OptiNose Receives Grant to Fund Nose-to-Brain Research in Autism Spectrum Disorders

The Associated Press

OptiNose US Inc., today announced that its Norwegian affiliate was awarded NOK 12.3 million (USD $2.1 million) by the Research Council of Norway to study its unique nasal drug delivery technology in the treatment of autism spectrum disorders (ASDs). The OptiNose project was one of 59 company projects selected among the nearly 200 applications submitted to the Research Council's program for User-Driven, Research-Based Innovation Research. OptiNose will use this research grant to investigate "nose-to-brain" transport of oxytocin via the patented OptiNose Bi-DirectionalT delivery technology for the treatment of ASDs.

Partners who have agreed to collaborate with OptiNose in the project include the Department of Psychiatry at Oslo University Hospital, SINTEF and Smerud Medical Research and Norwegian academic institutions. It is anticipated that the Department of Psychiatry at the University of Minnesota will also participate in the program.

"The opportunity to investigate nose-to-brain drug transport with the OptiNose technology in an effort to develop a new treatment for autism spectrum disorders is very exciting," said Per G. Djupesland, M.D., Ph.D, Chief Scientific Officer (CSO) of OptiNose. "Autism spectrum disorders are growing in prevalence and there are no drugs approved to treat the core symptoms which burden children, adults and families with these conditions. We hope to see significant benefits from delivering treatment with our innovative nasal technology." The Research Council of Norway Program for Innovation (BIA) The BIA (Norwegian title: Brukerstyrt innovasjonsarena) 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. A record-breaking number of grant applications submitted to the Research Council's BIA program has resulted in a total of NOK 500 million (USD $85 million) being allocated across 59 company projects for this initiative.

About Autism Spectrum Disorders Autism spectrum disorders (ASDs) are a group of complex disorders of brain development, including autism.

According to the Centers for Disease Control and Prevention, approximately 1 out of every 110 children in the United States have ASD, as well as millions of children worldwide. These disorders are characterized, in varying degrees, by difficulties in social interaction, verbal and nonverbal communication and repetitive behaviors. ASD can also be associated with intellectual disability, difficulties in motor coordination and attention and physical health issues, but social behavior dysfunction is the core clinical characteristic. With prevalence rates increasing from 10 to 17 percent in recent years, autism appears to have its roots in very early

brain development abnormalities. There are no available effective treatments for ASD and most symptoms are rarely detected before 2-3 years of age, when demands for social interaction increase.

-- Studies show that ASD is three to four times more common among boys than girls. An estimated 1 out of 70 boys is diagnosed with ASD in the United States. More children will be diagnosed with ASD this year than with childhood cancer, juvenile diabetes and pediatric AIDS combined.

-- Autism statistics from the U.S. Centers for Disease Control and Prevention (CDC) identify around 1 in 110 American children as on the ASD spectrum (CDC Surveillance Summary Dec 18, 2009/58(SS10);1-20) - a 600 percent increase in prevalence over the past two decades.

-- In Europe it is estimated that up to 1 in 166 children has autism (European Commission: Health and Consumer Protection Directorate General: Some Elements about Prevalence of ASD in the EU 2005).

Oxytocin Oxytocin is a small, naturally occurring peptide currently safely used to stimulate lactation in breastfeeding women. It has recently attracted attention as a potential novel treatment alternative in several psychiatric disorders, including autism (Bartz 2008, Ishak 2010, Feifel 2010, Neumann 2008, Kosfeld 2005). Oxytocin has very poor oral bioavailability and with standard nasal delivery (liquid spray) approximately 3 percent of the drug reaches the systemic circulation blood. However, because it is estimated that only a tiny fraction (less than 0.01 percent) of oxytocin in the blood enters the brain across the blood brain barrier, achieving direct "nose to brain" delivery is an exciting possibility.

The effects of conventional intranasal spray delivery of oxytocin on multiple psychiatric disorders have been examined in a number of small clinical studies (Hollender 2007, Gaustella 2009, Andari 2010). Most of these studies suggest beneficial effects, mainly on social, aggressive and paranoid behavior.

-- In these studies, high doses (40-80IU) are typically used, representing a logistical challenge given the volumes of liquid required to deliver these doses and posing a risk of long-term adverse-effects related to water and electrolyte imbalance.

-- The OptiNose Bi-DirectionalT nasal delivery device, using a dry powder, is uniquely capable of targeting the upper posterior nasal regions. These regions provide greater access to the olfactory nerve, projecting directly to regions of the brain regulating behavior and emotions, and thus the potential for "nose to brain" activity.

-- The OptiNose device offers the potential for a more efficient and consistent direct transport of oxytocin into the brain itself, via this nerve, using relatively low doses -- which will significantly reduce drug levels in the rest of the body, reducing the risk of side-effects.

About Bi-DirectionalT Nasal Delivery Technology OptiNose's Bi-DirectionalT nasal

delivery technology significantly improves delivery to difficult to reach target sites deep into the nose. A user exhales into the device, automatically closing the soft palate and sealing off the nasal cavity completely. The natural exhaled breath then carries medication from the device into one side of the nose through a sealing nosepiece. Narrow nasal passages are gently expanded and medication is carried well beyond the nasal valve to targeted sites. After delivering medication to the targeted sites, air painlessly flows in the opposite direction, exiting the nasal cavity through the other side of the nose rather than into the throat or lungs.

About OptiNose OptiNose is a drug delivery company with breakthrough "Bi-DirectionalT" nasal technology set to transform the static nasal drug delivery market. OptiNose devices are designed to reliably deliver intranasal medication (large molecule, small molecule, or vaccines) to target regions of the nasal cavity, including the sinus and olfactory regions, while preventing lung deposition. The simple devices are intended to unlock the potential for significant new benefits, including better local activity, better systemic bioavailability and pharmacodynamics, better immunogenicity, and for "nose-to-brain" activity for treating neurologic and psychiatric disorders.

OptiNose offers both single and multi-use intranasal delivery devices for delivering both liquid and powder formulations. The strongly patent-protected technology has been successfully tested in a number of clinical trials evaluating the advantages of the technology compared to traditional nasal sprays. OptiNose is actively developing internal products using the new technology, which is also available for technology licensing for delivery of proprietary medications.

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. For more information please visit www.optinose.com.

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