

## Opiant Pharmaceuticals, Inc.

(OPNT-NASDAQ)

### OPNT: KOL Event Highlights Medications for Addictions and Related Disorders...

Based on our probability adjusted DCF model that takes into account potential future revenues from opioid antagonists, eating disorder treatments, and alcohol use disorder (AUD) treatments, OPNT is valued at \$55/share. This model is highly dependent upon the commercial and clinical success of opioid antagonists and clinical success in treating eating disorders and AUD.

Current Price (05/15/18) **\$18.08**  
Valuation **\$55.00**

### OUTLOOK

On May 10, 2018, Opiant Pharmaceuticals, Inc. (OPNT) held a Key Opinion Leader (KOL) luncheon on Medications for Addictions and Related Disorders. Presentations were given by members of the company's scientific advisory board, including Sandra Comer, PhD, Susan McElroy, MD, and Stephanie O'Malley, PhD. Included in this report are highlights from each of those presentations.

On May 7, 2018, the company announced financial results for the first quarter of 2018. The company reported a net loss of \$9.3 million, which was primarily driven by a one-time license fee of \$5.6 million paid to Adapt Pharma. Royalty revenue totaled \$1.6 million for the first quarter of 2018 and was slightly ahead of our estimate. We continue to estimate royalty income for 2018 will be approximately \$8.7 million.

### SUMMARY DATA

52-Week High **\$50.50**  
52-Week Low **\$5.35**  
One-Year Return (%) **178.15**  
Beta **-0.57**  
Average Daily Volume (sh) **18,348**

Shares Outstanding (mil) **3**  
Market Capitalization (\$mil) **\$47**  
Short Interest Ratio (days) **N/A**  
Institutional Ownership (%) **4**  
Insider Ownership (%) **64**

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 2018 Estimate **N/A**  
P/E using 2019 Estimate **N/A**

Risk Level **High**  
Type of Stock **Small-Growth**  
Industry **Med-Drugs**

### ZACKS ESTIMATES

#### Revenue

(In millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0.0 A	0.0 A	0.0 A	11.8 A	11.8 A
2018	1.7 A	2.1 E	2.4 E	2.6 E	8.7 E
2019					13.2 E
2020					37.0 E

#### Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-\$0.30 A	\$5.31 A	-\$1.55 A	-\$0.17 A	\$0.66 A
2018	-\$3.68 A	-\$1.26 E	-\$1.11 E	-\$1.00 E	-\$5.04 E
2019					-\$3.92 E
2020					\$4.50 E

## WHAT'S NEW

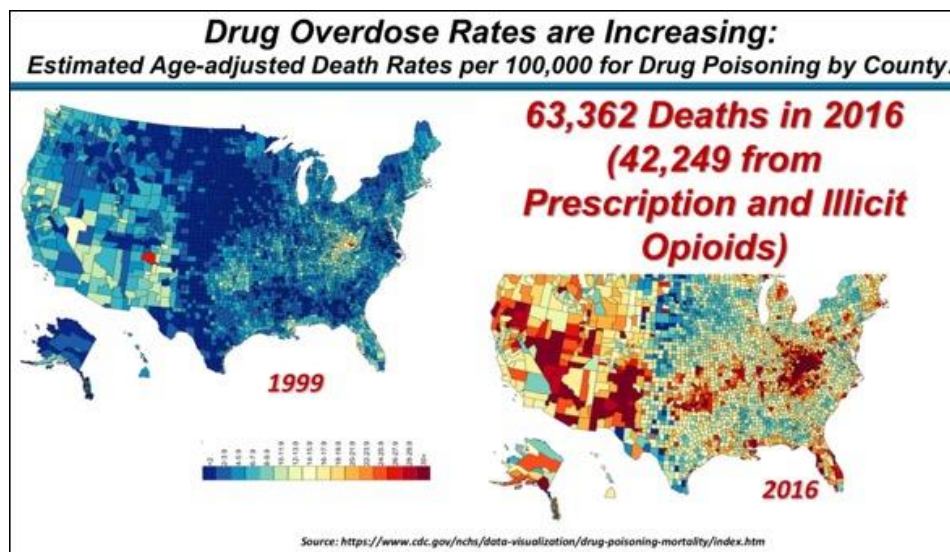
### Business Update

#### *KOL Event Highlights Addiction Problems and Treatments*

On May 10, 2018, Opiant Pharmaceuticals, Inc. (OPNT) held a key opinion leader (KOL) event on Medications for Addictions and Related Disorders. Below we provide some of the highlights from each of the talks. Interested investors can view the full presentations [here](#).

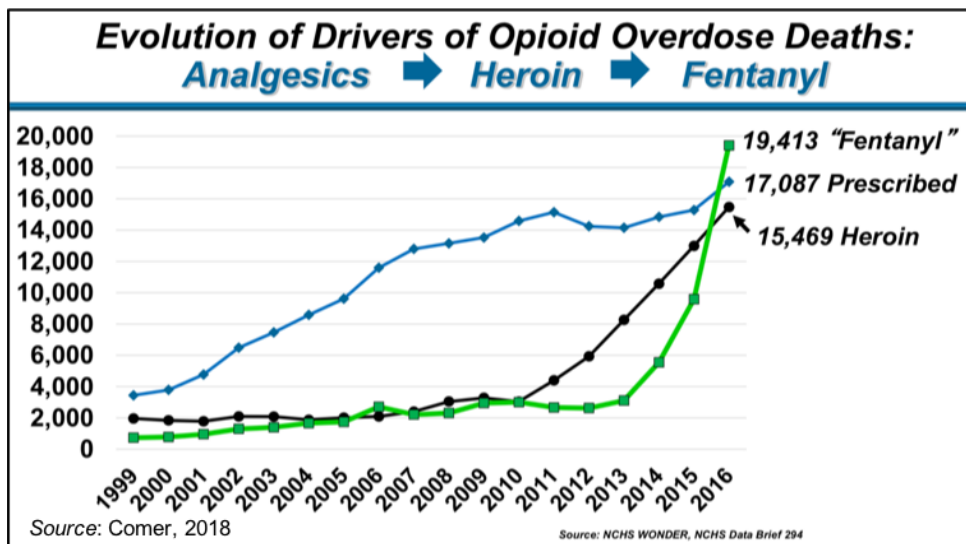
#### Dr. Sandra Comer

Dr. Comer is a Professor of Neurobiology in the Department of Psychiatry at the College of Physicians and Surgeons at Columbia University. Her talk was titled "The Opioid Epidemic: How We Got Here, What We Know and What We Don't Know". Dr. Comer began her talk with an overview of the epidemiology of the opioid epidemic. The following graphic shows the startling increase in drug overdose deaths from 1999 to 2016.



Source: Comer, 2018

A look at the opioid overdose deaths since 1999 shows an evolution in the driving force behind those deaths, with a steady increase in prescription overdose deaths and the incredibly sharp rise in deaths from heroin (since 2010) and fentanyl (since 2014).



The reason for the rapid rise in fentanyl deaths is multifactorial and includes the potency of the drug in comparison to morphine and heroin. This is best exemplified by the following picture, which shows the lethal dose of heroin compared to fentanyl.



Lethal Doses of Heroin and Fentanyl

Moving on to potential treatments for fentanyl, Dr. Comer stated that one of the problems with fentanyl is that it is a highly efficacious opioid agonist, thus it is difficult to treat with buprenorphine, which is effective in treating heroin addiction. However, both naloxone and naltrexone could be effective blockers of fentanyl activity at higher doses than what would be necessary for heroin treatment. Unfortunately, the dose of fentanyl used by drug addicts (which is almost exclusively from non-prescription fentanyl) is unknown, thus making it difficult to determine a proper dose of an opioid antagonist to treat an overdose.

Researchers are also unsure whether higher doses of naloxone are necessary to reverse fentanyl-induced respiratory depression. Dr. Comer stated that treatment centers across the country are saying the standard doses of naloxone aren't effective in fentanyl overdoses. However, there are multiple reasons this could be the case such as the dose of naloxone just isn't high enough, the person is already dead by the time the naloxone is administered, or it could be a fentanyl derivative that naloxone is ineffective against and about which nothing is known.

A particular fentanyl derivative of interest is carfentanil, which is approved for use as a tranquilizer in large animals (e.g., elephants). However, this drug is also being sold on the streets and it is 10,000 times more potent than heroin! Dr. Comer stated that a recent drug confiscation in Canada resulted in the seizure of enough carfentanil to kill that country's entire population.

Dr. Comer finished her talk by stating that additional research is necessary in ways to increase the effectiveness of existing medications, discover new medications, and develop new approaches such that the opioid crisis currently ongoing can be brought under control.

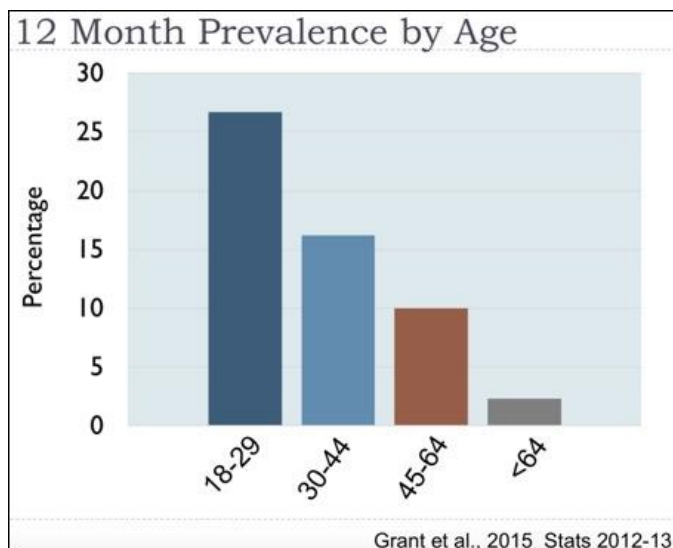
#### Dr. Stephanie O'Malley

Dr. O'Malley is a Professor and the Deputy Chair for Clinical Research in the Department of Psychiatry at the Yale University School of Medicine. Her talk focused on the epidemiology of alcohol use disorder (AUD), the consequences of AUD, current treatments, and guidance for drug development.

Dr. O'Malley began her talk with a general overview of AUD. Just as with other drugs, AUD involves compulsive drug seeking and the loss of control over the use of alcohol. Withdrawal symptoms associated with AUD include racing heartbeat, nausea, and (in severe cases) seizures. The development of AUD is dictated by various genetic, psychological, and social factors.

AUD is very prevalent as approximately 29% of the U.S. population has a history of AUD and in the past year approximately 14% of the population met the criteria for a diagnosis of AUD. The rates of AUD are higher in men than women, however the rate in women is not insignificant. The following graphic shows that the highest rate of AUD is found in young adults. Dr. O'Malley stated that most of those patients will grow out of the condition, but she

believes that treatment should still be targeted to younger individuals than it currently is, as the majority of the patients she treats in her clinic are in their 40's.



There are approved medications for the treatment of AUD. Disulfiram interferes with the metabolism of alcohol and prevents the degradation of acetaldehyde. Thus, if someone drinks after taking disulfiram they get very sick. It is used to maintain abstinence from alcohol. Acamprosate is thought to dampen heightened glutamatergic activity during withdrawal and is also used for the maintenance of abstinence. Naltrexone is an opiate antagonist approved for both oral and injectable use. It is used to reduce the risk of heavy drinking.

The efficacy of naltrexone in treating AUD was examined through a Cochrane review of over 50 studies that contained almost 7,800 patients. It concluded that naltrexone reduced the risk of heavy drinking compared to placebo by 83%, it decreased drinking days by 4% compared to placebo, and reduced the amount of alcohol consumed by 10%.

Dr. O'Malley then discussed the advantages of using opioid antagonists to treat AUD. Most importantly, opioid antagonists do not lead to addiction or withdrawal, which is important when considering they are being used in populations already pre-disposed to addictive behavior. In addition, there is no risk of overdosing, no evidence for an increase in depression or suicidality, and it is well tolerated.

Lastly, Dr. O'Malley mentioned that the FDA has released draft guidance for developing drugs intended for the treatment of AUD. According to those guidelines, the FDA is allowing for abstinence and no heavy drinking days to be considered as trial outcomes, as both of those are associated with how the patient feels and functions.

#### Dr. Susan McElroy

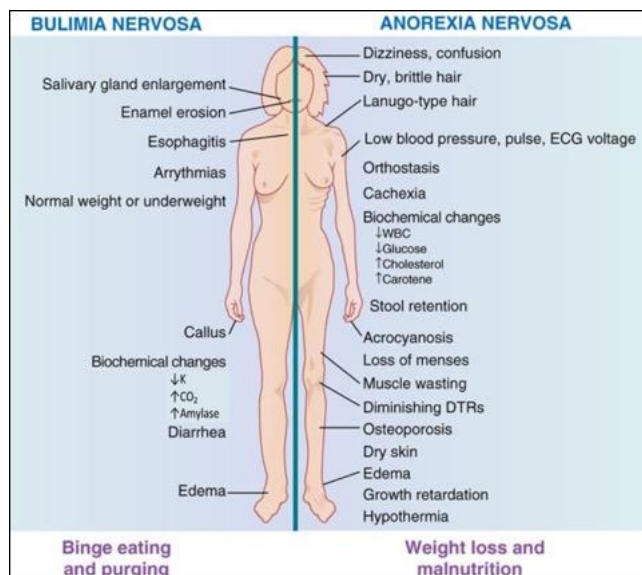
Dr. McElroy is the Chief Research Officer of the Lindner Center of HOPE and a Professor of Psychiatry and Neuroscience at the University of Cincinnati College of Medicine. Her talk provided an overview of eating disorders with a focus on bulimia nervosa and binge eating disorder, the causes of BN and BED, current treatments for BN and BED, and the use of intranasal opioid antagonists as treatments for BN and BED.

The presentation began with Dr. McElroy defining what an "eating binge" is, since she stated that a number of people, including those in the eating disorder field, do not have a clear understanding of the definition. A binge is eating an unusually large amount of food considering the situation and there is a sense of a loss of control over the eating. It is a very psychologically painful situation.

The epidemiology of eating disorders shows that the estimated lifetime prevalence of BN is at least 1% while for BED it is at least 3%. Dr. McElroy stressed that those data are based upon the DSM-IV classification system, which in her opinion was too rigid. She stated that it is easier to get an eating disorder diagnosis according to the DSM-5 criteria, thus she believes that the actual prevalence of these conditions is much higher. All eating disorders are associated with increased morbidity while BN is associated with increased mortality.

BN is caused by recurrent binge eating episodes followed by recurrent inappropriate compensatory behavior to prevent weight gain (e.g., self-induced vomiting, misuse of laxatives, excessive exercises). In order to be diagnosed with BN the binge eating and inappropriate compensatory behaviors must occur at least once a week for three months. BED is similar to BN but without the compensatory behaviors.

There are a whole host of medical complications that arise from eating disorders, some of which are shown in the following chart for BN and anorexia nervosa (AN). Dr. McElroy stated that it is scary to treat patients with eating disorders because there are so many different side effects that could ultimately lead to death.



Source: McElroy, 2018

At this point it is unknown what causes eating disorders. Twin studies suggest that genetic factors play a key role, possibly up to 40-70% of the cause. There are also environmental factors such as food addictions, which are more prevalent in our society since there is such a wide variety and amount of food available. Lastly, there are several neurotransmitter dysfunctions that are associated with eating disorders, such as dopamine function and the endogenous opioid system.

Counseling and nutritional education are the mainstay for treatment, however most patients also receive psychiatric medication. Only two medications have been approved for the treatment of eating disorders, fluoxetine for BN and lisdexamfetamine for moderate to severe BED. Neither treatment is wholly effective and lisdexamfetamine has the potential for abuse.

The endogenous opioid system is involved in eating behavior and binge eating in animal models as shown by the ability of opioid antagonists to block binge eating in animals. However, randomized controlled trials of oral naltrexone in BN and two other agents in BED (ALKS-33 and GSK1521498) were negative. Dr. McElroy believes this may be due to the fact that BN and BED patients often need higher doses due to differences in dose response between those patients and healthy individuals. Large doses of naltrexone (200-400 mg/day) have been reported to reduce binge eating in patients, however those doses are associated with liver toxicity. Thus, Dr. McElroy wonders if opioid antagonists would work if delivered intranasally (to deliver high concentrations in the brain) in order to reduce the chance for toxic side effects.

#### *Opiant Receives \$7.4 Million Grant to Fund OPNT003 Development*

On April 18, 2018, Opiant [announced](#) the receipt of a \$7.4 million grant from the National Institute on Drug Abuse (NIDA) to fund the development of OPNT003, a long-lasting opioid antagonist for the treatment of opioid overdose. OPNT003 is an intranasal formulation of nalmefene, a naltrexone derivative. Based on its favorable pharmacokinetic profile, we believe OPNT003 could become a novel opioid overdose treatment, particularly for overdoses caused by synthetic opioids such as fentanyl and its derivatives.

Synthetic opioids such as fentanyl and carfentanil are particularly problematic due to their potency and longer half-lives. For example, heroin has a half-life of approximately 30 minutes while fentanyl's half-life is two to four hours, thus necessitating opioid antagonism for an extended period of time. Naloxone has a half-life of approximately 1-2

hours and typically requires repeated administration during the treatment of someone suffering from a fentanyl overdose.

Nalmefene is an opioid antagonist with a much longer half-life than naloxone (7-9 hours). It was approved by the FDA in 1995 as an injectable treatment for opioid overdose sold under the brand name Revex<sup>®</sup>, however Baxter discontinued it in the U.S. in 2008. Opiant has developed an intranasally administered nalmefene formulation using the Intravail<sup>®</sup> technology, which was developed by Aegis Therapeutics, LLC. It comprises a broad class of chemically synthesizable transmucosal absorption enhancement agents to allow the intranasal (although other routes of administration are available including oral, rectal, ocular, etc.) administration of therapeutics up to 30,000 Daltons molecular weight.

Opiant has successfully completed a Phase 1 study of intranasally administered nalmefene that showed rapid increases in plasma levels with an onset faster than an intramuscular injection along with a long half-life (6.7-7.8 hours). These data formed the basis for a meeting with the FDA regarding the planned development of OPNT003. Based on the guidance received from the FDA, Opiant believes it will be in a position to file an NDA in 2020.

Opiant owns all commercial rights to OPNT003 and the company's prospects for partnering remain wide open at this point. We believe that if the company were to enter into a commercialization partnership it would be able to command favorable terms given the commercial success of NARCAN<sup>®</sup> Nasal Spray and the company's strong financial position.

### **Financial Update**

On May 7, 2018, Opiant announced financial results for the first quarter of 2018. The company recorded approximately \$1.7 million in revenue for the first quarter of 2018 compared to \$11,000 during the corresponding three months of 2017. The increase was due to the recognition of \$1.6 million in royalty revenue from Adapt Pharma. Based upon the agreement with Adapt and the fact that Opiant receives 90% of royalty income we estimate that Adapt sold approximately \$30.5 million worth of NARCAN<sup>®</sup> Nasal Spray in the first quarter of 2018. G&A expenses for the first quarter of 2018 were \$3.0 million compared to approximately \$1.9 million for the corresponding period of 2017. The increase was primarily due to increased stock-based compensation and professional fees. R&D expenses totaled \$2.4 million for the first quarter of 2018 compared to \$0.9 million for the corresponding period of 2017. The increase was primarily due to increased share-based compensation. Opiant was required to pay \$5.6 million in the first quarter of 2018 for a license fee related to the License Agreement with Adapt. We anticipate this being a one-time charge. Net loss for the first quarter of 2018 was \$9.3 million, or \$3.68 per share, compared to a net loss of \$2.8 million, or \$1.39 per share, for the comparable period of 2017. The increase was mostly due to the \$5.6 million license fee payment to Adapt.

As of March 31, 2018, Opiant had approximately \$11.3 million in cash and cash equivalents, which we believe will be enough to fund operations for at least the next 12 months. As of May 4, 2018, the company had approximately 2.7 million shares outstanding and when factoring in options and warrants a fully diluted share count of approximately 5.9 million.

### **Conclusion**

The KOL event provided a nice overview of the disorders that Opiant is targeting and we encourage investors to listen to the entire event. The information on the opioid crisis was particularly interesting and lends support to the idea that additional opioid overdose treatments are needed. We will be following the development of OPNT003 closely, and with a \$7.4 million grant from NIDA the company has that project funded through the filing of the NDA.

Our initial estimate of 2018 sales for NARCAN<sup>®</sup> Nasal Spray was \$125 million, and we are sticking with this following estimated sales in the first quarter of 2018 of \$30.5 million. Based on \$125 million in sales for NARCAN<sup>®</sup> Nasal Spray we calculate Opiant would receive approximately \$8.7 million in royalties for 2018.

Based on our probability adjusted discounted cash flow model that takes into account potential future revenues from royalties for NARCAN<sup>®</sup> Nasal Spray and revenues from OPNT003, OPNT001 in BN, and OPNT002 in AUD our current valuation stands at \$55 per share.

## PROJECTED FINANCIALS

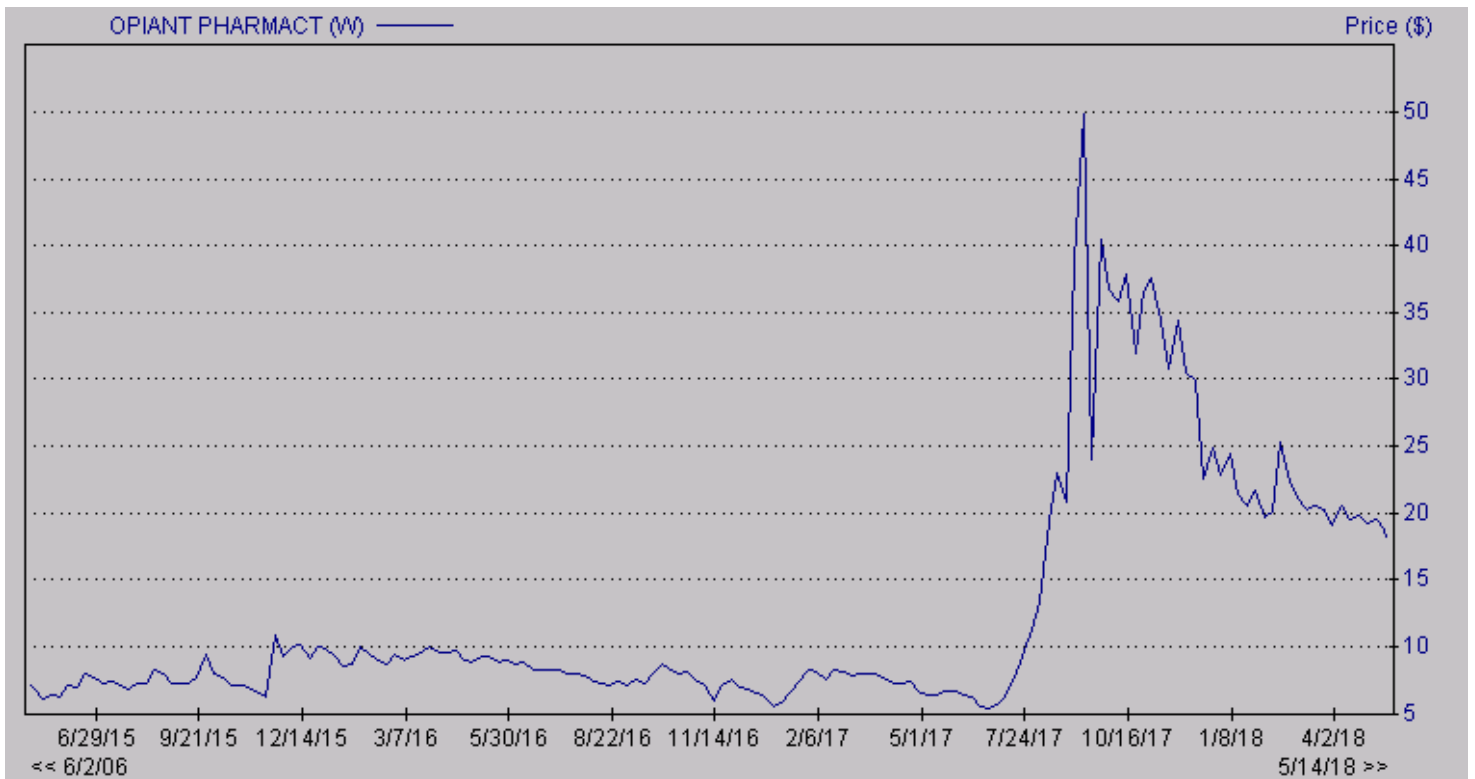
### Opiant Pharmaceuticals, Inc. Income Statement

Opiant Pharmaceuticals, Inc.	Five Months Ending Dec-17	1Q18 A	2Q18 E	3Q18 E	4Q18 E	2018 E	2019 E	2020 E
NARCAN royalty	\$11.7	\$1.6	\$2.1	\$2.4	\$2.6	\$8.7	\$13.2	\$37.0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
OPNT003	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Binge Eating Disorder	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Bulimia Nervosa	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Licensing, Milestones, and Grants	\$0.1	\$0.1	\$0.0	\$0.0	\$0.0	\$0.1	\$0.0	\$0.0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
<b>Total Revenues</b>	<b>\$11.8</b>	<b>\$1.7</b>	<b>\$2.1</b>	<b>\$2.4</b>	<b>\$2.6</b>	<b>\$8.8</b>	<b>\$13.2</b>	<b>\$37.0</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
Research & Development	\$2.5	\$2.4	\$2.5	\$2.5	\$2.5	\$9.9	\$10.0	\$10.0
General & Administrative	\$5.9	\$3.0	\$3.0	\$3.0	\$3.0	\$12.0	\$12.0	\$12.5
Selling Expenses	\$0.4	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$1.0	\$1.0
Other Expenses	\$1	\$5.6	\$0	\$0	\$0	\$0	\$0	\$0
Operating Income	\$1.5	(\$9.3)	(\$3.4)	(\$3.1)	(\$2.9)	(\$13.1)	(\$9.8)	\$13.5
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.0	(\$0.0)	\$0.0	\$0.0	\$0.0	(\$0.0)	\$0.0	\$0.0
Pre-Tax Income	\$1.5	(\$9.3)	(\$3.4)	(\$3.1)	(\$2.9)	(\$13.1)	(\$9.8)	\$13.5
Income Taxes Paid	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
<b>Net Income</b>	<b>\$1.4</b>	<b>(\$9.3)</b>	<b>(\$3.4)</b>	<b>(\$3.1)</b>	<b>(\$2.9)</b>	<b>(\$13.1)</b>	<b>(\$9.8)</b>	<b>\$13.5</b>
<i>Net Margin</i>	-	-	-	-	-	-	-	-
<b>Reported EPS</b>	<b>\$0.66</b>	<b>(\$3.68)</b>	<b>(\$1.26)</b>	<b>(\$1.11)</b>	<b>(\$1.00)</b>	<b>(\$5.04)</b>	<b>(\$3.92)</b>	<b>\$4.50</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.1	2.5	2.7	2.8	2.9	2.6	2.5	3.0

Source: Zacks Investment Research, Inc.  
PhD

David Bautz,

## HISTORICAL STOCK PRICE





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