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): November 14, 2022

RESPIRERX PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**1-16467**	**33-0303583**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S Employer Identification No.)**

126 Valley Road, Suite C **Glen Rock, New Jersey**	**07452**
(Address of principal executive offices)	**(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 7.01 Regulation FD Disclosure.

On November 14, 2022, RespireRx Pharmaceuticals Inc. (the "Company") entered into a letter of intent ("LOI") with an Australia headquartered bespoke clinical research organization ("CRO") focused on cannabinoid and psychedelic clinical research. The LOI calls for a target execution date for a definitive contract that is 30 days from the date of the LOI, at which time RespireRx will be required to make a US$50,000 deposit to be applied to the final studies budget and credited against the first invoice under the definitive contract. Under the definitive contract, the CRO is expected to provide full service CRO services, including regulatory, compliance, GMP (good manufacturing practices) manufacturing services in addition to human pharmacokinetic and pivotal human efficacy and safety studies of dronabinol for the treatment of obstructive sleep apnea.

The press release dated November 17, 2022 announcing the LOI, which includes further details with respect to the LOI, is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

A list of exhibits that are furnished and filed as part of this report is set forth in the Exhibit Index, which follows, and is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Exhibit Description
99.1*	Press Release dated November 17, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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: November 17, 2022

RESPIRERX PHARMACEUTICALS INC.
(Registrant)

By: */s/ Jeff E. Margolis*
Jeff E. Margolis
SVP, CFO, Secretary and Treasurer

Exhibit 99.1

RespireRx Pharmaceuticals Inc. Announces Entry into Letter of Intent with Australian Headquartered CRO for Dronabinol Development for Obstructive Sleep Apnea

Glen Rock, N.J., November 17, 2022 /Globe Newswire – RespireRx Pharmaceuticals Inc. (OTC Pink Market:RSPI) ("RespireRx" or the "Company"), a leader in the discovery and development of innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling, is pleased to announce that, on November 14, 2022, the Company entered into a letter of intent ("LOI") with an Australia headquartered bespoke clinical research organization focused on cannabinoid and psychedelic clinical research.

This press release contains forward looking statements. Please carefully read the sections below entitled "*Not a Securities Offering"* and "*Cautionary Note Regarding Forward-Looking Statements."*

The LOI calls for a target execution date for a definitive contract that is 30 days from the date of the LOI, at which time RespireRx will be required to make a US$50,000 deposit to be applied to the final studies budget and credited against the first invoice under the definitive contract. Under the definitive contract, the CRO is expected to provide full service CRO services, including regulatory, compliance, GMP (good manufacturing practices) manufacturing services in addition to human pharmacokinetic and pivotal human efficacy and safety studies of dronabinol for the treatment of obstructive sleep apnea.

The entry into this LOI is anticipated to be the first step in a series of transactions that are expected to include:

- Formation of an Australian subsidiary of RespireRx, and all that is required in the formation process, including, among other things, the establishment of a board of directors and the engagement of accountants. The subsidiary, anticipated to be named ResolutionRx (or a similar name), is being formed primarily to engage in the research and development ("R&D") activities that will be the subject of the definitive contract. In good faith, the Company intends to commence the formation of the Australian subsidiary as soon as practical.
- Contribution of, or the making available of certain dronabinol assets and certain liabilities to the newly formed Australian subsidiary.
- Agreement on the final budget for the scope of the work in the definitive contract, currently anticipated to be approximately US$17 million, but which is subject to change.
- Obtaining an independent valuation report of the assets contributed to the subsidiary by the Company.
- If consummated, of which no assurance can be provided, an equity or equity-linked financing of up to 25% of the research and development budget at either the subsidiary level or at the Company level to be utilized exclusively to support the R&D budget.
- Participation in the 43.5% Australian research and development tax credit program, which the Company believes may be financeable in advance of final receipt of the tax credit funds, over the course of the R&D timeline and at a reasonable discount to the ultimate amount of the expected credit.
- The equity or equity-linked financing plus the financing of the research and development tax credit, if consummated, of which no assurance can be provided, are anticipated to represent approximately 60% of the total R&D budget and approximately 49% of the total funding required by ResolutionRx inclusive of non-R&D budget overhead.
- The Company will need to identify one or more additional sources of capital to fund the balance of the R&D and the non-R&D overhead of which no assurance can be provided.
- The Company cannot assure that a definitive contract will be executed, or that any of the anticipated financings described above will consummate on terms acceptable to the Company or ResolutionRx or at all.

About RespireRx Pharmaceuticals Inc.

RespireRx Pharmaceuticals Inc. is a leader in the discovery and development of medicines for the treatment of psychiatric and neurological disorders, with a focus on treatments that address conditions affecting millions of people, but for which there are few or poor treatment options, including (i) pharmaceutical cannabinoids, which include dronabinol, a synthetic form of Δ9-tetrahydrocannabinol ("Δ9-THC") that acts upon the nervous system's endogenous cannabinoid receptors and (ii) neuromodulators, which include AMPAkines and GABAkines, proprietary chemical entities that positively modulate (positive allosteric modulators or "PAMs") AMPA-type glutamate receptors and $GABA_A$ receptors. RespireRx is developing a pipeline of re-purposed and new drug products based on our broad patent portfolios for the above two drug platforms including obstructive sleep apnea ("OSA"), attention deficit hyperactivity disorder ("ADHD"), epilepsy, pain, recovery from spinal cord injury ("SCI"), and certain neurological orphan diseases.

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.

***ResolutionRx: Pharmaceutical Cannabinoids*.**

Dronabinol. RespireRx's ResolutionRx business unit is developing dronabinol, Δ-9-THC, a synthetic version of the 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 $162 billion according to the AASM. There are no approved drug treatments for OSA.

Two Phase 2 clinical trials have been completed demonstrating the ability of dronabinol to significantly reduce the symptoms of OSA and, subject to raising sufficient financing (of which no assurance can be provided) and pending the outcome of an intended meeting with the FDA, RespireRx believes that it will be able to commence a pharmacokinetic study for a recently discovered and to-be-developed formulation followed by a Phase 3 clinical study for the treatment of OSA with the new formulation. Because dronabinol is already FDA approved for the treatment of AIDS related anorexia and chemotherapy induced nausea and vomiting, the Company believes that its re-purposing strategy would only require approval by the FDA of a 505(b)(2) new drug application ("NDA"), an efficient regulatory pathway that allows the use of publicly available data.

EndeavourRx: Neuromodulators

AMPAkines. Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, the Company has developed a family of novel, low impact AMPAkines, including CX717, CX1739 and CX1942 that may have clinical application in the treatment of CNS-driven neurobehavioral and cognitive disorders, spinal cord injury, neurological diseases, and certain orphan indications. Our lead clinical compounds, CX717 and CX1739, have successfully completed multiple Phase 1 safety trials. Both compounds have also completed Phase 2 proof of concept trials demonstrating target engagement, by antagonizing the ability of opioids to induce respiratory depression.

AMPAkines have demonstrated positive activity in animal models of ADHD, results that have been extended translationally into statistically significant improvement of symptoms observed in a Phase 2 human clinical trial of CX717 in adult patients with ADHD. Statistically significant therapeutic effects were observed within one week. We believe AMPAkines may represent a novel, non-stimulant treatment for ADHD with a more rapid onset of action than alternative non-stimulants, such as Straterra® (atomoxetine), and without the drawbacks of amphetamine-type stimulants.

In a series of important studies funded by grants from the National Institutes of Health and published in a number of peer reviewed articles, Dr. David Fuller (University of Florida), a long-time RespireRx collaborator, has demonstrated the ability of CX1739 and CX717, the Company's lead AMPAkines, to improve motor nerve activity and muscle function in animal models of spinal cord injury (SCI).

GABAkines. Under a License Agreement with the University of Wisconsin-Milwaukee Research Foundation, Inc. ("UWMRF") and on behalf of its EndeavourRx business unit, RespireRx has licensed rights to certain selectively acting GABAkines because of their ability to selectively amplify inhibitory neurotransmission at a highly specific, subset of $GABA_A$ receptors, thus producing a unique efficacy profile with reduced side effects. Preclinical studies have documented their efficacy in a broad array of animal models of interrelated neurological and psychiatric disorders including epilepsy, pain, anxiety, and depression in the absence of or with greatly reduced propensity to produce sedation, motor-impairment, tolerance, dependence and abuse. The Company currently is focusing on developing KRM-II-81 for the treatment of epilepsy and pain.

KRM-II-81 has displayed a high degree of anti-convulsant activity in a broad range of preclinical studies, including in treatment resistant and pharmaco-resistant models. Not only was KRM-II-81 highly effective in these models, but pharmaco-resistance or tolerance did not develop to its anti-convulsant properties. These latter results are particularly important because pharmaco-resistance occurs when medications that once controlled seizures lose efficacy as a result of chronic use and it is a principal reason some epileptic patients require brain surgery to control their seizures. In support of its potential clinical efficacy, translational studies have demonstrated the ability of KRM-II-81 to dramatically reduce epileptiform electrical activity when administered in situ to brain slices excised from treatment resistant epileptic patients undergoing surgery.

In addition, KRM-II-81 has displayed a high degree of analgesic activity in a broad range of preclinical studies. In intact animal models of pain, the analgesic efficacy of KRM-II-81 was comparable to or greater than commonly used analgesics. At the same time, KRM-II-81 did not display side effects such as sedation and motor impairment, but even more importantly, it did not produce tolerance, dependence, respiratory depression or behavioral changes indicative of abuse liability, which are produced by opioid narcotics and are at the heart of the opioid epidemic.

Additional information about RespireRx 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.

Not a Securities Offering or Solicitation

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sales of securities in any jurisdiction in which such offer, solicitation or sale of securities would be unlawful before registration or qualification under the laws of such jurisdiction.

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, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 "assumes," "could," "ongoing," "potential," "predicts," "projects," "should," "will," "would," "anticipates," "believes," "intends," "estimates," "expects," "plans," "contemplates," "targets," "continues," "budgets," "may," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words, 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 product candidates, (iv) reorganization plans, and (v) the need for, and availability of, additional financing. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this press release.

These factors include but are not limited to, regulatory policies or changes thereto, available cash, research and development results, issuance of patents, competition from other similar businesses, interest of third parties in collaborations with us, and market and general economic factors, and other risk factors disclosed in "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on April 15, 2022 (the "2021 Form 10-K").

You should read these risk factors and the other cautionary statements made in the Company's filings as being applicable to all related forward-looking statements wherever they appear in this press release. We cannot assure you that the forward-looking statements in this press release will prove to be accurate and therefore prospective investors, as well as potential collaborators and other potential stakeholders, are encouraged not to place undue reliance on forward-looking statements. You should read this press release completely. Other than as required by law, we undertake no obligation to update or revise these forward-looking statements, even though our situation may change in the future.

We caution investors, as well as potential collaborators and other potential stakeholders, not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described in the 2021 Form 10-K and in this press release, as well as others that we may consider immaterial or do not anticipate at this time. 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 we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties, including those described in the 2021 Form 10-K and in this press release. These risks and uncertainties are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time.

For more information about the risks and uncertainties the Company faces, see "Item 1A. Risk Factors" in our 2021 Form 10-K. Forward-looking statements speak only as of the date they are made. The Company does not undertake and specifically declines any obligation to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments. We advise investors, as well as potential collaborators and other potential stakeholders, to consult any further disclosures we may make on related subjects in our annual reports on Form 10-K and other reports that we file with or furnish to the SEC.

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