Executive Summary

Reiley Pharmaceutical Inc. (RPI) is a precision medical company developing diagnostic imaging agents. These imaging agents include a selective COX-2 inhibitor combined with a Technetium 99m radioisotope to target regions with overexpressed COX-2, ingeniously identifying the epicenter of Lower Back Pain (LBP). These novel diagnostic agents, when injected into a patient as part of a LBP diagnostic test, can localize to the region with overexpressed COX-2, bind to COX-2 and "light up" the cells, which enables standard hospital scanners to quickly and accurately identify and image the precise location of the pain source.

Market and State of LBP Diagnosis

Approximately a 100 million people a year in the U.S. have chronic pain, costing $635B (Direct/Indirect). RPI believes that its diagnostic imaging agent to be used in concert with the RPI SPECT Imaging Test has a patient universe of at least 10M patients per year, with a $750 USD per test price point. Today, pain remains an ever-elusive costly conundrum for medical professionals and their patients, due to the current inability to discover accurately the source of pain. There is no GPS-like tool that can isolate for the physician the exact pain source location and no current examination that can shine a light on the precise cause of LBP – until now.

Mark Reiley, Founder's Epiphany Informs the Pain Treatment Landscape

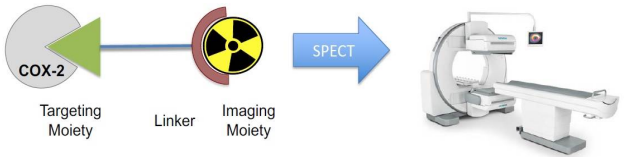
Mark Reiley, MD, Founder and Chief Medical Officer of RPI, is best known as the creative engine behind Kyphon (bought by Medtronic), Archus (bought by Globus), Reiley Orthopedics (merged with INBONE and then bought by Wright Mitchel), INBONE (bought by Wright Medical), SI-BONE (IPO 2018) and now Reiley Pharmaceuticals Inc. In his medical practice, he experienced firsthand the inherent diagnosis and treatment struggle when a patient presents with LBP. Dr. Reiley had an epiphany, "where pain is, COX-2 enzymes are expressing" and theorized that he could create novel diagnostic imaging agents to help better pinpoint and treat LBP. Furthermore, he hypothesized, that by using standard imaging techniques combined with existing COX-2 inhibitors, he could develop a new diagnostic agent for pain. *Essentially, Dr. Reiley invented novel diagnostic imaging agents that can find, bind with, and illuminate the underlying human biological signal, pinpointing the cause of pain, a first in science, and revolutionized precision medicine diagnostic drugs for LBP.*

World Class Experienced Drug Design and Drug Development Team

Dr. Reiley and Jeffrey Dunn, MBA, Founder, Chairman & Director of RPI, then recruited Dr. Michael Silber as CEO, to establish RPI as a drug discovery, drug development, and product-oriented company, and is a co-inventor of the RPI drugs. Dr. Silber successfully contributed to the development and commercialization of 23 drugs, including 13 blockbusters. He joined Reiley with more than 35 years of experience as a senior executive in the Pharma and Biotech industry. His first objective was to create a world-class R&D team that would synthesize and test candidate drugs that would selectively attach to COX-2. Over 1,000 of these were tested. From these, about 15% were synthesized and tested in enzyme and cell-based assays to select those with the right potency, as well as other key physicochemical properties, including pharmacokinetics, drug metabolism, and drug delivery. The Tc99m labeled drugs reached the site of action and rapidly bound to binding COX-2 resulting in illumination, as demonstrated in living animals.

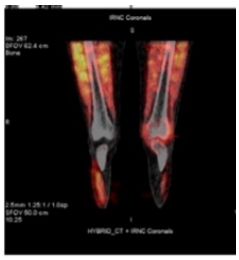
RPI Technology Theme

RPI leverages sophisticated computational chemistry modeling to design drug products that target specific regions in the body associated with LBP. RPI utilizes rational drug design concepts to efficiently identify clinical candidates. The RPI products can also be used as a theragnostic in connection with therapeutic treatments.



Significant Development Milestones

After intense dynamic screening, the leading clinical candidate was selected to go into animal toxicology/safety studies to support entry into the first Phase Ia/b clinical trial. That led to testing of the 1st generation imaging drug, which was evaluated in healthy subjects and patients with single-knee osteoarthritis to establish safety, toleration and proof-of-concept (POC) imaging. It was clear that the imaging drug lit up COX-2 overexpression in the affected knee only. RPI has designed and is testing its 2nd generation imaging drugs setting the company up for its current round of funding to support the next IND and Phase 1a/b trial.



Funding

RPI has raised $6.1M and is seeking $6M to complete two milestones leading to filing an IND & completion of a Phase Ia/b trial establishing POC in a small cohort of patients. Phase II trials will be initiated, and that will take an estimated 12-18 months at an estimated cost of $20M. RPI is open to combining and syndicating the two rounds.

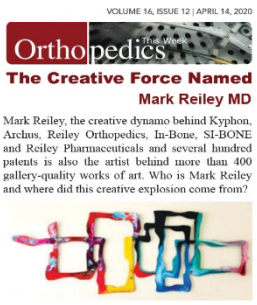
Other Applications of the RPI Diagnostic Imaging Agents

In addition to the current RPI focus in LBP, the exact same drug can be used for additional indications, given the fact that each of these maladies overexpress COX-2: earlier diagnosis in rheumatoid arthritis (RA) affecting 1.5M patients and as a companion diagnostic in RA treatments; opiate misuse, an epidemic in the U.S. affecting over 1.7M people. In addition, $69B is spent per year on employees receiving workers' compensation. The RPI pain biomarker could be used as an effective quantitative assessment tool for confirming the presence of a patient's pain. These four indications for the Reiley diagnostic agent represent a multi-billion-dollar opportunity for RPI's diagnostic imaging agents and technology.

RPI's Diagnostics Agents Dramatically Impact the Medical Pain Arena

The planet is currently in the middle of a golden age of life science technology, and thus breakthrough products like RPI's LBP test will become a standard of care, which will create a new silo in the diagnostic landscape. Basically, by creating a new paradigm based on pinpointing **the biological signal of pain,** all facets of the precision diagnostic imaging drugs arena will expand.

RPI creates demand for many products in the diagnostic arena. The SPEC-CT vendors, pharmaceutical manufacturers, radiopharmacies, imaging and AI all poised to experience explosive growth from this new diagnostic silo. Thousands of medical, surgical practitioners, and providers will utilize these groundbreaking RPI diagnostic agents, beginning with the standard LBP test, and that will affect millions of patients.


VOLUME 16, ISSUE 12 | APRIL 14, 2020

Orthopedics This Week

The Creative Force Named Mark Reiley MD

Mark Reiley, the creative dynamo behind Kyphon, Archus, Reiley Orthopedics, In-Bone, SI-BONE and Reiley Pharmaceuticals and several hundred patents is also the artist behind more than 400 gallery-quality works of art. Who is Mark Reiley and where did this creative explosion come from?