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

FORM SD
SPECIALIZED DISCLOSURE REPORT

Windtree Therapeutics, Inc.

(Exact Name of Registrant as Specified in 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, PA 18976-3622
(Address of Principal Executive Offices)

Mary B. Templeton, Esq. **(215) 488-9300**
(Name and telephone number, including area code, of the person to contact in connection with this report.)

Check the appropriate box to indicate the rule pursuant to which this form is being filed, and provide the period to which the information in this form applies:

Rule 13p-1 under the Securities Exchange Act (17 CFR 240.13p-1) for the reporting period from January 1 to December 31, 2015.

Section 1 - Conflict Minerals Disclosure

Item 1.01 Conflict Minerals Disclosure

This Form SD of Windtree Therapeutics, Inc. (referred to as “we,” “us,” or the “Company”) is filed pursuant to Rule 13p-1 under the Securities Exchange Act of 1934 for the reporting period from January 1, 2015 to December 31, 2015. We are a biotechnology company focused on developing novel KL4 surfactant therapies for respiratory diseases and other potential applications.

In 2015, we contacted the manufacturers of our products and requested that they inform us as to whether those products contained conflict minerals. The manufacturers provided us bills of materials setting forth the components of each of our products, from which we determined that certain of our products include “conflict minerals”¹ that are necessary to the functionality or production of such products. In order to determine if our necessary conflict minerals included in products we manufacture may have originated in the Democratic Republic of the Congo or an adjoining country (collectively, the “Covered Countries”), we requested our manufacturers to complete a Reasonable Country of Origin (“RCOI”) questionnaire for each such conflict mineral. At this time we are unable to determine whether any of our necessary conflict minerals included in products we manufactured in 2015 may have originated in the Covered Countries or from recycled or scrap sources.

We recognize that the global supply chain tracing of these materials is complex; however, we are committed to working with our suppliers to determine whether the products we manufacture or contract to manufacture are “conflict free;” that is, that they either do not contain conflict minerals from the Covered Countries or originate from recycled or scrap materials.

Item 1.02 Exhibits

[Exhibit 1.01](#) is hereby incorporated into this item by reference.

¹ As defined in Rule 13p-1 under the Securities Exchange Act of 1934, as amended.

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 duly authorized undersigned.

Windtree Therapeutics, Inc.

By: /s/ Craig Fraser

Name: Craig Fraser

Title: President and Chief Executive Officer

Date: May 31, 2016

Windtree Therapeutics, Inc.

May 31, 2016

Conflict Minerals Report

For the Year Ended December 31, 2015

This report for the year ended December 31, 2015 is presented to comply with Rule 13p-1 and Form SD (collectively, the “Rule”) promulgated under the Securities Exchange Act of 1934, as amended. The Rule was adopted by the Securities and Exchange Commission (“SEC”) to implement reporting and disclosure requirements related to conflict minerals as directed by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (“Dodd-Frank Act”). The Rule imposes certain reporting obligations on SEC registrants whose manufactured products contain conflict minerals which are necessary to the functionality or production of their products. Conflict Minerals are defined as cassiterite, columbite-tantalite, gold, wolframite, and their derivatives, which are limited to tin, tantalum, tungsten, and gold².

I. Company Overview

Windtree Therapeutics, Inc. is a biotechnology company focused on developing novel KL₄ surfactant therapies for respiratory diseases and other potential applications. The Company’s 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.

Our core development program, AEROSURF® (lucinactant for inhalation), is focused on improving the management of respiratory distress syndrome (RDS) in premature infants. AEROSURF is an investigational combination drug/device product that combines our proprietary KL₄ surfactant with our novel aerosol delivery system (ADS), which is based primarily on our capillary aerosol generator technology. We contract with third parties to manufacture our AEROSURF devices.

The drug product component of our AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL₄ surfactant liquid instillate drug product that was approved by the U.S. Food and Drug Administration (FDA) in 2012 under the name SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. We made available to hospitals that purchased SURFAXIN a WARMING CRADLE® dry-block heater, which is listed with the FDA as a Class I, exempt laboratory device. WARMING CRADLE devices warm drug vials at the temperature and for the time designated in the SURFAXIN prescribing information. In mid-April 2015, we implemented a plan to cease the commercialization of SURFAXIN. As a result, WARMING CRADLE devices are no longer being manufactured or distributed.

We have also developed a disposable aerosol-conducting airway connector for infants that is intended to simplify the delivery of aerosolized medications (including our aerosolized KL₄ surfactant) and other inhaled therapies to critical-care infants requiring ventilatory support. This device introduces aerosolized medications directly at the patient interface and minimizes the number of connections in the ventilator circuit. We have registered this device as a Class I, exempt medical device in the United States under the name AFECTAIR®. We have determined to reserve AFECTAIR for use with our AEROSURF system and aerosol development program and no longer plan to make this product available commercially. We have determined that our AFECTAIR device does not contain any conflict minerals.

² For a more complete definition, see Rule 13p-1 under the Securities Exchange Act of 1934, as amended.

II. Due Diligence and Reasonable Country of Origin Inquiry Process and Results

In 2015, the manufacturer of our AEROSURF device (CMO) began contacting its vendors, on our behalf, regarding the presence of conflict minerals in the AEROSURF components and requested those vendors to complete a Reasonable Country of Origin (“RCOI”) questionnaire for each identified conflict mineral. Most of the vendors contacted represented that the components they supplied our CMO did not contain conflict minerals. We will continue to work with the vendors who have not yet provided information concerning the components they supplied to our CMO in order to determine the presence of conflict minerals in those components, and with respect to any such components that contain conflict minerals, their origin.

Following receipt of our RCOI questionnaire, the manufacturer of our WARMING CRADLE device provided us documentation evidencing that we had completed the purchase of all of the components containing conflict minerals included in all of the WARMING CRADLEs prior to January 31, 2013. In addition, we have not had any WARMING CRADLEs manufactured since December 31, 2013, and will not have any WARMING CRADLEs manufactured in the future. Accordingly, the conflict minerals included in those WARMING CRADLEs are not subject to the Rule for this 2015 Report.

III. Conclusion

Based on our evaluation as described above, while we have concluded that the AEROSURF device is the only product that we manufactured in 2015 that contains conflict minerals that are subject to reporting on Form SD, at this time we are not certain whether any such conflict minerals may have originated in the Covered Countries or from recycled or scrap sources. We will continue to work with our manufacturers and their vendors to gather additional information regarding the presence of conflict minerals in our products and the origin of such conflict minerals.