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November 8, 2018
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Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: Data from Phase 2 Study of OPNT001 in Bulimia Nervosa in 1Q19…

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 $52/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 (11/08/18)	$17.35
Valuation	**$52.00**

OUTLOOK

On November 7, 2018, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the third quarter of 2018. The company reported revenue of $4.4 million, which included $4.2 million in royalty revenue from the sale of NARCAN® Nasal Spray. By our calculations, Adapt Pharma sold approximately $48.5 million of NARCAN® Nasal Spray in the third quarter of 2018. We continue to estimate 2018 sales of NARCAN® Nasal Spray of $180 million.

The company recently announced the last patient visit in the Phase 2 trial of OPNT001 in bulimia nervosa and we continue to anticipate topline results in the first quarter of 2019. In October 2018, Opiant's collaborators were awarded an NIH grant to advance OPNT005, a heroin vaccine candidate, through Phase 1/2a safety and efficacy trials.

SUMMARY DATA

52-Week High	**$35.99**
52-Week Low	**$12.89**
One-Year Return (%)	**-51.78**
Beta	**0.34**
Average Daily Volume (sh)	**30,577**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$52**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**5**
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	3.2 A	4.4 A	5.2 E	14.8 E
2019					40.8 E
2020					30.6 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	-$0.52 A	-$0.32 A	-$0.08 E	-$2.27 E
2019					$4.70 E
2020					$1.88 E

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WHAT'S NEW

Business Update

Bulimia Nervosa Trial Fully Enrolled

On November 5, 2018, Opiant Pharmaceuticals, Inc. (OPNT) announced that the last patient has completed their last visit in the Phase 2 trial of OPNT001, a naloxone nasal spray, in bulimia nervosa (BN). BN is a serious and potentially life-threatening eating disorder characterized by a cycle of binge eating and purging. BN affects approximately 1-2% of the adult population with 80% of those affected being female. Complications of BN include dehydration, heart problems, severe tooth decay and gum disease, anxiety and depression, and increased risk of suicide.

The only pharmacological agent approved to treat BN is fluoxetine (Prozac®). Two multicenter, double blind, placebo controlled randomized clinical trials of fluoxetine found that a 60 mg dose resulted in a statistically significant reduction in binge eating and vomiting episodes compared to placebo regardless of whether a patient was also suffering from depression, while a 20 mg dose of fluoxetine was only effective in those that did not also have depression (Goldstein *et al*., 1999). While effective, fluoxetine has a number of potential adverse side effects including increased suicidal thoughts, sleep problems, headache, dizziness, and gastrointestinal issues.

The randomized, double blind, placebo controlled Phase 2 clinical trial of OPNT001 enrolled 86 patients at 19 clinical sites in the United Kingdom who have been diagnosed with BN. The study will evaluate OPNT001's safety and tolerability as well as its impact on various clinical outcomes, including change in eating behavior. The primary endpoint of the study is a reduction in binge eating days. We anticipate topline results in the first quarter of 2019.

Opiant Awarded $4.6 Million Contract for OPNT003

On September 20, 2018, Opiant announced it has entered into a $4.6 million contract with the Biomedical Advanced Research and Development Authority (BARDA), which is part of the U.S. Health and Human Services Office of the Assistant Secretary for Preparedness and Response. The contract is intended to speed up development of OPNT003, the company's lead product candidate. OPNT003 is a nasally administered formulation of nalmefene, a potent and long-acting opioid antagonist that is currently being developed as a treatment for opioid overdose. The BARDA contract is designed to cover those expenses that are not covered by the previously announced $7.4 million grant from the National Institute on Drug Abuse (NIDA).

Potential for OPNT003 as a Chemical Warfare Antidote

The BARDA contract signifies the government's potential interest in utilizing nalmefene as a treatment in the event of a chemical attack using a synthetic opioid. While not traditionally thought of as the basis for a chemical warfare attack, powerful opioids could certainly be utilized to inflict a mass casualty event. The basis for this idea comes from an event in Russia 15 years ago in which an aerosolized synthetic opioid, likely a derivative of fentanyl, was utilized in an attempt to rescue hostages that were being held by Chechen rebels in the Moscow Dubrovka Theatre (Wax *et al*., 2003).

On October 23, 2002, approximately 800 people attending a theatre show were taken hostage by Chechen rebels. The rebels had rigged the theatre with explosives and threatened to blow it up unless their demands were met. On the morning of October 26, 2002, the Russian government pumped an unidentified gas into the theatre approximately 30 minutes before staging a siege. 127 hostages died during the rescue operation, and 650 others required hospitalization. Four days after the siege, the Russian Health Minister announced that a fentanyl derivative was used to neutralize the terrorists, however the true identity of the chemical(s) used during the raid are still unknown due to the Russian governments unwillingness to provide that information. The hospitalized hostages all showed signs of opioid overdose, thus it is reasonable to conclude that if treating physicians had been instructed to administer opioid antagonists early on many more deaths could have been prevented.

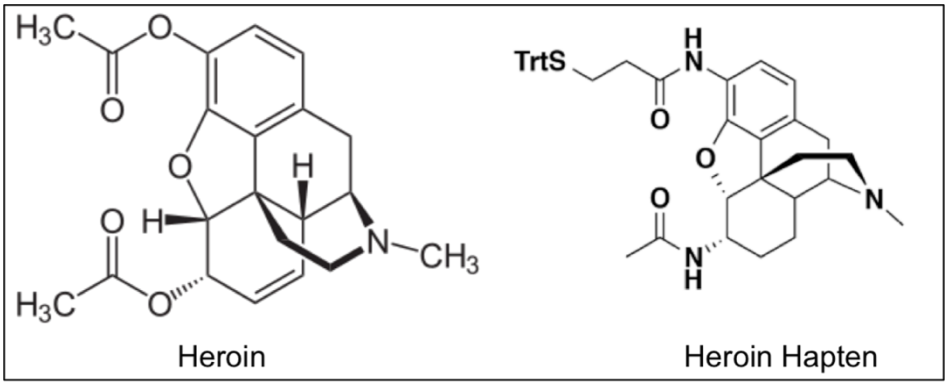
While this example is of the use of a synthetic opioid agent to try to neutralize terrorists and rescue hostages, it would certainly not be much of a stretch to consider how a synthetic opioid agent could be used in a chemical warfare attack by terrorists or rogue nations. Thus, we believe the U.S. government is potentially interested in

stockpiling a powerful opioid antagonist, such as OPNT003, as an antidote against a future chemical attack involving a synthetic opioid.

Grant for Development of Heroin Vaccine

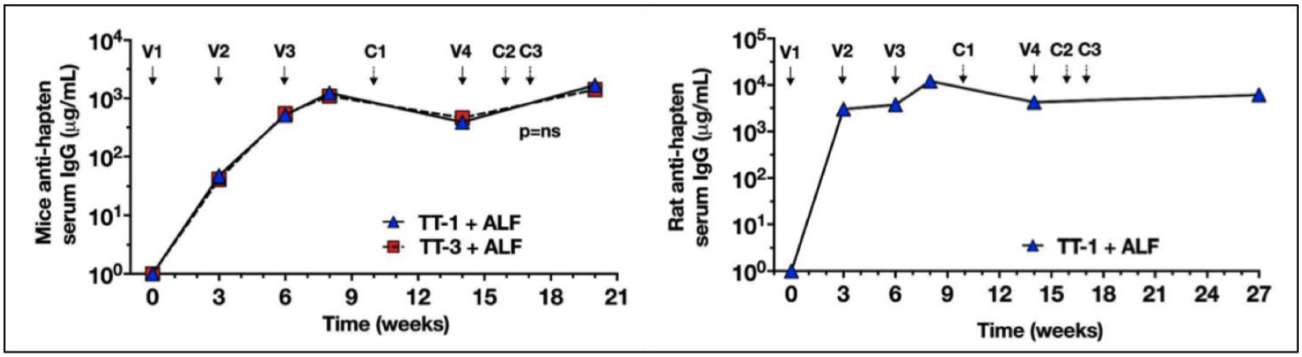
On October 18, 2018, Opiant announced that researchers at the U.S. Military HIV Research Program (MHRP) at the Walter Reed Army Institute of Research (WRAIR) and SUNY Upstate Medical University have been awarded a grant by the NIH to advance the development of OPNT005, a heroin vaccine candidate, through Phase 1/2a clinical trials. The approximately $3.7 million grant will fund production and preliminary safety testing of OPNT005. Assuming those actions are successful, the grant will fund a clinical trial evaluating the efficacy of OPNT005 in healthy volunteers.

Last year, Opiant announced the publication of preclinical results for OPNT005 (Sulima *et al*., 2017). The results describe the synthesis of a haptogenic heroin surrogate (shown in the figure below) that was used to immunize rodents.



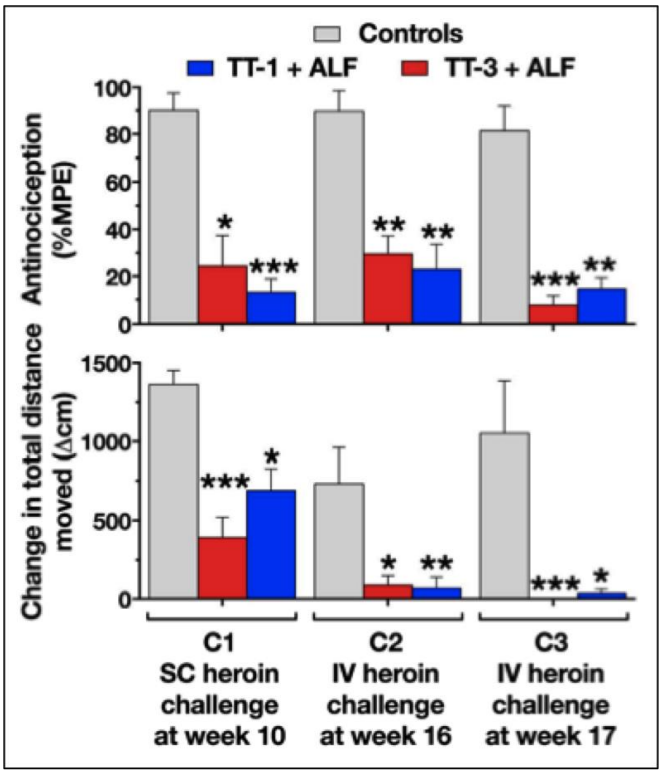
Source: Wikipedia / Sulima *et al*., 2017

The hapten was conjugated to tetanus toxoid (TT) and administered with Army Liposome Formulation (ALF) as an adjuvant. Two different conjugations were performed and are denoted as TT-1 and TT-3. Following immunization, the rodents developed a high titer of anti-hapten IgG antibodies that reduced the physiologic effects of repeated subcutaneous administrations of heroin. The following graphs show that both mice and rats developed similar levels of anti-hapten antibodies that persisted following four total immunizations (indicated by V1-V4). C1-3 denote when the mice were challenged with heroin.



Source: Sulima *et al*., 2017

The following figure shows the results of administering heroin both subcutaneously (SC) and intravenously (IV) to control mice as well as those administered haptens TT-1 or TT-3. The top panel shows a statistically significant decrease in heroin-induced antinociception in the tail flick assay for mice administered TT-1 or TT-3, while the bottom panel shows a statistically significant decrease in heroin-induced hyperlocomotion as judged by the total distance moved.



Source: Sulima *et al.*, 2017

These results are encouraging as they show the development of a high titer of antibodies along with protection from heroin challenges. The antibodies were shown to cross-react with heroin as well as its metabolites (6-AM, morphine, and M-6G) while not showing reactivity to drugs that are used for opioid abuse therapy (methadone, buprenorphine, naloxone, and naltrexone).

Strengthens Board of Directors

On October 29, 2018, Opiant announced the appointment of Craig A. Collard to the Board of Directors. Mr. Collard is currently serving as the CEO of Veloxis Pharmaceuticals A/S, which is a commercial-stage pharmaceutical company that markets a drug to prevent organ transplant rejection. Previously, Mr. Collard was Founder, Chairman, and CEO of Cornerstone Therapeutics, Inc., which was ultimately sold to Chiesi Farmaceutici S.p.A. for more than $250 million. We believe his expertise in business development and commercialization of drugs makes him a valuable addition to Opiant's Board.

Financial Update

On November 7, 2018, Opiant announced financial results for the third quarter of 2018. The company recorded approximately $4.4 million in revenue (royalty payments from Adapt Pharma comprised approximately $4.2 million of that amount for the third quarter of 2018 compared to $22 thousand for the third quarter of 2017. Based upon the agreement with Adapt and the fact that Opiant receives 90% of royalty income we estimate that Adapt sold approximately $48.5 million worth of NARCAN® Nasal Spray in the third quarter of 2018.

G&A expenses for the third quarter of 2018 were $3.4 million compared to $2.2 million for the third quarter of 2017. The increase was due to increased stock based compensation and general corporate expenses. R&D expenses were $1.9 million for the third quarter of 2018 compared to $0.7 million for the third quarter of 2017. The increase was due to increased clinical trial expenses, personnel expenses, and stock based compensation. Net loss for the third quarter of 2018 was $0.9 million, or $0.32 per share, compared to a net loss of $3.4 million, or $1.68 per share, for the third quarter of 2017.

As of September 30, 2018, Opiant had approximately $24.8 million in cash and cash equivalents, which was due in part to a public offering in September 2018 that resulted in net proceeds to the company of approximately $12.7 million from the sale of 811,764 shares of common stock at an offering price of $17 per share. As of Nov. 5, 2018, the company had approximately 3.8 million shares of common stock and when factoring in options and warrants a fully diluted share count of approximately 7.2 million.

Conclusion

Since most investors are focused on the potential for NARCAN® Nasal Spray and OPNT003 given the nation's current opioid epidemic, we believe that OPNT001 offers additional upside for the company that may not be fully appreciated. We conservatively model for peak sales of OPNT001 of over $300 million and believe that number could be increased depending upon the strength of the Phase 2 results. Our valuation currently stands at $52 per share, however the stock continues to trade at a significant discount to our valuation, which could represent a nice buying opportunity ahead of the Phase 2 BN data next year.

PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	Five Months Ending Dec-17	1Q18 A	2Q18 A	3Q18 A	4Q18 E	2018 E	2019 E	2020 E
NARCAN royalty	$11.7	$1.6	$3.1	$4.2	$4.6	$13.5	$34.3	$26.2
YOY Growth	-	-	-	-	-	-		
OPNT003	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-		
Binge Eating Disorder	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-		
Bulimia Nervosa	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-		
Licensing, Milestones, and Grants	$0.1	$0.1	$0.1	$0.2	$0.6	$0.9	$6.5	$4.4
YOY Growth	-	-	-	-	-	-		
Total Revenues	**$11.8**	**$1.7**	**$3.2**	**$4.4**	**$5.2**	**$14.4**	**$40.8**	**$30.6**
YOY Growth	-	-	-	-	-	-		
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-		
Research & Development	$2.5	$2.4	$1.6	$1.9	$2.5	$8.4	$10.0	$10.0
General & Administrative	$5.9	$3.0	$2.9	$3.4	$3.0	$12.2	$12.0	$12.5
Selling Expenses	$0.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Expenses	$1	$5.6	$0	$0	$0	$0	$0	$0
Operating Income	$1.5	($9.3)	($1.3)	($0.9)	($0.3)	($6.2)	$18.8	$8.1
Operating Margin	-	-	-	-	-	-		
Non-Operating Expenses (Net)	$0.0	($0.0)	($0.1)	$0.0	$0.0	($0.1)	$0.0	$0.0
Pre-Tax Income	$1.5	($9.3)	($1.4)	($0.9)	($0.3)	($6.3)	$18.8	$8.1
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**$1.4**	**($9.3)**	**($1.4)**	**($0.9)**	**($0.3)**	**($6.3)**	**$18.8**	**$8.1**
Net Margin	-	-	-	-	-	-		
Reported EPS	**$0.66**	**($3.68)**	**($0.52)**	**($0.32)**	**($0.08)**	**($2.27)**	**$4.70**	**$1.88**
YOY Growth	-	-	-	-	-	-		
Basic Shares Outstanding	2.1	2.5	2.7	2.9	3.8	2.8	4.0	4.3

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

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