Quivive Pharma Executive Summary

San Diego based Quivive Pharma ('kee-veev') is pioneering a unique and revolutionary approach to combatting the opioid crisis by combining an opioid analgesic with an FDA approved respiratory stimulant to create a safer generation of abuse-deterrent analgesic products.

The Crisis: In 2016 in the US, 145 people died each day from opioid overdose, more than from auto accidents or gun violence. The US economic burden of this crisis exceeds $100 billion annually.

The Challenge: All opioids induce respiratory depression, which is invariably the cause of death in cases of overdose. This lethal side effect is mediated by the same receptor pathway responsible for analgesia. Doctors routinely prescribe laxatives to deal with opioid-induced constipation and anti-emetics to deal with opioid induced nausea, but nothing for respiratory depression - the most serious opioid side-effect. It would be great if we could switch to new analgesics that did not have these dangerous side effects, but there is currently nothing that can treat severe pain as well as opioids.

The Solution: Our approach is to make these existing products safer through the combination of an opioid analgesic with an approved respiratory stimulant using the 505(b)(2) regulatory path, which affords an accelerated path to approval. Our first product (QEV-817) is an immediate release combination of hydrocodone and acetaminophen (ie. Vicodin®, Norco®, Lortab®, etc.) with a respiratory stimulant, which will be sub-therapeutic when used as directed but will prevent respiratory depression following overdose. Abuse deterrence is achieved by aversion to unpleasant, but not dangerous, dysphoric effects that occur only when excessive doses are consumed.

The Market: Hydrocodone has been the most prescribed drug in the US for many years, peaking at 137 million prescriptions written for hydrocodone products in 2013. The total opioid market exceeds $10 billion dollars and 90% of opioid prescriptions are for immediate release hydrocodone and oxycodone products.

The Competition: New chemical entities (NCEs) are many years away from approval and will have new and unknown side effect profiles. In addition, these NCEs will not be therapeutically equivalent to exiting products, hindering their uptake and widespread use. Abuse-deterrent reformulations of existing opioids do not offer any safety benefit, nor do they limit oral overconsumption – the most common form of abuse of Rx opioids.

The Intellectual Property: Quivive Pharma has a strong IP position with both granted and pending USPTO and WO-PCT patents covering the combination of multiple opioids with respiratory stimulants – ie. a platform for a pipeline of future products that are both abuse deterrent and safer than current options.

The Team: Quivive Pharma has assembled a highly experienced executive management team combined with top scientists, drug development experts and key advisors. We have also partnered with an outstanding group of contract research organizations for the development of our first products.

The Opportunity: Quivive is seeking seed investment of $500K to $1 MM from a limited number of Accredited Investors. Proceeds will support the completion of ongoing preclinical studies and the FDA submission of an IND to allow clinical proof of concept studies of our first product; QEV-817.

For more information, please contact:

Peter J Rix,
Chief Scientific Officer
Quivive Pharma, Inc.
Mobile: (858) 336-2334
peter.rix@quivivepharma.com
www.quivivepharma.com