

Reiley Pharmaceuticals Inc.

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Reiley Pharmaceuticals Inc.

Biomarker-Based Diagnostic Drug for Pinpointing Lower Back Pain

Industry: Diagnostics

- **Target Indication:** Lower Back Pain
- **Future indications:** Opioid Misuse, Rheumatoid Arthritis, Worker's Compensation Assessment

Management

- **B. Michael Silber, PhD**
President, CEO & Director
Dr. Silber successfully contributed to the development and commercialization of 23 drugs, including 13 blockbusters in 35 years

- **Mark R. Reiley, MD**
Founder & CMO

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.

Advisory Team & Board of Directors

- Jeffrey W. Dunn, MBA
Founder, Chairman & Director
- Keith Valentine
Director
- Allan Basbaum, PhD
Scientific Advisory Board, UCSF
- Leslie Z. Benet, PhD
Scientific Advisory Board, UCSF
- Ronald T Borchardt, PhD
Scientific Advisory Board, U Kansas
Scientific Advisory Board, ex-Pfizer
- Donald R. Kiepert
Board Advisor, Ex-Lantheus CEO,
Curium BOD
- Stephen Hochschuler, MD
Board Advisor, Chair, Texas Back
Institute
- Frank Kayser, PhD
Drug Discovery Advisor
- Daniel Cher, MD
Clinical Development Advisor

Intellectual Property

- Exclusive worldwide license to all technology. Several issued patents covering composition of matter.
- Patents cover key links incorporating radioactive imaging substances.

Funding to Date & Future

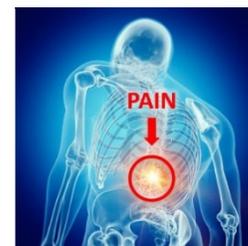
RPI has raised \$6.1M and is seeking \$6M to complete two milestones leading to filing an IND & completion of a Phase 1a/b trial establishing POC in a small cohort of patients. Phase II trials will take 12-18 months at a cost of \$20M.

Executive Summary:

- Reiley Pharmaceutical Inc. (RPI) is a precision medicine diagnostic company that will dramatically impact the Lower Back Pain (LBP) medical arena with its targeted diagnostic drugs that can pinpoint the exact source of LBP.
- RPI is the first to pursue diagnostic imaging agents in pain based on the key human biological signal involved in eliciting pain. These novel diagnostic agents, when injected into a patient as part of a LBP diagnostic test, can find the site of COX-2 overexpression, bind to the intracellular COX-2 enzyme and "light up" the cells, which enables a standard hospital- or office-based SPECT-CT scanner to quickly, sensitively and accurately identify and image the precise location of the pain source.
- RPI's technology is a game changer for the LBP diagnostic market, affecting millions of patients who suffer from LBP with a test that authenticates and facilitates a more precise and accurate treatment of their LBP condition – a first in the industry.

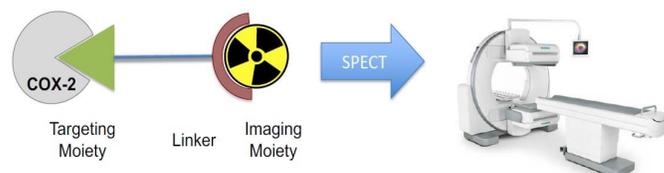
Market Opportunity/Unmet Need:

- 100 million people a year in the US have chronic pain, which costs the U.S. \$300B (Direct) and \$635B (Direct/Indirect). RPI believes that its diagnostic drug product, to be used in the RPI SPECT Imaging Test, has a patient universe of at least 10M patients per year, with a \$750 USD per test price point.
- Back surgery success rates are only ~80%, solely due to bad diagnostics, \$1.25 billion a year is spent on wrong lumbar spine fusions. RPI can become the standard diagnostic test for more informed decisions.
- There is no "GPS-like" tool that isolates the exact location, and no current examination process that can shine a light on the precise cause of LBP. A patient can walk into a doctor's office presenting with LBP and, many times, the physician struggles to pinpoint the exact source of the LBP.



RPI Technology:

- Leveraging sophisticated computational chemistry modeling to design drug products that will be capable of reaching the intracellular COX-2 enzyme, to potentially bind and illuminate COX-2 overexpression in specific regions in the body associated with LBP.
- RPI utilizes rational drug design concepts to efficiently identify clinical candidates. This requires virtual and actual state-of-the-art compound screening of candidates, cell-based assays to ensure drugs are capable of crossing cell walls, and *in vitro* and *in vivo* pharmacokinetic, drug metabolism, pharmacology and SPECT studies in animals.
- This process creates a novel family of targeted precision diagnostics agents, literally changing the pain treatment paradigm for COX-2 pain related disorders.
- The Reiley products can also be used as a theragnostic in connection with therapeutic treatments, including drug or surgical.



Technical Milestones Achieved:

- After intense dynamic screening, the leading clinical candidate was selected to go into animal toxicology/safety studies to support entry into the first Phase 1a/b clinical trial.
- 1st generation product was evaluated in healthy subjects and patients with single-knee osteoarthritis to establish safety, toleration and proof-of-concept (POC) imaging studies. 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.
- Phase 2 and 3 trials would be expected to take an additional 2-3 years. Regulatory strategy developed, with target for approval in 4 years. Broad IP position established, with several granted patents and several more provisional patents filed.