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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: Encouraging Pharmacokinetic Data for OPNT003…

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 (05/13/19)	$11.76
Valuation	**$44.00**

OUTLOOK

In April 2019, Opiant Pharmaceuticals, Inc. (OPNT) announced data from a pilot pharmacokinetic (PK) study of OPNT003 (nasal nalmafene) was presented at the 2019 American Society for Pharmacology and Experimental Therapeutics Annual Meeting. The data show that intranasal nalmafene containing Intravail® results in very rapid and robust increases in nalmafene plasma levels comparable to intramuscular injection. The company is planning a pivotal PK study of OPNT003 set to initiate later in 2019 and we anticipate an NDA filing in 2020.

On May 9, 2019, Opiant announced financial results for the first quarter of 2019. Royalties from the sale of NARCAN® Nasal Spray totaled $3.7 million due to higher than anticipated sales of the drug during the first quarter. Emergent BioSolutions (EBS) reaffirmed full year revenue guidance, thus we continue to anticipate full year royalty net revenues for Opiant of approximately $15.4 million.

SUMMARY DATA

52-Week High	**$23.43**
52-Week Low	**$11.09**
One-Year Return (%)	**-37.88**
Beta	**0.37**
Average Daily Volume (sh)	**17,862**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$46**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**19**
Insider Ownership (%)	**31**
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	**Average**
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	3.7 A	2.4 E	3.6 E	5.6 E	15.4 E
2020					37.0 E
2021					32.3 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	-$0.44 A	-$0.62 E	-$0.36 E	$0.12 E	-$1.30 E
2020					$4.07 E
2021					$2.51 E

WHAT'S NEW

Financial Update

On May 9, 2019, Opiant announced financial results for the first quarter of 2019. The company recorded a total of $5.4 million in revenue for the three months ending Mar. 31, 2019, which consisted of $3.7 million in royalty revenue from the sale of NARCAN® Nasal Spray, $1.6 million of grant and contract revenue, and $0.08 million from treatment investment revenue. This compares to royalty revenue of $1.6 million for the three months ended Mar. 31, 2018. The increase in royalty revenue is due to the increase in sales of NARCAN® Nasal Spray by Emergent BioSolutions (EBS), which totaled $65.5 million in the first quarter of 2019. This was well ahead of our estimate, which was due to the effects of co-prescribing legislation that began on Jan. 1, 2019 in California. Emergent stated that revenues are likely to be more in line with the historical run rate for the rest of the year and we continue to believe that full-year revenues for NARCAN® Nasal Spray will be approximately $250 million.

Based on $250 million in NARCAN® sales, we estimate Opiant will receive approximately $15.4 million in net royalties 2019. In addition, Opiant will receive a $13.5 million net milestone payment due to the company upon sales exceeding $200 million for the first time in a calendar. We believe that payment would be received 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 over the next three quarters and the remaining $2.7 million deducted from the $13.5 million milestone payment. Our $15.4 million in estimated royalties for 2019 takes into account the $5.4 million deduction for the license fee.

Net loss for the first quarter of 2019 was $1.7 million, or $0.44 per share. R&D expenses in the first quarter of 2019 were $3.6 million compared to $2.4 million in the first quarter of 2018. The increase was due to an increase in third party clinical trial and development expenses and an increase in personnel and related expenses. G&A expenses in the first quarter of 2019 were $3.7 million compared to $3.0 million for the first quarter of 2018. The increase was primarily due to an increase in legal, accounting, and professional fees, an increase in personnel expenses, and an increase in royalty expenses partially offset by a decrease in stock-based compensation.

Opiant exited the first quarter of 2019 with approximately $23.8 million in cash and cash equivalents, which does not include the remaining amounts due from the NIDA grant and the BARDA contract. We forecast that the company will have approximately $17-$20 million in cash and cash equivalents at the end of 2019.

Business Update

OPNT003 Pharmacokinetic Data Presented

On April 8, 2019, Opiant Pharmaceuticals, Inc. (OPNT) announced the publication of clinical pharmacokinetic (PK) data for OPNT003, an intranasal (IN) formulation of nalmafene (a naltrexone derivative) that is being developed as a long-lasting opioid antagonist for the treatment of opioid overdose. The data was presented at the American Society for Pharmacology and Experimental Therapeutics 2019 Annual Meeting. The study was conducted in healthy volunteers and consisted of examining PK parameters for IN nalmafene, IN nalmafene formulated with the absorption enhancer dodecyl maltoside (Intravail®), and intramuscular (IM) nalmafene. IN nalmafene was absorbed slowly with a median T_{max} of two hours. Addition of Intravail® to IN nalmafene decreased T_{max} to 0.25 hours and increased C_{max} by approximately 2.2-fold. These results were comparable to IM nalmafene (1.5 mg) and C_{max} was approximately 3-fold higher through IN administration than through IM administration.

Opiant will be conducting a pivotal PK study for OPNT003 later in 2019 and we anticipate a New Drug Application (NDA) filing in 2020.

The development of OPNT003 is being supported by a $7.4 million grant from the National Institute on Drug Abuse (NIDA) and 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 company recently announced receipt of the second tranche of approximately $3.0 million from the NIDA grant. The grant and contract for OPNT003 are intended to support its development through the NDA filing.

OPNT002 Pharmacokinetic Data Published

On April 3, 2019, Opiant announced the publication of PK data for OPNT002, nasal naltrexone containing Intravail®, in *The Journal of Clinical Pharmacology*. The study involved 14 subjects who were each administered 4 mg IN naltrexone, 4 mg IN naltrexone with Intravail®, 2 mg IM naltrexone, or 50 mg oral naltrexone on different days. The following table shows PK results from the study. The addition of Intravail® to IN naltrexone resulted in an approximately 3-fold increase in C_{max} and a decrease in T_{max}, however the half-life of IN naltrexone was only 2.2 – 2.5 hours, which is very similar to naloxone (used in NARCAN® Nasal Spray), thus limiting the potential usefulness of IN naltrexone against longer-lived synthetic opioids such as fentanyl.

PK Parameter[a]	4 mg Intranasally	4 mg Intranasally + DDM	2 mg Intramuscularly	50 mg Orally
N[b]	13	12	10	10
C_{max} (ng/mL)	5.4 (66.8)	15.7 (52.0)	4.1 (34.0)	9.3 (31.8)
C_{max}/dose (ng/mL/mg)	1.5 (66.8)	4.4 (52.0)	2.3 (34.0)	0.2 (31.8)
T_{max} (h)	0.5 (0.2-2.0)	0.2 (0.1-0.3)	0.3 (0.2-1.0)	0.5 (0.3-3.0)
$AUC_{0-\infty}$ (ng·h/mL)	12.0 (33.7)	18.5 (31.0)	12.3 (25.6)	26.9 (31.8)
$AUC_{0-\infty}$/dose (ng·h/mL/mg)	3.3 (33.7)	5.1 (31.0)	6.8 (25.6)	0.6 (31.8)
CL/F (L/h)[f]	330 (28.9)	214 (33.6)	154 (19.0)	1890 (41.4)
$t_{1/2}$, (h)	2.5 (14.9)	2.2 (14.9)	2.0 (15.5)	6.4 (36.6)

Source: Krieter *et al.*, 2019

While IN naltrexone is likely not a good candidate to treat overdose from synthetic opioids, it is well-suited for "on demand" dosing to treat alcohol use disorder (AUD). Multiple studies show that alcohol consumption results in release of endogenous opioids that bind to δ-opioid receptors with high affinities (Weerts *et al*., 2008; Mitchell *et al*., 2012). Since naltrexone is a high-affinity opioid antagonist, the ability to achieve high plasma concentrations of naltrexone through IN administration while an individual is craving alcohol may increase its efficacy compared to the oral or injectable form, for which it is currently approved to treat AUD.

Opiant will be conducting a formulation selection study for OPNT002 in the second quarter of 2019 and we anticipate a Phase 2 clinical trial initiating later in the year.

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 Δ-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.

Conclusion

Opiant is in a strong financial position with the incoming royalties from the sale of NARCAN® Nasal Spray, particularly since Emergent reaffirmed guidance for 2019 sales of NARCAN® and stated that results are likely to come in at the top of that guidance. For the remainder of 2019, we anticipate the pivotal PK study for OPNT003 and the Phase 2 study for OPNT002 to initiate. Our valuation remains at $44 and we continue to see the potential for significant upside for investors as the stock continues to trade at a significant discount to that valuation.

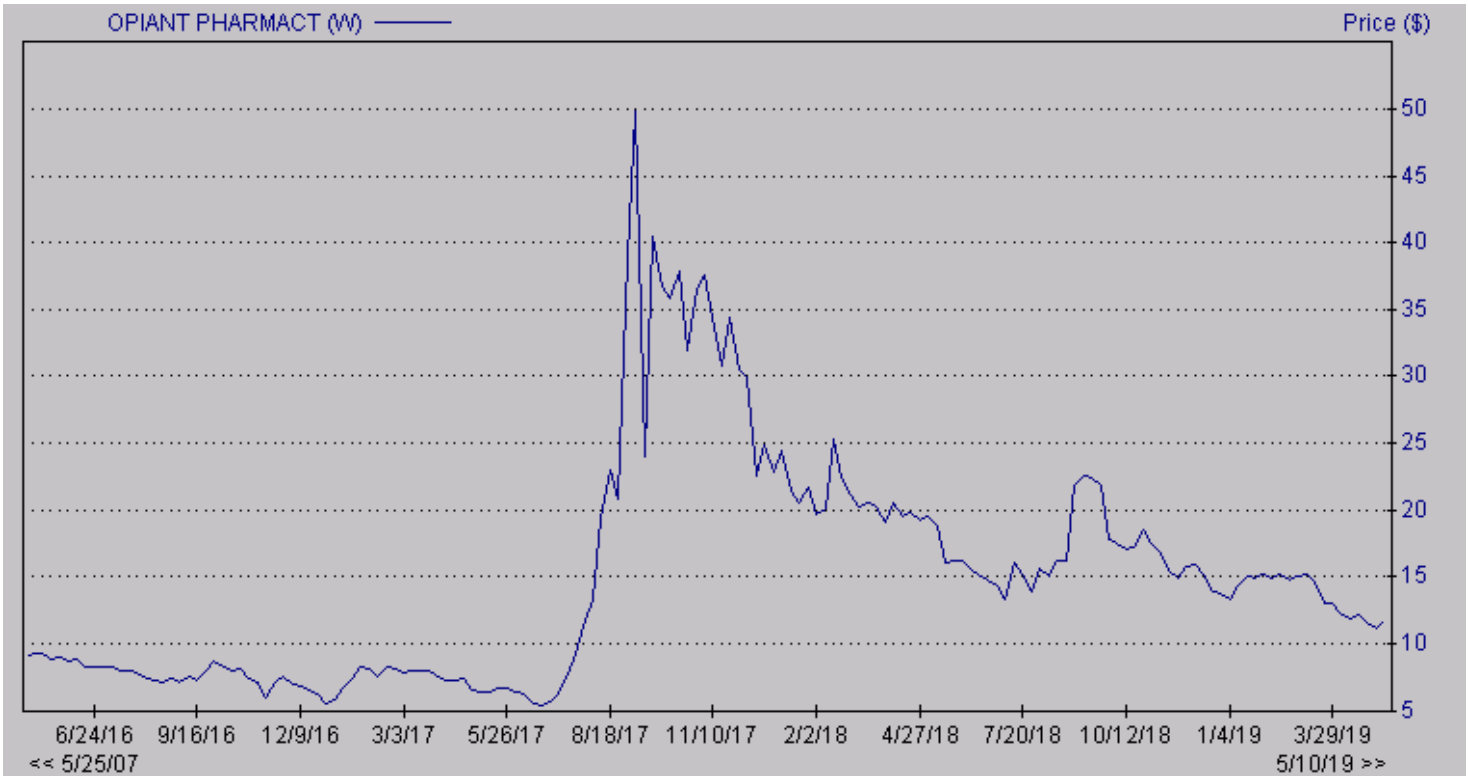
PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	2018 A	1Q A	2Q E	3Q E	4Q E	2019 E	2020 E	2021 E
NARCAN royalty	$13.3	$3.7	$2.4	$3.6	$5.6	$15.4	$37.0	$32.3
YOY Growth	-	-	-	-	-	*16%*	*140%*	*-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	$1.7	$0.5	$0.5	$0.5	$3.2	$3.0	$3.0
Total Revenues	**$14.0**	**$5.4**	**$2.9**	**$4.1**	**$6.1**	**$18.6**	**$40.0**	**$35.3**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Research & Development	$8.5	$3.6	$2.1	$2.2	$2.3	$10.2	$9.0	$10.0
General & Administrative	$11.3	$3.7	$3.2	$3.3	$3.3	$13.5	$13.5	$14.0
Selling Expenses	$0.2	$0.0	$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)	($1.8)	($2.4)	($1.5)	$0.5	($5.2)	$17.5	$11.3
Non-Operating Expenses (Net)	$0.0	$0.1	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($21.1)	($1.7)	($2.5)	($1.4)	$0.5	($5.2)	$17.5	$11.3
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	**($21.2)**	**($1.7)**	**($2.5)**	**($1.4)**	**$0.5**	**($5.2)**	**$17.5**	**$11.3**
Reported EPS	**($7.10)**	**($0.44)**	**($0.62)**	**($0.36)**	**$0.12**	**($1.30)**	**$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*

HISTORICAL STOCK PRICE



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