

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

February 16, 2017

Date of Report (Date of earliest event reported)

Windtree Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-26422
(Commission File Number)

94-3171943
(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))
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Item 8.01. Other Events.

On February 16, 2017, Windtree Therapeutics, Inc. (the "Company") will host a conference call and live webcast at 8:00 a.m. to provide updates relating to: (i) the previously reported \$10.5 million offering of Series A Convertible Preferred Units and the Company's financial and cash position, (ii) the ongoing AEROSURF[®] phase 2 clinical program in premature infants, and (iii) business development initiatives.

To participate in the live call and take part in the question and answer session, dial (844) 802-2436 (domestic) or (412) 317-5129 (international). The live webcast, including a slide presentation, can be accessed at <http://windtretrx.investorroom.com/events>.

A replay of the conference call will be accessible one hour after completion by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing passcode 10101774. An archive of the webcast can be accessed on the Company's website at <http://windtretrx.investorroom.com/events>.

Financial Update

The Company's recent offering of Series A Convertible Preferred Units (the "Offering"), which closed on February 15, 2017, is described in detail in a Current Report on Form 8-K filed with the Securities and Exchange Commission on February 15, 2017. Each unit consists of (i) one share of Series A Convertible Preferred Stock, par value \$0.001 per share, of the Company; and (ii) 1,000 Series A-1 Warrants to purchase one share of Common Stock at an exercise price equal to \$1.37. The Offering was conducted by the Company directly without the assistance of an investment bank or placement agent. The Offering was made to investors known to the Company who represented a mix of new and existing holders. Of the \$10.5 million proceeds, \$1.6 million was non-cash consideration in the form of a reduction in future payments of current development services that otherwise would have been payable in cash in the first and second quarters of 2017.

The Company reported that, as of December 31, 2016, it had cash and cash equivalents totaling \$5.6 million. The Company's net operating cash outflows for the quarter ended December 31, 2016 were \$6.9 million, compared to \$8.3 million for the quarter ended September 30, 2016. The fourth quarter cash outflows were partially offset by net \$0.2 million of proceeds from financings under the Company's at-the-market equity sales (ATM) Program with Stifel, Nicolaus & Company, Incorporated. In addition, to conserve capital resources, the Company has implemented approximately \$1.4 million in cash outflow reductions and expects to pursue similar non-dilutive opportunities to increase or conserve its cash resources. Before any additional financings or other transactions, the Company believes that it will have sufficient cash resources to support its development activities, fund its business operations and debt service obligations through completion of the AEROSURF phase 2b clinical trial and announcement of results in mid-year 2017.

AEROSURF Phase 2 Clinical Program Update

AEROSURF is the Company's novel, investigational drug/device combination product that combines the Company's proprietary KL4 surfactant with its proprietary aerosol delivery system (ADS). AEROSURF is being developed to potentially reduce or eliminate the need for endotracheal intubation and mechanical ventilation in the treatment of premature infants with RDS.

AEROSURF phase 2a clinical trial in premature infants 26 to 28 week gestational age

The Company provided a status report on the ongoing phase 2a clinical trial in premature infants 26 to 28 week gestational age. The trial is a multicenter, randomized, open-label, controlled clinical study in premature infants 26 to 28 week gestational age receiving nCPAP for RDS. The study has progressed to a third dose group, which is designed to assess 60 minute doses of aerosolized KL4 surfactant administered using the Company's ADS. The third dose group is expected to be completed in the first quarter of 2017. To date, safety and tolerability objectives have been met. The Company plans to assess the results of this study and consider potential additional dose-response evaluations in the 26-28 week gestational age range after completion of the phase 2b clinical trial in premature infants 28 to 32 week gestational age.

AEROSURF phase 2b clinical trial in premature infants 26 to 32 week gestational age

The ongoing AEROSURF phase 2b clinical trial is a multicenter, randomized, controlled study with masked treatment assignment in up to approximately 240 premature infants and is designed to evaluate aerosolized KL4 surfactant (including with up to two potential repeat doses) administered in two dose groups (25 and 50 minutes) compared to infants receiving nCPAP alone. The Company is conducting this trial in approximately 45 clinical sites in the U.S., Canada, Europe and Latin America. The increase in the number of clinical sites has increased the rate of enrollment and, as a result, the Company expects to be in a position to release top-line data in mid-year 2017, as previously forecast.

Business Development Initiatives

The Company continues its efforts to secure the additional capital that will be required to continue its AEROSURF development program and fund its operations. The Company is actively pursuing all or a combination of potential strategic alliances, collaboration agreements and other strategic transactions. The Company is currently focused on identifying select geographical licensing opportunities that could provide strategic partners with financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) to support the AEROSURF development program, as well as local development and commercial expertise to support the development of AEROSURF in markets outside the United States. The Company is currently actively engaged in discussions with a potential partner that has expressed its commitment to negotiating a licensing arrangement for select Asian markets.

In addition, following completion of the phase 2 clinical program, the Company expects that it may be better positioned to identify and potentially enter into one or more strategic transactions with medium-to-large companies focused in such areas as acute or institutional and/or pulmonary care or neonatology.

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 us in this Current Report on Form 8-K is based only on information currently available to us and speaks only as of the date on which it is made. We 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.

Windtree Therapeutics, Inc.

By: /s/ Craig Fraser
Name: Craig Fraser
Title: President and Chief Executive Officer

Date: February 16, 2017