Corporate Fact Sheet

MicroDoseTherapeutx

Company Overview

MicroDose Therapeutx, Inc. is a privately-held pharmaceutical company dedicated to improving the quality of life for people suffering from serious diseases. The company focuses on developing proprietary products that address large unmet market opportunities, and on drug delivery platforms for the pulmonary and oral delivery of medications. The company develops its products and technologies independently and through acquisition, as well as in license partnerships with leading pharmaceutical companies. MicroDose's drug products and delivery platforms currently target respiratory diseases such as asthma, COPD, RSV (respiratory syncytial virus) and other lung viruses and infections, as well as IBS-C (irritable bowel syndrome) and constipation.

- Founded in 1998, with ~50 employees with headquarters and laboratory facilities located just North of Princeton, NJ
- Named the 13th Fastest Growing Company of NJ in 2010 by NJBIZ
- Nine products under development as part of its proprietary and partnered programs

Proprietary Products

MDT-637: Inhaled anti-viral for respiratory syncytial virus (RSV)

MDT-637 is a first-in-class, inhaled, anti-viral fusion inhibitor being developed for the treatment of RSV disease, a serious and highly contagious respiratory infection that is a major threat to several high-risk populations and, with no effective treatments available, represents a major unmet medical need. RSV infects over 90% of children worldwide during the first two years of life and causes considerable morbidity and mortality in premature infants, the immuno-compromised, the elderly, and individuals with asthma and COPD. This highly potent compound has demonstrated antiviral activity in preclinical studies, and was generally well tolerated in multiple adult volunteer Phase I studies. The worldwide market for RSV treatments is estimated to exceed $4 billion.

MDT-006: Oral treatment for IBS-C and chronic constipation

MDT-006 is a novel first in class, oral small molecule P2Y2 agonist being developed for the treatment of two related diseases: Chronic Constipation (CC) and Irritable Bowel Syndrome with Constipation (IBS-C). Constipation afflicts between 10–20% of the population in western countries, with up to 46 million in the U.S. alone suffering from CC and IBS-C. MDT-006 is highly potent, highly selective and non-absorbed which should provide significant advantages over competitive products in terms of its efficacy, dosing and particularly its side effects profile.

MDT-011: Inhaled atropine sulfate nerve gas antidote

An inhaled atropine delivery system is being developed as an antidote against nerve gas poisoning for the U.S. Department of Defense and for Homeland Security applications. Atropine sulphate is a specific antidote for the treatment of poisoning from organophosphorus (OP) nerve agents. The MicroDose atropine inhaler will enable the rapid pulmonary and systemic delivery of atropine to reverse the three most toxic effects of OP poisoning. A Phase 1 study was successfully completed in October 2009 and development work is ongoing toward a pivotal trial.

Asset acquisition and internal development candidate screening is ongoing for novel treatments in COPD, CF and viral diseases.

Proprietary delivery platforms

The MicroDose DPI is among a number of key proprietary drug delivery platforms developed by MicroDose. By employing piezo electronics, the MicroDose DPI has the potential to deliver enhanced performance versus other inhalers, for efficient and reproducible delivery independent of patient coordination, inhalation rate and posture. The flexibility of the inhaler makes it a true platform technology, able to support a broad pipeline of products across the spectrum of patient populations and therapeutic categories.

MicroDose's PolyCap® system is a proprietary approach that enables the rapid development of fixed-dose-combination therapies in a single capsule, but separated by a physical barrier. This innovative approach relies on the proven strengths of capsules and the advantages of a barrier system, allowing for more rapid product development timelines, reduced development risk, and lower regulatory requirements.

Partnerships

Gilead Sciences

In April 2011, MicroDose entered into an exclusive worldwide license and collaboration agreement for the development and commercialization of MDT-637, MicroDose's inhalable small molecule antiviral fusion inhibitor for the treatment of respiratory syncytial virus (RSV). Clinical development is underway under MicroDose's sponsorship, with multiple trials planned within 2011.

Merck & Co., Inc.

In 2008, MicroDose entered into a global, multi-product license agreement with Merck & Co. for the use of MicroDose's dry powder inhaler (DPI) with Merck's proprietary compounds. Initiation of Phase 1 study involving first product to be developed was announced in August 2008, and expansion of collaboration to include development of a second proprietary product announced in July 2009.

Novartis

In 2006, MicroDose entered into a multi-product development and licensing agreement with Novartis for use of MicroDose's dry powder inhaler with Novartis' proprietary respiratory products. To date four respiratory NCEs have been named for development in conjunction with MicroDose's dry powder inhaler, and clinical development is underway.

Other partnerships are forthcoming that are in various stages of License Term Sheet and/or feasibility agreement status.