

## Executive Summary: rhMFG-E8 for Inflammatory Bowel Disease (IBD)



**Company Profile:** TheraSource LLC is an early-stage biotech company located in Greater New York City Area, currently employing 9 scientists, mostly with MD or PhD degrees. Our mission is to develop and commercialize protein and peptide-based therapeutics for human inflammatory diseases. The company has 14 utility patents covering 5 molecules.

**Product Description - Recombinant Human MFG-E8 (rhMFG-E8):** Milk fat globule-epidermal growth factor-factor VIII (MFG-E8) is a protein produced in the human body. TheraSource R&D team has discovered that MFG-E8 remarkably improves models of inflammatory bowel disease by clearing away dying cells, promoting intestinal healing, and suppressing the release of inflammatory mediators.

**Unmet Medical Need in Inflammatory Bowel Disease (IBD):** IBD is a group of chronic and recurring inflammatory conditions of the digestive that often lead to bleeding, obstruction, and fistula formation. Many patients respond poorly to existing treatments, and one fifth need intestinal surgery despite 2-5 years of treatment.

**Value Proposition:** rhMFG-E8 will be administered daily or weekly as a subcutaneous injection to treat IBD. The success of rhMFG-E8 treatment will benefit patients, decrease the need for surgery, shorten hospital stay, and reduce overall healthcare cost.

**Market Opportunity:** IBD is relatively common, annually affecting 1.4 million persons in the US and accounting for 700,000 physician visits, 100,000 hospitalizations, and 119,000 disability cases. The market of IBD therapeutics was \$1.7 billion in 2011 and is estimated to reach \$3.2 billion in 2017.

**Market Entry Strategy:** TheraSource has developed the technology to produce rhMFG-E8 and multiple assays to monitor its bioactivity and stability. The efficacy of rhMFG-E8 in the treatment of IBD has been demonstrated in two animal models and published in a peer-reviewed journal. Our patent on the use of rhMFG-E8 for IBD has been issued in European Union (pending in other countries including the US). We are currently preparing for IND-enabling studies and plan to file an IND within 18 months.

**Leadership Team:** Ping Wang, MD, Founder and President, >25-year experience in critical care-related research; well-funded by NIH since 1995; president-elect of the Shock Society; council member of the Surgical Infection Society. Weng-Lang Yang, PhD, CSO, extensive knowledge in protein chemistry, biochemistry, cellular, and molecular biology; experience in drug discovery and pre-clinical development.

**Operations:** We are in the process of contracting CROs for manufacturing, analytical testing, PK/PD, toxicity and immunogenicity testing of rhMFG-E8.

**Financial Position:** TheraSource has raised more than \$12 million from industry and government with 14 SBIR awards from the NIH. We have secured sufficient funding for the next 18 months of operation.

**Objective:** TheraSource seeks strategic VC funding and pharma partners to co-develop and commercialize rhMFG-E8 for IBD as well as for other human disease indications.

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