any Subsidiary or Affiliate of the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. To the Company's knowledge, there are no other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its stockholders that may affect the Underwriters' compensation, as determined by FINRA. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

(u) Investment Company. The Company is not, and immediately after receipt of payment for the Securities will not be, required to register as an "investment company" within the meaning of the Investment Company Act of 1940, as amended.

(v) Registration Rights. Except as set forth in the SEC Reports, no Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) 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. 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. 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 of the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(x) 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 as a result of the Underwriters and the Company fulfilling their obligations or exercising their rights under the Transaction Documents.

(y) Disclosure; 10b-5. The Registration Statement (and any further documents to be filed with the Commission in connection with the Offering) contains all exhibits and schedules as required by the Securities Act. Each of the Registration Statement and any post-effective amendment thereto, if any, at the time it became effective, complied in all material respects with the Securities Act and the applicable rules and regulations under the Securities Act and did not and, as amended or supplemented, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. Each of the Preliminary Prospectus, Prospectus and the Prospectus Supplement, each as of its respective date, did or will as of the date thereof, comply in all material respects with the Securities Act and the applicable rules and regulations. Each of the Preliminary Prospectus, Prospectus and the Prospectus Supplement, as amended or supplemented, did not and will not contain as of the date thereof any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The SEC Reports, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, and none of such 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 (with respect to the SEC Reports incorporated by reference in the Preliminary Prospectus, Prospectus or Prospectus Supplement), in light of the circumstances under which they were made not misleading; and any further documents so filed and incorporated by reference in the Preliminary Prospectus, Prospectus or Prospectus Supplement, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the applicable rules and regulations, 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. No post-effective amendment to the Registration Statement reflecting any facts or events arising after the date thereof which represent, individually or in the aggregate, a fundamental change in the information set forth therein is required to be filed with the Commission as of the date hereof. Notwithstanding any of the foregoing, the Company makes no representation or warranty with respect to any underwriter information provided for use in the Preliminary Prospectus or the Prospectus. There are no documents required to be filed with the Commission in connection with the transaction contemplated hereby that (x) have not been filed as required pursuant to the Securities Act or (y) will not be filed within the requisite time period. There are no contracts or other documents required to be described in the Preliminary Prospectus, Prospectus or Prospectus Supplement, or to be filed as exhibits or schedules to the Registration Statement, which have not been described or filed as required.

(z) No Integrated Offering. Neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(aa) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (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 Closing Date. 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. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(bb) 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. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all material accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. The term "taxes" mean all federal, state, local, foreign, and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatsoever, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements, and other documents required to be filed in respect to taxes.

(cc) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company, any agent or other person acting on behalf of the Company, 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. The Company has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the FCPA.

(dd) Accountants. To the knowledge and belief of the Company, the Company Auditors (i) are independent registered public accounting firms as required by the Exchange Act and (ii) shall express their opinions with respect to the financial statements to be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022. Except as set forth in the SEC Reports, the Company Auditors have not, during the periods covered by the financial statements included in the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the Exchange Act.

(ee) 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.

(ff) 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 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.

(gg) 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.

(hh) 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 Representative's request.

(ii) 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 (25%) 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.

(jj) 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 material 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, threatened.

(kk) FINRA Affiliation. To the Company's knowledge, no officer, director or any beneficial owner of 5% or more of the Company's unregistered securities has any direct or indirect affiliation or association with any FINRA member (as determined in accordance with the rules and regulations of FINRA) that is participating in the Offering. The Company will advise the Representative and EGS if it learns that any officer, director or owner of 5% or more of the Company's outstanding shares of Common Stock or Common Stock Equivalents is or becomes an affiliate or associated person of a FINRA member firm.

(ll) Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to the Representative or EGS hereunder shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

(mm) Board of Directors. The Board of Directors is comprised of the persons set forth in the SEC Reports. The qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder applicable to the Company and the rules of the Trading Market. At least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and the rules of the Trading Market. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent" as defined under the rules of the Trading Market.

(nn) Cybersecurity. (i)(x) There has been no material security breach or other compromise of or relating to any of the Company's or any Subsidiary's information technology and computer systems, networks, hardware, software, data (including the data of its respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of it), equipment or technology (collectively, "IT Systems and Data") and (y) the Company and the Subsidiaries have not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any material security breach or other compromise to its IT Systems and Data; (ii) to the knowledge of the Company, the Company and the Subsidiaries are presently in compliance in all material respects with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) the Company and the Subsidiaries have implemented and maintained commercially reasonable safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data; and (iv) the Company and the Subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices.

(oo) 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.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Amendments to Registration Statement. The Company has delivered, or will as promptly as practicable deliver, to the Underwriters complete conformed copies of the Registration Statement and of each consent and certificate of experts, as applicable, filed as a part thereof, and conformed copies of the Registration Statement (without exhibits), the Prospectus and the Prospectus Supplement, as amended or supplemented, in such quantities and at such places as an Underwriter reasonably requests. Neither the Company nor any of its directors and officers has distributed and none of them will distribute, prior to the Closing Date, any offering material in connection with the offering and sale of the Securities other than the Prospectus, the Prospectus Supplement, the Registration Statement, copies of the documents incorporated by reference therein and any free writing prospectus approved by the Representative.

4.2 Federal Securities Laws.

(a) Compliance. During the time when a Prospectus is required to be delivered under the Securities Act, the Company will use its reasonable best efforts to comply with all requirements imposed upon it by the Securities Act and the rules and regulations thereunder and the Exchange Act and the rules and regulations thereunder, as from time to time in force, so far as necessary to permit the continuance of sales of or dealings in the Securities in accordance with the provisions hereof and the Prospectus. If at any time when a Prospectus relating to the Securities is required to be delivered under the Securities Act, any event shall have occurred as a result of which, in the opinion of counsel for the Company or counsel for the Underwriters, the Prospectus, as then amended or supplemented, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, or if it is necessary at any time to amend the Prospectus to comply with the Securities Act, the Company will notify the Underwriters promptly and prepare and file with the Commission, subject to Section 4.1 hereof, an appropriate amendment or supplement in accordance with Section 10 of the Securities Act.

(b) Filing of Final Prospectus. The Company will file the final Prospectus (in form and substance satisfactory to the Representative) with the Commission pursuant to the requirements of Rule 424.

(c) Exchange Act Registration. For a period of three years from the Execution Date (except in connection with a going private transaction that is approved by a majority of disinterested members of the board of directors and shareholders), (i) the Company will use its reasonable best efforts to maintain the registration of the Common Stock under the Exchange Act, and (ii) the Company will not deregister the Common Stock under the Exchange Act without the prior written consent of the Representative.

(d) Free Writing Prospectuses. The Company represents and agrees that it has not made and will not make any offer relating to the Securities that would constitute an issuer free writing prospectus, as defined in Rule 433 of the rules and regulations under the Securities Act, without the prior written consent of the Representative. Any such free writing prospectus consented to by the Representative is herein referred to as a "Permitted Free Writing Prospectus." The Company represents that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus" as defined in rule and regulations under the Securities Act, and has complied and will comply with the applicable requirements of Rule 433 of the Securities Act, including timely Commission filing where required, legending and record keeping.

4.3 Delivery to the Underwriters of Prospectuses. The Company will deliver to the Underwriters, without charge, from time to time during the period when the Prospectus is required to be delivered under the Securities Act or the Exchange Act such number of copies of each Prospectus as the Underwriters may reasonably request and, as soon as the Registration Statement or any amendment or supplement thereto becomes effective, deliver to the Representative two original executed Registration Statements, including exhibits, and all post-effective amendments thereto and copies of all exhibits filed therewith or incorporated therein by reference and all original executed consents of certified experts.

4.4 Effectiveness and Events Requiring Notice to the Underwriters. The Company will use its reasonable best efforts to cause the Registration Statement to remain effective with a current prospectus until the later of nine (9) months from the Execution Date and the date on which the Warrants are no longer outstanding, and will notify the Underwriters and holders of the Warrants promptly and confirm the notice in writing: (i) of the effectiveness of the Registration Statement and any amendment thereto, provided that the filing of an amendment to the Registration Statement on the SEC's EDGAR system, and the posting of the notice of effectiveness on EDGAR, shall be deemed to be such notification; (ii) of the issuance by the Commission of any stop order or of the initiation, or the threatening, of any proceeding for that purpose; (iii) of the issuance by any state securities commission of any proceedings for the suspension of the qualification of the Securities for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose; (iv) of the mailing and delivery to the Commission for filing of any amendment or supplement to the Registration Statement or Prospectus, provided that the filing of an amendment or supplement to the Registration Statement on the SEC's EDGAR system shall be deemed to be such notification; (v) of the receipt of any comments or request for any additional information from the Commission with respect to the Registration Statement; and (vi) of the happening of any event during the period described in this Section 4.4 that, in the judgment of the Company, makes any statement of a material fact made in the Registration Statement or the Prospectus untrue or that requires the making of any changes in the Registration Statement or the Prospectus in order to make the statements therein, in light of the circumstances under which they were made, not misleading. If the Commission or any state securities commission shall enter a stop order or suspend such qualification at any time, the Company will make every reasonable effort to obtain promptly the lifting of such order.

4.5 Expenses of the Offering.

(a) General Expenses Related to the Offering. The Company hereby agrees to pay on the Closing Date and each Option Closing Date, if any, to the extent not paid at the Closing Date, all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the Securities to be sold in the Offering with the Commission; (b) all FINRA Public Offering Filing System fees associated with the review of the Offering by FINRA; all fees and expenses relating to the listing of such Closing Shares, Option Shares, if any, and Warrant Shares on the Trading Market and such other stock exchanges as the Company and the Representative together determine; (c) all fees, expenses and disbursements relating to the registration or qualification of such Securities under the "blue sky" securities laws of such states and other foreign jurisdictions as the Representative may reasonably designate (including, without limitation, all filing and registration fees, and the fees and expenses of Blue Sky counsel in an amount not to exceed $15,000), (d) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, Selected Dealers' Agreement, Underwriters' Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (e) the costs and expenses of the Company's public relations firm; (f) the costs of preparing, printing and delivering the Securities; (g) fees and expenses of the Transfer Agent for the Securities (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company); (h) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (i) the fees and expenses of the Company's accountants; and (j) the fees and expenses of the Company's legal counsel and other agents and representatives. The Underwriters may also deduct from the net proceeds of the Offering payable to the Company on the Closing Date the documented expenses set forth herein to be paid by the Company to the Underwriters.

(b) Expenses of the Representative. The Company further agrees that, in addition to the expenses payable pursuant to Section 4.5(a), on the Closing Date or Option Closing Date, if applicable, it will (i) pay the Representative a management fee equal to 1.0% of the total gross proceeds raised in the Offering on the Closing Date and each Option Closing Date, if any, and (ii) reimburse the Representative for its reasonable and documented out-of-pocket expenses related to the Offering in an amount up to $110,000 in the aggregate, which shall be paid by deduction from the proceeds of the Offering contemplated herein. It is understood, however, that, except as provided in this Section, Section 7.1(b), and Article VI hereof, the Representative and the Underwriters will pay all of their own costs and expenses, including the fees of their counsel, and stock transfer taxes on resale of any of the Public Securities.

4.6 Application of Net Proceeds. The Company will apply the net proceeds from the Offering received by it in a manner consistent with the application described under the caption "Use of Proceeds" in the Prospectus.

4.7 Delivery of Earnings Statements to Security Holders. The Company will make generally available to its security holders as soon as practicable, but not later than the first day of the fifteenth full calendar month following the Execution Date, an earnings statement (which need not be certified by independent public or independent certified public accountants unless required by the Securities Act or the Rules and Regulations under the Securities Act, but which shall satisfy the provisions of Rule 158(a) under Section 11(a) of the Securities Act) covering a period of at least twelve consecutive months beginning after the Execution Date.

4.8 Stabilization. Neither the Company, nor, to its knowledge, any of its employees, directors or shareholders (without the consent of the Representative) has taken or will take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

4.9 Internal Controls. The Company will maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (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 existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

4.10 Accountants. The Company shall continue to retain a nationally recognized independent certified public accounting firm for a period of at least three years after the Execution Date. The Underwriters acknowledge that the Company Auditors are acceptable to the Underwriters.

4.11 FINRA. The Company shall advise the Underwriters (who shall make an appropriate filing with FINRA) if it is aware that any 5% or greater shareholder of the Company becomes an affiliate or associated person of an Underwriter.

4.12 No Fiduciary Duties. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual and commercial in nature, based on arms-length negotiations and that neither the Underwriters nor their affiliates or any selected dealer shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement. Notwithstanding anything in this Agreement to the contrary, the Company acknowledges that the Underwriters may have financial interests in the success of the Offering that are not limited to the difference between the price to the public and the purchase price paid to the Company by the Underwriters for the shares and the Underwriters have no obligation to disclose, or account to the Company for, any of such additional financial interests. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any breach or alleged breach of fiduciary duty.

4.13 Warrant Shares. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the issuance of the Warrant Shares or if the Warrant is exercised via cashless exercise, the Warrant Shares issued pursuant to any such exercise shall be issued free of all restrictive legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Warrant Shares) is not effective or is not otherwise available for the sale of the Warrant Shares, the Company shall promptly notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale of the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any holder thereof to sell, any of the Warrant Shares in compliance with applicable federal and state securities laws).

4.14 Board Composition and Board Designations. The Company shall ensure that: (i) the qualifications of the persons serving as board members and the overall composition of the Board of Directors comply with the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder and with the listing requirements of the Trading Market and (ii) if applicable, at least one member of the Board of Directors qualifies as a "financial expert" as such term is defined under the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder.

4.15 Securities Laws Disclosure; Publicity. At the request of the Representative, by [8:30 a.m.] (New York City time) on the date hereof, the Company shall issue a press release disclosing the material terms of the Offering. The Company and the Representative shall consult with each other in issuing any other press releases with respect to the Offering, and neither the Company nor any Underwriter shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of such Underwriter, or without the prior consent of such Underwriter, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. The Company will not issue press releases or engage in any other publicity, without the Representative's prior written consent, for a period ending at 5:00 p.m. (New York City time) on the first business day following the 45th day following the Closing Date, other than normal and customary releases issued in the ordinary course of the Company's business.

4.16 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Underwriter of the Securities is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Underwriter of Securities could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities.

4.17 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Option Shares pursuant to the Option and Warrant Shares pursuant to any exercise of the Warrants.

4.18 Listing of Common Stock. The Company hereby agrees to use reasonable best efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed, and concurrently with the Closing, the Company shall apply to list or quote all of the Closing Shares, Option Shares and Warrant Shares on such Trading Market and promptly secure the listing of all of the Closing Shares, Option Shares and Warrant Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Closing Shares, Option Shares and Warrant Shares, and will take such other action as is necessary to cause all of the Closing Shares, Option Shares and Warrant Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all material respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to maintain the eligibility of the Common Stock and Common Warrants for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.19 Subsequent Equity Sales.

(a) From the date hereof until 75 days following the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents.

(b) Notwithstanding the foregoing, this Section 4.19 shall not apply in respect of an Exempt Issuance.

4.20 Research Independence. The Company acknowledges that each Underwriter's research analysts and research departments, if any, are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriter's research analysts may hold and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the offering that differ from the views of its investment bankers. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against such Underwriter with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by such Underwriter's investment banking divisions. The Company acknowledges that the Representative is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short position in debt or equity securities of the Company.

ARTICLE V.
DEFAULT BY UNDERWRITERS

If on the Closing Date or any Option Closing Date, if any, any Underwriter shall fail to purchase and pay for the portion of the Closing Securities or Option Securities, as the case may be, which such Underwriter has agreed to purchase and pay for on such date (otherwise than by reason of any default on the part of the Company), the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, shall use their reasonable best efforts to procure within 36 hours thereafter one or more of the other Underwriters, or any others, to purchase from the Company such amounts as may be agreed upon and upon the terms set forth herein, the Closing Securities or Option Securities, as the case may be, which the defaulting Underwriter or Underwriters failed to purchase. If during such 36 hours the Representative shall not have procured such other Underwriters, or any others, to purchase the Closing Securities or Option Securities, as the case may be, agreed to be purchased by the defaulting Underwriter or Underwriters, then (a) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur does not exceed 10% of the Closing Securities or Option Securities, as the case may be, covered hereby, the other Underwriters shall be obligated, severally, in proportion to the respective numbers of Closing Securities or Option Securities, as the case may be, which they are obligated to purchase hereunder, to purchase the Closing Securities or Option Securities, as the case may be, which such defaulting Underwriter or Underwriters failed to purchase, or (b) if the aggregate number of Closing Securities or Option Securities, as the case may be, with respect to which such default shall occur exceeds 10% of the Closing Securities or Option Securities, as the case may be, covered hereby, the Company or the Representative will have the right to terminate this Agreement without liability on the part of the non-defaulting Underwriters or of the Company except to the extent provided in Article VI hereof. In the event of a default by any Underwriter or Underwriters, as set forth in this Article V, the applicable Closing Date may be postponed for such period, not exceeding seven days, as the Representative, or if the Representative is the defaulting Underwriter, the non-defaulting Underwriters, may determine in order that the required changes in the Prospectus or in any other documents or arrangements may be effected. The term "Underwriter" includes any Person substituted for a defaulting Underwriter. Any action taken under this Section shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

ARTICLE VI.
INDEMNIFICATION

6.1 Indemnification of the Underwriters. Subject to the conditions set forth below, the Company agrees to indemnify and hold harmless the Underwriters, and each dealer selected by each Underwriter that participates in the offer and sale of the Securities (each a "Selected Dealer") and each of their respective directors, officers and employees and each Person, if any, who controls such Underwriter or any Selected Dealer ("Controlling Person") within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, against any and all loss, liability, claim, damage and expense whatsoever (including but not limited to any and all legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between such Underwriter and the Company or between such Underwriter and any third party or otherwise) to which they or any of them may become subject under the Securities Act, the Exchange Act or any other statute or at common law or otherwise or under the laws of foreign countries, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) any Preliminary Prospectus, if any, the Registration Statement or the Prospectus (as from time to time each may be amended and supplemented); (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically); or (iii) any application or other document or written communication (in this Article VI, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, Trading Market or any securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon and in conformity with written information furnished to the Company with respect to the applicable Underwriter by or on behalf of such Underwriter expressly for use in any Preliminary Prospectus, if any, the Registration Statement or Prospectus, or any amendment or supplement thereto, or in any application, as the case may be. With respect to any untrue statement or omission or alleged untrue statement or omission made in the Preliminary Prospectus, if any, the indemnity agreement contained in this Section 6.1 shall not inure to the benefit of an Underwriter to the extent that any loss, liability, claim, damage or expense of such Underwriter results from the fact that a copy of the Prospectus was not given or sent to the Person asserting any such loss, liability, claim or damage at or prior to the written confirmation of sale of the Securities to such Person as required by the Securities Act and the rules and regulations thereunder, and if the untrue statement or omission has been corrected in the Prospectus, unless such failure to deliver the Prospectus was a result of non-compliance by the Company with its obligations under this Agreement. The Company agrees promptly to notify each Underwriter of the commencement of any litigation or proceedings against the Company or any of its officers, directors or Controlling Persons in connection with the issue and sale of the Public Securities or in connection with the Registration Statement or Prospectus.

6.2 Procedure. If any action is brought against an Underwriter, a Selected Dealer or a Controlling Person in respect of which indemnity may be sought against the Company pursuant to Section 6.1, such Underwriter, such Selected Dealer or Controlling Person, as the case may be, shall promptly notify the Company in writing of the institution of such action and the Company shall assume the defense of such action, including the employment and fees of counsel (subject to the reasonable approval of such Underwriter or such Selected Dealer, as the case may be) and payment of actual expenses. Such Underwriter, such Selected Dealer or Controlling Person shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such Underwriter, such Selected Dealer or Controlling Person unless (i) the employment of such counsel at the expense of the Company shall have been authorized in writing by the Company in connection with the defense of such action, or (ii) the Company shall not have employed counsel to have charge of the defense of such action, or (iii) such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from or additional to those available to the Company (in which case the Company shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events the reasonable and documented fees and expenses of not more than one additional firm of attorneys selected by such Underwriter and approved in writing by the Company (in addition to local counsel), Selected Dealer and/or Controlling Person shall be borne by the Company. Notwithstanding anything to the contrary contained herein, if any Underwriter, Selected Dealer or Controlling Person shall assume the defense of such action as provided above, the Company shall have the right to approve in writing the terms of any settlement of such action which approval shall not be unreasonably withheld.

6.3 Indemnification of the Company. Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its directors, officers and employees and agents who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the foregoing indemnity from the Company to such Underwriter, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, written information furnished to the Company with respect to such Underwriter by or on behalf of such Underwriter expressly for use in such Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or in any such application. In case any action shall be brought against the Company or any other Person so indemnified based on any Preliminary Prospectus, if any, the Registration Statement or Prospectus or any amendment or supplement thereto or any application, and in respect of which indemnity may be sought against such Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other Person so indemnified shall have the rights and duties given to such Underwriter by the provisions of this Article VI. Notwithstanding the provisions of this Section 6.3, no Underwriter shall be required to indemnify the Company for any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriters' obligations in this Section 6.3 to indemnify the Company are several in proportion to their respective underwriting obligations and not joint.

6.4 Contribution.

(a) Contribution Rights. In order to provide for just and equitable contribution under the Securities Act in any case in which (i) any Person entitled to indemnification under this Article VI makes a claim for indemnification pursuant hereto but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Article VI provides for indemnification in such case, or (ii) contribution under the Securities Act, the Exchange Act or otherwise may be required on the part of any such Person in circumstances for which indemnification is provided under this Article VI, then, and in each such case, the Company and each Underwriter, severally and not jointly, shall contribute to the aggregate losses, liabilities, claims, damages and expenses of the nature contemplated by said indemnity agreement incurred by the Company and such Underwriter, as incurred, in such proportions that such Underwriter is responsible for that portion represented by the percentage that the underwriting discount appearing on the cover page of the Prospectus bears to the initial offering price appearing thereon and the Company is responsible for the balance; provided, that, no Person guilty of a fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation. For purposes of this Section, each director, officer and employee of such Underwriter or the Company, as applicable, and each Person, if any, who controls such Underwriter or the Company, as applicable, within the meaning of Section 15 of the Securities Act shall have the same rights to contribution as such Underwriter or the Company, as applicable. Notwithstanding the provisions of this Section 6.4, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Securities purchased by such Underwriter. The Underwriters' obligations in this Section 6.4 to contribute are several in proportion to their respective underwriting obligations and not joint.

(b) Contribution Procedure. Within fifteen days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made against another party ("contributing party"), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid fifteen days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 6.4 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available.

ARTICLE VII.
MISCELLANEOUS

7.1 Termination.

(a) Termination Right. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event or act or occurrence has materially disrupted, or in its opinion will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on any Trading Market shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction, or (iii) if the United States shall have become involved in a new war or an increase in major hostilities, that materially adversely impacts the United States securities markets, or (iv) if a banking moratorium has been declared by a New York State or federal authority, or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets, or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in the Representative's opinion, make it inadvisable to proceed with the delivery of the Securities, or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder, or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's reasonable judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Securities or to enforce contracts made by the Underwriters for the sale of the Securities.

(b) Expenses. In the event this Agreement shall be terminated pursuant to Section 7.1(a), within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Representative its actual and accountable reasonable and documented out of pocket expenses related to the transactions contemplated herein then due and payable, including the fees and disbursements of EGS; provided, however, that such expenses shall not exceed $25,000 in the aggregate (provided, further, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement).

(c) Indemnification. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Article VI shall not be in any way effected by such election or termination or failure to carry out the terms of this Agreement or any part hereof.

7.2 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, and the Prospectus and the Prospectus Supplement, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules. Notwithstanding anything herein to the contrary, the Investment Banking Agreement, dated October 25, 2022 ("Engagement Agreement"), by and between the Company and the Representative, shall continue to be effective and the terms therein, including, without limitation, Section 4(e) and Section 5 with respect to any future offerings, shall continue to survive and be enforceable by the Representative in accordance with its terms, provided that, in the event of a conflict between the terms of the Engagement Agreement and this Agreement, the terms of this Agreement shall prevail.

7.3 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via e-mail attachment at the email address set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail attachment at the e-mail address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

7.4 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 Representative. 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.

7.5 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

7.6 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

7.7 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an Action or Proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Article VI, the prevailing party in such Action or Proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Action or Proceeding.

7.8 Survival. The representations and warranties contained herein shall survive the Closing and the Option Closing, if any, and the delivery of the Securities.

7.9 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" signature page were an original thereof.

7.10 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

7.11 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, the Underwriters and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

7.12 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

7.13 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

7.14 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVE FOREVER ANY RIGHT TO TRIAL BY JURY.**

(Signature Pages Follow)

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement among the Company and the several Underwriters in accordance with its terms.

Very truly yours,

WINDTREE THERAPEUTICS, INC.

By: _____
Name:
Title:

Address for Notice:
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
Attn: Chief Financial Officer

Copy to:

Goodwin Procter LLP
2929 Arch Street, Suite 1700
Philadelphia, Pennsylvania 19104
Email:
Attn:

Accepted on the date first above written.
LADENBURG THALMANN & CO. INC.
As the Representative of the several
Underwriters listed on Schedule I
By: Ladenburg Thalmann & Co. Inc.

By: _____
Name:
Title:

Address for Notice:

640 Fifth Avenue, 4th Floor
New York, NY 10019
E-mail:
Attention:

Copy to:

Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas
New York, New York 10105
E-mail: capmkts@egsllp.com
Attention: Michael Nertney

SCHEDULE I

SCHEDULE OF UNDERWRITERS

Underwriters	Closing Shares	Pre-Funded Warrants	Closing Warrants	Closing Purchase Price
Ladenburg Thalmann & Co. Inc.				
Total				

Exhibit 4.19

COMMON STOCK PURCHASE WARRANT

WINDTREE THERAPEUTICS, INC.

Warrant Shares: _____ Initial Exercise Date: _____, 2023

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on _____, 2028 (the "Termination Date") but not thereafter, to subscribe for and purchase from Windtree Therapeutics, Inc., a Delaware corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee ("DTC") shall initially be the sole registered holder of this Warrant, subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means 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 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Board of Directors" means the board of directors of the Company.

"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" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means 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.

"Registration Statement" means the Company's registration statement on Form S-1 (File No. 333-269775).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Subsidiary" means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the Common Stock may be traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

"Transfer Agent" means Continental Stock Transfer and Trust Company, the current transfer agent of the Company, with a mailing address of 1 State Street 30th Floor, New York, NY 10004-1561 Attention: Compliance Department, a facsimile number of 212-616-7608 or 212-616-7616 and an email address of compliance@continentalstock.com, and any successor transfer agent of the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Warrant Agency Agreement" means that certain warrant agency agreement, dated on or about the Initial Exercise Date, between the Company and the Warrant Agent.

"Warrant Agent" means the Transfer Agent and any successor warrant agent of the Company.

"Warrants" means this Warrant and other Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer pursuant to wire instructions provided by the Company or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions), shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be **$____**, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by book entry, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise and (ii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period, in each case following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $5.00 per Trading Day (increasing to $10.00 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue but in no event shall such liquidated damages in the aggregate exceed more than $10,000 per failed delivery) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or the Holder rescinds such exercise. The Company agrees to use best efforts to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date (other than any such failure that is solely due to any action or inaction by the Holder with respect to such exercise), and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto and all required documents. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder shall be deemed to represent to the Company each time it delivers a Notice of Exercise that such Notice of Exercise has not violated the restrictions set forth in this paragraph, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% (or 19.99% upon prior written approval of the Company) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, 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"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation). To the extent that this Warrant has not been partially or completely exercised at the time of such Distribution, such portion of the Distribution shall be held in abeyance for the benefit of the Holder until the Holder has exercised this Warrant.

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (and all of its Subsidiaries, taken as a whole), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company's control, including not approved by the Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity, the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock shall be deemed to have received common stock of the Successor Entity (which entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg, L.P. ("Bloomberg") determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (i) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the remaining term of this Warrant as of such date of request, (ii) an expected volatility equal to the remaining term of this Warrant obtained from the HVT function on Bloomberg as of the Trading Day immediately prior to the public announcement of the applicable Fundamental Transaction or, if the Fundamental Transaction is not publicly announced, the date the Fundamental Transaction is consummated, (iii) the underlying price per share used in such calculation shall be the greater of (A) the sum of the price per share being offered in cash, if any, plus the per share value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (B) the greater of (x) the last weighted average price of the Common Stock immediately prior to the public announcement of such Fundamental Transaction and (y) the last weighted average price of the Common Stock immediately prior to the consummation of such Fundamental Transaction, (iv) a zero cost of borrow and (v) a 360 day annualization factor. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds within five Business Days of the Holder's election (or, if later, on the effective date of the Fundamental Transaction). The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company or Warrant Agent shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (and all of its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified but in no event earlier than the date on which the Company makes a public announcement, a notice (unless such information is filed with the Commission, in which case a notice shall not be required) stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of its Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

g) Voluntary Adjustment By Company. Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with any applicable securities laws, this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto, duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depositary), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that all rights hereunder terminate on the Termination Date. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976 Attention: Controller, facsimile number: 215-488-9557, email address: warrants@windtreetx.com, or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder or the beneficial owner of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Warrant Agency Agreement. If this Warrant is held in global form through DTC (or any successor depositary), this Warrant is issued subject to the Warrant Agency Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agency Agreement, the provisions of this Warrant shall govern and be controlling.

(Signature Page Follows)

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

WINDTREE THERAPEUTICS, INC.

By: _____
Name: Craig E. Fraser
Title: President and Chief Executive Officer

(Signature Page of Warrant)

NOTICE OF EXERCISE

TO: WINDTREE THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted, the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____
Holder's Signature: _____
Holder's Address: _____

PRE-FUNDED COMMON STOCK PURCHASE WARRANT

WINDTREE THERAPEUTICS, INC.

Warrant Shares: _____ Initial Exercise Date: _____, 2023

THIS PRE-FUNDED COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") until this Warrant is exercised in full (the "Termination Date") but not thereafter, to subscribe for and purchase from Windtree Therapeutics, Inc., a Delaware corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means 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 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"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" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means 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.

"Registration Statement" means the Company's registration statement on Form S-1 (File No. 333-269775).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Subsidiary" means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the Common Stock may be traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

"Transfer Agent" means Continental Stock Transfer and Trust Company, the current transfer agent of the Company, with a mailing address of 1 State Street 30th Floor, New York, NY 10004-1561 Attention: Compliance Department, a facsimile number of 212-616-7608 or 212-616-7616 and an email address of compliance@continentalstock.com, and any successor transfer agent of the Company.

"Underwriting Agreement" means the underwriting agreement, dated as of _____, 2023, among the Company and Ladenburg Thalmann & Co. Inc. as representative of the underwriters named therein, as amended, modified or supplemented from time to time in accordance with its terms.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is not then listed or quoted for trading on a Trading Market and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported or (c) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Warrants" means this Warrant and other Pre-Funded Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer pursuant to wire instructions provided by the Company or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The aggregate exercise price of this Warrant, except for a nominal exercise price of $0.001 per Warrant Share, was pre-funded to the Company on or prior to the Initial Exercise Date and, consequently, no additional consideration (other than the nominal exercise price of $0.001 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever. The remaining unpaid exercise price per share of Common Stock under this Warrant shall be $0.001, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. This Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by book entry, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise and (ii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period, in each case following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $5.00 per Trading Day (increasing to $10.00 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue but in no event shall such liquidated damages in the aggregate exceed more than $10,000 per failed delivery) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or the Holder rescinds such exercise. The Company agrees to use best efforts to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 12:00 p.m. (New York City time) on the Initial Exercise Date, which may be delivered at any time after the time of execution of the Underwriting Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date and the Initial Exercise Date shall be the Warrant Share Delivery Date for purposes hereunder, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by such Warrant Share Delivery Date.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date (other than any such failure that is solely due to any action or inaction by the Holder with respect to such exercise), and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto and all required documents. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder shall be deemed to represent to the Company each time it delivers a Notice of Exercise that such Notice of Exercise has not violated the restrictions set forth in this paragraph, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% (or 19.99% upon prior written approval of the Company) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, 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"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation). To the extent that this Warrant has not been partially or completely exercised at the time of such Distribution, such portion of the Distribution shall be held in abeyance for the benefit of the Holder until the Holder has exercised this Warrant.

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (and all of its Subsidiaries, taken as a whole), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (and all of its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified but in no event earlier than the date on which the Company makes a public announcement, a notice (unless such information is filed with the Commission, in which case a notice shall not be required) stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of its Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with any applicable securities laws, this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto, duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that all rights hereunder terminate on the Termination Date. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976 Attention: Controller, facsimile number: 215-488-9557, email address: warrants@windtreetx.com, or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. This Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder or the beneficial owner of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

(Signature Page Follows)

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

WINDTREE THERAPEUTICS, INC.

By: _____
Name: Craig E. Fraser
Title: President and Chief Executive Officer

(Signature Page of Warrant)

NOTICE OF EXERCISE

TO: WINDTREE THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted, the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder's Signature: _____

Holder's Address: _____

Exhibit 4.21

Windtree Therapeutics, Inc.

and

Continental Stock Transfer & Trust Company, as
Warrant Agent

Warrant Agency Agreement

Dated as of _____, 2023

WARRANT AGENCY AGREEMENT

WARRANT AGENCY AGREEMENT, dated as of _____, 2023 ("Agreement"), between Windtree Therapeutics, Inc., a Delaware corporation (the "Company"), and Continental Stock Transfer & Trust Company, a New York corporation (the "Warrant Agent").

W I T N E S S E T H

WHEREAS, pursuant to a registered offering by the Company of an aggregate of _____ shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), or pre-funded warrants in lieu of Common Stock, and warrants to purchase an aggregate of _____ shares of Common Stock (each a "Warrant" and collectively, the "Warrants"), pursuant to an effective registration statement, as amended on Form S-1 (File No. 333-269775) (the "Registration Statement") and prospectus (the "Prospectus"), the Company wishes to issue the Warrants in book entry form entitling the respective holders of the Warrants (the "Holders", which term shall include a Holder's transferees, successors and assigns and "Holder" shall include, if the Warrants are held in "street name," a Participant (as defined below) or a designee appointed by such Participant) to purchase an aggregate of _____- shares Common Stock upon the terms and subject to the conditions hereinafter set forth (the "Offering");

WHEREAS, the shares of Common Stock and Warrants to be issued in connection with the Offering shall be immediately separable and will be issued separately, but will be purchased together in the Offering; and

WHEREAS, the Company wishes the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing so to act, in connection with the issuance, registration, transfer, exchange, exercise and replacement of the Warrants and, in the Warrant Agent's capacity as the Company's transfer agent, the delivery of the Warrant Shares (as defined below).

NOW, THEREFORE, in consideration of the premises and the mutual agreements herein set forth, the parties hereby agree as follows:

Section 1. Certain Definitions. For purposes of this Agreement, the following terms have the meanings indicated:

(a) "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 are generally are open for use by customers on such day.

(b) "Close of Business" on any given date means 5:00 p.m., New York City time, on such date; provided, however, that if such date is not a Business Day it means 5:00 p.m., New York City time, on the next succeeding Business Day.

(c) "Person" means an individual, corporation, association, partnership, limited liability company, joint venture, trust, unincorporated organization, government or political subdivision thereof or governmental agency or other entity.

(d) "Warrant Certificate" means a certificate issued to a Holder, representing such number of Warrant Shares as is indicated therein.

(e) "Warrant Shares" means the shares of Common Stock underlying the Warrants and issuable upon exercise of the Warrants.

All other capitalized terms used but not otherwise defined herein shall have the meaning ascribed to such terms in the Warrant.

Section 2. Appointment of Warrant Agent. The Company hereby appoints the Warrant Agent to act as agent for the Company in accordance with the terms and conditions hereof, and the Warrant Agent hereby accepts such appointment. The Company may from time to time appoint a Co-Warrant Agent as it may, in its sole discretion, deem necessary or desirable. The Warrant Agent shall have no duty to supervise, and will in no event be liable for the acts or omissions of, any co-Warrant Agent.

Section 3. Global Warrants.

(a) The Warrants shall be issuable in book entry form (the "Global Warrants"). All of the Warrants shall initially be represented by one or more Global Warrants deposited with the Warrant Agent and registered in the name of Cede & Co., a nominee of The Depository Trust Company (the "Depositary"), or as otherwise directed by the Depositary. Ownership of beneficial interests in the Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained by (i) the Depositary or its nominee for each Global Warrant or (ii) institutions that have accounts with the Depositary (such institution, with respect to a Warrant in its account, a "Participant").

(b) If the Depositary subsequently ceases to make its book-entry settlement system available for the Warrants, the Company may instruct the Warrant Agent regarding other arrangements for book-entry settlement. In the event that the Warrants are not eligible for, or it is no longer necessary to have the Warrants available in, book-entry form, the Warrant Agent shall provide written instructions to the Depositary to deliver to the Warrant Agent for cancellation each Global Warrant, and the Company shall instruct the Warrant Agent to deliver to each Holder a Warrant Certificate.

(c) A Holder has the right to elect at any time or from time to time a Warrant Exchange (as defined below) pursuant to a Warrant Certificate Request Notice (as defined below). Upon written notice by a Holder to the Warrant Agent for the exchange of some or all of such Holder's Global Warrants for a Warrant Certificate evidencing the same number of Warrants, which request shall be in the form attached hereto as Annex A (a "Warrant Certificate Request Notice" and the date of delivery of such Warrant Certificate Request Notice by the Holder, the "Warrant Certificate Request Notice Date" and the deemed surrender upon delivery by the Holder of a number of Global Warrants for the same number of Warrants evidenced by a Warrant Certificate, a "Warrant Exchange"), the Warrant Agent shall promptly effect the Warrant Exchange and shall promptly issue and deliver to the Holder a Warrant Certificate for such number of Warrants in the name set forth in the Warrant Certificate Request Notice. Such Warrant Certificate shall be dated the original issue date of the Warrants and shall be manually executed by an authorized signatory of the Company. In connection with a Warrant Exchange, the Company agrees to deliver, or to direct the Warrant Agent to deliver, the Warrant Certificate to the Holder within three (3) Business Days of the Warrant Certificate Request Notice pursuant to the delivery instructions in the Warrant Certificate Request Notice ("Warrant Certificate Delivery Date"). If the Company fails for any reason to deliver to the Holder the Warrant Certificate subject to the Warrant Certificate Request Notice by the Warrant Certificate Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares evidenced by such Warrant Certificate (based on the VWAP (as defined in the Warrant) of the Common Stock on the Warrant Certificate Request Notice Date), $5.00 per Business Day (increasing to $10.00 per Business Day on the fifth Business Day after such liquidated damages begin to accrue) for each Business Day after such Warrant Certificate Delivery Date until such Warrant Certificate is delivered or, prior to delivery of such Warrant Certificate, the Holder rescinds such Warrant Exchange. The Company covenants and agrees that, upon the date of delivery of the Warrant Certificate Request Notice, the Holder shall be deemed to be the holder of the Warrant Certificate and, notwithstanding anything to the contrary set forth herein, the Warrant Certificate shall be deemed for all purposes to contain all of the terms and conditions of the Warrants evidenced by such Warrant Certificate and the terms of this Agreement, other than Section 3(c), which shall not apply to the Warrants evidenced by a Warrant Certificate. In the event a beneficial owner requests a Warrant Exchange, upon issuance of the paper Warrant Certificate, the Company shall act as warrant agent and the terms of the paper Warrant Certificate so issued shall exclusively govern in respect thereof. For purposes of clarity, the Company and the Warrant Agent acknowledge and agree that, with respect to the terms of the Warrants, the Warrant Certificate or Global Warrant shall set forth the terms of the Warrants and, in the event of any conflict between the Warrant Certificate or the Global Warrant and this Agreement, the Warrant Certificate or the Global Warrants, as the case may be, shall control. For purposes of Regulation SHO, a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC shall be deemed to have exercised its interest in this Warrant upon instructing its broker that is a DTC participant to exercise its interest in this Warrant, except that, if the date of exercise is a date when the stock transfer books of the Company are closed, such person shall be deemed to have become the holder of such shares at the open of business on the next succeeding date on which the stock transfer books are open

Section 4. Form of Warrant. The Warrants, together with the form of election to purchase Common Stock (the "Exercise Notice") and the form of assignment to be printed on the reverse thereof, whether a Warrant Certificate or a Global Warrant, shall be substantially in the form of Exhibit 1 hereto.

Section 5. Countersignature and Registration. The Warrants shall be executed on behalf of the Company by its Chief Executive Officer or Chief Financial Officer, either manually or by facsimile signature. The Warrants shall be countersigned by the Warrant Agent either manually or by facsimile signature and shall not be valid for any purpose unless so countersigned. In case any officer of the Company who shall have signed a Warrant shall cease to be such officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Warrant, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Warrant had not ceased to be such officer of the Company; and any Warrant may be signed on behalf of the Company by any person who, at the actual date of the execution of such Warrant, shall be a proper officer of the Company to sign such Warrant, although at the date of the execution of this Warrant Agreement any such person was not such an officer.

The Warrant Agent will keep or cause to be kept, at one of its offices, or at the office of one of its agents, books for registration and transfer of the Warrant Certificates issued hereunder. Such books shall show the names and addresses of the respective Holders of the Warrant Certificates, the number of warrants evidenced on the face of each of such Warrant Certificate and the date of each of such Warrant Certificate. The Warrant Agent will create a special account for the issuance of Warrant Certificates.

Section 6. Transfer, Split Up, Combination and Exchange of Warrant Certificates; Mutilated, Destroyed, Lost or Stolen Warrant Certificates. Subject to the provisions of the Warrant and the last sentence of this first paragraph of Section 6 of this Agreement and subject to applicable law, rules or regulations, or any "stop transfer" instructions the Company may give to the Warrant Agent, at any time after the closing date of the Offering, and at or prior to the Close of Business on the Termination Date, any Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants may be transferred, split up, combined or exchanged for another Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants, entitling the Holder to purchase a like number of shares of Common Stock as the Warrant Certificate or Warrant Certificates or Global Warrant or Global Warrants surrendered then entitled such Holder to purchase. Any Holder desiring to transfer, split up, combine or exchange any Warrant Certificate or Global Warrant shall make such request in writing delivered to the Warrant Agent, and shall surrender the Warrant Certificate or Warrant Certificates to be transferred, split up, combined or exchanged at the principal office of the Warrant Agent, provided that no such surrender is applicable to the Holder of a Global Warrant. Any requested transfer of Warrants, whether a Global Warrant or a Warrant Certificate, shall be accompanied by reasonable evidence of authority of the party making such request that may be required by the Warrant Agent. Thereupon the Warrant Agent shall, subject to the last sentence of this first paragraph of Section 6 of this Agreement, countersign and deliver to the Person entitled thereto any Warrant Certificate or Global Warrant, as the case may be, as so requested. The Company may require payment from the Holder of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with any transfer, split up, combination or exchange of Warrants. The Company shall compensate the Warrant Agent per the fee schedule mutually agreed upon by the parties hereto and provided separately on the date hereof.

Upon receipt by the Warrant Agent of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of a Warrant Certificate, which evidence shall include an affidavit of loss, or in the case of mutilated certificates, the certificate or portion thereof remaining, and, in case of loss, theft or destruction, of indemnity in customary form and amount, and satisfaction of any other reasonable requirements established by Section 8-405 of the Uniform Commercial Code as in effect in the State of Delaware, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Company will make and deliver a new Warrant Certificate of like tenor to the Warrant Agent for delivery to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated.

Section 7. Exercise of Warrants; Exercise Price; Termination Date.

(a) The Warrants shall be exercisable commencing on the Initial Exercise Date. The Warrants shall cease to be exercisable and the right to exercise such Warrants shall terminate and become void as set forth in the Warrant Certificate. Subject to the foregoing and to Section 7(b) below, the Holder of a Warrant may exercise the Warrant in whole or in part upon providing the items required by Section 7(c) below to the Warrant Agent at the principal office of the Warrant Agent or to the office of one of its agents as may be designated by the Warrant Agent from time to time. In the case of the Holder of a Global Warrant, the Holder shall deliver the executed Exercise Notice and payment of the Exercise Price pursuant to Section 2(a) of the Warrant. Notwithstanding any other provision in this Agreement, a holder whose interest in a Global Warrant is a beneficial interest in a Global Warrant held in book-entry form through the Depositary (or another established clearing corporation performing similar functions), shall effect exercises by delivering to the Depositary (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by the Depositary (or such other clearing corporation, as applicable). The Company acknowledges that the bank accounts maintained by the Warrant Agent in connection with the services provided under this Agreement will be in its name and that the Warrant Agent may receive investment earnings in connection with the investment at Warrant Agent risk and for its benefit of funds held in those accounts from time to time. Neither the Company nor the Holders will receive interest on any deposits or Exercise Price.

(b) Upon receipt of an Exercise Notice for a cashless exercise pursuant to Section 2(c) of the Warrant (each, a "Cashless Exercise"), the Company will promptly calculate and transmit to the Warrant Agent the number of Warrant Shares issuable in connection with such Cashless Exercise and deliver a copy of the Exercise Notice to the Warrant Agent, which shall issue such number of Warrant Shares in connection with such Cashless Exercise.

(c) Upon the Warrant Agent's receipt, at or prior to the Close of Business on the Termination Date set forth in a Warrant, of the executed Exercise Notice, accompanied by payment of the Exercise Price pursuant to Section 2(a) of the Warrant, the shares to be purchased (other than in the case of a Cashless Exercise), an amount equal to any applicable tax, governmental charge or expense reimbursement referred to in Section 6 by wire transfer, or by certified check or bank draft payable to the order of the Warrant Agent and, in the case of an exercise of a Warrant in the form of a Warrant Certificate for all of the Warrant Shares represented thereby, the Warrant Certificate, the Warrant Agent shall cause the Warrant Shares underlying such Warrant to be delivered to or upon the order of the Holder of such Warrant, registered in such name or names as may be designated by such Holder, no later than the Warrant Share Delivery Date. If the Company is then a participant in the DWAC system of the Depositary and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) the Warrant is being exercised via Cashless Exercise, then the certificates for Warrant Shares shall be transmitted by the Warrant Agent to the Holder by crediting the account of the Holder's broker with the Depositary through its DWAC system. For the avoidance of doubt, if the Company becomes obligated to pay any amounts to any Holders pursuant to Section 2(d)(i) or 2(d)(iv) of the Warrant, such obligation shall be solely that of the Company and not that of the Warrant Agent. Notwithstanding anything else to the contrary in this Agreement, except in the case of a Cashless Exercise, if any Holder fails to duly deliver payment to the Warrant Agent of an amount equal to the aggregate Exercise Price of the Warrant Shares to be purchased upon exercise of such Holder's Warrant as set forth in Section 7(a) hereof, the Warrant Agent will not obligated to deliver certificates representing any such Warrant Shares (via DWAC or otherwise) until following receipt of such payment, and the applicable Warrant Share Delivery Date shall be deemed extended by one day for each day (or part thereof) until such payment is delivered to the Warrant Agent.

(d) The Warrant Agent shall deposit all funds received by it in payment of the Exercise Price for all Warrants in the account of the Company maintained with the Warrant Agent for such purpose (or to such other account as directed by the Company in writing) and shall advise the Company via telephone at the end of each day on which funds for the exercise of any Warrant are received of the amount so deposited to its account. The Warrant Agent shall promptly confirm such telephonic advice to the Company in writing.

(e) In case the Holder of any Warrant Certificate exercises fewer than all Warrants evidenced thereby and surrenders such Warrant Certificate in connection with such partial exercise, a new Warrant Certificate evidencing the number of Warrant Shares equivalent to the number of Warrant Shares remaining unexercised may be issued by the Warrant Agent to the Holder of such Warrant Certificate or to his duly authorized assigns in accordance with Section 2(d)(ii) of the Warrant, subject to the provisions of Section 6 hereof.

Section 8. Cancellation and Destruction of Warrant Certificates. All Warrant Certificates surrendered for the purpose of exercise, transfer, split up, combination or exchange shall, if surrendered to the Company or to any of its agents, be delivered to the Warrant Agent for cancellation or in canceled form, or, if surrendered to the Warrant Agent, shall be canceled by it, and no Warrant Certificates shall be issued in lieu thereof except as expressly permitted by any of the provisions of this Agreement. The Company shall deliver to the Warrant Agent for cancellation and retirement, and the Warrant Agent shall so cancel and retire, any other Warrant Certificate purchased or acquired by the Company otherwise than upon the exercise thereof. The Warrant Agent shall deliver all canceled Warrant Certificates to the Company, or shall, at the written request of the Company, destroy such canceled Warrant Certificates, and in such case shall deliver a certificate of destruction thereof to the Company, subject to any applicable law, rule or regulation requiring the Warrant Agent to retain such canceled certificates.

Section 9. Certain Representations; Reservation and Availability of Shares of Common Stock or Cash.

(a) This Agreement has been duly authorized, executed and delivered by the Company and, assuming due authorization, execution and delivery hereof by the Warrant Agent, constitutes a valid and legally binding obligation of the Company enforceable against the Company in accordance with its terms, and the Warrants have been duly authorized, executed and issued by the Company and, assuming due authentication thereof by the Warrant Agent pursuant hereto and payment therefor by the Holders as provided in the Registration Statement, constitute valid and legally binding obligations of the Company enforceable against the Company in accordance with their terms and entitled to the benefits thereof; in each case except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and other similar laws relating to or affecting creditors' rights generally or by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(b) As of the date hereof and prior to the Offering, the authorized capital stock of the Company consists of (i) _____ shares of Common Stock, of which _____ shares of Common Stock are issued and outstanding, and (ii) _____ shares of undesignated preferred stock, par value $0.001 per share, none of which are issued and outstanding. As of the date hereof, an aggregate of _____ shares of Common Stock are reserved for issuance upon exercise of the Warrants. Except as disclosed in the Registration Statement, there are no other outstanding obligations, warrants, options or other rights to subscribe for or purchase from the Company any class of capital stock of the Company.

(c) The Company covenants and agrees that it will cause to be reserved and kept available out of its authorized and unissued shares of Common Stock or its authorized and issued shares of Common Stock held in its treasury, free from preemptive rights, the number of shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Warrants.

(d) The Warrant Agent will create a special account for the issuance of Common Stock upon the exercise of Warrants.

(e) The Company further covenants and agrees that it will pay when due and payable any and all federal and state transfer taxes and charges which may be payable in respect of the original issuance or delivery of the Warrant Certificates or certificates evidencing Common Stock upon exercise of the Warrants. The Company shall not, however, be required to pay any tax or governmental charge which may be payable in respect of any transfer involved in the transfer or delivery of Warrant Certificates or the issuance or delivery of certificates for Common Stock in a name other than that of the Holder of the Warrant Certificate evidencing Warrants surrendered for exercise or to issue or deliver any certificate for shares of Common Stock upon the exercise of any Warrants until any such tax or governmental charge shall have been paid (any such tax or governmental charge being payable by the Holder of such Warrant Certificate at the time of surrender) or until it has been established to the Company's reasonable satisfaction that no such tax or governmental charge is due.

Section 10. Common Stock Record Date. Each Holder shall be deemed to have become the holder of record for the Warrant Shares pursuant to Section 2(d)(i) of the Warrants.

Section 11. Adjustment of Exercise Price, Number of Shares of Common Stock or Number of the Company Warrants. The Exercise Price, the number of shares covered by each Warrant and the number of Warrants outstanding are subject to adjustment from time to time as provided in Section 3 of the Warrant. In the event that at any time, as a result of an adjustment made pursuant to Section 3 of the Warrant, the Holder of any Warrant thereafter exercised shall become entitled to receive any shares of capital stock of the Company other than shares of Common Stock, thereafter the number of such other shares so receivable upon exercise of any Warrant shall be subject to adjustment from time to time in a manner and on terms as nearly equivalent as practicable to the provisions with respect to the shares contained in Section 3 of the Warrant, and the provisions of Sections 7, 9 and 13 of this Agreement with respect to the shares of Common Stock shall apply on like terms to any such other shares. All Warrants originally issued by the Company subsequent to any adjustment made to the Exercise Price pursuant to the Warrant shall evidence the right to purchase, at the adjusted Exercise Price, the number of shares of Common Stock purchasable from time to time hereunder upon exercise of the Warrants, all subject to further adjustment as provided herein.

Section 12. Certification of Adjusted Exercise Price or Number of Shares of Common Stock. Whenever the Exercise Price or the number of shares of Common Stock issuable upon the exercise of each Warrant is adjusted as provided in Section 11 or 13 of this Agreement, the Company shall (a) promptly prepare a certificate setting forth the Exercise Price of each Warrant as so adjusted, and a brief statement of the facts accounting for such adjustment, (b) promptly file with the Warrant Agent and with each transfer agent for the Common Stock a copy of such certificate and (c) instruct the Warrant Agent to send a brief summary thereof to each Holder of a Warrant.

Section 13. Fractional Shares of Common Stock.

(a) The Company shall not issue fractions of Warrants or distribute a Global Warrant or Warrant Certificates that evidence fractional Warrants. Whenever any fractional Warrant would otherwise be required to be issued or distributed, the actual issuance or distribution shall reflect a rounding of such fraction down to the nearest whole Warrant.

(b) The Company shall not issue fractions of shares of Common Stock upon exercise of Warrants or distribute stock certificates that evidence fractional shares of Common Stock. Whenever any fraction of a share of Common Stock would otherwise be required to be issued or distributed, the actual issuance or distribution in respect thereof shall be made in accordance with Section 2(d)(v) of the Warrant.

Section 14. Conditions of the Warrant Agent's Obligations. The Warrant Agent accepts its obligations herein set forth upon the terms and conditions hereof, including the following to all of which the Company agrees and to all of which the rights hereunder of the Holders from time to time of the Warrant shall be subject:

(a) Compensation and Indemnification. The Company agrees promptly to pay the Warrant Agent the compensation detailed on Exhibit 2 hereto for all services rendered by the Warrant Agent and to reimburse the Warrant Agent for reasonable out-of-pocket expenses (including reasonable and documented counsel fees) incurred without gross negligence, bad faith or willful misconduct by the Warrant Agent in connection with the services rendered hereunder by the Warrant Agent. The Company also agrees to indemnify the Warrant Agent for, and to hold it harmless against, any loss, liability or expense incurred without gross negligence, bad faith or willful misconduct on the part of the Warrant Agent, arising out of or in connection with its acting as Warrant Agent hereunder, including the reasonable costs and expenses of defending against any claim of such liability.

(b) Agent for the Company. In acting under this Warrant Agreement and in connection with the Warrant Certificates, the Warrant Agent is acting solely as agent of the Company and does not assume any obligations or relationship of agency or trust for or with any of the Holders of Warrant Certificates or beneficial owners of Warrants.

(c) Counsel. The Warrant Agent may consult with counsel satisfactory to it, which may include counsel for the Company, and the written advice of such counsel shall be full and complete authorization and protection in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with the advice of such counsel.

(d) Documents. The Warrant Agent shall be protected and shall incur no liability for or in respect of any action taken or omitted by it in reliance upon any Warrant Certificate, notice, direction, consent, certificate, affidavit, statement or other paper or document reasonably believed by it to be genuine and to have been presented or signed by the proper parties.

(e) Certain Transactions. The Warrant Agent, and its officers, directors and employees, may become the owner of, or acquire any interest in, Warrants, with the same rights that it or they would have if it were not the Warrant Agent hereunder, and, to the extent permitted by applicable law, it or they may engage or be interested in any financial or other transaction with the Company and may act on, or as depositary, trustee or agent for, any committee or body of Holders of Warrant Securities or other obligations of the Company as freely as if it were not the Warrant Agent hereunder. Nothing in this Warrant Agreement shall be deemed to prevent the Warrant Agent from acting as trustee under any indenture to which the Company is a party.

(f) No Liability for Interest. Unless otherwise agreed with the Company, the Warrant Agent shall have no liability for interest on any monies at any time received by it pursuant to any of the provisions of this Agreement or of the Warrant Certificates.

(g) No Liability for Invalidity. The Warrant Agent shall have no liability with respect to any invalidity of this Agreement or any of the Warrant Certificates (except as to the Warrant Agent's countersignature thereon).

(h) No Responsibility for Representations. The Warrant Agent shall not be responsible for any of the recitals or representations herein or in the Warrant Certificates (except as to the Warrant Agent's countersignature thereon), all of which are made solely by the Company.

(i) No Implied Obligations. The Warrant Agent shall be obligated to perform only such duties as are herein and in the Warrants specifically set forth and no implied duties or obligations shall be read into this Agreement or the Warrants against the Warrant Agent. The Warrant Agent shall not be under any obligation to take any action hereunder which may tend to involve it in any expense or liability, the payment of which within a reasonable time is not, in its reasonable opinion, assured to it. The Warrant Agent shall not be accountable or under any duty or responsibility for the use by the Company of any of the Warrants authenticated by the Warrant Agent and delivered by it to the Company pursuant to this Agreement or for the application by the Company of the proceeds of the Warrants. The Warrant Agent shall have no duty or responsibility in case of any default by the Company in the performance of its covenants or agreements contained herein or in the Warrants or in the case of the receipt of any written demand from a Holder of a Warrant Certificate with respect to such default, including, without limiting the generality of the foregoing, any duty or responsibility to initiate or attempt to initiate any proceedings at law.

Section 15. Purchase or Consolidation or Change of Name of Warrant Agent. Any corporation into which the Warrant Agent or any successor Warrant Agent may be merged or with which it may be consolidated, or any corporation resulting from any merger or consolidation to which the Warrant Agent or any successor Warrant Agent shall be party, or any corporation succeeding to the corporate trust business of the Warrant Agent or any successor Warrant Agent, shall be the successor to the Warrant Agent under this Agreement without the execution or filing of any paper or any further act on the part of any of the parties hereto, provided that such corporation would be eligible for appointment as a successor Warrant Agent under the provisions of Section 17 of this Agreement. In case at the time such successor Warrant Agent shall succeed to the agency created by this Agreement any of the Warrants shall have been countersigned but not delivered, any such successor Warrant Agent may adopt the countersignature of the predecessor Warrant Agent and deliver such Warrants so countersigned; and in case at that time any of the Warrants shall not have been countersigned, any successor Warrant Agent may countersign such Warrants either in the name of the predecessor Warrant Agent or in the name of the successor Warrant Agent; and in all such cases such Warrants shall have the full force provided in the Warrants and in this Agreement.

In case at any time the name of the Warrant Agent shall be changed and at such time any of the Warrants shall have been countersigned but not delivered, the Warrant Agent may adopt the countersignature under its prior name and deliver Warrants so countersigned; and in case at that time any of the Warrants shall not have been countersigned, the Warrant Agent may countersign such Warrants either in its prior name or in its changed name; and in all such cases such Warrants shall have the full force provided in the Warrants and in this Agreement.

Section 16. Duties of Warrant Agent. The Warrant Agent undertakes the duties and obligations imposed by this Agreement upon the following terms and conditions, by all of which the Company, by its acceptance hereof, shall be bound:

(a) The Warrant Agent may consult with legal counsel reasonably acceptable to the Company (who may be legal counsel for the Company), and the opinion of such counsel shall be full and complete authorization and protection to the Warrant Agent as to any action taken or omitted by it in good faith and in accordance with such opinion.

(b) Whenever in the performance of its duties under this Agreement the Warrant Agent shall deem it necessary or desirable that any fact or matter be proved or established by the Company prior to taking or suffering any action hereunder, such fact or matter (unless other evidence in respect thereof be herein specifically prescribed) may be deemed to be conclusively proved and established by a certificate signed by the Chief Executive Officer or Chief Financial Officer of the Company; and such certificate shall be full authentication to the Warrant Agent for any action taken or suffered in good faith by it under the provisions of this Agreement in reliance upon such certificate.

(c) Subject to the limitation set forth in Section 14 of this Agreement, the Warrant Agent shall be liable hereunder only for its own gross negligence, bad faith or willful misconduct, or for a breach by it of this Agreement.

(d) The Warrant Agent shall not be liable for or by reason of any of the statements of fact or recitals contained in this Agreement or in the Warrants (except its countersignature thereof) by the Company or be required to verify the same, but all such statements and recitals are and shall be deemed to have been made by the Company only.

(e) The Warrant Agent shall not be under any responsibility in respect of the validity of this Agreement or the execution and delivery hereof (except the due execution hereof by the Warrant Agent) or in respect of the validity or execution of any Warrant (except its countersignature thereof); nor shall it be responsible for any breach by the Company of any covenant or condition contained in this Agreement or in any Warrant; nor shall it be responsible for the adjustment of the Exercise Price or the making of any change in the number of shares of Common Stock required under the provisions of Section 11 or 13 or responsible for the manner, method or amount of any such change or the ascertaining of the existence of facts that would require any such adjustment or change (except with respect to the exercise of Warrants evidenced by Warrant Certificates after actual notice of any adjustment of the Exercise Price); nor shall it by any act hereunder be deemed to make any representation or warranty as to the authorization or reservation of any shares of Common Stock to be issued pursuant to this Agreement or any Warrant or as to whether any shares of Common Stock will, when issued, be duly authorized, validly issued, fully paid and nonassessable.

(f) Each party hereto agrees that it will perform, execute, acknowledge and deliver or cause to be performed, executed, acknowledged and delivered all such further and other acts, instruments and assurances as may reasonably be required by the other party hereto for the carrying out or performing by any party of the provisions of this Agreement.

(g) The Warrant Agent is hereby authorized to accept instructions with respect to the performance of its duties hereunder from the Chief Executive Officer or Chief Financial Officer of the Company, and to apply to such officers for advice or instructions in connection with its duties, and it shall not be liable and shall be indemnified and held harmless for any action taken or suffered to be taken by it in good faith in accordance with instructions of any such officer, provided Warrant Agent carries out such instructions without gross negligence, bad faith or willful misconduct.

(h) The Warrant Agent and any shareholder, director, officer or employee of the Warrant Agent may buy, sell or deal in any of the Warrants or other securities of the Company or become pecuniarily interested in any transaction in which the Company may be interested, or contract with or lend money to the Company or otherwise act as fully and freely as though it were not Warrant Agent under this Agreement. Nothing herein shall preclude the Warrant Agent from acting in any other capacity for the Company or for any other legal entity.

(i) The Warrant Agent may execute and exercise any of the rights or powers hereby vested in it or perform any duty hereunder either itself or by or through its attorney or agents, and the Warrant Agent shall not be answerable or accountable for any act, default, neglect or misconduct of any such attorney or agents or for any loss to the Company resulting from any such act, default, neglect or misconduct, provided reasonable care was exercised in the selection and continued employment thereof.

Section 17. Change of Warrant Agent. The Warrant Agent may resign and be discharged from its duties under this Agreement upon 30 days' notice in writing sent to the Company and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. The Company may remove the Warrant Agent or any successor Warrant Agent upon 30 days' notice in writing, sent to the Warrant Agent or successor Warrant Agent, as the case may be, and to each transfer agent of the Common Stock, and to the Holders of the Warrant Certificates. If the Warrant Agent shall resign or be removed or shall otherwise become incapable of acting, the Company shall appoint a successor to the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after such removal or after it has been notified in writing of such resignation or incapacity by the resigning or incapacitated Warrant Agent or by the Holder of a Warrant Certificate (who shall, with such notice, submit his Warrant Certificate for inspection by the Company), then the Holder of any Warrant Certificate may apply to any court of competent jurisdiction for the appointment of a new Warrant Agent. Any successor Warrant Agent, whether appointed by the Company or by such a court, shall be a corporation organized and doing business under the laws of the United States or of a state thereof, in good standing, which is authorized under such laws to exercise corporate trust powers and is subject to supervision or examination by federal or state authority and which has at the time of its appointment as Warrant Agent a combined capital and surplus of at least $50,000,000. After appointment, the successor Warrant Agent shall be vested with the same powers, rights, duties and responsibilities as if it had been originally named as Warrant Agent without further act or deed; but the predecessor Warrant Agent shall deliver and transfer to the successor Warrant Agent any property at the time held by it hereunder, and execute and deliver any further assurance, conveyance, act or deed necessary for the purpose. Not later than the effective date of any such appointment, the Company shall file notice thereof in writing with the predecessor Warrant Agent and each transfer agent of the Common Stock, and mail a notice thereof in writing to the Holders of the Warrant Certificates. However, failure to give any notice provided for in this Section 17, or any defect therein, shall not affect the legality or validity of the resignation or removal of the Warrant Agent or the appointment of the successor Warrant Agent, as the case may be.

Section 18. Issuance of New Warrants. Notwithstanding any of the provisions of this Agreement or of the Warrants to the contrary, the Company may, at its option, issue a new Global Warrant or Warrant Certificates, if any, evidencing Warrants in such form as may be approved by its Board of Directors to reflect any adjustment or change in the Exercise Price per share and the number or kind or class of shares of stock or other securities or property purchasable under the Global Warrant or Warrant Certificates, if any, made in accordance with the provisions of this Agreement.

Section 19. Notices. Notices or demands authorized by this Agreement to be given or made (i) by the Warrant Agent or by the Holder of any Warrant Certificate to or on the Company, (ii) subject to the provisions of Section 17, by the Company or by the Holder of any Warrant Certificate to or on the Warrant Agent or (iii) by the Company or the Warrant Agent to the Holder of any Warrant Certificate, shall be deemed given (a) on the date delivered, if delivered personally, (b) on the first Business Day following the deposit thereof with Federal Express or another recognized overnight courier, if sent by Federal Express or another recognized overnight courier, (c) on the fourth Business Day following the mailing thereof with postage prepaid, if mailed by registered or certified mail (return receipt requested), and (d) the date of transmission, if such notice or communication is delivered via facsimile or email attachment at or prior to 5:30 p.m. (New York City time) on a Business Day and (e) the next Business Day after the date of transmission, if such notice or communication is delivered via facsimile or email attachment on a day that is not a Business Day or later than 5:30 p.m. (New York City time) on any Business Day, in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

(a) If to the Company, to:

Windtree Therapeutics, Inc.
2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
Facsimile: 215-488-9557
Attention: Chief Financial Officer

(b) If to the Warrant Agent, to:

Continental Stock Transfer & Trust Company
1 State Street, 30 Floor
New York, NY 10004-1561
Facsimile: [●]
Attention: [●]

(c) If to the Holder of any Warrant Certificate, to the address of such Holder as shown on the registry books of the Company. Any notice required to be delivered by the Company to the Holder of any Warrant may be given by the Warrant Agent on behalf of the Company. Notwithstanding any other provision of this Agreement, where this Agreement provides for notice of any event to a Holder of any Warrant Certificate, for a Global Warrant, such notice shall be sufficiently given if given to the Depositary (or its designee) pursuant to the procedures of the Depositary or its designee.

For any notice delivered by email to be deemed given or made, such notice must be followed by notice sent by overnight courier service to be delivered on the next business day following such email, unless the recipient of such email has acknowledged via return email receipt of such email.

Section 20. Supplements and Amendments.

(a) The Company and the Warrant Agent may from time to time supplement or amend this Agreement without the approval of any Holders of Warrant Certificates in order to cure any ambiguity, to correct or supplement any provision contained herein which may be defective or inconsistent with any other provisions herein, or to make any other provisions with regard to matters or questions arising hereunder which the Company and the Warrant Agent may deem necessary or desirable and which shall not adversely affect the interests of the Holders of the Warrants Certificates in any material respect.

(b) In addition to the foregoing, with the consent of Holders of Warrants entitled, upon exercise thereof, to receive not less than a majority of the shares of Common Stock issuable thereunder, the Company and the Warrant Agent may modify this Agreement for the purpose of adding any provisions to or changing in any manner or eliminating any of the provisions of this Warrant Agreement or modifying in any manner the rights of the Holders of the Warrant Certificates; provided, however, that no modification of the terms (including but not limited to the adjustments described in Section 11 of this Agreement) upon which the Warrants are exercisable or reducing the percentage required for consent to modification of this Agreement may be made without the consent of the Holder of each outstanding warrant certificate affected thereby. As a condition precedent to the Warrant Agent's execution of any amendment, the Company shall deliver to the Warrant Agent a certificate from a duly authorized officer of the Company that states that the proposed amendment complies with the terms of this Section 20 of this Agreement.

Section 21. Successors. All covenants and provisions of this Agreement by or for the benefit of the Company or the Warrant Agent shall bind and inure to the benefit of their respective successors and assigns hereunder.

Section 22. Benefits of this Agreement. Nothing in this Agreement shall be construed to give any Person other than the Company, the Holders of Warrant Certificates and the Warrant Agent any legal or equitable right, remedy or claim under this Agreement; but this Agreement shall be for the sole and exclusive benefit of the Company, the Warrant Agent and the Holders of the Warrant Certificates.

Section 23. Governing Law. This Agreement and each Warrant issued hereunder shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to the conflicts of law principles thereof.

Section 24. Counterparts. This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

Section 25. Captions. The captions of the sections of this Agreement have been inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

Section 26. Information. The Company agrees to promptly provide to the Holders of the Warrants any information it provides to all holders of the Common Stock, except to the extent any such information is publicly available on the EDGAR system (or any successor thereof) of the Securities and Exchange Commission.

Section 27. Force Majeure. Notwithstanding anything to the contrary contained herein, Warrant Agent shall not be liable for any delays or failures in performance resulting from acts beyond its reasonable control including, without limitation, acts of God, terrorist acts, shortage of supply, breakdowns or malfunctions, interruptions or malfunction of computer facilities, or loss of data due to power failures or mechanical difficulties with information storage or retrieval systems, labor difficulties, war, or civil unrest, it being understood that the Warrant Agent shall use reasonable best efforts which are consistent with accepted practices in the banking industry to resume performance as soon as practicable under the circumstances.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

WINDTREE THERAPEUTICS, INC.

By: _____
Name:
Title:

CONTINENTAL STOCK TRANSFER & TRUST COMPANY

By: _____
Name:
Title:

[Signature Page to Warrant Agency Agreement]

Annex A: Form of Warrant Certificate Request Notice

WARRANT CERTIFICATE REQUEST NOTICE

To: Continental Stock Transfer & Trust Company as Warrant Agent for Windtree Therapeutics, Inc. (the "Company")

The undersigned Holder of Common Stock Purchase Warrants ("Warrants") in the form of Global Warrants issued by the Company hereby elects to receive a Warrant Certificate evidencing the Warrants held by the Holder as specified below:

1. Name of Holder of Warrants in form of Global Warrants: _____

2. Name of Holder in Warrant Certificate (if different from name of Holder of Warrants in form of Global Warrants): _____

3. Number of Warrants in name of Holder in form of Global Warrants: _____

4. Number of Warrants for which Warrant Certificate shall be issued: _____

5. Number of Warrants in name of Holder in form of Global Warrants after issuance of Warrant Certificate, if any: _____

6. Warrant Certificate shall be delivered to the following address:

_____

_____

_____

_____

The undersigned hereby acknowledges and agrees that, in connection with this Warrant Exchange and the issuance of the Warrant Certificate, the Holder is deemed to have surrendered the number of Warrants in form of Global Warrants in the name of the Holder equal to the number of Warrants evidenced by the Warrant Certificate.

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

Exhibit 1: Form of Warrant

Exhibit 5.1

Goodwin Procter llp
2929 Arch Street, Suite #1700
Philadelphia, PA 19104

goodwinlaw.com
+1 445 207 7800

April 6, 2023

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

Re: Securities Registered under Registration Statement on Form S-1

We have acted as counsel to you in connection with your filing of a Registration Statement on Form S-1 (File No. 333-269775) (as amended or supplemented, the "Registration Statement") 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 (i) up to an aggregate of 1,948,051 shares (the "Shares") of the Company's common stock, $0.001 par value per share ("Common Stock"), (ii) pre-funded warrants to purchase up to an aggregate of 1,948,051 shares of Common Stock (the "Pre-Funded Warrants," and shares of Common Stock underlying the Pre-Funded Warrants, the "Pre-Funded Warrant Shares"), and (iii) accompanying warrants to purchase up to an aggregate of 1,948,051 shares of Common Stock (the "Common Warrants," and shares of Common Stock underlying the Common Warrants, the "Common Warrant Shares") covered by the Registration Statement. The Pre-Funded Warrants and the Common Warrants are referred to collectively herein as the "Warrants" and the Pre-Funded Warrant Shares and the Common Warrant Shares are referred to collectively herein as the "Warrant Shares." The Shares and Warrants are being sold to the several underwriters named in, and pursuant to, an underwriting agreement among the Company and such underwriters (the "Underwriting Agreement").

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

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

Based on the foregoing, we are of the opinion that:

1. The Shares have been duly authorized and, when delivered and paid for in accordance with the terms of the Underwriting Agreement, will be validly issued, fully paid and non-assessable.

2. The Warrants have been duly authorized and, when issued, delivered and paid for in accordance with the terms of the Underwriting Agreement, will be valid and binding obligations of the Company.

3. Assuming a sufficient number of authorized but unissued shares of Common Stock are available for issuance when the Warrants are exercised, the Warrant Shares, when and if issued upon exercise of the Warrants in accordance with the terms of the Warrants, will be validly issued, fully paid and non-assessable

This opinion letter and the opinion it contains shall be interpreted in accordance with the Core Opinion Principles as published in 74 *Business Lawyer* 815 (Summer 2019).

We hereby consent to the inclusion of this opinion as Exhibit 5.1 to the Registration Statement and to the references to our firm under the caption "Legal Matters" in the Registration Statement. 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

Exhibit 23.1

We consent to the incorporation by reference in this Amendment No. 1 to the Registration Statement of Windtree Therapeutics, Inc. on Form S-1 (No. 333-2269775) to be filed on or about April 6, 2023 of our report dated March 31, 2023, on our audit of the financial statements as of December 31, 2022 and for the year then ended, which report was included in the Annual Report on Form 10-K filed March 31, 2023. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern. We also consent to the reference to our firm under the caption “Experts” in this Registration Statement.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
April 6, 2023

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in Amendment No. 1 to the Registration Statement (Form S-1 No. 333-269775) and related Prospectus of Windtree Therapeutics, Inc. and to the incorporation by reference therein of our report dated March 31, 2022 (except for the second paragraph of Note 2, as to which the date is March 31, 2023), with respect to the consolidated financial statements of Windtree Therapeutics, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 2022, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
April 6, 2023

Exhibit 107

Calculation of Filing Fee Tables

Form S-1
(Form Type)

Windtree Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities and Carry Forward Securities

	Security type	Security class title	Fee calculation or carry forward rule	Amount registered	Proposed maximum offering price per unit	Maximum aggregate offering price(1)(2)	Fee rate	Amount of registration fee(1)
Fees to Be Paid	Equity	Common Stock, par value $0.001 per share(3)	457(o)	—	—	$10,350,000	0.00011020	$1,140.57
Fees to Be Paid	Equity	Pre-funded warrants(3)(4)	457(g)	—	—	Included above	—	—
Fees to Be Paid	Equity	Shares of Common Stock issuable upon exercise of pre-funded warrants(3)	457(o)	—	—	Included above	—	—
Fees to Be Paid	Equity	Common warrants(4)	457(g)	—	—	Included above	—	—
Fees to Be Paid	Equity	Shares of Common Stock issuable upon exercise of Common warrants	457(o)	—	—	$10,350,000	0.00011020	$1,140.57
				Total Offering Amounts		$ 20,700,000		$ 2,281.14
				Total Fees Previously Paid				$ 881.60
				Total Fee Offsets				$ 0
				Net Fee Due				$ 1,399.54

(1) Estimated solely for the purpose of calculating the registration fee pursuant Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Pursuant to Rule 416(a) under the Securities Act, this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

(3) The proposed maximum aggregate offering price of the common stock will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants issued in the offering, and the proposed maximum aggregate offering price of the pre-funded warrants to be issued in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any common stock issued in the offering. Accordingly, the proposed maximum aggregate offering price of the common stock, pre-funded warrants and common stock warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is $10,350,000.

(4) No fee pursuant to Rule 457(g) of the Securities Act.