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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 **September 30, 2023**

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 (State or other jurisdiction of incorporation or organization)	**94-3171943** (I.R.S. Employer Identification No.)
2600 Kelly Road, Suite 100 **Warrington, Pennsylvania** (Address of principal executive offices)	**18976-3622** (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 November 9, 2023, there were 5,148,219 shares of the registrant's common stock outstanding, par value $0.001 per share.

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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;
- potential delays and uncertainties in our anticipated timelines and milestones and additional costs associated with the impact of the residual effects of the coronavirus pandemic 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 AEROSURF and KL4 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 business development 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, 2022, as supplemented by our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 2023, 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)

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

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

See notes to condensed consolidated financial statements

WINDTREE THERAPEUTICS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in 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, 2021	**-**	**$ -**	**565**	**$ -**	**$ 830,259**	**$ (785,324)**	**-**	**$ (3,054)**	**$ 41,881**
Net loss	-	-	-	-	-	(8,127)	-	-	(8,127)
Stock-based compensation expense	-	-	-	-	770	-	-	-	770
Issuance of common stock, ATM Program, net of issuance costs of $6	-	-	4	-	205	-	-	-	205
Balance - March 31, 2022	**-**	**$ -**	**569**	**$ -**	**$ 831,234**	**$ (793,451)**	**-**	**$ (3,054)**	**$ 34,729**
Net loss	-	-	-	-	-	(17,333)	-	-	(17,333)
Stock-based compensation expense	-	-	-	-	781	-	-	-	781
Issuance of common stock, ATM Program, net of issuance costs of $32	-	-	19	-	1,020	-	-	-	1,020
Balance - June 30, 2022	**-**	**$ -**	**588**	**$ -**	**$ 833,035**	**$ (810,784)**	**-**	**$ (3,054)**	**$ 19,197**
Net loss	-	-	-	-	-	(4,056)	-	-	(4,056)
Stock-based compensation expense	-	-	-	-	744	-	-	-	744
Issuance of common stock, ATM Program, net of issuance costs of $47	-	-	65	-	1,535	-	-	-	1,535
Balance - September 30, 2022	**-**	**$ -**	**653**	**$ -**	**$ 835,314**	**$ (814,840)**	**-**	**$ (3,054)**	**$ 17,420**

	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	**39**	**$ -**	**772**	**$ -**	**$ 837,598**	**$ (824,532)**	**-**	**$ (3,054)**	**$ 10,012**
Net loss	-	-	-	-	-	(4,111)	-	-	(4,111)
Redemption of Series A Preferred Stock	(39)	-	-	-	-	-	-	-	-
Vesting of restricted stock units	-	-	2	-	-	-	-	-	-
Exercise of common stock warrants, net of expenses of $276	-	-	118	1	842	-	-	-	843
Reverse split adjustments - fractional share round ups	-	-	17	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	285	-	-	-	285
Balance - March 31, 2023	**-**	**$ -**	**909**	**$ 1**	**$ 838,725**	**$ (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 $1,630	-	-	4,239	4	10,790	-	-	-	10,794
Stock-based compensation expense	-	-	-	-	382	-	-	-	382
Balance - June 30, 2023	**-**	**$ -**	**5,148**	**$ 5**	**$ 849,897**	**$ (835,244)**	**-**	**$ (3,054)**	**$ 11,604**
Net loss	-	-	-	-	-	(4,425)	-	-	(4,425)
Stock-based compensation expense	-	-	-	-	305	-	-	-	305
Balance - September 30, 2023	**-**	**$ -**	**5,148**	**$ 5**	**$ 850,202**	**$ (839,669)**	**-**	**$ (3,054)**	**$ 7,484**

See notes to condensed consolidated financial statements

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

(in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (15,137)	$ (29,516)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	60	509
Stock-based compensation	972	2,295
Non-cash lease expense	309	417
Loss on impairment of goodwill	3,058	12,090
Loss on sale and disposal of property and equipment	12	19
Unrealized gain on foreign exchange rate changes	(261)	(941)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	443	687
Accounts payable	695	(283)
Accrued expenses	317	(898)
Operating lease liabilities	(338)	(451)
Net cash used in operating activities	(9,870)	(16,072)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	-	210
Purchase of property and equipment	(15)	(13)
Net cash (used in) provided by investing activities	(15)	197
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of issuance costs	10,794	-
Proceeds from exercise of common stock warrants, net of expenses	843	-
Principal payments on loans payable	(563)	(797)
Proceeds from ATM Program, net of issuance costs	-	2,760
Net cash provided by financing activities	11,074	1,963
Net increase (decrease) in cash, cash equivalents, and restricted cash	1,189	(13,912)
Cash, cash equivalents, and restricted cash - beginning of period	6,326	22,502
Cash, cash equivalents, and restricted cash - end of period	$ 7,515	$ 8,590
Supplementary disclosure of non-cash activity:		
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	1,132

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 clinical-stage biopharmaceutical company focused on the development of novel therapeutics intended to address significant unmet medical needs in important cardiovascular care markets. Our development programs are primarily focused on the treatment of cardiovascular diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to 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. We also plan to demonstrate that istaroxime can produce a therapeutic benefit in these settings with a differentiated safety profile compared to drugs currently used in these patients. 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, 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. We completed the SEISMiC Study and, in April 2022, announced positive topline results. Istaroxime rapidly and significantly increased SBP while also improving cardiac function and preserving renal function. In May 2022, we presented the SEISMiC Study results at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain and, in September 2022, the results were published in the European Journal of Heart Failure. A second manuscript comparing the two doses used in the trial was published in the Journal of Cardiac Failure in April 2023. 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. We are currently initiating 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 sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a. The SEISMiC Extension trial is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in mid-2024. Additionally, we are engaged in start-up procedures and exploring the possibility of commencing a small study in more severe SCAI Stage C cardiogenic shock.

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

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

The reader is referred to, and encouraged to read in its entirety, “Item 1 – Business” in our Annual Report on Form 10-K for the year ended December 31, 2022 that we filed with the Securities and Exchange Commission, or the SEC, on March 31, 2023, 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 nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. The consolidated balance sheet at December 31, 2022 has been derived from the Company’s audited consolidated financial statements. There have been no changes to our significant accounting policies since December 31, 2022. 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, 2022 contained in our Annual Report on Form 10-K for the year ended December 31, 2022.

The accompanying condensed consolidated financial statements reflect the 1-for-50 reverse split of our common stock that was approved by our Board of Directors and stockholders and made effective on February 24, 2023. 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 $4.4 million and $15.1 million, respectively, for the three and nine months ended September 30, 2023. Our net loss was $4.1 million and $29.5 million, respectively, for the three and nine months ended September 30, 2022. Included in our net loss for the nine months ended September 30, 2023 is a $3.1 million loss on impairment of goodwill. Included in our net loss for the three and nine months ended September 30, 2022 is a $0.5 million and $12.1 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 September 30, 2023, we had an accumulated deficit of $839.7 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.

On November 9, 2023, we entered into an At-The-Market Offering Agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock through Ladenburg as agent and/or principal (subject to the limitations of General Instruction I.B.6 of Form S-3) through an at-the-market program, or the ATM Program (See the section titled, "Note 11 – Subsequent Event").

The shares of common stock we may issue or sell under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-261878), which was declared effective by the SEC on January 3, 2022. 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 November 9, 2023, we have approximately $2.05 million 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. There can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

In April 2023, we received gross proceeds of approximately $12.4 million and net proceeds of approximately $10.8 million related to a public offering of 4,238,906 units, inclusive of 552,900 units related to a fully exercised over-allotment option, at a price per unit of $2.93. Each unit consisted of one share of our common stock and a warrant to purchase one share of common stock, or the Warrant. The Warrants are immediately exercisable for shares of common stock at a price of $2.93 per share and expire five years from the date of issuance.

As of September 30, 2023, we had cash and cash equivalents of $7.4 million and current liabilities of $3.7 million.

We believe that we have sufficient resources available to support our development activities and fund our business operations through the first quarter of 2024. However, 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 for at least 12 months after the date that the financial statements are issued.

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. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition. 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 nine months ended September 30, 2023, 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. Our company consists of one reporting unit. In order to perform the quantitative goodwill impairment test, we compare the estimated fair value of our reporting unit to its carrying value. If the fair value exceeds the carrying value, no further evaluation is required, and no impairment exists. If the carrying value exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill. When performing a goodwill impairment assessment, we estimate the fair value of our reporting unit, including the use of the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium based on transactions completed by comparable companies.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that goodwill may be impaired. For example, a significant decline in the closing share price of our common stock and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying amount, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. Since early 2022, we have experienced a declining trend in the closing share price of our common stock, on a split-adjusted basis.

During each of the first and second quarters of 2023, the continued declining trend in the closing share price of our common stock, on a split-adjusted basis, suggested that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, in each quarter we performed the interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment and determined that the fair value of our reporting unit was more likely than not less than its carrying value. 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 nine months ended September 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 September 30, 2023, goodwill was zero on our condensed consolidated balances sheet.

The following table represents identifiable intangible assets and goodwill as of September 30, 2023 and December 31, 2022:

(in thousands)	**September 30, 2023**	**December 31, 2022**
Istaroxime drug candidate	$ 22,340	$ 22,340
Rostafuroxin drug candidate	2,910	2,910
Intangible assets	25,250	25,250
Goodwill	$ -	$ 3,058

Foreign Currency Transactions

The functional currency for our foreign subsidiaries 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 income, net. Foreign currency transactions resulted in net gains of approximately $0.2 million and $0.5 million for the three-month periods ended September 30, 2023 and 2022, respectively. Foreign currency transactions resulted in net gains of approximately $0.3 million and $0.9 million for the nine-month periods ended September 30, 2023 and 2022, 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 for the three and nine months ended September 30, 2023 or the year ended December 31, 2022.

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 September 30, 2023, approximately $0.1 million was paid. The remaining liability as of September 30, 2023 is approximately $0.4 million and is included in accrued expenses.

In June 2023, we implemented certain reductions in headcount. The total severance cost for impacted employees is approximately $0.2 million, which was accrued in research and development expense at the date of the separations and will be paid ratably through December 2023. As of September 30, 2023, approximately $0.1 million of severance costs was paid. The remaining liability as of September 30, 2023 is approximately $0.1 million and is included in accrued expenses.

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 (See the section titled, "Note 7 – Restructured Debt Liability"), 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 Exchange and Termination 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 will continue to be carried at full value until the milestones are achieved and paid or the milestones are not achieved and the liability is written off as a gain on debt restructuring.

Research and Development

We account for research and development expense by the following categories: (a) product development and manufacturing, (b) clinical, medical, and regulatory operations, and (c) direct clinical and preclinical development programs. Research and development expense includes personnel, facilities, manufacturing and quality operations, pharmaceutical development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. 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 since realization is not assured.

Net Loss per Common Share

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 September 30, 2023 and 2022, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants, as well as the vesting of restricted stock units, was 5.1 million and 0.4 million shares, respectively. For the three and nine months ended September 30, 2023 and 2022, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share.

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

Recent Accounting Pronouncements

In May 2021, the Financial Accounting Standards Board issued Accounting Standards Update, or ASU, 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*, or ASU 2021-04. ASU 2021-04 provides guidance regarding the accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The ASU was effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted. We adopted ASU 2021-04 on January 1, 2023, which did not have a material impact on our consolidated financial statements and related disclosures. We apply ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date of this guidance.

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 measured at fair value on a recurring basis for the periods presented:

(in thousands)	Fair Value September 30, 2023	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 6,472	$ 6,472	$ -	$ -
Total Assets	$ 6,472	$ 6,472	$ -	$ -

(in thousands)	Fair Value December 31, 2022	Fair value measurement using Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 4,212	$ 4,212	$ -	$ -
Total Assets	$ 4,212	$ 4,212	$ -	$ -

Fair Value on a Non-Recurring Basis

Certain of our assets were measured at fair value on a non-recurring basis during the nine months ended September 30, 2023 and the year ended December 31, 2022. The IPR&D intangible asset related to our rostafuroxin drug candidate was recorded at its estimated fair value as a result of the impairment tests performed during 2022. Our goodwill was also recorded at its estimated fair value as a result of the impairment tests performed in 2022 and during the six months ended June 30, 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”).

Significant factors considered in estimating the fair value of the IPR&D intangible asset related to our rostafuroxin drug candidate include the risks inherent in the development process, including the likelihood of achieving commercial success and the cost and related time to complete the remaining development. Future cash flows for the IPR&D intangible asset were estimated based on forecasted revenue and costs, taking into account the expected product life cycle, market penetration, and growth rates. Other significant estimates and assumptions inherent in this approach include (i) the amount and timing of the projected net cash flows associated with the IPR&D intangible asset; (ii) the discount rate, which seeks to reflect the various risks inherent in the projected cash flows; and (iii) the tax rate, which considers geographic diversity of the projected cash flows. Quantitative information about the significant unobservable inputs used in the fair value measurement of the IPR&D intangible asset included a discount rate of 20.0% and a tax rate of 30.0%, respectively, for 2022. While we use the best available information to prepare our cash flows and discount rate assumptions, actual future cash flows could differ significantly based on the commercial success of the related drug candidate and market conditions which could result in future impairment charges related to the indefinite-lived intangible asset balance.

In order to perform the goodwill impairment test, we compare the estimated fair value of our reporting unit to its carrying value. Significant factors considered in estimating the fair value of our reporting unit include 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 – 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 are due monthly from July 2023 through April 2024. As of September 30, 2023, the outstanding principal of the loan was $0.5 million.

In June 2022, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 3.90% fixed annual interest rate. Payments of approximately $126,000 were due monthly from July 2022 through March 2023. As of December 31, 2022, the outstanding principal of the loan was $0.3 million. The balance of the loan was repaid during the first quarter of 2023.

Note 7 – Restructured Debt Liability

On October 27, 2017, we and Deerfield entered into the Exchange and Termination Agreement pursuant to which (i) promissory notes evidencing a loan with affiliates of Deerfield, or the Deerfield Loan, in the aggregate principal amount of $25.0 million and (ii) warrants to purchase up to 167 shares of our common stock at an exercise price of $118,020 per share held by Deerfield were cancelled in consideration for (x) a cash payment in the aggregate amount of $2.5 million, (y) 474 shares of common stock, representing 2% of fully-diluted shares outstanding (as defined in the Exchange and Termination Agreement) on the closing date, and (z) the right to receive certain 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 Exchange and Termination Agreement (See the section titled, “Note 4 – Summary of Significant Accounting Policies”). The liability was recorded at the full value of the contingent milestones and will continue to be carried at full value until the milestones are achieved and paid or the milestones are not achieved and the liability is written off as a gain on debt restructuring.

As of September 30, 2023 and December 31, 2022, the restructured debt liability balance was $15.0 million.

Note 8 – Mezzanine Equity and Stockholders’ Equity

April 2023 Public Offering

On April 20, 2023, we commenced the April 2023 Offering for a public offering of an aggregate of 3,686,006 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 $2.93 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 the Overallotment Option to purchase up to 552,900 additional shares of common stock and/or warrants to purchase up to 552,900 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 $2.93 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, or ASC 480, 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, or ASC 815, 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 1,573 shares of common stock with an exercise price of $604.50 per share; (ii) warrants issued in May 2020 to purchase 5,598 shares of common stock with an exercise price of $398.75 per share, and (iii) warrants issued in March 2021 to purchase 89,001 shares of common stock with an exercise price of $180.00 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 $10.00 per share. Additionally, the exercising holders agreed to exercise for cash all of their January 2023 Existing Warrants to purchase an aggregate of 96,172 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 192,344 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 $10.76, will initially be 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 1,250 shares of common stock with an exercise price of $600.00 per share; (ii) warrants issued in December 2018 to purchase 9,960 shares of common stock with an exercise price of $607.50 per share; (iii) warrants issued in December 2019 to purchase 5,519 shares of common stock with an exercise price of $604.50 per share; and (iv) warrants issued in May 2020 to purchase 5,517 shares of common stock with an exercise price of $398.75 per share (collectively, the February 2023 Existing Warrants).

Pursuant to the terms of the inducement letter, we agreed to amend the February 2023 Existing Warrants by lowering the exercise price of the February 2023 Existing Warrants to $7.06 per share. Additionally, Panacea agreed to exercise for cash all of their February 2023 Existing Warrants to purchase an aggregate of 22,246 shares of common stock in exchange for our agreement to issue to Panacea new warrants, or the February 2023 New Warrants, to purchase up to an aggregate of 44,492 shares of common stock. We received aggregate gross 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 $10.76, will initially be 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.

Preferred Stock

We are authorized to issue 5,000,000 shares of preferred stock, with a par value of $0.001 per share.

On November 17, 2022, our Board of Directors declared a dividend of one one-thousandth (1/1,000th) of a share of Series A Preferred Stock, par value $0.001 per share, or Series A Preferred Stock, for each outstanding share of our common stock to stockholders of record at 5:00 p.m. Eastern Time on November 28, 2022. The Certificate of Designation of Series A Preferred Stock was filed with the Delaware Secretary of State and became effective on November 18, 2022 and authorized the issuance of 40,000 shares of Series A Preferred Stock. The dividend was based on the number of outstanding shares of common stock as of November 28, 2022 and resulted in 38,610.119 shares of Series A Preferred Stock that were declared as a stock dividend on December 2, 2022. Each share of Series A Preferred Stock entitles the holder thereof to 1,000,000 votes per share. The shares of Series A Preferred Stock vote together with the outstanding shares of common stock as a single class exclusively with respect to (1) any proposal to adopt an amendment to our Amended and Restated Certificate of Incorporation, as amended, to reclassify the outstanding shares of common stock into a smaller number of shares of common stock at a ratio specified in or determined in accordance with the terms of such amendment, or the Reverse Stock Split, and (2) any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Reverse Stock Split. The Series A Preferred Stock was not entitled to vote on any other matter, except to the extent required under the General Corporation Law of the State of Delaware.

All shares of Series A Preferred Stock that are not present in person or by proxy at any meeting of stockholders held to vote on the Reverse Stock Split and the adjournment proposal as of immediately prior to the opening of the polls at such meeting, or the Initial Redemption Time, will automatically be redeemed in whole, but not in part, by the Company at the Initial Redemption Time. All shares that were not redeemed pursuant to the Initial Redemption Time will be redeemed if ordered by the Board of Directors or automatically upon the approval by our stockholders of the Reverse Stock Split at any meeting of the stockholders held for the purpose of voting on such proposal. Each share of Series A Preferred Stock is entitled to receive $0.01 in cash for each 10 whole shares of Series A Preferred Stock immediately prior to the redemption.

Upon issuance of the Series A Preferred Stock, the Company was not solely in control of the redemption of the shares of Series A Preferred Stock since the holders had the option of deciding whether to attend or return a proxy card for the Special Meeting, which determined whether a given holder’s shares of Series A Preferred Stock were redeemed at the Initial Redemption Time. Since the redemption of the Series A Preferred Stock was not solely in the control of the Company, the shares of Series A Preferred Stock were classified within mezzanine equity. The shares of Series A Preferred Stock were recorded at redemption value, which approximates fair value.

On February 7, 2023, we held a Special Meeting of Stockholders, or the Special Meeting, where our stockholders voted on and approved an amendment to our Amended and Restated Certificate of Incorporation, as amended, to effect the Reverse Stock Split and adjourn the Special Meeting, at which point all shares of Series A Preferred Stock were redeemed, and were no longer issued and outstanding as of such date.

At-The-Market Program

On September 17, 2020, we entered into an At-The-Market Offering Agreement with Ladenburg, or the 2020 ATM Program, pursuant to which we were able to offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through the 2020 ATM Program.

For the nine months ended September 30, 2022, we sold 87,556 shares of our common stock under the 2020 ATM Program resulting in net proceeds of approximately $2.8 million. For the nine months ended September 30, 2023, we did not sell any shares of our common stock under the 2020 ATM Program.

The shares of common stock issued and sold under the 2020 ATM Program were registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020 and expired on September 29, 2023. The 2020 ATM Program was terminated by us and Ladenburg on November 9, 2023.

On November 9, 2023, we entered into an At-The-Market Offering Agreement with Ladenburg pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock through Ladenburg as agent and/or principal (subject to the limitations of General Instruction I.B.6 of Form S-3) through an at-the-market program (See the section titled, “Note 11 – Subsequent Event”).

Note 9 – 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 thousands, except for weighted-average data)

Stock Options	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at January 1, 2023	78	$ 381.00	
Granted	213	1.21	
Forfeited or expired	(12)	259.02	
Outstanding at September 30, 2023	279	$ 93.29	9.0
Vested and exercisable at September 30, 2023	57	$ 434.41	6.0
Vested and expected to vest at September 30, 2023	259	$ 94.61	9.0

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2023	11	$ 49.50
Awarded	142	1.21
Vested	(3)	48.55
Cancelled	(3)	49.57
Outstanding at September 30, 2023	147	$ 2.94

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Research and development	$ 93	$ 198	$ 280	$ 580
General and administrative	212	546	692	1,715
Total	$ 305	$ 744	$ 972	$ 2,295

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.

	Nine Months Ended September 30,	
	2023	2022
Weighted average expected volatility	112%	106%
Weighted average expected term (in years)	6.0	6.9
Weighted average risk-free interest rate	4.33%	1.70%
Expected dividends	-	-

Note 10 – Licensing and Research Funding Agreements

Term Sheet 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 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.

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 September 30, 2023, 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 program, 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. 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 reporting period and as uncertain events are resolved or other changes in circumstances occur.

Note 11 – Subsequent Event

On November 9, 2023, we entered into an At-The-Market Offering Agreement with Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock through Ladenburg as agent and/or principal (subject to the limitations of General Instruction I.B.6 of Form S-3) through an at-the-market program, or the ATM Program. We are not obligated to make any sales under the ATM Program, and as of November 9, 2023, we have not sold any shares under the ATM Program. If we issue a sale notice to Ladenburg, we will 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 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, relating to the issuance and sale of up to approximately $2.05 million of shares of common stock.

Either party may suspend the offering under the ATM Program by notice to the other party. The ATM Program will terminate upon the earlier of (i) the sale of all shares subject to the ATM Program or (ii) termination of the ATM Program in accordance with its terms. Either party may terminate the 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 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.

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, 2022 that we filed with the Securities and Exchange Commission, or SEC, on March 31, 2023, as supplemented by our Quarterly Reports on Form 10-Q for the three months ended March 31, 2023 and the three and six months ended June 30, 2023 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, 2022. 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 clinical-stage biopharmaceutical company focused on the development of novel therapeutics intended to address significant unmet medical needs in important cardiovascular care markets. Our development programs are primarily focused on the treatment of cardiovascular diseases. Our lead product candidate, istaroxime, is a first-in-class, dual-acting agent being developed to 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. We also plan to demonstrate that istaroxime can produce a therapeutic benefit in these settings with a differentiated safety profile compared to drugs currently used in these patients. 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, 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. We completed the SEISMiC Study and, in April 2022, announced positive topline results. Istaroxime rapidly and significantly increased SBP while also improving cardiac function and preserving renal function. In May 2022, we presented the SEISMiC Study results at the European Society of Cardiology Heart Failure Meeting in Madrid, Spain and, in September 2022, the results were published in the European Journal of Heart Failure. A second manuscript comparing the two doses used in the trial was published in the Journal of Cardiac Failure in April 2023. 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. We are currently initiating 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 sarco endoplasmic reticulum Ca2+ -ATPase 2a, or SERCA2a. The SEISMiC Extension trial is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in mid-2024. Additionally, we are engaged in start-up procedures and exploring the possibility of commencing a small study in more severe SCAI Stage C cardiogenic shock.

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

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

We have incurred operating losses since our incorporation on November 6, 1992. Our operating loss was $4.7 million and $15.6 million, respectively, for the three and nine months ended September 30, 2023. Our operating loss was $4.7 million and $30.5 million, respectively, for the three and nine months ended September 30, 2022. As of September 30, 2023, we had an accumulated deficit of $839.7 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.

Business and Program Updates

The reader is referred to, and encouraged to read in its entirety, “Item 1 – Business” in our Annual Report on Form 10-K for the year ended December 31, 2022 that we filed with the SEC on March 31, 2023, 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 the SEISMiC Study, a Phase 2 clinical study of istaroxime for the acute treatment of early 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 SEISMiC 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 the SEISMiC Study 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. A second manuscript comparing the two doses used in the trial was published in the Journal of Cardiac Failure in April 2023. 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. We are currently initiating the SEISMiC Extension to evaluate a longer dosing period and to continue to characterize the effects of istaroxime, including those due to activation of SERCA2a. The SEISMiC Extension trial is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock with data anticipated in mid-2024.

Additionally, we are engaged in start-up procedures and exploring the possibility of commencing a small study in more severe SCAI Stage C cardiogenic shock. SCAI Stage C is characterized by hypotension and hypoperfusion (reduced blood flow to vital organs). It is sometimes referred to as “classic shock.” Patients with Stage C cardiogenic shock require treatment with inotropes, vasopressors, and/or mechanical cardiac support devices. It is hoped that istaroxime can provide pharmacological support to SCAI Stage C patients without some of the deleterious side effects that are associated with currently available inotropes and vasopressors. SCAI Stage C cardiogenic shock patients will be a very important population to study for regulatory approval.

Istaroxime (AHF)

We plan to utilize cardiogenic shock Phase 2 data and experience, along with the positive Phase 2a and 2b AHF studies, to potentially proceed toward Phase 3 for acute decompensated heart failure in the normal to low SBP population subject to obtaining adequate funding.

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 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 titled: “17BETA-HETEROCYCLYL-DIGITALIS LIKE COMPOUNDS FOR THE TREATMENT OF HEART FAILURE,” provides patent protection through late 2039.

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 arrangement or partnership.

CRITICAL ACCOUNTING POLICIES

There have been no changes to our critical accounting policies since December 31, 2022. 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, 2022, 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.

Goodwill and Intangible Assets

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 nine months ended September 30, 2023, 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. Our company consists of one reporting unit. In order to perform the quantitative goodwill impairment test, we compare the estimated fair value of our reporting unit to its carrying value. If the fair value exceeds the carrying value, no further evaluation is required, and no impairment exists. If the carrying value exceeds the fair value, the difference between the carrying value and the fair value is recorded as an impairment loss, the amount of which may not exceed the total amount of goodwill. When performing a goodwill impairment assessment, we estimate the fair value of our reporting unit, including the use of the quoted market price and related market capitalization of our common stock, adjusted for an estimated control premium based on transactions completed by comparable companies.

Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that goodwill may be impaired. For example, a significant decline in the closing share price of our common stock and market capitalization may suggest that the fair value of our reporting unit has fallen below its carrying amount, indicating that an interim goodwill impairment test is required. Accordingly, we monitor changes in our share price during interim periods between annual impairment tests and consider overall stock market conditions, the underlying reasons for the decline in our share price, the significance of the decline, and the duration of time that our securities have been trading at a lower value. Since early 2022, we have experienced a declining trend in the closing share price of our common stock, on a split-adjusted basis.

During each of the first and second quarters of 2023, the continued declining trend in the closing share price of our common stock, on a split-adjusted basis, suggested that the fair value of our reporting unit was more likely than not less than its carrying value. As a result, in each quarter we performed the interim goodwill impairment test consistent with the methodology that we use when performing our annual goodwill impairment assessment and determined that the fair value of our reporting unit was more likely than not less than its carrying value. 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 nine months ended September 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 September 30, 2023, goodwill was zero on our condensed consolidated balances sheet.

The following table represents identifiable intangible assets and goodwill as of September 30, 2023 and December 31, 2022:

(in thousands)	**September 30, 2023**	**December 31, 2022**
Istaroxime drug candidate	$ 22,340	$ 22,340
Rostafuroxin drug candidate	2,910	2,910
Intangible assets	25,250	25,250
Goodwill	$ -	$ 3,058

RESULTS OF OPERATIONS

Comparison of the Three and Nine Months EndedSeptember 30, 2023 and 2022

(in thousands)	Three Months Ended September 30, 2023	2022	Change	Nine Months Ended September 30, 2023	2022	Change
Expenses:						
Research and development	$ 2,110	$ 1,543	$ 567	$ 5,288	$ 9,883	$ (4,595)
General and administrative	2,580	2,653	(73)	7,292	8,548	(1,256)
Loss on impairment of goodwill	-	454	(454)	3,058	12,090	(9,032)
Total operating expenses	4,690	4,650	40	15,638	30,521	(14,883)
Operating loss	(4,690)	(4,650)	(40)	(15,638)	(30,521)	14,883
Other income (expense):						
Interest income	112	39	73	264	57	207
Interest expense	(13)	(14)	1	(38)	(40)	2
Other income, net	166	569	(403)	275	988	(713)
Total other income, net	265	594	(329)	501	1,005	(504)
Net loss	$ (4,425)	$ (4,056)	$ (369)	$ (15,137)	$ (29,516)	$ 14,379

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) stock-based compensation; (iv) rents and utilities; (v) depreciation; (vi) travel; (vii) raw materials and supplies; and (viii) other. We expect that our research and development expenses will increase in 2023 as we continue the SEISMiC Extension trial of istaroxime for the treatment of early cardiogenic shock and start-up procedures for a possible small study in more severe SCAI Stage C cardiogenic shock. 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 September 30, 2023	2022	Increase (Decrease)	Nine Months Ended September 30, 2023	2022	Increase (Decrease)
Istaroxime – cardiogenic shock program	$ 1,264	$ 685	$ 579	$ 2,305	$ 2,859	$ (554)
Istaroxime – AHF	17	48	(31)	9	704	(695)
KL4 surfactant	-	109	(109)	(34)	400	(434)
Total direct clinical and preclinical programs	1,281	842	439	2,280	3,963	(1,683)
Product development and manufacturing	249	239	10	735	2,281	(1,546)
Clinical, medical, and regulatory operations	580	462	118	2,273	3,639	(1,366)
Total research and development expenses	$ 2,110	$ 1,543	$ 567	$ 5,288	$ 9,883	$ (4,595)

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $0.1 million for both the three months ended September 30, 2023 and 2022, and $0.3 million and $1.1 million, respectively, for the nine months ended September 30, 2023 and 2022.

Direct Clinical and Preclinical Programs

Direct clinical and preclinical programs include: (i) activities associated with conducting clinical trials, including 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 $0.4 million for the three months ended September 30, 2023 compared to the same period in 2022 primarily due to an increase in expenses in our istaroxime – cardiogenic shock program due to the initiation of the SEISMiC Extension study during the third quarter of 2023 and planning and start-up costs for the potential study of istaroxime in more severe SCAI Stage C cardiogenic shock patients as described below.

Total direct clinical and preclinical programs expenses decreased $1.7 million for the nine months ended September 30, 2023 compared to the same period in 2022 primarily due to the timing of trial execution costs for the SEISMiC Extension study, which was initiated during the third quarter of 2023, compared to the SEISMiC Study, which was completed in mid-2022, as well as decreases in expenses in our istaroxime – AHF costs and KL4 surfactant costs as described below.

Istaroxime – cardiogenic shock program costs increased $0.6 million for the three months ended September 30, 2023 compared to the same period in 2022 due to the initiation of the SEISMiC Extension study during the third quarter of 2023, which is expected to enroll up to 30 subjects with SCAI Stage B cardiogenic shock, and planning and start-up costs for the potential study of istaroxime in more severe SCAI Stage C cardiogenic shock. Istaroxime – cardiogenic shock program costs decreased $0.6 million for the nine months ended September 30, 2023 compared to the same period in 2022 due to the timing of trial execution costs for the SEISMiC Extension study, which was initiated during the third quarter of 2023, compared to the SEISMiC Study, which was completed in mid-2022.

Istaroxime – AHF costs for the three months ended September 30, 2023 are comparable to the same period in 2022 and relate to limited ongoing clinical and preclinical development activities. Istaroxime – AHF costs decreased $0.7 million for the nine months ended September 30, 2023 compared to the same periods in 2022 due to focusing our resources on the start-up and initiation of the SEISMiC Extension study.

KL4 surfactant costs decreased $0.1 million and $0.4 million, respectively, for the three and nine months ended September 30, 2023 compared to the same periods in 2022. Costs decreased following the completion of enrollment in January 2022 of our Phase 2b study of lucinactant for patients with severe COVID-19 associated acute respiratory distress syndrome. Costs related to the KL4 surfactant platform are expected to continue to decrease as we complete close-out activities on prior KL4 surfactant platform clinical trials and focus our resources on the development of our istaroxime program.

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 months ended September 30, 2023 are comparable to the same period in 2022.

Product development and manufacturing expenses decreased $1.5 million for the nine months ended September 30, 2023 compared to the same period in 2022 due to (i) headcount reductions of $0.6 million; (ii) a decrease of $0.5 million related to our decision in January 2022 to begin reducing costs associated with the KL4 surfactant platform including analytical testing and support; and (iii) $0.4 million in accelerated depreciation following the abandonment and decommissioning of certain manufacturing and laboratory equipment assets related to the KL4 surfactant platform during the first quarter of 2022.

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 increased $0.1 million for the three months ended September 30, 2023 compared to the same period in 2022 due to (i) a decrease of $0.4 million in personnel costs related to reductions in headcount for the KL4 surfactant platform; and (ii) a decrease of $0.1 million in non-cash stock-based compensation expense; offset by (iii) a $0.6 million reversal of royalty expense in the third quarter of 2022 related to the KL4 surfactant platform.

Clinical, medical, and regulatory operations expenses decreased $1.4 million for the nine months ended September 30, 2023 compared to the same period in 2022 due to (i) a decrease of $1.1 million in personnel costs related to reductions in headcount for the KL4 surfactant platform; (ii) a decrease of $0.3 million in incentive bonus expense; and (iii) a decrease of $0.2 million in non-cash stock-based compensation expense; partially offset by (iii) a $0.2 million reversal of royalty expense in 2022 related to the KL4 surfactant platform.

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 $0.1 million for the three months ended September 30, 2023 compared to the same period in 2022 due to (i) a decrease of $0.3 million in non-cash stock-based compensation expense due to the timing of equity grants during 2023 compared to 2022; (ii) a decrease of $0.2 million in personnel costs due to headcount reductions; (iii) a decrease of $0.2 million in incentive bonus expense; and (iv) a decrease of $0.1 million in insurance costs; partially offset by (v) an increase of $0.4 million in severance expense related to a former executive; and (vi) an increase of $0.3 million in professional fees.

General and administrative expenses decreased $1.3 million for the nine months ended September 30, 2023 compared to the same period in 2022 due to (i) a decrease of $1.0 million in non-cash stock-based compensation expense due to the timing of equity grants during 2023 compared to 2022; (ii) a decrease of $0.5 million in personnel costs due to headcount reductions; (iii) a decrease of $0.5 million in incentive bonus expense; and (iv) a decrease of $0.2 million in insurance costs; partially offset by (v) an increase of $0.5 million in professional fees; and (vi) an increase of $0.4 million in severance expense related to a former executive.

Other Income, Net

Interest income relates to interest on our money market account for the three and nine months ended September 30, 2023 and 2022.

For the three and nine months ended September 30, 2023 and 2022, interest expense consists of interest expense associated with loans payable.

For the three and nine months ended September 30, 2023 and 2022, other 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.

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 $4.4 million and $15.1 million, respectively, for the three and nine months ended September 30, 2023. Our net loss was $4.1 million and $29.5 million, respectively, for the three and nine months ended September 30, 2022. Included in our net loss for the nine months ended September 30, 2023 is a $3.1 million loss on impairment of goodwill. Included in our net loss for the three and nine months ended September 30, 2022 is a $0.5 million and $12.1 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 September 30, 2023, we had an accumulated deficit of $839.7 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.

On November 9, 2023, we entered into an At-The-Market Offering Agreement with Ladenburg Thalmann & Co. Inc., or Ladenburg, pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock through Ladenburg as agent and/or principal (subject to the limitations of General Instruction I.B.6 of Form S-3) through an at-the-market program, or the ATM Program (See the section titled, “Note 11 – Subsequent Event”).

The shares of common stock we may issue or sell under the ATM Program are registered under our Registration Statement on Form S-3 (File No. 333-261878), which was declared effective by the SEC on January 3, 2022. 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 November 9, 2023, we have approximately $2.05 million 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. There can be no assurance that our public float will increase or that we will no longer be subject to such limitations.

In April 2023, we received gross proceeds of approximately $12.4 million and net proceeds of approximately $10.8 million related to a public offering of 4,238,906 units, inclusive of 552,900 units related to a fully exercised over-allotment option, at a price per unit of $2.93. Each unit consisted of one share of our common stock and a warrant to purchase one share of common stock, or the Warrant. The Warrants are immediately exercisable for shares of common stock at a price of $2.93 per share and expire five years from the date of issuance.

As of September 30, 2023, we had cash and cash equivalents of $7.4 million and current liabilities of $3.7 million.

We believe that we have sufficient resources available to support our development activities and fund our business operations through the first quarter of 2024. However, 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 for at least 12 months after the date that the financial statements are issued.

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. The failure to obtain sufficient capital on acceptable terms when needed would have a material adverse effect on our business, results of operations, and financial condition. 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 nine months ended September 30, 2023 consist of $9.9 million of net cash used in operating activities and $11.1 million of net cash provided by financing activities. Cash flows for the nine months ended September 30, 2022 consist of $16.1 million of net cash used in operating activities, $0.2 million of net cash provided by investing activities, and $2.0 million of net cash provided by financing activities.

Operating Activities

Net cash used in operating activities was $9.9 million for the nine months ended September 30, 2023 and consisted primarily of (i) a net loss of $15.1 million; and (ii) an unrealized gain on foreign exchange rate changes of $0.3 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 $1.1 million; (v) non-cash stock-based compensation of $1.0 million; (vi) non-cash lease expense of $0.3 million; and (vii) depreciation and amortization of $0.1 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 $16.1 million for the nine months ended September 30, 2022 and consisted primarily of (i) a net loss of $29.5 million; (ii) changes in operating assets and liabilities of $0.9 million; and (iii) an unrealized gain on foreign exchange rate changes of $0.9 million, partially offset by (iv) a non-cash loss on impairment of goodwill of $12.1 million; (v) non-cash stock-based compensation of $2.3 million; (vi) depreciation and amortization of $0.5 million; and (vii) non-cash lease expense of $0.4 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.

Investing Activities

Net cash provided by investing activities was $0.2 million for the nine months ended September 30, 2022 and primarily includes proceeds from sale of property and equipment related to the decommissioning and sale of certain manufacturing and laboratory equipment assets previously used for the KL4 surfactant platform. There was a de minimis amount of net cash used in investing activities during the nine months ended September 30, 2023.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was $11.1 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) $0.6 million of principal payments on loans payable.

Net cash provided by financing activities for the nine months ended September 30, 2022 was $2.0 million and includes (i) $2.8 million in net proceeds from the ATM Program; partially offset by (ii) $0.8 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 3,686,006 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 $2.93 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 552,900 additional shares of common stock and/or warrants to purchase up to 552,900 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 $2.93 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 September 17, 2020, we entered into an At-The-Market Offering Agreement with Ladenburg, or the 2020 ATM Program, pursuant to which we were able to offer and sell, from time to time at our sole discretion, up to a maximum of $10.0 million of shares of our common stock through Ladenburg as agent and/or principal through the 2020 ATM Program.

For the nine months ended September 30, 2022, we sold 87,556 shares of our common stock under the 2020 ATM Program resulting in net proceeds of approximately $2.8 million. For the nine months ended September 30, 2023, we did not sell any shares of our common stock under the 2020 ATM Program.

The shares of common stock issued and sold under the 2020 ATM Program were registered under our Registration Statement on Form S-3 (File No. 333-248874), which was declared effective by the SEC on September 29, 2020 and expired on September 29, 2023. The 2020 ATM Program was terminated by us and Ladenburg on November 9, 2023.

On November 9, 2023, we entered into an At-The-Market Offering Agreement with Ladenburg pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock through Ladenburg as agent and/or principal (subject to the limitations of General Instruction I.B.6 of Form S-3) through an at-the-market program (See the section titled, “Note 11 – Subsequent Event”).

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 are due monthly from July 2023 through April 2024. As of September 30, 2023, the outstanding principal of the loan was $0.5 million.

In June 2022, we entered into an insurance premium financing and security agreement with Bank Direct. Under the agreement, we financed $1.1 million of certain premiums at a 3.90% fixed annual interest rate. Payments of approximately $126,000 were due monthly from July 2022 through March 2023. As of December 31, 2022, the outstanding principal of the loan was $0.3 million. The balance of the loan was repaid during the first quarter of 2023.

Supplementary Disclosure of Non-Cash Activity

During the three months ended March 31, 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 8 – Mezzanine Equity and Stockholders’ Equity”).

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at September 30, 2023 and 2022 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 our Interim Chief Financial Officer (principal financial officer), do 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 and our Interim Chief Financial Officer have 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 and our Interim Chief Financial 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 and our Interim Chief Financial 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 September 30, 2023 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, 2022, as supplemented by risk factors included in our Quarterly Reports 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, 2022 or our Quarterly Reports 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, 2022, 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*.

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

None.

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
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act.	Filed herewith.
32.1	Certification of Chief Executive Officer and Chief 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 September 30, 2023, formatted in Inline Extensive Business Reporting Language (XBRL): (i) Balance Sheets as of September 30, 2023 (unaudited) and December 31, 2022, (ii) Statements of Operations (unaudited) for the three and nine months ended September 30, 2023 and September 30, 2022, (iii) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2023 and September 30, 2022, 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.

(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: November 9, 2023

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

Date: November 9, 2023

By: /s/ John A. Tattory
John A. Tattory
Interim Chief 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: November 9, 2023

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

Exhibit 31.2

CERTIFICATION

I, John A. Tattory, 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: November 9, 2023

/s/ John A. Tattory
John A. Tattory
Interim Chief Financial Officer
(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 September 30, 2023, 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: November 9, 2023

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

/s/ John A. Tattory
John A. Tattory
Interim Chief Financial Officer
(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.