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

March 31, 2017
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 March 31, 2017, Windtree Therapeutics, Inc. (the "Company") issued a press release highlighting the results of operations for the quarter ended December 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 December 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 reports that, before any additional financings, the Company anticipates that it will have sufficient cash to fund its operations through the planned completion of the AEROSURF phase 2b clinical trial and announcement of results in mid-year 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 March 31, 2017

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: March 31, 2017

Exhibit 99.1

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

Company Continues to Advance Phase 2 Program and is On-Track for Mid-Year Phase 2b Results

WARRINGTON, PA – March 31, 2017 – Windtree Therapeutics, Inc. (Nasdaq: WINT), a biotechnology company focused on developing aerosolized KL4 surfactant therapies for respiratory diseases, today reported financial results for the fourth quarter ended December 31, 2016 and provided key business updates.

Key Business and Financial Updates

- Enrollment in the AEROSURF® phase 2b clinical trial in up to 240 premature infants 28 to 32 week gestational age for respiratory distress syndrome (RDS) is progressing and the Company reaffirms its plan to announce top-line results from this study in mid-year 2017.

- Enrollment in the third dose group of the AEROSURF phase 2a clinical trial in 48 premature infants 26 to 28 week gestational age for RDS is progressing. This study is designed to evaluate safety and tolerability of AEROSURF. Due to a lower number of premature infants who are eligible for enrollment in this age range, enrollment has required additional time and the Company now expects to complete enrollment and announce top-line results in mid-second quarter of 2017.

- The Company previously reported positive results from two NIH funded preclinical studies evaluating (i) KL4 surfactant as a possible countermeasure to mitigate acute and chronic/late-phase radiation induced lung injury; and, (ii) as a potential medical intervention to reduce morbidity and mortality associated with both seasonal and pandemic influenza pneumonia.

- As of December 31, 2016, the Company had cash and cash equivalents of $5.6 million. In February 2017, the Company completed a private placement offering of 7,049 Series A Convertible Preferred Stock units for net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration in the form of a reduction in amounts due for current development services that otherwise would have become payable in cash in the first and second quarters of 2017.

- The Company anticipates that, before any additional financings, its currently existing cash resources are sufficient to fund its operations through the planned completion of the AEROSURF phase 2b clinical trial and announcement of results in mid-year 2017.

“The fourth quarter of 2016 was one of meaningful progress for Windtree and our AEROSURF phase 2 program,” commented Craig Fraser, President and Chief Executive Officer. “The expansion of our phase 2b clinical trial to select sites in Europe and Latin America resulted in an increased rate of patient screening and enrollments. We have enrolled patients from all regions and active sites and are on track with previously stated guidance to release top-line data by mid-year 2017. In addition, with the successful completion of the $10.5 million private placement in February, we have met our previously stated goal of securing the additional capital necessary to adequately fund our operations through announcement of top line phase 2b data.”

Select Financial Results for the Fourth Quarter ended December 31, 2016

For the quarter ended December 31, 2016, the Company reported an operating loss of $6.4 million, compared to $9.8 million for the fourth quarter of 2015.

Grant revenue for the fourth quarter of 2016 was $0.9 million compared to $0.7 million for the fourth quarter of 2015. Grant revenue for 2016 primarily represents funds received and expended under Small Business Innovation Research (SBIR) Grants from the National Institutes of Health (NIH) to study the Company's aerosolized KL4 surfactant as (i) a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury; and, (ii) to provide support for the AEROSURF phase 2b clinical trial in premature infants 28 to 32 week gestational age with RDS. The 2015 grant revenue was from a SBIR Grant from the NIH to study the Company's aerosolized KL4 surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury.

Research and development expenses were $5.9 million for the fourth quarter of 2016, compared to $8.2 million for the fourth quarter of 2015. The decrease was due to reductions in (i) development costs under the Battelle collaboration agreement for the next generation aerosol delivery system for use in our remaining AEROSURF development activities and, if approved, initial commercial activities; and, (ii) the technology transfer of our lyophilized surfactant manufacturing process to a new facility at our CMO to conserve our cash resources and better align the manufacture of our clinical drug supply with our expected revised clinical time lines.

Selling, general and administrative expenses for the fourth quarter of 2016 were $1.3 million, compared to $2.2 million for the fourth quarter of 2015. The decrease was primarily due to cost reduction initiative initiated in the second quarter of 2016 as we focus our limited resources on advancing the AEROSURF clinical development program.

Interest expense for the fourth quarter of 2016 and 2015 was $0.6 million.

The Company reported a net loss of $6.6 million ($0.77 per basic share) on 8.5 million weighted-average common shares outstanding for the quarter ended December 31, 2016, compared to a net loss of $10.1 million ($1.26 per basic share) on 8.1 million weighted average common shares outstanding for the comparable period in 2015.

Net cash outflows before financing activities for the fourth quarter of 2016 were $6.9 million.

As of December 31, 2016, the Company had cash and cash equivalents of $5.6 million. In February 2017, the Company completed a private placement offering which generated net proceeds of approximately $10.5 million, including $1.6 million of non-cash consideration in the form of a reduction in amounts due for current development services that otherwise would have become payable in cash in the first and second quarters of 2017. In addition, from January 1, 2017 through March 23, 2017, we completed registered offerings under our at-the-market equity sales program resulting in net proceeds to us of $0.9 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 mid-year 2017.

In addition, as of December 31, 2016, the Company reported current liabilities of $13.4 million and long-term debt 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 Annual Report on Form 10-K for the year ended December 31, 2016 which is expected to be filed with the Securities and Exchange Commission on March 31, 2017, which includes discussion about the Company's business plans and operations, financial condition and results of operations.

About AEROSURF®
Windtree's lead product candidate is AEROSURF®, a novel, investigational drug/device combination 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 28 to 32-week gestational age receiving nasal continuous positive airway pressure (nCPAP) for RDS, comparing AEROSURF 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: the risk that, as a development company, with limited resources and no operating revenues, the Company's ability to continue as a going concern in the near term is highly dependent upon the successful completion of the AEROSURF phase 2b clinical trial in mid-2017 and obtaining results sufficient to support a strategic or financing transaction; 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 Windtree's AEROSURF development program and other development programs 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 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:
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Windtree Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Revenues:				
Product sales	$ –	$ –	$ –	$ 7
Grant revenue	900	655	2,042	980
	900	655	2,042	987
Operating expenses: [1]				
Cost of product sales	–	–	–	929
Research and development	5,948	8,225	31,705	28,888
Selling, general and administrative	1,320	2,211	8,373	11,004
Total expenses	7,268	10,436	40,078	40,821
Operating loss	(6,368)	(9,781)	(38,036)	(39,834)
Change in fair value of common stock warrant liability [1]	–	274	223	851
Loss on debt extinguishment	–	–	–	(11,758)
Interest income / (expense), net	(608)	(604)	(2,500)	(4,579)
Other income / (expense), net	374	2	823	150
Net loss	$ (6,602)	$ (10,109)	$ (39,490)	$ (55,170)
Net loss per common share – basic and diluted	$ (0.77)	$ (1.26)	$ (4.74)	$ (7.98)
Weighted avg. common shares outstanding – basic and diluted	8,523	8,050	8,328	6,967

[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 December 31, 2016 and 2015, the charges for depreciation and stock-based compensation were $0.4 million ($0.2 million in R&D and $0.2 million in S, G & A) and $0.4 million ($0.2 million in R&D and $0.2 million in S, G & A), respectively. For the twelve months ended December 31, 2016 and 2015, the charges for depreciation and stock-based compensation were $1.7 million ($0.9 million in R&D and $0.8 million in S, G & A) and $2.2 million ($1.1 million in R&D and $1.1 million in S, G & A), respectively.

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

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,588	$ 38,722
Prepaid interest, current portion	1,094	1,710
Prepaid expenses and other current assets	512	362
Total current assets	7,194	40,794
Property and equipment, net	1,054	1,039
Restricted cash	225	225
Prepaid interest, non-current portion	1,226	2,319
Total Assets	$ 9,699	$ 44,377
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable, collaboration payable and accrued expenses	$ 13,391	$ 10,845
Common stock warrant liability	–	223
Total current liabilities	13,391	11,068
Long-term debt	25,000	25,000
Other liabilities	138	43
Stockholders' Equity	(28,830)	8,266
Total Liabilities and Stockholders' Equity	$ 9,699	$ 44,377