



## **RespireRx Pharmaceuticals Inc. Announces \$2 Million Funding Commitment Allowing Option Exercise with UWM Research Foundation, Inc. and Entry into a License Agreement for GABA(A) Receptor Allosteric Neuromodulator Intellectual Property**

Glen Rock, N.J., August 4, 2020 /Globe Newswire – RespireRx Pharmaceuticals Inc. (OTCQB: RSPI) (“RespireRx” or the “Company”), has historically been and remains a leader in the research and development of ampakines for a variety of central nervous system (CNS) disorders and cannabinoids for the treatment of sleep-related breathing disorders. On March 2, 2020, the Company and the UWM Research Foundation, Inc. (“UWMRF”), an affiliate of the University of Wisconsin-Milwaukee entered into an option agreement (“Option Agreement”) to license the identified intellectual property pursuant to license terms substantially in the Form of Patent License Agreement that is attached to the Option Agreement as Appendix I (“Form of Patent License”). For a detailed description, see our Form 8-K filing with the Securities and Exchange Commission on March 4, 2020 at [www.sec.gov](http://www.sec.gov).

RespireRx is pleased to announce that the Company has exercised the Option Agreement and, as of August 1, 2020, entered into a patent license agreement (“License Agreement”) for GABA<sub>A</sub> receptor neuromodulator intellectual property from UWMRF. The exercise of the option was pursuant to the successful closing of a \$2 million funding commitment described in a Form 8-K filed on August 3, 2020. The Company had met all of its obligations in the Option Agreement, including having a contractual commitment of at least \$1 million of aggregate financing to the Company, UWMRF’s acceptance of the Company’s proposed development plan, satisfactory responses to reasonable UWMRF requests for information and the receipt of appropriate approvals by each party. For a more complete description of the Option Agreement, refer to the complete Form 8-K filing on March 4, 2020.

The License Agreement, described in Form 8-K filed on August 4, 2020, grants the Company rights to practice the licensed subject matter, including United States Patents 9,006,233, 9,597,342, and 10,259,815 and Canadian patent application serial No. 2979701, and all other patents and patent applications in lineage with these priority applications, including divisional, continuation, continuation-in-part, and any corresponding patent applications. In return, RespireRx is required to provide annual development plan updates, to remit to UWMRF, in installment payments, past patent costs, annual license maintenance fees beginning on the second anniversary, clinical milestone payments upon the dosing of the first patient in a Phase II clinical trial, upon the dosing of the first patient in a Phase III clinical trial, and upon the approval of a new drug applications (“NDA”) with the Food and Drug Administration (“FDA”). Royalties on net sales would also be due to UWMRF. In addition, in the event of sub-licenses to third parties, the Company will owe a portion of sub-license revenue to UWMRF. In lieu of an upfront payment upon exercise of the option and at the effectiveness of the License Agreement and consistent with the Company’s view that the relationship with the University of Wisconsin is as much a partnership as a license, UWMRF has been granted an appreciation right associated with the neuromodulator program if sold or assigned equal to 4.9 percent of the consideration received.

The compounds that are the subject of the License Agreement with UWMRF act to enhance the actions of GABA (GABA<sub>A</sub>kinines), the major inhibitory transmitter in the brain, at certain sub-type specific GABA<sub>A</sub> receptors. Certain of these compounds have shown impressive activity in a broad range of animal models of refractory/drug resistant epilepsy and other convulsant disorders. Epilepsy is a chronic and highly prevalent neurological disorder that affects millions of people world-wide. While many anticonvulsant drugs have been approved to decrease seizure probability, seizures are not well controlled and, in as many as 60-70% of patients, existing drugs are not efficacious at some point in the disease progression. We believe new drugs are clearly needed. In addition, these GABA<sub>A</sub>kinines have shown positive activity in animal models of migraine, trigeminal pain, anxiety and other areas of interest. Because of their GABA<sub>A</sub> receptor sub-type specificity, the compounds have a greatly reduced liability to produce sedation, motor

incoordination, memory impairments and tolerance, side effects commonly associated with non-specific GABA<sub>A</sub> PAMs, such as benzodiazepines.

As described in our previous press release of February 12, 2020, the Company intends to re-structure the corporation by creating two separate business units. In that press release, we described our plans for creating a new, stand-alone pharmaceutical cannabinoid company (“Newco”) with a focus on developing a new formulation of dronabinol for the treatment of obstructive sleep apnea and to exploit opportunities that may result from our new patent filing. Building upon our ampakine platform as a foundation, we also are planning the establishment of a second business unit, which we currently call Project Endeavor, that will focus on developing novel classes of drugs that fall under the broad category of “neuromodulators”. The term neuromodulators refers to drugs that do not act directly at the receptor sites for brain neurotransmitters, but instead act at accessory sites that enhance (Positive Allosteric Modulators – “PAMs”) or reduce (Negative Allosteric Modulators – “NAMs”) the actions of neurotransmitters at their primary receptor sites. Ampakines act as PAMs at the AMPA receptors for glutamate, the major excitatory neurotransmitter in the brain. Through an extensive series of translational studies from the cellular level up to human Phase 2 clinical trials, selected ampakines have demonstrated target site engagement and positive results in patients with Attention Deficit Hyperactivity Disorder.

“With the consolidation of the ampakine and GABA<sub>A</sub> modulator platforms, Project Endeavor is rapidly becoming one of the major CNS programs in the field of neuromodulation,” said Dr. Arnold Lippa, Executive Chairman of the Board and Chief Scientific Officer. “I am particularly excited by the article published by our scientific collaborators describing results from an elegant series of translational experiments in which brain tissue was excised from patients with severe drug resistant epilepsy (Witkin *et al.* Brain Res., 2019). The application of a GABA<sub>A</sub> modulator to this tissue at concentrations we believe to be achievable with oral administration produced dramatic reductions in the epileptogenic activity of this tissue, confirming the potential of our GABA<sub>A</sub> modulators to treat epilepsy. We eagerly look forward to working with this highly experienced scientific team led by Dr. James Cook at the University of Wisconsin-Milwaukee and Dr. Jeffrey Witkin of the Indiana University School of Medicine.”

Dr. Jessica Silvaggi, Director of Technology Commercialization at UW-MRF added, “We are extremely enthusiastic about the collaboration of our researchers with our new partners at RespireRx which is an excellent marriage of scientific and start-up expertise. We look forward to the next stages of pre-clinical testing of the lead GABA<sub>A</sub> modulator compound which shows great promise for epilepsy patients.”

### **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, Δ-9-tetrahydrocannabinol (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.

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.

## **Project Endeavor**

**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 Straterra<sup>®</sup> (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.

**GABAkines.** The third platform of proprietary medicines, added to the Project Endeavor portfolio via the License Agreement are the GABAkines described above.

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.*

Company Contact:

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

RespireRx Pharmaceuticals, Inc.  
126 Valley Road,  
Suite C,  
Glen Rock, NJ 07452  
[www.respirerx.com](http://www.respirerx.com)

About UWMRF: The UWM Research Foundation Inc. is a private nonprofit corporation that fosters research and innovation at UW-Milwaukee through a variety of programs, including invention evaluation, patenting, marketing, industry partnering, out-licensing, catalyst grant funding, start-up mentorship, and start-up support. [Uwmrf.org](http://Uwmrf.org)