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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Larta Institute

National Institutes of Health Commercialization Assistance Program (NIH-CAP)

Company Profile

Industry Sector: Pharmaceuticals

Company Overview: TSRL, Inc. is a biopharmaceutical company focused on enabling oral delivery of approved and investigational drug candidates that are currently delivered by inhalation or injection. Using its absorption platform technology, TSRL has demonstrated improved delivery of its lead candidate TSR-026, an analogue of zanamivir, and other antiviral and anti-cancer therapeutics. TSRL's business model is to develop novel oral products of existing drugs with improved clinical outcomes and then seek strategic partnerships with established larger pharmaceutical companies with an ultimate goal of licensing the product.

Target Market(s): The global market for influenza antivirals fluctuates based on outbreak severity and can range from $0.5 to $5 billion. It is dominated by two drugs, Tamiflu® (oseltamivir) and Relenza® (zanamivir), with $3.4B and $1.1B in sales in 2009, respectively. Tamiflu® is given orally and Relenza® is an inhalation product. Given the reports of increasing resistance to Tamiflu starting in the 2007/8 flu season, zanamivir is now the drug of last resort. However, inhalation therapy of respiratory infections such as the flu has many limitations and an oral form of zanamivir would be a highly superior product in this market segment.

Key Value Drivers*

Technology*: TSRL has developed a proprietary medicinal chemistry approach for enhancing the absorption of charged or highly polar small molecules by targeting endogenous intestinal transporters. Specifically, TSRL has demonstrated that an analog of zanamivir (TSR-026), which is currently administered via inhalation, has the potential for commercial and clinical feasible oral bioavailability. TSRL's proprietary technology has been successfully employed pre-clinically for oral delivery of other anti-viral drugs.

Competitive Advantage: TSR-026 provides a solution for treatment of the respiratory flu and bypasses the problems with delivering an drug by inhalation to the already compromised lung tissue. Furthermore, the drug is superior to the current market leader, Tamiflu, as it has demonstrated a better resistance profile against current circulating virus strains. TSR-026 is protected by patents and, given that the parent drug zanamivir is an already approved product, will follow a de-risked product development plan.

Plan & Strategy: TSRL will develop its therapeutics internally until the end of phase 2a (clinical proof-of-concept efficacy) and then seek high value partnerships with larger corporate partners who would continue product scale-up and manufacturing, late stage clinical testing and ultimately be responsible for launch and product sales.

*Technology funded by NIAID and commercialized under NIH-CAP

Management

Leadership: Gordon Amidon, PhD, Chairman and CSO, is an internationally recognized expert in the field of drug absorption. John Hilfinger, PhD, President brings to TSRL more than 25 years of research and management experience. Elke Lipka, PhD, MBA, VP of Business Development, has 15+ year of experience in drug development and management of strategic alliances at Parke-Davis, Esperion Therapeutics and Pfizer.

Scientific Advisory Board: Arnold Monto, MD, Professor of Epidemiology at the University of Michigan, is a veteran in influenza vaccine and therapeutics development and was involved with the development of Tamiflu®, Relenza® and Flumist®. Robert Guttendorf, PhD, Senior Advisor at Aclairo Pharmaceutical Development Group, brings over 20 years of experience directing anti-infective preclinical and clinical development programs to the team. Ray Dagger, PhD., Director CMC, PPD Consulting, advises on all product manufacturing aspects.

Product Pipeline