
**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

Date of Report (Date of earliest event reported): September 4, 2018

RESPIRERX PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

1-16467
(Commission
File Number)

33-0303583
(I.R.S Employer
Identification No.)

126 Valley Road, Suite C
Glen Rock, New Jersey
(Address of principal executive offices)

07452
(Zip Code)

Registrant's telephone number, including area code: (201) 444-4947

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01. Entry into a Material Definitive Agreement

On September 4, 2018 (the “Effective Date”), RespireRx Pharmaceuticals Inc. (the “Company”) entered into a Development and Supply Agreement (the “Agreement”) with Noramco, Inc. (“Noramco”), by which Noramco agreed to (i) provide all of the active pharmaceutical ingredient (“API”) estimated to be needed for the clinical development process for both the first- and second-generation products (each a “Product” and collectively, the “Products”), three validation batches for NDA filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files (“DMFs”) with the Food and Drug Administration (“FDA”) or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company, and participate in all FDA or Drug Enforcement Agency meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company (i) agreed to purchase exclusively from Noramco during the commercialization phase all API for its Products at a pre-determined price subject to certain producer price adjustments, and (ii) agreed to Noramco’s participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time. The Agreement will expire five years after the commercialization of the Products unless sooner terminated by the terms of the Agreement. The Agreement includes customary termination, indemnification, confidentiality, intellectual property and other provisions.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the Agreement, a copy of which the Company intends to file as an exhibit to the Company’s Form 10-Q for the quarterly period ending September 30, 2018, with portions omitted and separately filed with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Item 8.01. Other Events

On September 10, 2018, the Company issued a press release announcing its entry into the Agreement. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

A list of exhibits required to be filed as part of this report is set forth in the Exhibit Index, which is presented elsewhere in this document, and is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number

Exhibit Description

99.1

[Press Release dated September 10, 2018.*](#)

* Furnished herewith.

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.

Date: September 10, 2018

RESPIRERX PHARMACEUTICALS INC.
(Registrant)

By: /s/ Jeff E. Margolis

Jeff E. Margolis
SVP, CFO, Secretary and Treasurer



**RespireRx Pharmaceuticals Inc. Secures Clinical and Commercial Supply of Dronabinol for
Obstructive Sleep Apnea with the Signing of a
Development and Supply Agreement with Noramco, Inc.**

Glen Rock, N.J., September 10, 2018 /Globe Newswire – RespireRx Pharmaceuticals Inc. (OTCQB: RSPI) (“RespireRx” or the “Company”), is pleased to announce that on September 4, 2018, it entered into a dronabinol Development and Supply Agreement (“Agreement”) with Noramco, Inc. RespireRx is developing dronabinol for Obstructive Sleep Apnea (“OSA”), a condition that affects an estimated 29.4 million Americans and for which there is no approved pharmaceutical therapy. RespireRx believes, subject to meeting with the Food and Drug Administration (“FDA”), that dronabinol is Phase 3 ready.

Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient (“API”) estimated to be needed for the clinical development process for both the first- and second-generation products (each a “Product” and collectively, the “Products”), three validation batches for NDA filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files (“DMFs”) with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in all FDA or Drug Enforcement Agency (“DEA”) meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company agreed to purchase exclusively from Noramco during the commercialization phase all API for its Products at a pre-determined price subject to certain producer price adjustments, and agreed to Noramco’s participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.

“We are very pleased and excited to enter into this development and supply agreement with Noramco, a leading dronabinol manufacturer,” said Dr. Arnold Lippa, the Company’s Executive Chairman and Chief Scientific Officer. “There are significant FDA and DEA regulatory and manufacturing complexities surrounding the dronabinol supply chain, considered a DEA Schedule I drug as API and a Schedule III drug as a gel capsule. Through this arrangement with Noramco, we believe that we have solved not only some of our regulatory concerns, but also secured appropriate manufacturing capacity. We believe that the potential OSA market is extremely large, many times larger than the current market for dronabinol for currently approved indications, so the commitment by Noramco to provide clinical material and to ensure commercial supply demonstrates our mutual belief that dronabinol for OSA can be a commercial success.”

“Supplying a high-purity dronabinol to RespireRx to meet such a significant unmet medical need reflects the core of our capability,” said Tim Jones, Director of Global Cannabinoids Portfolio, Noramco. “We appreciate that RespireRx recognizes our ten years of experience in cannabinoids manufacture for pharmaceutical products, including the regulatory and supply chain expertise we bring to DEA Schedule I through III APIs. We look forward to partnering with RespireRx with high-quality dronabinol as the company moves toward regulatory approval.”

About RespireRx Pharmaceuticals Inc.

RespireRx Pharmaceuticals Inc. is a leader in the development of medicines for respiratory disorders and CNS indications, with a focus on obstructive sleep apnea, attention deficit hyperactivity disorder (ADHD), spinal cord injury, other neurological conditions and drug-induced respiratory depression. The Company holds exclusive licenses and owns patents and patent applications or rights thereto for certain families of chemical compounds that claim the chemical structures and their uses in the treatment of a variety of disorders, as well as claims for novel uses of known drugs.

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Cannabinoids. RespireRx is developing dronabinol, a synthetic derivative of a naturally occurring substance in the cannabis plant, for the treatment of OSA, a serious respiratory disorder that impacts an estimated 29.4 million people in the United States according to the American Academy of Sleep Medicine (“AASM”), published in August 2016. OSA has been linked to increased risk for hypertension, heart failure, depression, and diabetes, and has an annual economic cost in the United States of approximately \$162 billion according to the AASM. There are no approved drug treatments for OSA.

RespireRx believes, pending the outcome of an intended meeting with the FDA, that it will be able to commence a Phase 3 clinical study for the treatment of OSA with dronabinol. The Company further believes that it would only require approval by the FDA of a 505(b)(2) new drug application (“NDA”), an efficient regulatory pathway.

RespireRx believes that the most direct route to commercialization is to proceed directly to a Phase 3 pivotal trial using the currently available dronabinol formulation (2.5, 5 and 10 mg gel caps) and to then commercialize a RespireRx branded dronabinol capsule (“RBDC”).

RespireRx also believes that there are numerous opportunities for reformulation of dronabinol to produce a second-generation proprietary, branded product for the treatment of OSA with an improved profile. Therefore, simultaneous with the development of the RBDC, RespireRx plans to develop a proprietary dronabinol formulation to optimize the dose and duration of action for treating OSA.

Ampakines. The second platform of proprietary medicines being developed by RespireRx are ampakines, which act to enhance the actions of the excitatory neurotransmitter glutamate at AMPA glutamate receptors. Several ampakines, in both oral and injectable forms, are being developed by the Company for the treatment of a variety of CNS disorders including ADHD and spinal cord injury.

Ampakines have shown potential as possible therapeutic agents for the treatment of certain neuropsychiatric and neurological disorders. Ampakines have demonstrated statistically significant improvement of symptoms observed in a Phase 2 clinical trial of CX717 in adults with ADHD. This represents a successful translation from earlier animal and preclinical studies. At present, the major pharmacotherapies available for ADHD are made up of two types of drugs. Stimulants, such as amphetamine, rapidly produce robust effects, but suffer from side effects typical of stimulants, including tolerance, dependence, withdrawal and abuse. For these reasons, stimulants are scheduled by the FDA. Non-stimulants, such as Strattera® (atomoxetine) tend to be less effective than stimulants, with a much longer (approximately 4 – 8 week) latency to onset of action. In a number of animal and human studies, CX717 and other ampakines did not display any stimulant properties typically associated with drugs like amphetamine. In the Phase 2 ADHD clinical trial, statistically significant therapeutic effects were observed within one week. Therefore, we believe ampakines may represent a novel, non-stimulant treatment for ADHD with a more rapid onset of action than alternative non-stimulant treatment options. Additionally, in clinical studies of respiratory function, select ampakines have shown preliminary efficacy in central sleep apnea and in the control of respiratory depression produced by opioids, without altering the opioid analgesic effects. In animal models of spinal cord injury, an ampakine has been shown to improve motor function. In animal models of certain orphan disorders, such as Pompe Disease, Rett’s Syndrome and perinatal respiratory distress, certain ampakines have been shown to improve breathing function.

RespireRx owns certain composition of matter and use patents and patent applications with respect to ampakines CX1739, CX717 and other ampakines. The Company has received notice from the University of Alberta that purports to terminate the Company’s license in respect of patents associated with respiratory applications of ampakines. RespireRx has been in contact with the University of Alberta and is engaging in a dispute resolution process with respect to its license with the University of Alberta in respect to use patents associated only with respiratory applications of ampakines.

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Additional information about the Company and the matters discussed herein can be obtained on the Company's web-site at www.RespireRx.com or in the Company's filings with the Securities and Exchange Commission at www.sec.gov.

About Noramco, Inc.

Noramco, headquartered in Wilmington, Delaware, is a leading North American producer of controlled substances bulk APIs for the pharmaceutical industry. The company offers cannabinoids and APIs for use in abuse deterrence, attention deficit disorder, pain management, and addiction management. Established in 1979, Noramco maintains production and R&D facilities in Delaware and Georgia (USA), and Neuhausen, Switzerland. Noramco leverages decades of expertise in controlled substance development, licensing and scale up thereby offering pharmaceutical companies a fully integrated supply chain for synthetic cannabinoid-based APIs. Additional information about Noramco can be obtained by visiting www.Noramco.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Company intends that such forward-looking statements be subject to the safe harbor created thereby. These might include statements regarding the Company's future plans, targets, estimates, assumptions, financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about research and development efforts, including, but not limited to, preclinical and clinical research design, execution, timing, costs and results, future product demand, supply, manufacturing, costs, marketing and pricing factors.

In some cases, forward-looking statements may be identified by words including "anticipates," "believes," "intends," "estimates," "expects," "plans," "contemplates," "targets," "continues," "budgets," "may," and similar expressions and such statements may include, but are not limited to, statements regarding (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of the Company's proposed products, (iv) reorganization plans, (v) the clinical development, regulatory review and commercialization process, and (vi) the need for, and availability of, additional financing.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. These forward-looking statements are based on assumptions regarding the Company's business and technology, which involve judgments with respect to, among other things, future scientific, economic, regulatory and competitive conditions, collaborations with third parties, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the Company's control. Although the Company believes that the assumptions underlying the forward-looking statements are reasonable, actual results may differ materially from those set forth in the forward-looking statements. In light of the significant uncertainties inherent in the forward-looking information included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the Company's objectives or plans will be achieved.

Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, interest of third parties in collaborations with us, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements (unaudited) and notes thereto included in Item 1 of the Company's Quarterly Report on Form 10-Q and the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including the section entitled "Item 1A. Risk Factors." The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

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