



## **RespireRx Pharmaceuticals Inc. Announces the Filing of Broad Enabling Cannabinoid Continuation-in-Part and New Provisional Patent Applications**

Glen Rock, N.J., February 5, 2020 /Globe Newswire – RespireRx Pharmaceuticals Inc. (OTCQB: RSPI) (“RespireRx” or the “Company”), a leader in the research and development of cannabinoids for the treatment of sleep-related breathing disorders, is pleased to announce the recent filing of a continuation-in-part patent application for its pending patent claiming novel doses, controlled release compositions and methods of use for cannabinoids, as well as a new U.S. Provisional Patent Application further disclosing novel dosage and controlled release compositions and methods of use for cannabinoids, alone or in combination, including with non-cannabinoid molecules. Specific claims cover low cannabinoid dosage strengths and controlled release formulations for attaining a desired therapeutic window of cannabinoid blood levels that produces the desired therapeutic effect(s) for a controlled period of time, while minimizing undesirable side effects. Additional claims include cannabinoid compositions and methods for treating cannabinoid-sensitive disorders, including sleep apnea, pain, glaucoma, muscle spasms, anorexia and other conditions. As previously disclosed, the original patents were filed by RespireRx and are now included in an exclusive license agreement with the University of Illinois.

According to Dr. Arnold Lippa, Executive Chairman and Chief Scientific Officer, “New cannabinoid formulation technology is headed in the direction of enhanced absorption and controlled release. We believe that our patent priority relating back to 2010 predates the efforts of others seeking to develop low-dose or extended release formulations of cannabinoids. To the extent that new technologies result in lower doses and/or controlled release formulations, we believe they would infringe on our pending patents once issued, not only in our current clinical programs directed to the treatment of obstructive sleep apnea (“OSA”), but for a wide range of additional clinical indications. For these reasons, our new and continuing intellectual property initiatives are expected to afford expanding strategic options and market exclusivity in the burgeoning pharmaceutical cannabinoid business sector.”

### **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 and other neurological conditions. The Company owns and has exclusive rights to patents and patent applications for certain families of chemical compounds that claim the chemical structures, formulations and their uses in the treatment of a variety of disorders, as well as claims for novel uses of known drugs.

**Cannabinoids.** RespireRx is developing dronabinol,  $\Delta$ -9-tetrahydrocannabinol ( $\Delta$ -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.

Pending the outcome of an intended meeting with the FDA, RespireRx believes that it will be able to commence a pharmacokinetic study for a to-be-developed new 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 further 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.

**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. 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 certain orphan disorders, such as Pompe Disease, Rett's Syndrome and perinatal respiratory distress, certain ampakines have been shown to improve breathing function. Although the Company does not intend to pursue respiratory indications for ampakines at the present time, we view these findings as proof of target engagement and signals of clinical efficacy.

Ampakines have shown potential as possible therapeutic agents for the treatment of certain neuropsychiatric and neurological disorders. 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 adults with ADHD. 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.

RespireRx owns certain composition of matter and use patents and patent applications with respect to ampakines CX1739, CX717 and other ampakines.

Additional information about the Company and the matters discussed herein can be obtained on the Company's website at [www.RespireRx.com](http://www.RespireRx.com) or in the Company's filings with the Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov).

### **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, and (v) 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. For more information about the risks and uncertainties the Company faces, see “Item 1A. Risk Factors” of the RespireRx Pharmaceuticals Inc. Annual Report of Form 10-K as of December 31, 2018. For more current information about the Company, see the Company’s Quarterly Report on Form 10-Q as of September 30, 2019. 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-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.*

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