



RespireRx Pharmaceuticals Inc. and Impression Healthcare Limited Announce Agreement to Explore Commercialization of Dronabinol for the Treatment of Obstructive Sleep Apnea (OSA) in Australia, New Zealand and Southeast Asia

Glen Rock, N.J., February 19, 2019 /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 that it has entered into a non-binding memorandum of understanding ("MOU") and exclusivity agreement with Impression Healthcare Limited (ASX: IHL) ("Impression") for the purpose of negotiating terms by which the parties would enter in an arrangement, such as a license, joint venture or partner agreement, so as to commercialize dronabinol for the treatment of OSA in Australia, New Zealand and Southeast Asia.

OSA, a sleep-related breathing disorder characterized by interrupted breathing, represents a significant global health challenge that increases the risk of health problems, including diabetes, cardiovascular disease and mental disorders. To date, RespireRx has focused on dronabinol development in the United States, where approximately 29.4 million individuals have OSA, according to the American Academy of Sleep Medicine. However, Australia also represents a potentially significant market opportunity. According to SNORE Australia, approximately 9% of women and 25% of men in Australia have clinically significant OSA.

While continuous positive airway pressure ("CPAP"), the front-line treatment for OSA, is highly effective, it is cumbersome and difficult for many patients to tolerate so that most studies report that 25-50% of patients refuse to initiate or completely discontinue CPAP use within the first several months and that most patients who continue to use the device do so only intermittently. Therefore, there is a significant opportunity for alternative therapies, including pharmaceutical alternatives such as dronabinol.

As an alternative to CPAP, Impression currently markets and sells the Sleep Guardian Dorsal, a dental, mandibular advancement device, which is sold through the Company's Preferred Practitioner Network. On December 4, 2018, Impression disclosed its intentions for commercializing dronabinol for certain indications and on February 15, 2019 disclosed its discussions with RespireRx about OSA.

The initial intent of the parties is to create an appropriate commercial vehicle in order to rapidly introduce dronabinol to the Australian market through the Special Access Scheme which permits, under certain circumstances, prescriptions of identified unregistered drug products. It is anticipated that this potentially rapid commercialization will be followed by the introduction of a registered product following the completion of RespireRx's planned phase 3 clinical trial program and marketing authorization.

"RespireRx looks forward to its discussions with Impression," said Dr. Arnold Lippa, Executive Chairman, Chief Scientific Officer and Interim CEO of RespireRx. "Their ability to access the Australian OSA market through their existing distribution and sales network, along with their commitment to commercializing dronabinol, makes them an ideal partner to bring dronabinol to this market."

"Dronabinol has the potential to change the way in which sleep apnea is treated throughout the world and we're excited to work with Respire towards our mutual goal to open this new market for dronabinol," said Mr. Joel Latham, Chief Executive Officer of Impression.

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 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.

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 \$162 billion according to the AASM. There are no approved drug treatments for OSA.

RespireRx believes, for the United States, 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 in the US 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 breathing and 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.

Ampakines also 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 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 Straterra® (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. 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 has been engaging in a process with the University to resolve the matter.

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.

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.

Company Contact:

Jeff Margolis
Senior Vice President, Chief Financial Officer, Treasurer and Secretary
Telephone: (917) 834-7206
E-mail: jmargolis@respirerx.com