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Bridge Therapeutics - Commercializing Safe Pain and Addiction Therapies



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CEOCFO: *Mr. Peara, the Bridge Therapeutics homepage shows, "Bridge to a better therapy. We separate pain from addiction." How are you doing?*

Mr. Peara: Bridge is doing great. We are focused on solving a key part of the opioid crisis, which is providing safe pain relief. Since the year 2000, one million Americans have lost their lives to opioid overdose. However, the majority weren't trying to get high, at least not originally. Instead, they sought pain relief, but their meds let them down. To save thousands of lives and disrupt multi-billion-dollar markets, Bridge is commercializing safe pain and addiction therapies.

CEOCFO: *Why has safe pain relief been so elusive?*

Mr. Peara: The starting point is that all of our strongest pain relievers are opioids, which carry with them the risks of addiction, overdose, and death. There is an alternative drug, buprenorphine; it is a partial agonist, or partial acting opioid. It behaves the same way as other opioids for pain relief, but blocks the addiction response, and counteracts the physical depression which may cause overdose.

Buprenorphine was developed in England 50 years ago to treat pain, yet for commercial reasons came to America to treat addiction. The drug was approved in 2002 to treat addiction under the brand-name Suboxone®. Yet buprenorphine is underappreciated as a pain reliever despite being almost as strong as the strongest pain reliever, fentanyl. Meanwhile buprenorphine's safety is shown by the CDC removing it from its monitoring list for drug overdose in 2016.

CEOCFO: *What is your approach at Bridge Therapeutics? What have you developed?*

Mr. Peara: Bridge is overcoming the chief drawback of this drug, namely slow oral delivery. Just like nitroglycerin for heart conditions, buprenorphine is ineffective if swallowed so it dissolves under the tongue or inside the cheek. Current versions of the drug take about 10 minutes to administer and, this January, the FDA warned of dental problems resulting from long-term use of the drug.

To fix these problems Bridge will deliver the drug 99 times faster, in just 3 seconds using proprietary technology.

CEOCFO: *What can you tell us about the technology?*

Mr. Peara: It is called Zydis® which we license from Catalent, a \$16 billion New York Stock Exchange company (CTLT). Zydis itself is a freeze-dried gelatin used by 9 of the world top 10 pharma companies for one or more of their drugs. The most popular one is the Reditabs® version of Claritin® which dissolves so quickly that it can be taken without water. The newest drug is called Nurtec®, which is for migraine headaches, and also dissolves in about 3 seconds. It's worth noting that Pfizer bought BioHaven, the manufacturer of Nurtec®, this May for \$11.6 billion.

CEOCFO: *Where are you in the process of developing this drug?*

Mr. Peara: We have licensed the technology, manufactured clinical samples and conducted pilot studies. In consultation with the FDA, they agreed that the only study needed for approval is of delivery, rather than the expensive and lengthy safety and effectiveness trials needed for entirely new medicine. FDA is allowing a simpler approval process, called 505(b)(2), because buprenorphine is generic and Zydis is well known. In our case, the pivotal study will involve 50 patients, cost about \$800,000 and take two weeks.

CEOCFO: *Would that same dose be given for everyone?*

Mr. Peara: Dosing is guided by our chief science officer, Dr. Greg Sullivan's practical experience running a large family clinic focused on pain and addiction for the last 35 years. He has led 16 trials of buprenorphine in America. We will start with a single dose to treat opioid use disorder (OUD), yet will need a range of doses to treat a range of pain severity. Also, the dosing frequency is once a day for OUD, but three times a day for pain.

"Bridge's safe therapies can save thousands of lives by stopping the problem of addiction before it starts." Tim Peara

CEOCFO: *Why do you think the medical community and the public in general, is ready for this now?*

Mr. Peara: About half of our investors are pain specialists who are putting their money with their mouth is. They would prescribe this drug today, if it were available. As to the general population, America is searching desperately for a safe alternative to opioids. So, the time is ripe.

CEOCFO: *It almost seems too simple!*

Mr. Peara: I like it simple! After 20 years raising money for startups, I've seen dozens of complex business plans. They sound may sound really cool, but they can't get funded. Bridge can and is.

CEOCFO: *What does your timetable look like?*

Mr. Peara: We are about 12 months from sales and look to complete trials and apply for FDA approval this year. Because there is precedence of granting rapid review for buprenorphine drugs, we hope the approval process to take about 6 months, as opposed to the statutory period of 10 months. That means we could be in sales by the end of next year.

CEOCFO: *Would you be marketing your first drug yourself? Would you be partnering?*

Mr. Peara: For the first drug, we will be launching it ourselves. We will start with addiction where market is very concentrated by geography, by clinic and by certification. The result is that only 5,000 doctors are active prescribers of buprenorphine, so we should be able to gain a large market share with a small sales force. By contrast, marketing our first pain drug will require a national effort, so partnering may make sense down the road.

CEOCFO: *What keeps you up at night regarding this?*

Mr. Peara: Little delays. I have no doubt that Bridge Therapeutics is going to be a success, but delays outside our control are troubling which leaves us to wait for test results, for new clinical samples or for funding of investments. Faster execution would improve my sleep!

CEOCFO: *Are you seeking funding at this point in time?*

Mr. Peara: Yes.

CEOCFO: *How are you reaching out? You said that many doctors have invested, but when you are talking with investors, do they understand?*

Mr. Peara: Medical professional, and especially pain doctors, understand what we are doing immediately. I spend virtually no time at all with them explaining what we are doing and why it makes sense. They get it in a heartbeat. By contrast, general investors question, "Does it really matter?" Meaning, is delivery in 3 seconds verses 10 minutes really that important? This reminds me of TV advertising for pills taken once day as opposed to 4 times a day, and what a nuisance it is to take it 4 times a day. However, you can swallow those. Buprenorphine is a drug that has to sit in your mouth, and you cannot swallow, and you should not speak for 10 minutes, verses 3 seconds. Plus, with current formulations roughly one in five patients end up with mouth irritation, so rapid delivery matters.

I also need to confront general investors' concerns about generics drugs. The perception is a race to the bottom; that is, the cheapest version wins. Yet the technology that we are licensing is protected by patents and trade secrets. Two global pharma companies are alleged to have spent ~3 years each, and about \$250 million each, trying to come up with their own freeze-dried tablets. They abandoned these efforts and now pay a licensing fee to Catalent to use this technology.

I also explain that as Bridge advances, we can increase the intellectual property around a branded-generic drug portfolio, tapping big markets while avoiding the huge up-front cost of drug discovery.

CEOCFO: *How do you deal with some of the frustration of when you have something that seems to be so important, that helps so many people, yet it is still a slow and arduous road to get to the end?*

Mr. Peara: Give a lot of pitches. Speak at a lot of places. Investment interest goes in waves. Crypto was all the rage up until when it cracked. If some other theme is hot, then one just has got to keep banging on doors. The other key is refining the message; trying to make it as simple and understandable as possible.

Otherwise have different pitches for different audiences. In our case we have one for general investors and another for medical professionals, since they understand and are focused on different things.

CEOCFO: *Why is Bridge Therapeutics an important company?*

Mr. Peara: First and foremost is our social mission. Bridge's safe therapies can save thousands of lives by stopping the problem of addiction before it starts. Secondly, we offer a huge opportunity attacking \$30 billion in markets for pain therapies plus a further \$6 billion for addiction. Given these huge markets, even a small slice will should make our investors a lot of money.

