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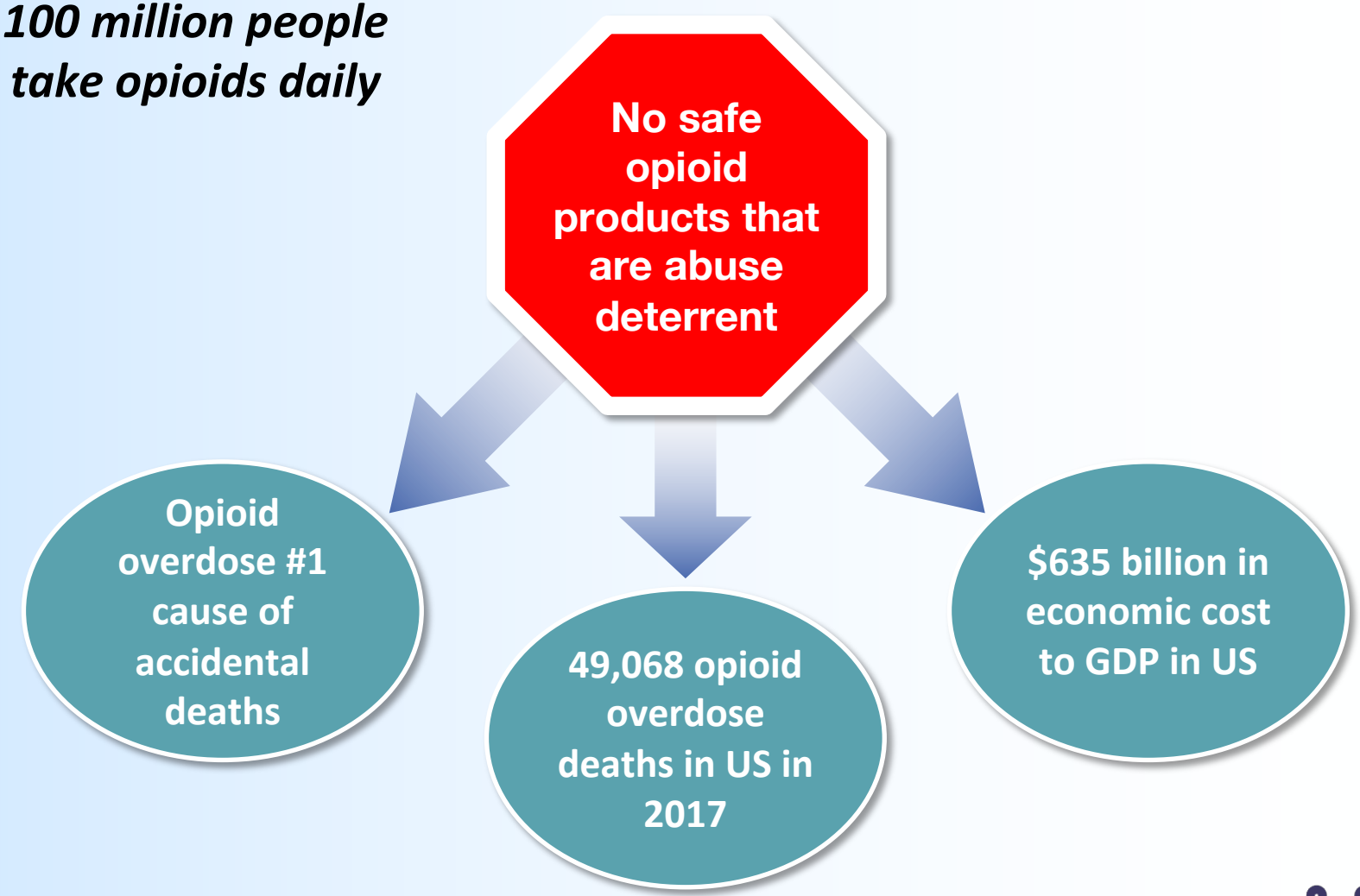
# *A Safer Abuse Deterrent Opioid Analgesic*

*November, 2018*

# The Problem: Opioid Abuse Is Out of Control

***100 million people take opioids daily***



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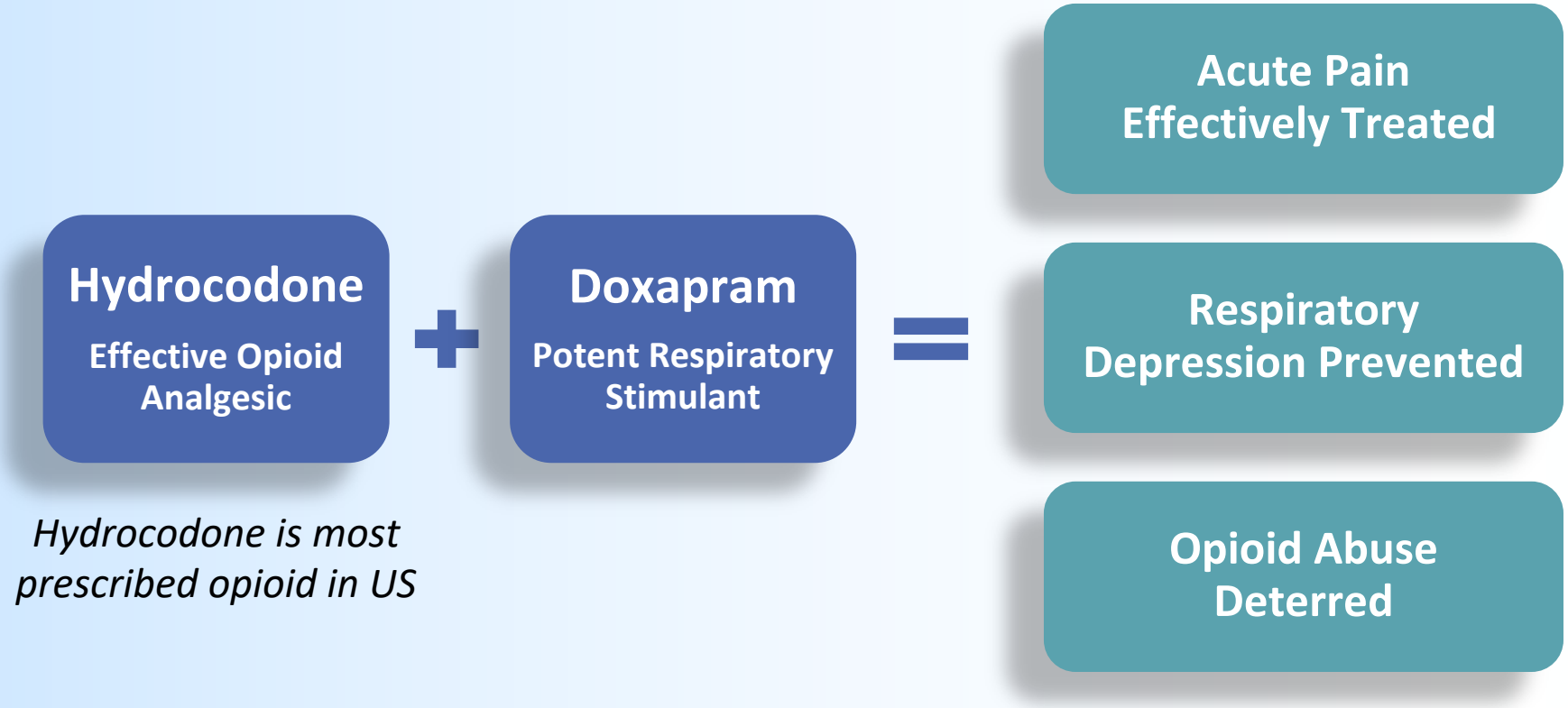
# The Solution: QEV-817

***An opioid pain killer that is both safer and orally abuse deterrent***




*Hydrocodone is most prescribed opioid in US*



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# Patented Abuse Deterrence Technology

## *QEV-817 Deters Abuse by Transforming Behavior*

**When used as Prescribed** → **1 pill treats pain w/out side effects**

**When abused by overconsumption** → **5 pills feel awful anxiety/dysphoria**

- *Psychiatrists use Doxapram as a model for anxiety*
- *pharma uses it to test new anti-anxiety drugs*

- *94% of addicts started abusing Rx opioids*
- *QEV-817 closes primary gateway to opioid addiction*



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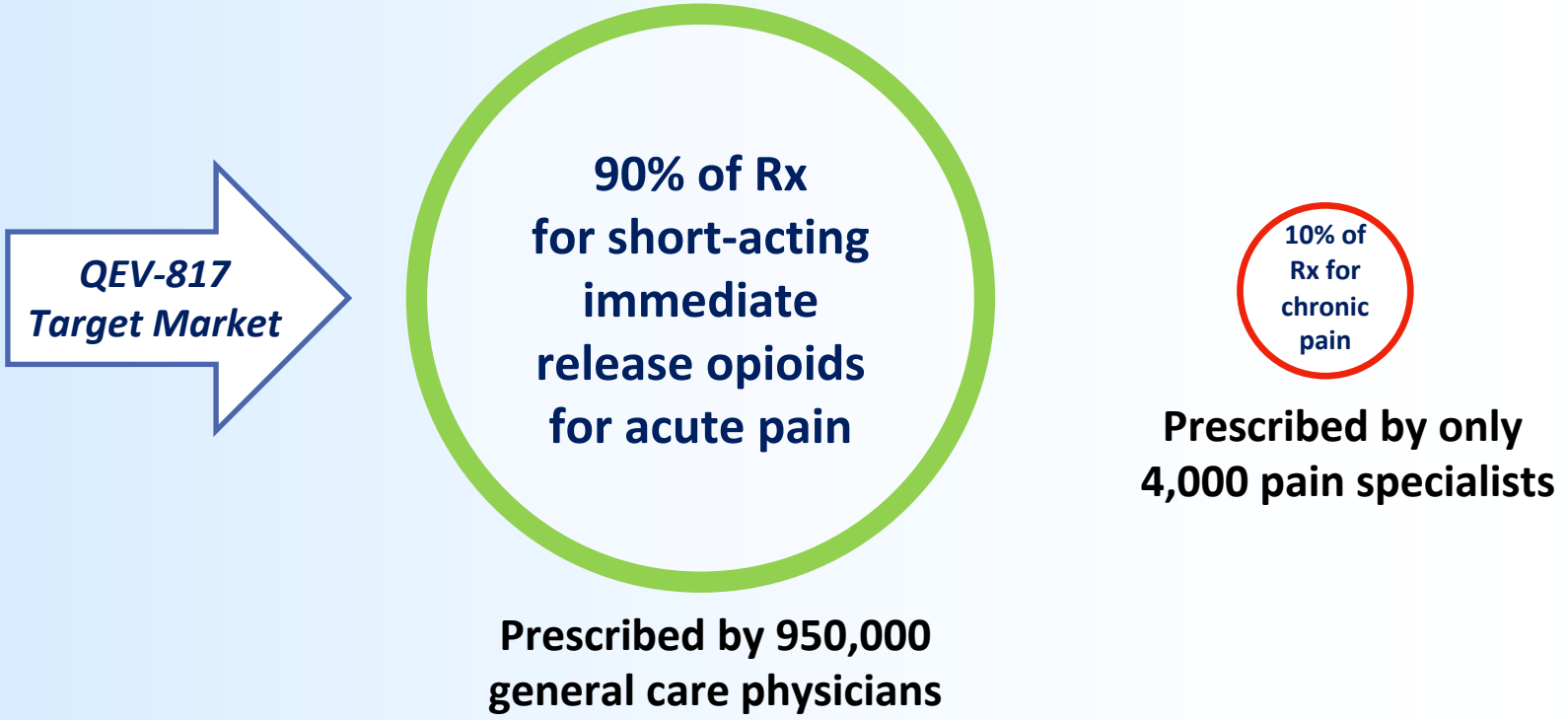
# The Opportunity: $10 Billion Opioid Market

***191 million opioid prescriptions written in US annually***



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# Quivive's Experienced Executive Team

**John Hsu, MD**
**CEO and Founder**

- Anesthesiologist
- Pain mgmt. physician
- 28 years of practice
- Built multiple successful companies

https://www.linkedin.com/in/john-hsu-300a8b2a

**Peter Rix, DABT**
**Chief Scientific Officer**

- 26 years in Pharma R&D
- 6 Marketed products (Allergan and Ligand)
- Major exits: Aragon to Janssen ($1B) and Seragon to Genentech-Roche ($1.75B)

https://www.linkedin.com/in/peter-rix-40b3703

**Gary Seelhorst MS, MBA**
**Senior VP Business Dev**

- 22 years exp. clinical and corporate development
- Eli Lilly, Pfizer, Naviscan
- licensing and M&A transactions

https://www.linkedin.com/in/gary-seelhorst-1a798b1



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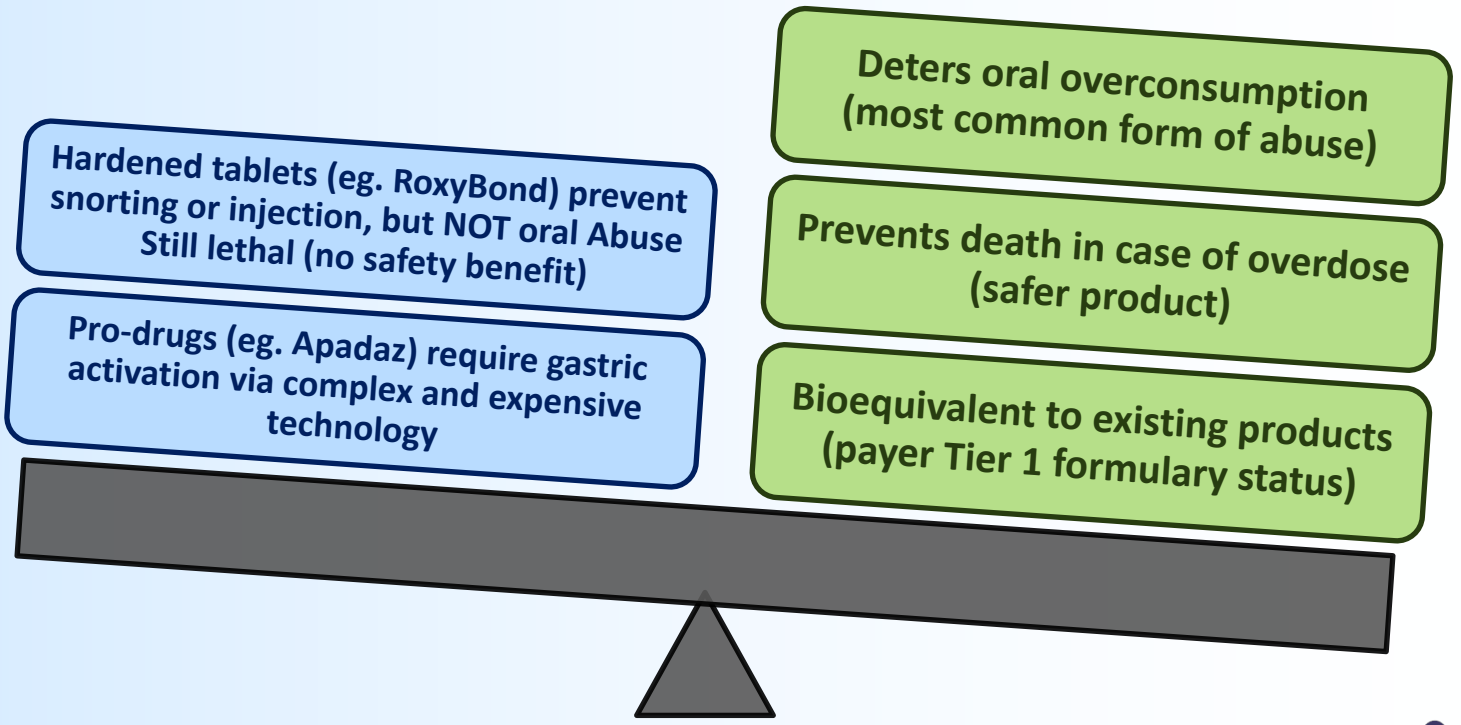
# Advisory Board, Consultants and Partners

| | | |
|---|---|---|
| Advisory Board | Robert Rappaport, MD | Former Dir. of DAAAP at FDA |
| | Brian Harvey, MD, PHD | Former Dir. of GI, Pain at FDA |
| | Lynn Webster, MD | Clinical Pain Specialist & KOL |
| | Joseph Cotten, MD, PhD | Clinician, Harvard Med & KOL |
| | Lacarya Scott, MS, MBA | Corporate Development |
| | Sherie Hsieh, BS | Marketing |
| Consultants | Andrew Parkinson, PhD | Clinical Pharmacology |
| | Drazen Ostovic, PhD | Combo Drug Product / CMC |
| Partners | Camargo Pharma Services | Leader in 505(b)(2) |
| | PRA Health Services | Clinical Studies |
| | Catalent Pharma Solutions | Combo Drug Product |

# The Competition vs. The QEV-817 Edge

*FDA may soon withdraw all IR opioids without abuse deterrence*
*Which products can dominate the new market?*



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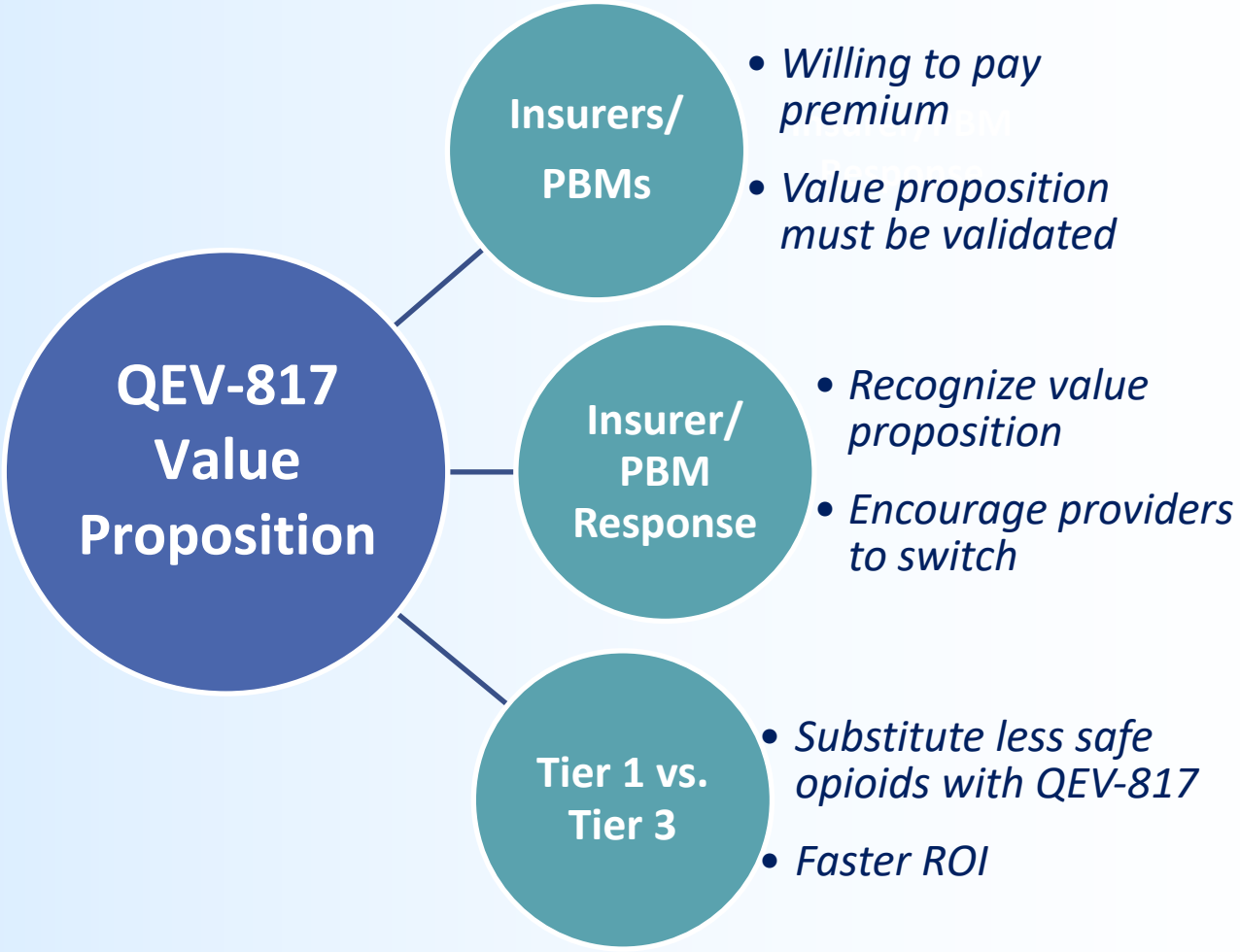
# Commercialization: Value Proposition

A safer ADF opioid to reduce the overall cost of healthcare



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# Commercialization: Projected Revenues

| Year | Market Share | Revenues |
|---|---|---|
| 2022 | 1% | $73,652,200 |
| 2023 | 2% | $147,247,600 |
| 2024 | 3% | $220,953,000 |
| 2025 | 5% | $368,256,000 |
| 2026 | 10% | $736,512,000 |

- Assumes first commercial sale following FDA approval in 2022
- Estimates assume conservative growth
- 3 yrs Hatch-Waxman exclusivity and 20 yrs patent protection

# IP Strength: Patent Protection

*Broad application covering combination of any opioid with any respiratory stimulant - supporting two patent families:*

**Oral abuse deterrence via combination with respiratory stimulant**

- Granted US Patent No. 10,004,479 – Combination of Hydrocodone and Doxapram
- Pending application for combination of Oxycodone and Doxapram

**Combination delivered via transdermal delivery and other novel means**

- Pending application for combination with transdermal fentanyl patch
- Combination with Buprenorphine/Suboxone transdermal patch



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# Timeline to Approval for QEV-817

| | |
|---|---|
| **Pre-IND Meeting** | FDA agreed to 505(b)(2) pathway<br>success rate of 505(b)(2) is 60% |
| **Results** | Clear development plan<br>Fast Track and Priority Review |
| **IND Submission** | Filed in 1Q2019 clinical trials for<br>bioequivalence, abuse potential and efficacy |
| **NDA Submission** | Expected in 2022 |

**Near Term Future Pipeline of Multiple Drugs:**
**Oxycodone + Doxpram**
**Fentanyl patch + Doxapram**
**Alprazolan + Doxapram**



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# Quivive Pharma: Use of Proceeds

| QEV-817 Related Activities | Costs |
|---|---|
| Phase 1 Clinical Studies | $5,250,000 |
| Combo Drug Product / CMC | $950,000 |
| Non-clinical Toxicology / DMPK | $1,400,000 |
| Consulting / Regulatory / Submissions | $650,000 |
| General Operations / Travel / IP | $1,500,000 |
| **Total** | **$9,750,000** |



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# Seeking Investors

## Round A

Seeking to close a priced round of $10 MM to support:

- Nonclinical Studies
- Clinical Studies
- Commercial Product Development

***Contact:***
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*John.Hsu@Quivivepharma.com*
*(626) 695-5985*



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