DESTINATION STARTUP

Ensign Pharmaceutical, Inc.

One-Sentence Summary of What You Do: Ensign Pharmaceutical, Inc. develops and markets pharmaceutical prodcts that free patients with musculoskeletal disorders and inflammatory diseases from pain and disability wihout harmful side effects.

Affiliated Institution: University of Nebraska Medical Center

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Angel Funding (including Self or Friends/Family)

Please describe your company and the problem you are trying to solve: Ensign Pharmaceutical has obtained the exclusive license from UNeMed, the technology transfer and commercialization office of University of Nebraska Medical Center, to further develop and commercialize the ProGel technology (Patent Publication Number: WO 2020/087057 A1). ProGel technology has multiple innovative features, making it optimally suited for commercial development. ProGel-Dex is a macromolecular glucocorticoid prodrugbased thermoresponsive hydrogel, with a sol-gel transition temperature close to 37 °C. This unique thermoresponsive property allows the macromolecular prodrug formulation to be deposited in the synovial cavity with sustained presence for a protracted period of time (>3 month in a preliminary study). With continuous exposure to the synovial fluid, the ProGel-Dex is gradually solubilized and released followed by internalization by synovial cells, which through the metabolism of an acid-cleavable linker gradually release free Dex into the joint. The unique capacity of the ProGel-Dex formulation to provide continuous active drug release results in sustained suppression of inflammation and associated pain. The ProGel technology overcame the short action of traditional steroids and reduced its systemic toxicity. Ensign has received a $1.93M fast-track SBIR funding on ProGel technology and two $100k state matched funds. The current SBIR funding and future private funds will permit Ensign to quickly approach IND readiness. At that point, Ensign may seek a pharmaceutical partner or continue to entertain equity investment for clinical trials.

What is/was your go-to-market strategy? Osteoarthritis (OA) affects more than 270 million individuals worldwide. Although the ultimate goal of therapy is to prevent the development of OA joint pathology, currently, there are no approved therapies that have been shown to alter the progression of structural joint damage. Therefore, effective control of joint pain, which is the key factor impairing the quality of life among OA patients currently represents the primary objective of therapy. The widespread use of intraarticular glucocorticoids (IA GCs) is based on both the demonstrated efficacy of the injections in providing pain relief and improved function and the ease of administration of the treatments in the outpatient setting by trained medical professionals.

However, the long-term efficacy of GCs for pain management has been hampered by the short half-life of the GC preparations in the joint and the risk of repeated injections on both local and potential systemic side effects. The ProGel-Dex addresses these needs due to its prolonged presence in the joint, sustained therapeutic efficacy and reduced systemic GC toxicity. Presently, only one long acting GC formulation has been approved for clinical use. Based on our preclinical data, we predict ProGel-Dex will provide superior clinical efficacy and reduced local and systemic toxicity. Although IA GCs are most commonly utilized for the treatment of knee and hip OA, they can also be used for other joints including the spine. In addition, the ProGel-Dex may also be used for treatment of soft tissue inflammation, e.g. tendonitis or bursitis, or injury.

How will/do you generate revenue? The osteoarthritis (OA) drug market is large. There will be more than 30 million patients with OA in the US. CDC reports one in four adults with arthritis experience severe pain. Presently, only one long acting GC formulation has been approved for clinical use. It is currently priced at ~$600 per dose and has limited market penetration. Based on predicted manufacturing costs and the expenses for preclinical and clinical validation, we predict that ProGel-Dex will be marketed at a very competitive price. Importantly, we predict that ProGel-Dex will provide superior clinical efficacy and reduced local and systemic toxicity. Based on the present treatment frequency of IA GCs for treatment of OA pain, with 33% market penetration, we predict that the Serviceable Obtainable Market will exceed one billion dollars annually. Ensign has received a $1.93M fast-track SBIR grant for the development of ProGel technology and two $100k NE state matching grants. The current funding and future private funds will permit Ensign to quickly approach IND readiness. At that point, Ensign will seek a pharmaceutical partner or continue to entertain equity investments for clinical trials.

How will this showcase benefit your company or technology? Ensign Pharmaceutical is actively looking for Series A investors. Ensign is looking for a $5M investment to complete the preclinical studies, cGMP manufacturing and GLP toxicity studies which are necessary for IND filing. This showcase would give Ensign exposure to potential investors.

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Who are the members of your team and why is this the right team to get the job done?

- Dr. Dong Wang, President, Chief Scientific Officer, Co-Founder. Dr. Wang is a tenured full Professor of Pharmaceutical Sciences at UNMC, College of Pharmacy. Dr. Wang is an experienced pharmaceutical chemist and an expert in nanomedicine technologies whose research focuses on drug development for musculoskeletal conditions and inflammatory diseases.
- Dr. Steven Goldring, Chief Medical Officer, Co-Founder. Dr. Goldring previously has served as Chief of Rheumatology at Beth Israel Deaconess Hospital and a Professor of Medicine at Harvard Medical School and subsequently was appointed to the position of Chief Scientific Officer at the Hospital for Special Surgery (HSS) and a Professor of Medicine at Weill Cornell Medical College in New York City. Dr. Goldring is an internationally recognized clinician scientist with extensive experience in the study of musculoskeletal diseases with a focus on rheumatoid arthritis, osteoarthritis and periprosthetic osteolysis, and has published extensively within these fields.
- Mr. Brian Beck, Chief Executive Officer, Chief Financial Officer and Co-Founder. Mr. Brian Beck is an Omaha entrepreneur with a wide network of venture capital, private equity and angel investor connections, as well as being a rule 501 accredited investor.
- Dr. Gang Zhao, Director of Technology Development. Dr. Zhao is an expert in macromolecular pharmaceutical prodrug design and evaluation focusing on inflammatory diseases.