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

FORM 8-K

CURRENT REPORT

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

May 12, 2016
Date of Report (Date of earliest event reported)

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(Address of principal executive offices)

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

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

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

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

Item 2.02. Results of Operations and Financial Condition.

On May 12, 2016, Windtree Therapeutics, Inc. (the "Company") issued a press release highlighting the results of operations for the quarter ended March 31, 2016, and providing key financial and business updates. The press release is attached as Exhibit 99.1 hereto.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 hereto relating to the announcement of the results of operations for the quarter ended March 31, 2016 and all other matters except for those discussed under Item 8.01 below shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filings.

Item 8.01. Other Events.

The press release referred to in Item 2.02 also provides certain program updates relating to the Company's AEROSURF® phase 2 clinical development program. In addition, the Company reaffirms its forecast that, before any additional financings, the Company anticipates that it will have sufficient cash available to support the AEROSURF phase 2b clinical program, pay debt service and fund its operations through the first quarter of 2017, and anticipates net cash outflows in the second quarter of 2016 of approximately $8.5 million.

Subject to the note relating to the press release contained in Item 2.02 of this Current Report on Form 8-K, the press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release dated May 12, 2016

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development, cash flows, future revenues, the timing of planned clinical trials or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement made by the Company in this Current Report on Form 8-K is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

SIGNATURES

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

By /s/ John Tattory
Name: John Tattory
Title: Senior Vice President and
Chief Financial Officer

Date: May 12, 2016

Exhibit 99.1

Windtree Therapeutics Reports First Quarter 2016 Financial Results and Provides Business Updates

WARRINGTON, PA – May 12, 2016 – Windtree Therapeutics, Inc. (Nasdaq: WINT), a biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases, today reported financial results for the first quarter ended March 31, 2016 and provided key business updates. The Company will also host a conference call today at 8:00 a.m. EDT.

Key Business and Financial Updates

- Recently achieved an important milestone in the AEROSURF® phase 2b clinical trial in respiratory distress syndrome (RDS) with the initiation of sites and enrollment at selected clinical sites in Canada, Europe and Latin America. The Company continues to expect to release top-line results from this study in the first quarter of 2017.

- Enrollment is ongoing in the AEROSURF phase 2a clinical trial in 32 premature infants 26 to 28 week gestational age (GA) receiving nCPAP for RDS, which is designed to evaluate safety and tolerability of AEROSURF. The Company continues to expect to release top-line results from this study in the third quarter of 2016.

- In April, the Company met with the FDA to discuss key elements of the AEROSURF clinical development program. The Company believes that these discussions reaffirmed its current and planned approach to the clinical development program for AEROSURF.

- In April, the Company completed the first phase of its Noninterventional Observational Study to collect data on the treatment and outcomes of premature infants 26 to 34 week GA with RDS. The study was initiated in 2015 and over 1,700 premature infants have been enrolled to date. The results of the study have better informed our assessment of the unmet medical need in RDS, the design of a potential Phase 3 trial, and the RDS market opportunity. Additionally, based on this study, the Company has enhanced some of the operational aspects of the AEROSURF phase 2 program.

- The Company continued to advance its Lung Deposition Study in nonhuman primates. This study consists of a series of experiments to assess the distribution and deposition of aerosolized KL4 surfactant in the lung when using the Company's innovative aerosol drug delivery technology. The Company continues to expect to complete the final phase of the study and report results in the third quarter of 2016.

- As of March 31, 2016, the Company had cash and cash equivalents of $29.4 million.

"The first quarter of 2016 was one of meaningful progress for Windtree," commented Craig Fraser, President and Chief Executive Officer. "We expanded our AEROSURF phase 2 program to include sites in Europe and Latin America, conducted a successful meeting with the FDA that will guide our AEROSURF development program, collected data from over 1,700 premature infants in the Noninterventional Observational Study, and advanced the Lung Deposition Study. Our primary objective for 2016 remains the rigorous and timely execution of the AEROSURF phase 2 program while effectively managing existing cash resources."

Select Financial Results for the First Quarter ended March 31, 2016

For the quarter ended March 31, 2016, the Company reported an operating loss of $13.9 million, compared to $11.2 million for the first quarter of 2015.

Grant revenue for the first quarter of 2016 was $0.1 million, compared to $0.2 million for the first quarter of 2015. Grant revenue for 2016 represents funds received and expended under a $1.0 million Phase II SBIR grant from the National Institutes of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) to study the Company's aerosolized KL_4 surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury. Grant revenue for 2015 represents funds received and expended under (i) a $1.9 million SBIR grant from the National Heart, Lung and Blood Institute (NHLBI) of the NIH to provide support for the initial AEROSURF phase 2a clinical trial in premature infants 29 to 34 week GA with RDS; and, (ii) a $1.0 million Phase II SBIR grant from NIAID to study the Company's aerosolized KL_4 surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury.

Research and development expenses were $10.4 million for the first quarter of 2016, compared to $7.1 million for the first quarter of 2015. The increase was primarily due to a $3.4 million increase in AEROSURF clinical trial activities, including patient enrollment costs, ongoing clinical site initiations and the manufacture of additional clinic-ready AEROSURF Delivery Systems.

Selling, general and administrative expenses for the first quarter of 2016 were $3.7 million, compared to $3.4 million for the first quarter of 2015. During the first quarter of 2016, the Company recorded a severance charge of $1.2 million under the terms of our former CEO's separation agreement, including $0.2 million related to stock-based compensation expense for certain common stock options that will continue to vest through the 18-month severance period. Excluding this charge, selling, general and administrative expenses decreased $0.9 million in the first quarter of 2016 compared to the comparable period in 2015. The decrease was primarily due to the Company's decision in April 2015 to voluntarily cease commercial and manufacturing activities for SURFAXIN®, resulting in a reduction in workforce related primarily to commercial infrastructure.

Interest expense for the first quarter of 2016 was $0.6 million, compared to $1.2 million for the first quarter of 2015. The decrease in interest expense was due to the July 2015 restructuring of our long-term debt with affiliates of Deerfield Management Company, L.P. (Deerfield), which resulted in the write-off of previously capitalized debt discount costs which were being amortized to interest expense.

The Company reported a net loss of $13.9 million ($1.70 per basic share) on 8.2 million weighted-average common shares outstanding for the quarter ended March 31, 2016, compared to a net loss of $12.2 million ($1.96 per basic share) on 6.1 million weighted average common shares outstanding for the comparable period in 2015.

Net cash outflows before financing activities for the first quarter of 2016 were $9.3 million and included $1.5 million of 2015 employee incentive compensation payments. The Company anticipates second quarter 2016 net cash outflows before financing activities of approximately $8.5 million.

As of March 31, 2016, the Company had cash and cash equivalents of $29.4 million, an amount the Company anticipates is sufficient to support the planned completion of the AEROSURF phase 2b clinical program and fund operations through the first quarter of 2017. In addition, as of March 31, 2016, the Company reported accounts payable and accrued expenses of $14.6 million, including $4.1 million due under the collaboration agreement with the Battelle Memorial Institute, and long-term debt with Deerfield of $25 million. The debt is payable in two equal installments of $12.5 million in each of February 2018 and 2019. The payment due in February 2018 may be deferred if certain conditions are satisfied.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which is expected to be filed today with the Securities and Exchange Commission, which includes discussion about the Company's business plans and operations, financial condition, and results of operations.

Conference Call and Webcast Details

The Company will also host a live teleconference and webcast, including a slide presentation, today at 8:00 a.m. EDT to discuss the 2016 first quarter financial results along with providing other business updates. The live webcast and archive of the conference call can be accessed at http://windtreetx.investorroom.com/events.

For "listen-only" participants and those who wish to take part in the question and answer portion of the call, dial (877) 870-4263 (domestic) or (412) 317-0790 (international). After placing the call, request to be joined into the Windtree Therapeutics conference call. A replay of the conference call will be accessible one hour after completion through May 19, 2016 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing conference ID number 10085848.

About AEROSURF®
Windtree's lead product candidate is AEROSURF, a novel, investigational drug/device product that combines the Company's proprietary KL_4 surfactant and aerosolization technologies. AEROSURF is being developed to potentially reduce or eliminate the need for endotracheal intubation and mechanical ventilation in the treatment of premature infants with respiratory distress syndrome (RDS). A phase 2b clinical trial in up to 240 premature infants was initiated late last year to study AEROSURF in premature infants 26 to 32-week gestational age receiving nasal continuous positive airway pressure (nCPAP) for RDS, compared to infants receiving nCPAP alone. The phase 2b trial is a global trial with clinical sites in North America, Europe and Latin America. The Company remains on track to complete enrollment in this trial by the end of 2016 and release top-line results in the first quarter of 2017.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is a clinical-stage biotechnology company focused on developing novel surfactant therapies for respiratory diseases and other potential applications. Windtree's proprietary technology platform includes a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to endogenous pulmonary surfactant and novel drug-delivery technologies being developed to enable noninvasive administration of aerosolized KL_4 surfactant. Windtree is focused initially on improving the management of respiratory distress syndrome (RDS) in premature infants and believes that its proprietary technology may make it possible, over time, to develop a pipeline of KL_4 surfactant product candidates to address a variety of respiratory diseases for which there are few or no approved therapies.

For more information, please visit the Company's website at www.windtreetx.com.

Forward-Looking Statements
To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results, including projections of future cash balances and anticipated cash outflows, to differ materially from the statements made. Examples of such risks and uncertainties include: risks related to Windtree Therapeutics' AEROSURF development program and other development programs that we may undertake in the future, which may involve time-consuming and expensive pre-clinical studies and clinical trials, which may be subject to potentially significant delays or regulatory holds, or fail; risks that Windtree Therapeutics will be unable to secure significant additional capital as needed, and may be unable in a timely manner, if at all, to identify potential strategic transactions (including strategic partnerships and other transactions) that would provide funding and support product development, regulatory and, if approved, commercialize our products, or to access debt or equity financings, which could result in substantial equity dilution; risks related to maintaining continued compliance with The Nasdaq Capital Market listing requirements; risks related to technology transfers to contract manufacturers and problems or delays encountered by Windtree Therapeutics, contract manufacturers or suppliers in manufacturing drug products, drug substances, aerosol delivery systems (ADS) and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the FDA or other regulatory authorities may not agree with Windtree Therapeutics on matters raised during regulatory reviews, may require significant additional activities, or may not accept or may withhold or delay consideration of applications, or may not approve or may limit approval of Windtree Therapeutics' products, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals; risks related to Windtree Therapeutics' efforts to maintain and protect the patents and licenses related to its products; and other risks and uncertainties described in Windtree Therapeutics' filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Contact Information:
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Windtree Therapeutics, Inc.
Condensed Consolidated State of Operations
(in thousands, except per share data)

	Three Months Ended March 31, (unaudited)	
	2016	2015
Revenues:		
Product sales	$ –	$ 7
Grant revenue	75	184
	75	191
Operating expenses:(1)		
Cost of product sales	–	929
Research and development	10,360	7,082
Selling, general and administrative	3,657	3,353
Total expenses	14,017	11,364
Operating loss	(13,942)	(11,173)
Change in fair value of common stock warrant Liability	223	(31)
Interest expense	(622)	(1,208)
Other income / (expense), net	440	233
Net loss	$ (13,901)	$ (12,179)
Net loss per common share	$ (1.70)	$ (1.96)
Weighted avg. common shares outstanding	8,191	6,114

(1) For the three months ended March 31, 2016 and 2015, non-cash charges for depreciation and stock-based compensation were $0.7 million ($0.3 million in R&D and $0.4 million in S, G & A) and $0.8 million ($0.4 million in R&D and $0.4 million in S,G & A), respectively.

Windtree Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

ASSETS	March 31, 2016 (Unaudited)	December 31, 2015
Current Assets:		
Cash and cash equivalents	$ 29,400	$ 38,722
Prepaid interest, current portion	1,435	1,710
Prepaid expenses and other current assets	500	362
Total current assets	31,335	40,794
Property and equipment, net	1,100	1,039
Restricted cash	225	225
Prepaid interest, non-current portion	2,050	2,319
Total Assets	$ 34,710	$ 44,377
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 14,647	$ 10,845
Common stock warrant liability	–	223
Total current liabilities	14,647	11,068
Long-term debt	25,000	25,000
Other liabilities	40	43
Stockholders' Equity	(4,977)	8,266
Total Liabilities and Stockholders' Equity	$ 34,710	$ 44,377

Note: All share and per share amounts related to common stock have been adjusted to reflect the 1-for-14 reverse stock split made effective on January 22, 2016.