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): May 29, 2024

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** **(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
N/A	N/A	N/A

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.

RespireRx Pharmaceuticals Inc. (the "Company") issued a press release entitled "RespireRx Pharmaceuticals Inc. Announces a Department of Defense Award to Fund a Phase 2 Clinical Study to Determine the Safety and Efficacy of CX1739, its Lead AMPAkine, to Improve Bladder Function in Patients with Spinal Cord Injury." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. In the press release attached as Exhibit 99.1, the Company indicated that it is delighted to announce that, as part of an ongoing collaboration among scientist teams led Dr. Milap Sandhu, PT, PhD, research scientist at the Shirley Ryan AbilityLab, a rehabilitation research hospital in Chicago, and Dr. Arnold Lippa from RespireRx and Dr. David Fuller from the University of Florida, the Department of Defense has approved a $1.8 million translational research award to the Shirley Ryan AbilityLab to fund a two stage Phase 2A and 2B clinical trial in order to determine the safety and efficacy of CX1739, its lead clinical AMPAkine, to improve bladder function and motor activity in patients with spinal cord injury.

The U.S. Army Medical Research Acquisition Activity, in support of the Congressionally Directed Medical Research Program (CDMRP), is the awarding and administering acquisition office and this work will be supported by the Department of Defense, in the amount of $1,793,411, through the Spinal Cord Injury Research Program under Award No. HT94252410497. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Assistant Secretary of Defense for Health Affairs or the Department of Defense.

The description above, of the press release, does not purport to be complete and is qualified in its entirety by reference to the full press release attached as Exhibit 99.1.

The press release attached as Exhibit 99.1 includes certain forward-looking information.

The information in this Item 7.01 and the press release attached as Exhibit 99.1 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), nor otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	**Exhibit Description**
99.1*	RespireRx Pharmaceuticals Inc. Press Release
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: May 29, 2024

RESPIRERX PHARMACEUTICALS INC.
(Registrant)

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

Exhibit 99.1

RespireRx Pharmaceuticals Inc. Announces a Department of Defense Award to Fund a Phase 2 Clinical Study to Determine the Safety and Efficacy of CX1739, its Lead AMPAkine, to Improve Bladder Function in Patients with Spinal Cord Injury

Glen Rock, N.J., May 29, 2024 /Globe Newswire - RespireRx Pharmaceuticals Inc. (OTC Pink Markets: RSPI) (RespireRx or the Company), focused on the discovery and development of innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling, is delighted to announce that the Department of Defense (DOD) has approved a $1.8 million translational research award to Shirley Ryan AbilityLab to fund a two stage Phase 2A and 2B clinical study in order to determine the safety and efficacy of CX1739, its lead clinical AMPAkine, to improve bladder function and motor activity in individuals with spinal cord injury (SCI). This grant award supports the ongoing collaboration among scientist teams led by Milap Sandhu, PT, PhD, research scientist at Shirley Ryan AbilityLab, a rehabilitation research hospital in Chicago, and Dr. Arnold Lippa from RespireRx and Dr. David Fuller from the University of Florida.

The U.S. Army Medical Research Acquisition Activity, in support of the Congressionally Directed Medical Research Program (CDMRP), is the awarding and administering acquisition office and this work will be supported by the Department of Defense, in the amount of $1,793,411, through the Spinal Cord Injury Research Program under Award No. HT94252410497. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Assistant Secretary of Defense for Health Affairs or the Department of Defense.

Shirley Ryan AbilityLab has been ranked number one in rehabilitation by *U.S. News & World Report* since 1991 and cares for patients with the most severe, complex conditions, including SCI.

As the Principal Investigator, Dr. Sandhu will conduct the clinical trials at Shirley Ryan AbilityLab. Dr. Sandhu and Shirley Ryan AbilityLab have been allocated $1.8 million to conduct the actual clinical study of which RespireRx has been allocated $252,200 to manufacture and formulate the clinical material, as well as update and submit the CX1739 investigational new drug application (IND). Budget projections have determined that these amounts should be sufficient to pay for manufacturing and clinical costs and the plan is to begin testing in patients by the 4th quarter 2024. The trial will consist of two stages, the first being a Phase 2A will be an ascending single dose safety and efficacy study and the second Phase 2B will consist of a double blind, placebo-controlled study in which participants will be given CX1739 or placebo twice daily for a total of seven days.

As we have disclosed in an earlier press release and peer review publications, traumatic SCI often results in neurogenic bladder dysfunction that produces a plethora of urological complications leading to reductions in the quality of life and an increased risk of premature death. Restoration of bladder function is ranked as one of the highest priorities by individuals with SCI (Bourbeau et al., *Spinal Cord* **58**:1216–1226; 2020). Current treatment approaches usually require interventions such as catheterization for urinary voiding, which have their own set of potentially significant risks and complications. World-wide incidence rates range from 12 to 59 cases per million depending on the country (Amidei et al., *Spinal Cord* **60**:812-819; 2022) and of these 70 - 84% showed neurogenic bladder dysfunction (Kumar et al., *World Neurosurgery* **113**:e345–e363;2018).

“I am delighted and grateful for this government funding that now allows us to extend Dr. Fuller’s preclinical studies into the human domain. If CX1739 produces the same effects in humans that it has produced in animals, it potentially represents a novel and needed treatment for SCI,” said Dr. Sandhu.

Dr. Arnold Lippa, CEO and CSO of RespireRx, commented that, “CX1739 has successfully completed multiple Phase 1 safety trials and Phase 2 proof of concept trials demonstrating target engagement. With this new non-dilutive funding, we have begun planning to conduct translational, Phase 2 studies in SCI patients late this year. We believe that this research has the potential to represent a breakthrough in the treatment of SCI, where it is badly needed.”

He added that, “It has been a pleasure to work with Dr. Fuller, a long-time RespireRx collaborator, and his team of scientists. In a series of important studies funded by grants from the National Institutes of Health and published in a number of peer reviewed articles, he has demonstrated the ability of RespireRx’s lead AMPAkines to improve motor nerve activity and muscle function in a number of animal models of SCI, including respiration and bladder functions.

About RespireRx Group

RespireRx Pharmaceuticals Inc. and its subsidiaries and business units (RespireRx Group) are discovering and developing 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 epilepsy, pain, attention deficit hyperactivity disorder (ADHD), recovery from SCI, certain neurological orphan diseases and obstructive sleep apnea (OSA). The RespireRx Group is developing a pipeline of new and repurposed drug products based on our broad patent portfolios for two drug platforms: (i) neuromodulators, which include GABAkines and AMPAkines, proprietary chemical entities that positively modulate (positive allosteric modulators or "PAMs") $GABA_A$ receptors and AMPA-type glutamate receptors, respectively, and (ii) pharmaceutical cannabinoids, which include dronabinol, a synthetic compound that acts upon the nervous system's endogenous cannabinoid receptors.

The RespireRx Group 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.

EndeavourRx: Neuromodulators

AMPAkines. Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, RespireRx 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, SCI, 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, RespireRx's lead AMPAkines, to improve motor nerve activity and muscle function in a number of animal models of SCI. The DOD has recently approved a $1.8 million grant to fund a Phase 2A/2B clinical study of CX1739 in individuals with SCI.

GABAkines. Under a License Agreement with the University of Wisconsin-Milwaukee Research Foundation, Inc. and on behalf of its EndeavourRx business unit, RespireRx has in-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. EndeavourRx 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 animal 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 who underwent 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.

ResolutionRx: Pharmaceutical Cannabinoids.

ResolutionRx Ltd (Australian Company Number a/k/a ACN 664 925 651) was formed in Australia on January 11, 2023 by RespireRx as an unlisted public company. RespireRx has contributed by sublicense and license with ResolutionRx, its sleep apnea drug development program subject to certain liabilities. ResolutionRx now engages in the research and development (R&D) associated with that program, initially for the development of a new formulation of dronabinol for use in a Phase 3 clinical trial and the filing of regulatory approval for the treatment of OSA. The current total budget for that program over the next several years is approximately US$16.5 million, most, but not all of which is expected to be eligible for the Australian R&D Tax Incentive (R&DTI). The R&DTI in the case of ResolutionRx is anticipated to be approximately 43.5% of qualified R&D expenditures. Dronabinol, an endocannabinoid receptor agonist, has already demonstrated significant improvement in the symptoms of OSA in two Phase 2 clinical trials. OSA is a serious respiratory disorder that impacts an estimated 90 million people in the United States, Australia, the United Kingdom and Germany and that has been linked to increased risk for hypertension, heart failure, depression, and diabetes. There are no approved drug treatments for OSA.

Because dronabinol is already FDA approved for the treatment of AIDS related anorexia and chemotherapy induced nausea and vomiting, RespireRx and ResolutionRx further believe that its repurposing strategy would only require, in the United States, 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.

Additional information about RespireRx and the matters discussed herein can be obtained on the RespireRx website at www.RespireRx.com or RespireRx's filings with the U.S. Securities and Exchange Commission (the SEC) at www.sec.gov. Additional information about ResolutionRx and the matters discussed herein can be obtained on the ResolutionRx website at https://www.resolutionrx.com.au.

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, 2022, as filed with the SEC on April 17, 2023 (the 2022 Form 10-K). We have not yet filed our Annual Report on Form 10-K for the year ended December 31, 2023.

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 current and prospective investors, as well as current and potential collaborators and other current and 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 current and prospective investors, as well as current and potential collaborators and other current and 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 2022 Form 10-K, in our quarterly reports on Form 10-Q, in our Current Reports on Form 8-K, and other reports that we file with or furnish to the SEC 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 2022 Form 10-K, in our quarterly reports on Form 10-Q, in our Current Reports on Form 8-K, and other reports that we file with or furnish to the SEC 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 2022 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 current and prospective investors, as well as current and potential collaborators and other current and 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 including but not limited to our most recent Form 10-Q as of September 30, 2023 filed with the SEC on November 17, 2023. As noted above, we have not yet filed our Annual Report on Form 10-K for the year ended December 31, 2023.

Company Contact:

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