
EXECUTIVE SUMMARY

Asana Medical Inc. (“Asana”), a regenerative medicine company, is developing a novel treatment for Inflammatory Bowel Disease (“IBD”) and other gastrointestinal (“GI”) diseases. Crohn’s Disease and Ulcerative Colitis (“UC”), the two major forms of IBD, are characterized by chronic diarrhea, pain, bleeding, urgency, and an increased risk of cancer. IBD affects as many as 1.6 million Americans and more than 5 million people worldwide.

The Problem

IBD exacts a heavy societal toll on personal and financial health. Estimates put the total economic burden from IBD at \$19 billion to \$30 billion in the US and €14 billion to €45 billion in Europe. Even with the introduction of high-profile and costly immunomodulators, statistics reveal that 20% to 30% of UC patients require surgery to remove their colon as a form of therapy, while certain Crohn’s patients may experience surgery rates as high as 40% to 60%. There is a genuine need for a new and different treatment approach to IBD.

The Solution: ECMH™

Asana holds an exclusive world-wide license from the University of Pittsburgh for ECMH™, a patented, non-surgical hydrogel therapy composed of extracellular matrix (ECM), a porcine-derived material. ECMH™ is delivered directly to the affected area as a liquid that gels upon reaching body temperature, forming a protective barrier that acts as a scaffold for natural tissue recovery to occur. This scaffolding mechanism has been demonstrated in multiple ECM applications including esophageal repair, hernia grafts, pericardial closures, and others. Several of these applications have been successfully marketed for more than a decade, demonstrating a substantial record of safety and efficacy in human applications. Asana recently completed a Pivotal Animal Study to confirm earlier, Proof of Concept studies. This compelling, statistically significant data was published in the *Oxford Journal of Crohn’s and Colitis** and will serve as the basis for a regulatory filing to commence First-in-Man studies (“FIM”).

Market Opportunity

GlobalData, a reliable source for clinical market research, reported pharmaceutical sales to treat UC totaled \$4.2 billion in 2012. Asana will position ECMH™ to treat patients unresponsive to the first-tier medical therapy, entering a market dominated by immunomodulators and biologics such as Remicade, Humira, and Entyvio, with costs ranging from \$25,000 to over \$60,000 annually. In spite of an array

of pharmaceutical treatments, UC patients continue to face high rates of colon removal surgery while being exposed to serious adverse events such as infections, tuberculosis, histoplasmosis, and malignancies.

The total UC therapeutic market from GlobalData is projected to be \$6.8 billion the year Asana’s UC product is commercialized. ECMH™ will be priced to reflect development, manufacturing, clinical, and licensing costs. Management will exploit the competitive advantages of ECMH™ in a global marketing and distribution alliance. Leveraging this strategy, Asana believes peak year revenues for ECMH™ to treat UC will exceed \$2 billion.

Key Personnel

Asana is led by CEO and Founder Dr. Christine V. Sapan. Dr. Sapan’s 35-year career, including a successful record in leadership roles at biopharmaceutical companies, makes her uniquely qualified to lead ECMH™ through development and into commercialization. All members of Asana’s leadership team have experience with various stages of life science companies in multiple disciplines and functions. Asana recruited key players in ECM and GI disease research, Key Opinion Leaders in gastroenterology and colorectal surgery, business leaders at hospital organizations, and a world-class medical device company as resources to aid in the advancement and development of Asana’s commercialization efforts. Through its agreements with the University of Pittsburgh McGowan Institute for Regenerative Medicine, Asana collaborates with Dr. Stephen Badylak (considered an ECM expert) to assist with the research and development efforts of ECMH™.

Intellectual Property

Asana co-owns, with the University of Pittsburgh, pending patent applications claiming the use of ECM (“derived from any source, manufactured in any form, and delivered by any method to the intestines”) to treat certain gastrointestinal diseases. Asana has also exclusively licensed from the University of Pittsburgh, field-specific rights in certain patented methods for the manufacture and sterilization of ECM gels. Asana has also filed a provisional patent application disclosing the positive results generated in its animal studies using ECMH for treating conditions in colon tissue and an additional application related to the use of ECM in treating certain urogenital diseases.

* Restoring Mucosal Barrier Function and Modifying Macrophage Phenotype with an Extracellular Matrix Hydrogel: Potential Therapy for Ulcerative Colitis; Timothy J. Kean, Jenna Dziki, Eric Sobieski et, al. Corresponding Author Stephen F. Badylak, DVM, Ph.D., MD. [Published by Oxford University Press, Journal of Crohn’s and Colitis Advance Access published August 20, 2016]