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

August 10, 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 August 10, 2016, Windtree Therapeutics, Inc. (the "Company") issued a press release highlighting the results of operations for the quarter ended June 30, 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 June 30, 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 reports that, before any additional financings, the Company anticipates that it will have sufficient cash to support its operations through the planned completion of the AEROSURF phase 2b clinical trial and the release of top line results, which is expected in the first quarter of 2017.

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 August 10, 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 undertakes 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: August 10, 2016

Windtree Therapeutics Reports Second Quarter 2016 Financial Results and Provides Key Business Updates

WARRINGTON, PA – August 10, 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 second quarter ended June 30, 2016 and provided key business updates.

Key Business and Financial Updates

- Enrollment in the AEROSURF phase 2b trial in RDS is ongoing and the Company continues to be on track to announce top-line results from this study in the first quarter of 2017.

- Following a planned Safety Review Committee review of the first dose group, enrollment is proceeding in the second dose group in the AEROSURF phase 2a clinical trial in 32 premature infants 26 to 28 week gestational age receiving nCPAP for RDS. This study is designed to evaluate safety and tolerability of AEROSURF. The Company anticipates completing enrollment in September and releasing top-line results of this trial in late September or early October 2016.

- The Company recently completed a Lung Deposition Study in nonhuman primates. The study consists of a series of experiments designed to assess the distribution and deposition of aerosolized KL4 surfactant in the lung when administered using the Company's innovative aerosol drug delivery technology. The Company is finalizing the analysis of the study data and anticipates reporting these results in September 2016.

- In the second quarter of 2016, 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 analysis of data collected in the first phase of its Noninterventional Observational Study on the treatment and outcomes of premature infants 26 to 34 week gestational age with RDS. The study was initiated in 2015 and over 2,000 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. Based on this study, the Company has enhanced some of the operational aspects of the AEROSURF phase 2 program.

- The Company recently announced that it has been awarded a Phase II Small Business Innovation Research Grant (SBIR) valued at up to $2.6 million from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to support the on-going AEROSURF phase 2b RDS clinical trial. Under the terms of the grant, the Company has been awarded $1.0 million initially, and, over the next two years, may be awarded up to an additional $1.6 million through the completion of the phase 2b clinical trial and one-year patient follow-up. The Company also received a separate grant of $1.0 million under a previously announced Phase II SBIR grant valued at up to $3.0 million to support continued development of the Company's aerosolized KL_4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury.
- As of June 30, 2016, the Company had cash and cash equivalents of $20.3 million.

"The second quarter of 2016 was one of meaningful progress for Windtree and our AEROSURF phase 2 program," commented Craig Fraser, President and Chief Executive Officer. "We expanded our clinical trial to include sites in Europe and Latin America, conducted a successful meeting with the FDA that will guide our AEROSURF development program, completed collection and analysis of data from over 2,000 premature infants in the Noninterventional Observational Study, and completed the Lung Deposition Study in non-human primates. 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 Second Quarter ended June 30, 2016

For the quarter ended June 30, 2016, the Company reported an operating loss of $10.0 million, compared to $10.4 million for the second quarter of 2015.

Grant revenue for the second quarter of 2016 and 2015 was $0.1 million. Grant revenue represents funds received and expended under SBIR grants from the NIH to (i) in both 2015 and 2016, study the Company's aerosolized KL4 surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury; and, (ii) in 2015, provide support for the initial AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age with RDS.

Research and development expenses were $8.3 million for the second quarter of 2016, compared to $7.1 million for the second quarter of 2015. The increase was due to a $2.6 million increase in AEROSURF clinical trial activities, including patient enrollment costs, ongoing clinical site initiations and the manufacture of additional clinic-ready aerosol delivery systems (ADS), partially offset by a decrease of $1.3 million in manufacturing costs following the closure of our manufacturing operations at our leased facility in Totowa, NJ in June 2015.

Selling, general and administrative expenses for the second quarter of 2016 were $1.8 million, compared to $3.4 million for the second quarter of 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 second quarter of 2016 was $0.6 million, compared to $1.3 million for the second 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., 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 $10.6 million ($1.29 per basic share) on 8.2 million weighted-average common shares outstanding for the quarter ended June 30, 2016, compared to a net loss of $11.3 million ($1.82 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 second quarter of 2016 were $9.1 million.

As of June 30, 2016, the Company had cash and cash equivalents of $20.3 million. Based on current projections and development timelines, the Company anticipates that it has sufficient cash to support its operations through the planned completion of the AEROSURF phase 2b clinical trial and the release of top line results, which is expected in the first quarter of 2017. In addition, as of June 30, 2016, the Company reported accounts payable and accrued expenses of $15.1 million, including $4.5 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 June 30, 2016, which is expected to be filed today with the Securities and Exchange Commission, and includes discussion about the Company's business plans and operations, financial condition, and results of operations.

The Company plans on updating investors in September and providing a comprehensive update on the AEROSURF development program including the ongoing AEROSURF phase 2a and 2b clinical trials in premature infants, the Lung Deposition Study in nonhuman primates, and other business updates.

About AEROSURF®
Windtree's lead product candidate is AEROSURF, a novel, investigational drug/device product that combines the Company's proprietary KL4 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). Enrollment is ongoing in a phase 2b clinical trial in up to 240 premature infants 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.

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 (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant and novel drug-delivery technologies being developed to enable noninvasive administration of aerosolized KL4 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 KL4 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's 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 and which may be subject to potentially significant delays or regulatory holds, or fail; risks that Windtree 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 the Company's receipt of a deficiency notification from The NASDAQ Stock Market concerning its failure to comply with The Nasdaq Capital Market listing requirements and the Company's ability to regain compliance in a timely manner, if at all; risks related to technology transfers to contract manufacturers and problems or delays encountered by Windtree, 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 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's 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's efforts to maintain and protect the patents and licenses related to its products; and other risks and uncertainties described in Windtree'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.

Contact Information:
John Tattory
Senior Vice President and Chief Financial Officer
215.488.9418 or jtattory@windtreetx.com

Windtree Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except per share data)

	Three Months Ended June 30, (unaudited)		Six Months Ended June 30, (unaudited)	
	2016	2015	2016	2015
Revenues:				
Product sales	$ –	$ –	$ –	$ 7
Grant revenue	106	75	181	259
	106	75	181	266
Operating expenses: [1]				
Cost of product sales	–	–	–	929
Research and development	8,316	7,129	18,676	14,211
Selling, general and administrative	1,783	3,383	5,440	6,736
Total expenses	10,099	10,512	24,116	21,876
Operating loss	(9,993)	(10,437)	(23,935)	(21,610)
Change in fair value of common stock warrant liability [1]	–	469	223	438
Interest income / expense, net	(632)	(1,259)	(1,247)	(2,466)
Other income / (expense), net	1	(99)	434	133
Net loss	$ (10,624)	$ (11,326)	$ (24,525)	$ (23,205)
Net loss per common share – basic and diluted	$ (1.29)	$ (1.82)	$ (2.99)	$ (3.78)
Weighted avg. common shares outstanding – basic and diluted	8,238	6,125	8,215	6,119

[1] Material non-cash items include the change in fair value of certain outstanding warrants accounted for as derivative liabilities, and in operating expenses, depreciation and stock-based compensation. For the three months ended June 30, 2016 and 2015, the charges for depreciation and stock-based compensation were $0.3 million ($0.2 million in R&D and $0.1 million in S, G & A) and $0.5 million ($0.3 million in R&D and $0.2 million in S, G & A), respectively. For the six months ended June 30, 2016 and 2015, the charges for depreciation and stock-based compensation were $1.0 million ($0.5 million in R&D and $0.5 million in S, G & A) and $1.3 million ($0.7 million in R&D and $0.6 million in S, G & A), respectively.

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

	June 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,330	$ 38,722
Prepaid interest, current portion	1,164	1,710
Prepaid expenses and other current assets	454	362
Total current assets	21,948	40,794
Property and equipment, net	1,048	1,039
Restricted cash	225	225
Prepaid interest, non-current portion	1,777	2,319
Total Assets	$ 24,998	$ 44,377
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 15,055	$ 10,845
Common stock warrant liability	–	223
Total current liabilities	15,055	11,068
Long-term debt	25,000	25,000
Other liabilities	162	43
Stockholders' Equity	(15,219)	8,266
Total Liabilities and Stockholders' Equity	$ 24,998	$ 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.