

## BioGaia invests in development of a drug against NEC

**The board of BioGaia has decided to invest in the first phase of a long-term project aimed at developing a drug with rigorous hygiene, analysis and documentation requirements, to treat the highly fatal disease Necrotising Enterocolitis (NEC), which affects premature infants.**

BioGaia will invest SEK 42 million in the project over a two-year period. The project will be driven by BioGaia's subsidiary Infant Bacterial Therapeutics (IBT), of which 9% is owned by the company's President, Staffan Strömberg, and its Research Director, Eamonn Connolly. The remaining 91% is owned by BioGaia.

IBT will develop a new formulation and a manufacturing process that are wholly adapted to the stringent quality requirements placed by the FDA (the U.S. Food and Drug Administration) for a biological drug and the product's area of use in neonatal intensive care units. The company's assessment is that around SEK 26 million of the total of SEK 42 million will be capitalised in IBT, which will result in costs of approximately SEK 8 million per year in 2014 and 2015. Should the drug development not be completed it is BioGaia's intention to market the formulation under a different product category.

In August this year the company was granted "Orphan Drug Designation" for the use of *Lactobacillus reuteri* in a drug to treat NEC. In addition to tax credits, this qualifies the sponsor of the drug for various incentives from the US government, seven-year exclusivity and certain support from FDA in the application process leading to an approved drug. IBT has had a first meeting with the FDA regarding the possible development of a drug. Parallel to this, discussions are underway with other parties on financing of the drug development project. A decision on the continued development of a drug will be made if and when reasonable financing is obtained.

"We consider the NEC project very promising since we have already been granted "Orphan Drug Designation" and, with a limited impact on earnings, can create additional value in a project that can lead to a valuable drug with the potential to save lives and become a very profitable product. If we don't reach all the way we will still have succeeded in developing a product that is ideally adapted for use in neonatal intensive care units, which opens a new market for our products," says Peter Rothschild, President BioGaia.

BioGaia is a healthcare company that develops, markets and sells probiotic products with documented health benefits. The products are primarily based on the lactic acid bacterium *Lactobacillus reuteri* which has probiotic, health-enhancing effects. The class B share of the Parent Company BioGaia AB is quoted on the Mid Cap list of the NASDAQ OMX Nordic Exchange Stockholm. [www.biogaia.com](http://www.biogaia.com)



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BioGaia has published this information in accordance with the Swedish Securities Market Act. The information was issued for publication on 12 November 2013, 08:00 am CET.

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