Zacks Small-Cap Research

June 20, 2016
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Opiant Pharmaceuticals Inc. (OPNT-OTC)

OPNT: Initiating Coverage of Opiant Pharmaceuticals: Developing Treatments for Substance Use, Addictive, and Eating Disorders…

Based on our probability adjusted DCF model that takes into account potential future revenues from treating opioid abuse, binge eating disorder, and cocaine use disorder, OPNT is valued at $20/share. This model is highly dependent upon the commercial success of NARCAN® Nasal Spray and clinical success in treating binge eating and cocaine use disorder.

Current Price (06/20/16)	$8.31
Valuation	**$20.00**

OUTLOOK

Opiant Pharmaceuticals, Inc. (OPNT) is a specialty pharmaceutical company developing treatments for substance use, binge eating disorder, and cocaine use disorder. The company currently has one product on the market, NARCAN® Nasal Spray, which is promoted by Adapt Pharma, Ltd. for the treatment of opioid overdose. The agreement with Adapt calls for over $55 million in regulatory and milestone payments along with up to double-digit royalties.

Opiant is focused on developing novel treatments based on the company's expertise in opioid antagonists. Thus far, it has led to one commercial product (NARCAN® Nasal Spray), and we are confident that the company will follow the same path in developing novel treatments for binge eating disorder and cocaine use disorder, which have few if any treatment options and significant unmet medical needs.

SUMMARY DATA

52-Week High	**$10.93**
52-Week Low	**$6.21**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**5,767**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**34**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2015	0.0 A	0.6 A	0.1 A	0.9 A	1.6 A
2016	0.1 A	6.9 A	2.6 A	0.1 E	9.7 E
2017					3.6 E
2018					7.4 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2015	-$0.65 A	-$1.54 A	-$1.01 A	-$0.68 A	-$3.88 A
2016	-$6.00 A	$2.11 A	$0.22 A	-$1.52 E	-$5.11 E
2017					-$2.43 E
2018					-$1.34 E

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WHAT'S NEW

Initiating Coverage

We are initiating coverage of Opiant Pharmaceuticals, Inc. with a $20.00 valuation. Opiant is a specialty pharmaceutical company developing treatments based on its expertise in opioid receptor antagonists. Opioid receptors are a group of cell surface receptors found in the brain, central nervous system, and intestines that bind natural opioids (e.g., endorphins), opioid medications (e.g., oxycodone), and opioid drugs (e.g., heroin). Binding of opioid drugs to opioid receptors results in activation of the brain's reward pathway and can lead to dependence and addiction. Blocking this pathway has to potential to ameliorate dependency and aid in ending an addiction. The company is currently focused on three main areas of treatment:

- **Opioid Overdose Reversal**: Death from overdose of an opioid drug is fast becoming an epidemic in the U.S. Close to 30,000 people died as a result of opioid overdose in the U.S. in 2014. One of the main reasons for this is the widespread use of opioid prescription medications. Approximately 227 million prescriptions were filled in the U.S. in 2015 for opioid medications, which include hydrocodone (Vicodin®), oxycodone (OxyContin®), morphine, and codeine. Naloxone is a drug first approved in 1971 for the treatment of opioid overdose and has been available as an injection since that time. It has a very quick onset of action and can rescue those who overdose from opioid drugs. Opiant developed NARCAN® Nasal Spray, an intranasally formulated version of naloxone that is more easily administered than the injectable form of the drug. It was approved by the FDA in late 2015 and is being marketed by Adapt Pharma, Ltd. Opiant could receive more than $55 million in regulatory and sales milestones along with up to double digit royalties on net sales.

- **Binge Eating Disorder**: Binge eating disorder (BED) is the most common eating disorder in the U.S. and affects approximately 8 million individuals. There appears to be an overlap between substance use disorder and BED, as approximately 25% of those diagnosed with BED have substance use disorder at some point in their lifetime. Dopaminergic and opioid pathways are both involved in feeding behavior and maintenance of addiction, and opioid antagonists have shown efficacy in treating substance use disorder. A clinical trial conducted with an intranasally administered naloxone showed that treatment with the drug resulted in a statistically significant decrease in time spent binge eating. The company will be initiating a Phase 2b trial of intranasally administered naloxone in BED in the fourth quarter of 2016.

- **Cocaine Use Disorder**: Cocaine is a highly addictive stimulant that affects the reward pathway in the brain and thus users are very prone to developing dependence and/or addiction. There are currently no pharmacological treatments for those addicted to cocaine. Opiant has initiated a clinical trial in collaboration with the National Institute on Drug Abuse (NIDA) to examine the effect of an opioid antagonist on neural pathways known to be associated with addiction. Results from this study are expected in the third quarter of 2016.

With a drug approved by the FDA, the management team at Opiant has proven that they can get a product to market. The agreement with Adapt Pharma has provided the company with more than $5 million of non-dilutive capital thus far, and we anticipate royalty payments to supply additional cash that the company can use for the development of binge eating and cocaine use disorder treatments. The opioid overdose reversal market alone is upwards of $2 billion, and we believe that investors do no fully appreciate this opportunity since Opiant has a current market cap of only $17 million. We have constructed a discounted cash flow model with a discount rate of 12% that takes into account potential revenues from the sale of NARCAN® Nasal Spray and treatments for binge eating disorder and cocaine use disorder. Our target price is $20, and we feel that as more investors become aware of Opiant's story the share price is likely to align further with our valuation.

INVESTMENT THESIS

Opiant Pharmaceuticals is a specialty pharmaceutical company developing treatments for substance use, addictive, and eating disorders using the company's expertise in opioid antagonists. Opiant has developed a novel nasal spray formulation of naloxone as a treatment for opioid overdose, which was approved by the U.S. Food and Drug Administration (FDA) in November 2015. The company is also working on a treatment for overweight and obese patients with Binge Eating Disorder (BED) and cocaine use disorder.

Opioid Overdose Reversal

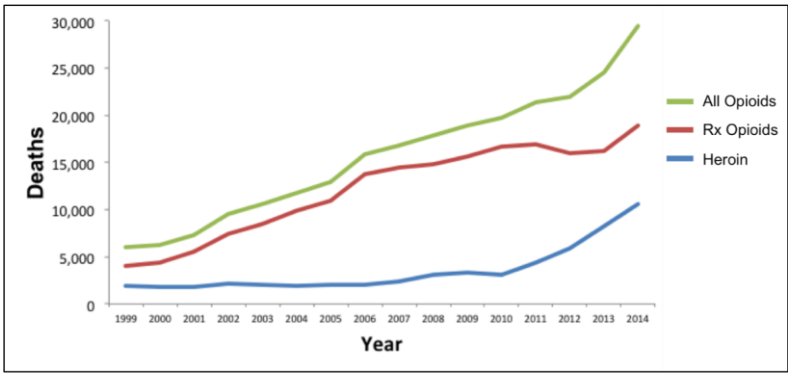
Opioids are a class of drugs that are chemically similar to alkaloids found in opium poppies. They are typically utilized to manage pain, however they have a high potential for misuse and abuse. They work through binding of the opioid receptors, a group of cell surface receptors found in the brain, central nervous system, and digestive tract that normally bind endogenous opioids such as dynorphins, enkephalins, endorphins, and endomorphins. Opioid medications include hydrocodone (Vicodin®), oxycodone (OxyContin®), morphine, and codeine. Heroin is an opioid drug derived from morphine that is less commonly used for pain relief, but is widely abused by recreational drug users.

Opioid medications are the most commonly prescribed class of drugs in the U.S., where in 2015 a total of 227 million prescriptions were dispensed (IMS Health). The Centers for Disease Control (CDC) reported that sales of prescription opioids in the U.S. almost quadrupled from 1999 to 2014 (CDC), however there has not been any change in the amount of pain reported by Americans (Chang *et al*., 2014). The majority of opioid prescriptions are for short-term use (less than three weeks), however there exists a rather sizeable group of patients of approximately 10 million individuals that take opioids long-term (Boudreau *et al*., 2009).

In addition to reducing the perception of pain, opioids can also result in drowsiness, mental confusion, nausea, constipation, and depressed respiration. Some users of the drug also experience a euphoric response to opioid drugs, which can lead to the misuse of the drugs through administration in ways other than prescribed (i.e., injected, snorted, etc.). Chronic use can lead to tolerance, which means that patients need to take more of an opioid medication for the same pain relief. Dependence is also an issue, as some patients can experience withdrawal symptoms when they quit taking the drug.

The U.S. is currently experiencing what many consider to be an epidemic of opioid overdose deaths and addiction. The reason opioids can result in overdose is in part due to the tolerance that arises after repeated administration, which results from changes to both the opioid receptors and the signaling pathways in which they operate (Williams *et al*., 2001). When no longer taken (for instance when an addict quits taking the drug), tolerance is quickly lost. Thus, if an addict has a relapse and attempts to take an equivalent amount of drug that they had taken previously, their body is no longer able to tolerate it and the drug can overwhelm their system and lead to an overdose. Symptoms of opioid overdose include blue lips and fingernails, shallow breathing, erratic heartbeat, and loss of consciousness. Death is usually the result of depressed respiratory activity.

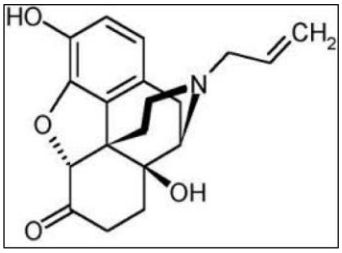
In 2014, more people died from drug overdoses than in any year on record, with more than 60% of the drug overdose deaths involving an opioid (CDC). This translates to approximately 29,000 deaths due to prescription opioids and heroin. The following graph shows the rise in opioid overdose deaths from 1999-2014, including a very large increase in heroin overdose deaths since 2010.



Source: CDC Wonder / Zacks SCR

Naloxone for Treating Opioid Overdose

When an individual overdoses on an opioid medication death usually does not occur right away, thus allowing for a limited amount of time to administer medical treatment. Naloxone was approved by the FDA for the treatment of opioid overdose in 1971. It is a competitive opioid receptor antagonist with greater affinity for opioid receptors than agonists such as opioids, however it does not activate the receptors.



Source: opioids.com

Naloxone can be administered through intravenous injection, intramuscularly, or intranasally. It has a very rapid onset of action (typically within minutes for intravenous or intramuscular administration; less than a minute for intranasal administration) and its effects last for between 30 and 60 minutes. When administered to an individual who does not have opioids in their system there are few if any effects. For a patient suffering from an opioid overdose, side effects include restlessness, agitation, nausea, vomiting, and increased heart rate (similar to symptoms of withdrawal). Since there is no euphoric effect upon naloxone administration there is no potential for abuse.

Naloxone has historically been given as an injection by a healthcare professional or first responders. It is currently sold by Amphastar as an injectable formulation that can be administered intravenously, intramuscularly, or subcutaneously in a healthcare setting. Amphastar reported 2015 revenues for naloxone of $38.6 million. In addition, nasal atomizer devices are available that can be used with the injectable formulation for intranasal delivery, however these require assembly and are not FDA approved. Evzio® is an injectable formulation of naloxone that comes in a pre-filled auto-injector. It is manufactured by Kaleo, Inc. and costs approximately $3750 for two single-dose injectors. Revenue information for Evzio® is unavailable.

NARCAN® Nasal Spray

In an effort to make naloxone administration easier and more reliable, Opiant collaborated with the National Institute on Drug Abuse to develop an intranasally administered naloxone product. NARCAN® Nasal Spray was approved by the FDA in November 2015 for the treatment of opioid overdose. Since it is administered intranasally, NARCAN® Nasal Spray can be more easily used by friends, family members, or others to treat suspected opioid overdose until first responders arrive. It does not require any type of special training to use and eliminates any risk associated with needles with an injectable formulation. In contrast to the intranasal "kits" that are sold to convert the injectable naloxone formulation for intranasal administration, there is no assembly required to use NARCAN® Nasal Spray.



Source: Opiant Pharmaceuticals., Inc.

It is the first intranasally administered naloxone product to be approved by the FDA, as the "kits" that can convert the injectable formulation of naloxone into a nasally administered product are not FDA approved and Amphastar is unable to promote its naloxone product except as an injectable to be used in a healthcare setting. It is sold in a box with two single-use cartridges for approximately $125, which is much cheaper than Evzio®. The company previously announced an initiative to offer NARCAN® Nasal Spray at a discounted price of $75 for a two-pack carton to 62,000 agencies in state and local governments and the non-profit sector. In addition, the company is making a single carton available for free to every high school in the U.S.

On December 15, 2014, Opiant and Adapt Pharma, Ltd entered into a license agreement whereby Adapt received a global license to develop and commercialize Opiant's naloxone overdose reversal treatment for an upfront payment of $500,000, potential milestone payments of more than $55 million, and up to double-digit percentage royalties based on net sales. Thus far, Opiant has received the following payments from Adapt stemming from the license agreement:

* On December 15, 2015, Opiant received a milestone payment of $2 million from Adapt based on the FDA approval of NARCAN® Nasal Spray.

* On March 7, 2016, Opiant received a milestone payment of $2.5 million from Adapt based on the first commercial sale of NARCAN® Nasal Spray.

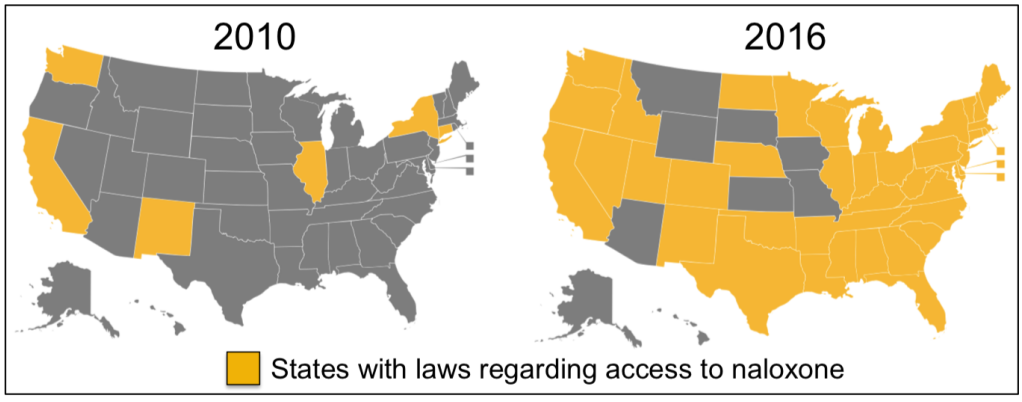
* On April 29, 2016, Opiant received $105,097 in royalty payments from Adapt from commercial sales of NARCAN Nasal Spray in the U.S. during the first quarter of 2016.

Access to Naloxone

Naloxone is a proven treatment to aid those experiencing an opioid overdose. However, the drug is still only available by prescription in the U.S., as no company has approached the FDA about converting it to over-the-counter (OTC) status. Even so, some outreach organizations have worked with state and local governments to make it possible for naloxone to be administered to opioid drug users and their families. The first organization to distribute naloxone in the U.S., the Chicago Recovery Alliance, began doing so 19 years ago. During that time, 38,000 people have received naloxone and more than 6,000 cases of opioid overdose reversal have been reported. A 2015 report by the CDC showed a 243% increase in groups that provide naloxone and a 160% increase in the number of overdose reversals. Of the 26,000 reported reversals since the mid-1990's, 8,000 of them took place in 2013, thus demonstrating that wider access to naloxone can be used to save lives.

Community-based advocacy groups have been at the forefront of making naloxone available to those at the highest-risk (e.g., illicit drug users), however other opioid users (e.g., those taking long-term opioid prescriptions) don't have the same type of access. In addition, there continue to exist a number of barriers that prevent naloxone from being available in areas where it could be most effective, such as public parks, bars, and neighborhoods known to have a large number of opioid drug users.

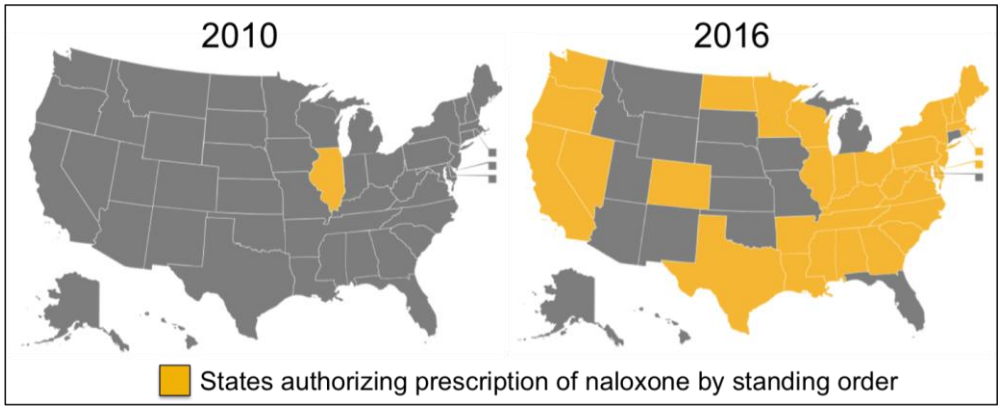
Due to the rapidly increasing number of opioid overdoses in the U.S. every year, a number of states are changing their laws to make naloxone easier to obtain and use in an emergency situation. The following maps show a rapid increase in the number of states that have laws regarding access to naloxone (depicted in yellow) in the past six years.



Adapted from: www.lawatlas.org

One of the ways in which states have attempted to make access to naloxone easier is by issuing a statewide "standing order" at pharmacies. A standing order is a physician's order that can be carried out by other health care workers when predefined conditions have been met. Since naloxone is only available by prescription, anyone who wished to purchase the drug would need a prescription from a physician. However, in the standing order model a physician with prescription authority issues a written order that allows other healthcare professionals to dispense a drug (e.g., naloxone), as long as those individuals meet certain criteria outlined in the standing order (e.g., employees at a drug assistance program).

The following maps show that in 2010 only one state (Illinois) allowed the use of a standing order, which allowed the Chicago Recovery Alliance to distribute naloxone and which led to its reported use in averting 6,000 opioid overdoses. As of February 1, 2016, there were 33 states that allow the use of a standing order for naloxone, thus greatly increasing the number of individuals that can have access to the drug. CVS and Walgreens have both announced plans to make naloxone available without a prescription in these states by the end of 2016.



Adapted from: www.lawatlas.org

Additional changes to laws regarding naloxone that a number of states have taken include removing civil and criminal liability from those who prescribe naloxone, removing criminal penalties for those who possess naloxone, and granting immunity from criminal prosecution and civil liability for lay administrators of naloxone (e.g., a bystander administering naloxone to someone suspected of experiencing an opioid overdose). The increased access to naloxone afforded by these changes in state laws should make it easier for those with opioid addictions to get the drug. In addition, these changes in state law may also pave the way for increased access through co-prescription of naloxone to those prescribed high-dose and/or long-term opioid treatments.

The American Medical Association (AMA) recently announced that it will encourage doctors to co-prescribe naloxone with opioid painkillers. The AMA is also working to encourage both private and public payers to include all forms of naloxone on their preferred drug lists and formularies with little to no cost sharing.

Naloxone Market Opportunity

We believe that Adapt Pharma will attempt to reach three target markets with NARCAN® Nasal Spray: 1) Current heroin addicts; 2) first responders who could administer naloxone in an emergency response situation; and 3) those who have opioid prescriptions.

According to the National Survey on Drug Use and Health, which is compiled by the Substance Abuse and Mental Health Services Administration (SAMHSA), there are an estimated 2.5 million individuals addicted to opioid medications or heroin in the U.S. A number of these addicts are prescribed buprenorphine, an opioid agonist, to help minimize withdrawal symptoms while trying to quit. We estimate approximately one million addicts are prescribed buprenorphine, either as a generic or as Suboxone (a mixture of buprenorphine and naloxone to deter abuse), and would be suitable for NARCAN® Nasal Spray being co-prescribed along with it.

We estimate there are approximately 67,000 first responder units in the U.S., which are comprised of emergency room departments, fire and police departments, and emergency medical services (EMS) agencies. Police officers are typically the first to arrive on the scene of an overdose, thus a large number of the approximately 18,000 police departments in the U.S. are beginning to enact programs to allow their officers to carry naloxone. We believe that NARCAN Nasal Spray would be the preferred formulation for police officers as it requires no special training or assembly to be used.

The largest target market is individual's who take opioids for pain management. Given an estimated 227 million opioid prescriptions in the U.S. every year, we estimate a reasonable target market of approximately 20 million unique users of opioids who could be co-prescribed NARCAN® Nasal Spray as a universal precaution. Based on the position taken by the AMA, we believe more and more doctors will become comfortable with the idea of co-prescribing naloxone to those who are prescribed opioid painkillers. We also believe that payers will continue to increase coverage of the drug, thus allowing access to an ever increasing number of patients.

With an estimated average selling price of $100 per pack, the total addressable market for NARCAN® Nasal Spray is over $2 billion.

Binge Eating Disorder

Binge Eating Disorder (BED) is the most common eating disorder in the U.S. and affects approximately 8 million individuals (National Institute of Mental Health). The condition is characterized by recurrent binge-eating episodes where a person does not feel in control during the binge. Unlike bulimia, purging does not follow the binge eating, thus many people with BED are overweight or obese. In addition to a loss of control, many BED patients experience shame or guilt and the condition is commonly associated with a number of comorbid conditions such as functional impairment, suicide ideation, and various other psychiatric conditions.

The Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association (APA) published in 2013 (DSM-5) listed BED as a diagnosable eating disorder with a list of diagnostic criteria including: A) recurrent episodes of binge eating; B) binge eating associated with eating more than normal; eating until feeling uncomfortably full; eating alone due to embarrassment; feeling of guilt or shame following the binge; C) Marked distress regarding binge eating; D) binge eating at least once a week for 3 months; and E) binge eating not associated with compensatory behaviors (e.g., purging, vigorous exercise). Having BED listed as diagnosable in DSM-5 was important as most insurance companies will not cover treatment for a condition without a DSM diagnosis, and the DSM diagnosis leads to increased recognition by healthcare professionals and patients.

Current treatment options include both pharmacological and behavior modification therapies. The treatment of choice for BED is cognitive behavior therapy (CBT), which was found to be superior to fluoxetine (Prozac®) in a randomized, placebo-controlled clinical trial (Grilo *et al*., 2012). CBT encompasses numerous specific approaches for various psychiatric disorders, with the unifying theme being a combination of both cognitive and behavioral adaptations to change unhelpful thinking and actions. Additional types of psychotherapy shown to be effective for treating BED include family therapy, interpersonal therapy, and dialectic behavior therapy.

Pharmacological treatments include fluoxetine and other medications typically used to treat depression including sertraline (Zoloft®), fluvoxamine (Luvox®), paroxetine (Paxil®), and escitalopram (Lexapro®). However, these medications all are associated with weight gain, which can preclude their successful use in BED patients. In January 2015, the FDA approved lisdexamfetamine (Vyvanse®) to treat patients with moderate-to-severe BED, which was the first FDA-approved medication for that condition. Two clinical studies involving 724 adults with moderate-to-severe BED showed that treatment with Vyvanse® led to a decrease in the number of binge eating days per week and fewer obsessive-compulsive binge eating behaviors compared to placebo (Vyvanse® prescribing information). Vyvanse® was already approved for the treatment of attention deficit hyperactivity disorder (ADHD), and sales of the drug are expected to grow to approximately $500 million for BED treatment in 2022 (EvaluatePharma).

While shown to be effective in treating BED, Vyvanse® does have a number of significant drawbacks that do not make it suitable for all patients. Vyvanse® is a controlled substance with a "black box" warning about the potential for abuse and dependence. In addition, a vast majority of those taking Vyvanse® will experience side effects that can include dry mouth, sleeplessness, increased heart rate, constipation, and anxiety. More serious side effects include cardiac complications (e.g., stroke and heart attack) and psychiatric problems (e.g., hallucinations and delusional thinking).

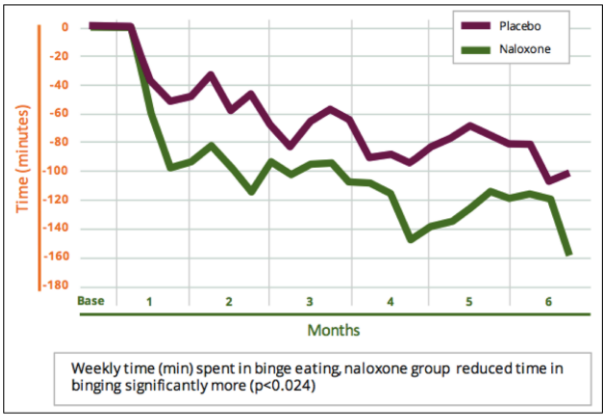
Naloxone for Treating BED

The endogenous opioid system, including both peptides and receptors, has been linked with the rewarding impact of palatable food intake and also regulates hedonic overeating. Exposure to drugs and palatable food as well as food-associated stimuli are known to increase dopamine in the brain. This increase in dopamine can drive the brain's reward system through the connection between the brain's opioid and dopaminergic systems. This pathway is a dopaminergic pathway that plays a central role in the neurobiology of addiction through release of dopamine,

which affects motivation for rewarding stimuli and the perception of pleasure (Berridge *et al*., 2015). Additional data supporting the connection between opioid receptors and overeating comes from the fact that opioid receptor agonists decrease food consumption while opioid receptor antagonists decrease it (Kelley, 2004). These facts support the notion of using an opioid antagonist such as naloxone to treat BED.

In 2012, a clinical trial was conducted testing intranasally administered naloxone as a treatment for BED (NCT01567670). Results of the Phase 2, randomized, double blind, placebo controlled study were presented at the American Psychiatric Association's 2013 Annual Meeting. The 24-week study included 127 adults with BED, with the majority being female and obese or severely obese. Since the urge to binge in BED has a rapid onset, participants in the study were told to carry the spray (either naloxone or placebo) with them at all times and administer it (up to two doses of 2 mg each) prior to binging. The primary outcomes of the study were the mean minutes spent binge eating and the mean scores on the Binge Eating Scale (BES).

The following chart shows the reduction in time spent binge eating for treatment and placebo groups, with those taking naloxone experiencing a significant reduction compared to the placebo group (*P*=0.024).



Source: Opiant Pharmaceuticals, Inc.

Opiant is planning to initiate a Phase 2 clinical trial in BED in the fourth quarter of 2016. Based upon the previous results in BED, the company may also initiate a clinical trial in an additional eating disorder as well.

Cocaine Use Disorder

Cocaine is a highly addictive stimulant produced from the leaves of coca plant of South America. While it can be used for legitimate medical purposes (e.g., numbing during surgery), it is an illegal compound that is mostly used as a recreational drug. Users typically ingest the drug through snorting, inhalation, or injection. Following ingestion, users report intense feelings of happiness, which lasts for anywhere from five to 90 minutes. There is a very high risk of dependence after using cocaine for only a short period of time due to the fact that the drug affects the reward pathway in the brain.

DSM-5 no longer uses the terms "substance abuse" and "substance dependence", but instead refers to substance use disorders, which occur when the recurrent use of a drug causes clinically and functionally significant impairment. According to DSM-5, a diagnosis for a substance use disorder is based on evidence of impaired control, social impairment, risky use, and pharmacological criteria. There are approximately 1.5 million individuals in the U.S. that meet the diagnosis for cocaine use disorder.

Cocaine use leads to the blocking of dopamine reuptake, thus increasing the amount of dopamine in the brain and resulting in the euphoria most often reported by cocaine users. Over time a tolerance develops, as more opioid receptors are expressed by neurons, meaning that more and more cocaine is required to get the same effect. Suddenly stopping cocaine use results in withdrawal and an extremely strong craving for more cocaine. It can also lead to fatigue, depression, anxiety, and suicide ideation. Medical complications from continued use of cocaine include cardiac abnormalities, stroke, and sudden death.

There are no pharmacological treatments for cocaine use disorder, thus treatment is typically centered on behavioral interventions. Therapies such as contingency management, which uses motivational incentives as a means to induce initial abstinence, and CBT, which can help patients develop critical skills that support long-term abstinence, have both been shown to be somewhat effective for a minority of patients, however all behavioral interventions suffer from a lack of strong efficacy and high relapse rates.

On December 23, 2015, Opiant announced a collaboration with the National Institute on Drug Abuse (NIDA) and the University of Pennsylvania whereby an opioid antagonist drug will be tested in patients with cocaine use disorder. The study will involve 12 patients with cocaine use disorder. Each patient will undergo functional magnetic resonance imaging (fMRI) to examine neural networks related to addiction in the presence and absence of an opioid antagonist. The first patient was recruited in the fourth quarter of 2015 and we anticipate results from this study being available in late 2016 or the first quarter of 2017.

Financials and Capital Structure

As of April 30, 2016, Opiant had approximately $2.4 million in cash and cash equivalents. While we believe the company will continue to receive royalties from Adapt Pharma from the sale of NARCAN® Nasal Spray, Opiant will need to raise additional capital to continue the planned clinical development of a treatment for BED and cocaine use disorder. As of June 8, 2016, the company had approximately 2.0 million shares outstanding. In addition, there are approximately 4.3 million exercisable stock options and 0.5 million exercisable warrants for a fully diluted share count of approximately 6.8 million.

Risks to Consider

Opiant is highly reliant on Adapt Pharma to sell NARCAN® nasal spray: Opiant does not have a marketing or sales organization and thus is dependent upon the agreement with Adapt to market NARCAN® nasal spray. The loss of the partnership with Adapt would have a detrimental effect on the company and lead to a delay or inability to market NARCAN® nasal spray.

Opiant will need to raise additional capital: As of April 30, 2016, the company had approximately $2.4 million in cash and cash equivalents due in part to a milestone payment of $2.5 million was received from Adapt Pharma in March 2016. Royalty payments from the sale of NARCAN® Nasal Spray are unlikely to be sufficient to fully fund the company's operations for the foreseeable future, thus the company will need to raise additional capital. There are many options available to the company to raise the necessary capital, some of which may result in dilution to current shareholders, however historically the company has chosen to raise cash through non-dilutive means.

Development of treatments for binge eating disorder or cocaine use disorder may be unsuccessful: In addition to NARCAN® nasal spray, the company is also developing opioid antagonist nasal sprays for the treatment of other addictions, including binge eating disorder and cocaine use disorder. There is no guarantee that the company will be successful in developing treatments for those or any other indications the company may pursue in the future.

MANAGEMENT PROFILES

Roger Crystal, MD – Chief Executive Officer

Dr. Crystal led Opiant's development of nasal naloxone for opioid overdose and is the lead inventor on the product's patents. He has several years' experience as a clinician, and began his career as an ENT surgeon at Imperial College Healthcare, London. He holds degrees in Medicine and Physiology from the University of Birmingham. He was also awarded Membership of The Royal College of Surgeons of England. He was an Honorary Research Fellow at University College London and has authored of a number of peer-reviewed scientific articles. After completing an MBA at London Business School, he worked for Goldman Sachs in Mergers and Acquisitions and then consulted for A.T. Kearney specializing in healthcare strategy management. He served on the Global Business Development Product Acquisition and Licensing team at GE Healthcare where he was responsible for evaluating acquisitions, licensing, and partnering deals. Most recently he served as Chief Business Officer for ImaginAb, a Los Angeles based venture capital backed biotechnology company, developing immuno-oncology imaging agents. In this capacity he led the company's turnaround, to establish the strategy for the development of its immune-imaging platform and managed its partnerships, pharmaceutical company engagements, and licensing deals.

Kevin Pollack, Esq. – Chief Financial Officer

Mr. Pollack has been an investment banker and securities attorney at Banc of America Securities LLC and Sidley Austin LLP (formerly Brown & Wood LLP), respectively, and has previous asset management experience at Paragon Capital LP. He is a magna cum laude graduate of the Wharton School of the University of Pennsylvania and holds JD and MBA degrees from Vanderbilt University, where he graduated with Beta Gamma Sigma honors. Currently, Mr. Pollack sits on the Boards of Directors of MagneGas Corporation and Pressure BioSciences, Inc. He also is President of Short Hills Capital LLC.

Arvind Agrawal – Executive Vice President, Medical Affairs

As Head of Medical Affairs and New Products at Mundipharma International, Mr. Agrawal made significant advances towards the development of a novel treatment for opioid addiction. While acting as European Clinical and Scientific Affairs Director at Reckitt Benckiser Pharmaceuticals, he developed strategies leading to positive clinical, political, and legislative changes for the treatment of opioid dependence. His earlier professional experience included various senior management positions in medical affairs and clinical development at: AstraZeneca plc, GlaxoSmithKline plc, SmithKline Beecham plc, and Wellcome Pharmaceuticals. There he was instrumental in launching the pharmaceutical blockbusters Crestor (rosuvastatin) and Avandia (rosiglitazone). Mr. Agrawal holds an MSc in Human & Applied Physiology from King's College, University of London. He is also the Managing Director of Ekagra Ltd, a pharmaceutical medical affairs consultancy in the U.K.

Mark Ellison – Executive Vice President, Development, Manufacturing and Quality

Dr. Ellison brings more than 15 years of experience in the pharmaceutical industry developing products in the therapeutic areas of gastrointestinal, malignant disease, critical care, respiratory, wound healing and diabetes. Dr. Ellison was most recently Head of Technical Affairs at S.L.A. Pharma and has also held management positions at the Medicines and Healthcare products Regulatory Agency (MHRA), Link Pharmaceuticals, DMV International and Merck. His career focus has been in the areas of product development, regulatory strategy and compliance, quality assurance, clinical development and project management. Dr. Ellison received his Ph.D. in pharmaceutical technology, from the University of Sunderland. He is a qualified pharmacist and member of the General Pharmaceutical Council in the U.K. He is also the Director of Phax Pharma, a pharmaceutical consultancy.

VALUATION

Opiant Pharmaceuticals is a specialty pharmaceutical company developing treatments for substance use, binge eating disorder, and cocaine use disorder based on the company's expertise in opioid receptor antagonists. Opiant currently has one FDA approved drug, NARCAN® Nasal Spray, which is marketed by Adapt Pharmaceuticals through an exclusive collaboration.

Opioid Overdose Reversal

Opioid's are a class of drugs utilized for pain management that are chemically similar to alkaloids found in opium poppies. They work through binding of the opioid receptors, a group of cell surface receptors found in the brain, central nervous system, and digestive tract that normally bind endogenous opioids such as dynorphins, enkephalins, endorphins, and endomorphins. Examples of opioid medications include hydrocodone (Vicodin®), oxycodone (OxyContin®), morphine, and codeine. Heroin is an opioid drug derived from morphine that is less commonly used for pain relief, but is widely abused by recreational drug users.

Opioid medications are the most commonly prescribed class of drugs in the U.S., where in 2015 a total of 227 million prescriptions were dispensed (IMS Health). The majority of opioid prescriptions are for short-term use (less than three weeks), however there exists a rather sizeable group of patients of approximately 10 million individuals that take opioids long-term.

The U.S. is currently experiencing what many consider to be an epidemic of opioid overdose deaths and addiction. In 2014, more people died from drug overdoses than in any year on record, with more than 60% of the drug overdose deaths involving an opioid (CDC). This translates to approximately 29,000 deaths due to prescription opioids and heroin.

The FDA first approved naloxone for the treatment of opioid overdose in 1971. Naloxone is a competitive opioid receptor antagonist with greater affinity for opioid receptors than agonists such as opioid medications, however it does not activate the receptors. It can be administered through intravenous injection, intramuscularly, or intranasally. It has a very rapid onset of action (typically within minutes for intravenous or intramuscular administration; less than a minute for intranasal administration) and its effects last for between 30 and 60 minutes. Since there is no euphoric effect upon naloxone administration there is no potential for abuse.

Naloxone has historically been given as an injection by a healthcare professional or first responder. It is currently sold by Amphastar as an injectable formulation that can be administered intravenously, intramuscularly, or subcutaneously in a healthcare setting. Evzio®, which is produced by Kaleo, Inc., is an injectable formulation of naloxone that comes in a pre-filled auto-injector.

In an effort to make naloxone administration easier, Opiant collaborated with the National Institute on Drug Abuse to develop an intranasally administered naloxone product. NARCAN® Nasal Spray was approved by the FDA in November 2015 for the treatment of opioid overdose. Since it is administered intranasally, NARCAN® Nasal Spray can be more easily used by friends, family members, or others to treat suspected opioid overdose until first responders arrive. It does not require any type of special training to use and eliminates any risk associated with needles with an injectable formulation.

Binge Eating Disorder

Binge Eating Disorder (BED) is the most common eating disorder in the U.S. and affects approximately 8 million individuals (NIMH). BED is listed as a diagnosable eating disorder in The Diagnostic and Statistical Manual of Mental Disorders (DSM-5). The condition is characterized by recurrent binge-eating episodes where a person does not feel in control during the binge. In addition to a loss of control, many BED patients experience shame or guilt and the condition is commonly associated with a number of comorbid conditions such as functional impairment, suicide ideation, and various other psychiatric conditions.

Current treatment options include both pharmacological and behavior modification therapies. The most common psychotherapy is cognitive behavior therapy (CBT), which encompasses numerous specific approaches for various psychiatric disorders, with the unifying theme being a combination of both cognitive and behavioral adaptations to change unhelpful thinking and actions.

Pharmacological treatments include a number of anti-depressants and anti-anxiety drugs, although these medications all are associated with weight gain, which can preclude their successful use in BED patients. In January 2015, the FDA approved lisdexamfetamine (Vyvanse®) to treat patients with moderate-to-severe BED. While shown to be effective in treating BED, Vyvanse® does have a number of significant drawbacks that do not make it suitable for all patients. Vyvanse® is a controlled substance with a "black box" warning about the potential for abuse and dependence. In addition, a vast majority of those taking Vyvanse® will experience side effects that can include dry mouth, sleeplessness, increased heart rate, constipation, and anxiety. More serious side effects include cardiac complications (e.g., stroke and heart attack) and psychiatric problems (e.g., hallucinations and delusional thinking).

Intranasally administered naloxone was previously tested in a Phase 2, randomized, double blind, placebo controlled study. The 24-week trial included 127 adults who met the DSM-5 criteria for BED, with the majority being female and obese or severely obese. Treatment with naloxone resulted in a statistically significant decrease in time spent binge eating compared to treatment with placebo. Opiant is planning to follow up on these results with a Phase 2 study in BED and potentially another eating disorder that we anticipate initiating in the fourth quarter of 2016.

Cocaine Use Disorder

Cocaine is a highly addictive stimulant that is mostly used as a recreational drug. Users typically ingest the drug through snorting, inhalation, or injection. Following ingestion, users report intense feelings of happiness, which lasts for anywhere from five to 90 minutes. Cocaine use leads to the blocking of dopamine reuptake, thus increasing the amount of dopamine in the brain and resulting in the euphoria most often reported by cocaine users. Over time a tolerance develops, as more opioid receptors are expressed by neurons, meaning that more and more cocaine is required to get the same effect. Suddenly stopping cocaine use results in withdrawal and an extremely strong craving for more cocaine. It can also lead to fatigue, depression, anxiety, and suicide ideation. Medical complications from continued use of cocaine include cardiac abnormalities, stroke, and sudden death.

There are no pharmacological treatments for cocaine use disorder, thus treatment is typically centered on behavioral interventions. Therapies such as contingency management, which uses motivational incentives as a means to induce initial abstinence, and CBT, which can help patients develop critical skills that support long-term abstinence, have both been shown to be somewhat effective for a minority of patients, however all behavioral interventions suffer from a lack of strong efficacy and high relapse rates.

On December 23, 2015, Opiant announced a collaboration with the National Institute on Drug Abuse (NIDA) and the University of Pennsylvania whereby an opioid antagonist drug will be tested in patients with cocaine use disorder. The study will involve 12 patients with cocaine use disorder. Each patient will undergo functional magnetic resonance imaging (fMRI) to examine neural networks related to addiction in the presence and absence of an opioid antagonist. The first patient was recruited in the fourth quarter of 2015 and we anticipate results from this study being available in the third quarter of 2016.

Valuation Methodology

We value Opiant using a probability adjusted discounted cash flow model that takes into account potential future revenues for NARCAN® Nasal Spray and binge eating disorder and cocaine use disorder treatments. For all indications we model for a 10% royalty to Opiant, which we believe is an appropriate approximation based on the disclosure of "up to double digit royalties" from Adapt.

For NARCAN® Nasal Spray, we model for peak sales of approximately $200 million, which is derived from selling the drug to first responders, heroin addicts, and opioid prescription drug users. We believe that awareness of opioid drug overdose deaths will continue, and with the possibility of co-prescribing of an opioid receptor antagonist as a precautionary measure for all opioid prescriptions, there is additional upside possible for our current forecasts. Using a 12% discount rate yields a net present value for NARCAN® Nasal Spray of $63 million.

For BED, we model for an NDA filing in 2019 and approval in 2020. We estimate there are approximately eight million individuals who suffer from BED in the U.S. and that 45% of them will seek treatment for their condition. Based on a yearly cost of $2500 (which is in line with the cost of Vyvanse®), we model for peak sales of approximately $500 million. We assign a 12% discount rate and a 50% probability of approval to arrive at a net present value for the BED program of $52 million.

For Cocaine Use Disorder, we model for an NDA filing in 2019 and approval in 2020. We estimate that approximately 1.5 million individuals in the U.S. suffer from cocaine use disorder, and with no other pharmacological treatments available we believe all of them would be targeted for treatment. We model for a yearly cost to treat of $2500 and peak sales of approximately $300 million. We assign a 12% discount rate and a 50% probability of approval, which yields a net present value for the cocaine use disorder program of $30 million.

Combining the net present value for the company's three programs along with the current cash position and an expected $10 million net operating burn we arrive at a net present value for the company of $138 million. Dividing by the company's fully diluted share count of approximately 6.8 million shares leads to a valuation of approximately $20. The stock is currently trading at less than 50% of this valuation, and data from the ongoing Phase 2 study in cocaine use disorder and additional measures to increase access to naloxone products to combat opioid drug overdose could move the stock price closer to our valuation.

PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	FY 2015	Oct-15 A	Jan-16 A	Apr-16 A	Jul-16 E	FY 2016 E	FY 2017 E	FY 2018 E
NARCAN royalty	$0.0	$0.0	$0.0	$0.1	$0.1	$0.2	$1.6	$3.4
YOY Growth	-	-	-	-	-	-	-	
Binge Eating Disorder	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	
Cocaine Use Disorder	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	
Licensing and Milestones	$1.6	$0.1	$6.9	$2.5	$0.0	$9.5	$2.0	$4.0
YOY Growth	-	-	-	-	-	-	-	
Total Revenues	**$1.6**	**$0.1**	**$6.9**	**$2.6**	**$0.1**	**$9.7**	**$3.6**	**$7.4**
YOY Growth	-	-	-	-	-	-	-	
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	
Research & Development	$2.4	$0.4	$0.4	$1.1	$0.4	$2.3	$2.0	$3.0
General & Administrative	$6.0	$10.8	$2.5	$1.1	$2.7	$17.1	$10.0	$11.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($6.9)	($11.1)	$4.0	$0.4	($3.0)	($9.7)	($8.4)	($6.6)
Operating Margin	-	-	-	-	-	-	-	
Non-Operating Expenses (Net)	($0.1)	($0.0)	($0.0)	$0.0	($0.0)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	($7.0)	($11.1)	$4.0	$0.4	($3.0)	($9.8)	($8.5)	($6.7)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($7.0)**	**($11.1)**	**$4.0**	**$0.4**	**($3.0)**	**($9.8)**	**($8.5)**	**($6.7)**
Net Margin	-	-	-	-	-	-	-	
Reported EPS	**($3.88)**	**($6.00)**	**$2.11**	**$0.22**	**($1.52)**	**($5.11)**	**($2.43)**	**($1.34)**
YOY Growth	-	-	-	-	-	-	-	
Basic Shares Outstanding	1.8	1.9	1.9	1.9	2.0	1.9	3.5	5.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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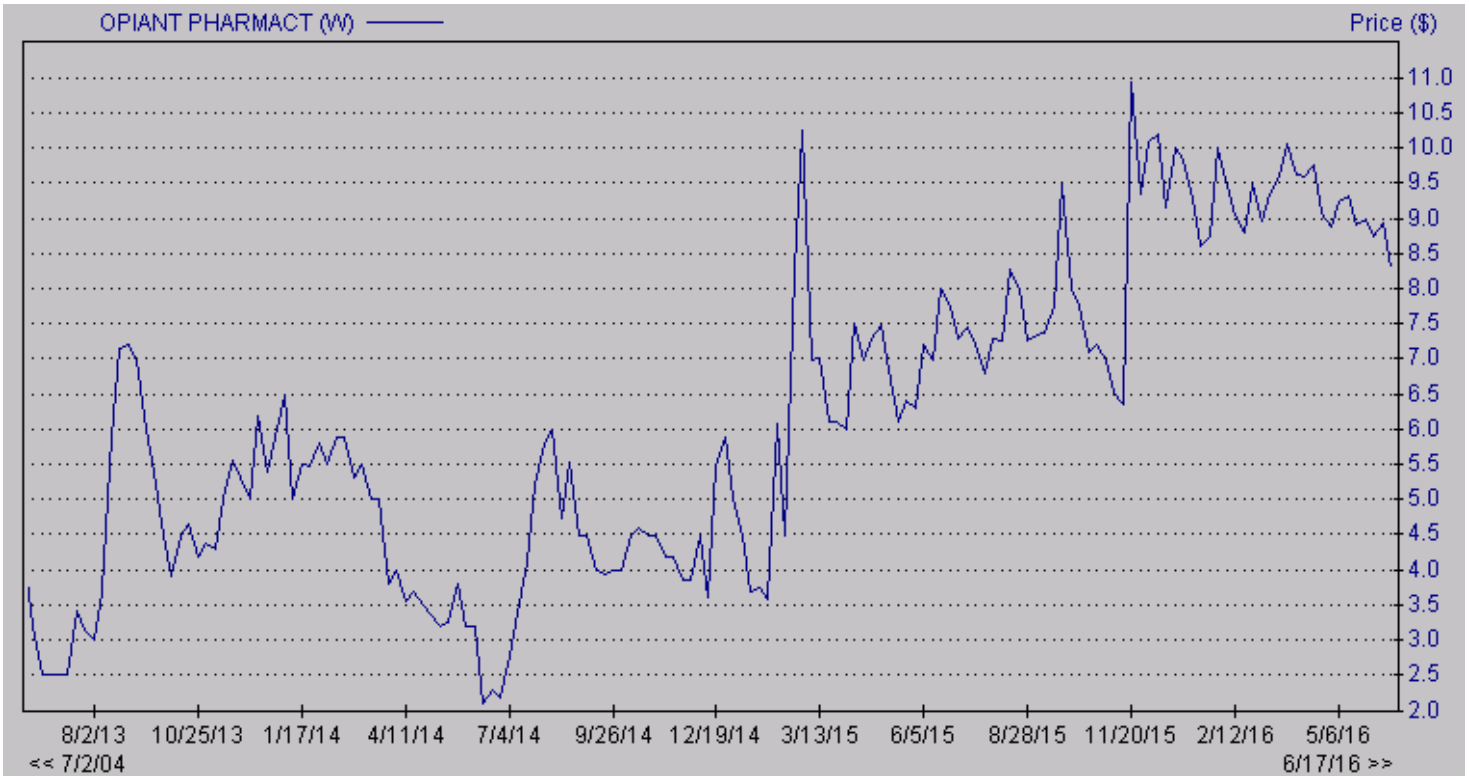
HISTORICAL STOCK PRICE



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