

## **February 1, 2016 - OptiNose® Announces Pipeline Project to Evaluate Nose-to-Brain Application of Bi-Directional™ Breath Powered® Technology Selected for Norwegian Government Funding**

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*The Research Council of Norway Recognizes OptiNose Technology as Innovative*

**YARDLEY, PA, February 1, 2016**— OptiNose Inc., a privately-held Delaware specialty biopharmaceutical company, today announced that its Norwegian affiliate (OptiNose AS) was selected to receive up to NOK 15.9 million (USD \$1.8 million) by the Research Council of Norway to study its unique nasal drug delivery technology in the treatment of Narcolepsy. The OptiNose proposal was one of 50 company projects selected from among 181 applications submitted to the Research Council's program for User-Driven, Research-Based Innovation Research. Subject to successful contract negotiations with the Research Council and project partners, OptiNose would be able to use this research grant to help defray the cost of investigating "nose-to-brain" activity of Orexin-A delivered using patented OptiNose Bi-Directional Breath Powered delivery technology for the treatment of Narcolepsy. Partners who have agreed to collaborate with OptiNose in the project include the Norwegian Centre of Expertise for Neurodevelopmental Disorders and Hypersomnias at Oslo University Hospital (OUS-NevSom), Hovione Farma Ciencia SA, Lisbon, Portugal and Smerud Medical Research, Oslo, Norway.

"The opportunity to further investigate nose-to-brain drug transport in an effort to develop a new and much needed treatment for narcolepsy is very exciting," said Per G. Djupesland, M.D., Ph.D, Chief Scientific Officer (CSO) of OptiNose AS. "Narcolepsy is a chronic neurological disorder caused by destruction of neurons in the brain that produce Orexin-A, a neuropeptide regulating sleep and wakefulness. Currently available drugs primarily target the symptoms of narcolepsy and have many side effects. Patients suffering from narcolepsy experience excessive daytime sleepiness, disturbed nocturnal sleep and episodes of sudden muscle paralysis triggered by emotions. We hope to advance the science and generate positive outcomes by directing treatment closer to the root of the problem by using Orexin-A powder delivered with our innovative exhaler device."

"2016 is off to an exciting start. We continue to advance both our near-term assets and our early-phase projects for conditions where there is real need for improved treatments," added Peter Miller, Chief Executive Officer of OptiNose. "We have invested in research and development of novel therapies with significant differentiation, and we are pleased the Research Council of Norway believes it could be valuable to support this new project."

### **Background Information**

#### **The Research Council of Norway Program for Innovation (BIA)**

The BIA (Brukerstyrt Innovasjons Arena) program, developed by the Norwegian government, is designed to stimulate research and development that will result in new products, processes or services across a wide range of diverse business sectors in Norway. The grant applications submitted to the Research Council's BIA program have resulted in a total of NOK 532 million (USD \$61.5 million) being allocated across company projects.

### **Narcolepsy**

Narcolepsy is a chronic neurological disorder caused by destruction of orexin-producing neurons (orexin is also called hypocretin) in a part of the brain called the hypothalamus. Orexin neuron loss is believed to be due to an autoimmune attack. Orexin neurons connect widely in the brain, especially with areas that control sleep-wake and muscle tone functions (brainstem), thalamus emotional control (the limbic system/amygdala), and consciousness (brain cortex). In animal models, orexin deficiency in the brain results in an unstable regulation of the sleep-wake cycles and of REM-sleep (Rapid Eye Movement) related muscle tone. Correspondingly, patients with narcolepsy experience frequent excessive daytime sleepiness, described as comparable to how healthy individuals feel after 24 to 48 hours of sleep deprivation, as well as disturbed nocturnal sleep, which often is confused with insomnia. In narcoleptic humans, severe REM sleep

dysregulation results in increased sense of dreaming and nightmares, hallucinations and muscle paralysis occurring during wakefulness, which can be bizarre and frightening. Another common symptom of narcolepsy is cataplexy, a sudden and transient episode of muscle weakness accompanied by full conscious awareness, typically triggered by emotions such as laughing, crying, terror, etc., affecting roughly 70% of narcoleptics. Orexins are also involved in the regulation of glucose metabolism, and appetite and weight gain are frequently observed in narcoleptic patients.

### **About OptiNose Technology: Bi-Directional™ Breath Powered® Drug Delivery Systems**

OptiNose's patented technology for closed-palate Bi-Directional Breath Powered drug delivery systems is unique in that its exhaler devices use the natural functions of a patient's breath to help effectively and efficiently deliver medications beyond the nasal valve into deep, targeted areas of the nasal cavity. A user exhales into the device, naturally closing the soft palate and sealing off the nasal cavity from the throat. The exhaled breath carries medication from the device into one side of the nose through a specially shaped sealing nosepiece, balancing the pressure on the soft palate. Narrow nasal passages are gently expanded and medication is transported well beyond the nasal valve to targeted sites. After delivering medication to the targeted sites, air flows around to the opposite side of the nasal cavity and exits through the other side of the nose rather than into the throat or lungs.

### **About OptiNose**

"OptiNose" as used above refers to OptiNose, Inc. and its wholly owned subsidiaries, as applicable. OptiNose is a Specialty Biopharmaceutical Company developing a promising pipeline of late stage new products. The Company's patented closed-palate Bi-Directional™ Breath Powered® drug delivery systems enable differentiated treatments using exhaler devices that serve to target delivery of drugs high and deep in the nose. OptiNose successfully out-licensed a first product at the end of phase 3, ONZETRA™ Xsail™ (formerly AVP-825), to Avanir Pharmaceuticals, Inc. (now a subsidiary of Otsuka America, Inc.) in North America, and has reported clinical success with other product candidates, including OPN-375, a treatment in development for Chronic Nasal Inflammatory Diseases. Other OptiNose pipeline product candidates also target large markets with significant unmet need, including "nose-to-brain" applications of the technology such as OPN-300 for Autism.

Data from an ongoing BIA-supported project to study OptiNose-delivered intranasal oxytocin (OPN-300) supports direct nose-to-brain activity of oxytocin (OT) in healthy volunteers when the molecule was delivered with an OptiNose exhaler device. The results, recently published in the journal "Translational Psychiatry" (Quintana et al. 2015), provide unique behavioral evidence that a low dose of intranasal oxytocin delivered with an OptiNose exhaler device designed to optimize opportunity for nose-to-brain applications has different activity on the brain, influencing social cognition in healthy volunteers, versus an intravenously administered dose of OT that produced comparable plasma OT concentrations. OptiNose is currently pursuing a follow-on study, partly supported by a BIA grant, in patients with autism spectrum disorder to investigate possible benefits in treating this common disease.

OptiNose has corporate offices in the US, Norway and the UK. For more information, please visit [www.optinose.com](http://www.optinose.com).

Investors in OptiNose include Avista Capital Partners in New York, WFD Ventures LLC located in New York and Entrepreneurs Fund LP based in Jersey, Channel Islands.

### **Forward Looking Statements**

In addition to historical facts or statements of current condition, this press release may contain forward looking statements, which may provide OptiNose's current expectations or forecasts of future events or statements about future plans, including with regard to anticipated scientific progress on its research programs, development of potential pharmaceutical products, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, sales and earnings guidance, and other statements regarding matters that are not historical facts. OptiNose's performance and financial results could differ materially from those reflected in

these forward-looking statements due to general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries as well as more specific risks and from time to time. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, OptiNose does not intend to update publicly any forward-looking statement, except as required by law. The Private Securities Litigation Reform Act of 1995 permits this discussion.

This press release may also contain statements, opinions, assumptions, summaries of study results or characterizations that are projections or aspirational in nature, that have not been reviewed and/or approved by the Food and Drug Administration (FDA), Patent and Trademark Office (PTO) or other applicable governmental or regulatory bodies. Moreover, some or all of these statements have not been evaluated by FDA in connection with a regulatory review of the OptiNose Products OPN-375 and OPN-300 and you are advised that these are investigational products that have not been approved by any regulatory authority.

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