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March 25, 2019
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Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: Strong Revenue Growth for NARCAN® Nasal Spray…

Based on our probability adjusted DCF model that takes into account potential future revenues from opioid antagonists, alcohol use disorder, and acute cannabinoid overdose (ACO) treatments, OPNT is valued at $44/share. This model is highly dependent upon the commercial and clinical success of opioid antagonists and clinical success in treating eating disorders and ACO.

Current Price (03/25/19)	$13.15
Valuation	**$44.00**

OUTLOOK

On March 21, 2018, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the fourth quarter and full year 2018. The company reported revenue of $4.8 million, which included $4.4 million in royalty revenue from the sale of NARCAN® Nasal Spray. By our calculations, NARCAN® Nasal Spray sales totaled $177.5 million. In February 2019, Emergent Biosciences, Inc. reaffirmed previous guidance for net NARCAN® sales of $200-$220 million in 2019, and on the conference call to discuss fourth quarter results management indicated it will likely come in at the higher end of that range. We are maintaining our 2019 estimate for gross sales of NARCAN of $250 million, which would lead to $15.5 million in net royalty payments to Opiant, which includes the subtraction of third-party license fees.

SUMMARY DATA

52-Week High	**$23.43**
52-Week Low	**$12.89**
One-Year Return (%)	**-35.16**
Beta	**0.57**
Average Daily Volume (sh)	**26,616**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$52**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
Insider Ownership (%)	**38**
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	**Above Avg.**
Type of Stock	**Small-Blend**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	1.7 A	3.2 A	4.4 A	4.8 A	14.0 A
2019	1.9 E	3.3 E	5.5 E	6.9 E	17.5 E
2020					40.0 E
2021					35.3 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$3.68 A	$0.52 A	-$0.32 A	-$2.72 A	-$7.10 A
2019	-$0.88 E	-$0.53 E	-$0.02 E	$0.29 E	-$1.08 E
2020					$4.07 E
2021					$2.51 E

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WHAT'S NEW

Financial Update

On March 21, 2019, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the fourth quarter and full year 2018. For the fourth quarter of 2018, Opiant reported total revenue of $4.8 million, with $4.4 million of revenue from the license agreement with Adapt Pharma for the sale of NARCAN® Nasal Spray. For 2018, Opiant had total revenues of $14.0 million, which included $13.3 million of revenue from the sale of NARCAN® Nasal Spray. Opiant is owed royalties on NARCAN® sales based upon an agreement signed with Adapt in 2014. Adapt was acquired by Emergent BioSolutions, Inc. (EBS) earlier in 2018 for $635 million. Opiant receives 90% of the royalty payment from Emergent, with the other 10% going to SWK Holdings Corporation based on the agreement signed in 2016, with royalties paid out according to the following table (based on yearly sales).

Net Sales of NARCAN® Nasal Spray	Royalty Rate
<$50 Million	6%
≥$50 Million < $75 Million	7.5%
≥$75 Million < $100 Million	9%
≥$100 Million < $200 Million	10%
≥$200 Million	12%

Source: Opiant SEC Filing

Based on the royalties received by Opiant, we estimate that sales of NARCAN® Nasal Spray in 2018 totaled $177.5 million. In February 2019, Emergent reaffirmed 2019 net sales guidance for NARCAN® of $200-$220 million, net of royalty payments to Opiant. Thus, we are maintaining our estimate for gross revenues of approximately $250 million in 2019 for NARCAN®, which would result in Opiant receiving approximately $15.5 million in net royalties. We estimate that Opiant would receive a $13.5 million net milestone payment due to the company upon sales exceeding $200 million for the first time in a calendar year in the first quarter of 2020. Opiant owes $8.1 million due to a third-party license agreement entered into between Adapt and another company, with $5.4 million to be deducted from royalties and the remaining $2.7 million deducted from the $13.5 million milestone payment. Our $15.5 million in estimated royalties takes into account the $5.4 million deduction for the license fee.

Net loss for 2018 was approximately $21.2 million, or $7.10 per share, compared to a net loss of $2.6 million, or $1.28 per share, for the year ended Dec. 31, 2017. For 2018, G&A expenses totaled $11.3 million, compared to $10.3 million in 2017. The increase was primarily due to increased stock-based compensation and external marketing research costs partially offset by a decrease in personnel expense. R&D expenses totaled $8.5 million in 2018 compared to $4.9 million in 2017. The increase was primarily due to increased third-party research expenses, stock-based compensation, and personnel expenses. Royalty expenses were $1.5 million and $1.4 million in 2018 and 2017, respectively, and are related to NARCAN® sales and milestone payments. There was a $13.7 million license fee recorded in 2018, of which $5.6 million was paid and $8.1 million is due to be paid, as discussed previously. Selling expenses decreased by $0.6 million to $0.2 million in 2018 compared to 2017.

Opiant exited 2018 with approximately $24.6 million in cash and cash equivalents, which does not include the remaining amounts due from the NIDA grant of approximately $7.4 million and the BARDA contract of approximately $4.6 million. We forecast that the company will have approximately $17-$20 million in cash and cash equivalents at the end of 2019.

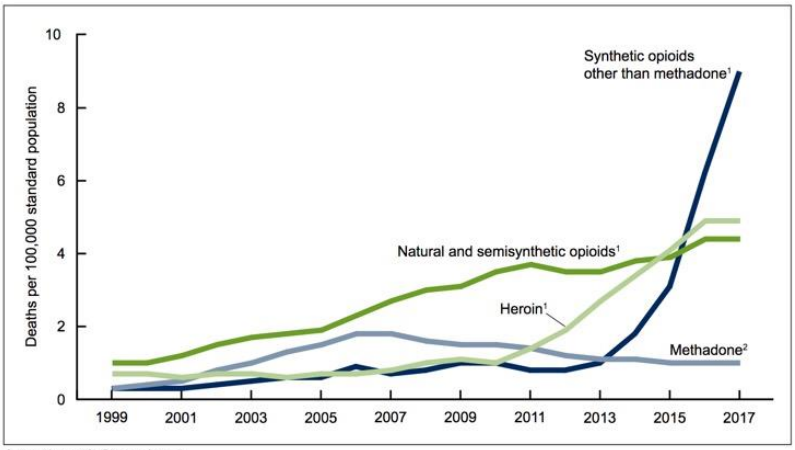
Business Update

OPNT003 Update

Opiant is currently developing OPNT003, an intranasal formulation of nalmefene (a naltrexone derivative), as a long-lasting opioid antagonist for the treatment of opioid overdose. In 2018, Opiant received a $7.4 million grant from the National Institute on Drug Abuse (NIDA) to fund development of OPNT003. In addition, in September 2018 Opiant received 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, which is intended to help fund development of OPNT003 through the new drug application (NDA) filing.

The following chart shows the number of overdose deaths in the U.S. from 1999 – 2017 from certain drugs, with the rapid rise in deaths from synthetic opioids just since 2013 particularly striking. This increase in synthetic opioid deaths has led the National Institutes of Health (NIH) to call for improved opioid antagonists that are capable of counteracting their effects (Volkow *et al*., 2017).



Source: Centers for Disease Control

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®, however Baxter discontinued it in the U.S. in 2008. Opiant has developed an intranasally administered nalmefene formulation using the Intravail® 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). The company is planning to conduct a pivotal pharmacokinetic study with top-line data expected later this year. We believe Opiant will be in a position to file an NDA for OPNT003 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® Nasal Spray and the company's strong financial position.

OPNT004 Update

In December 2018, Opiant announced the acquisition of drinabant, a novel CB-1 receptor antagonist, for the treatment of acute cannabinoid overdose (ACO). Opiant paid Sanofi an upfront payment of $500,000 and will be responsible for all development and commercialization activities.

ACO in adults, which typically occurs from the ingestion of marijuana edibles or the use of synthetic cannabinoids, can result in anxiety, nausea, agitation, and hallucinations. In children, in which the cause is almost always accidental ingestion of edibles, ACO can be more serious and present as lethargy, ataxia, hypoventilation, and possibly vomiting and seizures (Richards *et al*., 2017). ACO from edible marijuana is typically more pronounced due to the delayed onset from oral absorption, which can lead novice users to take additional edible products before the effects are felt. This can ultimately result in severe effects if left untreated, including reports of suicide from

marijuana-induced psychosis. Synthetic cannabinoids ("spice" or "K2") present a unique challenge due to their potency and the potential for neuropsychiatric and cardiovascular symptoms (Monte *et al*., 2014) along with the potential for death (Shanks *et al*., 2015).

Due to the legalization of marijuana in an increasing number of states, the rate of ACO is expected to rise from an estimated one million visits to the ER in 2016. In addition, there is evidence to suggest that ACO from the use of synthetic cannabinoids is increasing (Trecki *et al*., 2015).

Drinabant is one of a number of CB-1 receptor antagonists developed by pharmaceutical companies in the 2000's. These compounds were tested for a number of indications, including obesity, schizophrenia, Alzheimer's, and smoking cessation. Sanofi conducted multiple Phase 1 and 2 clinical trials with drinabant and has an extensive safety database on the oral administration of the drug. A study by the Center for Human Drug Research showed that orally administered drinabant inhibits the effect of ∆-9-tetrahydrocannabinol (THC), the major psychoactive component of cannabis (Zuurman *et al*., 2010). Although effective when administered orally, Opiant will be developing an injectable form of drinabant for use in treating ACO such that it can rapidly reverse the symptoms of the condition, which may not be possible with oral administration due to the drug's prolonged onset of action. Following reformulation of the drug in 2019, we anticipate clinical studies commencing in 2020.

Discontinuing OPNT001 in Bulimia Nervosa

On February 21, 2019, Opiant announced that the Phase 2 clinical trial of OPNT001 for the treatment of bulimia nervosa did not meet the primary endpoint of reducing the number of binging days from baseline to Week 8 and that the company will be discontinuing development of OPNT001 for that indication. OPNT001 was generally safe and well tolerated and had minimal adverse events and good patient compliance.

Conclusion

Opiant is in a strong financial position with the incoming royalties from the sale of NARCAN® Nasal Spray, particularly since Emergent recently reaffirmed guidance for 2019 sales of NARCAN® and stated that results are likely to come in at the top of that guidance. While disappointing that the Phase 2 results in bulimia nervosa were negative, that indication (along with binge eating disorder) only made up a small portion of our valuation. In addition, this allows for the company's resources to be directed toward conducting the pivotal trial for OPNT003, preparing for a Phase 2 study of OPNT002 in alcohol use disorder, and continuing the development of OPNT004. Based on the negative results in the bulimia nervosa trial we have removed it and binge eating disorder from our model. In addition, we made a slight correction to our estimated income for 2019 based on the license fee that is due. These changes have reduced our valuation slightly to $44 per share, however there is the potential for significant upside for investors as the stock continues to trade at a significant discount to that valuation.

PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	2018 A	1Q E	2Q E	3Q E	4Q E	2019 E	2020 E	2021 E
NARCAN royalty	$13.3	$1.4	$2.8	$5.0	$6.4	$15.5	$37.0	$32.3
YOY Growth	-	-	-	-	-	*17%*	*139%*	*-13%*
OPNT002	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
OPNT003	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
OPNT004	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Licensing, Milestones, and Grants	$0.7	$0.5	$0.5	$0.5	$0.5	$2.0	$3.0	$3.0
Total Revenues	**$14.0**	**$1.9**	**$3.3**	**$5.5**	**$6.9**	**$17.5**	**$40.0**	**$35.3**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Research & Development	$8.5	$2.0	$2.1	$2.2	$2.3	$8.6	$9.0	$10.0
General & Administrative	$11.3	$3.2	$3.2	$3.3	$3.3	$13.0	$13.5	$14.0
Selling Expenses	$0.2	$0.1	$0.1	$0.1	$0.1	$0.2	$0.0	$0.0
Royalty Expenses	$1.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
License Fees	$13.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($21.2)	($3.4)	($2.0)	($0.1)	$1.2	($4.3)	$17.5	$11.3
Non-Operating Expenses (Net)	$0.0	($0.0)	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($21.1)	($3.4)	($2.1)	($0.1)	$1.2	($4.3)	$17.5	$11.3
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	**($21.2)**	**($3.4)**	**($2.1)**	**($0.1)**	**$1.2**	**($4.3)**	**$17.5**	**$11.3**
Reported EPS	**($7.10)**	**($0.88)**	**($0.53)**	**($0.02)**	**$0.29**	**($1.08)**	**$4.07**	**$2.51**
Basic Shares Outstanding	3.0	3.9	4.0	4.0	4.1	4.0	4.3	4.5

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

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