BUSINESS PLAN

June – 2021

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US Bunalz 50
$0 50
$34 50

$75 50
$55 50
$60 50
2% 50
US BupHD\BupLD 50
$0 50
$0 50
$95 50
$145 50
$175 50
1% 50
US Bucam 50
$0 50
$0 50
$0 50
$65 50
$130 50
1% 50
Overseas Sales 50
$0 50
$0 50
$5 50
$75 50
$175 50
1% 50
Total Direct Costs 50
$0 50
($17) 50
($50) 50
($70) 50
($105) 50
Target Case 50
US Bunalz 50
$0 50

$102 50
$230 50
$160 50
$185 50
6% 50
US BupHD\BupLD 50
$0 50
$0 50
$290 50
$430 50
$525 50
2% 50
US Bucam 50
$0 50
$0 50
$5 50
$190 50
$395 50
4% 50
Overseas Sales 50
$0 50
$0 50
$20 50
$225 50
$520 50
3% 50
Total Direct Costs 50
$0 50
($52) 50
($145) 50
($210) 50
($310) 50
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1. EXECUTIVE SUMMARY

Bridge Therapeutics, Inc. ("Safe alternatives to Opioids") is a quick-to-sales biopharma company disrupting **$25B+ markets**. By improving on generic drugs, Bridge has little of the approval risk of a typical pharma startup. By protecting its products, Bridge can establish a franchise which addresses root causes of the Opioid Crisis, namely the needs for strong, yet safe pain relievers and easy to administer addiction therapies. Bridge's team is relevant, capable and experienced, guiding it to become a multi-billion-dollar company.

Problem: **Opioids** were involved in **~50,000 overdose deaths** in 2019 (or **70.6%** of all drug overdose deaths).[1] Owing to social isolation under COVID, drug overdose deaths rose 27% in the year to August, 2020.[2] **The majority** of those getting addicted to opioids (~70%) and of those using heroin (~80%) **start by seeking pain relief**, rather than seeking to get "high".

Without safe pain relief, the Opioid Crisis will most likely fester.

Mission: To improve the healthcare of millions of patients through safer and more effective therapies for chronic pain and opioid use disorder by building and protecting value in the innovative combination, delivery and indication of generic active pharmaceutical ingredients.

Opportunity: Therapies for Opioid Use Disorder (***OUD***) comprise a **$6B market** covering **6M patients**. **Chronic pain** is a **$20B market with 50M patients**.

Goal: By delivering safer drugs than opioids (Schedule III vs II), Bridge's goal is to become the standard of care and to secure government guidance leading to 40%+ market shares.

Product #1: **BT-219** or **Bunalz** (***Bu****prenorphine/****Nal****oxone)* uses **Z**ydis fast-dissolve technology under exclusive license from its manufacturer, Catalent (NYSE: CTLT). This under-the-tongue (sublingual) technology is best known in Claritin Reditabs®. Zydis allows Bunalz to deliver its active ingredients in 3-seconds versus 6-16 minutes for competing formulations. This vastly more **convenient delivery** should **aid compliance** with Medication Assisted Therapy (***MAT***) to treat addiction while **relieving the mouth irritation** currently experienced by 22% of patients. Rapid delivery should simplify *"observed dosing"* and help to **expand MAT in prisons** by avoiding the fights that can occur when prisoners spit out and then try to sell or trade their medicine. Lastly note that Zydis tablets cost far less to manufacturer than Suboxone® film (~1/6th) or Zubsolv® tablets (~1/3rd).

Product #2: **BupHD/LD**. A significant percentage of Suboxone prescriptions (~80%) are written *"off-label"* to treat pain, rather than for the *"on-label"* or FDA-approved usage for OUD. Off-label scripts are ineligible for insurance reimbursement, leaving patients to pay for them out of pocket or falsely claiming to be addicted to opioids. By conducting a placebo-controlled pain study, Bridge expects to receive *exclusive rights* to the **"on label" use of BupHD for pain** and hence be the sole pain product with insurance reimbursement for 2-5 years. Given that there are already low-dosage forms of Buprenorphine for chronic pain, e.g., BDSI's Belbuca®, Bridge cannot get exclusivity for BupLD.

Before the end of FDA exclusivity, Bridge plans to introduce a safer, patented form of this drug (*US:20160213680*) and migrate its patients to the new version (BupHD+) in order to protect and grow its franchise. Note: by using the same tablet (BT-219) for both addiction and pain, Bridge can save on the time and costs of formulation and of FDA approval.

[1] https://www.cdc.gov/drugoverdose/data/statedeaths.htm
[2] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Product #3: **BT-205** or **Bucam** (***Bu****prenorphine/Meloxi****cam***) is Bridge's patented drug combination for the management of chronic pain severe enough to require daily, continuous treatment (*US:8410092*). Bucam will be prescribed for patients currently taking opioids at 60 milligrams Morphine Sulfate Equivalent (MSE) or higher. Buprenorphine been shown to be **30% stronger than fentanyl without dose-dependent respiratory depression** (Centers for Disease Control). Meloxicam allows Bucam to **treat both neuropathic and inflammatory pain** which is experienced by most chronic pain patients. Fast delivery is even more important for these patients, since Bucam is taken 3x/day for pain versus 1x/day for addiction. Bridge has also an advanced version of Bucam.

Customers: Primary purchasers will be doctors/prescribers, pharmacy benefit managers (e.g., Express Scripts, CVS, United Health), hospital systems, pharmacy wholesalers/distributors, private insurers and public insurers, e.g., Medicare.

Management team strengths include extensive experience in pharmaceutical formulation development and subsequent FDA approval, fundraising for startup companies, and expertise in regulatory affairs and clinical research (170 clinical trials).

Support team strengths include extensive experience in FDA operations (Division Head for Analgesia, Addiction & Anesthesia), expertise in the research and treatment of addiction and pain as well as $15B+ in drug commercialization. To facilitate sales within 12 months, the company has hired a market access consultancy to plan the launch and will staff an experienced EVP for sales & marketing.

Funding: The company has already raised ~$7 million.

Exit opportunities include licensing, trade sale or acquisition, initial public offering (IPO) or merging into a special purpose acquisition company (SPAC).

Return on Investment potential: based on industry multiples for licensing deals and acquisitions, an investment in Bridge could return 15-100x on one's capital. Public listing via an IPO or SPAC could produce even greater returns.

- Website: https://www.bridgetherapeutics.com/
- Press releases on Bridge's milestones in the commercialization of Bunalz
- NBC News Night on Buprenorphine in France, the key component in both our drugs
- Zydis rapid dissolve technology licensed from Catalent
- Statistics on opioid overdose deaths from the National Institute on Drug Abuse

2. BUSINESS DESCRIPTION

COMPETITIVE ADVANTAGE

Within the broader bio-pharma industry (described below), Bridge has the ability to design, develop, prosecute FDA approval and commercialize desirable new drugs inexpensively from generic Active Pharmaceutical Ingredients (**APIs**) in advanced delivery technologies through the expertise of its staff and advisors and through outsourcing manufacturing and certain regulatory and marketing functions to major firms. The Company also has substantial experience and expertise in designing clinical trials that control for the placebo effect which is particularly pronounced in neurological conditions, such as addiction, chronic pain, anxiety and depression, etc.

DEVELOPMENT FOCUS

Bridge is focused in the immediate term on developing therapeutics with buprenorphine (or ***Bupe***) as their main API for both chronic pain and addiction. *Bupe* is a partial agonist (or partial acting) which treats pain in the same way as other opioids yet blocks the addiction response and counter-acts the mental and physical depression common to full agonist opioids such as morphine, oxycodone and fentanyl, etc. *Bupe* is discussed at length below.

PRODUCT DESCRIPTION

Bridge Therapeutics' safer and more convenient addiction drug can help patients stay with Medication-Assisted Treatment to end opioid use disorder (OUD) while the Company's safer and more effective treatments for chronic pain can tackle a root cause of the opioid crisis, namely that today all strong pain relievers risk OUD. By focusing on the Company's addiction drug ($6B market, 6M patients), Bridge believes it can start sales in approximately 12 months and soon thereafter introduce two drugs to treat chronic pain ($20B market, 50M patients), thereby minimizing the time and capital needed to commercialize its business.

THE PROBLEM AND PROPOSED SOLUTION

Drug overdose is the leading cause of accidental death in the United States, with opioids being the most common drug.[3] Yet the top addiction drug is inconvenient and often causes mouth irritation and while opioids provide strong pain relief, the carry with them serious side effects, e.g., constipation, depression, addiction, overdose and death.

ADDICTION SOLUTION:

The branded drug Suboxone is safer than methadone since it virtually eliminates overdose risk, yet it cannot be swallowed; instead, it dissolves in the mouth in 6-minutes (the current film) to 16-minutes (the original tablet). This slow delivery is inconvenient to all patients and causes mouth irritation in 22% of users. The irritation ranges from bleeding ulcers, to lesions, to soreness.

Bridge's drug Bunalz has the same active ingredients as Suboxone yet dissolves in 3-seconds making it more convenient for all patients and a significant improvement to those who experience mouth irritation. The active ingredients in both Suboxone and Bunalz are **bu**prenorphine (to block addiction) and **nal**oxone (to deter abuse). The "**z**" in Bunalz stands for the rapid delivery technology *Zydis*.

[3] Opioid-involved overdose deaths rose from 21,088 in 2010 to 47,600 in 2017 and remained steady in 2018 with 46,802 deaths. *National Institute on Drug Abuse*, March, 2020, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

PAIN SOLUTION #1:

Opioids are strong pain relievers yet have serious side effects including constipation, depression, overdose and death. In addition to relieving pain, opioids are strongly addictive because they capture the brain's reward center (nucleus accumbens). Opioids are both mental and physical depressants causing those addicted to withdraw socially and to risk fatal overdose from respiratory depression.

Bridge's first pain drug, **BupHD**, provides better pain relief than the strongest regularly prescribed opioid (fentanyl) without its overdose risk. The Company expects that BupHD (for **Bup**renorphine **H**igh **D**osage) and later **BupLD** will get FDA approval to treat pain, with the result that insurance can cover its cost. By contrast and despite common off-label prescription of Suboxone for pain, insurers by law cannot reimburse for off-label scripts, providing an economic incentive to use BupHD instead. Buprenorphine is a partial agonist (or partial acting) opioid. Its safety is reflected by its being scheduled III like codeine, rather than schedule II for full agonist (or fully acting) opioids such as morphine, oxycodone or fentanyl, etc.[4] While patients may become dependent on BupHD/LD, they do not become addicted. This is similar to wanting a morning cup of coffee versus the craving caused by opioids. Additionally, buprenorphine (*Bupe*) acts as a mild stimulant similar to chocolate or iced tea, rather than as a mental and physical depressant. Finally, *Bupe* is much safer than opioids because it has a "ceiling effect" on dosage, meaning that the euphoria (or buzz) from exceeding one's dosage quickly maxes out while depression is counter-acted; taking any more drug just results in expensive urine. As a consequence, in 2016 the Centers for Disease Control (CDC) removed *Bupe* from its monitoring list for overdose risk.[5]

PAIN SOLUTION #2:

Since most chronic pain occurs with inflammatory pain, Bridge's second pain therapy (**Bucam**) improves on BupHD by adding the nonsteroidal anti-inflammatory drug (NSAID) Meloxicam for even better pain relief. Opioids and *Bupe* only treat pain conducted along one set of nerves (C-fibers); whereas inflammation is felt through a different set of nerves (A-fibers). While there are several drugs that combine opioids with NSAID's to treat both sets of nerves, Bridge Therapeutics received a patent for Bucam based on the fact that *Bupe* is qualitatively different than full-agonist opioids.

THE PRODUCTS:

ADDICTION THERAPY

Bunalz (*Buprenorphine/Naloxone)* uses Zydis[6] fast-dissolve technology under exclusive license from its manufacturer, Catalent (NYSE: CTLT) (a major contract manufacturer with sales of $2.5B and a market cap of ~$9B). This under-the-tongue (sublingual) technology is best known in Claritin Reditabs®. Through Zydis, Bunalz delivers its active ingredients in 3-seconds versus 6 -16-minutes for competing formulations. This more convenient delivery is expected to aid compliance with Medication-Assisted Treatment (MAT) to end opioid addiction while relieving the mouth irritation currently experienced by 22% of patients. Bunalz should also help to expand MAT in prisons by reducing the time (and hence wage cost) of guards *"observing dosing".* Also, by dissolving in seconds it should prevent prisoners from spitting out the tablet for later sale or trading which has been known to create fights. Bridge's goal is to become the standard of care for addiction therapy allowing it to capture 30% of this $5.6B market covering 6M patients.

[4] The 1970 Controlled Substances Act (CSA) instructs the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) to classify certain drugs in schedules based upon their accepted medical benefits versus their potential for abuse and addiction.

[5] See *CDC Clarifies Opioid Guideline Dosage Thresholds* https://www.aafp.org/news/health-of-the-public/20180112cdcopioidclarify.html

[6] https://www.catalent.com/oral-dose/oral-technologies/orally-disintegrating-tablets/

Bunalz should be relatively easy and quick to get approved since (1) it addresses a top priority of the FDA, namely the Opioid Crisis, (2) there is precedence of buprenorphine drugs receiving rapid review (i.e., shorter than the 10-month statutory target under PDUFA[7]) and (3) the FDA agreed, in its written response to a pre-IND application (see Appendix), that only a PK Study would be required.

PAIN THERAPY #1

BupHD (*buprenorphine high dosage*) uses the same fast-dissolve tablet as Bunalz, yet will be indicated for moderate-to-severe chronic pain, rather than for addiction. BupHD will be prescribed for patients currently taking opioids at 60 milligrams Morphine Sulfate Equivalent (MSE) or more; this is currently a $20B market with 50M patients and come in dosage strengths of 2mg, 4mg and 8mg of Buprenorphine with one-quarter that dose of naloxone (i.e., 0.5, 1 and 2mg) Buprenorphine has been shown to be 30% stronger than fentanyl[8] without dose-dependent respiratory depression, i.e., overdose risk (Centers for Disease Control, 10/2016). Fast delivery is even more important for BupHD, since it's taken three times per day for pain versus one time per day for addiction.

BupLD (*buprenorphine low dosage*) covers a low-dosage range (0.1-0.3mg vs 2-8mg of *Bupe*) intended for short-term, continuous treatment of moderate-to-severe chronic pain. This is estimated as a $10B market with ~300M patients. To aid pain management Bridge is contemplating a "Pez candy" or Dsuvia®-type dispenser. This should appeal to payers as being cheaper for Enhanced Recovery After Surgery (ERAS) versus morphine or Dilaudid® cartridges. For that portion of acute pain patients who develop chronic pain (~5-10%), starting with BupLD should help build patient confidence in using Bridge's therapies long term.

PAIN THERAPY #2

Bucam (*Buprenorphine/Meloxicam*) extends the pain relief in BupHD by also treating the inflammatory pain experienced by most chronic pain patients. Bucam is protected by US Patent No. 8410092. Combining the drugs in a single tablet is important for compliance since the majority of pain relief is from *Bupe* which is also faster acting. (If prescribed separately, most patients will stop taking the Meloxicam before its benefits can be felt.)

CUSTOMERS

Primary purchasers will be doctors/prescribers, pharmacy wholesalers/ distributors, pharmacy benefit managers (e.g., Express Scripts, CVS, United Health), private insurance and other public insurance (e.g., Medicare, Medicaid, Veterans Administration). Management team strengths include extensive experience in pharmaceutical formulation development and subsequent FDA approval, fundraising for startup companies, and expertise in regulatory affairs and clinical research (170 clinical trials). Support team strengths include extensive experience in FDA operations (Division Head, FDA Analgesia, Addiction & Anesthesia), and expertise in the research and treatment of addiction and pain. To facilitate sales within 12 months, the Company has hired a market access consultancy to plan the launch.

[7] Orexo's branded-generic version of Suboxone called Zubsolv® was approved in 8-months (7/2013) as was BDSI's Bunavail® (6/2014). The Prescription Drug User Fee Act (*PDUFA*) was a law passed by the United States Congress in 1992 which allowed the Food and Drug Administration to collect fees from drug manufacturers to fund the new drug approval process.

[8] *Conversion of Chronic Pain Patients from Full Opioid Agonists to Sublingual Buprenorphine*, Pain Physician, 2012, J.Daitch, M.Frey, D.Silver, C. Mitnick, D. Daitch, BA, and J. Pergolizzi 15:ES59-ES66 • ISSN 2150-1149

MARKET APPEAL - THREE P'S

There are three parties to a prescription decision: the patients themselves, the providers (or doctors) and the payors (or insurers, both private and public). Bridge's drugs appeal to all three P's.

(i) **Bunalz**: patients will like greater convenience and mouth safety; providers will hear less complaining and payors will like its modest price which is planned to be at a discount to the branded drug (Suboxone).

(ii) **BupHD/LD:** patients will prefer the stronger and far safer pain relief than from opioids; providers will have less risk because their patients won't overdose and die; payors will save on treatments for the side effects of opioids such as depression and constipation.

(iii) **Bucam**: for those patients who can take NSAIDs (~97%), they will get even better pain relief than from BupHD; the appeals to providers and payors are the same as for BupHD.

PRINCIPAL FEATURES

The principal features of these products:

All three drugs will be delivered as a 3-second Orally Dissolving Tablets (**ODTs**) which are more convenient than the 6-16-minutes dissolving tablets and films and much more pleasant than injections, implants and all-day arm patches.

Dosing of Bunalz for addiction is once daily to treat addiction, since *Bupe* binds to receptors in the brain's reward center (i.e., the nucleus accumbens) for 24-36 hours. Treatment to end opioid dependence typically lasts 6-months to two-years.

Dosing of BupHD/LD and Bucam is three times daily, since treating the brain's pain center[9] requires a minimum level of drug in the blood stream. Treatment for chronic pain can last several years and sometimes the rest of one's life, thus convenient delivery is vital.

VALUE:

Superior delivery While other versions of *Bupe* are available (such as implants, all-day patches, and depot injections) Bridge will provide superior administration that is fast and that should be pain free.

Why Rapid Delivery Matters Even healthcare professionals can vastly underestimate the significance of advanced formulation, unless they treat the effected patients.

In the case of Suboxone® and its generics, patients have complained for years about its long delivery time (6-16 minutes), horrible taste (50-95%) and mouth irritation (20-24%). Such grumbling is too easily overlooked, however, in recognition of the dramatic improvement in patients' lives achieved by buprenorphine therapies. So, why bring another version of this drug?

Bridge's market access consultant Percipient witnessed a similar phenomenon with a pain patch. In that case, a survey of doctors alone saw little value in offering an easier to apply, more secure patch. Yet when the same questions were asked to their nurses who heard ceaseless complaints about patches being difficult to apply, falling off or failing to deliver the drug, a very different result was reported in the form of a desperate plea for an improved product. In a second wave of research,

[9] The periaqueductal gray (PAG, also known as the central gray) is a nucleus that plays a critical role in autonomic function, motivated behavior and behavioral responses to threatening stimuli. PAG is also the primary control center for descending pain modulation.

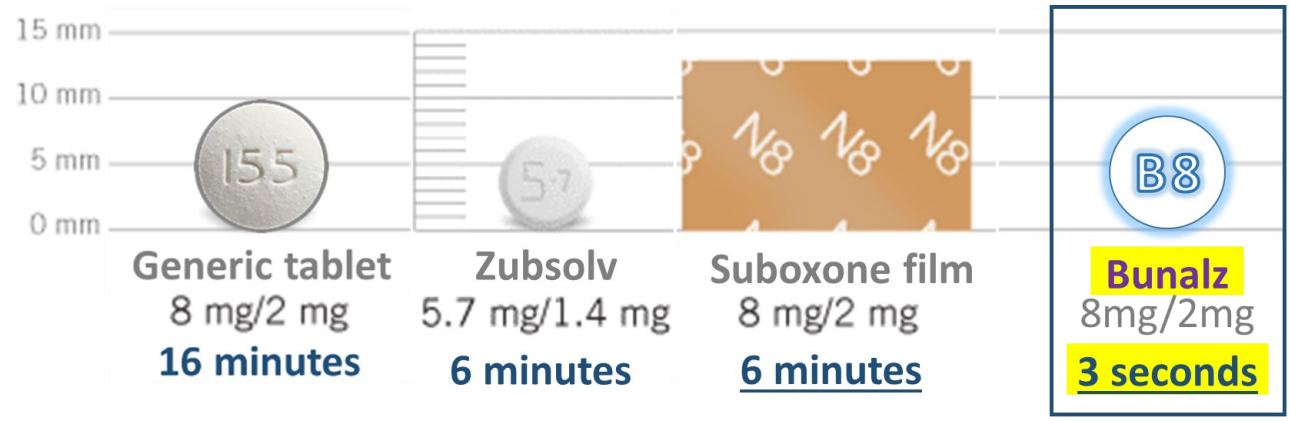
physicians, after trying the improved pain patch, showed a remarkably high adoption rate of the new patch. Ultimately the new patch – ZTLido® – became a huge commercial success.

Today Bridge faces the same skepticism from armchair analysts while offering big upside to discerning investors.

Readers should appreciate that applying Zydis rapid delivery to buprenorphine was conceived by our chief science officer, Dr Greg Sullivan, who has been treating addiction and pain for over 30 years.

Click this link for patient comments on the current buprenorphine products which our Bunalz can displace via rapid delivery (3-seconds), pleasant taste and no expected mouth irritation.

Save money on pain relief The key active pharmaceutical ingredient (**API**) in of all Bridge's drugs is buprenorphine (or simply *Bupe*). *Bupe* was developed in order to treat pain, yet brought to America to treat addiction after it was used successfully in France to treat a heroin epidemic in the mid-1990's.[10] Since being first approved in in the United States in 2002, a growing number of doctors have prescribed Suboxone to treat pain, precisely because it is stronger and safer than opioids. Such prescriptions are considered "**off-label**" since the drug is not being used for its FDA approved use or "indication" that appears on the product labeling. Doctors are free to write off-label prescriptions, yet insurance companies by law should only reimburse for the prescribed usage of a drug. The result is that patients taking Suboxone for pain have to pay for it out of their own pocket. By getting the "pain indication" for BupHD/LD and Bucam, Bridge will enable patients to get insurance coverage for these prescriptions. This will benefit both existing patients of the drug, but also expand the market for *Bupe* as a pain medication.



CURRENT DEVELOPMENT

Since the active pharmaceutical ingredients (**APIs**) in all the Company's drugs are generic, Bridge can use the FDA's 505(b)(2) approval pathway which allows a developer to rely on research done by other parties to demonstrate safety and effectiveness (efficacy), greatly reducing the time and cost of bringing a new drug to market.

[10] Click for this video: NBC News Night on Buprenorphine in France or cut and paste this URL in a browser: https://www.nbcnews.com/nightly-news/video/this-opioid-addiction-treatment-helped-france-combat-its-own-epidemic-1268114499857

In October, 2019, the FDA wrote in response to Bridge's proposed testing protocol, that only a study of drug delivery was required for approval (assuming no unexpected results).

On April 27, 2020, the FDA informed Bridge that its Investigational New Drug (IND) application for Bunalz is "Open and Safe to Proceed," assigning it number 142396. There were no additional questions or constraints included in the FDA communication, allowing Bridge to import the drug and test it in humans.

In the second half of last year Bridge conducted two pilot pharmacokinetic (**PK**) studies of Bunalz that show Bunalz demonstrates bio-equivalence to a reference drug (RD) on a small scale before conducting a 36-patient, definitive study for the New Drug Application. The pilots were successful. See the Appendix for graphs and more detail.

In addition to clinical work, Bridge continues to prepare for commercial launch of Bunalz by working with the Company's market access consultant Percipient to refine the market, assemble focus groups and prepare initial marketing materials.

DESIGN AND ENGINEERING ACTIVITIES

Current Good Manufacturing Practice (**cGMP**) tablets of Bunalz have already been formulated and are ready for export from Catalent's site in Swindon, England. These are approved for human trials and have undergone one-month stability trials; further tests of stability will be taken at three-months and one-year. Bridge has worked with Catalent for almost two-years on the formulation and testing of Bunalz. The initial costs of formulating a drug with the Zydis technology are expensive, but the unit cost is modest. This means that Bunalz' unit cost is roughly ¼ that of Suboxone film and ½ that of Zubsolv.[11] The unit costs of hard-compressed, generic tablets are cheaper than Bunalz, but they dissolve in 16-minutes vs 3-seconds.

Once the definitive PK study is conducted and assuming no reformulation is required, Catalent will work to design and test commercial production. Upon FDA approval, Catalent will have to produce and test three 1/10th commercial-scale batches to demonstrate consistent manufacturing of quality product. These batches can be exported and sold commercially, with or without a full-scale batch.

When funding allows, development focus will shift to performing a 12-week, placebo-controlled pain study of the Bunalz tablet (as BupHD). Considering that *Bupe* was developed to treat pain, the Company expects that effectiveness of BupHD will be demonstrated. The study for BupLD will also be 12-weeks, but be less expensive since the dosing portion will cover only the first 2-4 weeks.

Bridge's Chief Science Officer (**CSO**), Dr Sullivan, in consultation with Bridge's Scientific Advisor Dr Rappaport, will use his expertise to design the pain studies for BupHD/LD, Bucam and BupIM that control for the placebo effect. [12]

The placebo effect is the tendency for patients to report that they feel better simply because they want to feel better. This effect is pronounced in any self-reported, neurological condition such as pain, anxiety or depression. Difficulty in designing trials to control for the placebo effect is a reason why many manufacturers shy away developing such therapies. Yet given its principals, ***Bridge's ability to control for the placebo effect is a strategic advantage.***

NEW PRODUCTS IN DEVELOPMENT

[11] Zubsolv is a "branded generic" tablet by Orexo that uses sodium bicarbonate to dissolve in 6 ½ minutes.
[12] Dr Sullivan has designed and led clinical trials for FDA approval of 16 Bupe drugs, 4 other pain drugs and 11 other drugs for neurological conditions like anxiety and depression.

SAFER BT-219 AS BUNALZ+, BUPHD+ AND BUPLD+

Dr Sullivan is a joint-patent holder on a safer version of Bunalz that would protect against overdosing both from opioids and benzodiazepines (benzos).[13] While the minor ingredient in Bunalz – naloxone -- protects against opioid overdosing, it does not protect against benzo overdosing. Benzos are prescribed with opioids in 15-20% of patients to treat opioid-induced anxiety; benzos are also abused in the same ratio since they accentuate the euphoria (or *high)*. In either case, because opioids are depressants while benzos lessen a patient's concern about danger, the combined risk of fatal overdose increases significantly. The APIs in this safer version of Bunalz (buprenorphine and flumazenil) are generic, so pre-clinical, phase 1 and 2 studies won't be necessary. Instead only a Phase 3 effectiveness study lasting 3-months is expected to be required. However, the new drug combination will need to be formulated and a new IND will need to be opened with the accompany regulatory work.

SAFER BUCAM

Dr Sullivan has a patent pending on a tracer molecule that will extend the time that physicians can monitor for abusing or diverting drugs from 24-hours to 25-60 days. The issue being addressed is that doctors have a difficult time determining if a patient has been taking their medications as prescribed or abusing or diverting them to the black market; this is especially true of opioids. The patent pending describes an invention that adds a sub-therapeutic dosage of a chemical to the drug formulation to determine the amount of active drug that has been taken. Standard in-office urinalysis can then determine if a patient has been compliant with prescribed medication on a quantitative level (that is, not only did they take the medication, but how much of it did they take). This has the potential to dramatically improve a physician's ability to prevent abuse and diversion by extending the monitoring period from 24-hours to 25-60 days. Several candidates have been found which can be used in order to extend the patent life of Bucam and gain international patent protection for Bucam and BupHD. However, the tracer may also apply to any other controlled substance where abuse deterrence is needed, opening up the opportunity to license this technology. Because sub-therapeutic dosages are to be combined with existing drugs, many early studies won't be necessary. Yet proving that the technology works as intended could require a study of 100-200 patients lasting 3-months for effectiveness or 6-months for safety. It is assumed that each drug using this technology will require separate trials.

POSSIBLE PRODUCT, BUPIM

Bridge is in a position to license a small-needle, 1-month depot intramuscular (IM) injection that can compete with Indivior's 5-injection, large-diameter needle addiction drug Sublocade®. Currently, Sublocade® is used primarily on prisoners shortly before release to block euphoria for their first month of freedom. Because of its long duration, it also ensures compliance with Medication Assisted Therapy (MAT) when given at monthly, physician appointments. It is expensive compared to oral products ($1,650 vs $300-540/month) opening the possibility for Bridge to bring a lower cost, more comfortable therapy to this patient population.

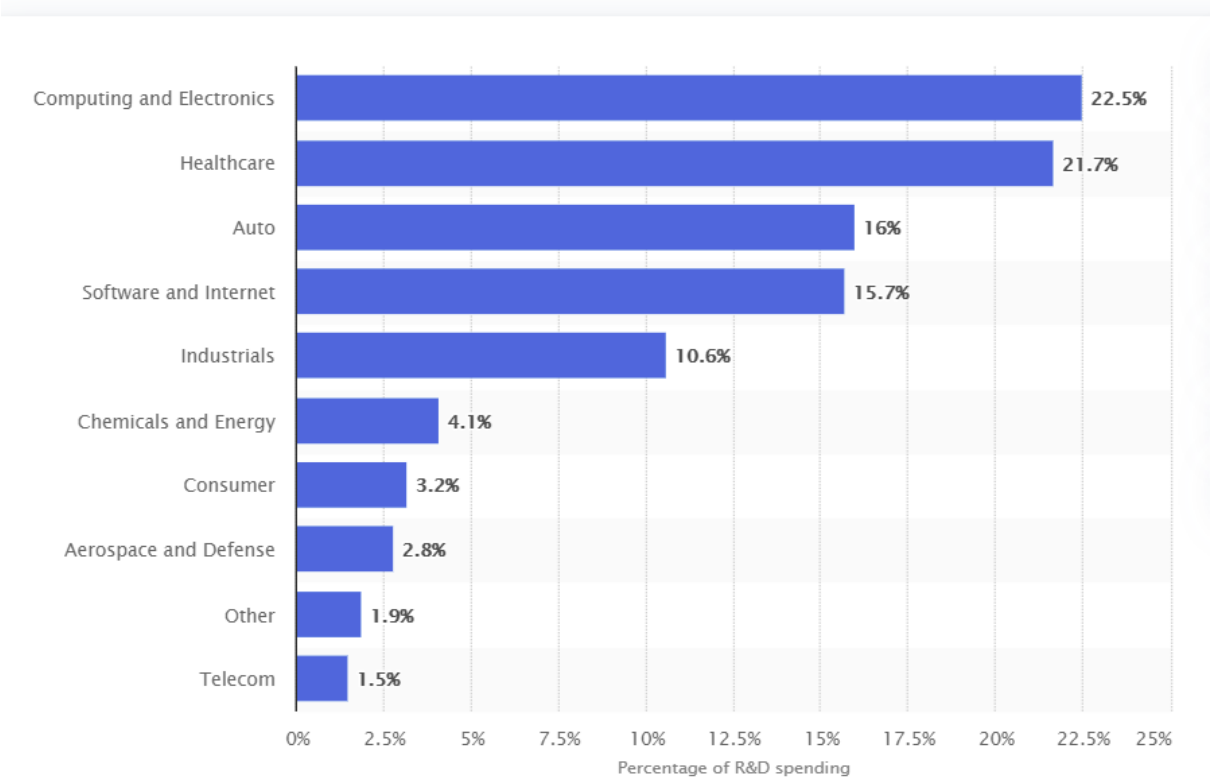
The Company has further product ideas involving better delivery of existing drugs, getting on-label approval and hence marketing exclusivity for popular, off-label drug usage, and treatments for rare disease conditions.

[13] Compositions and Methods Using Flumazenil With Opioid Analgesics For Treating Pain and/or Addiction, and with Diversion and/or Overdose Mitigation; https://patents.justia.com/patent/20160213680

PHARMACEUTICAL INDUSTRY OVERVIEW[14]

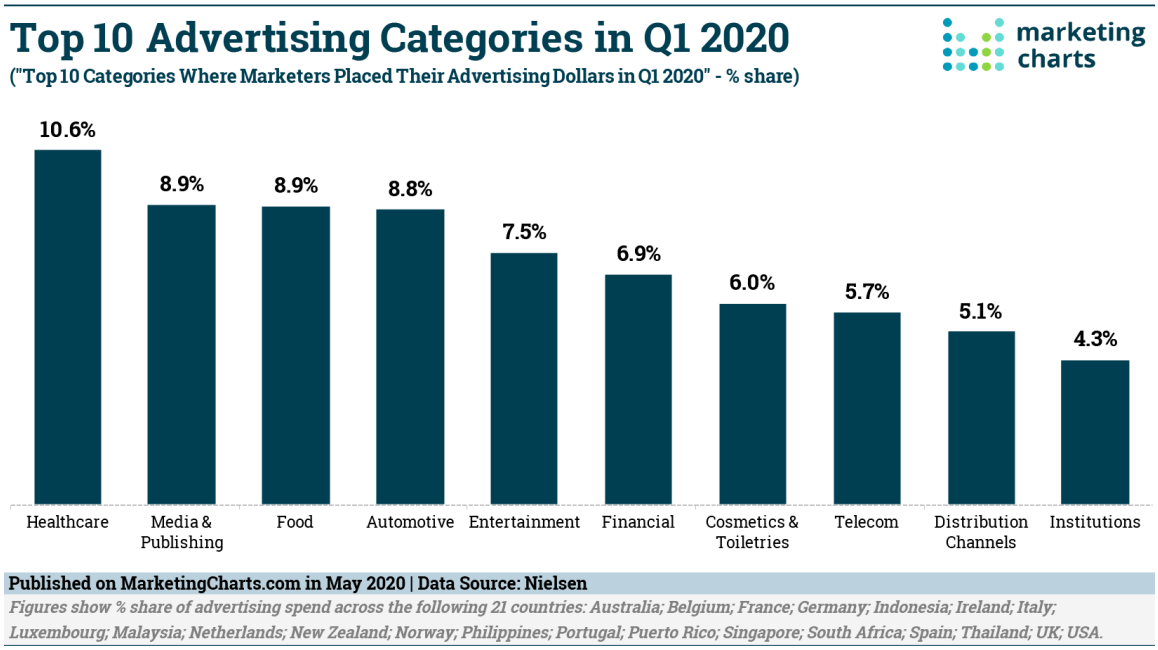
As with Tech, the Pharmaceutical Industry is driven by innovation and spends a high proportion of its revenues on R&D. Yet Pharma also spends a high proportion of revenues on marketing with its need to influence 3 P's: patients, providers and payers.

PERCENTAGE OF GLOBAL RESEARCH AND DEVELOPMENT SPENDING IN 2018, BY INDUSTRY[15]



[14] Taken from ***An Easier Way to Understand the Pharma Industry***, BY Sybil Prowse, Jan'15, updated 12'19 and 7'20. https://marketrealist.com/2019/12/easier-way-understand-pharma-industry/

[15] https://www.statista.com/statistics/270233/percentage-of-global-rundd-spending-by-industry/



The pharmaceutical industry is the part of the healthcare sector that deals with medications. The industry comprises different subfields pertaining to the development, production, and marketing of medications.

The main goal of the pharmaceutical industry is to provide drugs that prevent infections, maintain health, and cure diseases. This industry directly affects the global population, so a number of international regulatory bodies monitor things like drug safety, patents, quality, and pricing. Here are some of those regulatory entities:

- World Health Organization (WHO)
- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- Medicines and Healthcare Products Regulatory Agency (MHRA) of the UK

What drives the pharmaceutical industry?

The pharmaceutical industry has made a great deal of progress over the last decade due to a research-oriented approach that has improved technologies, developed infrastructures, and increased research in the field of bioscience. Thanks to biotechnology, various formulations have been developed to cure or stop the growth of several major infections, including HIV and certain types of cancer.

The global pharmaceutical industry was worth an estimated $1 trillion in 2014. In 2013, global pharmaceutical markets generated revenues of $980.1 billion. That year, North America (the US and Canada) contributed 41% of sales, while Europe contributed 27.4%. More recently, in 2018, the global pharma industry stood at $1.2 trillion, and the IQVIA Institute for Human Data Science expects $1.5 trillion by 2023.

Publicly traded pharma industry stocks and ETFs

In the drug manufacturing category, the major publicly traded companies include Johnson & Johnson, Novartis AG, Pfizer Inc., Merck, Sanofi, and GlaxoSmithKline.

Gilead Sciences Inc., Amgen Inc., Celgene Corporation, Biogen Idec Inc., and Regeneron Pharmaceuticals Inc. are the major publicly traded biotechnology companies.

Pharmaceutical ETFs include the PowerShares Dynamic Pharmaceuticals ETF (PJP), the SPDR S&P Pharmaceuticals ETF (XPH), the iShares US Pharmaceuticals ETF (IHE), the iShares NASDAQ Biotechnology ETF (IBB), and the VanEck Vectors Pharmaceutical ETF (PPH).

Supply chain

The supply chain of the pharmaceutical industry is similar to that of any other industry in the manufacturing sector. However, in the US, the pharmaceutical industry has only two drug distribution channels: prescription and OTC (over-the-counter). The US Food and Drug Administration regulates both of these channels.

Here is a typical pharma industry supply chain:

Because pharmaceuticals directly affect millions of people's health, industry manufacturers are very strict about ensuring the safety and quality of drugs at each level of the supply chain. These companies use fixed, regulator-certified suppliers of raw materials. Companies also store the raw and packaging materials in separate warehouses.

After a company processes the raw materials, it makes the final drug at the manufacturing unit. A company that has a single manufacturing unit uses only one warehouse, while a company with multiple manufacturing units stores its drugs in central

and regional warehouses. Next, distributors and super stockists receive the drugs and supply them to entities in the retail segment:

- hospitals
- pharmacy stores
- health care centers
- clinics

Then, retailers sell OTC drugs directly to consumers. A prescription drug purchase requires authorization from a qualified doctor.

Supply chain importance for pharma companies

Pharmaceutical companies with large turnover place a particular emphasis on supply chain management. This is because any variation in the supply chain could lead to multiple disturbances in the system.

GlaxoSmithKline spends over $4.5 billion each year manufacturing and supplying products. Johnson & Johnson spends approximately $30 billion annually in leveraging its purchasing power to set sustainability expectations beyond its operations.

Similarly, companies like Teva Pharmaceuticals (TEVA), Pfizer (PFE), and Merck spend millions of dollars to ensure the safety and supply of their products, even though they have manufacturing units in multiple locations.

A number of ETFs focus on the pharmaceutical industry. One of them is the VanEck Vectors Pharmaceutical ETF (PPH). Over 58% of PPH's investments are in large pharma companies.

Pharma industry regulations

There's a web of regulations in the research-intensive, highly dynamic pharmaceutical sector. In fact, the industry regulates the entire drug life cycle, including the patent application, competition with generics, marketing approval, and patent expiration. Regulations also control all prescribing physicians, wholesalers, retailers, and manufacturers in the pharma industry.

Regulation objectives

Pharma industry regulators seek to monitor various drug-related concerns:

- safety
- quality
- quantity
- market flow
- research and development incentives
- pricing
- patents

According to the FDA (US Food and Drug Administration), American consumers benefit from having access to the safest, most advanced pharmaceutical system in the world. The main consumer watchdog in this system is the FDA's Center for Drug Evaluation and Research (or CDER), which assesses new drugs before they hit the market. The center ensures that brand-name and generic drugs work correctly and that their health benefits outweigh their known risks.

International regulatory bodies

International regulatory bodies for the pharma industry include the WHO (World Health Organization), the FDA, and the MHRA (Medicines and Healthcare Products Regulatory Agency). It is important for companies in the pharmaceutical industry to follow the policies set by these organizations. Regulatory bodies monitor not only manufacturers, but also drug sellers and prescribing physicians.

Subindustries: What makes the pharma industry different

The pharmaceutical industry functions just like any other industry. It has raw materials manufacturers, finished goods manufacturers, R&D (research and development) companies, marketing companies, and consumers. Yet, it's far more regulated and capital-intensive than other industries.

Drug manufacturing

Drug makers include API (active pharmaceutical ingredients) and formulations manufacturers. These companies make the following types of drugs:

- APIs. These are the raw materials used to manufacture drugs. Generally, large setups make APIs because these capital-intensive materials require special environmental conditions.
- Generic drugs. Companies sell these off-patented, cost-effective drugs at low prices using no specific brand name in order to serve the public. Abbott Laboratories (ABT), Allergan (AGN), and many other pharma companies make generics.
- Patented drugs. Companies develop these drugs through in-house research or licenses from other firms and then manufacture the drugs under licenses from patent holders. Patented drugs have high profit margins. Pfizer Inc., Merck & Co. (MRK), Sanofi, GlaxoSmithKline, Teva Pharmaceutials (TEVA), and many others make patented drugs.
- CRMOs (contract research and manufacturing organizations). Companies that provide these contract services conduct research and manufacture drugs under licenses from other companies.

Drug marketing

Marketing companies in the pharma industry help increase the market reach of drugs. At times, a manufacturing company can't sell its product in a specific region because the company lacks a license or marketing network to do so. This is where drug marketing companies come in to facilitate sales.

Biotechnology and R&D

Pharmaceutical companies are either dependent on their in-house R&D centers, or they rely on biotechnology companies to provide them with licenses to manufacture patented products. Holdings of the PowerShares Dynamic Pharmaceuticals ETF **(PJP)** include drug manufacturers and biotechnology companies.

Questions about the pharma industry's growth outlook

A number of questions arise when we think about the current state of the pharmaceutical industry:

- Why is there an increasing need for pharmaceuticals?
- Why have medications become so complex?
- What factors have led to the growth of the pharmaceutical industry?

Aging population

Worldwide, the average human life span has increased substantially over the last few decades. However, more infections and diseases have come along with this longevity growth. This has led to increased research on aging populations. The goals are to prevent infections and maintain health so that these populations can enjoy better lives.

Changing lifestyles

Hectic daily schedules have led to **unhealthy eating habits**, a lack of exercise, less sleep, and other problematic lifestyle choices. This has resulted in high obesity rates, poor digestion, hallucinations, breathing difficulties, and other physical problems. Health supplements have been introduced to remedy all of these issues, reduce the chance of getting sick, and meet daily nutritional needs through vitamins and minerals.

Increased income and chronic diseases

The middle class has been growing in both the emerging and developed markets. People in these markets have more disposable income and expect better healthcare solutions.

Chronic disease cases have risen in number. This has made people become more dependent on medications and health supplements.

Other economic trends

Globalization and urbanization have led to increased environmental disturbances. These are major driving forces in the growing demand for improved medication and health supplements for each age group and geographic location.

Industry players

Companies like Abbott Laboratories (ABT), Novartis AG (NVS), GlaxoSmithKline (GSK), and Teva Pharmaceutical Industries (TEVA) are constantly looking at consumer needs and upgrading drugs based on research and innovation. All four of these companies are part of the VanEck Vectors Pharmaceutical ETF (PPH).

KEY TRENDS IN THE INDUSTRY[16]

Several major trends are reshaping the pharmaceutical industry and may cause challenges for pharma companies

- Healthcare budgets are experiencing greater pressure due to the rising incidence of chronic diseases
- Increase in demand for medicines in emerging economies compared to industrialized economies
- Innovative medicines are influencing regulators to become more cautious about approving new medicines.
- Drug-pricing concerns will worsen

Risks

The pharmaceutical industry undertakes several risky ventures that are a growing concern for pharmaceutical companies. Due to technological advances, pharma companies take risks to have a competitive edge. Some of the risk exposure can affect the advancement of pharma companies. Patient advocacy groups are creating challenges for pharma companies. For example, existence of rare diseases is influencing patient advocacy groups to present the needs of patients with rare diseases to governments and regulators and lobby for changes to enhance inequalities for medical services. Pharma companies must take risks to compete to develop medicine for rare diseases.

Tax reform, U.S pricing legislation and the repeal and replace of the Affordable Care Act is posing a risk for M&A activity. Although, opportunistic deals will be evident in the future, pharma companies that have significant amounts of overseas cash will not take risk to overpay on taxes to engage in M&A acquisitions.

Between the year 2017 and 2021, it is anticipated that $147 billion of pharmaceutical sales are at risk due to expiring patents. This risk might potentially put a brake on the pharmaceutical industry's upward trajectory and could indicate a second patent cliff for pharma companies.

Challenges

Pharma companies are facing challenges with developing new medicines and meeting the complex demands of clients. Unprecedented challenges in the pharmaceutical industry are raising concerns about innovations that increase R&D, administrative and sales cost. Some of the challenges include:

- Expiring patents
- Increase in competition by generic companies
- Slower sales growth rates

[16] Taken from *Pharmaceutical Industry Overview: Trends, Risks, Opportunities & Deals,* https://investmentbank.com/pharma-industry-overview/

- Decrease in the number of innovative drugs under development
- Tighter regulatory reviews and standards

These factors are causing pharma companies to change their strategies or growth and sales.

Pharma companies may experience more declines in sales, unless patents are renewed.

Several issues in the competitive environment are influencing pharma companies to engage in acquisitions of various sizes. Rising customer expectations continue to challenge innovative medicines. Customers are currently seeking new alternative therapies that are clinically and economically feasible.

Opportunities

The pharmaceutical industry looks forward to several opportunities in the future. More than 220 drugs are expected to be introduced in the pharma market by 2021. Most of the drug manufacturing will be outsourced. Pharma companies have opportunities to develop new businesses and increase market share by outsourcing manufacturers. As pharma companies lose sales due to increase in generic drugs, the companies can create portfolios of generic pharmaceutical ingredients (APIs) and present the generic APIs to customers. Outsourcing is expected to increase and provide pharma companies with $105.0 billion in 2021.

A survey showed that pharma CEOs choose innovation as an area to capitalize on for opportunities in the future. Pharma companies are more driven to be innovative than most sectors. Human capital is a second area of opportunity that pharma companies will like to focus on.

The strong growth in the China pharma market will increase opportunities for U.S based pharma companies to invest and increase their market share. Although, the China pharmaceutical market is valued at $155 billion, a value half of that of the U.S market, the expected growth rate of 10% makes it attractive to invest in the market. The Indian pharma market, valued at $27 billion, is expected to grow by 1.5 times by 2020. The Indian pharma market will create opportunities for pharma companies to develop diabetic drugs since India is expected to have 100 million diabetic patients by the year 2030.

The pharmaceutical industry is also benefiting from the aging U.S population. The industry has experienced a season of aggressive growth in the last five years and continues to invest in R&D. Pharma companies are also conducting research and participating in clinical trials to develop new products that can meet the healthcare needs of their clients.

3. MARKET ANALYSIS

ADDICTION THERAPY MARKET

In this section we start with demand statistics for key markets for *Bupe* and then extrapolate this worldwide to achieve approximately $6B in 2021. One should further observe that *Bupe* represents roughly 60% of the total market for opioid use disorder (OUD) therapies, so another source of growth would be displacing the other main therapies, i.e., methadone and naltrexone.

Recent data from IQVIA show that aggregate US sales of Buprenorphine alone and combined with Naloxone at $2.75B. Sales in the EU are a further $0.5B. Extrapolating from the USA's 48.9% share of global pharmaceutical sales[17] adds a further $2.36B in sales for an estimated global market of $5.6B for Bunalz.

Market concentration is described in the following table and charts.

TABLE OF BUPRENORPHINE SALES DATA IN THE USA AND EUROPE[18]

Country	Dec'16-Nov'17	Dec'17-Nov'18	Dec'18-Nov'19	% of D18-N19
FRANCE	$80,819,759	$84,150,757	$76,612,172	2.4%
GERMANY	$84,492,243	$84,651,320	$78,395,710	2.4%
ITALY	$19,475,488	$23,073,751	$25,061,280	0.8%
SPAIN	$24,892,255	$21,060,674	$19,843,440	0.6%
UK	$89,444,171	$85,498,869	$100,516,235	3.1%
28 Euro Nations[19]	$204,451,700	$203,981,078	$205,343,616	6.3%
US	$2,493,616,503	$2,755,753,112	$2,742,868,301	84.4%
Grand Total	**$2,997,192,119**	**$3,258,169,561**	**$3,248,640,754**	**100%**

BUPRENORPHINE REPRESENTS ~60% OF GLOBAL MARKET FOR ADDICTION THERAPIES[20]

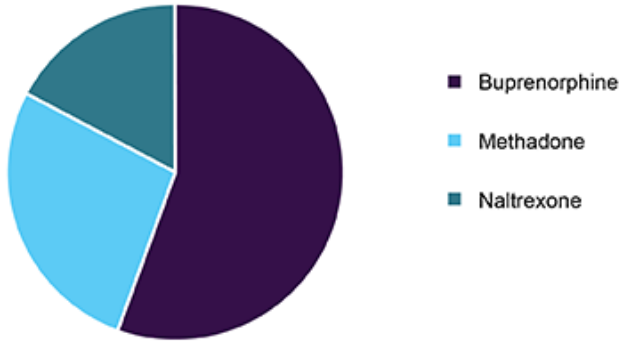
[17] *Global Pharmaceutical Industry - Statistics & Facts* estimates 2018 worldwide market pharmaceuticals at $1.2T of which North America represents 48.9% https://www.statista.com/topics/1764/global-pharmaceutical-industry/

[18] Source: IQVIA https://www.iqvia.com/solutions/real-world-evidence/real-world-data-and-insights

[19] 40.6% share of 28 nations including Russia and Turkey, from *Market value of pharmaceutical industry by European country 2017 of other European nations*, https://www.statista.com/statistics/316076/european-pharmaceutical-market-value-by-country/

[20] https://www.grandviewresearch.com/industry-analysis/opioid-use-disorder-market

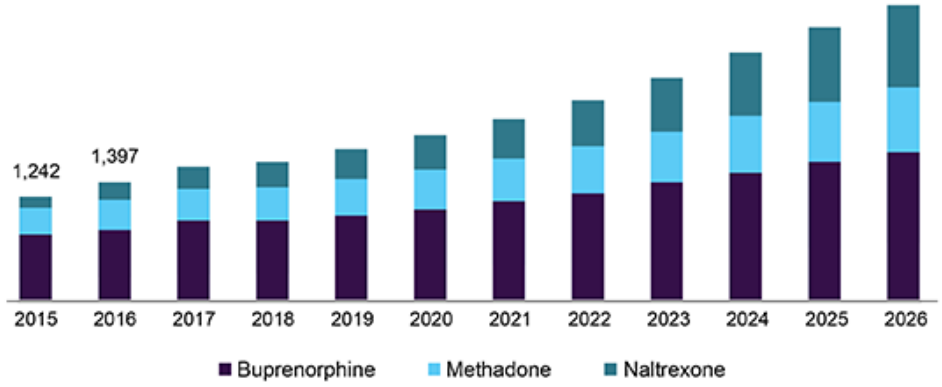
Global opioid use disorder market share, by drug, 2018 (%)



Source: www.grandviewresearch.com

Note: Naltrexone is used principally to treat alcoholism, not opioid addication

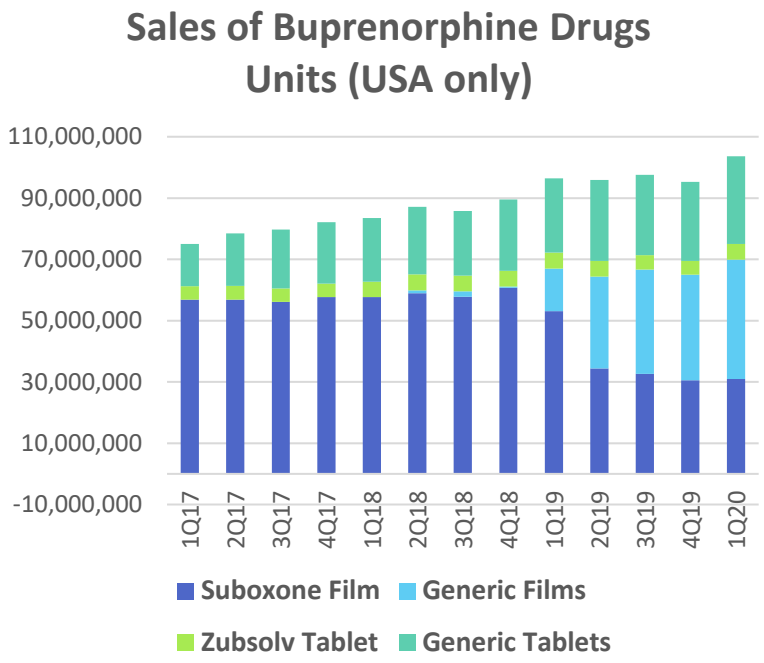
U.S. opioid use disorder market size, by drug, 2015 - 2026 (USD Million)

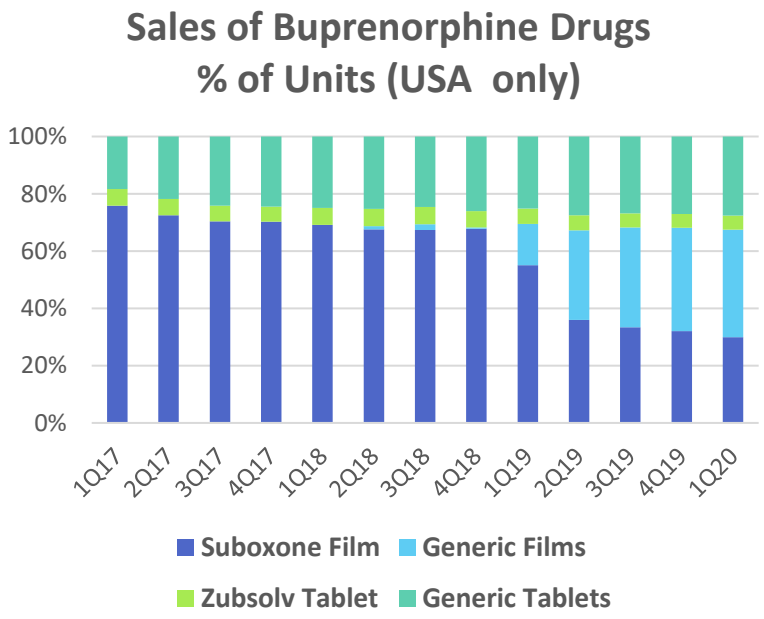


Source: www.grandviewresearch.com

THERAPIES FOR ADDICTION

Addiction	Type of Drug	Examples
Opioid Addiction	**Partial Agonist Opioid**	**Buprenorphine (Suboxone)**
	Full Agonist Opioid	Methadone (Methadose, Dolophine)
Opioid Depression	**Opiate Antagonist**	Naloxone (Narcan, Evzio)
Alcoholism	**Opiate Antagonist**	Naltrexone (ReVia, Vivitrol); Disulfiram (Antabuse); Acamprosate (Campral)





CHRONIC PAIN MARKET

CHRONIC PAIN

Pain lasting longer than tissue healing or 3-6 months is termed "*chronic*" and indicates nerve damage or "*neuropathy*". 70 million Americans suffer from chronic pain of which about 20 million have "*moderate to severe*" chronic pain which requires strong, daily medication.

CHRONIC PAIN MARKET SIZE

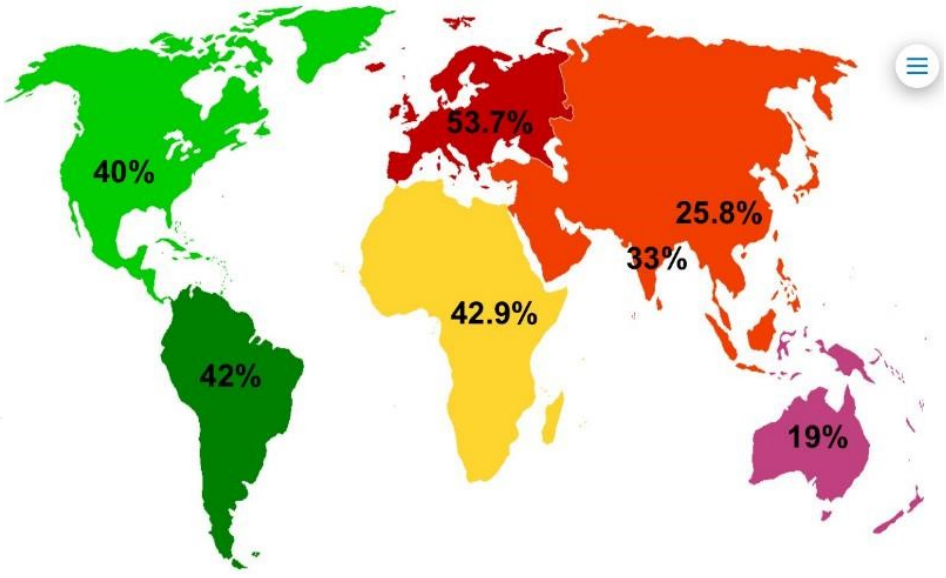
Estimates of the size of the global market for pain therapies range from $60-$100B of which roughly one-quarter or $20B are for chronic pain and the balance for acute pain. Within chronic pain, the largest segment is muscular-skeletal, particularly pain of the lower back.

Within the therapeutics market most all the lies in treatment of lighter pain levels (i.e., for mild to moderate pain), whereas all the strong pain relivers (for moderate to severe pain) are opioids.

THERAPIES FOR PAIN

Chronic Pain Severity	Type of Drug	Examples
Mild	Acetaminophen	Tylenol
	Non-Steroidal Anti-Inflammatory Drugs	NSAIDS: Aspirin, Ibuprofen (Advil), Naproxen Sodium (Aleve), Celecobix (Celebrex)
	Cannabinoids	Cannabidiol, or CBD
Mild-Moderate	Corticosteroids	Prednisone (Deltasone) and Decadron (Dexamethasone)
	Anti-seizure, anti-anxiety & anti-depressants	Pregabalin (Lyrica) and Gabapentin (eg, Gabarone); Diazepam (Valium); TCA (Nopramin,) SNRIs (Cymbalta)
	Weak Agonist Opioid	Codeine, Codeine + Tylenol
Moderate	**Full Agonist Opioid + Acetaminophen**	Hydrocodone + aceteominopnen (Lorcet, Lortab, and Vicodin); Oxycodone + acetaminophen (Percocet, Roxicet, Tylox)
Moderate-Severe	**Weak Agonist Opioid**	Tramadol hydrochloride (Ultram)
Severe	**Full Agonist Opioid**	Oxycodone (OxyContin), Hydromorphone (Dilaudid), Fentanyl (Actiq, Fentora, Duragesic); Methadone (for terminal cancer)

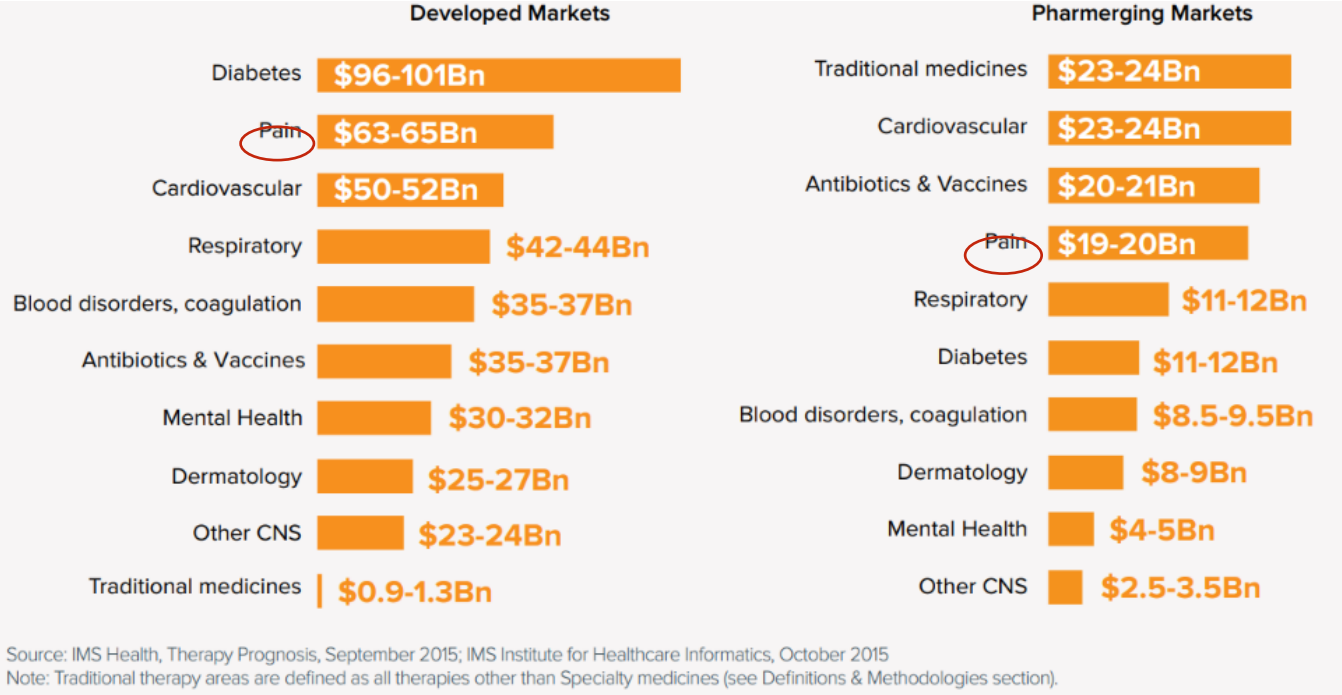
CHRONIC PAIN % PREVALENCE WORLDWIDE



Source: *Northwest Neuroscience Outreach Group: Growing in Networks,*

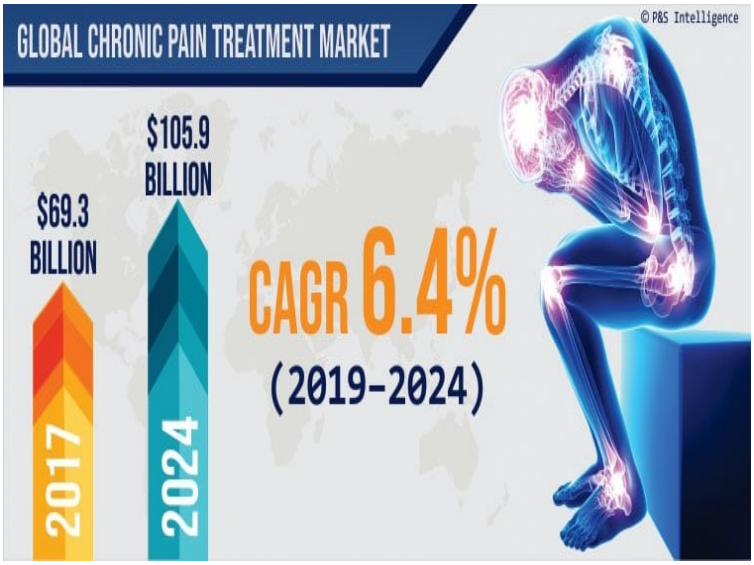
www.nwnoggin.org

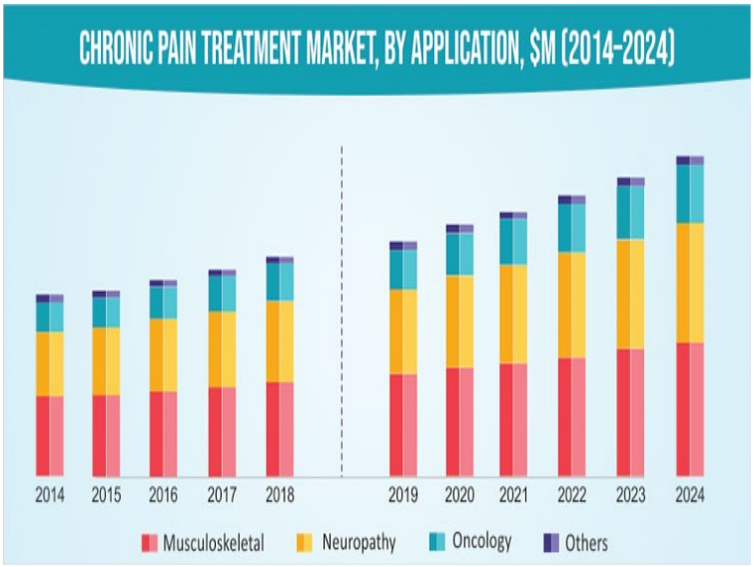
TRADITIONAL MEDICINES SPENDING IN 2020, CONSTANT US $BN



Source: IMS Health, Therapy Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Traditional therapy areas are defined as all therapies other than Specialty medicines (see Definitions & Methodologies section).

$20B MARKET FOR MODERATE TO SEVERE CHRONIC PAIN





INCIDENCE OF CHRONIC PAIN: REGIONAL COMPARISON

	USA	EUROPE	GCC
Population	331M	741M	54M
Chronic Pain Patients	100M	260M	22M
Patients on Daily Opioids	18 M	27M	1.4M
Daily Opioid Deaths	145 (2020)	30 (2017)	?
Regulator	Food & Drug Administration	European Medicines Agency	Ministries of Health

BT-219 PRODUCT APPEAL – LOW HANGING FRUIT

Peeing in a cup: The safety of *Bupe* is reflected by its being scheduled III like codeine, rather than schedule II for full agonist (or fully acting) opioids such as morphine, oxycodone or fentanyl, etc.[21] The practical implication is that *Bupe* patients can avoid the monthly ritual of peeing in a cup to verify compliance with the prescriptions, an often embarrassing requirement for opioid patients.

Mouth irritation: BT-219 will have most appeal to the one-fifth of patients using Suboxone (and its related generics) who experience mouth irritation which ranges from bleeding ulcers, to lesions, to soreness.

21 The 1970 Controlled Substances Act (CSA) instructs the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) to classify certain drugs in schedules based upon their accepted medical benefits versus their potential for abuse and addiction.

Bridge's chief science officer (**CSO**) has conducted studies for the FDA which found a causal link between oral residence time and mouth irritation. Indivior has also found incidences of mouth irritation with Suboxone. Overall, the original, tablet form of Suboxone produced irritation in 20% of patients while the new Suboxone film rate was 24% presumably because of its larger, rigid shape. Zubsolv and generic versions of tablets and films produce similar results.

By dissolving in a few seconds, Bunalz is expected to greatly reduce or eliminate the incidence of mouth irritation which is expected to prove very popular among patients and reduce their complaints to providers.

Pain patients: Once BT-219 secures the pain indication as BupHD, it will appeal to the estimated 80% of the 3 million US patients who currently take Suboxone off-label to treat pain, since dosing is 3x/day (vs 1x for addiction) heightening the desirability of convenient delivery. On-label usage will also qualify for insurance reimbursement.

Observed dosing: Bunalz will appeal to prison wardens and halfway house administrators who must pay guards to "observe the dosing" of inmates, since "time is money." Additionally, the quick dissolution virtually eliminates the possibility of drug diversion, improving compliance and eliminating a source of fights among inmates.

The market for "observed dosing" is small today, perhaps 50,000 persons, but it provides an opportunity to grow the market, since only ~1% of America's 4,100 jails and prisons offer Medication-Assisted Treatment (MAT) programs for opioid treatment despite the fact that roughly half of America's 2.3 million prisoners suffer from addiction.

BT-219 PRODUCT APPEAL – MOTHER LODE

Safe alternative to opioids for pain: Upon BupHD/LD being approved for pain, the "mother lode" event will be raising awareness that it is the safe alternative to opioids for high level pain. Upon politicians learning of BupHD/LD, U.S. Government officials, aka "Uncle Sam", will become Bridge's top sales advocates, soon to be joined by class action lawyers.

Government support: The US Department of Health & Human Services (HHS) Task Force on Pain demonstrates government's knowledge of and support for using *Bupe* to treat chronic pain. The Company's BupHD/LD and Bucam do exactly that, which is expected to lead to broad public support, even above any clamor from competitors in the pain space.

Comparator in lawsuits: Litigation is ongoing against the over-promotion and indiscriminate prescription and distribution of opioids, yet today there is no safe alternative for treating moderate-to-severe pain. Upon the introduction of the Company's products, opioid manufactures, distributors and providers will also face scrutiny and risk litigation for prescribing drugs with the known risk of overdose and death. That is strong incentive for the Company's products.

4. COMPETITIVE ANALYSIS

COMPETITIVE LANDSCAPE

The pharmaceutical industry is highly regulated and research driven, since new drugs produce the bulk of profits. While the industry "majors" are fully integrated from R&D, to regulatory approval, to marketing and distribution, other companies focus on just one of these functions.

The pharmaceutical industry is very competitive, with nine out of the world's top ten pharmaceutical companies based in the US. In recent years though, the market has become even more competitive both with branded and generic product segments. Major companies compete among themselves and practically all of them are active in the R&D and production of drugs. For patented and branded products, competition is based on R&D and product innovation. Product innovation is costly, involving high levels of risk and long lead times, with just one in 5,000 newly discovered chemicals actually becoming a medicine. Furthermore, only 30% of approved products recover their money spent on R&D, while it normally takes around 10 to 15 years and more than $1 billion to develop a new product.[22]

Developing a novel combination, delivery or indication for generic drugs is far less costly and time consuming than new chemical entity (NCE) drugs, yet requires an economic moat or competitive advantage to be successful. Bridge has such advantages through its experience controlling for the placebo effect, its licensing of the Zydis technology, its expected market exclusivity and its succession of patented products.

MAJOR COMPETITORS

Bridge's main competitors are also its most likely licensee or distribution partners.

Indivior PLC (INDV.L) With trailing-twelve-month (**TTM**) revenue of $785M, Indivior is the market leader with the branded drug Suboxone.[23] It's 6-minute dissolve-time film is facing competition from generic strip manufacturers and its prior aggressive marketing and litigation strategies have been upended. Even still, the company has $1B in cash on its balance sheet, so has the liquidity needed to buy Bunalz if it wants to retain market leadership.

Pfizer (PFE, $52B TTM revenue) has two opioids with chemical deterrence: Embeda (morphine + naltrexone) and Troxyea ER (oxycodone + naltrexone; ER = Extended Release). As such they are familiar with the abuse deterrence approach in Bridge's Bunalz and hence may wish to see it applied as well to Bucam.

Novartis (NVS, $49B TTM revenue). In Dec'2018 Sandoz Inc., a division of Swiss pharmaceutical giant Novartis, and US company Pear Therapeutics announced that the FDA approved an app that can be prescribed to help treat opium addicts called *reSET-O*. In 4'2019 Sandoz began to market and distribute a generic version of sublingual film Suboxone on behalf of Indivior.

In June 2017, FDA announced that it was seeking to spur innovation by allowing for accelerated approvals of generic drugs without competitors as part of its Drug Competition Action Plan. In June 2018, the FDA approved the first generic versions of Suboxone sublingual films (from both Mylan Technologies and Dr. Reddy's Laboratories) as part of an ongoing effort to promote drug competition, lower prices, and expand access to medication-assisted treatment.

Alkermes plc (ALKS, $1.2B TTM revenue) Alkermes markets Vivitrol® (naltrexone for extended-release injectable suspension), a once-monthly medication for the treatment of alcohol dependence as well as for the prevention of relapse to opioid

[22] https://www.drugpatentwatch.com/blog/the-importance-of-pharmaceutical-competitor-analysis/
[23] http://indivior.com/

dependence. Since buprenorphine has been successfully applied to opioid dependence, Bunalz could fit nicely in their product portfolio or distribution network.

Allergan plc (AGN), a specialty pharmaceutical company, develops, manufactures, markets, and distributes medical aesthetics, biosimilar, generics and over-the-counter pharmaceutical products worldwide. It has a market cap of $62B and sales of $16B. The company offers a portfolio of products that provide treatment for the central nervous system, gastroenterology, women's health and urology, ophthalmology, neurosciences, medical aesthetics, dermatology, plastic surgery, liver disease, inflammation, metabolic syndromes, and fibrosis, as well as Alzheimer's disease. The company distributes generic and branded pharmaceutical products primarily to independent and chain pharmacies, nursing homes, mail order pharmacies, hospitals, clinics, and physician offices.

Johnson & Johnson (JNJ) is the world's largest independent biotech company by market cap ($355B); it has TTM revenues of $81.3B.[24] The company manufactures, markets and/or distributes more than 71 drugs in the United States including NSAIDs and the opioids Nucynta (tapentadol) and Ultram (tramadol). Having acquired the developer of Nucynta and Ultram, JNJ could well seek to expand its portfolio of strong, yet safer pain relievers by buying BupHD/LD, Bucam or Bridge.

Grünenthal (Private, German) sees itself as a global leader in pain management.[25] The company had revenues in 2019 of €1.4B ($1.5B). Like JNJ it markets versions of tapentadol and tramadol. It also markets a buprenorphine patch (Transtec) for chronic pain. With its 50-year history in the space and its traditional base in Europe, Grünenthal could find Bridge attractive both for its products and its US roots.

Endo International plc (ENDP). With $767M market cap and $3B TTM revenues Endo has the firepower to bid competitively for Bridge. The company focuses on generics and specialty branded drugs. Endo is experienced with buprenorphine, having licensed the distribution of BDSI's Belbuca patch in 2012 and relinquishing it in 2016. The company markets two opioid drugs, Opana (oxymorphone) and Percocet (oxycodone + acetaminophen). It also has a range of other drugs with non-standard delivery systems.[26]

Perrigo Company plc (PRGO) is manufacturer of private label over-the-counter pharmaceuticals with net sales of $4.7B and a market capitalization of $8B. It manufactures and supplies over-the-counter (OTC) healthcare products, infant formulas, branded OTC products, and generic pharmaceutical products worldwide. The company offers its products through retail drug, supermarket, and mass merchandise chains; hospitals; pharmacies; wholesalers; drug and grocery stores; and para pharmacies, as well as through a network of pharmacy sales force in North America, Europe, Australia, Israel, and China.

Teva Pharmaceutical Industries Limited (TEVA) Teva is an Israeli generic drug manufacturer with $17.7B in TTM revenue and a market cap of $7.5B, down about 70% from a year ago. In 4Q2017 Teva acquired Actavis, whose generic version of buprenorphine + naloxone hard compressed tablet will be the reference drug for Bunalz.

Mallinckrodt plc (MNK)[27] is an Irish–tax registered manufacturer of specialty pharmaceuticals, generic drugs and imaging agents. In 2017 it generated 90% of sales from the U.S. healthcare system. While its stock price is deeply depressed owing to opioid litigation, should it survive, then with $3.25B in TTM revenue, it could be a future suitor or distribution partner for Bridge.

[24] https://www.jnj.com/
[25] See https://www.grunenthal.com/en/about-us/company-overview
[26] http://www.endo.com/endopharma/our-products
[27] http://www.mallinckrodt.com/about/

BioHaven (BHVN) is a launched its first product in 2020 which uses the Zydis freeze-dried technology for Nurtec, a therapy migraine headaches. It has a ~$4B market capitalization on $64MM in sales from a wide an expanding sales network. Its portfolio is comprised of innovative, late-stage product candidates targeting neurological and neuropsychiatric diseases, including rare disorders.

COMPETITOR STRENGTHS & WEAKNESSES

Principal Strengths In general, large market size and established cash flows give the companies listed above huge resources to develop drugs for a given indication as well as to dominate market segments.

Principal Weaknesses Most large pharmaceutical companies suffer from a bias against products that they themselves don't develop. This can make them ignore significant advances by smaller competitors like Bridge until it's late in the game at which time they look to buy-out, rather than compete head-on, with innovators.

Large companies focus on new block-buster drugs with the potential to define new multi-billion categories. For this reason, they tend to ignore market niches and established markets, such as addiction therapies.

Many companies have also abandoned the search for new pain medicines because of opioid litigation. Instead, they tend to focus on new areas with little competition, such as genetically caused diseases and any variety of cancers. The global impact of COVID-19 has revived interest in virus research.

MARKET TRENDS

Bridge sees the following trends in the market for pharmaceuticals.[28]

The **Chinese market comes into its own** from being largely a consumer of drugs developed elsewhere to being a designer of new drugs.

The rise of **digital analysis** is a phenomenon so broad and diverse in nature, it's impossible to define into a few specific metrics. However, artificial intelligence and machine learning (AI/ML) will increasingly play a role in the development of New Chemical Entities (NCEs) as well as with make testing of all drugs and the repurposing of generic drugs more precise.

Harnessing **genomics** and real-world evidence from large, shared databases will aid in the ability to treat genetically driven diseases with a range of gene-based therapies.

Biosimilars thrive, but generic markets struggle. The ability to mimic the action of large biological molecules without the cost of refining their function will benefit the specialist makers of biosimilar drugs. Pure generics with few barriers to entry and without competitive advantages will continue to compete on low-cost supply and mass production, leading to consolidation.

Consolidation wave among the global top 20 of Pharma companies extends into mid-sized European companies.

BRIDGE INTENDS TO EXPLOIT THESE TRENDS:

As to China, Bridge has met with a few Chinese VC funds to explore the issues surrounding expanding into China. Given the Company's status, it's best only to monitor the situation and to act strategically when the opportunity arises.

[28] Adapted from ***Nine pharma trends for 2020***, January 14, 2020, https://pharmaphorum.com/views-analysis-digital/nine-pharma-trends-for-2020/

Unlike many research-driven biopharma companies who might apply artificial intelligence and massive data sets to explore early-stage drug candidates, Bridge is positioned later in the drug development process. The Company relies on generic APIs that already have been proven safe and effective. The gap Bridge fills is to innovate in the combination, delivery and indication of these APIs. The IP and strategic barriers to entry that the Company builds come from the skills of the Company's staff and especially of its CSO to spot deficiencies in the market and fill them much faster and less expensively than NCEs. This is a niche strategy, yet Bridge is uniquely qualified to pursue it. Hence the role of AI/ML for Bridge is in the identification of novel indications for existing drugs (i.e., their repurposing), novel combinations of existing drugs (and warning of adverse interactions), screening of delivery technologies to minimize side effects and the selection (or exclusion) of patients for clinical trials to make them more precise.

With respect to consolidation in the pharma industry, Bridge can be an attractive licensing partner or take-over candidate for major firms. Such outside interest would boost the value of Bridge's stock many times over.

MARKET IMPACT

In the first three years after closing Bridge expects to be disruptive in the addiction market and at least start to disrupt the pain market.

By offering a superior therapy for opioid addiction and by launching a comprehensive marketing program, Bridge expects to grab market share from the brand leader, Indivior. This is unlikely to result in a price war, since the unit cost of Bunalz is about one-fourth that of Suboxone. Yet, Indivior has historically been known to be litigious. The problem that Indivior would face in suing Bridge is that, owing to its previous anti-competitive practices, it no longer has rights to the tablet form of Suboxone. So, the reference drug for Bunalz is Actavis' version of *Bupe*/naloxone.[29] With litigation blocked, Indivior may be motivated instead to maintain market leadership by offering to buy Bunalz.

Concerning the pain market, it is possible that BupHD and Bucam could take a major share of the $20B market for moderate-to-severe chronic pain, as today all therapies for this level of pain are opioids. Meanwhile BupLD is expected to compete for with short-duration dosing of opioids for moderate-to-severe pain, roughly a $10B market. While the arrival of some super-strong, non-opioid pain reliever cannot be ruled out, the risks, time-line and cost to develop a novel mechanism for pain relief are considerable. Bridge's therapies should be well-established for many years before such NCEs come to market, allowing it to maintain a significant market share afterwards.

BRIDGE'S COMPETITIVE ADVANTAGE

Bridge has the ability to design, develop, prosecute FDA approval and commercialize desirable new drugs inexpensively from generic APIs in proven delivery technologies through the expertise of its staff and advisors and by outsourcing manufacturing and certain regulatory and marketing functions to major firms. The Company also has substantial experience and expertise in designing clinical trials that control for the placebo effect which is particularly pronounced in neurological conditions, such as addiction, chronic pain, anxiety and depression, etc.

By using *Bupe* as the main API in its current product portfolio, Bridge is starting with a well understood medicine across 50-years and hundreds of studies, greatly shortening the time and cost of bringing new products. This is in contrast to NCE's which can take 8-12 years and ~$1B or more to commercialize.

By being a Schedule III drug, like codeine, *Bupe* has advantages in the addiction market, since it can dispensed in 30-day or event 90-day prescriptions, whereas methadone (Schedule II with risk of overdose and death) must be administered daily in

[29] Actavis Generics was acquired Israel's Teva in August 2016.

a clinic. Scheduling is also significant when comparing *Bupe* to full agonist opioids, e.g., oxycodone or hydromorphone, since these are Schedule II requiring monthly office visits wherein urine samples are taken to confirm compliance. As a Schedule III drug, similar to codeine, *Bupe* may be prescribed for 90-days at a time.

Catalent's Zydis lyophilization (or freeze-dried) technology is difficult to replicate. Each of Johnson & Johnson and Pfizer spent ~$250M and several years on trying to devise their own process before abandoning it and paying Catalent to use Zydis.

TABLE OF ZYDIS DRUGS AND THEIR MARKETERS

Trade name	**Indication**	**Manufacturer**
Ativan	Anxiety disorders	Valeant (Bausch)
Claritin RediTabs	Allergy	Merck & Co.
Feldene melt	Pain relief	Pfizer
Imodium	Diarrhea	Johnson & Johnson
Maxalt MLT	Headache	Merck & Co.
Motilium	Nausea and vomiting	Johnson & Johnson
Nurtec	Migraine headaches	BioHaven
Pepcid RPD	Peptic ulcer, acid reflux	Johnson & Johnson
Zelapar	Parkinson's, depression	Valeant (Bausch)
Zofran ODT	Nausea and vomiting	GlaxoSmithKline
Zyprexa	Schizophrenia, bipolar	Eli Lilly & Co.

By using the Zydis technology, Bridge enjoys not only superior delivery compared other formulations, but also a significant cost advantage, since the unit cost of its tablets is roughly 1/6th that of the branded drug (i.e., Indivior's Suboxone film) and 1/3rd of the quicker dissolve tablet (i.e., Orexo's Zubsolv). The only form of buprenorphine (or simply, *Bupe*) that is cheaper than Zydis are the hard compressed tablets, yet these take 12-16 minutes to dissolve vs 3-seconds.

5. SALES & MARKETING PLAN

Bridge Therapeutics' goal is to improve the lives of millions of patients with a better delivery of the addiction drug Suboxone and a stronger and far safer pain medication than Opioids. By focusing on our addiction drug ($6B market, 6M patients), Bridge can start sales in ~12 months and then self-fund our pain drug ($20B market, 50M patients), thereby minimizing the time & capital needed to commercialize the business.

MARKETING STRATEGY - OVERVIEW

Bridge believes that it will offer superior products -- a much better delivery of Suboxone and stronger and far safer pain therapies than opioids.

In addition, Bridge intends to price its drugs below that of the brand in order to provide an economic incentive for payors to include the Company's products on their formularies of approved drugs for reimbursement. To providers we will offer free samples for their patients which will be backed-up with coupons to reduce the co-pay on prescriptions of its drugs.

As to direct marketing to providers, Bridge is exploring two options: developing its own small salesforce and entering a distribution agreement with an established player.

In either case, Bridge intends to deploy its CSO and SAs to make technical presentations to large groups of doctors. Bridge will also tailor advertising and marketing activities to each of the 3 P's, patients, providers and payors.

The Company will advertise to patients primarily via the internet. Through this outreach, the public will learn the benefits of Bunalz and be encouraged to inquire about free samples, coupons and discounts from their healthcare providers. Patients will also be encouraged to blog about their experience taking Bunalz, especially about the presence or absence of mouth irritation compared to other versions of *Bupe*

Healthcare providers (i.e., doctors, nurses, physician assistants) will be addressed in groups by our CSO and SAs. Follow-up visits will be conducted by dedicated salespersons in urban areas and by "shared" salespersons in rural areas.

Payers: the key focus is to get onto the formularies of drugs that are approved for reimbursement by both private and public Pharmacy Benefit Managers.[30] Bridge will this conduct this activity, called "market access," through Percipient.

LICENSING VERSUS SELF-DIRECTED MARKETING:

1) Bridge is exploring two avenues for distribution: one is to contract this out to another company, the other is to develop our own small salesforce.

    a. **Licensing/Distribution Agreement**: Bridge is in various stages of negotiations with both national and multi-national distribution companies to license or possibly sell Bunalz, the most logical of which is the brand leader, Indivior. Concluding such an agreement could greatly reduce our direct marketing expenditures, though at the cost of slimmer margins. The goal is secure several million dollars in staged payments to get the drug through FDA approval and into manufacturing as well as to fund the development and pain trials

[30] PBMs are third-party administrators of prescription drug programs for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans. In 2016 there were fewer than 30 major PBM companies in this category in the US, and three major PBMs (Express Scripts, CVS Health, and OptumRx of UnitedHealth Group) comprising 78% of the market and cover 180 million enrollees.

of BupHD and possibly of Bucam. We would expect as well to receive a portion of net revenue on the back end. A separate memo on Return on Investment (ROI) provides an estimate of the economics of such deals.

b. **Small Sales Force with Big Impact**: Owing to the concentration of OUD prescriptions, Bridge could make a big sales impact with a small sales force. The plan being evaluated builds up to 30 sales persons as revenue accelerates. Where possible, Bridge plans to stretch its marketing budget through contract sales organizations (CSOs) and Zoom-marketing which have become increasingly popular and effective over this past year. The ability to stretch the marketing budget is even more promising in support functions such as Distribution, Market Access and Back Office. Later, once in sales, Bridge can evaluate bringing some or all of these activities in-house.

AREAS FOR OUTSOURCING MARKETING ACTIVITIES[31]

	Full Commercial $$$	Hybrid $$	Outsource $
Sales Force	~$250k/rep	Contract Sales Org ~$150-200k/rep	Fee per call ~$75k/rep
Distribution Trade / State Lic	Inhouse	Inhouse + Contract	All contract
Market Access MCO / PBM	Inhouse	Inhouse + Contract	All contract
Back Office Govt / GTN	Inhouse	Inhouse + Contract	All contract

2) **Market Launch Activities**: This next table outlines the range of activities needed to launch Bunalz into the market. Many of them will need to be undertaken by Bridge regardless whether it licenses Bunalz or not. However, the most expensive item is Field Force Deployment and several of the supporting activities which obviously would be laid off to a licenser or acquirer of this drug.

MARKETING ACTIVITIES WITH BUDGET, QUARTERS BEFORE LAUNCH

Workstream	Launch -4Q	L -3Q	L -2Q	L -1Q	Post Launch 1st year
Product/Brand Marketing	50,500	147,500	435,000	750,000	4,000,000
Payer Access	45,250	55,250	60,000	100,500	305,000
Medical Affairs	-	15,000	15,000	30,000	150,000
PR Communications	-	10,000	15,000	45,000	75,000
Field Force Deployment	-	12,500	612,500	2,675,000	7,500,000
Commercial Analytics	25,000	35,000	62,500	122,500	250,000
Trade and Distribution	25,000	20,000	135,000	370,000	835,000
Patient Programs	-	-	50,000	105,000	200,000
Compliance and Reporting	-	-	-	120,000	100,000
Home Office Staffing	-	15,000	65,000	150,000	-
Total	**145,750**	**310,250**	**1,450,000**	**4,468,000**	**13,415,000**
Cumulative	145,750	456,000	1,906,000	6,374,000	19,789,000

ASSUMING BRIDGE MARKETS BUNALZ…

[31] MCO: Managed Care Organization; PBM: Pharmacy Benefits Manager; GTN: Gross to Net accounting

The following Sections are most relevant if Bridge launches and markets Bunalz itself and less so if the product is licensed or sold to another pharma company.

3) **Honing the Message**: for best sales results, Bridge will need to shape the message about Bunalz for different parties. The following are general arguments and means of spreading the messages. Going forward, these messages are expected to be honed through focus groups of patient advocates, physicians, payers and prison administrators.

    a. **Appeal to Patients:** the initial and most cost-effective way to reach patients directly is via a website and web advertising. These can only start after FDA approval. They will provide product information, when and how to take it, side-effects, etc. We plan also to encourage patients to blog about their experience with the expectation that mouth irritation will be substantially less (if not entirely absent) with Bunalz versus competing formulations.

        i. A recent Bridge initiative is to assemble a *Social Impact Advisory Board* of professional athletes, entertainers and prominent advocates who can boost awareness of OUD and our therapeutic solutions.

    b. **Appeal to Healthcare Providers:** our chief science officer Dr Sullivan and three distinguished scientific advisors are already well known in the addiction and pain space, lecturing at teaching hospitals, medical schools and public conferences. Once we have FDA approval, the plan is to get them on the lecture circuit to address large audiences of healthcare professionals (50-300+). These group presentations will be complemented by a dedicated salesforce (described above).

    c. **Appeal to Payers:** A key part of launching a new drug is to provide insurance reimbursement for it or so called "Market Access". Specifically, this involves marketing to Pharmacy Benefit Managers (PBM's) and Governmental insurers (Medicare/Medicaid/ VA) to get on their formularies which are their list of drugs they will reimburse in part or in full. To make this happen Bridge has engaged ***Percipient, LLC*** who does this work already for such majors as Novartis, Pfizer and J&J.

    d. **Appeal to Prisons:** Institutions such as prisons and half-way houses will incur less patient observation time (drug administration observance to enforce compliance) with Bunalz, thereby reducing staffing expense as well as virtually eliminating the instance of drug diversion, i.e., patients/prisoners trying to pocket the tablet for later sale or trade.[32] Strategies for marketing both public and private will be developed under Market Launch.

4) **Pricing**: as with any consumer, patients are creatures of habit, so having gotten used to one therapy (regardless how inconvenient, irritating or bad tasting), there is resistance to switching to a new product, even if vastly superior. Assuming that Bridge runs the Bunalz marketing program, then the plan is to price Bunalz at a discount to the branded drug, i.e., *Suboxone*. This adds an economic incentive to switch, especially by those paying for it

[32] Observed Dosing: Without making any new claims, we can also go after the prison population. By saving money on wages for guards in prisons and staff in halfway houses, Bunalz will have an economic advantage compared to existing therapies. Currently only ~1% of America's 4,000 jails and prisons offer medication assisted therapy (MAT) to end Opioid Use Disorder (OUD), yet half of America's 3.2MM prisoners are incarcerated for drug offenses. An impediment for expanding coverage has been the fights and sometimes riots that have occurred by inmates tricking their guards during observed dosing and then selling or trading their drugs afterwards, i.e. from diversion. Our rapid dissolve technology should make diversion practically impossible and hence promote MAT in more institutions. So, in addition to capturing demand for the ~150,000 prisoners who have access to MAT today, Bridge can grow this market.

themselves. A further consideration is that to gain the broadest coverage by insurance companies, the premium above the price of the generic version of the drug cannot be excessive. The result is that we expect to price our addiction therapy (**Bunalz**) at roughly 2/3rds the price of the branded drug which happens to be about 30% more than the price of generics.

- *Suboxone's* list prices is ~$8/strip for the most popular dose (8mg bup/2mg nalox); with coupons and discounts the drug may be purchased for ~$6; it dissolves in ~6 minutes.
    a. Generic version of the strip cost roughly $1 less and take 1-2 minutes longer to dissolve
    b. Formulation costs $1.65 each + $0.10 for active pharmaceutical ingredients (API).
- *Zubsolv* -- a branded generic tablet that uses sodium bicarbonate to dissolve in ~7 minutes – sells for ~$4/tablet.
    a. Formulation costs ~$0.80 each + $0.10 for API.
- *Buprenorphine/naloxone* hard pressed tablets are priced at $2-3/tablet depending upon the pharmacy; Walmart is the cheapest, CVS the most expensive; they take 12-16 minutes to dissolve.
    a. Formulation costs ~$0.05 + $0.10 for API.
- We expect that the list or gross price of Bunalz will be close to that of Suboxone in order to maximize the payment to channel partners. That said, Bridge intends to put the net price of Bunalz at or a little below Zubsolv; it dissolves in 3 seconds.
    a. The financial model assumes a net sales price of $3.50 (= $4.00 less $0.50 discounts)
    b. Production costs = $1.27 = formulation ($0.30) + API ($0.10) + distribution ($0.80) + 3% royalty ($0.07)
    c. Net margin = $2.23 or 56%
        i. NB: this net margin is conservative as pharma margins are typically 70%+

5) **Medicaid**: our consultant ***Percipient*** finds that 50% of the addiction therapy prescriptions are commercial, i.e., privately insured, with the balance coming from a mixture of Medicaid, self-pay, VA and other. Yet Medicaid recipients remain an important patient population. While marketing to them is little different than to other patients, it is vital to secure Medicaid reimbursement which, in turn, revolves around price discounts. The standard Medicaid discount rate nationally is 27.5% for all drugs. In addition, roughly 30 states require the negotiation of supplemental discounts for two cases:

High-priced drugs, but this won't apply as we plan to price below the brand.

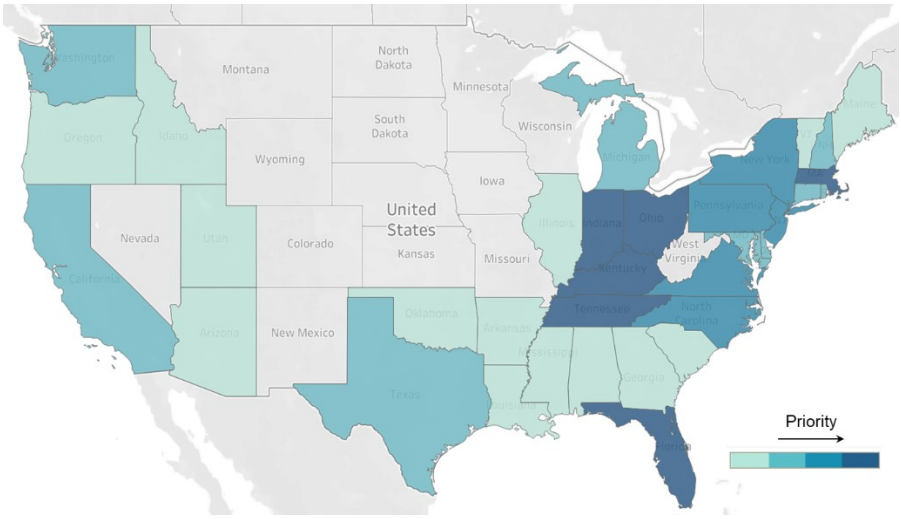
Bad pricing behavior, e.g., raising prices above inflation or engaging in predatory behavior, but this can't apply until we've been on the market for a few years.

While Bridge does not fit either of these two categories, we will negotiate supplemental discounts where a particular state requires it and, in future, Bridge intends to moderate any price increase in line with the market.

6) **Concentration of Prescriptions**: Bridge expects to gain a large market share with a smaller sales force, because of the concentrations of OUD prescriptions:

a. **First,** the opioid crisis is not spread uniformly throughout the country. Demographically the problem follows the Appalachian Mountains with the hardest hit state overall being West Virginia, and the worst effected large states being Ohio, Pennsylvania and Florida. (The CDC has an interactive map). That said, when devising a salesforce, one needs also to factor in population density, hence Massachusetts (population 6.7 million) has a higher priority than West Virginia (1.8 million).[33]

PRIORITY STATES FOR BUNALZ SALESFORCE



b. **Second**, most prescriptions of OUD therapies are written in addiction clinics of which there are only ~300, half of which are controlled by 12 companies. It doesn't take a large salesforce or a long time to contact a dozen companies.

c. **Third**, only 5% or ~50,000 of doctors are certified to treat addiction with a smaller number (4,700) being large prescribers. By identifying these prescribers now, Bridge can better focus its efforts in the future.

   i. While it may take an act of Congress to implement fully, on January 21, 2021, the Department of Health & Human Services has proposed the eliminate the X-waiver requirement for physicians who register with the DEA.

   ii. For Bridge, this has the effect of expanding the market.

d. Concentrate on doctors writing the top decile (10%) of scripts, then the next and the next

e. Bridge will have already built a core team with OUD in advance of its Pain therapies

EXPANDING INTO THE PAIN MARKET

By starting with Bunalz for the smaller and concentrated addiction market, Bridge will be able to build its sales and marketing team gradually before launching into the larger pain market.

[33] The map was constructed based upon identifying the top 15 states in each of 5 different categories: usage per person; prescriptions per HCP; population density; # of prescribers; volumes of scripts.

Getting the pain indication for BupHD will start the process for accessing the $20B pain market. Launch activities will be similar to for Bunalz, but spread across all 50 states starting with the more populous ones. This will require a much larger sales force than for Bunalz (~200 staff versus ~30 for Bunalz) and, in time, will require political lobbying and TV advertising.

PAIN STRATEGY – MOTHER LODE

A key goal for marketing BupHD (and later for Bucam) will be to educate providers that a strong dosage of *Bupe* is very effective in treating moderate-to-severe chronic pain. Currently, it's mostly pain specialists who know about *Bupe*'s virtues. By contrast, the average physician believes (1) that oral *Bupe* is meant only for addiction (since that's the on-label use of the branded drug, Suboxone) or (2) that *Bupe* is not effective because the two available versions of *Bupe* indicated for pain (Butrans and Bunavail) have dosages that are too weak to treat moderate-to-severe chronic pain. These drugs are between $1/10^{th}$ and $1/100^{th}$ the effective dosage which is found in Suboxone and which will be contained in BupHD and Bucam, i.e., 8mg. Bridge will educate providers and payors as to what constitutes an effective dose and familiarize them with the numerous studies that demonstrate *Bupe*'s pain credentials as a chronic or daily, long-term therapy. (Note, as an acute/short-term therapy, many emergency rooms use injectable *Bupe* – Buprenex – for three very painful conditions: emergency C-Sections, kidney stones and third-degree burns.)

In addition to the marketing activities described above, the Company's CSO and SAs will be asked to write and lecture on the comparative safety and effectiveness of BupHD and Bucam vs full-agonist opioids. Bridge will also participate and possibly help organize industry seminars to explore various pain therapies in order to demonstrate its products in context with competing therapies.

BRANDING

Bridge's goal is to be the market leader for buprenorphine drugs for treating addiction and pain. Such a franchise will allow the Company to protect market share once FDA's market exclusivity lapses for BupHD and Bucam as well as allowing Bridge to introduce new and improved versions of all its therapies in order to boost sales, raise prices and protect its IP.

Through the 505(b)(2) approval pathway Bridge believes it will receive FDA approval for "branded generic" versions of generic APIs. Unlike pure generic drugs which (i) can only ever be known by their chemical names (e.g., buprenorphine-naloxone), (ii) can only make the same claims as their branded or reference drug (i.e., those of Suboxone) and (iii) cannot add claims or indications, branded generics (i) can be promoted with their own brand name (e.g., Zubsolv or Bunalz), (ii) can add claims (e.g., reduces mouth irritation) and (iii) can add indications (e.g., also treats pain). Together these will build a public impression for Bridge as bringing a significantly new product while relying on 50 years of clinical safety and effectiveness data.

The Company believes that it is not important whether the trade names *Bunalz, BupHD* and *Bucam* survive market launch or are changed to improve their appeal to consumers. The critical issue is that once launched, Bridge will promote these brands and establish its reputation for quality, safety and effectiveness. Such a reputation will be important in winning over new patients, providers and payors as well as convincing active providers to switch from competing delivers of *Bupe* to the Company's therapies.

6. OWNERSHIP AND MANAGEMENT PLAN

LEGAL ENTITY

Bridge Therapeutics is a Delaware C-Corporation formed on March 20, 2015 into which an LLC of the same name was converted on December 27, 2016. The firm seeks to be actively engaged in the business of development and commercialization of certain proprietary pharmaceuticals and related and ancillary goods and services. The business office of the company is located at 18 Forest Road, Asheville, NC 28803 while research and development are conducted at the Parkway Medical Center, 1160 Huffman Road, Birmingham, AL 35215. The company's registered office in the State of Delaware is located at 1209 Orange Street, Wilmington, DE 19801. The company's registered agent in the State of Delaware is The Corporation Trust Company at the same address. The Company has a wholly owned subsidiary formed and domiciled in Ireland – Bridge Therapeutics Europe, Ltd. The company could be described as a development stage enterprise.

CAPITAL STRUCTURE

Bridge ownership is split between Common Shares and two classes of Preferred Equity as follows:

Series	Common	Total Preferred	Series AA	Series AB	Totals
Shares Issued	9,353,206	1,230,597	1,102,950	127,647	10,583,803
Warrants Issued	646,010	65,334	13,289	52,045	711,344
Shares & Warrants	9,999,216	1,295,931	1,116,239	179,692	11,295,147
Authorized	16,000,000	2,225,113	1,159,395	1,065,718	18,225,113
Unissued	6,000,784	929,182	43,156	886,026	6,929,966

See the appendix for a Capitalization Table and an Options/Warrants Table as well as for detailed financial statements for the past three years.

MANAGEMENT TEAM

Dr. James "Greg" Sullivan, MD, Chief Science Officer (**CSO**), Chairman, Founder is a key opinion leader (**KOL**) in the pain and addiction space. He is also an experienced physician treating primarily addiction and pain from the Parkway Medical Center in Birmingham, Alabama since 1988.

He speaks weekly to the FDA, advises the National Institutes of Health (NIH) on research and lectures regularly at medical schools and teaching hospitals and fields 3-5 consultations/day with outside physicians.

Dr Sullivan, is uniquely well qualified to develop *Bupe* products, having performed the original trial of *Bupe* in the US and 16 trials overall covering most all *Bupe* drugs approved on the U.S. market including Suboxone, Zubsolv, Butrans, Bunavail and Belbuca.

Dr. Sullivan is one of America's top clinical researchers: Since 2002 he has been the principal investigator of 170 clinical trials for FDA approval for such major pharmaceutical companies as Pfizer, J&J, Reckitt, Roche, ENDO, Forest, etc. and including approval in the US of such blockbusters as for Viagra (sildenafil) and Cialis (tadalafil) as well as four pain drugs (tramadol, tapentadol, hydrocodone and oxycodone) and 11 more treating neurological conditions such as anxiety and depression.

In addition to making him a top clinical researcher, this broad experience across wide classes of ailments gives him great perspective on the status of and gaps in pharmaceuticals, especially of their indicated vs off-label usage and of various delivery technologies.

His combined experience as a practicing physician and medical researcher across wide classes of ailments gives him great perspective on the status of and gaps in pharmaceuticals, especially of their indicated vs off-label usage and of various delivery technologies.

He is a graduate of Auburn University (BS) and the University of Alabama (MD) and is board certified in both internal and addiction medicine. His ongoing investigation of treatments for pain, addiction and mental disorders led him to patent BT-205 (Bucam) in 2005 and found Bridge in 2015.

Tim Peara, MBA, President. Mr. Peara brings to Bridge deep experience in business development and finance, building departments for large companies as well as developing projects and small technology companies, both in the USA and abroad. For 20 years Tim has developed technology start-ups (Greenfuel Technologies) and energy projects (Koch, GE) preceded by 14 years on Wall Street as an investment strategist (Prudential, Lehman). He earned a BA from Wesleyan University, Connecticut and an MBA from the University of Chicago's Booth School of Business.

David H. Bergstrom, Ph.D., COO. Dr. Bergstrom has 35 years of new product development and commercialization experience in the pharmaceutical industry. He has overseen and been intimately involved in moving new products from the research phase to commercial production and launch across numerous therapeutic areas and dosage form delivery technologies. Dave has experience in large, small, semi-virtual and contract development companies. For 7-years he ran the Zydis division of Cardinal Health which was later separately incorporated as Catalent. He earned his Ph.D., M.S. and B.S. degrees in Pharmaceutics, Pharmaceutical Chemistry and Pharmacy from the University of Utah, The University of Michigan and Ferris State University, respectively.

SCIENTIFIC ADVISORS

Bob Rappaport, MD has worked on advancing anesthesia, analgesia, and addiction drug-treatment research, discovery, and evaluation, in the private sector through his consulting firm Analgesic Concepts LLC. Dr. Rappaport also has an impressive resume in the public sector through his 20 year career at the FDA and has published extensively on addiction, pain clinical trial design, sleep disorders, and opioids for acute and chronic pain. Dr. Rappaport led the FDA's Anesthesia, Analgesia, and Addiction Products Division at the Center for Drug Evaluation and Research for 12 years. There he oversaw the approvals of drug products for that sector. He worked within the FDA to build the public-private partnership ACTTION (Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks) which has been highly successful in improving the study and development of treatments in these areas.

Joseph Pergolizzi, MD, is Chief Operating Office of NEMA Research in Naples, Florida and chairman of the Abstract and Poster Selection Committee for PAIN Week, and a member of the CHANGE PAIN Board. Dr. Pergolizzi's research interests focus on acute and chronic pain in adults with a particular focus on pain in the elderly. In the past, Dr. Pergolizzi held leadership positions with the Association of Chronic Pain Patients, the Coalition for Pain Education (COPE), the International Pain Research and Treatment Foundation, and the National Institute of Pain. Dr. Pergolizzi has held various academic positions over the past decade. He has served as NEMA CEO since 1997 with direct responsibilities for turn-key clinical trial

management and implementation (Phase I-IV). Prior to joining NEMA, Dr. Pergolizzi was the Director of Business Development and Financial and Affairs for the Johns Hopkins University School of Medicine's Clinical Trials Unit. Dr. Pergolizzi earned a BS in physical chemistry from St. John's University and an MD with highest honors from Ross University School of Medicine. He completed his residency in anesthesia at Georgetown University School of Medicine and a clinical research fellowship in the Department of Medicine at Johns Hopkins University School of Medicine.

Robert Raffa, PhD is Adjunct Professor at the University of Arizona College of Pharmacy and Professor Emeritus at Temple University School of Pharmacy. He was a Research Fellow and a Team Co-Leader for analgesics drug discovery at Johnson & Johnson, where he was pivotal in the elucidation of the mechanism of action and development of the analgesic drug tramadol (Ultram™). He is the co-holder of several patents, including for the combination of tramadol plus acetaminophen (Ultracet™). He has published more than 300 papers in refereed journals, and co-authored or edited several books on pharmacology and thermodynamics, and is a Co-Editor of Journal of Clinical Pharmacy and Therapeutics. More than a dozen of his works concern buprenorphine. He is a past president of the Mid-Atlantic Pharmacology Society and is the recipient of research and teaching awards. He lectures and consults worldwide on pain pathways and analgesics. He earned bachelor's degrees in Chemical Engineering and in Physiological Psychology (both from the University of Delaware), master's degrees in Biomedical Engineering (from Drexel University) and Toxicology (Thomas Jefferson University), and a doctorate in Pharmacology (Temple University School of Medicine). Dr Pergolizzi frequently collaborates with Prof Bob Raffa, PharmD, on peer-reviewed studies in pain and addiction.

See Appendix for links to studies published by Dr Pergolizzi and Prof Raffa.

BOARD OF DIRECTORS

Dr. James "Greg" Sullivan, MD, Chairman

Greg Sullivan, MD, who co-founded Bridge Therapeutics with the goal of helping patients beyond the walls of his own medical practice, has over 25 years of experience conducting human studies for new drugs. Since 2003, he has performed numerous buprenorphine studies, including FDA safety and efficacy studies for every buprenorphine product currently approved for the U.S. market. He is board-certified in both addiction medicine and internal medicine and treats chronic pain patients at his practice in Birmingham, Alabama.

Jason Bailey, Director

Jason is currently the CFO of Smith & Nephew for the global wound management franchise which encompasses pharmaceutical and medical device products. Prior to joining Smith & Nephew in 2014, Jason was the Head of Finance for Galderma's US prescription drug business. During his career, he has been actively involved in the commercialization and launch of multiple drugs with both Sanofi Aventis and Galderma. Additionally, he has worked on the development, out-licensing and in-licensing of different pharmaceutical compounds. Jason has also held operations and planning roles with Sanofi Aventis and 3M/Acelity. Jason began his career in the Financial Advisory Services group of Ernst & Young. Jason has a long history with one of Bridge's major investors, **JAR Capital**, a multi-family office in the St James's district of London. Jason holds an MBA in Finance from Vanderbilt University and a BS in Finance from Trinity University.

Joseph Mullin, Director

Mr. Mullin has over 20 years of experience in finance restructuring consulting and asset management. He is the founder of Joseph E. Mullin LLC, where he has worked on projects for a variety of companies in the retail, energy and media space. He previously worked at Millennium Global, Invesco, WL Ross and Goldman Sachs. He has an AB from Harvard College.

Elizabeth Kelley, Director / Company Secretary

Elizabeth has over 13 years in healthcare and pharmaceuticals. In addition to working in key positions in startup healthcare companies, she is a regular attendee of industry conferences focusing on packaging, delivery systems, pain management and anti-aging therapies. She is also a wife and mother of three.

Diana Harshbarger, PharmD, ex-Director

Dr. Harshbarger has over 30 years' experience in the pharmaceutical industry, specializing in customized patient medications. Diana holds a Doctorate of Pharmacy from Mercer University College of Pharmacy with expertise in the development of innovative alternative delivery systems for both sterile and non-sterile commercially available products. She has clinical proficiency and practical experience working in collaboration with physicians and other qualified health care practitioners throughout the United States in pain management, hormone therapy, infectious disease, dermatology and nutritional support. As an early and major investor in Bridge, Dr Harshbarger brings with her a **profitable exit from King Pharmaceuticals** which was acquired by Pfizer in 10/2010 for $3.6 billion. *Having been elected to the US House of Representative for Tennessee's 1st Congressional District in November, 2020, Dr Harshbarger resigned from the Board to avoid a conflict of interest.*

Edward J. Minskoff, ex-Director

Though retired from Bridge's board, Mr Minskoff remains a **major investor** in Bridge. As a major Manhattan real estate acquirer and developer of 40 million square feet of commercial space, he brings decades of financial and business experience to Bridge. Mr. Minskoff is also known for his philanthropy to NYU Medical Center as well as to numerous cultural and educational institutions including Columbia University and his alma mater Michigan State University. In recognition of his accomplishments and support, Michigan State University awarded him an honorary doctorate degree in business and also named its new business Pavilion in his honor.

LAWYERS & ACCOUNTANTS

General Legal Counsel: Luke Richbourg, Richbourg Law, 306 West 91st Street, Suite #2, New York, NY 10024.

Corporate Accountant Certified Public Accountant: Harriet Salupsky, auditor, Martin J. Finkle, CPA, 450 Seventh Avenue, Suite 2102, New York, NY 10123.

Patent Lawyer: Roberta "Bert" Jean Hanson, Ph.D., Polsinelli PC, 1401 Lawrence Street, Suite 2300, Denver, CO 80202.

Patent Lawyer: Eric Kelly, Patent Attorney, USPTO Registration No. 70,302, 32622 Nantasket Drive, No. 059, Rancho Palos Verdes, CA 90275.

7. OPERATING PLAN

INDUSTRIAL PARTNERS

Bridge's operations are aided by outsourcing key functions to industrial partners, namely drug development and manufacturing (Catalent), FDA approval (Camargo) and market access (Percipient).

CONTRACT DEVELOPMENT & MANUFACTURING ORGANIZATION (CDMO)

Bridge's licenser of the Zydis technology, drug development and manufacturing partner **Catalent**[34] is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable global clinical and commercial product supply. Catalent employs nearly 13,000 people, including approximately 2,400 scientists and technicians, at more than 35 facilities, and in fiscal year 2019 generated over $2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey.

It is worth noting that Bridge's Chief Operating Officer, Dr Dave Bergstrom, ran Catalent's Zydis division for 7-years and is intimately familiar with the process and personnel.

REGULATORY CONSULTANT

Bridge's consultant **Camargo** is America's second largest regulatory consulting firm. It focuses on the FDA's 505(b)(2) pathway for new deployments of generic drugs and has achieved over 250 drug approvals with a 98% first-pass approval rate.[35]

MARKET ACCESS CONSULTANT

Bridge's consultant **Percipient**[36] specializes in market access and market launch which it has done for both startups and such industry majors as Novartis and J&J. Market access concerns getting onto the formularies of drugs approved for reimbursement by Pharmacy Benefit Mangers (**PBMs**); this is fundamental to launching a new drug since otherwise patients have to pay for prescriptions out of their own pocket. Market launch encompasses a wide range of activities such as defining which doctors, clinics and hospitals to approach and crafting separate marketing packages for patients, providers (i.e., doctors and nurse practitioners) and payors (i.e., private insurers and Medicare/ Medicaid, Veterans Administration, etc.).

While Bridge has outsourced the manufacture of Bunalz to Catalent, it is worth noting that Bridge's Chief Operating Officer, Dr Dave Bergstrom, ran Catalent's Zydis division for 7-years and is intimately familiar with the process and personnel.

REGULATORY ENVIRONMENT

Bridge filed the Investigational New Drug (IND) for BT-219 in April, 2020 and that Autumn conducted a pilot PK study of 10 patients. Once the definitive PK study is completed on 36 patients and assuming it is successful, the Company will apply for approval through a New Drug Application (NDA).

[34] https://www.catalent.com
[35] https://camargopharma.com/the-camargo-way/expertise
[36] http://percipientllc.com/

While addressing COVID-19 has become the top priority of the FDA, the Opioid Crisis remains a serious concern both to FDA and to politicians on national, state and local levels. As such the FDA has reason to act promptly and incentive to review the Bunalz NDA more quickly than the statutory 10-month period. While no guarantee, there is precedent with other *Bupe* drugs getting fast-track review by the FDA of approximately three months.

Massive litigation and damage awards for opioid manufacturers and distributors has regulators and politicians cautious of new pain drugs and eager to find safe alternatives to opioids for treating pain (e.g., Bunalz, BupHD, and Bucam).

To help treat opioid addiction there are bills before Congress and in several State legislatures to relax or eliminate the certification requirement for doctors before they can treat addiction. If these bills become law, this should expand the number of doctors treating addiction and hence grow the market for Bunalz.

The government is strongly supportive of using *Bupe* for treating pain. In May, 2019 the Dept of Health & Human Services' Task Force issued its ***Final Report on Pain Management***[37] in which only one therapeutic recommendation is made, namely for industry to develop a *Bupe* drug to treat chronic pain.

QUALITY CONTROL

Bridge will rely first on Catalent's QA/QC[38] team and processes.

Next, in preparation for product launch, Bridge will hire a Logistics/Supply Chain Manager and a Head of QA/QC/Regulatory Affairs who will report to the Company's COO. Other hires include:

(i) General Counsel

(ii) Customer Service Manager

(iii) Back Office Manager

(iv) Contract and Government Support team

(v) Chargeback/Rebate Processing staff

(vi) Claims Management

The requirements for Quality Control and Quality Assurances are clearly outlined and mandated for both new development products being administered to humans during clinical trials as well as for commercial products. By following these requirements, Bridge expects to control quality.

The specific quality tests performed are mandated by FDA and the exact criteria for each product is established, based on scientific data and conclusions generated during the development process. In general, for a product like Bunalz, the type of quality testing performed on each specific batch of product includes assay of the amount of active ingredients present, content uniformity, disintegration time and the extent and rate of dissolution. Sufficient samples of each batch are placed on stability at various temperatures and humidities to assure that the product quality does not deteriorate over time. Subsequent to completion of testing and assessment of the results, each batch is formally "Released" or "Rejected" based on the Specifications in the FDA approved IND or NDA. These requirements are absolute and cannot be changed without formally amending each document.

[37] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

[38] Quality assurance (**QA**) is the process or set of processes used to measure and assure the quality of a product while quality control (**QC**) is the process of ensuring products and services meet consumer expectations.

OPERATIONAL MILESTONES

OBJECTIVES – FIRST 90 DAYS POST-CLOSING

In its first 90 days post-closing, Bridge will conduct a pharmacokinetic (**PK**) study of Bunalz to determine bio-equivalence with its reference drug, then use data from this study to complete a New Drug Application (**NDA**) for FDA approval with the help of Camargo and Catalent.

Bridge will also work to refine and elaborate its strategy for market launch along with interviewing candidates to serve as Marketing Director.

Finally, Bridge work with Camargo to file a supplemental IND to conduct a pain study with the Bunalz tablet (BupHD). Bridge will commission Catalent to produce three further dosage strengths of the Bunalz tablet so it can be used to titrate the dosage of addiction and pain patients.

Rather than filing a separate IND for BupHD, time and money can be saved by extending Bunalz' IND for pain study. Camargo will help to prepare and submit the required paperwork.

Bunalz has been formulated in a single strength (8mg *Bupe* / 2mg naloxone) which captures the majority of prescriptions (80%). However, further strengths are required to titrate patients into and out of MAT as well as to enter the pain market. The 4:1 ratio will be the kept for three more strengths, e.g., 2mg/0.5mg, 4mg/1mg and 12mg/3mg. While Catalent has done the core formulation work already for 8mg/2mg, supplementation laboratory work and testing procedures will be required to produce cGMP tablets in the other strengths.

OBJECTIVES – FIRST 180 DAYS POST-CLOSING

In its next 90 days post-closing (the first 180 days):

(i) Bridge expects to file an NDA for FDA approval of Bunalz and to apply for fast-track review.

(ii) Market launch activities for Bunalz will continue with focus groups, decisions on pricing and promotion, hiring of key staff, finalizing marketing material, building a product website, etc.

(iii) Bridge also expects to have started the pain trials for BupHD with a single dosage while Catalent formulates three more dosages.

Camargo will manage the overall process of expanding the IND for Bunalz into a New Drug Application (**NDA**) with results of the PK study and contributions from Catalent on the manufacturing process. An NDA expands upon the IND application. It is a comprehensive document with 15 sections that provides data on animal and human studies, pharmacology of the drug, toxicology, and dosage, and contains information about the drug's manufacturing process. The purpose of an NDA is to provide the FDA reviewer adequate data to ensure the safety and efficacy of the drug, labeling, and manufacturing process. By following the 505(b)(2) approval pathway, Bridge can have Camargo assemble prior clinical studies rather than conducting new ones. Catalent will complete the manufacturing sections of the NDA.

In coordination with Percipient, Bridge's Marketing Director and CEO will prepare for market launch of Bunalz.

Bridge's CSO will design and oversee the pain trials of BupHD with contributions from our SAs. The pain study for BupHD is a Phase 3 double-blind effectiveness study versus placebo. It will likely involve 100 patients, take 12 weeks to conduct and cost

roughly $5 million. The whole study from signing up volunteers to preparing the final report is expected to take from 6 to 10 months.

OBJECTIVES – FIRST YEAR POST-CLOSING

(i) Assuming Bunalz is fast-tracked, then Bridge should have received FDA approval to market Bunalz for addiction, completed its manufacturing trials and have shipped commercial inventory to distributors in the USA to be ready for market launch.

(ii) For marketing, Bridge expects to have hired and trained its sales staff, secured market access for Bunalz on key formularies, launched its product website and have started a lecture/seminar series to educate PBMs and providers.

(iii) Start the process of getting European Medicines Agency approval of Bunalz.

(iv) Complete the clinical work for BupHD and finalize or possibly submit its NDA.

(v) Open a headquarters office and fill out HQ staff including finance, legal, QA/QC, customer support, personnel, etc.

(vi) Interview Wall Street firms to explore the prospect of a public listing/IPO.

Bridge intends to accomplish these objectives as follows:

(i) As with earlier stages of getting FDA approval, Bridge's COO will be chiefly responsible for directing and coordinating the efforts of Camargo and Catalent to submit the NDA and to respond promptly to any issues raised by the FDA during its review.

(ii) Bridge's Marketing Director and CEO will assume increasing control over the market launch of Bunalz from Percipient and other outside advisors. In addition to hiring a core salesforce, Bridge expects that it will have concluded a distribution deal or will have engaged a contract sales organization to augment its efforts.

(iii) Bridge's CSO will direct the development of BupHD and plan the trials of Bucam with the addition of support staff.

iv) Bridge intends to conduct a financial audit with a top firm for the benefit of its shareholders and to prepare for an IPO.

Bridge expects to transition from being a start-up to an operating company with the gradual addition of key staff members, more regular and regularized reporting structures and better integration and standardization of business processes. While steps for accomplishing key goals have been detailed above, standard business practices and procedures will be implemented in support functions such as personnel, legal, accounting and information technology (IT).

OBJECTIVES – SECOND YEAR POST-CLOSING

Bridge has the following objectives in its second-year post-closing.

Bridge plans to commence selling Bunalz in order to meet or exceed the revenue targets in the financial forecast and then gradually expand the number of states it which it markets.

Bridge expects to get BupHD approved and to initiate clinical trials of Bucam for pain. Patent and early formulation of Bridge's pipeline of other drugs will commence.

Assuming that capital markets are supportive, then Bridge expects to have publicly listed its shares or be well along in the process of doing so.

Bridge expects to prepare for expansion to European markets.

To accomplish these objectives, Bridge has the core team in place to design, formulate, test and get approval for of Bunalz, BupHD and Bucam. Adding further drugs will require expanding the resources under the CSO for development as well as the legal function for IP protection. It will be important for Bridge to establish its own core salesforce either to expand upon it or to attract the best terms in any distribution or licensing deal. Thereafter, Bridge can evaluate the most profitable option.

Camargo can support regulatory approval by the European Medicines Agency (**EMA**). As to marketing in Europe, Bridge will most likely partner with an established player rather than by building its own capacity.

OBJECTIVES – THIRD YEAR POST-CLOSING

In its third-year post closing, Bridge plans to:

(i) Get FDA approval and start US sales of Bucam.

(ii) If it's not already done so, publicly list Bridge.

(iii) Commence work on next generation versions of Bunalz/BupHD and Bucam.

(iv) Get EMA approval at least for Bunalz and start the process of getting marketing permission in key European nations.

Rather than adding new functionality to accomplish these objectives, Bridge will execute and extend the activities described above.

European drug approval is a two-stage process which combined take approximately two years. EMA approval takes roughly one year and covers all countries in the EU. (How this will affect the UK after Brexit remains to be seen.) Next there is national phase lasting a further year for each member state a company wishes to market. Additionally, most European countries have single buyers for national healthcare systems, so negotiations tend to be tighter resulting in slimmer margins than in the USA. Given the significant difference in the EU, Bridge will benefit from working with a strong, established partner.

RAMP-UP AND EXIT STRATEGY

Management is open to any exit strategy that provides an attractive return to its shareholders and is favored by a majority of its shareholders at the time it becomes feasible. Exits include IPO, reverse into a SPAC, licensing, distribution deals or trade sale of one or more products.

ALTERNATIVE DEVELOPMENT PLAN FOCUSED ON PAIN THERAPIES

Pain doctors who know buprenorphine are generally enthusiastic about delivering it in rapidly-dissolving, Zydis tablet. Despite understanding that our tablets for Bunalz (indicated for Opioid Use Disorder) and BupHD (for pain) are identical, some of these same doctors question the wisdom of starting with the addiction indication owing to the stigma associated with treating OUD. Their concern is that promoting Bunalz ahead of BupHD could adversely affect the launch of the more revolutionary product (safe alternative to opioids) into the larger market ($20B vs $6B).

Hence with adequate funding it may be preferrable to launch BT-219 with both indications for addiction (as Bunalz) and for pain (as BupHD), so that physicians may freely prescribe BupHD for pain, rather than risking their prescribing Bunalz off-label for the same purpose.

To better frame the debate, let us examine the expected time to market for Bridge's first three drugs.

MARKET SIZE VS SPEED TO SALES

The obvious attractions of starting with pain are its larger market size ($20B) and the desperate need for safe alternatives to full-agonist opioids compared to the smaller market ($6B) and common stigma associated with treating OUD.
On the other hand, minimizing the capital and time required to initiate sales has so far influenced Bridge's sequencing of the therapies (i.e., first Bunalz, next BupHD and then Bucam) by allowing early revenues to fund some or all of the development costs of later therapies.

DEVELOPING BUNALZ

The remaining capital need to commercialize Bunalz is ~$7-13M with the $5M swing dependent upon whether Bridge markets the drug itself or enters into a licensing agreement with an established player. (It's worth noting that Bridge has held discussions for this role with four companies.) The timing for launch is roughly 9-12 months with the wild-card being possible delay at the FDA has owing to its current focus on COVID. A study of the addiction therapy market Bunalz shows high concentration by geography, in clinics and by certified doctors, which should allow substantial penetration with a small sales force (~30). Use of fee-per-call or tele-sales should also reduce the marketing cost. A final consideration is the appeal of a rapid dissolving tablet to institutions which practice observed dosing. It's currently a small market, since only 1% of America's prisons offer MAT, yet one that we could grow since 50% of the 2.3 million prison population is behind bars for drug offence.

Within the limits of financial modeling here is the development budget for Bunalz, half of which has already been paid out. Note that this table excludes pre-launch marketing activities of roughly $4M.
The Gantt charts below which display the developing activities for the various therapies. The net result is that first sales of Bunalz are forecast to start about a year from funding. Note that the scale for Bunalz is monthly whereas the other charts are quarterly.

Source & Uses of Cash ($000's)	
Catalent - Bunalz	*($600)k*
Manufacturing Trials	*($1,500)k*
Sharp Clinical Services	*($120)k*
Formulation & Packaging	*($2,220)k*
WWCT - Bunalz	*($650)k*
Clinical Trials	*($650)k*
Camargo - Bunalz	*($800)k*
Regulatory Consulting	*($800)k*
Licensing - Zydis / Bup+Nal	*($850)k*
Licensing - Zydis / Bup only	*$0k*
PDUFA - Bunalz	*$0k*
Filing & Licensing fees	*($850)k*
Investment	**($4,520)**

BUNALZ	Done	M:1	M:2	M:3	M:4	M:5	M:6	M:7	M:8	M:9	M:10	M:11	M:12	M:13	M:14	M:15	M:16
Formulation - Catalent																	
Analytical Dev. + Validation																	
Pre-IND Meeting w/ FDA																	
Open IND																	
Regulatory - Camargo																	
Pilot PK Trial Final Results		X															
Pivotal PK Trial (30-36																	
Abuse Deterence Study																	
Scale-Up/Formulation Optimization																	
Registration Batch Stability (2yrs)																	
Manufacturing Trials																	
Launch Batches																	
NDA Submission							X										
FDA NDA Review																	
FDA Approval											X						
Market Study - IQVIA																	
Commercialization - Percipient																	
Launch Preparation - Advisors/Staff													X				
Post Approval Commercialization																	

DEVELOPING BUPHD

First a word of background, for reasons of economy the current Bunalz tablet was formulated in only one strength (8mg bup / 2mg nalox) which represents the majority of all prescriptions (~80%). This is adequate for maintenance treatment of OUD, though not for its initiation. Yet to address the pain market, a range of doses is need to allow titration to address greater and worse levels of pain. To this end Bridge plans to add further strengths, e.g., 4mg, 2mg, 1mg, 0.5mg and possibly 0.25mg of buprenorphine each with ¼ of that amount of naloxone. This will add ~$600k-$1M to development costs and require 4-6 months. Fortunately, this formulation can occur simultaneously with the effectiveness study of BupHD at 8mg, allowing a bridging study at the end to unify the results.

Next, we note that the clinical trial for BupHD will be more extensive than for Bunalz. Whereas Bunalz needs a $650k, one-week, 36-patient PK Study of drug delivery, BupHD will require a $5M, 12-week, 100-patient, placebo-controlled effectiveness study. If approved simultaneously for both addiction and pain, then PDUFA filing fees could avoided since the FDA approves a company's first therapy without charge. If BupHD is launched separately it would still benefit from a 50% reduction in PDUFA fees, since it would be a supplemental filing to the Bunalz IND, rather than a being a novel IND on its own. The net result is that simultaneous launch would add ~3-6 months to Bunalz alone, while sequential launch would see BupHD follow Bunalz to market by 9-12

Source & Uses of Cash ($000's)	
Catalent	*($800)k*
Manufacturing Trials	*($1,500)k*
Sharp Clinical Services	*($120)k*
Formulation & Packaging	*($2,420)k*
WWCT	*($5,000)k*
Clinical Trials	*($5,000)k*
Camargo	*($650)k*
Regulatory Consulting	*($650)k*
Licensing - Zydis / Bup+Nal	*($650)k*
PDUFA	*($1,400)k*
Filing & Licensing fees	*($2,050)k*
Investment	**($10,120)**

months. To summarize, simultaneous launch 12-15 months from funding while sequential launch would see sales of Bunalz 9-12 months from funding and BupHD 12-18 months.

The marketing challenge (and opportunity) for BupHD is both larger and more spread-out, i.e., the entire nation vs mostly the East Coast. In Bridge's planning we imagined establishing a sales management structure with Bunalz which could then be expanded nationally to address pain. If that step is left out, then the market launch of BupHD would be more costly as it would involve a larger sales force, i.e., 200 vs 30. This larger effort could be underwritten by an IPO or by taking on a licensing partner.

BUP-HD	Done	Q:1	Q:2	Q:3	Q:4	Q:1	Q:2	Q:3	Q:4	Q:1	Q:2	Q:3	Q:4
Formulation - Catalent (+4 strengths)													
Analytical Dev. + Validation													
Pre-IND Meeting w/ FDA			X										
Open IND													
Regulatory - Camargo													
Pain Study (12 week, 100 patients)				X									
Scale-Up/Formulation Optimization													
Registration Batch Stability													
Manufacturing Trials													
Launch Batches													
sNDA Submission						X							
FDA sNDA Review													
FDA Approval								X					
Market Study - IQVIA													
Commercialization - Percipient													
Launch Preparation - Advisors/Staff								X					
Post Approval Commercialization													

DEVELOPING BUCAM

Bucam is sequenced last because it will require new formulation, more involved trials, an entirely new IND and hence full PDUFA filing fees. Though Catalent has already worked on a Zydis version of meloxicam, it has not been completed and is not in sales. For Bucam, Bridge would first accept Catalent's offer to assume rights to meloxicam and then formulate multiple strengths in combination with buprenorphine. Clinical trials would cost ~8M, require 6-months and involve 200 patients. (This would entail a 3-month Contribution of Components study of pain relief run currently with a 6-month safety study of meloxicam.) Even if development were to start immediately on funding, first sales of Bucam are expected in roughly 2.5 years.

Source & Uses of Cash ($000's)	
Catalent	*($1,000)k*
Manufacturing Trials	*($1,500)k*
Sharp Clinical Services	*($120)k*
Formulation & Packaging	*($2,620)k*
WWCT	*($8,000)k*
Clinical Trials	*($8,000)k*
Camargo	*($800)k*
Regulatory Consulting	*($800)k*
Licensing - Zydis / Bup+Meloxicam	*($650)k*
PDUFA	*($2,800)k*
Filing & Licensing fees	*($3,450)k*
Investment	**($14,870)**

BUCAM	Done	Q:1	Q:2	Q:3	Q:4	Q:1	Q:2	Q:3	Q:4	Q:1	Q:2	Q:3	Q:4	Q:1	Q:2	Q:3
Formulation - Catalent (4 strengths)																
Analytical Dev. + Validation																
Pre-IND Meeting w/ FDA																
Open IND																
Regulatory - Camargo																
Pain Study (12 weeks, 200 patients)																
Safety Study (26 weeks, 200 patients)																
Scale-Up/Formulation Optimization																
Registration Batch Stability (2yrs)																
Manufacturing Trials																
Launch Batches																
NDA Submission																
FDA NDA Review																
FDA Approval												X				
Market Study - IQVIA																
Commercialization - Percipient																
Launch Preparation - Advisors/Staff													X			
Post Approval Commercialization																

8. FINANCIAL PLAN

FUNDING TARGET

In order to fund its pipeline of therapeutics, Bridge seeks to raise $40-55M with the first priority being to develop BT-219 for both addiction (as Bunalz) and pain (as BupHD/LD). The main categories for these funds are presented in the following table with the balance reserved for first year operations and development of the second pain drug, Bucam.

Bunalz & BupHD - Development Budget	
Additional Strengths	800,000
Validation Batches	1,650,000
Regulatory Consulting	1,000,000
Active Pharma Ingredients	100,000
PK / Abuse Studies: Bunalz	800,000
Pain Study: BupHD	5,000,000
Logistics	900,000
Licensing, Legal & Accounting	940,000
General & Admin.	1,610,000
Marketing	1,793,000
Sales Force	10,000,000
Contingency	407,000
Total	25,000,000

SALES FORECASTS

From this starting point, two sales forecasts are considered. First is a base case and second is the stretch or target case. Both cases are thought to be conservative in light of the size of the markets ($26B combined) and the general experience in Pharma that successful drugs capture 40-60% market share.

Safer scheduling & Government guidance should boost sales to their potential.

- **BupHD/BupLD/Bucam**, as the safe alternatives to Opioids (sched.III vs II), can become the *Standard of Care*
- CDC, FDA, DEA, HHS guide physicians to use the best available therapy or *Standard of Care*

The following forecasts display annual Income Statements only. The Appendix contains annual and quarterly financial statement forecasts.

BASE CASE

Income Statement $MM	2021	2022	2023	2024	2025	Mkt Share
US Bunalz	$0	$34	$75	$55	$60	2%
US BupHD\BupLD	$0	$0	$95	$145	$175	1%
US Bucam	$0	$0	$0	$65	$130	1%
Overseas Sales	$0	$0	$5	$75	$175	1%
Total Sales	**$0**	**$34**	**$175**	**$340**	**$540**	**2%**
Total Direct Costs	$0	($17)	($50)	($70)	($105)	
Operating Income	**$0**	**$17**	**$125**	**$270**	**$435**	
EBITDA	**($3)**	**($10)**	**$75**	**$205**	**$360**	
Net Income	**($2)**	**($11)**	**$60**	**$160**	**$285**	

TARGET CASE

Income Statement $MM	2021	2022	2023	2024	2025	Mkt Share
US Bunalz	$0	$102	$230	$160	$185	6%
US BupHD\BupLD	$0	$0	$290	$430	$525	2%
US Bucam	$0	$0	$5	$190	$395	4%
Overseas Sales	$0	$0	$20	$225	$520	3%
Total Sales	**$0**	**$102**	**$545**	**$1,005**	**$1,625**	**5%**
Total Direct Costs	$0	($52)	($145)	($210)	($310)	
Operating Income	**$0**	**$50**	**$400**	**$795**	**$1,315**	
EBITDA	**($3)**	**$25**	**$345**	**$740**	**$1,235**	
Net Income	**($2)**	**$18**	**$270**	**$585**	**$975**	

LICENSING AND TRADE SALE REVIEW

Next, we examine a table of licensing deals for specific therapeutics followed by a table of company acquisitions which therapies, facilities, staff and hence research capabilities and product pipelines. Both tables calculate the price to sales ratio (P/S) behind the deals to serve as reference points.

Best efforts were made to find licensing and corporate deals as relevant as possible to the pain and addiction space. Specifically, we sought first to identify deals for buprenorphine drugs, for opioids and for other pain drugs before venturing farther afield. From there, more recent deals (i.e., since 2016) were favored over those from older deals.

We also stayed away from deals at a different clinical stage than Bridge, e.g., company with Phase 1 or 2 prospects that traded on great things to come versus those with real sales figures. The assumption here is that Bridge will be appraised for its cash earnings, rather than its blue-sky potential, since we are entering mature markets rather than those with lots of speculation as to the prices that can be charged and the size of patient population that can be attracted.

The P/S ratios of licensing deals range from 1.5x to 3.5x expected annual revenue, though the consideration paid is often split between upfront and milestone payments wherein those with lower multiples typically have a trailing income stream in the form of a royalty interest on sales. The royalties are not typically disclosed, but understood to be ~15%. They have the effect of boosting the P/S ratio one or more times depending upon the subsequent commercial success of those therapies.

With corporate acquisitions the P/S ratios are higher, ranging from 3-23x. There is also a strong speculative component for drugs that are not yet approved. (Many more deals were found than included in this table, but were excluded owing lack of actual or projected sales data.)

LICENSING DEALS

Date	Acquirer	Licenser	Deal	Value	P/S
2016 Q2	Muntipharma Intl	Orexo AB	Rights to market Zubsolv (bup. tablet) outside USA	$7.76M + future royalties (15%?)	3x historical[39] + royalties
2016 Q4	Aralez Pharma	AstraZeneca	US rights to Toprol-XL (beta blocker for hypertension)	$175M + $48M in milestones	2.5x historical[40]
2017 Q3	Purdue Pharma (Canada)	BioDelivery Sciences Intl	Rights to Belbuca (bup. film for pain) in Canada	$3.49M + future royalties (15%?)	1.5x historical[41] + royalties
2017 Q2	Grunenthal	AstraZeneca	Global rights to Zomig (migranes) outside Japan	$200m + $102m in milestones	3.2x historical[42]
2018 Q4	Grunenthal	AstraZeneca	Rights to 33 Euro nations for Nexium (gastro reflux)	$700m + $90m in milestones	3.3x historical[43]
2018 Q4	Grunenthal	AstraZeneca	Global rights ex-US & Japan for Vimovo (arthritis)	$115m + $17m in milestones	1.8x historical[44]
2019 Q2	BioDelivery Sciences Intl	Shionogi Inc	Symproic (opioid induced constipation) in US	$30m + 8.5% - 17.5% Royalties	1.7x historical[45] + royalties
2019 Q3	Medicure Inc	Cadilla Healthcare	Zypitamag (high cholesterol)	$7M	3.5x historical[46]

[39] Zubsolv 2015/16 sales = $53m, of which ~5% outside; P/S = $7.76m/($53m x 5%) = 3x
[40] Toprol-XL 2015 sales = $89m; P/S = 2.5x
[41] Belbuca 1H2017 sales = $11.2m; Canadian population 10.7% of USA in 2017 (35m vs 327m); P/S = $3.49m/(11.2 x 2 x 10.7%) = 1.5x
[42] Zomig 2016 revenues outside Japan were $96m; P/S = $302m/$96m = 3.15x; see https://www.genengnews.com/topics/drug-discovery/grunenthal-to-buy-ex-japan-global-rights-to-astrazenecas-migraine-drug-for-up-to-302m/
[43] Nexium 1H18 sales = $121M; P/S = $790 / ($121m x 2) = 3.26x
[44] Vimovo 1H18 sales ex-US & Japan = $37m; P/S = ($115m+$17m)/($37m x 2) = 1.8x; see https://www.genengnews.com/news/grunenthal-acquires-partial-rights-to-nexium-vimovo-from-astrazeneca-for-up-to-922m/
[45] Symproic 2018 sales = $14m; P/S = 2.1x; source Global Data https://www.globaldata.com/
[46] Zypitamag 2018 sales = $2m; P/S = 3.5x; source Global Data https://www.globaldata.com/

ACQUISITIONS

Date	Acquirer	Licenser	Deal	Value	P/S
1/2018	Celgene	Juno Therap.	Buyout; cancer gene therapies w/ expected approval in 2019	$9B	9x initial or 3x global peak sales[47]
12/2018	GlaxoSmithKline	Tesaro	Buyout; selling Zejula (ovarian cancer); cancer drug pipeline	$5.1B	23x current[48]
8/2019	Amgen	Celgene's Otezla	Divestiture of Otezla (psoriasis and arthritis); required for Celgene to acq Bristol-Myers	$13B	8x historical[49]
9/2019	Lundbeck	Alder BioPharma	CPRG inhibitor (migraine), approval expected 2/2020	$1.95B	2-5x future sales[50]

[47] JCAR017 "potential global peak sales of approximately $3 billion."; P/S = $9B / $3B; see https://www.geekwire.com/2018/juno-therapeutics-acquired-celgene-9b-dramatic-deal-rising-biotech-star/

[48] Zejula 1-3Q18 sales $166m, full yr projection $221m; P/S = $5.1B/($221m) = 23x; see https://www.genengnews.com/news/gsk-to-acquire-parp-inhibitor-developer-tesaro-for-5-1b/

[49] Otezla 2018 sales = $1.6B; P/S = $13B/$1.6B = 8x; see https://www.biopharmadive.com/news/amgen-buy-otezla-celgene-13-billion-enbrel/561657/

[50] As a class, CPRG blockers could bring in $1 billion in sales its first full year; Alder's share 20-50%; P/S = $1.95B/($1B x 20-50%) = 5-2x; see https://www.biopharmadive.com/news/lundbeck-buys-into-migraine-acquiring-alder-for-2b/562987/

PROJECTION OF INVESTMENT RETURNS

Sales forecasts and sales multiples are combined in the next tables to estimate possible returns on investment into Bridge Therapeutics based on projected sales for different price to sales (P/S) ratios.

- The two, left-hand set of tables use sales from the Base Case sales while the three right-hand tables use sales from the Target Case scenario.
- The top tables calculate the trade price of BridgeRx based upon its sales in a given year.
    - For example, in 2024 in the Base Case, sales are projected at $340m. Assuming that a deal is struck at a price to sales ratio of 4x, then the company would be sold for **$1,360m** (= 4 x $340m). Under the Target Case with sales of $1,005mm in 2024, the company would sell for **$4,020m**.
- The bottom tables calculate the corresponding multiple of investment for such a liquidity event assuming a pre-money valuation of $100M; this lies within the terms currently being shown.
    - Returning to the same example, this would equate to **14x return on investment** in the Base Case. In other words, for each $100k invested, the investor would expect to receive $1.4M. In the Target Case the return would swell to **40x** or $4.0M.

BASE CASE

Revenue Forecast

P/S ratio	2022	2023	2024	2025
	$34m	**$175m**	**$340m**	**$540m**
2	$68m	$350m	$680m	$1,080m
4	$136m	$700m	$1,360m	$2,160m
6	$204m	$1,050m	$2,040m	$3,240m
8	$272m	$1,400m	$2,720m	$4,320m

TARGET CASE

Revenue Forecast

P/S ratio	2022	2023	2024	2025
	$102m	**$545m**	**$1,005m**	**$1,625m**
2	$204m	$1,090m	$2,010m	$3,250m
4	$408m	$2,180m	$4,020m	$6,500m
6	$612m	$3,270m	$6,030m	$9,750m
8	$816m	$4,360m	$8,040m	$13,000m

Projected ROI vs $100m pre-money

P/S ratio	2022	2023	2024	2025
	$34m	**$175m**	**$340m**	**$540m**
2	0.7x	4x	7x	11x
4	1.4x	7x	14x	22x
6	2x	11x	20x	32x
8	3x	14x	27x	43x

Projected ROI vs $100m pre-money

P/S ratio	2022	2023	2024	2025
	$102m	**$545m**	**$1,005m**	**$1,625m**
2	2x	11x	20x	33x
4	4x	22x	40x	65x
6	6x	33x	60x	98x
8	8x	44x	80x	130x

FINANCIAL ANALYSIS SUMMARY

From the forgoing revenue forecasts combined with industry multiples for licensing deals and acquisitions, we find a range of returns on investing in Bridge of between 15-100x on one's capital. Stock market multiples from public listing via IPO or merging into a SPAC could be even higher, where multiples of ten times or more are typical for small bio-pharma companies.

PUBLIC MARKET ANALOGS FOR BRIDGE

Another way to consider the return-on-investment potential of Bridge is to examine comparable companies in the public markets.

Consider the NASDAQ listed company Heron Therapeutics (HRTX). Similar to Bridge, Heron is commercializing generic APIs under the FDA's 505(B)(2) pathway for branded generics. Heron has achieved 43% market share with one of its drugs, Civanti, and expects to get ~40% market share with another, HRTX-011. Heron has a market capitalization of $1.5B on $89M in sales for a P/S ratio of **17x.**

An even closer analog is found in NYSE listed company BioHaven (BHVN). BioHaven is also treating pain, though a different type (migraine headaches). BioHaven is also improving on the delivery of its therapy with Zydis, identical to Bridge. The company listed in May, 2017 with a pre-money valuation of $420M. It is now valued at $6.4B on sales of $106M for a P/S ratio of **60x.** According to an investor presentation in 2019, the total market size for all 4 of BHVN's products (only one of which has been approved) was $5B or ~1/7th the size of Bridge's markets @ $27B.

Using either of these companies, the potential ROI on Bridge is considerable.

9. APPENDICES AND EXHIBITS

FDA'S WRITTEN RESPONSE TO BUNALZ PRE-IND APPLICATION

Because the active ingredients in Bunalz are well known and because ~20 drugs already use the Zydis (freeze-dried) delivery technology, the FDA did not see deem it necessary to meet with Bridge concerning its pre-Investigational New Drug application (pre-IND), but instead provided a written response to the Bunalz pre-IND application in October, 2019. Key points are as follows:

- FDA expressed no concern with potential efficacy and/or safety issues with our Bunalz product and gave no indication of concern approving a new opioid analog product
- FDA agreed with Bridge that the 505(b)(2) regulatory pathway was appropriate for our Bunalz product allowing Bridge to access an accelerated approval process compared to the usual new chemical entity NDA
- FDA agreed with Bridge that a PK based 505(b)(2) application was sufficient for approval and that no additional efficacy or safety clinical studies would be required
- FDA agreed with Bridge that Bunalz would be a Schedule III DEA product consistent with currently marketed buprenorphine/naloxone products utilizing different delivery systems
- FDA agreed with Bridge that no new or additional non-clinical studies would be required allowing Bridge to rely on preclinical data for currently marketed similar sublingual products
- FDA's comments on the proposed clinical protocol were accepted by Bridge by adding additional PK plasma draw sample timepoints not affecting the time to complete the clinical study and at a minimal increase in cost
- FDA requested that Bridge assess the PK parameters for the effect, if any, on absorption should the dose be administered with liquids at different temperature or pH; Bridge accepts this request
- FDA agreed with Bridge's proposal that a Category I Abuse Deterrent study would be sufficient for approval; this is an *in vitro* (i.e., test tube or petri dish) laboratory study to assess abuse potential of the formulation and dosage form

- FDA agreed with Bridge's proposal that the currently established REMS (Risk Evaluation and Mitigation Strategy) already established and in place for similar products currently on the market was appropriate and sufficient for Bridge's Bunalz product

- On its own initiative, Bridge will include a taste assessment PK protocol in the original IND to aid in selecting an optimal formulation assuring Bunalz will be the patient preferred buprenorphine/naloxone product

The full response is available by request or in Bridge's data room.

PILOT PK STUDIES

FIRST RUN

Last year Bridge conducted a pilot pharmacokinetic (**PK**) study[51] comparing the delivery of Bunalz to its reference drug (**RD**).[52] The pilot study was designed to quickly and inexpensively capture the main results and guide execution of the definitive study which will be used for the New Drug Application (**NDA**). As such the first pilot study involved 5 patients rather than the 36 patients specified in the definitive PK Study. Note:

- The FDA judges the Maximum Concentration (or **Cmax**) of drug in the liquid part of the blood (i.e., the serum) as well as the total amount of drug delivered as measured by the Area Under the drug concentration Curve (**AUC**) over time.
- The FDA typically does not use the Time till Maximum Concentration (or **Tmax**) to guide drug approval.

Here are the key points from the pilot PK Study:

- All patients greatly preferred Bunalz to the generic tablet as well as to Suboxone and generic films for its ease of administration, mouth feel and taste.

- Correct administration of Bunalz is critical to absorption.
    - Because our tablet dissolves so quickly, care must be taken to put it under the tongue before it touches saliva.
    - Placement of the tablet will be more carefully supervised in the pivotal study.

- Tmax was reached sooner with Bunalz than the RD.

- Significantly more active drug was delivered to patients from equivalent tabular dosages of Bunalz versus the RD as measured by Cmax and AUC.

[51] The FDA is concerned with the Maximum Concentration (or **Cmax**) of drug in the liquid part of the blood (i.e., the serum) as well as the total amount of drug delivered as measured by the Area Under the Curve (**AUC**) of drug concentration over time (see charts below). The FDA does not use the Time till Maximum Concentration (or **Tmax**) to guide drug approval.
[52] Because the manufacturer, Indivior, lost control of the tablet form of Suboxone, Bridge used a generic tablet of buprenorphine / naloxone made by Hikma.

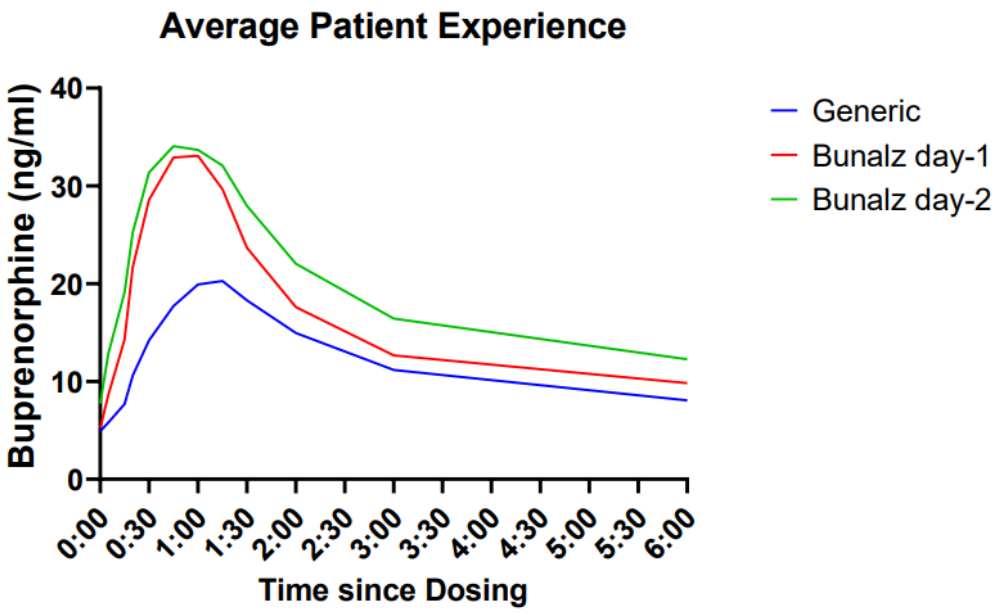
- Greater delivery is presumably the result of Bunalz' excipients and to its better adhesion to the lining of the mouth (i.e., the buccal mucosa).

- Change the RD in order to demonstrate bio-equivalence.
  - The simplest way to proceed is merely to repeat the pilot versus a stronger reference drug which has been identified[53] and is underway.
  - True generic drugs must show bio-equivalence under the Abbreviated New Drug Application (ANDA) pathway.[54]
  - However, the 5050(b)(2) pathway which Bridge is pursuing for Bunalz allows for much greater variability, yet can still be approved by the FDA.
    - Significantly almost all 505(b)(2) drugs do <u>not</u> meet bioequivalence.[55]

- Results are best summarized by the following table and graph:

• **Therapy:**	**Generic (Hikma)**	**Bunalz day-1**	**Bunalz day-2**
Area Under Curve	4,391	5,870	7,034
Cmax	20.3	33.1	34.1
Tmax	1:15	1:00	0:45

[53] Comparison will be made to Zubsolv 11.4mg/2.9mg (bup/nalox) tablet which is equivalent to Suboxone 16mg/4mg. Both formulations were approved, though only Zubsolv is currently available for testing.
[54] For the ANDA pathway, Cmax and AUC of a drug candidate must fall between 80% and 125% of the RD.
[55] Our regulatory consulting firm Camargo has sent us several examples: *Chiasma MYCAPSSA was approved on the basis of similar relative bioavailability and bridging to the Listed Drug but was not bio-equivalent. Camargo oversaw most of their PK program and all of their 5050(b)(2) strategy. It was approved in June NDA 208232.*
Another example is Brimonidine tartrate ophthalmic solution, 0.025% NDA 208144. This was an Rx to OTC switch relying on NDA 020613 without using a BE strategy. Other examples are Teva's Armonair RespiClick (NDA208798) and AirDuo RespiClick (NDA 208799) using Flovent and Advair as Listed Drugs. There are plenty more.


Average Patient Experience
Buprenorphine (ng/ml)
40
30
20
10
0
0:00
0:30
1:00
1:30
2:00
2:30
3:00
3:30
4:00
4:30
5:00
5:30
6:00
Time since Dosing
Generic
Bunalz day-1
Bunalz day-2

SECOND RUN

In an attempt to meet strict bio-equivalence, a second set of 7 patients went through a further pilot PK study was conducted in the 4th Quarter of 2020. The graph which follows are of the bloodwork done by World Wide Clinical Trials (WWCT) summarized by Formulation (or brand of drug) as follows:

Number of Trials by Formulation

Patient #	Bunalz	Hikma	Suboxone	Total
11	2	1	0	**3**
15	4	1	1	**6**
20	2	0	1*	**3**
21	4	1	2	**7**
23	2	2	0	**4**
24	2	2	0	**4**
25	3	0	2	**5**
Total Trials	**19**	**7**	**6**	**32**

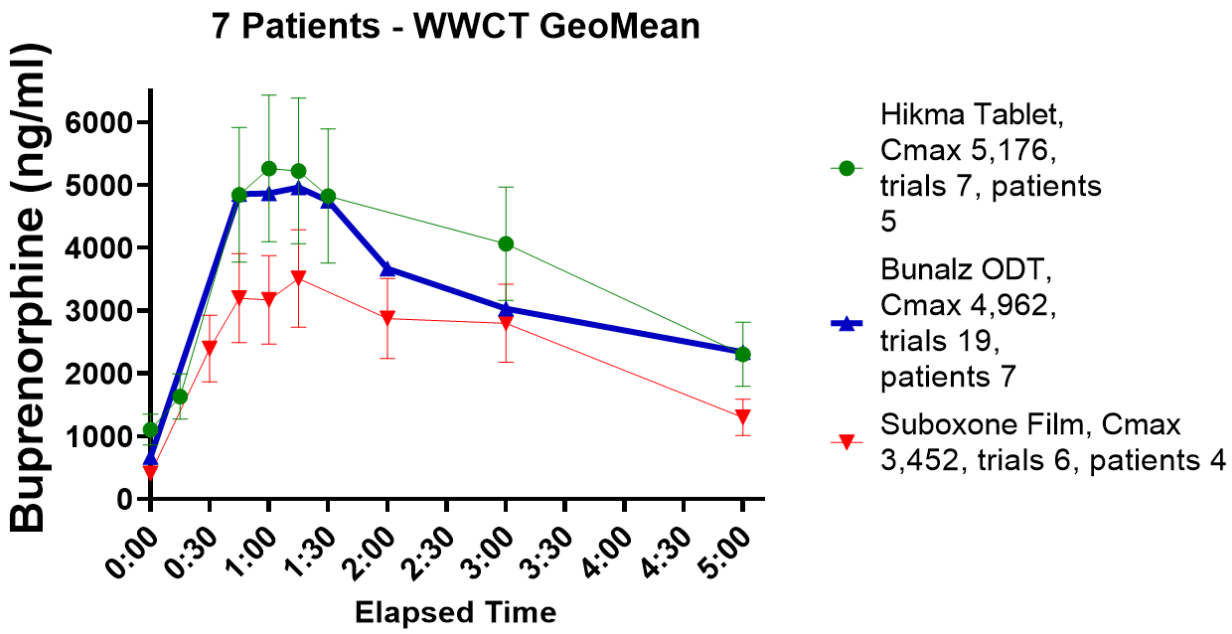
*A second trial of Suboxone on patient #20 was undertaken (33rd trial overall), but at a higher dosage (12mg/3mg) and so is not included in the graphs below, nor is it counted in this table.

Each graph displays the geometric mean at select time intervals which were chosen to provide the broadest comparable set.

Following the graphs are by tables by patient showing the maximum concentration (Cmax) for each trial-day along with the geometric mean and standard deviations where multiple trials were done on the same patient with the same formulation.

These tables include both the bloodwork done by World Wide Clinical Trials (WWCT) and, where available, ARUP Laboratories (Arup). They are not consistent with ARUP figures several times higher than those reported by WWCT.

What can be seen from the following graph is that delivery of Bunalz meets strict bio-equivalence with the Hikma tablet of buprenorphine-naloxone by falling within the band of 80% - 125% of the Hikma observations. Similarly, the total delivery of drug, measured by the Area Under the Curve, for Bunalz (@ 16,555 ng/ml) falls within a 95% confidence interval of the Hikma tablet (15,804 to 21,848).



Area Under Curve	Hikma	Bunalz	Suboxone
Total Area	18,826	16,555	12,360
Std. Error	1542	0.000	933.3
95% Confidence Interval	15,804 to 21,848	16,555 to 16,555	10,531 to 14,189

CAPITALIZATION TABLE AS OF 4/12/2021

ISSUED SHARES & WARRANTS

		Shares				Warrants					
Shareholder	Notes	Common	AA Pref	AB Pref	Total	Common*	AA Pref	AB Pref	Total	Total Shares & Warrants	$ Invested
Dr. Greg Sullivan	b,f,o	4,395,830			4,395,830					4,395,830	$350,000
Elizabeth Kelley	b,f	1,964,100			1,964,100					1,964,100	$55,000
Other Founders (7)	f/f'	2,710,000			2,710,000					2,710,000	$85,000
EJM	h	151,800	332,226		484,026					484,026	$1,000,000
EJM Loan	h									0	$500,000
JAR Bridge Limited	h	85,430	274,528		359,958					359,958	$800,000
HFT	h	2,237	166,113		168,350					168,350	$500,000
HFT Credit Line**	h									0	$1,500,000
HB		18,484	135,605		154,089					154,089	$400,000
JB		336	24,917	17,147	42,400					42,400	$175,000
Tim Peara	o					120,000			120,000	120,000	$140,000
AB			33,223	4,440	37,663			2,220	2,220	39,883	$125,000
HDG				18,117	18,117			9,059	9,059	27,176	$102,000
RFT				17,747	17,747			8,874	8,874	26,621	$100,000
HDG				18,117	18,117			9,059	9,059	27,176	$102,000
RFT				17,747	17,747			8,874	8,874	26,621	$100,000
AdR		2,800	10,000	7,778				3,889	3,889	24,467	$96,000
GB	x	335	24,917							25,252	$75,000
EE	c						13,289	2,664	15,953	15,953	$55,000
David Bergstrom	o		16,612		16,612	120,000			120,000	136,612	$50,000
HFT			16,612		16,612					16,612	$50,000
Angel Investors (14)		16,854	68,197	26,554	111,605			7,406	7,406	119,011	$290,700
Jason Bailey	b	5,000			5,000					5,000	$2,000
AK	e					72,000			72,000	72,000	$0
RBR	a					33,000			33,000	33,000	$0
BRT	a					100,000			100,000	100,000	$0
Joe Mullin	b					101,010			101,010	101,010	$0
JVP	a					100,000			100,000	100,000	$0
Total Shares / %		9,353,206	1,102,950	127,647	10,537,973	646,010	13,289	52,045	711,344	11,295,147	$6,737,700

(a) Advisor
(b) Board Member
(c) Commission
(e) Employee
(f) Founder; (f') bought from Founder
(h) High-Net Worth / Family Office
(o) Officer
(w) Warrant/option
(x) Transferee
(*) $150Mn Company valuation needed to exercise
(**) $700k drawn

WARRANTS ALLOCATED TO SHAREHOLDERS

Options Pool	Allocated	Awarded	Un-Awarded	Award Event	Exercise Price[6]	ISO[7]
Joe Mullin, former CFO, Board member	303,030	101,010	202,020	10/18/2017 Agmt	$0.40	No
Tim Peara, officer	360,000	120,000	240,000	On meeting performance goals[1]	$0.40	**YES**
Dave Bergstrom, officer	360,000	120,000	240,000	On meeting operating goals[2]	$0.40	**YES**
Alton Kelley, staff	96,000	72,000	24,000	Years of Service	$0.40	**YES**
Dr. Bob Rappaport, Scientific Advisor	100,000	100,000	0	1yr after joining SAB	$0.40	No
Dr. Bob Rappaport, Scientific Advisor			0	First year anniversary[6]	$0.40	No
Dr. Joe Pergolizzi, Scientific Advisor[5]	100,000	100,000	0	1yr after joining SAB	$0.40	No
Dr. Joe Pergolizzi, Scientific Advisor			0	First year anniversary[6,7]	$0.40	No
Prof Bob Raffa, Scientific Advisor	33,000	33,000	0	1yr after joining SAB	$0.40	No
Prof Bob Raffa, Scientific Advisor			0	First year anniversary[6]	$0.40	No
Detailed options/shares	1,352,030	646,010	706,020			
Reserved	1,599,011					
Total	2,951,041					

Other Options	Allocated	Awarded	Un-Awarded	Award Event	Exercise Price[6]	ISO[7]
Dr. Henry Balboa, shareholder[3]	1,426,025		1,426,025	12/23/16, amended 10/6/17	$0.40	No

(1) 1/3rd on Bridge holding a pre-IND or IND meeting with the FDA; 2/3rds on a significant Liquidity Event.

(2) 1/6th on submission of a pre-IND letter, 1/6th on conduct of an IND meeting, 2/3rds on FDA approval

(3) 100% on ”change of control” valuing the company @ $150M or more.

(4) 100% on "change of control".

(5) Contingent on entering into formal agreement to join the Scientific Advisory Board.

(6) According to 409A valuation by Carta, 12/29/2019

(7) Incentive Stock Options for staff only

Bridge Therapeutics, Inc Pro Forma Financial Model						Base Case
Income Statement $000's	**Closing**	**2021**	**2022**	**2023**	**2024**	**2025**
Total Tablets (000's)	**(16)**	**-**	**9,725**	**51,903**	**96,033**	**154,105**
US Bunalz	($1)	$0	$34,038	$76,935	$53,958	$60,942
US BupHD/BupLD	($2)	$0	$0	$96,852	$142,837	$174,301
US Bucam	($8)	$0	$0	$1,890	$64,130	$131,607
EMEA Bunalz/BupHD/LD	($1)	$0	$0	$5,985	$73,297	$107,146
EMEA Bucam	($4)	$0	$0	$0	$1,890	$65,370
Total Sales ($000's)	**($16)**	**$0**	**$34,038**	**$181,662**	**$336,112**	**$539,366**
Manufacturing ($000's)	**$0**	**$0**	**($6,198)**	**($23,261)**	**($41,066)**	**($63,783)**
Distribution	**$0**	**$0**	**($10,047)**	**($19,533)**	**($19,441)**	**($25,419)**
Royalty	**$0**	**$0**	**($1,140)**	**($4,822)**	**($8,965)**	**($14,067)**
Total Direct Costs	**$0**	**$0**	**($17,385)**	**($47,616)**	**($69,472)**	**($103,269)**
Net Sales	**($16)**	**$0**	**$16,653**	**$134,046**	**$266,640**	**$436,097**
Total HQ Staff	($267)	($640)	($1,595)	($2,685)	($4,049)	($5,048)
Office, Legal & Accts	$0	($175)	($465)	($922)	($2,242)	($6,036)
Marketing	$0	($340)	($21,865)	($54,984)	($55,769)	($62,795)
Sales, General & Admin	($267)	($1,155)	($23,925)	($58,590)	($62,060)	($73,878)
EBITDA	($517)	($1,905)	($8,523)	$75,456	$204,580	$362,219
Net Income	**($517)**	**($2,160)**	**($10,479)**	**$61,803**	**$161,618**	**$286,153**

Source & Uses of Cash ($000's)						
Operations	**(517)**	**(1,842)**	**(8,200)**	**61,266**	**156,854**	**277,380**
Formulation & Packaging	(150)	(1,523)	(2,857)	(1,500)	0	0
Clinical Trials	0	(650)	(13,000)	0	0	0
Regulatory & Consulting	(200)	(1,125)	(2,275)	0	0	0
Filing & Licensing fees	0	(200)	(8,600)	0	0	0
Investment	**(350)**	**(3,498)**	**(26,732)**	**(1,500)**	**0**	**0**
Equity	5,000	15,000	25,000	0	0	0
Debt	0	0	0	0	0	0
Debt Repayment	(1,114)	(1,534)	(280)	0	0	0
FinancePrior	**$3,886**	**$13,466**	**$24,720**	**$0**	**$0**	**$0**
Dividends	0	0	0	(48,722)	(156,854)	(277,380)
Ending Cash	**$0**	**$9,167**	**($1,045)**	**$10,000**	**$10,000**	**$10,000**

Balance Sheet ($000's)						
Cash	0	9,167	(1,045)	10,000	10,000	10,000
Other Assests	0	630	630	630	630	630
Working Capital	-	-	1,171	5,290	13,228	25,174
Net LT Assets	*0*	*3,180*	*26,461*	*24,378*	*21,205*	*18,032*
Total Assets	**-**	**12,978**	**27,218**	**40,299**	**45,063**	**53,836**
Total Liabilities	1,814	280	-	-	-	-
Equity Investment	-	21,483	46,483	46,483	46,483	46,483
Retained earnings	0	(8,260)	(19,514)	34,949	186,169	463,575
Net Income	0	(525)	249	7,588	17,987	26,734
Cum. Dividends	0	0	0	(48,722)	(205,576)	(482,956)
Total Owners' Equity	0	12,698	27,218	40,299	45,063	53,836
Total Liabilities and Equity	**1,814**	**12,978**	**27,218**	**40,299**	**45,063**	**53,836**

Bridge Therapeutics, Inc Pro Forma Financial Model

Base Case

Income Statement $000's	Closing	3Q:21	4Q:21	1Q:22	2Q:22	3Q:22	4Q:22	1Q:23	2Q:23
Total Tablets (000's)	-	-	-	-	-	3,072	6,653	10,986	14,442
US Bunalz	$0	$0	$0	$0	$0	$10,752	$23,286	$27,031	$24,769
US BupHD/BupLD	$0	$0	$0	$0	$0	$0	$0	$11,419	$25,779
US Bucam	$0	$0	$0	$0	$0	$0	$0	$0	$0
EMEA Bunalz/BupHD	$0	$0	$0	$0	$0	$0	$0	$0	$0
EMEA Bucam	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Sales ($000's)	**$0**	**$0**	**$0**	**$0**	**$0**	**$10,752**	**$23,286**	**$38,450**	**$50,549**
Manufacturing ($000's)	***0***	***0***	***0***	***0***	***(204)***	***(1,827)***	***(4,168)***	***(6,117)***	***(5,699)***
Distribution	*0*	*0*	*0*	*0*	*(408)*	*(3,653)*	*(5,986)*	*(6,931)*	*(5,444)*
Royalty	*0*	*0*	*0*	*0*	*(35)*	*(315)*	*(789)*	*(1,214)*	*(1,162)*
Total Direct Costs	$0	$0	$0	$0	($647)	($5,795)	($10,943)	($14,262)	($12,305)
Net Sales	**$0**	**$0**	**$0**	**$0**	**($647)**	**$4,957**	**$12,343**	**$24,188**	**$38,244**
Total HQ Staff	($267)	($115)	($258)	($291)	($368)	($438)	($498)	($513)	($532)
Office, Legal & Accts	$0	($85)	($90)	($75)	($108)	($113)	($170)	($150)	($215)
Marketing	$0	($70)	($270)	($890)	($3,520)	($7,170)	($10,285)	($12,855)	($15,962)
Sales, General & Admin	($267)	($269)	($618)	($1,256)	($3,996)	($7,721)	($10,953)	($13,518)	($16,709)
EBITDA	($517)	($519)	($868)	($1,256)	($5,143)	($3,514)	$1,390	$10,669	$21,535
Net Income	**($517)**	**($621)**	**($1,022)**	**($1,548)**	**($5,838)**	**($4,021)**	**$927**	**$10,305**	**$17,328**

Source & Uses of Cash ($000's)

Operations	**(517)**	**(511)**	**(815)**	**(1,106)**	**(5,041)**	**(3,344)**	**1,291**	**10,472**	**17,382**
Formulation & Packaging	(150)	(604)	(769)	(1,873)	(983)	0	0	(1,000)	(500)
Clinical Trials	0	(433)	(217)	(1,667)	(2,500)	(4,833)	(4,000)	0	0
Regulatory & Consulting	(200)	(300)	(625)	(800)	(992)	0	(483)	0	0
Filing & Licensing fees	0	0	(200)	(750)	(3,150)	(1,600)	(3,100)	0	0
Investment	**(350)**	**(1,338)**	**(1,811)**	**(5,090)**	**(7,625)**	**(6,433)**	**(7,583)**	**(1,000)**	**(500)**
Equity	5,000	5,000	5,000	0	10,000	15,000	0	0	0
Debt	0	0	0	0	0	0	0	0	0
Debt Repayment	(1,114)	(210)	(210)	(210)	(70)	0	0	0	0
FinancePrior	**3,886**	**4,790**	**4,790**	**(210)**	**9,930**	**15,000**	**0**	**0**	**0**
Dividends	0	0	0	0	0	0	0	0	(15,309)
Ending Cash 1,042	**$4,061**	**$7,003**	**$9,167**	**$2,761**	**$26**	**$5,248**	**($1,045)**	**$8,427**	**$10,000**

Balance Sheet ($000's)

Cash	4,061	7,003	9,167	2,761	26	5,248	(1,045)	8,427	10,000
Other Assests	630	630	630	630	630	630	630	630	630
Working Capital	-	-	-	(32)	167	463	1,171	2,129	2,947
Net LT Assets	*350*	*1,577*	*3,180*	*7,861*	*14,489*	*19,950*	*26,461*	*26,337*	*25,965*
Total Assets	**5,041**	**9,210**	**12,978**	**11,220**	**15,312**	**26,291**	**27,218**	**37,524**	**39,542**
Total Liabilities	700	490	280	70	-	-	-	-	-
Equity Investment	11,483	16,483	21,483	21,483	31,483	46,483	46,483	46,483	46,483
Retained earnings	(6,625)	(7,142)	(7,763)	(8,785)	(10,333)	(16,171)	(20,192)	(19,265)	(8,959)
Net Income	(517)	(621)	(1,022)	(1,548)	(5,838)	(4,021)	927	10,305	17,328
Cum. Dividends	0	0	0	0	0	0	0	0	(15,309)
Total Owners' Equity	4,341	8,720	12,698	11,150	15,312	26,291	27,218	37,524	39,542
Total Liabilities and Equity	**5,041**	**9,210**	**12,978**	**11,220**	**15,312**	**26,291**	**27,218**	**37,524**	**39,542**

Bridge Therapeutics, Inc Pro Forma Financial Model

Base Case

Income Statement $000's	3Q:23	4Q:23	1Q:24	2Q:24	3Q:24	4Q:24	1Q:25	2Q:25	3Q:25	4Q:25
Total Tablets (000's)	**12,005**	**14,470**	**18,669**	**22,385**	**25,807**	**29,171**	**33,567**	**37,300**	**40,185**	**43,051**
US Bunalz	$13,077	$12,058	$12,796	$13,313	$13,717	$14,132	$14,560	$15,002	$15,456	$15,924
US BupHD/BupLD	$28,941	$30,713	$32,593	$34,588	$36,705	$38,951	$41,336	$43,006	$44,309	$45,651
US Bucam	$0	$1,890	$7,976	$14,096	$18,647	$23,411	$28,204	$32,012	$34,635	$36,755
EMEA Bunalz/BupHD	$0	$5,985	$11,975	$16,350	$21,256	$23,715	$25,410	$26,436	$27,237	$28,063
EMEA Bucam	$0	$0	$0	$0	$0	$1,890	$7,976	$14,096	$19,012	$24,286
Total Sales ($000's)	**$42,018**	**$50,646**	**$65,340**	**$78,348**	**$90,324**	**$102,100**	**$117,486**	**$130,552**	**$140,649**	**$150,680**
Manufacturing ($000's)	*(4,954)*	*(6,491)*	*(8,151)*	*(9,583)*	*(10,891)*	*(12,441)*	*(14,100)*	*(15,411)*	*(16,557)*	*(17,716)*
Distribution	*(3,330)*	*(3,828)*	*(4,306)*	*(4,683)*	*(5,028)*	*(5,424)*	*(5,845)*	*(6,199)*	*(6,523)*	*(6,852)*
Royalty	*(1,052)*	*(1,394)*	*(1,766)*	*(2,088)*	*(2,381)*	*(2,730)*	*(3,103)*	*(3,397)*	*(3,654)*	*(3,913)*
Total Direct Costs	($9,335)	($11,714)	($14,223)	($16,353)	($18,301)	($20,595)	($23,047)	($25,007)	($26,734)	($28,481)
Net Sales	**$32,683**	**$38,932**	**$51,116**	**$61,995**	**$72,023**	**$81,505**	**$94,438**	**$105,545**	**$113,916**	**$122,199**
Total HQ Staff	($805)	($835)	($850)	($850)	($1,178)	($1,171)	($1,201)	($1,273)	($1,287)	($1,287)
Office, Legal & Accts	($242)	($314)	($350)	($512)	($561)	($818)	($883)	($1,359)	($1,446)	($2,348)
Marketing	($13,034)	($13,132)	($13,357)	($13,718)	($14,133)	($14,562)	($15,003)	($15,457)	($15,926)	($16,408)
Sales, General & Admin	($14,082)	($14,281)	($14,557)	($15,080)	($15,873)	($16,550)	($17,087)	($18,089)	($18,659)	($20,043)
EBITDA	$18,601	$24,651	$36,560	$46,915	$56,150	$64,955	$77,352	$87,455	$95,256	$102,156
Net Income	**$14,695**	**$19,474**	**$28,882**	**$37,063**	**$44,359**	**$51,315**	**$61,108**	**$69,090**	**$75,253**	**$80,703**

Source & Uses of Cash ($000's)

Operations	**14,490**	**18,922**	**28,101**	**36,002**	**43,083**	**49,669**	**59,252**	**66,973**	**72,986**	**78,170**
Formulation & Packaging	0	0	0	0	0	0	0	0	0	0
Clinical Trials	0	0	0	0	0	0	0	0	0	0
Regulatory & Consulting	0	0	0	0	0	0	0	0	0	0
Filing & Licensing fees	0	0	0	0	0	0	0	0	0	0
Investment	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Equity	0	0	0	0	0	0	0	0	0	0
Debt	0	0	0	0	0	0	0	0	0	0
Debt Repayment	0	0	0	0	0	0	0	0	0	0
FinancePrior	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Dividends	(14,490)	(18,922)	(28,101)	(36,002)	(43,083)	(49,669)	(59,252)	(66,973)	(72,986)	(78,170)
Ending Cash 1,042	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**

Balance Sheet ($000's)

Cash	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000
Other Assests	630	630	630	630	630	630	630	630	630	630
Working Capital	3,945	5,290	6,865	8,719	10,789	13,228	15,877	18,788	21,847	25,174
Net LT Assets	*25,172*	*24,378*	*23,585*	*22,792*	*21,999*	*21,205*	*20,412*	*19,619*	*18,826*	*18,032*
Total Assets	**39,747**	**40,299**	**41,080**	**42,141**	**43,418**	**45,063**	**46,919**	**49,036**	**51,303**	**53,836**
Total Liabilities	-	-	-	-	-	-	-	-	-	0
Equity Investment	46,483	46,483	46,483	46,483	46,483	46,483	46,483	46,483	46,483	46,483
Retained earnings	8,369	23,063	42,538	71,420	108,482	152,841	204,156	265,264	334,354	409,606
Net Income	14,695	19,474	28,882	37,063	44,359	51,315	61,108	69,090	75,253	80,703
Cum. Dividends	(29,800)	(48,722)	(76,822)	(112,824)	(155,907)	(205,576)	(264,828)	(331,800)	(404,786)	(482,956)
Total Owners' Equity	39,747	40,299	41,080	42,141	43,418	45,063	46,919	49,036	51,303	53,836
Total Liabilities and Equity	**39,747**	**40,299**	**41,080**	**42,141**	**43,418**	**45,063**	**46,919**	**49,036**	**51,303**	**53,836**

FINANCIAL PROJECTIONS - TARGET CASE

Bridge Therapeutics, Inc Pro Forma Financial Model					Target Case
Income Statement $000's	**2021**	**2022**	**2023**	**2024**	**2025**
Total Tablets (000's)	**-**	**29,175**	**155,710**	**288,096**	**462,314**
US Bunalz	$0	$102,114	$230,805	$161,874	$182,827
US BupHD/BupLD	$0	$0	$290,557	$428,510	$522,903
US Bucam	$0	$0	$5,670	$192,390	$394,820
EMEA Bunalz/BupHD/LD	$0	$0	$17,955	$219,891	$321,437
EMEA Bucam	$0	$0	$0	$5,670	$196,111
Total Sales ($000's)	**$0**	**$102,114**	**$544,987**	**$1,008,335**	**$1,618,099**
Manufacturing ($000's)	**$0**	**($18,594)**	**($69,783)**	**($123,197)**	**($191,350)**
Distribution	**$0**	**($30,142)**	**($58,600)**	**($58,324)**	**($76,256)**
Royalty	**$0**	**($3,419)**	**($14,466)**	**($26,894)**	**($42,201)**
Total Direct Costs	**$0**	**($52,155)**	**($142,849)**	**($208,415)**	**($309,807)**
Net Sales	**$0**	**$49,959**	**$402,138**	**$799,920**	**$1,308,292**
Total HQ Staff	($640)	($1,595)	($2,685)	($4,049)	($5,048)
Office, Legal & Accts	($175)	($465)	($922)	($2,242)	($6,036)
Marketing	($340)	($21,865)	($54,984)	($55,769)	($62,795)
Sales, General & Admin	($1,155)	($23,925)	($58,590)	($62,060)	($73,878)
EBITDA	($1,905)	$24,783	$343,548	$737,860	$1,234,414
Net Income	**($2,160)**	**$18,378**	**$271,050**	**$582,909**	**$975,187**

Source & Uses of Cash ($000's)					
Operations	**(1,842)**	**18,314**	**262,276**	**562,270**	**942,522**
Formulation & Packaging	(1,523)	(2,857)	(1,500)	0	0
Clinical Trials	(650)	(13,000)	0	0	0
Regulatory & Consulting	(1,125)	(2,275)	0	0	0
Filing & Licensing fees	(200)	(8,600)	0	0	0
Investment	**(3,498)**	**(26,732)**	**(1,500)**	**0**	**0**
Equity	15,000	25,000	0	0	0
Debt	0	0	0	0	0
Debt Repayment	(1,534)	(280)	0	0	0
FinancePrior	**$13,466**	**$24,720**	**$0**	**$0**	**$0**
Dividends	0	(15,470)	(260,776)	(562,270)	(942,522)
Ending Cash	**$9,167**	**$10,000**	**$10,000**	**$10,000**	**$10,000**

Balance Sheet ($000's)					
Cash	9,167	10,000	10,000	10,000	10,000
Other Assests	630	630	630	630	630
Working Capital	-	3,514	15,871	39,683	75,521
Net LT Assets	*3,180*	*26,461*	*24,378*	*21,205*	*18,032*
Total Assets	**12,978**	**40,606**	**50,880**	**71,518**	**104,183**
Total Liabilities	280	-	-	-	-
Equity Investment	21,483	46,483	46,483	46,483	46,483
Retained earnings	(8,260)	2,522	250,222	800,364	1,746,189
Net Income	(525)	7,071	30,420	63,187	92,549
Cum. Dividends	0	(15,470)	(276,245)	(838,516)	(1,781,038)
Total Owners' Equity	12,698	40,606	50,880	71,518	104,183
Total Liabilities and Equity	**12,978**	**40,606**	**50,880**	**71,518**	**104,183**

Bridge Therapeutics, Inc Pro Forma Financial Model — Target Case

Income Statement $000's	Closing	3Q:21	4Q:21	1Q:22	2Q:22	3Q:22	4Q:22	1Q:23	2Q:23
Total Tablets (000's)	-	-	-	-	-	**9,216**	**19,959**	**32,957**	**43,327**
US Bunalz	$0	$0	$0	$0	$0	$32,256	$69,858	$81,093	$74,308
US BupHD/BupLD	$0	$0	$0	$0	$0	$0	$0	$34,256	$77,338
US Bucam	$0	$0	$0	$0	$0	$0	$0	$0	$0
EMEA Bunalz/BupHD	$0	$0	$0	$0	$0	$0	$0	$0	$0
EMEA Bucam	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Sales ($000's)	**$0**	**$0**	**$0**	**$0**	**$0**	**$32,256**	**$69,858**	**$115,349**	**$151,646**
Manufacturing ($000's)	***0***	***0***	***0***	***0***	***(612)***	***(5,480)***	***(12,503)***	***(18,351)***	***(17,097)***
Distribution	*0*	*0*	*0*	*0*	*(1,224)*	*(10,960)*	*(17,958)*	*(20,792)*	*(16,332)*
Royalty	*0*	*0*	*0*	*0*	*(106)*	*(945)*	*(2,368)*	*(3,643)*	*(3,485)*
Total Direct Costs	$0	$0	$0	$0	($1,942)	($17,385)	($32,829)	($42,786)	($36,914)
Net Sales	**$0**	**$0**	**$0**	**$0**	**($1,942)**	**$14,871**	**$37,029**	**$72,563**	**$114,732**
Total HQ Staff	($267)	($115)	($258)	($291)	($368)	($438)	($498)	($513)	($532)
Office, Legal & Accts	$0	($85)	($90)	($75)	($108)	($113)	($170)	($150)	($215)
Marketing	$0	($70)	($270)	($890)	($3,520)	($7,170)	($10,285)	($12,855)	($15,962)
Sales, General & Admin	($267)	($269)	($618)	($1,256)	($3,996)	($7,721)	($10,953)	($13,518)	($16,709)
EBITDA	($517)	($519)	($868)	($1,256)	($6,437)	$6,400	$26,076	$59,045	$98,022
Net Income	**($517)**	**($621)**	**($1,022)**	**($1,548)**	**($7,132)**	**$5,893**	**$21,165**	**$46,358**	**$77,372**

Source & Uses of Cash ($000's)

Operations	**(517)**	**(511)**	**(815)**	**(1,041)**	**(6,734)**	**5,978**	**20,111**	**44,610**	**75,788**
Formulation & Packaging	(150)	(604)	(769)	(1,873)	(983)	0	0	(1,000)	(500)
Clinical Trials	0	(433)	(217)	(1,667)	(2,500)	(4,833)	(4,000)	0	0
Regulatory & Consulting	(200)	(300)	(625)	(800)	(992)	0	(483)	0	0
Filing & Licensing fees	0	0	(200)	(750)	(3,150)	(1,600)	(3,100)	0	0
Investment	**(350)**	**(1,338)**	**(1,811)**	**(5,090)**	**(7,625)**	**(6,433)**	**(7,583)**	**(1,000)**	**(500)**
Equity	5,000	5,000	5,000	0	10,000	15,000	0	0	0
Debt	0	0	0	0	0	0	0	0	0
Debt Repayment	(1,114)	(210)	(210)	(210)	(70)	0	0	0	0
FinancePrior	**3,886**	**4,790**	**4,790**	**(210)**	**9,930**	**15,000**	**0**	**0**	**0**
Dividends	0	0	0	0	0	0	(15,470)	(43,610)	(75,288)
Ending Cash 1,042	**$4,061**	**$7,003**	**$9,167**	**$2,826**	**($1,603)**	**$12,942**	**$10,000**	**$10,000**	**$10,000**

Balance Sheet ($000's)

Cash	4,061	7,003	9,167	2,826	(1,603)	12,942	10,000	10,000	10,000
Other Assests	630	630	630	630	630	630	630	630	630
Working Capital	-	-	-	(97)	502	1,389	3,514	6,386	8,842
Net LT Assets	*350*	*1,577*	*3,180*	*7,861*	*14,489*	*19,950*	*26,461*	*26,337*	*25,965*
Total Assets	**5,041**	**9,210**	**12,978**	**11,220**	**14,017**	**34,910**	**40,606**	**43,353**	**45,437**
Total Liabilities	700	490	280	70	-	-	-	-	-
Equity Investment	11,483	16,483	21,483	21,483	31,483	46,483	46,483	46,483	46,483
Retained earnings	(6,625)	(7,142)	(7,763)	(8,785)	(10,333)	(17,466)	(11,573)	9,592	55,950
Net Income	(517)	(621)	(1,022)	(1,548)	(7,132)	5,893	21,165	46,358	77,372
Cum. Dividends	0	0	0	0	0	0	(15,470)	(59,080)	(134,368)
Total Owners' Equity	4,341	8,720	12,698	11,150	14,017	34,910	40,606	43,353	45,437
Total Liabilities and Equity	**5,041**	**9,210**	**12,978**	**11,220**	**14,017**	**34,910**	**40,606**	**43,353**	**45,437**

Bridge Therapeutics, Inc Pro Forma Financial Model

Target Case

Income Statement $000's	3Q:23	4Q:23	1Q:24	2Q:24	3Q:24	4Q:24	1Q:25	2Q:25	3Q:25	4Q:25
Total Tablets (000's)	**36,015**	**43,411**	**56,006**	**67,155**	**77,421**	**87,514**	**100,702**	**111,901**	**120,556**	**129,154**
US Bunalz	$39,230	$36,174	$38,388	$39,939	$41,150	$42,396	$43,681	$45,005	$46,368	$47,773
US BupHD/BupLD	$86,824	$92,139	$97,778	$103,763	$110,114	$116,854	$124,007	$129,017	$132,926	$136,954
US Bucam	$0	$5,670	$23,927	$42,289	$55,940	$70,234	$84,613	$96,036	$103,906	$110,266
EMEA Bunalz/BupHD	$0	$17,955	$35,925	$49,051	$63,768	$71,146	$76,229	$79,309	$81,712	$84,188
EMEA Bucam	$0	$0	$0	$0	$0	$5,670	$23,927	$42,289	$57,036	$72,859
Total Sales ($000's)	**$126,054**	**$151,938**	**$196,019**	**$235,043**	**$270,972**	**$306,301**	**$352,457**	**$391,655**	**$421,947**	**$452,039**
Manufacturing ($000's)	***(14,861)***	***(19,474)***	***(24,453)***	***(28,748)***	***(32,673)***	***(37,322)***	***(42,299)***	***(46,233)***	***(49,671)***	***(53,147)***
Distribution	*(9,990)*	*(11,485)*	*(12,919)*	*(14,048)*	*(15,084)*	*(16,273)*	*(17,535)*	*(18,597)*	*(19,568)*	*(20,555)*
Royalty	*(3,155)*	*(4,183)*	*(5,298)*	*(6,263)*	*(7,144)*	*(8,189)*	*(9,308)*	*(10,191)*	*(10,961)*	*(11,740)*
Total Direct Costs	($28,006)	($35,142)	($42,670)	($49,059)	($54,902)	($61,785)	($69,142)	($75,021)	($80,201)	($85,443)
Net Sales	**$98,048**	**$116,796**	**$153,349**	**$185,984**	**$216,070**	**$244,516**	**$283,315**	**$316,634**	**$341,747**	**$366,596**
Total HQ Staff	($805)	($835)	($850)	($850)	($1,178)	($1,171)	($1,201)	($1,273)	($1,287)	($1,287)
Office, Legal & Accts	($242)	($314)	($350)	($512)	($561)	($818)	($883)	($1,359)	($1,446)	($2,348)
Marketing	($13,034)	($13,132)	($13,357)	($13,718)	($14,133)	($14,562)	($15,003)	($15,457)	($15,926)	($16,408)
Sales, General & Admin	($14,082)	($14,281)	($14,557)	($15,080)	($15,873)	($16,550)	($17,087)	($18,089)	($18,659)	($20,043)
EBITDA	$83,966	$102,515	$138,792	$170,904	$200,197	$227,966	$266,228	$298,545	$323,088	$346,553
Net Income	**$66,333**	**$80,987**	**$109,646**	**$135,014**	**$158,156**	**$180,093**	**$210,320**	**$235,850**	**$255,239**	**$273,777**

Source & Uses of Cash ($000's)										
Operations	**64,133**	**77,744**	**105,715**	**130,245**	**152,741**	**173,570**	**203,165**	**227,912**	**246,854**	**264,591**
Formulation & Packaging	0	0	0	0	0	0	0	0	0	0
Clinical Trials	0	0	0	0	0	0	0	0	0	0
Regulatory & Consulting	0	0	0	0	0	0	0	0	0	0
Filing & Licensing fees	0	0	0	0	0	0	0	0	0	0
Investment	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Equity	0	0	0	0	0	0	0	0	0	0
Debt	0	0	0	0	0	0	0	0	0	0
Debt Repayment	0	0	0	0	0	0	0	0	0	0
FinancePrior	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Dividends	(64,133)	(77,744)	(105,715)	(130,245)	(152,741)	(173,570)	(203,165)	(227,912)	(246,854)	(264,591)
Ending Cash 1,042	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**	**$10,000**

Balance Sheet ($000's)										
Cash	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000
Other Assests	630	630	630	630	630	630	630	630	630	630
Working Capital	11,835	15,871	20,595	26,158	32,367	39,683	47,631	56,363	65,541	75,521
Net LT Assets	*25,172*	*24,378*	*23,585*	*22,792*	*21,999*	*21,205*	*20,412*	*19,619*	*18,826*	*18,032*
Total Assets	**47,637**	**50,880**	**54,811**	**59,580**	**64,995**	**71,518**	**78,673**	**86,612**	**94,997**	**104,183**
Total Liabilities	-	-	-	-	-	-	-	-	-	0
Equity Investment	46,483	46,483	46,483	46,483	46,483	46,483	46,483	46,483	46,483	46,483
Retained earnings	133,322	199,655	280,642	390,288	525,302	683,458	863,551	1,073,871	1,309,722	1,564,961
Net Income	66,333	80,987	109,646	135,014	158,156	180,093	210,320	235,850	255,239	273,777
Cum. Dividends	(198,501)	(276,245)	(381,960)	(512,205)	(664,946)	(838,516)	(1,041,681)	(1,269,593)	(1,516,447)	(1,781,038)
Total Owners' Equity	47,637	50,880	54,811	59,580	64,995	71,518	78,673	86,612	94,997	104,183
Total Liabilities and Equity	**47,637**	**50,880**	**54,811**	**59,580**	**64,995**	**71,518**	**78,673**	**86,612**	**94,997**	**104,183**

2020 YEAR-END FINANCIAL STATEMENTS

Bridge Therapeutics, Inc.

2020 : Financial Statements

Income Statement: 1 Jan - 31 Dec'20

Sales			0
Interest Income			1
Total Income			1
- API		0	
- Licensing		0	
- Manufacturing		-41,004	
- Regulatory		-194,006	
- Inventory Used		-100,000	
Development Costs			-335,010
Gross Profit			**-335,009**
- Staff		-367,505	
- Payroll tax		-96,289	
- Interest Exp		-170,860	
- Acct, fees, regis		-1,568	
- Commissions		**-48,535**	
- Insurance		**-15,065**	
- Marketing		-17,841	
- Public Relations		-680	
- Research		-4,100	
- Legal		-5,725	
- Office		-12,257	
- Logistics		-45,271	
- Equipment		-40	
- Telecoms		-3,571	
- Meals	-684	-342	
Total Admin Expenses			**-800,803**
Earnings Before Tax			**-1,135,812**
Net Income/Loss			**-1,135,812**

Cash Flow Statement: 1 Jan - 31 Dec'20

Operating Activities	
Net Income	-1,135,812
Meals disallowed for tax	-342
Accrued Interest	140,000
Accounts Receivable	0
Inventory Draw	100,000
Active Accounts Payable	158,452
Suspended Payable	-23,000
Cash From/To Operations	-760,702
Investing Activities	
BT Europe, Ltd	-3,542
Cash From/To Investments	-3,542
Financing Activities	
Short-Term Loans	69,540
SBA PPP Loan	20,833
EJM Loan	-20,100
Long-Term Liabilities	0
Equity	651,662
Cash From/To Financing	721,935
Starting Cash Balance	84,694
Cash Added	-42,309
Ending Cash Balance	**42,385**

Balance Sheet as of	**31-Dec-19**	**Period Change**	**31-Dec-20**
Assets			
Cash	84,694	-42,309	42,385
BT Europe, Ltd	12,913	3,542	16,455
Raw Goods Inventory	700,000	-100,000	600,000
Accounts Receivable	0	0	0
Total Assets	**797,607**	**-138,767**	**658,840**
Liabilities & Equity			
Bunalz Payables	194,532	158,452	352,984
Short-Term Loans	133,296	69,540	202,836
SBA PPP Loan	0	20,833	20,833
EJM Loan	0	479,900	479,900
Suspended Operations	356,524	-23,000	333,524
Accrued Interest	140,000	140,000	280,000
Long-Term Liabilities	700,000	0	700,000
Total Liabilities	1,524,352	845,725	2,370,077
Owners' Equity			
Equity Investment	4,421,183	631,562	5,052,745
Equity to Debt	0.00	-479,900	-479,900
Retained Earnings	-3,021,312	-2,126,616	-5,147,928
Net Income	-2,126,616	990,462	-1,136,154
Total Owners' Equity	-726,745	-984,492	-1,711,237
Total Liabilities & Equity	**797,607**	**-138,767**	**658,840**

Bridge Therapeutics, Inc.

2019 : Financial Statements

Income Statement: 1 Jan - 31 Dec'19		
Sales		0
Interest Income		2
Total Income		2
- API	0	
- Licensing	-150,000	
- Manufacturing	-699,142	
- Regulatory	-434,752	
Development Costs		-1,283,894
Gross Profit		**-1,283,892**
- Acct, fees, regis	-21,458	
- Commissions	-66,000	
- Insurance	-10,839	
- Interest Exp	-154,541	
- Marketing	-87,186	
- Public Relations	-1,360	
- Research	-20,390	
- Legal	-54,162	
- Office	-29,539	
- Shipping	-2,705	
- Equipment	-1,866	
- Utilities	-2,112	
- Staff	-302,584	
- Payroll tax	-25,380	
- Telecoms	-2,097	
--- Airfare	-34,280	
--- Hotel	-9,664	
--- Ground	-9,275	
--- Other Travel	-893	
- Travel	-54,112	
- Meals	-6,393	
Total Admin Expense		-836,331
Total Expenses		**-842,724**
Earnings Before Tax		**-2,126,616**
Net Income/Loss		**-2,126,616**

Cash Flow Statement: 1 Jan - 31 Dec'19	
Operating Activities	
Net Income	-2,126,616
Accrued Interest	140,000
Accounts Receivable	0
Accounts Payable	229,768
Cash From/To Operations	-1,756,848
Investing Activities	
BT Europe, Ltd	-2,540
Cash From/To Investments	-2,540
Financing Activities	
Convertible Notes	-825,758
Short-Term Loans	82,811
Long-Term Liabilities	0
Notes converted to equity	825,758
Equity	1,750,224
Cash From/To Financing	1,833,035
Starting Cash Balance	11,047
Cash Added	73,647
Ending Cash Balance	**84,694**

Balance Sheet as of	31-Dec-18	Period Change	31-Dec-19
Assets			
Cash	11,047	73,647	84,694
BT Europe, Ltd	10,373	2,540	12,913
Raw Goods Inventory	700,000	0	700,000
Accounts Receivable	0	0	0
Total Assets	**721,420**	**76,187**	**797,607**
Liabilities & Equity			
Bunalz Payables	321,288	-126,756	194,532
Suspended Operations	0	356,524	356,524
Short-Term Loans	50,485	82,811	133,296
Accrued Interest	0	140,000	140,000
Long-Term Liabilities	1,525,758	-825,758	700,000
Total Liabilities	1,897,531	-373,179	1,524,352
Owners' Equity			
Equity Investment	1,845,201	2,575,982	4,421,183
Retained Earnings	-762,111	-2,259,201	-3,021,312
Net Income	-2,259,201	132,585	-2,126,616
Total Owners' Equity	-1,176,111	449,366	-726,745
Total Liabilities & Equity	**721,420**	**76,187**	**797,607**

Bridge Therapeutics, Inc.

Financial Statements

Income Statement: 1 Jan - 31 Dec'18		
Sales		0
Interest Income		1
Total Income		1
- API	-700,000	
- Manufacturing	-686,850	
- Regulatory	-126,823	
Development Costs		-1,513,673
Gross Profit		**-1,513,672**
- Acct, fees, regis	-7,889	
- Advert	-3,411	
- Conference	-26,035	
- Insurance	-2,281	
- Interest Exp	-25,758	
- InvBank	-74,157	
- Legal	-44,234	
- Office	-24,136	
- PayTax	-22,630	
- PR	-43,518	
- Research	-11,919	
- Staff	-299,989	
- Telecoms	-1,634	
- Travel	-157,938	
Total Admin Expense		-745,529
Earnings Before Tax		**-2,259,201**
Net Income/Loss		**-2,259,201**

Cash Flow Statement: 1 Jan - 31 Dec'18	
Operating Activities	
Net Income	-2,259,201
Accounts Receivable	0
Accounts Payable	241,002
Cash From/To Operations	-2,018,199
Investing Activities	
BT Europe, Ltd	-10,373
Cash From/To Investment	-10,373
Financing Activities	
Convertible Notes	650,000
Accrued Interest on Notes	25,758
Credit Line ($1.5M)	700,000
Equity pledged	0
Equity	255,101
Cash From/To Financing	1,630,859
Starting Cash Balance	408,760
Cash Added	-397,713
Ending Cash Balance	**11,047**

Balance Sheet as of	31-Dec-17	Period Change	31-Dec-18
Assets			
Cash	408,760	-397,713	11,047
BT Europe, Ltd	0	10,373	10,373
Raw Goods Inventory	0	700,000	700,000
Accounts Receivable	650,000	-650,000	0
Total Assets	**1,058,760**	**-337,340**	**721,420**
Liabilities & Equity			
Accounts Payable	*80,286*	*241,002*	*321,288*
Other Liabilities	*485*	*50,000*	50,485
Long Term Liabilities	*150,000*	*1,375,758*	1,525,758
Total Liabilities	230,771	1,666,760	1,897,531
Owners' Equity			
Equity Investment	1,590,100	255,101	1,845,201
Retained Earnings	-111,817	-650,294	-762,111
Net Income	-650,294	-1,608,907	-2,259,201
Total Owners' Equity	827,989	-2,004,100	-1,176,111
Total Liabilities & Equity	**1,058,760**	**-337,340**	**721,420**

RESEARCH BY BRIDGE'S SCIENTIFIC ADVISORS

Prof. Bob Raffa

- The clinical analgesic efficacy of buprenorphine
- Buprenorphine—The Unique Opioid Analgesic (Book)
- Identification of an additional supraspinal component to the analgesic mechanism of action of buprenorphine
- Buprenorphine – an attractive opioid with underutilized potential in treatment of chronic pain
- Buprenorphine & opioid use disorder
- Current knowledge of buprenorphine and its unique pharmacological profile
- Safety of buprenorphine transdermal system in the management of pain in older adults

Dr. Joe Pergolizzi

- Conversion from high-dose full-opioid agonists to sublingual buprenorphine reduces pain scores and improves quality of life for chronic pain patients
- Buprenorphine–Naloxone Therapy in Pain Management
- Current knowledge of buprenorphine and its unique pharmacological profile
- Examination of the preclinical antinociceptive efficacy of buprenorphine and its designation as full- or partial-agonist
- Safety of buprenorphine transdermal system in the management of pain in older adults
- Pain Control in Latin America: The Optimized Role of Buprenorphine in the Treatment of Cancer and Noncancer Pain
- The Unexpected Drug That Can Mitigate the Opioid Crisis (Article 2017)
- Buprenorphine Is a Weak Partial Agonist That Inhibits Opioid Receptor Desensitization (Prevents Tolerance)
- Buprenorphine transdermal system compared with placebo reduces interference in functioning for chronic low back
- Buprenorphine is a good choice in postoperative pain management
- Transdermal Buprenorphine Relieves Neuropathic Pain: A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Trial in Diabetic Peripheral Neuropathic Pain

WHERE OPIOIDS ACT IN THE BRAIN

Full agonist opioids like morphine and oxycodone affect three main areas of the brain: the reward center or nucelus accumbens, the energy center or locus coeruleus and the pain center or Periaquaductal Gray (PAG). Buprenorphine affects the same three centers, but differently in two of them (reward and energy) and for different time periods. Since *Bupe* binds to the receptors in the reward center for 36 hours, once per day dosing is adequate to block addiction. To treat pain, a certain level of *Bupe* needs to be maintained in the cerebral spinal fluid. This lasts for 6 hours 20 minutes, so dosing to treat pain is 3x / day.

- ***Nucelus Accumbens*: *reward center*,** *also euphoria and addiction*
    - *Opioids bounce 4000x/second*
    - *Buprenorphine blocks for 36 hours*
- ***Locus Coeruleus*: *energy & breathing***
    - *Opioid overstimulation in 10 days, so energy crashes, respiration slows*
    - *Buprenorphine restores function*
- ***Periaqueductal Gray*** *(PAG)*: ***senses pain***
    - *Opioids & Bupe bounce on receptors to relieve pain, so Bupe can accommodate adjunctive therapy*