



A Revolution in Pain Pharmaceuticals

PHOENIX
Pharma Labs™

The Problem

Opioids are the most widely prescribed drugs for moderate to severe pain. They are the most powerful analgesics for treatment of acute as well as chronic pain.

However, their use is plagued by significant side effects:

- Euphoria / Abuse & Addiction
- Withdrawal
- Constipation
- Death from Overdose

The Problem

From the CDC:

“Prescription opioid drug abuse is a major public health problem that is getting worse, and getting worse rapidly.”

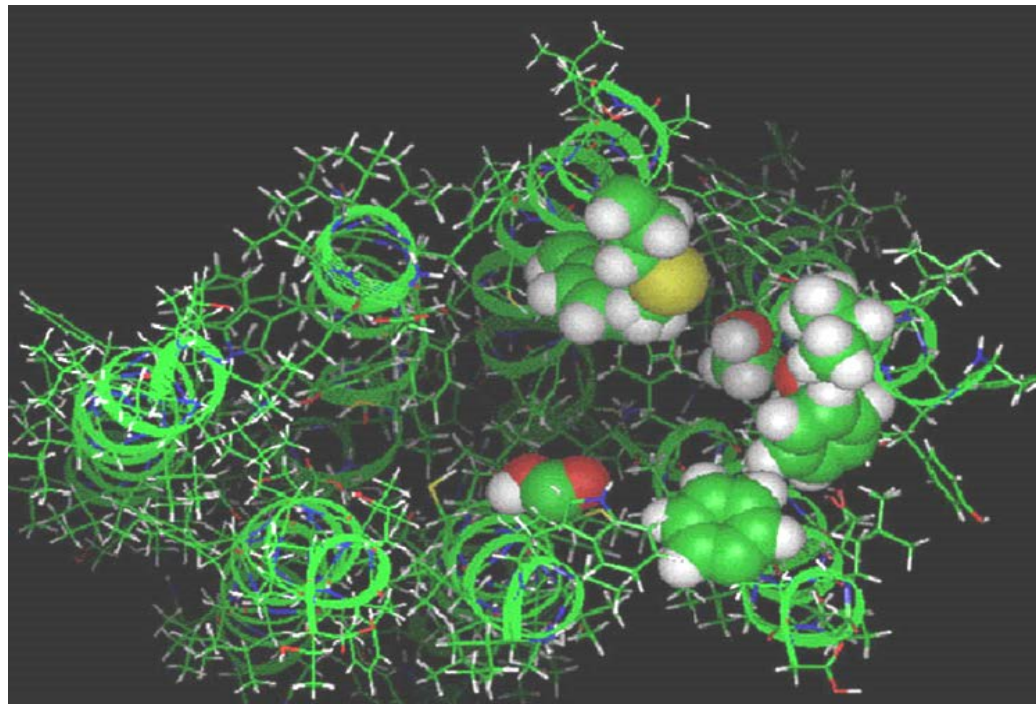
More than 2 million Americans are addicted to opioids, and approximately 80% of them initially became addicted after they had been given a prescription opioid for pain relief by a physician.

The Solution: Phoenix PPL-103

- ✓ **Robust analgesic potency** – 10-20x stronger than morphine
- ✓ **No euphoria / abuse & addiction**
- ✓ **No dysphoria**
- ✓ **No physical dependence or withdrawal**
- ✓ **No death from overdose** (even at 350x dose)
- ✓ **No significant constipation** (even at 350x dose)
- ✓ **Oral bioavailability**
- ✓ **Sustains addicted subjects without precipitating withdrawal**

The Brain's Opioid Receptors

All leading opioids bind to the **mu** receptor in the brain and then **aggressively** agonize that receptor. But there are actually three primary opioid pain receptors: **mu, kappa and delta**



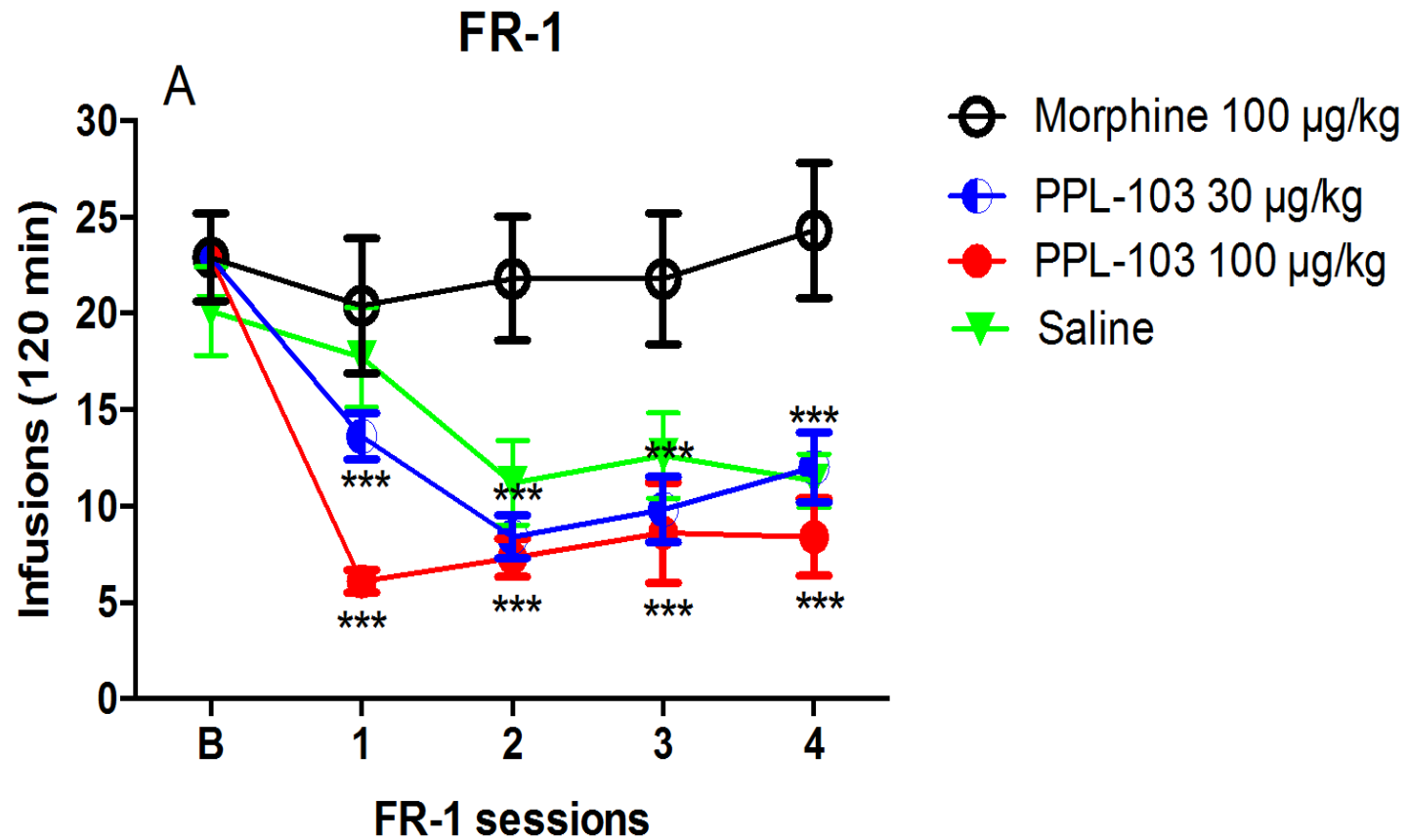
(diagram of G-protein receptor)

PPL-103 Profile

Characteristic	Mu Opioids	Kappa Opioids	PPL-103
Significant CPP / SA (Euphoria)	Yes	No	No
Significant CPA (Dysphoria)	No	Yes	No
Lethal Respiratory Depression at High Dose	Yes	No	No
Significant Constipation	Yes	No	No
Withdrawal Symptoms	Severe	No	No
Sustains Without Opiate Withdrawal	Yes	No	Yes

A potent opioid with a profile that is neither mu nor kappa – and is free of the serious side effects of both

PPL-103 Rat Self-administration



Predictive Validity of Rat SA Studies

The rat self-administration model has a very high correlation to abuse liability in humans

Source: “The predictive validity of the rat self-administration model for abuse liability” O'Connor et al. *Neuroscience & Biobehavioral Rev.* 35:912-938, 2011

Markets by Pain Condition

Market Values for Various Pain Conditions

Condition	2009	2014	2019
Arthritis	\$13.3 billion	\$19.6 billion	\$26.0 billion
Backache	\$3.1 billion	\$4.7 billion	\$7.0 billion
Cancer pain	\$16.7 billion	\$23.9 billion	\$33.0 billion
Migraine	\$4.6 billion	\$5.5 billion	\$7.5 billion
Neuropathic pain	\$3.9 billion	\$5.9 billion	\$8.9 billion
Postsurgical pain	\$2.9 billion	\$6.2 billion	\$8.0 billion
Fibromyalgia	\$0.5 billion	\$0.9 billion	\$2.1 billion
Rest of conditions	\$11.0 billion	\$13.3 billion	\$19.5 billion
Total	\$56.0 billion	\$80.0 billion	\$112.0 billion

(from Jain's Report on Pain Therapeutics)

Strategic Objective:

To enter into license agreements with appropriate market leader(s) that have the resources and motivation to further develop, commercialize, and maximize the market potential of, PPL's family of drugs.

PPL is currently advancing its lead compound for pain through preclinical studies and then to proof of concept (POC) in humans. At or before that point is reached the company expects to license that compound to a pharma company that meets the above criteria.

Clinical Trial Plan (Through POC)

	Year 1				Year 2				Year 3		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	
Synthesis	GLP Synthesis				GMP Synthesis						
Preclinical	Product Stability Testing										L I C E N S E
	DMPK										
	Safety Pharma										
	Genetic Tox										
	28-Day General Tox										
IND	Pre-IND				IND						
NHP Studies	Additional Efficacy Studies										
Phase I / II Clinical Trials*					Study 102 & 102 Study 201 - Pain & Study 202 - Drug Abuse Liab						
POC									POC		
Costs (\$000)	597	367	396	1,122	639	761	1,121	1,356	845		
Cumulative	597	964	1,360	2,482	3,121	4,426	5,547	6,903	7,748		

*Australia

Funding Strategy

Funding needed to reach POC =	\$7 – 8 M
Funding from grants	<u>- \$3 M</u>
Funding needed from investors	\$4 – 5 M

Proposed: \$1 M initial investment

The balance to be invested in milestone-based tranches

(Grant(s) of approximately \$3 M are expected to be received from the US Army and/or the NIH / National Institute for Drug Abuse (NIDA) to advance PPL-103 into human clinical trials.)

Management & Board Members

John Lawson, Ph.D., Founder, Board Chairman and Chief Scientist - the primary developer of PPL's intellectual property; formerly headed the Neurochemistry R&D Group at SRI International

William Crossman, President, CEO and Board Member - launched and developed numerous emerging technology companies; served as CEO, CFO and CDO of enterprises ranging from start-ups to Fortune 100 level companies

Timmy Chou, Vice President, CFO and Board Member - founding partner of Spectra Consulting Group; experience as CEO and CFO of numerous emerging companies, serves on the Boards of several public and private companies

Lawrence Toll, Ph.D., Chief Neuropharmacologist and Board Member; Director of the Neuropharmacology Department of Torrey Pines Institute for Molecular Studies and SRI International; co-discoverer of the nociceptin opioid peptide

Chris Tew, Vice President, Board Member - senior sales and marketing executive of bioscience companies including VP Sales for Protocol Systems (Welch Allyn)

Theodore Stanley, M.D., Board Member - Chairman and Founder of ZARS Pharma; formerly Director of Research of the University of Utah

Advisors

Mary Jeanne Kreek, M.D., Senior Attending Physician and Patrick E. and Beatrice M. Haggerty Professor, Head of Laboratory of Biology of Addictive Diseases, The Rockefeller University; recipient of numerous professional awards

John Mendelson, M.D., Senior Scientist, California Pacific Medical Center Research Institute; specific expertise in the design and supervision of human clinical trials of controlled substances

Shayne Gad, Ph.D., Principle, Gad Consulting; recipient of the American College of Toxicology Lifetime Contribution Award; 35 years experience in toxicology, statistics and risk assessment; authored or edited 44 published books in the fields.

Gary Robinson, Ph.D., Principal of PhaseDesign Research; provides regulatory and clinical planning expertise, deep experience in primary pharmacology and IND enabling preclinical studies, grant-funding and drug product manufacture.

Mei-Chuan (Holden) Ko, Ph.D. – Professor, Department of Physiology & Pharmacology, Wake Forest University School of Medicine

PPL Offers...

- A Novel Design Technology
- Multiple Therapeutic Licensing Opportunities
- A Very Large Market in Pain Therapeutics
- Relatively Low Clinical Trial Costs and Risks
- PPL Drug Family Expansion
- Multiple government grant opportunities

Thank You

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