

Reiley Pharmaceuticals Inc.

Biomarker-Based Diagnostic Drug for Pinpointing Lower Back Pain

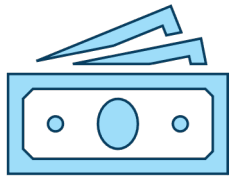
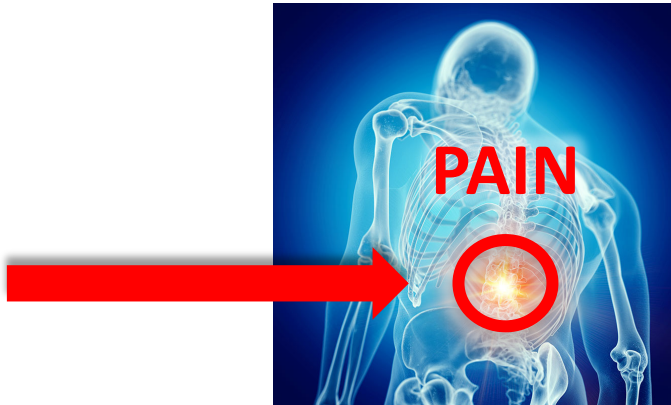
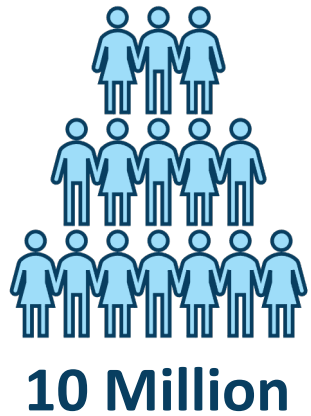
B. Michael Silber, PhD, CEO
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Reiley Pharmaceutical Inc. (RPI) is a precision medical company developing diagnostic imaging drugs. These imaging agents include a selective COX-2 inhibitor combined with a Technetium 99m radioisotope to target regions with overexpressed COX-2, ingeniously identifying the epicenter of Lower Back Pain (LBP).

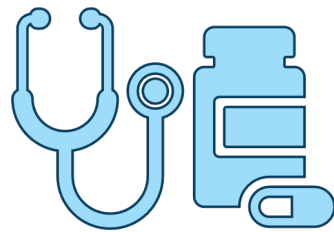
These novel diagnostic drugs, when injected into a patient as part of a LBP diagnostic test, can localize to the region with overexpressed COX-2, bind to COX-2 and “light up” the cells, which enables standard hospital scanners to quickly and accurately identify and image the precise location of the pain source.



Market and State of LBP Diagnosis



\$635B



Approximately a 100 million people a year in the U.S.
have chronic pain, costing \$635B (Direct/Indirect).

RPI believes that its diagnostic drug product 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 the source of pain accurately. 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 Founders Epiphany Informs the Pain Treatment Landscape



*Biomarker-Based Diagnostic Drug
for Pinpointing Lower Back Pain*



Mark Reiley, MD

*Founder & Chief Medical Officer
Reiley Pharmaceuticals Inc.*

Dr. Mark Reiley, 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 Mitchell), INBONE (bought by Wright Medical), SI-BONE (IPO 2018) and now Reiley Pharmaceuticals Inc.

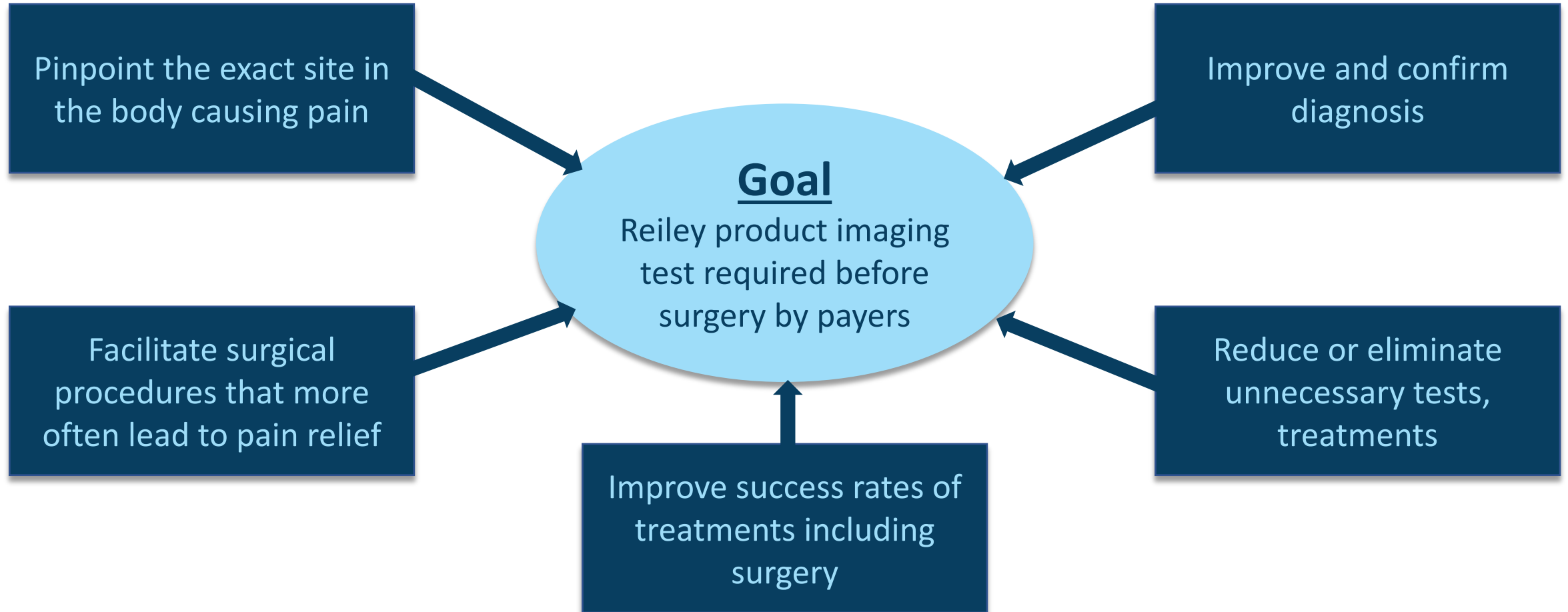
- Dr. Reiley had an epiphany, “where pain is, COX-2 enzymes are expressing” and theorized that he could create novel diagnostic imaging drugs to help better pinpoint and treat LBP.
- Furthermore, he hypothesized, that by using standard imaging techniques combined with existing COX-2 inhibitors, he could a new diagnostic drug for pain.

Essentially, Dr Reiley invented novel diagnostic imaging drugs that can find, bind with, and illuminate the underlying human biological cause of pain, a first in science, and revolutionary precision medicine diagnostic drugs for LBP.

Reiley Product Use in LBP



*Biomarker-Based Diagnostic Drug
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World Class Experienced Drug Design and Drug Development Team



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Dr. Reiley and Jeffrey Dunn, MBA, Founder, Chairman & Director of RPI, recruited Michael Silber, PhD as CEO to establish RPI as a drug discovery, drug development, and product-oriented company, and co-inventor of the RPI drugs.

Dr. Silber has contributed to 23 drugs that successfully went through development and commercialization including 13 blockbusters. Dr. Silber recruited a world-class R & D team that would synthesize and test candidate drugs to selectively attach to COX-2. Over 1,000 of these were tested. 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, drug delivery.

Remarkably, the Tc99m labeled drugs reached the site of action, rapid binding, and COX-2 illumination was demonstrated in living animals.

RPI Technology Theme

RPI Leverages sophisticated computational chemistry modeling to design drug products that are in 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.

Reiley Pharmaceuticals Team



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B. Michael Silber, PhD
President, CEO, Director

Mark R. Reiley, MD
Founder and CMO

Jeffrey W. Dunn, MBA
Founder, Chairman,
Director

Keith Valentine
Director

Frank Kayser, PhD
Chemistry and
Preclinical Development

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Morrison & Foerster

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Facet Life Sciences

Paul Anderson, PhD
Scientific Advisory Board

Donald R. Kiepert
Board & Capital Advisor

Stephen Hochschuler, MD
Board Advisor

Allan Basbaum, PhD
Scientific Advisory Board

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 1a/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



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2H 2021 – 1H 2026

3Q20	1H 21	2H 21	1H 22	2H 22	1H Q23	2H Q23	1H 24	2H 24	1H Q25	2H 25	1H 26
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→ Clinical Candidate Nomination to GLP Tox (FUNDED)



→ GLP Tox Studies

→ Prepare, File and Approve IND

Phase 1a/b (N = 20)

\$6 M

(Prepare Cold Kit for Phase 2 Trials)

Phase 2a/b (N = 150)

\$20 M

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 syndicating the two rounds

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.

Other Applications of the RPI Diagnostic Imaging Drugs



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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:

1

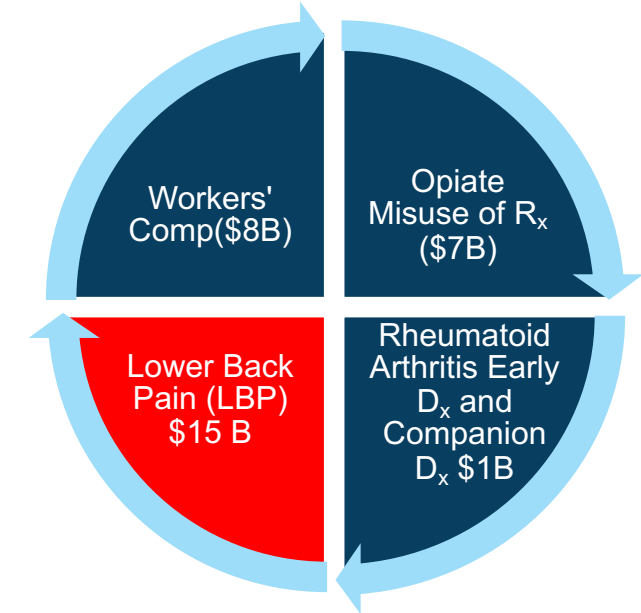
Earlier diagnosis in rheumatoid arthritis (RA) affecting 1.5M patients and as a companion diagnostic in RA treatments;

2

Opiate misuse, an epidemic in the U.S. affecting over 1.7M people. Clinicians could administer an irrefutable diagnostic test to confirm a patient's pain to justify use of opiates and therefore could stop prescribing them where there is no evidence of COX-2;

3

\$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. This diagnostic approach could identify when workers' compensation payments are justified or should be terminated.



**Potential indications
and revenue for the
RPI Product**

These four indications for the Reiley diagnostic agent - LBP, RA, opiate misuse, and workers' compensation markets - represent a multi- billion-dollar opportunity for RPI's diagnostic imaging drugs and technology.

RPI's Breakthrough Diagnostics Drugs Dramatically Impact the Medical Pain Arena-Game Changer



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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 human biology of pain** all facets of the precision diagnostic imaging drugs arena will expand.

RPI has an unparalleled management team and will create 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 drugs. Beginning with the standard LBP test and that will affect millions of patients.

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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?



**Founder Mark Reiley MD
featured in leading trade
journal April 2020**