

OUR COMPANY

Asana Medical, Inc., (“Asana”, the “Company”) a regenerative medicine company, is developing a novel treatment for Inflammatory Bowel Diseases (“IBD”) such as Ulcerative Colitis (“UC”) and Crohn’s Disease (“CD”) which are characterized by chronic diarrhea, pain, bleeding, urgency and an increase risk of cancer. IBD affects as many as 1.6 million Americans and more than 5 million people worldwide generating \$7.3 billion in pharmaceutical sales.

THE PRODUCT

The Company obtained an exclusive world-wide license from the University of Pittsburgh for ECMH™, a patented non-surgical hydrogel therapy composed of extracellular matrix (ECM).

ECMH is delivered directly to the affected area as a liquid that gels on 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 burn and wound treatments. Several of these applications have been successfully marketed for more than a decade, demonstrating a substantial record of safety and efficacy in human applications. ECMH’s other competitive advantages include strong IP protection with multiple issued and pending patents; its local (non-systemic) application; and a robust and well-established manufacturing process.

THE DISEASE

Asana’s initial target market is UC, a debilitating disease affecting more than 1.8 million people worldwide. UC is characterized by recurring episodes of inflammation of the innermost layer of the colon, *i.e.* the mucosa (**Figure 1**). Typical symptoms include pain, chronic diarrhea, bleeding, and urgency to use the restroom. More severe symptoms include malnutrition and dehydration. An increased risk of colon cancer has also been clinically documented.

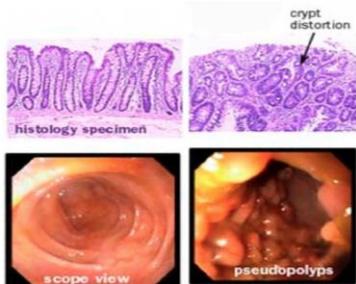


Figure 1: Healthy (left) vs colitic (right) colon tissue

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There is no cure for UC. Current first-tier drug treatment options for UC include aminosalicylates (5-ASA) for mild cases to systemic corticosteroids and potent immunosuppressants for moderate to severe cases (**Figure 2**). Many existing therapies have debilitating side effects. Despite the existing breadth of drugs and biologics, statistics reveal long-term colectomy rates for UC patients at 20-30%. Colectomy, major surgery to remove the colon, leads to challenging lifestyle changes. Asana believes ECMH will provide current and newly diagnosed patients with a superior treatment alternative by focusing its therapy on tissue regeneration, reduction in inflammation and clinical symptoms, and remodeling the cell barrier function.

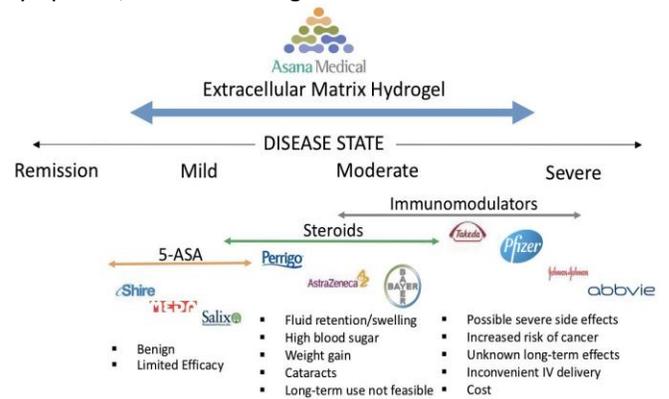


Figure 2: The New IBD treatment paradigm

THE OPPORTUNITY

GlobalData, a well-regarded source for clinical market research, reported for the 2012 calendar year 1.861 million UC patients in the 10 major pharmaceutical markets worldwide. Of those suffering from UC, more than 1.54 million were treated with pharmaceuticals and biologics (including 5-ASA, corticosteroids, immunomodulators, and biologics such as Remicade™ and Humira™) generating \$4.2 billion in revenues for pharmaceutical companies. Per patient costs for these drugs ranged from \$25,000 to over \$60,000 annually (ref: www.consumerreports.org).

Asana's marketing strategy is to initially position ECMH to treat patients unresponsive to 5-ASA (aminosalicylate) drugs, the common first-tier medical treatment. ECMH will be priced to reflect development, manufacturing, clinical, and licensing costs. Management will leverage the competitive advantages of ECMH with a global marketing and distribution strategy. GlobalData is projecting the total UC therapeutic market in 2022 to surpass \$6.8 billion annually.

DEVELOPMENT AND REGULATORY STRATEGY

Asana executed a Corporate Research Agreement with the University of Pittsburgh's McGowan Institute for Regenerative Medicine. The Institute and Dr. Stephen Badylak, its director, is globally recognized for work with ECM in tissue engineering and regenerative medicine. Dr. Badylak's laboratory conducted a canine proof of concept study resulting in compelling evidence of ECM's safety and efficacy in the colon (Figure 3). The data clearly validate Asana's scientific premise that ECM creates a scaffold for natural tissue recovery and regrowth.

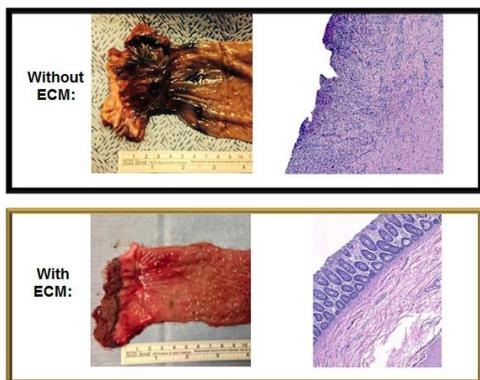


Figure 3: Proof of Concept Study

Top Images: Control animal (no ECM). Left: Gross anatomy. Right: Histology. Images show scarring and no mucosal tissue regrowth. *Bottom Images:* Experimental animal (with ECM) rectal tissue. Images show normal tissue and mucosal regrowth.

Following the canine study, a rodent study¹ was conducted with the McGowan Institute to establish the viability of a hydrogel version of ECM. That study was carried out in a widely used UC rodent model and confirmed the original findings of colon tissue regeneration. Asana recently completed a pivotal rodent study to corroborate the data generated in earlier studies. Through a well-controlled and blinded study protocol, the data established (a) proof of mucosal regeneration and reduction in inflammation and ulceration, (b) restoration of cell barrier function, (c) reduction in inflammatory biomarkers, and (d) significant improvement in UC clinical symptoms, similar to those in humans, such as weight loss and blood in the stool (Figures 4 & 5). This robust study is the foundation for regulatory filings to demonstrate safety and efficacy to proceed to First-In-Man.

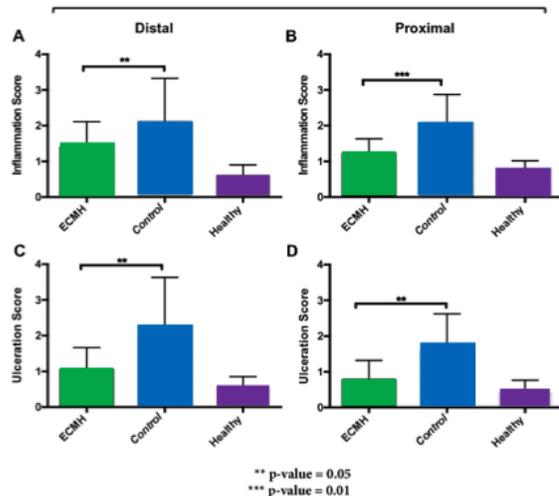


Figure 4: Pivotal Rodent Study Statistics

Statistically significant data indicating that ECMH reduces Ulceration and Inflammation activity in the Distal [A & C] and Proximal [B & D] portions of colon after 7 days of treatment (in all cases, lower scores are better)

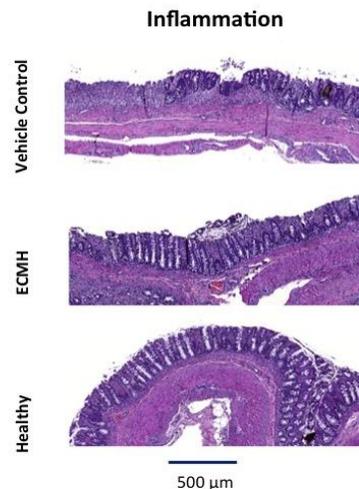


Figure 5: Pivotal Rodent Study Histology

Top image: control rats, UC induced not treated with ECMH, *Middle image:* UC induced, ECMH-treated rats and *Bottom image:* healthy rats, no ECMH.

The Company has established its process development and manufacturing strategy by aligning with a Contract Manufacturing Organization (CMO) widely considered to be the global market leader for the manufacture of tissue engineered products. Asana will manage and coordinate its strategic relationships to develop a scalable, commercial manufacturing process for ECMH.

Upon completion of production and testing of clinical product, Asana will conduct a First-In-Man (FIM) clinical trial in UC patients. This study, expected to start in 2017, will provide initial proof of safety and efficacy for ECMH in humans, accelerating Asana's value creation and positioning the company to leverage valuable and strategic distribution opportunities with established companies.

The FIM study will be followed by a pivotal clinical trial designed to obtain safety and efficacy data to file with FDA

for ECMH under a medical device classification. There is a well-defined regulatory path necessary for acceptance based on the prior approval and commercialization of multiple ECM products in the US and EU; thus reducing the hurdle for success.

Asana will leverage developmental and commercialization strategies utilized for Ulcerative Colitis for follow-on indications such as Crohn's Disease and Rectal Mucositis. GlobalData forecasts treatment therapies for CD will reach \$4.2 billion by 2022 in the 10 major pharmaceutical markets. Rectal Mucositis, caused by radiation and/or chemotherapy to the lower body, is a substantial market opportunity.

INTELLECTUAL PROPERTY

Asana co-owns and has secured exclusive, worldwide, field-specific rights to Intellectual Property (IP) covering the use of Extracellular Matrix, derived from any source, manufactured in any form, and delivered by any method to the small or large intestine, to treat gastrointestinal diseases. As part of its licensed rights, Asana has also received exclusive, worldwide, field-specific rights in certain Extracellular Matrix compositions and patented methods for its manufacture. We continue to enhance our IP. We believe this provides Asana with a comprehensive and strong IP portfolio.

THE BUSINESS STRATEGY

Asana requires regulatory approval to commercialize ECMH for UC. To obtain approval, the company will undertake technology transfer and scale up ECMH manufacturing, prepare for and conduct FIM studies, draft regulatory filings to conduct the pivotal study, and submit final regulatory applications. The company has secured strategic partners to help perform quality assurance, process development, testing, manufacturing, and reimbursement activities. By design, Asana has followed an out-sourcing model to maintain low overhead, effectively deploy capital, and efficiently leverage the core team to achieve timely commercialization objectives. With positive FIM data, Asana expects to contract with third parties to support sales, marketing, and distribution functions.

LEADERSHIP

Asana's leadership team is ideally suited to develop ECMH. Combined experiences include conception and management of successful early-stage life science companies as well as financing, product development introduction and commercialization, and execution of several successful exits. Asana's core team consists of:

Christine V. Sapan PhD *CEO, Chairman and Founder*

30 years' experience as a C-level business and scientific leader in the pharmaceutical and biotechnology industries included senior leadership roles in clinical affairs, regulatory affairs, R&D, and manufacturing at innovative companies including Neurologix (EVP), NABI Biopharmaceuticals (VP) and Beckman-Coulter. Dr. Sapan earned her BA degree (Biology) from Arcadia University, her MS degree (Human

Physiology) and PhD (Experimental Pathology) from the University of North Carolina at Chapel Hill, and completed her Post-Doctoral work at Duke University.

Scott Winston PhD, *Principal Consultant, Product Development*

Dr. Winston's career spans over 30 years in product development, manufacturing, preclinical and clinical testing, guiding vaccines, diagnostics, immunotherapeutics and smoking cessation products from inception to commercialization. Dr. Winston holds a BS degree from the University of Rhode Island and a PhD in Biology from University of Colorado. His Post-Doctoral studies were in Biochemistry at the University of Colorado.

Gerard S. Coombs, *EVP Operations, Director and Founder*

29-year financial and operational veteran, IVAX Corporation, Sano Corporation, Verid, Inc., Concordia Pharmaceuticals, Inc., Brickell Biotech, Inc., City Labs, PriceWaterhouse and PeatMarwick, BS University of Miami.

Brian W. Andersen, *Chief Business Officer*

20-year corporate, marketing and sales leadership with Horizon Pharma, Vidara Therapeutics, Dendreon, Lundbeck, Inc., PDL BioPharma and Pharmacia Corp. BS University of Illinois, MBA, Northwestern University.

Richard C. Bulman, Jr., Esq., *VP Legal and Founder*

29 years' experience, IVAX Corporation, SANO Corporation, Brickell Biotech and Oncomune practicing law at Kirkpatrick & Lockhart, Akerman Senterfitt among others. BA University at Albany, JD University of Buffalo.

Marc Ramer, *Biomedical Engineer Consultant and Founder*

A 21-year Medtech veteran, Mr. Ramer holds eight US patents, including one for Asana's core technology. BS Engineering, MS Materials Science, University of Florida.

DIRECTORS AND ADVISORS

The Board of Directors includes Michael Phalen (EVP, Boston Scientific) Reginald Hardy (CEO, Brickell Biotech) Sergio M Gonzalez (University of Miami) Dr. Hal Wrigley (former Division President Emerson Electric) Darren Sloniger (The Marquette Companies) and Dr. Sapan and Mr. Coombs.

The Medical Advisory Board includes Dr. Steven Wexner (Department Chair, Colorectal Surgery, Cleveland Clinic), Dr. Maria Abreu (Chief, Division of Gastroenterology, University of Miami), Dr. Steven Brant (Director, Meyerhoff Inflammatory Bowel Disease Center, Johns Hopkins), Dr. Mariana Berho (Chair, Robert Tomsich Pathology and Laboratory Medicine, Cleveland Clinic), Dr. Ray Sandler (Chief of Gastroenterology, Jackson North Medical Center), and Dr. Cathy Burnweit (Chief, Division of Surgery, Miami Children's Hospital).

[Restoring Mucosal Barrier Function and Modifying Macrophage Phenotype with an Extracellular Matrix Hydrogel: Potential Therapy for Ulcerative Colitis Timothy J. Keane; Jenna Dziki; Eric Sobieski; Adam Smoulder; Arthur Castleton; Neill Turner; Lisa J. White; Stephen F. Badylak Journal of Crohn's and Colitis 2016; doi: 10.1093/ecco-icc/jjw149](#)