Table of Contents

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

# FORM 10-Q

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

For the quarterly period ended **June 30, 2024**

or

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

For the transition period from _____ to _____

Commission **File Number**: 001-39290

# WINDTREE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware**<br>(State or other jurisdiction of incorporation or organization) | **94-3171943**<br>(I.R.S. Employer Identification No.) |
|---|---|
| **2600 Kelly Road, Suite 100**<br>**Warrington, Pennsylvania**<br>(Address of principal executive offices) | **18976-3622**<br>(Zip Code) |

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

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

| Title of each class | Trading symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, $0.001 par value** | **WINT** | **The Nasdaq Capital Market** |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 19, 2024, there were 591,909 shares of the registrant's common stock outstanding, par value $0.001 per share.

**Table of Contents**

**PART I - FINANCIAL INFORMATION**

Unless the context otherwise requires, all references to "we," "us," "our," and the "Company" include Windtree Therapeutics, Inc., and its consolidated subsidiaries.

## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will," "should," "could," "targets," "projects," "contemplates," "predicts," "potential" or "continues" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of such risks and uncertainties, which potentially could have a material adverse effect on our development programs, business and/or operations, include, but are not limited to the following:

- 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 on our condensed consolidated balance sheet, which could lead to material impairment charges in the future;
- our ability to repay indebtedness;
- potential delays and uncertainties in our anticipated timelines and milestones and additional costs associated with the impact of the residual effects of the COVID-19 pandemic and the evolving events in Israel and Gaza 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 licensee, Lee's Pharmaceutical (HK) Ltd., and its affiliate, Zhaoke Pharmaceutical (Hefei) Co. Ltd., and their ability to successfully source materials, execute necessary clinical and regulatory activities in a timely manner, if at all, to support development and commercialization of 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; and
- 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 the evolving events in Israel and Gaza.

Pharmaceutical, biotechnology, and medical technology companies have suffered significant setbacks conducting clinical trials, even after obtaining promising earlier preclinical and clinical data. In addition, data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products and may never become profitable.

The forward-looking statements contained in this Quarterly Report on Form 10-Q, or the documents incorporated by reference herein, speak only as of their respective dates. Factors or events that could cause our actual results to differ may emerge from time to time and it is not possible for us to predict them all. Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

You should also read carefully the factors described in the "Risk Factors" included in Part II, Item 1A of this Quarterly Report on Form 10-Q in conjunction with Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, to better understand the significant risks and uncertainties inherent in our business and underlying any forward-looking statements.

**ITEM 1. Financial Statements**

**WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES**
**Condensed Consolidated Balance Sheets**

*(in thousands, except share and per share data)*

| | June 30, 2024 (Unaudited) | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 1,803 | $ 4,319 |
| Prepaid expenses and other current assets | 256 | 1,060 |
| Total current assets | 2,059 | 5,379 |
| Property and equipment, net | 150 | 183 |
| Restricted cash | 9 | 150 |
| Operating lease right-of-use assets | 1,239 | 1,444 |
| Intangible assets | 25,250 | 25,250 |
| Total assets | $ 28,707 | $ 32,406 |
| **LIABILITIES, MEZZANINE EQUITY & STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable | $ 2,969 | $ 809 |
| Accrued expenses | 2,128 | 1,618 |
| Operating lease liabilities - current portion | 457 | 436 |
| Senior convertible notes payable, net | 1,311 | - |
| Derivative liability - senior convertible notes | 202 | - |
| ELOC commitment note payable | 306 | - |
| Derivative liability - ELOC commitment note | 286 | - |
| Senior secured notes payable | 391 | - |
| Loans payable | - | 233 |
| Other current liabilities | 725 | 900 |
| Total current liabilities | 8,775 | 3,996 |
| Operating lease liabilities - non-current portion | 912 | 1,161 |
| Restructured debt liability - contingent milestone payments | - | 15,000 |
| Other liabilities | 3,800 | 3,800 |
| Deferred tax liabilities | 4,772 | 5,058 |
| Total liabilities | 18,259 | 29,015 |
| Mezzanine Equity: | | |
| Series B redeemable preferred stock, $0.001 par value; 5,500 and 0 shares authorized; 5,500 and 0 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | 6,954 | - |
| Total mezzanine equity | 6,954 | - |
| Stockholders' Equity: | | |
| Preferred stock, $0.001 par value; 4,994,500 and 5,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | - | - |
| Common stock, $0.001 par value; 120,000,000 shares authorized; 591,910 and 333,145 shares issued at June 30, 2024 and December 31, 2023, respectively; 591,909 and 333,144 shares outstanding at June 30, 2024 and December 31, 2023, respectively | 1 | - |
| Additional paid-in capital | 853,175 | 851,268 |
| Accumulated deficit | (846,628) | (844,823) |
| Treasury stock (at cost); 1 share | (3,054) | (3,054) |
| Total stockholders' equity | 3,494 | 3,391 |
| Total liabilities, mezzanine equity & stockholders' equity | $ 28,707 | $ 32,406 |

*See notes to condensed consolidated financial statements*

**WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES**
**Condensed Consolidated Statements of Operations**
(Unaudited)

*(in thousands, except per share data)*

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Expenses: | | | | |
| Research and development | $ 9,863 | $ 1,763 | $ 12,116 | $ 3,178 |
| General and administrative | 1,589 | 2,420 | 3,741 | 4,712 |
| Loss on impairment of goodwill | - | 2,574 | - | 3,058 |
| Total operating expenses | 11,452 | 6,757 | 15,857 | 10,948 |
| Operating loss | (11,452) | (6,757) | (15,857) | (10,948) |
| | | | | |
| Other income (expense): | | | | |
| Gain on debt extinguishment | - | - | 14,520 | - |
| Interest income | 20 | 108 | 50 | 152 |
| Interest expense | (110) | (13) | (123) | (25) |
| Other (expense) income, net | (285) | 61 | (84) | 109 |
| Total other (expense) income, net | (375) | 156 | 14,363 | 236 |
| | | | | |
| Loss before income taxes | (11,827) | (6,601) | (1,494) | (10,712) |
| Income tax expense | (197) | - | (311) | - |
| Net loss | $ (12,024) | $ (6,601) | $ (1,805) | $ (10,712) |
| | | | | |
| Net loss per common share | | | | |
| Basic and diluted | $ (20.91) | $ (29.47) | $ (3.47) | $ (78.76) |
| | | | | |
| Weighted average number of common shares outstanding | | | | |
| Basic and diluted | 575 | 224 | 520 | 136 |

*See notes to condensed consolidated financial statements*

**WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES**
**Condensed Consolidated Statements of Changes in Mezzanine Equity and Stockholders' Equity**
(Unaudited)

*(in thousands)*

| | Mezzanine Equity | | Stockholders' Equity | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Series A Preferred Stock | | Common Stock | | | | Treasury Stock | | |
| | Shares | Amount | Shares | Amount | Additional Paid-in Capital | Accumulated Deficit | Shares | Amount | Total |
| **Balance - December 31, 2022** | **3** | **$ -** | **43** | **$ -** | **$ 837,598** | **$ (824,532)** | **-** | **$ (3,054)** | **$ 10,012** |
| Net loss | - | - | - | - | - | (4,111) | - | - | (4,111) |
| Redemption of Series A Preferred Stock | (3) | - | - | - | - | - | - | - | - |
| Exercise of common stock warrants, net of expenses of $276 | - | - | 7 | - | 843 | - | - | - | 843 |
| Reverse split adjustments - fractional share round ups | - | - | 1 | - | - | - | - | - | - |
| Stock-based compensation expense | - | - | - | - | 285 | - | - | - | 285 |
| **Balance - March 31, 2023** | **-** | **$ -** | **51** | **$ -** | **$ 838,726** | **$ (828,643)** | **-** | **$ (3,054)** | **$ 7,029** |
| Net loss | - | - | - | - | - | (6,601) | - | - | (6,601) |
| Issuance of common stock and common stock warrants, net of issuance costs of $1,630 | - | - | 236 | - | 10,794 | - | - | - | 10,794 |
| Stock-based compensation expense | - | - | - | - | 382 | - | - | - | 382 |
| **Balance - June 30, 2023** | **-** | **$ -** | **287** | **$ -** | **$ 849,902** | **$ (835,244)** | **-** | **$ (3,054)** | **$ 11,604** |

| | Mezzanine Equity | | Stockholders' Equity | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Series B Preferred Stock | | Common Stock | | | | Treasury Stock | | |
| | Shares | Amount | Shares | Amount | Additional Paid-in Capital | Accumulated Deficit | Shares | Amount | Total |
| **Balance - December 31, 2023** | **-** | **$ -** | **333** | **$ -** | **$ 851,268** | **$ (844,823)** | **-** | **$ (3,054)** | **$ 3,391** |
| Net income | - | - | - | - | - | 10,219 | - | - | 10,219 |
| Issuance of common stock, ATM Program, net of issuance costs of $44 | - | - | 143 | 1 | 1,366 | - | - | - | 1,367 |
| Issuance of common stock, equity consideration in debt extinguishment | - | - | 34 | - | 280 | - | - | - | 280 |
| Stock-based compensation expense | - | - | - | - | 164 | - | - | - | 164 |
| **Balance - March 31, 2024** | **-** | **$ -** | **510** | **$ 1** | **$ 853,078** | **$ (834,604)** | **-** | **$ (3,054)** | **$ 15,421** |
| Net loss | - | - | - | - | - | (12,024) | - | - | (12,024) |
| Issuance of preferred stock, net of issuance costs of $68 | 6 | 6,954 | - | - | - | - | - | - | - |
| Reverse split adjustments - fractional share round ups | - | - | 82 | - | - | - | - | - | - |
| Stock-based compensation expense | - | - | - | - | 97 | - | - | - | 97 |
| **Balance - June 30, 2024** | **6** | **$ 6,954** | **592** | **$ 1** | **$ 853,175** | **$ (846,628)** | **-** | **$ (3,054)** | **$ 3,494** |

*See notes to condensed consolidated financial statements*

**WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES**
**Condensed Consolidated Statements of Cash Flows**
(Unaudited)

*(in thousands)*

| | Six Months Ended June 30, | |
|---|---|---|
| | **2024** | **2023** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (1,805) | $ (10,712) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| In-process research and development expenses in connection with the Varian asset acquisition | 7,419 | - |
| Depreciation and amortization | 45 | 46 |
| Amortization of right-of-use assets | 205 | 213 |
| Amortization of debt discount and debt issuance costs | 60 | - |
| Stock-based compensation | 348 | 667 |
| Loss on ELOC commitment note and derivative liability | 590 | - |
| Loss on impairment of goodwill | - | 3,058 |
| Gain on debt extinguishment | (14,520) | - |
| Unrealized gain on foreign exchange rate changes | (300) | (85) |
| Change in fair value of derivative liabilities | (254) | - |
| Change in fair value of senior secured notes | 41 | - |
| Changes in assets and liabilities: | | |
| Prepaid expenses and other current assets | 807 | 132 |
| Accounts payable | 2,160 | 715 |
| Accrued expenses | 334 | 182 |
| Operating lease liabilities | (228) | (232) |
| Other current liabilities | (175) | - |
| Net cash used in operating activities | (5,273) | (6,016) |
| Cash flows from investing activities: | | |
| Purchase of property and equipment | (12) | - |
| Net cash used in investing activities | (12) | - |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of common stock and warrants, net of issuance costs | - | 10,794 |
| Proceeds from ATM Program, net of issuance costs | 1,367 | - |
| Proceeds from convertible notes, net of issuance costs | 1,312 | - |
| Proceeds from senior secured notes, net of issuance costs | 350 | - |
| Principal payments on loans payable | (233) | (330) |
| Issuance costs related to Series B Preferred Stock | (68) | - |
| Payments on debt extinguishment | (100) | - |
| Proceeds from exercise of common stock warrants, net of expenses | - | 843 |
| Net cash provided by financing activities | 2,628 | 11,307 |
| Net (decrease) increase in cash, cash equivalents, and restricted cash | (2,657) | 5,291 |
| Cash, cash equivalents, and restricted cash - beginning of period | 4,469 | 6,326 |
| Cash, cash equivalents, and restricted cash - end of period | $ 1,812 | $ 11,617 |
| **Supplementary disclosure of non-cash activity:** | | |
| Fair value of Series B Preferred Stock issued in connection with the Varian asset acquisition | $ 7,022 | $ - |
| Fair value upon issuance of derivative liability related to convertible notes | 458 | - |
| Fair value upon issuance of derivative liability related to ELOC commitment note | 284 | - |
| Fair value of common stock consideration related to debt extinguishment | 280 | - |
| Fair value of January 2023 warrant modifications related to the January 2023 warrant exercise inducement | - | 1,238 |
| Fair value of February 2023 warrant modifications related to the February 2023 warrant exercise inducement | - | 274 |
| Prepayment of insurance through third-party financing | - | 778 |

*See notes to condensed consolidated financial statements*

**Notes to Condensed Consolidated Financial Statements (unaudited)**

**Note 1 – The Company and Description of Business**

We are a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Our portfolio of product candidates includes istaroxime, a Phase 2 candidate that inhibits the sodium-potassium ATPase and also activates sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, for acute heart failure and/or associated cardiogenic shock; preclinical SERCA2a activators for heart failure; rostafuroxin for the treatment of hypertension in patients with a specific genetic profile; and a preclinical atypical protein kinase C iota, or aPKCi, inhibitor (topical and oral formulations), being developed for potential application in rare and broad oncology indications. We also have a licensing business model with partnership out-licenses currently in place.

Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to increase blood pressure and improve cardiac function in patients with cardiogenic shock and to improve cardiac function in patients with acute heart failure, or AHF, and reverse the hypotension and hypoperfusion associated with heart failure that deteriorates to cardiogenic shock. Istaroxime demonstrated significant improvement in both systolic and diastolic 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 and had a favorable renal profile, we initiated a Phase 2 global clinical study, or the SEISMiC Study, to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions, or SCAI, Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs and mortality. In April 2022, we announced our observations in the SEISMiC Study that istaroxime rapidly and significantly increased SBP while also improving cardiac function and preserving renal function. 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 the SEISMiC Study supports continued development in both cardiogenic shock and AHF. In the fourth quarter of 2023, we initiated an extension to the SEISMiC Study, or the SEISMiC Extension, to evaluate a longer dosing period and to continue to characterize the effects of istaroxime, including activation of SERCA2a. The SEISMiC Extension study is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in the second half of 2024. Additionally, we have recently initiated a small study in more severe SCAI Stage C cardiogenic shock, or the SEISMiC C Study, to evaluate the safety and efficacy of istaroxime in cardiogenic shock patients who are also receiving standard of care rescue therapy for shock. The SEISMiC C Study is expected to enroll up to 20 subjects with SCAI Stage C cardiogenic shock with enrollment anticipated to be completed in late 2024. Our ability to complete both of these studies with their intended sample size is dependent upon our ability to secure adequate resourcing for the program through financing efforts or business development activities.

Our heart failure cardiovascular portfolio also includes other SERCA2a activators. One family of compounds has the dual mechanism of action that includes inhibition of the sodium-potassium ATPase as well as activation of SERCA2a. The other family of compounds are considered selective SERCA2a activators and are devoid of activity against the sodium-potassium ATPase. 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 the development of rostafuroxin without securing such an arrangement or partnership.

Our cardiovascular assets and programs are associated with a regional licensed partnership with Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), for the development and commercialization of our product candidate, istaroxime, in Greater China. In addition to istaroxime, the agreement also licenses our preclinical next-generation dual mechanism SERCA2a activators, and rostafuroxin. In addition, we are supporting the efforts of Lee's (HK) in starting a Phase 3 trial in AHF with istaroxime.

On April 2, 2024, we entered into an Asset Purchase Agreement, or the Asset Purchase Agreement, with Varian Biopharmaceuticals, Inc., or Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian's business associated with a license agreement, dated as of July 5, 2019, by and between Varian and Cancer Research Technology Limited, or the Licence Agreement, which includes the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know-how and inventory of drug substance, or the Transferred Assets. The Transferred Assets include a novel, potential high-potency, specific, aPKCi inhibitor with possible broad use in oncology as well as certain rare malignant diseases. The asset platform includes two formulations (topical and oral) of an aPKCi inhibitor. We plan to advance investigational new drug enabling activities and are in the process of determining the expected clinical development plan for the platform.

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, 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, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations.

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, 2023 that we filed with the Securities and Exchange Commission, or the SEC, on April 16, 2024, 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.

**Note 2 – Basis of Presentation**

The interim unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., or US GAAP, for interim financial information in accordance with the instructions to Form 10-Q and include accounts of Windtree Therapeutics, Inc. and its wholly owned subsidiaries. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete consolidated financial statements. Intercompany balances and transactions have been eliminated in consolidation. All adjustments (consisting of normally recurring accruals) considered for fair presentation have been included. Operating results for the three and six months ended June 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. The consolidated balance sheet at December 31, 2023 has been derived from the Company's audited consolidated financial statements. There have been no changes to our significant accounting policies since December 31, 2023. The accompanying interim unaudited condensed consolidated financial statements should be read in conjunction with our annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2023 contained in our Annual Report on Form 10-K for the year ended December 31, 2023.

The accompanying condensed consolidated financial statements reflect the 1-for-18 reverse split of our common stock that was approved by our Board of Directors and stockholders and made effective on April 19, 2024. All share and per share information herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

**Note 3 – Going Concern and Management's Plans**

We are subject to risks common to companies in the biotechnology industry, including but not limited to the need for additional capital, risks of failure of preclinical and clinical studies, the need to obtain marketing approval and reimbursement for any drug product candidate that we may identify and develop, the need to successfully commercialize and gain market acceptance of our product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, and risks associated with our international operations in Taiwan and activities abroad, including but not limited to having foreign suppliers, manufacturers, and clinical sites in support of our development activities.

We have incurred net losses since inception. Our net loss was $12.0 million and $1.8 million, respectively, for the three and six months ended June 30, 2024. Included in our net loss for the three and six months ended June 30, 2024 is $7.5 million of non-cash R&D expense related to costs in connection with the Varian asset acquisition and a $14.5 million gain on debt extinguishment. For the three and six months ended June 30, 2023, our net loss was $6.6 million and $10.7 million, respectively. Included in our net loss for the three and six months ended June 30, 2023 is a $2.6 million and $3.1 million loss on impairment of goodwill, respectively (See the section titled, "Note 4 – Summary of Significant Accounting Policies"). We expect to continue to incur operating losses for at least the next several years. As of June 30, 2024, we had an accumulated deficit of $846.6 million. Our future success is dependent on our ability to fund and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development expense and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital, and accordingly, our ability to execute our future operating plans.

In June 2024, we entered into a Common Stock Purchase Agreement, or the ELOC Purchase Agreement, establishing an equity line of credit with the purchaser, or the Purchaser, whereby we have the right, but not the obligation, to sell to the Purchaser, and the Purchaser is obligated to purchase, up to the lesser of (i) $35 million of newly issued shares of our common stock, and (ii) the Exchange Cap (as defined below). We do not have a right to commence any sales of our common stock to the Purchaser under the ELOC Purchase Agreement until the time when all of the conditions to our right to commence sales of common stock to the Purchaser set forth in the ELOC Purchase Agreement have been satisfied, including that a registration statement covering the resale of such shares is declared effective by the SEC and the final form of prospectus contained therein is filed with the SEC, or the Commencement Date. Over the 36-month period from and after the Commencement Date, we will control the timing and amount of any sales of Common Stock to the Purchaser. Actual sales of shares of our common stock to the Purchaser under the ELOC Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of our common stock and determinations by us as to the appropriate sources of funding and our operations (See the section titled, "Note 12 - Mezzanine Equity and Stockholders' Equity - Common Stock Purchase Agreement").

As of June 30, 2024, we had cash and cash equivalents of $1.8 million and current liabilities of $8.8 million. On July 3, 2024, we agreed to issue and sell to (i) an institutional investor an aggregate principal amount of $0.1 million in senior secured notes due 2025, or the July Secured Note, and (ii) an additional institutional investor an aggregate principal amount of $0.1 million in senior unsecured notes due 2025, or the July Unsecured Note, and together with the July Secured Note, the July 2024 Notes, for aggregate gross proceeds of $0.2 million (See the section titled, "Note 16 - Subsequent Events - Senior Secured and Senior Unsecured Notes"). On July 18, 2024, we entered into a Securities Purchase Agreement, or the First Purchase Agreement, with the buyers named therein, pursuant to which we agreed to the private placement, or the First PIPE, of (i) 16,099 shares, or the Preferred Shares, of our Series C Convertible Preferred Stock, par value $0.001 per share, or the Series C Preferred Stock, and (ii) warrants, or the July 2024 Warrants, to acquire up to the aggregate number of 3,440,631 additional shares of our common stock for aggregate gross proceeds of approximately $12.9 million of which $9.5 million was paid through the cancellation and extinguishment of certain securities (See the section titled, "Note 16 - Subsequent Events - First Private Placement"). On July 26, 2024, we entered into a Securities Purchase Agreement, or the Second Purchase Agreement, with the buyer named therein, pursuant to which we agreed to a second tranche of the private placement, or the Second PIPE (and together with the First PIPE, the Private Placement), of (i) 1,250 Preferred Shares, and (ii) July 2024 Warrants to acquire up to the aggregate number of 267,380 additional shares of our common stock for aggregate gross proceeds of approximately $1.0 million (See the section titled, "Note 16 - Subsequent Events - Second Private Placement"). Following these financings, we believe that we have sufficient resources available to fund our business operations into October 2024. We do not have sufficient cash and cash equivalents as of the date of this Quarterly Report on Form 10-Q to support our operations for at least the 12 months following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern.

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 we fail to raise sufficient capital, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material

adverse effect on our business, financial condition, and results of operations. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern for at least 12 months after the issuance of the accompanying financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

**Note 4 – Summary of Significant Accounting Policies**

**Principles of Consolidation**

The interim unaudited condensed consolidated financial statements are prepared in accordance with US GAAP and include accounts of Windtree Therapeutics, Inc. and its wholly owned subsidiaries, CVie Investments Limited and its wholly owned subsidiary, CVie Therapeutics Limited; and a presently inactive subsidiary, Discovery Laboratories, Inc. (formerly known as Acute Therapeutics, Inc.).

**Intangible Assets and Goodwill**

We record acquired intangible assets and goodwill based on estimated fair value. The identifiable intangible assets resulting from the CVie Therapeutics acquisition in December 2018 relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin. The IPR&D assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. During the three and six months ended June 30, 2024, no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. It is reviewed for impairment at least annually or when events or changes in the business environment indicate that its carrying value may be impaired.

During each of the first and second quarters of 2023, the continued declining trend in the closing share price of our common stock suggested that the fair value of our reporting unit was more likely than not less than its carrying value. Based on an interim goodwill impairment tests, 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 first quarter of 2023 and an additional loss of $2.6 million, representing the remaining balance of goodwill, in the second quarter of 2023. For the six months ended June 30, 2023, the aggregate loss on impairment of goodwill is $3.1 million, recognized within operating expenses in our condensed consolidated statements of operations. As of June 30, 2023, goodwill was written down to zero on our condensed consolidated balances sheet. As of June 30, 2024 and December 31, 2023, goodwill was zero on our condensed consolidated balance sheet.

The following table represents identifiable intangible assets as of June 30, 2024 and December 31, 2023:

| *(in thousands)* | June 30, 2024 | December 31, 2023 |
|---|---|---|
| Istaroxime drug candidate | $ 22,340 | $ 22,340 |
| Rostafuroxin drug candidate | 2,910 | 2,910 |
| Intangible assets | 25,250 | 25,250 |

**Acquired In-Process Research and Development Expenses**

Acquired IPR&D expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones.

We evaluate in-licensed agreements for IPR&D projects to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and have no alternative future use, we expense payments made under such license agreements as research and development expense in the consolidated statements of operations. In those cases, payments for milestones achieved and payments for a product license prior to regulatory approval of the product are expensed in the period incurred. Payments made in connection with regulatory and sales-based milestones are capitalized and amortized to cost of revenue.

**Convertible Debt and Equity Instruments**

We review the terms of convertible debt and equity instruments to determine whether there are conversion features or embedded derivative instruments including embedded conversion options that are required to be bifurcated and accounted for separately as derivative financial instruments under ASC Topic 815, *Derivatives and Hedging*.

In circumstances where the convertible instrument contains more than one embedded derivative instrument, including conversion options that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single compound instrument. Also, in connection with the sale of convertible debt and equity instruments, we may issue free standing warrants that may, depending on their terms, be accounted for as derivative instrument liabilities, rather than as equity. When convertible debt or equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for separately, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of the bifurcated derivative instrument. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face amount. When we issue debt securities, which bear interest at rates that are lower than market rates, we recognize a discount, which is offset against the carrying value of the debt. Such discount from the face value of the debt, together with the stated interest on the instrument, is amortized over the life of the instrument through periodic charges to income.

**Derivative Financial Instruments**

Derivatives are recorded on the consolidated balance sheet at fair value. The conversion features of the convertible notes are embedded derivatives and are separately valued and accounted for on the consolidated balance sheet with changes in fair value recognized during the period of change as a separate component of other income (expense). Fair values for exchange-traded securities and derivatives are based on quoted market prices. The pricing model we use for determining the fair value of non-exchange traded derivatives is the Monte Carlo Model. Valuations derived from this model are subject to ongoing internal and external verification and review. The model uses market-sourced inputs such as interest rates and stock price volatilities.

**Foreign Currency Transactions**

The functional currency for our foreign subsidiary is U.S. Dollars. We remeasure monetary assets and liabilities that are not denominated in the functional currency at exchange rates in effect at the end of each period. Gains and losses from the remeasurement of foreign currency transactions are recognized in other (expense) income, net. Foreign currency transactions resulted in net gains of approximately $0.1 million and $0.1 million for the three-month periods ended June 30, 2024 and 2023, respectively. Foreign currency transactions resulted in net gains of approximately $0.3 million and $0.1 million for the six-month periods ended June 30, 2024 and 2023, respectively.

**Use of Estimates**

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including intangible assets and goodwill, at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

**Cash and Cash Equivalents**

Cash and cash equivalents are held at domestic and foreign financial institutions and consist of liquid investments and money market funds that are readily convertible into cash.

**Concentration of Credit Risk**

Financial instruments, which potentially subject us to credit risk, consist principally of cash and cash equivalents. All cash and cash equivalents are held in U.S. financial institutions and money market funds. At times, we may maintain cash balances in excess of the federally insured amount of $250,000 per depositor, per insured bank, for each account ownership category. Although we currently believe that the financial institutions with whom we do business will be able to fulfill their commitments to us, there is no assurance that those institutions will be able to continue to do so. We have not experienced any credit losses associated with our balances in such accounts.

**Severance**

In July 2023, we entered into a separation agreement with an executive, which provides that the former employee will be entitled to receive (i) a severance amount equal to the sum of the employee's base salary then in effect and (ii) subject to certain exceptions, a pro rata bonus commensurate with the bonus awarded to other contract executives for the year 2023, prorated for the number of days of the employee's employment during 2023, and payable at the time that other contract executives are paid bonuses with respect to 2023. The severance amount related to the departure of this executive is approximately $0.5 million, which was accrued in general and administrative expense at the date of the separation, and will be paid ratably through July 2024. As of June 30, 2024, approximately $0.4 million was paid. The remaining liability as of June 30, 2024 is approximately $0.1 million and is included in accrued expenses.

In June 2023, we implemented certain reductions in headcount. The total severance cost for impacted employees was approximately $0.2 million, which was accrued in research and development expense at the date of the separations and was paid ratably through December 2023.

**Property and Equipment**

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to ten years). Leasehold improvements are amortized over the shorter of the estimated useful lives or the remaining term of the lease. Repairs and maintenance costs are charged to expense as incurred.

**Restructured Debt Liability – Contingent Milestone Payment**

In conjunction with the November 2017 restructuring and retirement of long-term debt, we established a $15.0 million long-term liability for contingent milestone payments potentially due under the Exchange and Termination Agreement dated as of October 27, 2017, or the Milestone Agreement, between ourselves and affiliates of Deerfield Management Company L.P., or Deerfield. The liability was recorded at the full value of the contingent milestones and was to be carried at full value until the milestones were achieved and paid or the milestones were not achieved and the liability was written off as a gain on debt extinguishment.

On January 24, 2024, we and Deerfield entered into an Exchange and Termination Agreement, or the Exchange and Termination Agreement, wherein Deerfield agreed to terminate its rights to receive certain milestone payments in exchange for (i) cash in the aggregate amount of $0.2 million and (ii) an aggregate of 33,793 shares of our common stock, par value $0.001 per share (See the section titled, “Note 8 – Restructured Debt Liability”).

**Research and Development**

We account for research and development expense by the following categories: (a) direct clinical and preclinical development programs, (b) product development and manufacturing, and (c) clinical, medical, and regulatory operations. Research and development expense includes personnel, facilities, manufacturing and quality, pharmaceutical development, research, clinical, regulatory, and other preclinical and clinical activities. Research and development costs are charged to operations as incurred in accordance with Accounting Standards Codification, or ASC, Topic 730, *Research and Development*.

**Income Taxes**

We account for income taxes in accordance with ASC Topic 740, *Accounting for Income Taxes*, which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities.

We use a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Because we have never realized a profit, management has fully reserved the net deferred tax asset as there can be no assurance of realization.

**Net Loss per Common Share**

The senior convertible notes payable, ELOC commitment note payable, and the preferred stock are participating securities. Accordingly, in any period in which we report net income attributable to common stockholders, basic earnings per share is computed using the “two-class” method. Under this method, net income is reduced by any dividends earned and the remaining earnings (undistributed earnings) are allocated to common stock and each series of participating securities to the extent that each participating security may share in earnings as if all of the earnings for the period had been distributed. The total earnings allocated to common stock is then divided by the number of outstanding shares to which the earnings are allocated to determine the earnings per share. The two-class method is not applicable during periods with a net loss, as the holders of the participating securities have no obligation to fund losses. Diluted net income per common share is computed under the two-class method by using the weighted-average number of shares of common stock outstanding, plus the effect of any other potentially dilutive securities outstanding for the period. In addition, the Company analyzes the potential dilutive effect of the outstanding participating securities under the “if-converted” method when calculating diluted earnings per share, in which it assumes that the outstanding participating securities convert into common stock at the beginning of the period, or when issued if later. The Company reports the more dilutive of the approaches (two class or “if-converted”) as their diluted net income per share during the period.

For periods in which a net loss exists, basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period.

As of June 30, 2024 and 2023, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants, the vesting of restricted stock units, and the conversion of preferred stock, senior convertible notes payable, and the ELOC commitment note payable was 1.5 million and 0.3 million shares, respectively. For the three and six months ended June 30, 2024, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted weighted-average shares of common stock outstanding.

We do not have any components of other comprehensive (loss) income.

**Note 5 – Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 – Quoted prices in active markets for identical assets and liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

**Fair Value on a Recurring Basis**

The tables below categorize assets and liabilities measured at fair value on a recurring basis for the periods presented:

| *(in thousands)* | Fair Value June 30, 2024 | Fair value measurement using Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Assets: | | | | |
| Money market funds | $ 1,080 | $ 1,080 | $ - | $ - |
| Total Assets | $ 1,080 | $ 1,080 | $ - | $ - |
| Liabilities: | | | | |
| Derivative liability - convertible notes | $ (202) | $ - | $ - | $ (202) |
| Derivative liability - ELOC commitment note | (286) | - | - | (286) |
| Senior secured notes payable | (391) | - | - | (391) |
| Total Liabilities | $ (879) | $ - | $ - | $ (879) |

| *(in thousands)* | Fair Value December 31, 2023 | Fair value measurement using Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Assets: | | | | |
| Money market funds | $ 3,532 | $ 3,532 | $ - | $ - |
| Total Assets | $ 3,532 | $ 3,532 | $ - | $ - |

The money market funds were classified as cash and cash equivalents on the consolidated balance sheets and were within Level 1 of the fair value hierarchy. The aggregate fair value of the Company's money market funds approximated amortized cost.

The fair values of the derivative liability-convertible notes, derivative liability-ELOC commitment note and the senior secured notes payable are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. In determining the fair value of the derivative liabilities, we used a Monte Carlo simulation. The significant unobservable inputs used in the fair value measurements of the derivative liabilities include the expected term, expected volatility, risk-free interest rate and dividend yield. In determining the fair value of the senior secured notes payable, we used the final settlement amount of those notes from our First PIPE in July 2024, and then adjusted the settlement amount to 80% to represent the likelihood of the settlement occurring on June 30, 2024.

**Fair Value on a Non-Recurring Basis**

Certain of our assets were measured at fair value on a non-recurring basis during the six months ended June 30, 2024 and the year ended December 31, 2023. Our goodwill was recorded at its estimated fair value as a result of the impairment tests performed in 2023, which resulted in the goodwill being written down to zero as of June 30, 2023 (See the section titled, "Note 4 – Summary of Significant Accounting Policies – Intangible Assets and Goodwill").

In order to perform the goodwill impairment test, we compared the estimated fair value of our reporting unit to its carrying value. Significant factors considered in estimating the fair value of our reporting unit included 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. Quantitative information about the significant unobservable inputs used in the fair value measurement of the reporting unit included an estimated control premium of 50% for both periods.

**Note 6 – Senior Convertible Notes Payable**

On April 2, 2024, we entered into the April Purchase Agreement pursuant to which we agreed to sell the Senior Convertible Notes for $1.35 million of net proceeds. The Senior Convertible Notes are convertible into shares of our common stock at an initial conversion price of $6.4854, which is subject to adjustment upon the occurrence of specified events to no lower than $1.2978, subject to any stock split, stock dividend, stock combination, recapitalization or other similar transaction involving our common stock.

The Senior Convertible Notes are senior obligations and accrue interest at a rate of 10.0% per annum, payable in arrears on the first calendar day of each calendar month, beginning on May 2, 2024, unless an event of default has occurred, upon which interest will accrue at 18.0% per annum. The Senior

Convertible Notes mature on January 2, 2025 unless earlier converted or redeemed (upon the satisfaction of certain conditions).

The Senior Convertible Notes contain certain conversion and redemption features requiring bifurcation as separate derivative liabilities. We initially recorded the fair value of the embedded features in the amount of $0.5 million as a derivative liability in our condensed consolidated balance sheet. The derivative is adjusted to fair value at each reporting period, with the change in the fair value recorded in change in fair value of derivatives that is a component of other income (expense) in our condensed consolidated statement of operations. For the three and six months ended June 30, 2024, the change in fair value of the derivative was $0.3 million and was recorded in other expense.

In connection with the issuance of the Senior Convertible Notes, we incurred $38,000 in debt issuance costs. The associated debt issuance costs were capitalized and are presented as an offset to the Senior Convertible Notes and, along with the debt discount of $161,000 associated with the bifurcated derivative, are amortized as additional interest expense over the term of the Senior Convertible Notes at an effective interest rate of 30.32%. For the three and six months ended June 30, 2024, the interest expense was $96,000.

**Note 7 – ELOC Commitment Note Payable**

In June 2024, we entered into the ELOC Purchase Agreement establishing an equity line of credit for the right to sell shares of our common stock to the Purchaser. As consideration for the Purchaser's irrevocable commitment to purchase shares of our common stock upon the terms of and subject to satisfaction of the conditions set forth in the ELOC Purchase Agreement, concurrently with the execution and delivery of the ELOC Purchase Agreement, we issued a convertible promissory note, or the ELOC Commitment Note, to the Purchaser in the amount of $350,000. The ELOC Commitment Note matures on June 26, 2025 and will bear interest at 10% per annum on a 365-day basis, due and payable on June 26, 2025. The Purchaser, in its sole discretion and upon written notice to us may convert all or a portion of the entire unpaid principal balance of the ELOC Commitment Note, together with all accrued and unpaid interest, if any, or the Conversion Amount, into a number of shares of our common stock equal to (x) the Conversion Amount divided by, as of the date of such conversion notice or other date of determination, the lesser of (i) a 20% discount to the lowest intraday sale price of our common stock as traded on the principal market on June 26, 2024 and (ii) a 20% discount to the lowest intraday sale price of our common stock as traded on the principal market during the 20 trading days immediately preceding the date of such conversion notice, subject to adjustment as provided in the terms of the ELOC Commitment Note.

The ELOC Commitment Note in its entirety had an estimated fair value of $0.6 million at issuance, while the ELOC Commitment Note conversion option was required to be bifurcated as a separate derivative liability upon issuance. As a result, we recorded the fair value of the conversion option feature in the amount of $0.3 million as a derivative liability and $0.3 million as a ELOC Commitment Note payable in our condensed consolidated balance sheet. Because there was no consideration paid by the Purchaser in exchange for the ELOC Commitment Note, the entire initial fair value of both instruments was recorded to other expense in the amount of $0.6 million.

The derivative is adjusted to fair value at each reporting period, with the change in the fair value recorded in change in fair value of derivatives that is a component of other income (expense) in our condensed consolidated statement of operations. For the three and six months ended June 30, 2024, the change in fair value of the derivative was de minimis due to the ELOC Commitment Note being issued on June 26, 2024.

**Note 8 – Senior Secured Notes Payable**

On June 25, 2024, we issued senior secured notes with an aggregate principal amount of $0.3 million. The maturity date of such notes is June 25, 2025, unless extended at the holder's option in accordance with the terms of the notes. On June 28, 2024, we issued additional senior secured notes with an aggregate principal amount of $0.1 million. The maturity date of such notes is June 28, 2025, unless extended at the holder's option in accordance with the terms of the notes.

We collectively refer to such senior secured notes due 2025 as the June Senior Secured Notes. The aggregate gross proceeds from the issuances of the June Senior Secured Notes were $0.35 million. The June Senior Secured Notes include a 15% original issue discount. The June Senior Secured Notes will bear interest at 10% per annum on a 360-day and twelve 30-day month basis, payable monthly in cash and in arrears on each Interest Date (as defined in the June Senior Secured Notes) and such interest will compound each calendar month.

Certain conversion and redemption features of the June Senior Secured Notes would typically be considered derivatives that would require bifurcation. In lieu of bifurcating various features in the agreement, we have elected the fair value option for the June Senior Secured Notes and will record the changes in the fair value within the accompanying condensed consolidated statements of operations at the end of each reporting period. The excess of the initial fair value of $0.4 million of the June Senior Secured Notes over the proceeds received of $0.35 million was recorded to other expense in the amount of $41,000. As of June 30, 2024, the fair value of the June Senior Secured Notes was $0.4 million. Refer to Note 5, "Fair Value Measurements" for additional details regarding the fair value measurement.

**Note 9 – Loans Payable**

In June 2023, we entered into an insurance premium financing and security agreement with IPFS Corporation. Under the agreement, we financed $0.8 million of certain premiums at a 7.24% fixed annual interest rate. Payments of approximately $77,000 were due monthly from July 2023 through April 2024. As of December 31, 2023, the outstanding principal of the loan was $0.2 million. The balance of the loan was repaid during the first quarter of 2024.

**Note 10 - Other Current Liabilities**

In 2008, we entered into an Amended and Restated License Agreement with Philip Morris USA, Inc., or PMUSA, with respect to the U.S., or the U.S. License Agreement, and, as PMUSA had assigned its ex-U.S. rights to Philip Morris Products S.A., or PMPSA, effective on the same date and on substantially the same terms and conditions, we entered into a license agreement with PMPSA with respect to rights outside of the U.S., which we refer to, together with the U.S. License Agreement, as the PM License Agreements.

**Amendment No. 1 to the Amended and Restated License Agreement with Philip Morris USA for Aerosolization Technology**

On January 16, 2024, we entered into Amendment No. 1 to the U.S. License Agreement, effective as of January 17, 2024, or the U.S. License Agreement Amendment, which amended the U.S. License Agreement. The U.S. License Agreement licenses U.S. intellectual property rights to us in respect of our former acute pulmonary care platform that was globally outlicensed to the Licensee in August 2022. Pursuant to the U.S. License Agreement Amendment, we agreed to pay PMUSA (i) $100,000 by January 18, 2024, or the PMUSA Upfront Payment, (ii) $400,000 no later than the earlier of (a) July 1, 2024 or (b) the Company receiving a specified amount of net proceeds from debt or equity financings occurring on or after January 17, 2024 and (iii) up to an aggregate of $1.4 million upon the achievement of certain development and regulatory milestones, which milestone payments are expected to be funded from corresponding milestone payments received from the Licensee. Additionally, under the U.S. License Agreement Amendment, the parties extinguished and released their respective rights, obligations and claims in respect of quarterly payments under Section 7.3 of the U.S. License Agreement as in effect immediately prior to January 17, 2024. The U.S. License Agreement Amendment also grants PMUSA the right to terminate the U.S. License Agreement upon 30 days prior written notice to us if we have not paid a milestone payment to PMUSA by January 1, 2028.

As a result of us not paying the $400,000 payable to PMUSA by July 1, 2024, PMUSA issued a notice of default to us dated July 17, 2024. Such notice of default informed us that to avoid termination of the US License Agreement and a collection action via arbitration, we must pay the $400,000 by September 15, 2024.

**Amendment No. 1 to the License Agreement with Philip Morris Products for Aerosolization Technology**

On January 16, 2024, we also entered into Amendment No. 1 to the License Agreement with PMPSA, effective as of January 17, 2024, or the PMPSA License Amendment, which amended the License Agreement, dated March 28, 2008, between us and PMPSA, or the PMPSA License Agreement. The PMPSA License Agreement licenses ex-U.S. intellectual property to us in respect of our former acute pulmonary care platform that was globally outlicensed to the Licensee in August 2022. Pursuant to the PMPSA License Amendment, we agreed to pay PMPSA (i) $75,000 by January 19, 2024, or the PMPSA Upfront Payment, (ii) $325,000 no later than the earlier of (a) July 1, 2024 or (b) the Company receiving a specified amount of net proceeds from debt or equity financings occurring on or after January 17, 2024 (together with the PMPSA Upfront Payment, the Fixed Payments) and (iii) up to an aggregate of $1.4 million upon the achievement of certain development and regulatory milestones, which milestone payments are expected to be funded from corresponding milestone payments received from the Licensee. Additionally, but contingent upon our timely payment of the Fixed Payments, the parties extinguished and released their respective rights, obligations and claims in respect of quarterly payments under Section 6.2 of the PMPSA License Agreement as in effect immediately prior to January 17, 2024.

**Amendment No. 2 to the License Agreement with Philip Morris Products for Aerosolization Technology**

We did not pay $325,000 to PMPSA by July 1 as required by the PMPSA License Amendment. Rather, on July 31, 2024, we entered into Amendment No. 2 to the License Agreement with PMPSA, or the Second PMPSA License Amendment, to further amend the PMPSA License Agreement. Pursuant to the Second PMPSA License Amendment, we agreed to pay PMPSA (i) $200,000 no later than August 2, 2024, or the Initial Payment, and (ii) $125,000 no later than November 15, 2024, or the Deferred Payment, plus interest on the Deferred Payment at the rate of 18% per annum for the period beginning on July 2, 2024, and ending on the date of payment. In the event any balance on the Deferred Payment (including accrued interest) remains unpaid after November 15, 2024, interest on such remaining balance will then accrue at the rate of 27% per annum until December 31, 2024 or the date of payment, whichever is earlier. In the event any balance (including accrued interest) on the Deferred Payment remains unpaid after December 31, 2024, interest shall then accrue at the rate of 36% per annum on such balance until the date of payment.

**Accounting for the PMUSA and PMPSA Payments**

We accounted for these payments as a recognized subsequent event for 2023 in accordance with applicable accounting guidance provided in ASC Topic 855, *Subsequent Events.* For the year ended December 31, 2023, we accrued $0.9 million for payments to PMUSA and PMPSA to be paid in 2024. During the first quarter of 2024, the PMUSA Upfront Payment and the PMPSA Upfront Payment were both paid. As of June 30, 2024, the remaining liability related to PMUSA and PMPSA is $0.7 million and is recorded in other current liabilities. During July 2024, the PMPSA Initial Payment was paid.

**Note 11 – Restructured Debt Liability**

On October 27, 2017, we and Deerfield entered into the Milestone Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield in the aggregate principal amount of $25.0 million and (ii) warrants to purchase up to 10 shares of our common stock at an exercise price of $2,124,360 per share held by Deerfield were cancelled in consideration for (x) a cash payment in the aggregate amount of $2.5 million, (y) 27 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Milestone Agreement) on the closing date, and (z) the right to receive certain milestone payments, or Milestone Payments, based on achievement of specified AEROSURF development and commercial milestones, which, if achieved, could potentially total up to $15.0 million. In addition, a related security agreement, pursuant to which Deerfield held a security interest in substantially all of our assets, was terminated. We established a $15.0 million long-term liability for the contingent milestone payments potentially due to Deerfield under the Milestone Agreement. The liability was recorded at the full value of the contingent milestones and was to be carried at full value until the milestones were achieved and paid or the milestones were not achieved and the liability was written off as a gain on debt extinguishment. As of December 31, 2023, the restructured debt liability balance was $15.0 million.

On January 24, 2024, we and Deerfield entered into an Exchange and Termination Agreement wherein Deerfield agreed to terminate its rights to receive the Milestone Payments.

Pursuant to the Exchange and Termination Agreement, Deerfield agreed to terminate its rights to receive the Milestone Payments and all related rights and obligations in respect of such Milestone Payments in exchange for (i) cash in the aggregate amount of $0.2 million, $0.1 million of which was paid on January 24, 2024 and $0.1 million of which is included in accrued expenses and will be paid no later than the earlier to occur of (a) January 24, 2025 and (b) us receiving a specified amount of gross proceeds from debt or equity financings occurring on or after January 24, 2024, and (ii) an aggregate of 33,793 shares of our common stock, par value $0.001 per share. The shares of the common stock were issued to Deerfield in a transaction exempt from registration pursuant Section 4(a)(2) of the Securities Act of 1933.

Contemporaneously with the execution of the Exchange and Termination Agreement, we and Deerfield entered into a Registration Rights Agreement pursuant to which we have agreed to, among other matters, register for resale with the SEC the shares of the common stock issued to Deerfield pursuant to the Exchange and Termination Agreement. On February 14, 2024, we filed a resale registration statement on Form S-3 (File No. 333-277073) with respect

to 33,793 shares of our common stock, which was amended on April 17, 2024. Such resale registration statement was declared effective by the SEC on April 19, 2024.

The Exchange and Termination Agreement was accounted for as an extinguishment of debt in accordance with ASC Topic 470, *Debt – Modifications and Extinguishments*, and, as a result, we recognized a $14.5 million non-cash gain on debt extinguishment during the six months ended June 30, 2024 consisting of the difference between the $15.0 million of the extinguished Milestone Payments and the consideration to Deerfield under the Exchange and Termination Agreement, which includes $0.2 million in cash and $0.3 million in fair value of common stock issued to Deerfield.

**Note 12 – Mezzanine Equity and Stockholders' Equity**

**Common Stock Purchase Agreement**

In June 2024, we entered into the ELOC Purchase Agreement establishing an equity line of credit with the Purchaser, whereby we have the right, but not the obligation, to sell to the Purchaser, and the Purchaser is obligated to purchase, up to the lesser of (i) $35 million of newly issued shares of our common stock, and (ii) the Exchange Cap (as defined below).

We do not have a right to commence any sales of our common stock to the Purchaser under the ELOC Purchase Agreement until the time when all of the conditions to our right to commence sales of common stock to the Purchaser set forth in the ELOC Purchase Agreement have been satisfied, including that a registration statement covering the resale of such shares is declared effective by the SEC and the final form of prospectus contained therein is filed with the SEC, or the Commencement Date. Over the 36-month period from and after the Commencement Date, we will control the timing and amount of any sales of Common Stock to the Purchaser. Actual sales of shares of our common stock to the Purchaser under the ELOC Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of our common stock and determinations by us as to the appropriate sources of funding and our operations.

In no event can we issue to the Purchaser under the ELOC Purchase Agreement more than 19.99% of the total number of shares of our common stock outstanding immediately prior to the execution of the ELOC Purchase Agreement, or the Exchange Cap, unless (i) we obtain the stockholder approval of the issuance of such shares in accordance with the applicable stock exchange rules or (ii) the average price of all applicable sales of our common stock are made at a price equal to or in excess of the lower of (A) the closing price on the Nasdaq Capital Market on June 26, 2024 and (B) the average of the closing prices of our common stock for the five business days immediately preceding June 26, 2024, such that the sales of such our common stock to the Purchaser would not count toward the Exchange Cap because they are "at market" under applicable stock exchange rules.

We have determined that the put option in the ELOC Purchase Agreement is a derivative within the scope of ASC Topic 815, *Derivatives and Hedging,* to be initially measured and recorded at fair value with subsequent changes in fair value to be recorded in earnings. However, as the exercise price is floating and is a discounted price to the exercise date fair value of the common stock, we have determined that the put option has a de minimis value (effectively zero value) and will not be recorded.

**Asset Purchase Agreement with Varian Biopharmaceuticals**

On April 2, 2024, we entered into the Asset Purchase Agreement with Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian's business associated with the Licence Agreement, which includes the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know-how and inventory of drug substance, or the Transferred Assets. We also assumed all liabilities arising on or after April 2, 2024, relating to the research, development, manufacturing, registration, commercialization, use, handling, supply, storage, import, export or other disposition or exploitation of any and all products associated with the Transferred Assets.

In consideration of the purchase of the Transferred Assets, (i) on April 2, 2024, we issued a total of 5,500 shares of our Series B Preferred Stock, par value $0.001 per share, or the Series B Preferred Stock, to certain creditors of Varian and (ii) agreed to pay up to $2.3 million in milestone payments upon the achievement of certain regulatory and clinical development milestones with our option to pay such milestone payments either in cash or our common stock.

The Asset Purchase Agreement contains customary representations and warranties, covenants, closing conditions and indemnification provisions for a transaction of this nature, including, without limitation, confidentiality and non-compete undertakings by Varian.

The fair value of the consideration transferred for the 5,500 shares of our Series B Preferred Stock was $7.0 million. Because the assets acquired do not meet the definition of a business, and the assets have not reached technological feasibility and have no alternative future use, we expensed the consideration paid as research and development expense in the consolidated statements of operations.

As of June 30, 2024, we have not recorded a liability or expense related to contingent consideration for future milestone payments to Varian, as the achievement of such milestones has not occurred and was not deemed probable.

**Series B Preferred Stock**

The terms of the Series B Preferred Stock are as set forth in the Series B Certificate of Designation of Series B Preferred Stock, as filed with the Delaware Secretary of State and effective on April 3, 2024. The Series B Certificate of Designation authorizes a total of 5,500 shares of Series B Preferred Stock, or the Series B Preferred Stock, with an initial conversion price of $6.4854, or the Series B Preferred Conversion Price, which is subject to adjustment as provided in the Series B Certificate of Designation to no lower than $1.2978. The Series B Preferred Stock has a stated value of $1,000 per share. Each share of Series B Preferred Stock is initially convertible into 155 shares of our common stock, subject to adjustment as provided in the Series B Certificate of Designation. No fractional shares will be issued upon conversion; rather any fractional share will be rounded up to the nearest whole share.

From and after April 2, 2024, each holder of a share of Series B Preferred Stock is entitled to receive dividends, or Dividends, which are computed on the basis of a 360-day year and twelve 30-day months and will increase the stated value of the Series B Preferred Stock on each dividend date (as defined in the Series B Certificate of Designation).

Dividends on the Series B Preferred Stock will accrue at 10.0% per annum and be payable by way of inclusion of the Dividends in the Conversion Amount (as defined in the Series B Certificate of Designation) on each Conversion Date (as defined in the Series B Certificate of Designation) in accordance with the Series B Certificate of Designation or upon any redemption in accordance with the Series B Certificate of Designation or upon any required payment upon any Bankruptcy Triggering Event (as defined in the Series B Certificate of Designation). From and after the occurrence and during the continuance of any Triggering Event (as defined in the Series B Certificate of Designation), the accrual of the dividends will automatically be increased to 18.0% per annum.

The Series B Preferred Conversion Price is subject to adjustment upon the occurrence of specified events and subject to price-based adjustment in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction involving our common stock at a price below the then-applicable Preferred Conversion Price, as described in further detail in the Series B Certificate of Designation.

Upon issuance of the Series B Preferred Stock, the Company was not solely in control of the redemption of the shares of Series B Preferred Stock as the Series B Preferred Stock has multiple redemption features that are outside of our control, including time-based maturity redemption and change of control redemption. Since the redemption of the Series B Preferred Stock was not solely in the control of the Company, the shares of Series B Preferred Stock are classified within mezzanine equity. The shares of Series B Preferred Stock were recorded at fair value of $7.0 million partially offset by issuance costs of $68,000. Because this initial carrying value of the Series B Preferred Stock is higher than the maturity redemption price (i.e., the stated value of $5.5 million with the 10% per annum dividend over the period from issuance until maturity on January 2, 2025), no accretion of Series B Preferred Stock dividends will be recorded. The Series B Preferred Stock could become redeemable at higher values than the initial carrying value under the standard and customary triggering events or a redemption in the event of a change of control, in each case, pursuant to the terms of the Series B Certificate of Designations, but these are not probable of occurrence as of June 30, 2024.

The Series B Preferred Stock have no voting rights, other than with respected to certain protective provisions as stated in the Certificate of Designation. We may not take or consent to certain actions without the consent or vote of the holders of the Series B Preferred Stock.

All other shares of capital stock of the Company are junior in rank to the Series B Preferred Stock with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company. In the event of a liquidation event, the holders of the Series B Preferred Stock are entitled to receive in cash out of the available assets of the Company, before any amount shall be paid to the holders of any of shares of stock, an amount per share equal to the greater of 125% of the conversion amount, where the conversion amount is, as of the applicable date of determination, the sum of the stated value plus all declared and unpaid dividends and any other amounts owed to the holder, and the amount per share such holder would receive if such holder converted the shares into common stock immediately prior to the date of such payment.

**April 2023 Public Offering**

On April 20, 2023, we entered into an underwriting agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, as the sole underwriter relating to a public offering, or the April 2023 Offering, of an aggregate of 204,779 units with each unit consisting of one share of common stock and a warrant, or the April 2023 Warrants. The April 2023 Warrants are immediately exercisable for shares of common stock at a price of $52.74 per share and expire five years from the date of issuance. The shares of common stock and the April 2023 Warrants were immediately separable and were issued separately in the April 2023 Offering.

In addition, Ladenburg exercised in full a 45-day option, or the Overallotment Option, to purchase up to 30,717 additional shares of common stock and/or warrants to purchase up to 30,717 additional shares of common stock.

The closing of the April 2023 Offering occurred on April 24, 2023, inclusive of the Overallotment Option. The offering price to the public was $52.74 per unit resulting in gross proceeds to us of approximately $12.4 million. After deducting underwriting discounts and commissions and other estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the April 2023 Warrants issued pursuant to this April 2023 Offering, the net proceeds to us were approximately $10.8 million.

We have determined that the appropriate accounting treatment under ASC 480, *Distinguishing Liabilities from Equity*, is to classify the shares of common stock and the April 2023 Warrants issued in the April 2023 Offering as equity. We have also determined that the April 2023 Warrants are not in their entirety a derivative under the scope of ASC 815, *Derivatives and Hedging*, due to the scope exception under ASC 815-10-15-74, nor are there any material embedded derivatives that require separate accounting. We allocated the net proceeds from the April 2023 Offering based on the relative fair value of the common stock and the April 2023 Warrants.

**January 2023 Warrant Exercise Inducement Offer Letters**

On January 20, 2023, we entered into warrant exercise inducement offer letters with certain holders of certain of our: (i) warrants issued in December 2019 to purchase 88 shares of common stock with an exercise price of $10,881.00 per share; (ii) warrants issued in May 2020 to purchase 311 shares of common stock with an exercise price of $7,177.50 per share, and (iii) warrants issued in March 2021 to purchase 4,945 shares of common stock with an exercise price of $3,240.00 per share (collectively, the January 2023 Existing Warrants).

Pursuant to the terms of the inducement letters, we agreed to amend the January 2023 Existing Warrants by lowering the exercise price of the January 2023 Existing Warrants to $180.00 per share. Additionally, the exercising holders agreed to exercise for cash all of their January 2023 Existing Warrants to purchase an aggregate of 5,343 shares of common stock in exchange for our agreement to issue to such exercising holders new warrants, or the January 2023 New Warrants, to purchase up to an aggregate of 10,686 shares of common stock. We received aggregate gross and net proceeds of approximately $1.0 million and $0.7 million, respectively, from the exercise of the January 2023 Existing Warrants by the exercising holders.

Each January 2023 New Warrant is exercisable into shares of common stock at a price per share of $193.68, was exercisable six months following its date of issuance, or the January 2023 Initial Exercise Date, and will expire on the fifth anniversary of the January 2023 Initial Exercise Date.

**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 70 shares of common stock with an exercise price of $10,800.00 per share; (ii) warrants issued in December 2018 to purchase 554 shares of common stock with an exercise price of $10,935.00 per share; (iii) warrants issued in December 2019 to purchase 307 shares of common stock with an exercise price of $10,881.00 per share; and (iv) warrants issued in May 2020 to purchase 307 shares of common stock with an exercise price of $7,177.50 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 $127.08 per share. Additionally, Panacea agreed to exercise for cash all of their February 2023 Existing Warrants to purchase an aggregate of 1,236 shares of common stock in exchange for our agreement to issue to Panacea new warrants, or the February 2023 New Warrants, to purchase up to an aggregate of 2,472 shares of common stock. We received aggregate gross and net proceeds of approximately $0.2 million and $0.1 million, respectively, from the exercise of the February 2023 Existing Warrants by Panacea.

Each February 2023 New Warrant is exercisable into shares of common stock at a price per share of $193.68, was exercisable six months following its date of issuance, or the February 2023 Initial Exercise Date, and will expire on the fifth anniversary of the February 2023 Initial Exercise Date.

**Accounting for the January 2023 and February 2023 Warrant Exercise Inducement Offer Letters**

The amendment of the January 2023 Existing Warrants and the February 2023 Existing Warrants by lowering the exercise prices and issuing the January 2023 New Warrants and the February 2023 New Warrants is considered a modification of the January 2023 Existing Warrants and the February 2023 Existing Warrants under the guidance of ASU 2021-04. The modification is consistent with the "Equity Issuance" classification under that guidance as the reason for the modification was to induce the holders to cash exercise their warrants, resulting in the imminent exercise of the January 2023 Existing Warrants and the February 2023 Existing Warrants, which raised equity capital and generated net proceeds for us of approximately $0.7 million and $0.1 million, respectively. The total fair value of the consideration of the modification includes the incremental fair value of the January 2023 Existing Warrants and the February 2023 Existing Warrants (determined by comparing the fair values immediately prior to and immediately after the modification) and the initial fair value of the January 2023 New Warrants and the February 2023 New Warrants. The fair values were calculated using the Black-Scholes model and we determined that the total fair value of the consideration related to the modification of the January 2023 Existing Warrants and the February 2023 Existing Warrants, including the initial fair value of the January 2023 New Warrants and the February 2023 New Warrants, was $1.2 million and $0.3 million, respectively.

**At-The-Market Program**

On November 9, 2023, we entered into the 2023 ATM Program with Ladenburg. We are not obligated to make any sales under the 2023 ATM Program. When we issue sale notices to Ladenburg, we designate the maximum amount of shares to be sold by Ladenburg daily and the minimum price per share at which shares may be sold. Ladenburg may sell shares by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or in privately negotiated transactions.

Sales under the 2023 ATM Program will be made pursuant to our "shelf" registration statement on Form S-3 (No. 333-261878) filed with the SEC on December 23, 2021, and declared effective on January 3, 2022, and a prospectus supplement related thereto. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited to selling no more than one-third of the aggregate market value of the equity held by non-affiliates, or the public float, during any 12-month period, and, as of August 19, 2024, we had sold substantially all that we are permitted to sell under the Form S-3 pursuant to General Instruction I.B.6. If our public float increases, we will have additional availability under such limitations, and if our public float increases to $75 million or more, we will no longer be subject to such limitations. However, there can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

Either party may suspend the offering under the 2023 ATM Program by notice to the other party. The 2023 ATM Program will terminate upon the earlier of (i) the sale of all shares subject to the 2023 ATM Program or (ii) termination of the 2023 ATM Program in accordance with its terms. Either party may terminate the 2023 ATM Program at any time upon five business days' prior written notification to the other party in accordance with the related agreement.

We agreed to pay Ladenburg a commission of 3% of the gross sales price of any shares sold pursuant to the 2023 ATM Program. The rate of compensation will not apply when Ladenburg acts as principal, in which case such rate shall be separately negotiated. We also agreed to reimburse Ladenburg for the fees and disbursements of its counsel in an amount not to exceed $60,000, in addition to certain ongoing disbursements of its legal counsel up to $3,000 per calendar quarter.

During the six months ended June 30, 2024, we sold 143,120 shares of our common stock under the 2023 ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.4 million.

**Note 13 – Stock-Based Compensation**

We recognize expense in our interim unaudited condensed consolidated financial statements related to all stock-based awards granted to employees and non-employee directors based on their fair value on the date of grant. Compensation expense related to stock options is calculated using the Black-Scholes option-pricing model and is recognized ratably over the vesting period, which is typically three years. Compensation expense related to restricted stock unit, or RSU, awards is also recognized ratably over the vesting period, which is typically between one to three years.

A summary of activity under our long-term incentive plans is presented below:

(in whole numbers)

| Stock Options | Shares | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (In Yrs) |
|---|---|---|---|
| Outstanding at January 1, 2024 | 15,400 | $ 1,664.00 | |
| Reverse split adjustments - fractional share round ups | 106 | (91.91) | |
| Forfeited or expired | (145) | 7,214.10 | |
| Outstanding at June 30, 2024 | 15,361 | $ 1,518.83 | 8.4 |
| | | | |
| Vested and exercisable at June 30, 2024 | 3,288 | $ 6,979.86 | 5.6 |
| | | | |
| Vested and expected to vest at June 30, 2024 | 14,078 | $ 1,533.64 | 8.4 |

(in whole numbers)

| Restricted Stock Units | Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Outstanding at January 1, 2024 | 8,180 | $ 52.49 |
| Reverse split adjustments - fractional share round ups | 66 | (0.42) |
| Vested | (139) | 912.01 |
| Outstanding at June 30, 2024 | 8,107 | $ 37.22 |

The table below summarizes the total stock-based compensation expense included in the interim unaudited condensed consolidated statements of operations for the periods presented:

| *(in thousands)* | Three Months Ended June 30, 2024 | 2023 | Six Months Ended June 30, 2024 | 2023 |
|---|---|---|---|---|
| | | | | |
| Research and development | $ 31 | $ 58 | $ 82 | $ 187 |
| General and administrative | 66 | 324 | 266 | 480 |
| Total | $ 97 | $ 382 | $ 348 | $ 667 |

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities are based upon the historical volatility of our common stock and other factors. We also use historical data and other factors to estimate option exercises and forfeiture rates. The risk-free interest rates are based upon the U.S. Treasury yield curve in effect at the time of the grant.

**Note 14 – Licensing and Research Funding Agreements**

**Asset Purchase Agreement with Varian Biopharmaceuticals**

On April 2, 2024, we entered into the Asset Purchase Agreement with Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian's business associated with the Licence Agreement, which includes the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know-how and inventory of drug substance, or the Transferred Assets. We also assumed all liabilities arising on or after April 2, 2024, relating to the research, development, manufacturing, registration, commercialization, use, handling, supply, storage, import, export or other disposition or exploitation of any and all products associated with the Transferred Assets.

In consideration of the purchase of the Transferred Assets, (i) on April 2, 2024, we issued a total of 5,500 shares of our Series B Preferred Stock to certain creditors of Varian and (ii) agreed to pay up to $2.3 million in milestone payments upon the achievement of certain regulatory and clinical development milestones with our option to pay such milestone payments either in cash or our common stock.

The Asset Purchase Agreement contains customary representations and warranties, covenants, closing conditions and indemnification provisions for a transaction of this nature, including, without limitation, confidentiality and non-compete undertakings by Varian.

The fair value of the consideration transferred for the 5,500 shares of our Series B Preferred Stock was $7.0 million. Because the assets acquired do not meet the definition of a business, and the assets have not reached technological feasibility and have no alternative future use, we expensed the consideration paid as research and development expense in the consolidated statements of operations.

As of June 30, 2024, we have not recorded a liability or expense related to contingent consideration for future milestone payments to Varian, as the achievement of such milestones has not occurred and was not deemed probable.

**Entry into a Material Definitive Agreement**

In order to reduce expected costs with our contract research organization, Momentum Research, Inc., or MRI, on May 9, 2024, or the Effective Date, we entered into Amendment No. 1 to the Master Services Agreement and Work Order Nos. 11 and 12, or the Amendment, with MRI. The Amendment amends the Master Services Agreement we entered into with MRI on February 13, 2020, or the Original MSA, and the original Work Order Nos. 11 and 12 we entered into with MRI on June 1, 2023, collectively, the Original Work Orders.

Under the Original MSA, we agreed to, among other things, engage MRI to provide non-exclusive research and development services, by executing individual work orders to be negotiated and specified in writing on terms agreed to by both parties on a later date.

Under the terms of the Amendment, we agreed to, among other things, be responsible for certain management, regulatory strategy, and reporting obligations in connection with our SEISMiC Extension study and MRI agreed to fully perform its obligations under the Original Work Orders with respect to the SEISMiC Extension study, including performance of all services and delivery of all deliverables required by the Original Work Orders. Additionally, with respect to the SEISMiC C Study, MRI agreed to be responsible for certain regulatory submissions, as provided in the Amendment.

Additionally, in consideration of and conditioned upon the payments described below, we and MRI each agreed to cancel and extinguish any and all amounts owed to MRI or us, respectively, each subject to the terms of the Amendment. The parties agreed that such cancellation and extinguishment shall not be construed as a waiver of claims by each party for breach of the Original MSA or either or both of the Original Work Orders other than for non-payment, nor a waiver of each party's respective indemnification rights under the Original MSA.

In consideration of MRI's full performance of the Original Work Orders and cancellation of accrued expenses as described above, we agreed to, among other things, pay MRI $1.2 million in a series of scheduled payments through September 20, 2024, subject to the terms of the Amendment. If services are not completed by October 31, 2024, the parties agree that MRI will continue its services until fully completed with no further compensation. In case of delayed payments, we agreed to pay MRI interest on any overdue amount from the due date until the date paid in full at a rate equal to 18% per annum. If the SEISMiC Extension study and the SEISMiC C Study are terminated prior to September 20, 2024, then the next payment due after termination will be made to MRI and remaining payments that would have become due automatically become no longer payable.

Additionally, we agreed that, for a transaction consummated by December 31, 2027, we shall pay MRI an amount equal to 2% of istaroxime license fees, milestone payments, royalties, securities or other property that we actually collect in respect of any license of istaroxime that we grant to any unaffiliated third party on or after the Effective Date; net of all legal and financial advisory fees and expenses actually paid by us in respect of the associated license transaction. Further, we agreed that if we commercialize istaroxime ourselves in the United States or another region, we shall also pay MRI an amount equal to 2% of our net profit derived from direct sales of istaroxime to clients in our territory where sales occurred, as determined in our US GAAP financial statements. Pursuant to the Amendment, such payments on istaroxime sales will end when data and market exclusivity protection expires for istaroxime.

Further, in connection with the first to occur of either a Change of Control (as defined in the Amendment) or the sale of all or substantially all of our rights in istaroxime not in the context of a Change of Control, we agree to pay MRI an amount equal to 2% of the sum of any cash and the fair market value of any securities or other property that we actually collect or receive that is attributable to our rights in istaroxime (subject to the terms of the Amendment), net of a ratable portion of certain fees and expenses as provided by the Amendment.

After December 1, 2025, we have the right to buy out the amounts due under certain provisions of the Amendment.

The foregoing descriptions of the Original MSA and Amendment are general descriptions only, do not purport to be complete descriptions of the rights and obligations of the parties thereunder, and are qualified in their entirety by reference to the terms of such agreements, which are filed as Exhibit 10.1 and 10.2, respectively, to this Quarterly Report on Form 10-Q.

**Term Sheet and Project Financing Agreement with Lee's (HK)**

In March 2020, we entered into a Term Sheet with Lee's (HK), pursuant to which Lee's (HK) provided financing for the development of AEROSURF. In August 2020, we entered into a Project Financing Agreement with Lee's (HK), or the PF Agreement, formalizing the terms of the Term Sheet, and under which we received payments totaling $2.8 million through October 2020. In November 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 were due under the PF Agreement.

Since the 2018 acquisition of CVie Investments Limited and CVie Therapeutics, istaroxime has become our primary focus for investment and execution due to what we believe represents a greater potential value opportunity for us and our stockholders. Since completing our Phase 2 study of lucinactant (KL4 surfactant) for patients with severe COVID-19 associated ARDS and lung injury in January 2022, in order to preserve resources for the highest priority programs, we have begun to reduce costs not already being performed by our licensee, Lee's (HK) and Zhaoke, under the terms of our Original License Agreement. These costs include certain reductions in headcount dedicated to KL4 surfactant and the decommissioning of both our analytical and technical support laboratory, which previously conducted release testing of APIs and supportive research for our lyophilized and aerosolized KL4 surfactant, and our medical device development laboratory, which was previously used to conduct development activities and testing for our ADS technologies. To support the future development of our KL4 surfactant platform in markets outside of Asia, including the U.S., we are pursuing one or more licensing transactions.

To repay the funds provided under the terms of the PF Agreement, until such time as we have repaid 125% of the amounts funded by Lee's (HK) for the development of AEROSURF, we will pay to Lee's (HK) 50% of all revenue amounts and payments received by us for any sale, divestiture, license or other development and/or commercialization of the KL4/AEROSURF patent portfolio, excluding (i) payments for bona fide research and development services; (ii) reimbursement of patent expenses and (iii) all amounts paid to us under the Original License Agreement, minus certain deductions and certain reductions for any payments made by us with respect to third party intellectual property not previously funded by Lee's (HK).

As of June 30, 2024, the liability balance related to the payments under the PF Agreement was $3.8 million and is recorded in other liabilities.

**A&R License Agreement with Lee's (HK)**

Previously, we were developing a 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 all 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 (HK) and Zhaoke, under the terms of 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. If and when the exclusive license granted to Esteve terminates as to any country, such country automatically becomes part of the Licensed Territory of Licensee.

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. We are also eligible to receive tiered royalties based on a percentage of Net Sales (as defined in the A&R License Agreement) that ranges from low single digit to low teen percentages, depending on the product. Royalties are payable on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid patent claim covering the product in the country of sale, (ii) the expiration or revocation of any applicable regulatory exclusivity in the country of sale, and (iii) ten years after the first commercial sale of the product in the country of sale. Thereafter, in consideration of licensed rights other than patent rights, royalties shall continue for the commercial life of each product but at substantially reduced rates. In addition, the royalty rates are subject to reduction by as much as 50% in a given country based on generic competition in such country.

The A&R License Agreement is considered to be a contract modification in accordance with ASC Topic 606, *Revenue from Contracts with Customers*. No additional performance obligations were identified in the contract modification, and no future material performance obligations are due.

All revenue related to the $1.0 million upfront payment under the Original License Agreement was appropriately recognized as of the second quarter of 2019. Regulatory and commercialization milestones under the A&R License Agreement were excluded from the transaction price, as all milestone amounts were fully constrained under the guidance. Consideration related to sales-based milestones and royalties under the A&R License Agreement will be recognized when the related sales occur, provided that the reported sales are reliably measurable and that we have no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to Licensee and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each future reporting period and as uncertain events are resolved or other changes in circumstances occur.

**License, Development and Commercialization Agreement with Lee's (HK)**

On January 12, 2024, we entered into a License, Development and Commercialization Agreement with Lee's (HK) effective as of January 7, 2024, or the Lee's (HK) License Agreement. Under the Lee's (HK) License Agreement, we granted an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute and otherwise commercialize products that incorporate istaroxime for intravenous administration, rostafuroxin for oral administration, and our proprietary dual-mechanism SERCA2a activators for intravenous or oral administration (collectively, the Products and each, a Product), in each case for the prevention, mitigation and/or treatment of any disease, disorder or condition in humans including acute decompensated heart failure, cardiogenic shock, and chronic use following discharge of an individual hospitalized for acute decompensated heart failure, or Field, in the People's Republic of China, Hong Kong, Macau, Taiwan, Singapore, South Korea, Thailand, Vietnam, Brunei, Myanmar, Cambodia, East Timor, Indonesia, Laos, Malaysia, and the Philippines, or the New Licensed Territory.

Under the Lee's (HK) License Agreement, we may receive up to $3.1 million in potential upfront pre-development, development, clinical, and regulatory milestone payments and up to $135.25 million in sales milestone payments. We are also entitled to receive a low double-digit percentage of Lee's (HK) non-royalty sublicense income.

We are eligible to receive tiered royalties based on a percentage of Net Sales (as defined in the Lee's (HK) License Agreement) that ranges from low single-digit to low double-digit percentages, depending on the Product. Royalties are payable on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid patent claim covering the Product in the country of sale, (ii) the expiration or revocation of any applicable regulatory exclusivity in the country of sale, and (iii) ten years after the first commercial sale of the Product in the country of sale. Thereafter, in consideration of licensed rights other than patent rights, royalties shall continue for the commercial life of each Product but at substantially reduced rates. In addition, the royalty rates are subject to reduction by as much as 50% in a given country based on generic competition in such country.

Under the Lee's (HK) License Agreement, Lee's (HK) will be solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval and commercialization of Products in the New Licensed Territory, with the exception of certain costs in connection with filing fees payable to regulatory authorities in the New Licensed Territory relative to a Product for which we hold the applicable marketing authorization. Lee's (HK) may sublicense its rights to its affiliates and may grant sublicenses to third-party subcontractors to perform certain activities under the Lee's (HK) License Agreement on behalf of Lee's (HK) or its affiliates but may not otherwise grant sublicenses to unaffiliated third parties without our prior consent. A sublicensee and a subcontractor may not be a competitor identified by us. Sublicenses granted under the Lee's (HK) License Agreement may not include the right to further sublicense. The Lee's (HK) License Agreement establishes a joint steering committee and a joint development committee to oversee the regional development (with us retaining final decision rights over clinical protocols) and a joint commercialization committee.

During the term of the Lee's (HK) License Agreement, we receive an exclusive (even as to Lee's (HK)), sublicensable license under any Lee's (HK) and its affiliate's intellectual property that covers a Product (including its manufacture and use) and any improvements to the licensed technology developed solely by or on behalf of Lee's (HK) or jointly with us, to (i) develop Product in the Field to obtain or maintain regulatory approval outside of the New Licensed Territory, and (ii) use, sell, offer for sale, import, export, make, have made, distribute, warehouse, market, promote, apply for and submit applications for drug approval and reimbursement approval and otherwise commercialize Product in the Field outside of the New Licensed Territory. After the term of the Lee's (HK) License Agreement, or in the event that we wish to obtain an exclusive license under certain patent rights during or after the term, we have the option to negotiate an exclusive royalty-bearing license under any such intellectual property, provided that such royalties shall not exceed specified low single-digit caps.

Under the Lee's (HK) License Agreement, each party is responsible for prosecution and maintenance of its respective solely-owned patents, and the parties shall decide on a case-by-case basis the appropriate allocation of costs and control concerning matters regarding the prosecution, maintenance, defense and infringement of any jointly-owned patents. The Lee's (HK) License Agreement provides for cooperation between the parties with respect to enforcement of patent rights. As between the parties, we have the first right to enforce patent rights against third parties at our own expense. If we decline to enforce such rights, Lee's (HK) has the right to enforce such rights at its own expense. In the event that a third party claims that a Product used or sold by Lee's (HK) (or its affiliate or sublicensee) is infringing on a patent in the New Licensed Territory, Lee's (HK) is responsible for defending against such third party claim at its cost and expense, with the exception of certain counterclaims that we may bring.

The term of the Lee's (HK) License Agreement will continue on a country-by-country basis for the commercial life of the Products. Either party may terminate the Lee's (HK) License Agreement in the event of bankruptcy or a material breach of the Lee's (HK) License Agreement by the other party that remains uncured for a period of sixty days (or within 30 days after delivery of a Default Notice (as defined in the Lee's (HK) License Agreement) if such material breach is solely based on the breaching party's failure to pay amount due under the Lee's (HK) License Agreement). In addition, either party may terminate the Lee's (HK) License Agreement with respect to any individual Product in a country if a regulatory authority in such country terminates, suspends or discontinues development of such Product and such termination, suspension or discontinuance persists for a period in excess of 18 months. Upon termination of the Lee's (HK) License Agreement in its entirety or with respect to a particular Product or country, generally all related rights and licenses granted to Lee's (HK) will terminate, all rights under our technology will revert to us, and Lee's (HK) will cease all use of our technology, in each case in relation to the terminated Product(s) and country(ies), as applicable.

The Lee's (HK) License Agreement constitutes a contract with a customer accounted for in accordance with ASC Topic 606. The promise of the istaroxime product, dual mechanism SERCA2a activator products, and rostafuroxin product license is the sole performance obligation provided in the Lee's (HK) License Agreement. The performance obligation was fully satisfied as of the effective date of the Lee's (HK) License Agreement, and no future material performance obligations are due.

No revenue has been recognized under the Lee's (HK) License Agreement. Clinical, regulatory and commercialization milestones under the Lee's (HK) License Agreement were excluded from the transaction price, as all milestone amounts were fully constrained under the guidance. Consideration related to sales-based milestones and royalties under the Lee's (HK) License Agreement will be recognized when the related sales occur, provided that the reported sales are reliably measurable and that we have no remaining performance obligations, as such sales were determined to relate predominantly to the license granted to Lee's (HK) and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each future reporting period and as uncertain events are resolved or other changes in circumstances occur.

**Note 15 – Income Taxes**

During the three and six months ended June 30, 2024, we recorded an income tax provision of $0.2 million and $0.3 million, respectively, related to tax on our estimated taxable income for the year, primarily due to the gain on debt extinguishment (See the section titled, "Note 8 – Restructured Debt Liability").

We have evaluated the positive and negative evidence bearing upon our ability to realize our deferred tax assets, which primarily consist of net operating losses, or NOLs. We considered the history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies, and have concluded that it is more likely than not that we will not realize the benefits of our deferred tax assets within United States jurisdiction. As such, we recorded a full valuation allowance against net deferred tax assets as of June 30, 2024 and December 31, 2023, for deferred taxes in the United States. We still have a net deferred tax liability related to our foreign operations.

Utilization of NOL and R&D credit carryforwards will be subject to a substantial annual limitation under Internal Revenue Code of 1986, or IRC, Section 382, due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes will limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and income tax liabilities, respectively. As a result of having undergone an ownership change under IRC 382, our ability to utilize our historical NOL carryovers will be limited. We will continue to monitor any limitations on our ability to use NOLs and R&D credits in the future for all jurisdictions.

**Note 16 – Subsequent Events**

**Senior Secured and Senior Unsecured Notes**

On July 3, 2024, we agreed to issue and sell to (i) an institutional investor an aggregate principal amount of $0.1 million in senior secured notes due 2025, or the July Secured Note, and (ii) an additional institutional investor an aggregate principal amount of $0.1 million in senior unsecured promissory notes due 2025, or the July Unsecured Note, and together with the July Secured Note, the July 2024 Notes, for aggregate gross proceeds of $200,000. The July 2024 Notes include 15% original issue discount and will mature on July 3, 2025, unless extended at the holder's option in accordance with the terms of the July 2024 Notes. The July 2024 Notes bear interest at 10% per annum on a 360-day and twelve 30-day month basis, payable monthly in cash and in arrears on each Interest Date (as defined in the applicable July 2024 Notes) and such interest will compound each calendar month. The interest rate will increase to 18% per annum upon the existence of an Event of Default (as defined in the applicable July 2024 Notes).

The July Secured Note is secured by first-priority security interests in all of our assets then presently existing, and constitutes a valid, first priority security interest in all of the assets that we later-acquire, as further defined in the July 2024 Secured Note.

**First Private Placement**

On July 18, 2024, we entered into a Securities Purchase Agreement, or the First Purchase Agreement, with the buyers named therein, pursuant to which we agreed to the private placement, or the First PIPE, of (i) 16,099 shares, or the Preferred Shares, of our Series C Convertible Preferred Stock, par value $0.001 per share, or the Series C Preferred Stock, and (ii) warrants, or the July 2024 Warrants, to acquire up to the aggregate number of 3,440,631 additional shares of our common stock for aggregate gross proceeds of approximately $12.9 million of which $9.5 million was paid through the cancellation and extinguishment of certain securities as further described below.

Additionally, we issued 161 Preferred Shares and 42,838 July 2024 Warrants as compensation for certain placement agent fees and expenses. We also reimbursed the lead buyer for certain fees and expenses of counsel in accordance with the terms of the First Purchase Agreement.

We agreed to seek stockholder approval for the issuance of all of the shares of our common stock issuable upon conversion of the Preferred Shares and exercise of the July 2024 Warrants in connection with the First PIPE in accordance with the rules and regulations of the Nasdaq Stock Market.

*Series C Preferred Stock*

The terms of the Series C Preferred Stock are as set forth in the Series C Certificate of Designation of Series C Preferred Stock, as filed with the Delaware Secretary of State and effective on July 19, 2024. The Series C Certificate of Designation authorizes a total of 18,820 shares of Series C Preferred Stock with an initial conversion price of $3.74, or the Series C Preferred Conversion Price, which is subject to adjustment as provided in the Series C Certificate of Designation to no lower than $1.28. The Series C Preferred Stock has a stated value of $1,000 per share. Each share of Series C Preferred Stock is initially convertible into 267 shares of our common stock, subject to adjustment as provided in the Series C Certificate of Designation. No fractional shares will be issued upon conversion; rather any fractional share will be rounded up to the nearest whole share.

From and after July 19, 2024, each holder of a share of Series C Preferred Stock is entitled to receive dividends, which are computed on the basis of a 360-day year and twelve 30-day months and will increase the stated value of the Series C Preferred Stock on each dividend date (as defined in the Series C Certificate of Designation).

Dividends on the Series C Preferred Stock will accrue at 10.0% per annum and be payable by way of inclusion of the dividends in the Conversion Amount (as defined in the Series C Certificate of Designation) on each Conversion Date (as defined in the Series C Certificate of Designation) in accordance with the Series C Certificate of Designation or upon any redemption in accordance with the Series C Certificate of Designation or upon any required payment upon any Bankruptcy Triggering Event (as defined in the Series C Certificate of Designation). From and after the occurrence and during the continuance of any Triggering Event (as defined in the Series C Certificate of Designation), the accrual of the dividends will automatically be increased to 18.0% per annum.

The Preferred Conversion Price is subject to adjustment upon the occurrence of specified events and subject to price-based adjustment in the event of any stock split, stock dividend, stock combination, recapitalization or other similar transaction involving our common stock at a price below the then-applicable Preferred Conversion Price, as described in further detail in the Series B Certificate of Designation.

*July 2024 Warrants*

The July 2024 Warrants are exercisable upon the six month and one day anniversary of the issuance date, or the Initial Exercisability Date, and expire on the fifth anniversary of the Initial Exercisability Date and will have an exercise price of $4.11 per share, subject to customary adjustments.

*Cancellation and Extinguishment of Certain Securities*

In connection with the First PIPE, $9.5 million of the aggregate gross proceeds was paid through the cancellation and extinguishment of certain holders' (x) outstanding principal amount, conversion/exchange premiums and all accrued interest and dividends thereon under our (i) Senior Convertible Notes, (ii) the June Senior Secured Notes, (iii) the July Secured Note, and (iv) the July Unsecured Note, and (y) 5,500 shares of the Series B Preferred Stock.

**Second Private Placement**

On July 26, 2024, we entered into a Securities Purchase Agreement, or the Second Purchase Agreement, with the buyer named therein, pursuant to which we agreed to a second tranche of the private placement, or the Second PIPE, of (i) 1,250 Preferred Shares, and (ii) July 2024 Warrants to acquire up to the aggregate number of 267,380 additional shares of our common stock for aggregate gross proceeds of approximately $1.0 million.

We agreed to seek stockholder approval for the issuance of all of the shares of our common stock issuable upon conversion of the Preferred Shares and exercise of the July 2024 Warrants in connection with the Second PIPE in accordance with the rules and regulations of the Nasdaq Stock Market.

The rights and preferences of the Series C Preferred Stock issued in connection with the Second PIPE, including the terms pursuant to which they are convertible into our common stock, are consistent with the rights and preferences of the Series C Preferred Stock issued in connection with the First PIPE. Similarly, the terms of the warrants issued in connection with the Second PIPE are consistent with the terms of the warrants issued in connection with the First PIPE.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing activities, includes forward-looking statements that involve risks, uncertainties and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. The reader should review the section titled "Forward-Looking Statements" and any risk factors discussed elsewhere in this Quarterly Report on Form 10-Q, which are in addition to and supplement the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2023 that we filed with the Securities and Exchange Commission, or SEC, on April 16, 2024, as supplemented by our Quarterly Report on Form 10-Q for the three months ended March 31, 2024 filed thereafter, and our other filings with the SEC, and any amendments thereto, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Quarterly Report on Form 10-Q.*

This Management's Discussion and Analysis, or MD&A, is provided as a supplement to the accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) to help provide an understanding of our financial condition and changes in our financial condition and our results of operations. This item should be read in connection with our accompanying interim unaudited Condensed Consolidated Financial Statements (including the notes thereto) and our Annual Report on Form 10-K for the year ended December 31, 2023. Unless otherwise specified, references to Notes in this MD&A refer to the Notes to Condensed Consolidated Financial Statements (unaudited) in this Quarterly Report on Form 10-Q.

### OVERVIEW

We are a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Our portfolio of product candidates includes istaroxime, a Phase 2 candidate that inhibits the sodium-potassium ATPase and also activates sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a, for acute heart failure and associated cardiogenic shock; preclinical SERCA2a activators for heart failure; rostafuroxin for the treatment of hypertension in patients with a specific genetic profile; and a preclinical atypical protein kinase C iota, or aPKCi, inhibitor (topical and oral formulations), being developed for potential application in rare and broad oncology indications. We also have a licensing business model with partnership out-licenses currently in place.

Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to increase blood pressure and improve cardiac function in patients with cardiogenic shock and to improve cardiac function in patients with acute heart failure, or AHF, and reverse the hypotension and hypoperfusion associated with heart failure that deteriorates to cardiogenic shock. Istaroxime demonstrated significant improvement in both systolic and diastolic 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 and had a favorable renal profile, we initiated a Phase 2 global clinical study, or the SEISMiC Study, to evaluate istaroxime for the treatment of early cardiogenic shock (Society for Cardiovascular Angiography and Interventions, or SCAI, Stage B shock), a severe form of AHF characterized by very low blood pressure and risk for hypoperfusion to critical organs and mortality. In April 2022, we announced our observations in the SEISMiC Study that istaroxime rapidly and significantly increased SBP while also improving cardiac function and preserving renal function. 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 the SEISMiC Study supports continued development in both cardiogenic shock and AHF. In the fourth quarter of 2023, we initiated an extension to the SEISMiC Study, or the SEISMiC Extension, to evaluate a longer dosing period and to continue to characterize the effects of istaroxime, including activation of SERCA2a. The SEISMiC Extension study is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in the second half of 2024. Additionally, we have recently initiated a small study in more severe SCAI Stage C cardiogenic shock, or the SEISMiC C Study, to evaluate the safety and efficacy of istaroxime in cardiogenic shock patients who are also receiving standard of care rescue therapy for shock. The SEISMiC C Study is expected to enroll up to 20 subjects with SCAI Stage C cardiogenic shock with enrollment anticipated to be completed in late 2024. Our ability to complete both of these studies with their intended sample size is dependent upon our ability to secure adequate resourcing for the program through financing efforts or business development activities.

Our heart failure cardiovascular portfolio also includes other SERCA2a activators. One family of compounds has the dual mechanism of action that includes inhibition of the sodium-potassium ATPase as well as activation of SERCA2a. The other family of compounds are considered selective SERCA2a activators and are devoid of activity against the sodium-potassium ATPase. 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 the development of rostafuroxin without securing such an arrangement or partnership.

Our cardiovascular assets and programs are associated with a regional licensed partnership with Lee's Pharmaceutical (HK) Ltd., or Lee's (HK), for the development and commercialization of our product candidate, istaroxime, in Greater China. In addition to istaroxime, the agreement also licenses our preclinical next-generation dual mechanism SERCA2a activators, and rostafuroxin. In addition, we are supporting the efforts of Lee's (HK) in starting a Phase 3 trial in AHF with istaroxime.

On April 2, 2024, we entered into an Asset Purchase Agreement, or the Asset Purchase Agreement, with Varian Biopharmaceuticals, Inc., or Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian's business associated with a license agreement, dated as of July 5, 2019, by and between Varian and Cancer Research Technology Limited, or the Licence Agreement, which includes the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know-how and inventory of drug substance, or the Transferred Assets. The Transferred Assets include a novel, potential high-potency, specific, aPKCi inhibitor with possible broad use in oncology as well as certain rare malignant diseases. The asset platform includes two formulations (topical and oral) of an aPKCi inhibitor. We plan to advance investigational new drug enabling activities and are in the process of determining the expected clinical development plan for the platform.

We have incurred net losses since inception. Our net loss was $12.0 million and $1.8 million, respectively, for the three and six months ended June 30, 2024. Included in net loss for the three and six months ended June 30, 2024 is $7.5 million of non-cash R&D expense related to costs in connection with the Varian asset acquisition and a $14.5 million gain on debt extinguishment. For the three and six months ended June 30, 2023, our net loss was $6.6 million and $10.7 million, respectively. Included in our net loss for the three and six months ended June 30, 2023 is a $2.6 million and $3.1 million loss on impairment of goodwill, respectively. As of June 30, 2024, we had an accumulated deficit of $846.6 million. To date, we have financed our operations primarily through private placements and public offerings of our common and preferred stock, warrants to purchase common stock, and borrowings from investors and financial institutions.

We expect to continue to incur significant research and clinical development, regulatory, and other expenses as we (i) continue to develop our product candidates; (ii) seek regulatory clearances or approvals for our product candidates; (iii) conduct clinical trials on our product candidates; and (iv) manufacture, market, and sell any product candidates for which we may obtain regulatory approval.

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, 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, as well as modify or cease our operations, either of 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, 2023 that we filed with the SEC on April 16, 2024, 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 (Cardiogenic Shock)*

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, during the third quarter of 2023, we initiated the SEISMiC Extension study, which is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock. We believe that this extension will advance the characterization of the physiology associated with longer dosing as well as enhancing dose optimization. Additionally, in the fourth quarter of 2023, we commenced with study start up activities for the SEISMiC C study, which is expected to enroll up to 20 subjects with SCAI Stage C cardiogenic shock. We also believe that the SEISMiC Extension and SEISMiC C studies 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 complete these clinical trials.

*Istaroxime (AHF)*

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, already completed, 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. We believe the Phase 3 AHF program being planned by our licensing partner in China may provide supportive data for potential AHF programs initiated in the future.

*SERCA2a Activators – Preclinical Oral, Chronic, and Acute Heart Failure Product Candidates*

We are pursuing several early exploratory research programs to assess potential product candidates, including oral and intravenous dual mechanism or selective 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. In April 2023, we announced that the European Patent Office has granted Patent No. 3599243, providing patent coverage for the dual mechanism SERCA2a Activator class of drug candidates. This patent provides protection until July 2038 for the family of compounds with a dual mechanism of action. To further advance these product candidates, we are actively exploring potential licensing transactions, research partnership arrangements, or other strategic opportunities. Additionally, the United States Patent and Trademark Office has issued US Patent No. 11,730,746 covering our dual mechanism SERCA2a activators. The new composition of matter patent provides patent protection through late 2039. Further, the European Patent Office has granted Patent No. 3805243, providing composition of matter patent coverage for the pure SERCA2a Activator class of drug candidates. The pure SERCA2a Activators are one of two families of preclinical drug candidates that act on SERCA2a in the Company's pipeline. The pure SERCA2a Activators are devoid of action on the Na+/K+ pump while activating SERCA2a. The new European patent provides patent protection until October 9, 2039 for the family of compounds with the pure SERCA2a mechanism of action.

*Rostafuroxin*

Rostafuroxin has demonstrated efficacy in Caucasian patients in treatment naïve hypertension in a Phase 2b trial. During the second quarter of 2021, we concluded an initial process to test the industry's interest in investing in our product candidate. We currently have not been able to secure a licensing transaction or other strategic opportunity. 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 African American patients in treatment resistant hypertension. We are continuing to pursue licensing arrangements and/or other strategic partnerships for rostafuroxin. We do not intend to conduct the additional Phase 2 clinical trial without securing such an arrangement or partnership.

*aPKCi inhibitor (topical formulation previously designated as VAR-101)*

The topical (cutaneous) formulation is a small molecule that may have potential for the treatment of basal cell carcinoma, or BCC. The active pharmaceutical ingredient, or API, in aPKCi inhibitor (topical) has demonstrated dose dependent anti-tumor activity in murine and human BCC cell lines, in studies performed at Cancer Research UK, or CRUK, a charity registered in England and Scotland, and based in London, United Kingdom. CRUK collaborators, including Stanford University under a sponsored research agreement with CRUK, completed the preclinical tumor cell line data and the BCC cell line data that formed the basis for additional "method of use" patents that are included in the License Agreement. These types of in vitro studies in tumor cell lines are typical early-stage models of activity or efficacy when testing a new chemical compound, the data from which is used in regulatory filings for first-in-man clinical trials. These mouse models of BCC and lung cancer were performed by CRUK and their collaborators.

*aPKCi inhibitor (oral formulation previously designated as VAR-102)*

The oral formulation is a small molecule that may have potential for the treatment of solid tumors. The API in the aPKCi inhibitor (oral) is the same as the API in aPKCi inhibitor (topical). In the scientific literature, the presence and activation of aPKCi has been implicated in the growth of multiple human cancers including non-small cell lung cancer, or NSCLC, pancreatic, and ovarian cancer. The API in aPKCi inhibitor (oral) has demonstrated dose dependent anti-tumor activity in a mouse model of NSCLC (squamous cell lung carcinoma), in studies performed at CRUK and with its collaborators. Preclinical experiments of the API in aPKCi inhibitor (oral), appears to show dose dependent anti-tumor activity in a xenograft NSCLC model.

**Reverse Stock Split**

On April 19, 2024, we filed an amendment to our Amended and Restated Certificate of Incorporation to implement a 1-for-18 reverse stock split of our issued and outstanding common stock. The reverse stock split of our outstanding common stock was effected at a ratio of 1 post-split share for every 18 pre-split shares as of 11:59 p.m. Eastern Time on April 19, 2024. The reverse stock split correspondingly adjusted the per share exercise price of all outstanding options and all shares underlying any of our outstanding warrants by reducing the conversion ratio for each outstanding warrant and increasing the applicable exercise price or conversion price in accordance with the terms of each outstanding warrant and based on the reverse stock split ratio. No fractional shares were issued in connection with the reverse stock split. The number of shares of common stock authorized under our Amended and Restated Certificate of Incorporation is unchanged at 120 million shares. The accompanying interim unaudited condensed financial statements reflect the 1-for-18 reverse split of our common stock. All share and per share information data herein that relates to our common stock prior to the effective date has been retroactively restated to reflect the reverse stock split.

**Continued Listing on The Nasdaq Capital Market**

On January 22, 2024, we received a deficiency letter from the Staff of Nasdaq notifying us that, for the last 31 consecutive business days, the closing bid price for our common stock has been below the minimum $1.00 per share required for continued listing on the Nasdaq Capital Market pursuant to 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 July 22, 2024, to regain compliance with Rule 5550(a)(2).

As described above, on April 19, 2024, 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 18 pre-split shares. On May 6, 2024, we received written confirmation from Nasdaq notifying us that we had regained compliance with Rule 5550(a)(2).

## CRITICAL ACCOUNTING POLICIES

For a discussion of our accounting policies, see the section titled, "Note 4 – Summary of Significant Accounting Policies" and, in the Notes to Consolidated Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2023, Note 4 – Accounting Policies and Recent Accounting Pronouncements. Readers are encouraged to review those disclosures in conjunction with this Quarterly Report on Form 10-Q.

**Intangible Assets and Goodwill**

We record acquired intangible assets and goodwill based on estimated fair value. The identifiable intangible assets resulting from the CVie Therapeutics acquisition in December 2018 relate to in-process research and development, or IPR&D, of istaroxime and rostafuroxin. The IPR&D assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. During the three and six months ended June 30, 2024, no events or changes in circumstances occurred indicating that our IPR&D intangible assets were more likely than not impaired.

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed in a business combination and is not amortized. It is reviewed for impairment at least annually or when events or changes in the business environment indicate that its carrying value may be impaired.

During each of the first and second quarters of 2023, the continued declining trend in the closing share price of our common stock suggested that the fair value of our reporting unit was more likely than not less than its carrying value. Based on an interim goodwill impairment tests, 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 first quarter of 2023 and an additional loss of $2.6 million, representing the remaining balance of goodwill, in the second quarter of 2023. For the six months ended June 30, 2023, the aggregate loss on impairment of goodwill is $3.1 million, recognized within operating expenses in our condensed consolidated statements of operations. As of June 30, 2023, goodwill was written down to zero on our condensed consolidated balances sheet. As of June 30, 2024 and December 31, 2023, goodwill was zero on our condensed consolidated balance sheet.

The following table represents identifiable intangible assets as of June 30, 2024 and December 31, 2023:

| *(in thousands)* | June 30, 2024 | December 31, 2023 |
|---|---|---|
| Istaroxime drug candidate | $ 22,340 | $ 22,340 |
| Rostafuroxin drug candidate | 2,910 | 2,910 |
| Intangible assets | 25,250 | 25,250 |

**Acquired In-Process Research and Development Expenses**

IPR&D expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones.

We evaluate in-licensed agreements for IPR&D projects to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the in-licensed agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and have no alternative future use, we expense payments made under such license agreements as research and development expense in the consolidated statements of operations. In those cases, payments for milestones achieved and payments for a product license prior to regulatory approval of the product are expensed in the period incurred. Payments made in connection with regulatory and sales-based milestones are capitalized and amortized to cost of revenue.

**Convertible Debt and Equity Instruments**

We review the terms of convertible debt and equity instruments to determine whether there are conversion features or embedded derivative instruments including embedded conversion options that are required to be bifurcated and accounted for separately as derivative financial instruments under ASC Topic 815, *Derivatives and Hedging*.

In circumstances where the convertible instrument contains more than one embedded derivative instrument, including conversion options that are required to be bifurcated, the bifurcated derivative instruments are accounted for as a single compound instrument. Also, in connection with the sale of convertible debt and equity instruments, we may issue free standing warrants that may, depending on their terms, be accounted for as derivative instrument liabilities, rather than as equity. When convertible debt or equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for separately, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of the bifurcated derivative instrument. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face amount. When we issue debt securities, which bear interest at rates that are lower than market rates, we recognize a discount, which is offset against the carrying value of the debt. Such discount from the face value of the debt, together with the stated interest on the instrument, is amortized over the life of the instrument through periodic charges to income.

**Derivative Financial Instruments**

Derivatives are recorded on the consolidated balance sheet at fair value. The conversion features of the convertible notes are embedded derivatives and are separately valued and accounted for on the consolidated balance sheet with changes in fair value recognized during the period of change as a separate component of other income (expense). Fair values for exchange-traded securities and derivatives are based on quoted market prices. The pricing model we use for determining the fair value of non-exchange traded derivatives is the Monte Carlo Model. Valuations derived from this model are subject to ongoing internal and external verification and review. The model uses market-sourced inputs such as interest rates and stock price volatilities.

## RESULTS OF OPERATIONS

**Comparison of the Three and Six Months EndedJune 30, 2024 and 2023**

| *(in thousands)* | Three Months Ended June 30, 2024 | 2023 | Change | Six Months Ended June 30, 2024 | 2023 | Change |
|---|---|---|---|---|---|---|
| Expenses: | | | | | | |
| Research and development | $ 9,863 | $ 1,763 | $ 8,100 | $ 12,116 | $ 3,178 | $ 8,938 |
| General and administrative | 1,589 | 2,420 | (831) | 3,741 | 4,712 | (971) |
| Loss on impairment of goodwill | - | 2,574 | (2,574) | - | 3,058 | (3,058) |
| Total operating expenses | 11,452 | 6,757 | 4,695 | 15,857 | 10,948 | 4,909 |
| Operating loss | (11,452) | (6,757) | (4,695) | (15,857) | (10,948) | (4,909) |
| | | | | | | |
| Other income (expense): | | | | | | |
| Gain on debt extinguishment | - | - | - | 14,520 | - | 14,520 |
| Interest income | 20 | 108 | (88) | 50 | 152 | (102) |
| Interest expense | (110) | (13) | (97) | (123) | (25) | (98) |
| Other (expense) income, net | (285) | 61 | (346) | (84) | 109 | (193) |
| Total other (expense) income, net | (375) | 156 | (531) | 14,363 | 236 | 14,127 |
| | | | | | | |
| Loss before income taxes | (11,827) | (6,601) | (5,226) | (1,494) | (10,712) | 9,218 |
| Income tax expense | (197) | - | (197) | (311) | - | (311) |
| Net loss | $ (12,024) | $ (6,601) | $ (5,423) | $ (1,805) | $ (10,712) | $ 8,907 |

**Research and Development Expenses**

Our research and development expenses are charged to operations as incurred and we incur both direct and indirect expenses for each of our programs. We track direct research and development expenses by preclinical and clinical programs, which include third-party costs such as contract research organization, contract manufacturing organizations, contract laboratories, consulting, and clinical trial costs. We do not allocate indirect research and development expenses, which include product development and manufacturing expenses and clinical, medical, and regulatory operations expenses, to specific programs. We also account for research and development and report annually by major expense category as follows: (i) contracted services; (ii) salaries and benefits; (iii) rents and utilities; (iv) stock-based compensation; (v) depreciation; and (vi) other. We expect that our research and development expenses related to istaroxime – cardiogenic shock program will continue to increase to the extent that we continue the SEISMiC Extension trial of istaroxime for the treatment of early cardiogenic shock and start-up procedures for a small study in more severe SCAI Stage C cardiogenic shock. We currently do not have sufficient capital to fully complete these clinical trials. At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates.

Research and development expenses are as follows:

| *(in thousands)* | Three Months Ended June 30, 2024 | 2023 | Increase (Decrease) | Six Months Ended June 30, 2024 | 2023 | Increase (Decrease) |
|---|---|---|---|---|---|---|
| Acquired IPR&D from Varian asset purchase | $ 7,495 | $ - | $ 7,495 | $ 7,495 | $ - | $ 7,495 |
| Istaroxime – cardiogenic shock program | 1,684 | 617 | 1,067 | 3,159 | 1,041 | 2,118 |
| Istaroxime – AHF | - | 12 | (12) | - | (8) | 8 |
| KL4 surfactant | - | 48 | (48) | - | (34) | 34 |
| Total direct clinical and preclinical programs | 1,684 | 677 | 1,007 | 3,159 | 999 | 2,160 |
| Product development and manufacturing | 215 | 241 | (26) | 439 | 486 | (47) |
| Clinical, medical, and regulatory operations | 469 | 845 | (376) | 1,023 | 1,693 | (670) |
| Total research and development expenses | $ 9,863 | $ 1,763 | $ 8,100 | $ 12,116 | $ 3,178 | $ 8,938 |

Research and development expenses include non-cash charges of $7.5 million associated with the acquired IPR&D related to the Asset Purchase Agreement with Varian (See the section titled, “Note 12 - Mezzanine Equity and Stockholders' Equity - Asset Purchase Agreement with Varian Biopharmaceuticals”).

*Direct Clinical and Preclinical Programs*

Direct clinical and preclinical programs include: (i) activities associated with conducting clinical trials, including contract research organization costs, patient enrollment costs, clinical site costs, clinical drug supply, and related external costs, such as consultant fees and expenses; and (ii) development activities, toxicology studies, and other preclinical studies.

Total direct clinical and preclinical programs expenses increased $1.0 million for the three months ended June 30, 2024 and increased $2.2 million for the six months ended June 30, 2024 compared to the same periods in 2023 primarily due to increases in istaroxime – cardiogenic shock program costs as described below.

Istaroxime – cardiogenic shock program costs increased$1.1 million for the three months ended June 30, 2024 and increased $2.1 million for the six months ended June 30, 2024 compared to the same periods in 2023 due to (i) the trial execution costs for the SEISMiC Extension study, which began enrollment in the fourth quarter of 2023 and (ii) the start-up procedures for the small study in more severe SCAI Stage C cardiogenic shock.

Istaroxime – AHF costs have been limited as we focus our resources on the execution of the istaroxime – cardiogenic shock program.

Costs related to the KL4 surfactant platform are expected to be minimal as prior KL4 surfactant platform clinical trials have now been closed out.

*Product Development and Manufacturing*

Product development and manufacturing includes (i) manufacturing operations with our contract manufacturing organization, validation activities, quality assurance; and (ii) pharmaceutical and manufacturing development activities of our drug product candidates, including development of istaroxime. These costs include employee expenses, facility-related costs, depreciation, costs of drug substances (including raw materials), supplies, quality assurance activities, and expert consultants and outside services to support pharmaceutical development activities.

Product development and manufacturing expenses for the three and six months ended June 30, 2024 are comparable to the same periods in 2023.

*Clinical, Medical, and Regulatory Operations*

Clinical, medical, and regulatory operations include medical, scientific, preclinical and clinical, regulatory, data management, and biostatistics activities in support of our research and development programs. These costs include personnel, expert consultants, outside services to support regulatory and data management, symposiums at key medical meetings, facilities-related costs, and other costs for the management of clinical trials.

Clinical, medical, and regulatory operations expenses decreased $0.4 million for the three months ended June 30, 2024 compared to the same period in 2023 due to a decrease of $0.4 million in personnel costs.

Clinical, medical, and regulatory operations expenses decreased $0.7 million for the six months ended June 30, 2024 compared to the same period in 2023 due to (i) a decrease of $0.6 million in personnel costs; and (ii) a decrease of $0.1 million in non-cash stock-based compensation expense.

**General and Administrative Expenses**

General and administrative expenses consist of costs for executive management, business development, intellectual property, finance and accounting, legal, insurance, human resources, information technology, facilities, and other administrative costs.

General and administrative expenses decreased $0.8 million for the three months ended June 30, 2024 compared to the same period in 2023 due to (i) a decrease of $0.2 million in professional fees; (ii) a decrease of $0.2 million in personnel costs; (iii) a decrease of $0.3 million in non-cash stock-based compensation expense; and (iv) a decrease of $0.1 million in insurance costs.

General and administrative expenses decreased $1.0 million for the six months ended June 30, 2024 compared to the same period in 2023 due to (i) a decrease of $0.1 million in professional fees; (ii) a decrease of $0.4 million in personnel costs; (iii) a decrease of $0.2 million in non-cash stock-based compensation expense; and (iv) a decrease of $0.3 million in insurance costs.

**Other (Expense) Income, Net**

On January 24, 2024, we and affiliates of Deerfield Management Company L.P., or Deerfield, entered into an Exchange and Termination Agreement, or the Exchange and Termination Agreement, wherein Deerfield agreed to terminate its rights to receive certain milestone payments in exchange for (i) cash in the aggregate amount of $0.2 million and (ii) an aggregate of 33,793 shares of our common stock, par value $0.001 per share (See the section titled, “Note 8 – Restructured Debt Liability”). This transaction was accounted for as an extinguishment of debt in accordance with ASC 470, *Debt-Modifications and Extinguishments*, and as a result, we recognized a $14.5 million non-cash gain on debt extinguishment.

Interest income relates to interest on our money market account for the three and six months ended June 30, 2024 and 2023.

For the three and six months ended June 30, 2024, interest expense consists primarily of interest expense associated with the amortization of the issuance costs and the debt discount related to our senior convertible notes payable. For the three and six months ended June 30, 2023, interest expense consists of interest expense associated with our notes payable.

For the three and six months ended June 30, 2024, other (expense) income, net primarily consists of initial recognition and remeasurement changes in the fair value of derivative liabilities associated with our senior convertible notes payable and our ELOC commitment note, partially offset by net gains on foreign currency translation. For the three and six months ended June 30, 2023, other (expense) income, net primarily consists of net gains on foreign currency translation. Foreign currency gains and losses are primarily due to changes in the New Taiwan dollar exchange rate related to activities of our wholly-owned subsidiary, CVie Therapeutics Limited, in Taiwan.

**Income Tax Expense**

During the three and six months ended June 30, 2024, we recorded an income tax provision of $0.2 million and $0.3 million, respectively, related to the tax on our estimated taxable income for the year, primarily due to the gain on debt extinguishment (See the section titled, “Note 8 – Restructured Debt Liability”). For the three and six months ended June 30, 2023, there was no income tax expense due to losses incurred and forecasted for 2023 as well as a full valuation allowance against deferred tax assets.

## LIQUIDITY AND CAPITAL RESOURCES

We are subject to risks common to companies in the biotechnology industry, including but not limited to the need for additional capital, risks of failure of preclinical and clinical studies, the need to obtain marketing approval and reimbursement for any drug product candidate that we may identify and develop, the need to successfully commercialize and gain market acceptance of our product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, and risks associated with our international operations in Taiwan and activities abroad, including but not limited to having foreign suppliers, manufacturers, and clinical sites in support of our development activities.

We have incurred net losses since inception. Our net loss was $12.0 million and $1.8 million, respectively, for the three and six months ended June 30, 2024. Included in net loss for the three and six months ended June 30, 2024 is $7.5 million of non-cash R&D expense related to costs in connection with the Varian asset acquisition and a $14.5 million gain on debt extinguishment. For the three and six months ended June 30, 2023, our net loss was $6.6 million and $10.7 million, respectively. Included in our net loss for the three and six months ended June 30, 2023 is a $2.6 million and $3.1 million loss on impairment of goodwill, respectively (See the section titled, “Note 4 – Summary of Significant Accounting Policies”). We expect to continue to incur operating losses for at least the next several years. As of June 30, 2024, we had an accumulated deficit of $846.6 million. Our future success is dependent on our ability to fund and develop our product candidates, and ultimately upon our ability to attain profitable operations. We have devoted substantially all of our financial resources and efforts to research and development expense and general and administrative expense to support such research and development. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders’ equity and working capital, and accordingly, our ability to execute our future operating plans.

In June 2024, we entered into the ELOC Purchase Agreement establishing an equity line of credit with the Purchaser, whereby we have the right, but not the obligation, to sell to the Purchaser, and the Purchaser is obligated to purchase, up to the lesser of (i) $35 million of newly issued shares of our common stock, and (ii) the Exchange Cap. We do not have a right to commence any sales of our common stock to the Purchaser under the ELOC Purchase Agreement until the time when all of the conditions to our right to commence sales of common stock to the Purchaser set forth in the ELOC Purchase Agreement have been satisfied, including that a registration statement covering the resale of such shares is declared effective by the SEC and the final form of prospectus contained therein is filed with the SEC, or the Commencement Date. Over the 36-month period from and after the Commencement Date, we will control the timing and amount of any sales of Common Stock to the Purchaser. Actual sales of shares of our common stock to the Purchaser under the ELOC Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of our common stock and determinations by us as to the appropriate sources of funding and our operations (See the section titled, “Note 12 - Mezzanine Equity and Stockholders' Equity - Common Stock Purchase Agreement”).

As of June 30, 2024, we had cash and cash equivalents of $1.8 million and current liabilities of $8.8 million. On July 3, 2024, we agreed to issue and sell to (i) an institutional investor an aggregate principal amount of $0.1 million in senior secured notes due 2025, or the July Secured Note, and (ii) an additional institutional investor an aggregate principal amount of $0.1 million in senior unsecured notes due 2025, or the July Unsecured Note, and together with the July Secured Note, the July 2024 Notes, for aggregate gross proceeds of $0.2 million (See the section titled, “Note 16 - Subsequent Events - Senior Secured and Senior Unsecured Notes”). On July 18, 2024, we entered into a Securities Purchase Agreement, or the First Purchase Agreement, with the buyers named therein, pursuant to which we agreed to the private placement, or the First PIPE, of (i) 16,099 shares, or the Preferred Shares, of our Series C Convertible Preferred Stock, par value $0.001 per share, or the Series C Preferred Stock, and (ii) warrants, or the July 2024 Warrants, to acquire up to the aggregate number of 3,440,631 additional shares of our common stock for aggregate gross proceeds of approximately $12.9 million of which $9.5 million was paid through the cancellation and extinguishment of certain securities (See the section titled, “Note 16 - Subsequent Events - First Private Placement”). On July 26, 2024, we entered into a Securities Purchase Agreement, or the Second Purchase Agreement, with the buyer named therein, pursuant to which we agreed to a second tranche of the private placement, or the Second PIPE (and together with the First PIPE, the Private Placement), of (i) 1,250 Preferred Shares, and (ii) July 2024 Warrants to acquire up to the aggregate number of 267,380 additional shares of our common stock for aggregate gross proceeds of approximately $1.0 million (See the section titled, “Note 16 - Subsequent Events - Second Private Placement”). Following these financings, we believe that we have sufficient resources available to fund our business operations into October 2024. We do not have sufficient cash and cash equivalents as of the date of this Quarterly Report on Form 10-Q to support our operations for at least the 12 months following the date that the financial statements are issued. These conditions raise substantial doubt about our ability to continue as a going concern.

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 we fail to raise sufficient capital, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations. Accordingly, management has concluded that substantial doubt exists with respect to our ability to continue as a going concern for at least 12 months after the issuance of the accompanying financial statements.

### Cash Flows

Cash flows for the six months ended June 30, 2024 consists primarily of $5.3 million of net cash used in operating activities and $2.6 million of net cash provided by financing activities. Cash flows for the six months ended June 30, 2023 consist of $6.0 million of net cash used in operating activities and $11.3 million of net cash provided by financing activities.

*Operating Activities*

Net cash used in operating activities was $5.3 million for the six months ended June 30, 2024 and consisted primarily of (i) a net loss of $1.5 million; (ii) a $14.5 million gain on debt extinguishment; (iii) an unrealized gain on foreign exchange rate changes of $0.3 million; (iv) a $0.3 million related to the change in fair value of derivative liabilities; partially offset (v) $7.4 million in non-cash IPR&D costs in connection with the Asset Purchase Agreement with Varian; (iv) changes in operating assets and liabilities of $2.9 million; (v) $0.6 million non-cash expense related to the fair value of the ELOC commitment note and the related derivative liability; (vi) non-cash stock-based compensation of $0.3 million; and (vi) depreciation and non-cash amortization of right-of-use assets of $0.3 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses, and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

Net cash used in operating activities was $6.0 million for the six months ended June 30, 2023 and consisted primarily of (i) a net loss of $10.7 million; and (ii) an unrealized gain on foreign exchange rate changes of $0.1 million; partially offset by (iii) a non-cash loss on impairment of goodwill of $3.1 million; (iv) changes in operating assets and liabilities of $0.8 million; (v) non-cash stock-based compensation of $0.7 million; and (vi) non-cash lease expense of $0.2 million. Changes in prepaid expenses and other current assets, accounts payable, accrued expenses, and operating lease liabilities result from timing differences between the receipt and payment of cash and when the transactions are recognized in our results of operations.

*Financing Activities*

Net cash provided by financing activities for the six months ended June 30, 2024 was $2.6 million and includes (i) $1.4 million in net proceeds from the 2023 ATM Program; (ii) $1.3 million in net proceeds from convertible notes; (iii) $0.3 million in net proceeds from senior secured notes; partially offset by (iv) $0.2 million of principal payments on loans payable; (v) $0.1 million in payments related to the debt extinguishment; and (vi) $0.1 million in issuance costs for the Series B Preferred Stock.

Net cash provided by financing activities for the six months ended June 30, 2023 was $11.3 million and includes (i) $10.8 million in net proceeds from the April 2023 public offering; and (ii) $0.8 million in proceeds from the exercise of common stock warrants, net of expenses; partially offset by (ii) $0.3 million of principal payments on loans payable.

The following sections provide a more detailed discussion of our available financing facilities.

Common Stock Offerings

Historically, we have funded, and expect that we will continue to fund, our business operations through various sources, including financings in the form of common stock offerings.

***April 2023 Public Offering***

On April 20, 2023, we entered into an underwriting agreement with Ladenburg as the sole underwriter relating to a public offering, or the April 2023 Offering, of an aggregate of 204,779 units with each unit consisting of one share of common stock and a warrant, or the April 2023 Warrants. The April 2023 Warrants are immediately exercisable for shares of common stock at a price of $52.74 per share and expire five years from the date of issuance. The shares of common stock and the April 2023 Warrants were immediately separable and were issued separately in the April 2023 Offering.

In addition, Ladenburg exercised in full a 45-day option, or the Overallotment Option, to purchase up to 30,717 additional shares of common stock and/or warrants to purchase up to 30,717 additional shares of common stock.

The closing of the April 2023 Offering occurred on April 24, 2023, inclusive of the Overallotment Option. The offering price to the public was $52.74 per unit resulting in gross proceeds to us of approximately $12.4 million. After deducting underwriting discounts and commissions and other estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the April 2023 Warrants issued pursuant to this April 2023 Offering, the net proceeds to us were approximately $10.8 million.

***At-The-Market Program***

On November 9, 2023, we entered into the 2023 ATM Program with Ladenburg. We are not obligated to make any sales under the 2023 ATM Program. When we issue sale notices to Ladenburg, we designate the maximum amount of shares to be sold by Ladenburg daily and the minimum price per share at which shares may be sold. Ladenburg may sell shares by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or in privately negotiated transactions.

Sales under the 2023 ATM Program will be made pursuant to our “shelf” registration statement on Form S-3 (No. 333-261878) filed with the SEC on December 23, 2021, and declared effective on January 3, 2022, and a prospectus supplement related thereto. We are currently subject to the limitations contained in General Instruction I.B.6 of Form S-3. As a result, we are limited to selling no more than one-third of the aggregate market value of the equity held by non-affiliates, or the public float, during any 12-month period, and, as of August 19, 2024, we had sold substantially all that we are permitted to sell under the Form S-3 pursuant to General Instruction I.B.6. If our public float increases, we will have additional availability under such limitations, and if our public float increases to $75 million or more, we will no longer be subject to such limitations. However, there can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

Either party may suspend the offering under the 2023 ATM Program by notice to the other party. The 2023 ATM Program will terminate upon the earlier of (i) the sale of all shares subject to the 2023 ATM Program or (ii) termination of the 2023 ATM Program in accordance with its terms. Either party may terminate the 2023 ATM Program at any time upon five business days' prior written notification to the other party in accordance with the related agreement.

We agreed to pay Ladenburg a commission of 3% of the gross sales price of any shares sold pursuant to the 2023 ATM Program. The rate of compensation will not apply when Ladenburg acts as principal, in which case such rate shall be separately negotiated. We also agreed to reimburse Ladenburg for the fees and disbursements of its counsel in an amount not to exceed $60,000, in addition to certain ongoing disbursements of its legal counsel up to $3,000 per calendar quarter.

During the six months ended June 30, 2024, we sold 143,120 shares of our common stock under the 2023 ATM Program resulting in aggregate gross and net proceeds to us of approximately $1.4 million.

Loans Payable

In June 2023, we entered into an insurance premium financing and security agreement with IPFS Corporation. Under the agreement, we financed $0.8 million of certain premiums at a 7.24% fixed annual interest rate. Payments of approximately $77,000 were due monthly from July 2023 through April 2024. As of December 31, 2023, the outstanding principal of the loan was $0.2 million. The balance of the loan was repaid during the first quarter of 2024.

*Supplementary Disclosure of Non-Cash Activity*

During the first quarter of 2024, we and Deerfield entered into the Exchange and Termination Agreement wherein Deerfield agreed to terminate its rights to receive certain milestone payments in exchange for (i) cash in the aggregate amount of $0.2 million and (ii) an aggregate of 33,793 shares of our common stock. The Exchange and Termination Agreement was accounted for as an extinguishment of debt in accordance with *ASC Topic 470, Debt – Modifications and Extinguishments*, and, as a result, we recognized a $14.5 million non-cash gain on debt extinguishment during the three months ended June 30, 2024 consisting of the difference between the $15.0 million of the extinguished milestone payments and the consideration to Deerfield of $0.2 million in cash and $0.3 million in fair value of common stock issued to Deerfield (See the section titled, "Note 8 – Restructured Debt Liability").

During the first quarter of 2023, we entered into amendments to the January 2023 Existing Warrants and the February 2023 Existing Warrants which were accounted for as "Equity Issuance" classification modifications under the guidance of ASU 2021-04. The total fair value of the consideration of each of the modifications includes the incremental fair value of the January 2023 Existing Warrants and the February 2023 Existing Warrants, respectively (determined by comparing the fair value immediately prior to and immediately after the modification), and the initial fair value of the January 2023 New Warrants and the February 2023 New Warrants, respectively. The fair values were calculated using the Black-Scholes model. We determined that the total fair value of the consideration related to the modification of the January 2023 Existing Warrants, including the initial fair value of the January 2023 New Warrants, was $1.2 million, and that the total fair value of the consideration related to the modification of the February 2023 Existing Warrants, including the initial fair value of the February 2023 New Warrants, was $0.3 million (See the section titled, "Note 9 – Stockholders' Equity").

**Off-Balance Sheet Arrangements**

We did not have any material off-balance sheet arrangements as of June 30, 2024 or 2023 or during the periods then ended.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

## ITEM 4. CONTROLS AND PROCEDURES

**Evaluation of disclosure controls and procedures**

Our management, including our President and Chief Executive Officer (principal executive officer and principal financial officer), does not expect that our disclosure controls or our internal control over financial reporting will prevent all error and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our President and Chief Executive Officer has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our President and Chief Executive Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer, to allow for timely decisions regarding required disclosures, and recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

**Changes in internal control**

There were no changes in our internal control over financial reporting identified in connection with the evaluation described above that occurred during the quarter ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# PART II – OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

We are not aware of any pending legal actions that would, if determined adversely to us, have a material adverse effect on our business and operations.

We have from time to time been involved in disputes and proceedings arising in the ordinary course of business, including in connection with the conduct of our clinical trials. In addition, as a public company, we are also potentially susceptible to litigation, such as claims asserting violations of securities laws. Any such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. 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.

## ITEM 1A. RISK FACTORS

Investing in our securities involves certain risks. In addition to any risks and uncertainties described elsewhere in this Quarterly Report on Form 10-Q, investors should carefully consider the risks and uncertainties discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, as supplemented by risk factors included in our Quarterly Report on Form 10-Q filed thereafter. These risks are not the only risks that could materialize. Other than as set forth below, there have been no material changes in our risk factors from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023 or our Quarterly Report on Form 10-Q filed thereafter. Additional risks and uncertainties not presently known to us or that we currently consider to be immaterial may also impair our business operations and development activities. Should any of the risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2023, as supplemented by our subsequent filings with the SEC, actually materialize, our business, financial condition, and/or results of operations could be materially adversely affected, the trading price of our common stock could decline, and an investor could lose all or part of his or her investment. In particular, the reader's attention is drawn to the discussion in *Part I, Item 2 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources*.

***Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations in the near term.***

We do not have sufficient resources available to fund our business beyond October 2024. To increase our cash runway, 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, or that such funding will be available 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.

Further, under the terms of the Purchase Agreements, we are subject to certain restrictive covenants that may make it difficult to procure additional financing. For additional details on such covenants, see "——*Uder the terms of the Purchase Agreements, we are subject to certain restrictive covenants that may make it difficult to procedure additional financing*." As a result of these covenants, our ability to respond to changes in business and economic conditions and engage in beneficial transactions, including to obtain additional debt or equity financing as needed in the future, on favorable terms or at all, may be limited, which could adversely affect our business, financial condition, and results of operations.

If we fail to raise sufficient capital, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations. In addition, sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, including pursuant to our existing equity line of credit or our recent private placement transactions, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. These conditions raise substantial doubt regarding our ability to continue as a going concern.

***The Series C Certificate of Designation and the Warrants each contain anti-dilution provisions that may result in the reduction of the conversion price of the Series C Preferred Stock and exercise price of the Warrants. These features may increase the number of shares of our common stock being issuable upon conversion of the Series C Preferred Stock and the exercise of the Warrants.***

The Series C Certificate of Designation authorizes a total of 18,820 shares of Series C Preferred Stock with an initial conversion price of $3.74, or the Conversion Price, which is subject to adjustment as provided in the Series C Certificate of Designations to no lower than $1.28. Our Warrants have an exercise price of $4.11, or the Exercise Price, subject to adjustment to no lower than $3.741. Both the Conversion Price and Exercise Price are subject to any stock split, stock dividend, stock combination, recapitalization or other similar transaction involving our common stock at a price below the then-applicable Conversion Price or Exercise Price, as applicable, each as described in further detail in the Series C Certificate of Designation or the Warrants, respectively.

If in the future, while any of our Series C Preferred Stock or Warrants are outstanding, we grant, issue or sell any shares of our common stock for a consideration per share of our common stock, or the New Issuance Price, less than a price equal to the Conversion Price or Exercise Price, respectively, as then in effect immediately prior to such granting, issuance or sale, we will be required, subject to certain limitations and adjustments (as provided in the Series C Certificate of Designation or the Warrants) to reduce the Conversion Price or the Exercise Price, as applicable, to be equal to the New Issuance Price, which will result in a greater number of shares of our common stock being issuable upon conversion, which in turn will increase the dilutive effect of such conversion on existing holders of our common stock. It is possible that we will not have a sufficient number of shares available to satisfy the conversion of the Series C Preferred Stock and/or the Warrants if we enter into a future transaction that reduces the applicable Conversion Price or Exercise Price. If we do not have a sufficient number of available shares for the conversion of any Series C Preferred Stock or Warrants, we may need to seek shareholder approval to increase the number of authorized shares of our common stock, which may not be possible and will be time consuming and expensive. The potential for such additional issuances may depress the price of our common stock regardless of our business performance and may make it difficult for us to raise additional equity capital while any of our Series C Preferred Stock or Warrants are outstanding.

***The Series C Preferred Stock have a liquidation preference senior to our common stock.***

Subject to certain exceptions, in accordance with the Series C Certificate of Designation, shares of our capital stock are junior in rank to the Series C Preferred Stock with respect to the preferences as to dividends, distributions and payments upon our liquidation, dissolution and winding up. The payment of the liquidation preferences could result in common stockholders and warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily. This liquidation preference may increase over time based on the payment of dividends.

The existence of the liquidation preferences may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control.

***Under the terms of the Purchase Agreements, we are subject to certain restrictive covenants that may make it difficult to procure additional financing.***

On July 18, 2024 and July 26, 2024, we entered into the First Purchase Agreement and the Second Purchase Agreement, respectively. The Purchase Agreements, pursuant to which we issued the Warrants, contain restrictive covenants, subject to certain exceptions. For example, without the consent of the holders holding at least a majority of the certain registrable securities for the period commencing on July 18, 2024 and July 26, 2024, respectively, and ending on the date immediately following the 90th trading day after the Applicable Date (as defined in the Purchase Agreements), neither we nor any of our subsidiaries will directly or indirectly issue, offer, sell, grant any option or right to purchase, or otherwise dispose of (or announce any issuance, offer, sale, grant of any option or right to purchase or other disposition of) any equity security or any equity-linked or related security, including, without limitation, any "equity security" (as that term is defined under Rule 405 promulgated under the Securities Act of 1933, as amended), any Convertible Securities (as defined in the Purchase Agreements), any debt, any preferred stock or any purchase rights (other than pursuant to the Common Stock Purchase Agreement), or a Subsequent Placement.

Subject to the limitations described in the Purchase Agreements, for so long as the Preferred Shares are outstanding, we are prohibited from effecting or entering into an agreement to effect any Subsequent Placement involving a Variable Rate Transaction (as defined in the Purchase Agreements).

Additionally, the Purchase Agreements contain a participation right, which provides that, subject to certain exceptions, at any time on or prior to the fourth anniversary of the respective closing dates, neither we nor our subsidiaries shall, directly or indirectly, effect any Subsequent Placement unless we comply with certain notice procedures as outlined in the applicable Purchase Agreement with respect to each investor, providing the opportunity for such investor to participate in such Subsequent Placement on a pro rata basis as described in the Purchase Agreement.

Any of these restrictions on our ability to operate our business in our discretion could adversely affect our business by, among other things, limiting our ability to adapt to changing economic, financial, or industry conditions and to take advantage of corporate opportunities, including opportunities to obtain debt financing, repurchase stock, refinance or pay principal on our outstanding debt, or complete acquisitions for cash or debt. If we require additional funding while these restrictive covenants remain in effect, we may be unable to effect a financing transaction while remaining in compliance with the terms of the applicable Purchase Agreement, or we may be forced to seek a waiver from the investors party to the applicable Purchase Agreement.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## ITEM 5. OTHER INFORMATION

In order to reduce expected costs with our contract research organization, Momentum Research, Inc., or MRI, on May 9, 2024, or the Effective Date, we entered into Amendment No. 1 to the Master Services Agreement and Work Order Nos. 11 and 12, or the Amendment, with MRI. The Amendment amends the Master Services Agreement we entered into with MRI on February 13, 2020, or the Original MSA, and the original Work Order Nos. 11 and 12 we entered into with MRI on June 1, 2023, collectively, the Original Work Orders.

Under the Original MSA, we agreed to, among other things, engage MRI to provide non-exclusive research and development services, by executing individual work orders to be negotiated and specified in writing on terms agreed to by both parties on a later date.

Under the terms of the Amendment, we agreed to, among other things, be responsible for certain management, regulatory strategy, and reporting obligations in connection with our SEISMiC Extension study and MRI agreed to fully perform its obligations under the Original Work Orders with respect to the SEISMiC Extension study, including performance of all services and delivery of all deliverables required by the Original Work Orders. Additionally, with respect to the SEISMiC C Study, MRI agreed to be responsible for certain regulatory submissions, as provided in the Amendment.

Additionally, in consideration of and conditioned upon the payments described below, we and MRI each agreed to cancel and extinguish any and all amounts owed to MRI or us, respectively, each subject to the terms of the Amendment. The parties agreed that such cancellation and extinguishment shall not be construed as a waiver of claims by each party for breach of the Original MSA or either or both of the Original Work Orders other than for non-payment, nor a waiver of each party's respective indemnification rights under the Original MSA.

In consideration of MRI's full performance of the Original Work Orders and cancellation of accrued expenses as described above, we agreed to, among other things, pay MRI $1.2 million in a series of scheduled payments through September 20, 2024, subject to the terms of the Amendment. If services are not completed by October 31, 2024, the parties agree that MRI will continue its services until fully completed with no further compensation. In case of delayed payments, we agreed to pay MRI interest on any overdue amount from the due date until the date paid in full at a rate equal to 18% per annum. If the SEISMiC Extension study and the SEISMiC C Study are terminated prior to September 20, 2024, then the next payment due after termination will be made to MRI and remaining payments that would have become due automatically become no longer payable.

Additionally, we agreed that, for a transaction consummated by December 31, 2027, we shall pay MRI an amount equal to 2% of istaroxime license fees, milestone payments, royalties, securities or other property that we actually collect in respect of any license of istaroxime that we grant to any unaffiliated third party on or after the Effective Date; net of all legal and financial advisory fees and expenses actually paid by us in respect of the associated license transaction. Further, we agreed that if we commercialize istaroxime ourselves in the United States or another region, we shall also pay MRI an amount equal to 2% of our net profit derived from direct sales of istaroxime to clients in our territory where sales occurred, as determined in our US GAAP financial statements. Pursuant to the Amendment, such payments on istaroxime sales will end when data and market exclusivity protection expires for istaroxime.

Further, in connection with the first to occur of either a Change of Control (as defined in the Amendment) or the sale of all or substantially all of our rights in istaroxime not in the context of a Change of Control, we agree to pay MRI an amount equal to 2% of the sum of any cash and the fair market value of any securities or other property that we actually collect or receive that is attributable to our rights in istaroxime (subject to the terms of the Amendment), net of a ratable portion of certain fees and expenses as provided by the Amendment.

After December 1, 2025, we have the right to buy out the amounts due under certain provisions of the Amendment.

The foregoing descriptions of the Original MSA and Amendment are general descriptions only, do not purport to be complete descriptions of the rights and obligations of the parties thereunder, and are qualified in their entirety by reference to the terms of such agreements, which are filed as Exhibit 10.1 and 10.2, respectively, to this Quarterly Report on Form 10-Q.

**ITEM 6. EXHIBITS**

Exhibits are listed on the Index to Exhibits at the end of this Quarterly Report on Form 10-Q. The exhibits required by Item 601 of Regulation S-K, listed on such Index in response to this Item, are incorporated herein by reference.

**INDEX TO EXHIBITS**

The following exhibits are included with this Quarterly Report on Form 10-Q.

| Exhibit No. | Description | Method of Filing |
|---|---|---|
| 2.1* | Form of Asset Purchase Agreement by and between Windtree and Varian Biopharmaceuticals, Inc., dated April 2, 2024. | Incorporated by reference to Exhibit 2.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 8, 2024. |
| 3.1 | Amended and Restated Certificate of Incorporation. | Incorporated by reference to Exhibit 3.1 to Windtree's Registration Statement on Form S-1, as filed with the SEC on May 9, 2024. |
| 4.1 | Convertible Promissory Note by and between Windtree and the Purchaser named therein, dated as of June 26, 2024. | Incorporated by reference to Exhibit 4.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 1, 2024. |
| 4.2 | Form of Senior Secured Notes due 2025. | Incorporated by reference to Exhibit 4.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 1, 2024. |
| 10.1† | Master Services Agreement and Work Orders Nos. 11 and 12, by and between Windtree and Momentum Research, Inc., dated February 13, 2020. | Incorporated by reference to Exhibit 10.1 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 15, 2024. |
| 10.2† | Amendment No. 1 to Master Services Agreement and Work Orders Nos. 11 and 12, by and between Windtree and Momentum Research, Inc., effective upon May 9, 2024. | Incorporated by reference to Exhibit 10.2 to Windtree's Quarterly Report on Form 10-Q, as filed with the SEC on May 15, 2024. |
| 10.3* | Form of Securities Purchase Agreement by and between Windtree and the Buyers named therein, dated April 2, 2024. | Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 8, 2024. |
| 10.4* | Form of Registration Rights Agreement, by and between Windtree and the Buyers named therein, dated April 2, 2024. | Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on April 8, 2024. |
| 10.5* | Common Stock Purchase Agreement, dated as of June 26, 2024, by and between Windtree and the Purchaser. | Incorporated by reference to Exhibit 10.1 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 1, 2024. |
| 10.6* | Registration Rights Agreement, dated as of June 26, 2024, by and between Windtree and the Purchaser. | Incorporated by reference to Exhibit 10.2 to Windtree's Current Report on Form 8-K, as filed with the SEC on July 1, 2024. |
| 31.1 | Certification of Chief Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act. | Filed herewith. |
| 32.1 | Certification of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | Furnished herewith. |

| | | |
|---|---|---|
| 101.1 | The following condensed consolidated financial statements from Windtree Therapeutics, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, formatted in Inline Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of June 30, 2024 (unaudited) and December 31, 2023, (ii) Statements of Operations (unaudited) for the three and six months ended June 30, 2024 and June 30, 2023, (iii) Statements of Cash Flows (unaudited) for the six months ended June 30, 2024 and June 30, 2023, and (iv) Notes to Condensed Consolidated Financial Statements. | |
| 101.INS | Inline XBRL Instance Document (the Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document) (1). | Filed herewith. |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document (1). | Filed herewith. |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document (1). | Filed herewith. |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document (1). | Filed herewith. |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document (1). | Filed herewith. |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document (1). | Filed herewith. |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and combined in Exhibit 101.1) | Filed herewith. |

* Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
† 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 of 1933, as amended, or Section 18 of the Securities Act of 1934, as amended, or otherwise subject to liability under those sections.

**SIGNATURES**

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

**Windtree Therapeutics, Inc.**
(Registrant)

Date: August 19, 2024

By: /s/ Craig E. Fraser
Craig E. Fraser
President and Chief Executive Officer
(*Principal Executive Officer and Principal Financial Officer*)

**Exhibit 31.1**

**CERTIFICATION**

I, Craig E. Fraser, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Windtree Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 19, 2024

/s/ Craig E. Fraser

Craig E. Fraser
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

**Exhibit 32.1**

**Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
**(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)**

In connection with the Quarterly Report of Windtree Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 19, 2024

/s/ Craig E. Fraser
Craig E. Fraser
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.