BRIDGE THERAPEUTICS - EXECUTIVE SUMMARY - SERIES B FINANCING

Chronic Pain: pain that remains after tissue healing in 3 to 6 months is termed "chronic" and implies that the nerves have been damaged by overstimulation. This pain can last from injury for the rest of one's life. 70 million Americans suffer from chronic pain. 17 million have such bad pain as to require daily medication, formally known as "moderate to severe chronic pain."

Main Problem: 116 Americans die each day from opioid overdose; 70% of these started by abusing prescription pain medication. Currently the only available treatments for moderate to severe chronic pain are strong opioids (e.g., morphine, oxycontin, fentanyl) which require <u>increasing dosage</u> to remain effective leading to <u>personality disorders</u>, and potentially to <u>overdose</u> and <u>death</u>.

Related Problem: the most popular drug for treating addiction (*Suboxone*) <u>cannot be swallowed</u>. Instead one usually dissolves it under the tongue or inside the cheek in 3 to 16 minutes, causing <u>mouth soreness and lesions</u> <u>in one-quarter of patients</u>. This mouth soreness discourages compliance with treatment plans.

The Connection: the active ingredient in Suboxone (*Buprenorphine*) is known by pain specialists to be <u>more</u> effective for treating chronic pain and far safer than conventional opioids.

- Opioids are sedatives; Buprenorphine is a mild stimulant.
- Opioids cause irritability, anxiety and depression; Buprenorphine relieves all of these.

The Solution: provide Buprenorphine drugs in an effective dosage for pain and in a convenient form for addiction, then improve the pain formula to treat the inflammation which usually accompanies chronic pain.

The Products: Bridge Therapeutics, Inc. (BTI) has Bucam[™] for chronic pain and Bunalz[™] for addiction.

<u>Bucam</u>: is <u>more effective</u> for chronic pain <u>than conventional opioids</u> as shown by Personal Outcome Measures. Recognizing its <u>safety</u>, the Drug Enforcement Agency lists Buprenorphine (and Codeine) as a <u>Schedule 3</u> drug, whereas all other opioids are Schedule 2 (or 1 heroin). The Centers for Disease Control removed Buprenorphine from its overdose risk list in October, 2016 because it is qualitatively safer than other opioids.

- Bucam combines <u>Buprenorphine for nerve pain</u> with <u>Meloxicam for inflammation</u>.
- Meloxicam has the lowest incidence of gastro-intestinal irritation of any non-steroidal anti-inflammatory drugs (NSAIDs).
- BTI <u>patented</u> Bucam in 2013; additional patents are being applied for.

<u>Bunalz</u>: is <u>more convenient</u> than Suboxone and its generics by dissolving in 3 seconds versus 3 to 6; this should greatly reduce or eliminate mouth soreness and thereby encourage compliance.

• The rapid dissolution of Bunalz comes from BTI's <u>worldwide</u>, <u>exclusive license</u> of the Zydis technology from Catalent (formerly named Cardinal Health). Zydis is the technology behind Claratin RediTabs[®].

The Opportunity: BTI is addressing very large markets:

- 17 million Patients take strong opioids daily for chronic pain, spending \$9 billion annually.
- 2.5 million Patients currently take Suboxone or one its generics, spending **\$2.5 billion** annually; sales are growing 20% per year.





• BTI also plans to bring its drugs to Europe where only the original, <u>16-minute dissolve-time</u> version of Suboxone is available.

Competition - Abuse Deterrence: the pharmaceutical industry has made opioids harder to grind up or chemically separate for snorting or injecting:

- Most formulas make it harder (though not impossible) for patients to abuse, yet <u>cost 4x more</u> than unprotected versions, so they have gained a relatively small, 20% market share.
- Opioids' other problems remain, i.e., increasing dosage and personality disorders.
- Bucam is dosage reducing over time and makes users feel happier and more secure.

Competition - New Chemical Entities (NCEs): research is being conducted into new, non-opioid ways to treat pain, such as sodium blockers to halt the pain signal from source to the brain:

- NCEs typically take <u>6-10 years</u> to come to market and cost \$0.5-\$1.5 billion to develop with a high risk of failure along the way.
- BTI uses proven molecules in novel ways to get to market for ~\$20 million in 1-2 years with tiny risk of delay or set-back.

The Team: Chairman & Chief Science Officer, *Dr. Greg Sullivan*, MD, is America's top clinical researcher, having conducted 144 FDA clinical trials, including 16 for Buprenorphine drugs, plus 14 more currently under review. For 30 years he has run the Parkway Medical Center in Birmingham, AL with a particular focus on treating pain and addiction. Dr. Sullivan is a key opinion leader (KOL) in this space, consulting weekly with the FDA, advising on NIH grants and lecturing regularly at medical schools and teaching hospitals.

- COO, *Dr. Dave Bergstrom*, PhD, has over 30-years' experience in the pharmaceutical industry taking drugs from the lab into production for both large and small companies.
- President & Finance Director, *Tim Peara* has a Chicago-Booth MBA and 30 years' experience with institutional investments, developing projects and leading small businesses.

The Offering: BTI is raising \$4 million in order to present both its drugs to the Food & Drug Administration (FDA) via the 5095(b)(2) process this fall or winter.

- After meeting with the FDA, BTI plans to double or triple its valuation when raising a further \$16 million for clinical trials of Bucam European approvals and marketing of Bunalz.
- Sales of Bunalz may start next year given that it addresses the top priority of the FDA, namely the Opioid Crisis; Bucam sales should start 6-12 months afterwards.
- BTI plans a Liquidity Event next year around first sales (or sooner if market conditions allow).
- Specialty pharma companies like BTI trade at 6-10x sales; by capturing only 1% of sales of its \$11 billion markets, BTI could trade at a \$1 billion valuation.

A slide deck is available on request and more information may be found at www.bridgetherapeutics.com





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