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Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: Expecting $26 Million in NARCAN® Nasal Spray Royalties in 2020…

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 (08/10/20)	$9.19
Valuation	**$44.00**

OUTLOOK

On August 6, 2020, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the second quarter of 2020 and provided a business update. Opiant reported $6.2 million in net royalties from the sale of NARCAN® Nasal Spray in the second quarter of 2020. Emergent BioSolutions has reiterated the previous guidance for between $285 and $315 million in NARCAN® full year revenues, and we are estimating approximately $26.2 million in royalties to Opiant in 2020.

Recently released data from the CDC shows that synthetic opioid-related deaths continue to increase, with over 36,000 overdose deaths in the U.S. in 2019, thus showing the urgent need for improved opioid overdose treatments, such as OPNT003. We continue to anticipate an NDA filing for OPNT003 in 2021.

SUMMARY DATA

52-Week High	**$16.48**
52-Week Low	**$8.64**
One-Year Return (%)	**-34.31**
Beta	**0.76**
Average Daily Volume (sh)	**26,512**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$39**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
Insider Ownership (%)	**28**
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-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	3.7 A	6.8 A	20.6 A	7.7 A	40.5 A
2020	4.3 A	6.3 A	8.2 E	9.8 E	28.9 E
2021					28.9 E
2022					35.6 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.44 A	$0.39 A	$2.62 A	$0.18 A	$2.88 A
2020	-$0.40 A	-$0.05 A	-$0.04 E	$0.18 E	-$0.33 E
2021					$0.02 E
2022					$0.89 E

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WHAT'S NEW

Business Update

Fentanyl-Related Overdose Deaths Continue to Rise

In July 2020, the Centers for Disease Control (CDC) published provisional data on drug overdose deaths for 2019, which showed a 4.6% increase for drug overdose deaths from the previous year. This follows an encouraging decrease seen in 2018, and unfortunately the number of overdose deaths is likely to continue to increase in 2020 due to the ongoing coronavirus pandemic. Of the 70,980 drug overdose deaths in 2019, approximately 36,509 (51%) were from synthetic opioids, and 75% of those deaths were due to fentanyl.

Fentanyl is a particularly dangerous opioid. It is 50x more potent than heroin due to the fact that it is more lipophilic than heroin (which leads to much faster brain penetration) as well as affecting respiration more than analgesia. In addition, fentanyl has a longer duration of action than heroin (>7 hours vs. 1-2 hours). Lastly, fentanyl is very easy to produce since it is synthetic. This increased potency means that while naloxone can be effective in reversing overdose due to fentanyl, multiple and continued doses are sometimes necessary for rescue.

Opiant Pharmaceuticals, Inc. (OPNT) is developing OPNT003 (intranasal nalmefene) for the treatment of opioid overdose. The following table shows that intranasal nalmefene has a number of characteristics that make it superior to intranasal naloxone (particularly for overdoses caused by fentanyl), including increased affinity at the μ opioid receptors, a much greater half-life (which can help avoid re-narcotization), and a faster rate of absorption.

Parameter	Nalmefene	Naloxone
Affinity at μ opioid receptors : K_i (nM)	1.0[1]	5.4[1]
Half-life: $t_{1/2}$ (h)	7.11[2]	2.08[3]
Speed of absorption: t_{max} (h)	0.25[2]	0.5[3]

Nalmefene and naloxone: a comparison of affinities at μ opioid receptors and pharmacokinetic properties following intranasal administration. [1] K_i values were estimated using [^{3}H]alvimopan binding to cloned human μ opioid receptors (Cassel, et al., 2005). The ~5-fold higher affinity of nalmefene compared to naloxone is consistent with both K_i values obtained (0.13 and 0.62 nM, respectively) using [^{3}H]DAMGO as a radioligand in monkey brain membranes (Emmerson, et al., 1994) and pA_2 values of 9.38 and 8.51, respectively, in functional assays using guinea pig ileum and mouse vas deferens (Toll, et al., 1998).[2]Data from Table 2.
[3] Data from FDA, 2015 (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf) (Krieter, et al, 2019)

Source: Opiant Pharmaceuticals, Inc.

Opiant recently signed an agreement with Summit Biosciences, Inc. in which Summit will be responsible for the method development, validation, GMP manufacturing, and stability of an opioid antagonist nasal spray product. The full cost of the project is expected to be approximately $6.5 million.

In 2018, Opiant was awarded 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, which are intended to help fund development of OPNT003 through the new drug application (NDA) filing.

Opiant has come to an agreement with the FDA regarding the proposed confirmatory PK study for OPNT003 and will also be performing a PD study in healthy volunteers to enhance the clinical profile of OPNT003. While the PD study is not a requirement, the company believes that the data collected in that study will enhance the commercial potential for the drug. Both of those studies are relatively short in duration, and we continue to anticipate an NDA filing for OPNT003 in 2021.

Collaboration to Develop OPNT004

In January 2020, Opiant announced that it had signed a Letter of Intent with the National Center for Advancing Translational Sciences (NCATS), a division of the National Institutes of Health (NIH), in which NCATS will provide development resources regarding certain preclinical activities and studies in support of an eventual IND filing by Opiant for OPNT004. Opiant had expected to incur approximately $4.5 million in expenses for OPNT004 in 2020,

however that number is expected to be much lower due to this collaboration, although the exact amount has not been determined. We anticipate human studies for OPNT004 initiating in 2021.

OPNT004 (drinabant) is a novel CB-1 receptor antagonist that is being developed for the treatment of acute cannabinoid overdose (ACO). The compound was licensed by Opiant from Sanofi in Dec. 2018 and the companies signed a second agreement in July 2019 that states Sanofi will be responsible for manufacturing the compound.

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.

Financial Update

On August 6, 2020, Opiant announced financial results for the second quarter of 2020. The company reported total revenue for the second quarter of 2020 of approximately $6.3 million, compared to approximately $6.8 million in the second quarter of 2020. In the second quarter of 2020, approximately $6.3 million in revenue was a result of the licensing agreement with Emergent BioSolutions (EBS) for the sale of NARCAN® Nasal Spray, compared to approximately $6.1 million in the second quarter of 2019. EBS reported second quarter 2020 sales of NARCAN® Nasal Spray of approximately $72.8 million.

R&D expenses in the second quarter of 2020 were approximately $0.6 million, compared to approximately $1.6 million in the second quarter of 2019. The decrease was primarily due to an approximately $0.8 million U.K. R&D tax credit and a decrease in clinical trials costs. G&A expenses for the second quarter of 2020 were approximately $2.8 million, which was flat compared with the second quarter of 2019. Sales and marketing expenses were approximately $1.7 million in the second quarter of 2020 while there were no such expenses in the second quarter of 2019. Sales and marketing expenses are expected to continue at the same level as the company moves closer to commercializing OPNT003.

As of June 30, 2020, Opiant had approximately $30.5 million in cash and cash equivalents, however this does not take into account the remainder of the NIDA grant or the BARDA contract, which together totals approximately $3.4 million. As of Aug. 5, 2020, Opiant had approximately 4.3 million shares and, when factoring in stock options and warrants, a fully diluted share count of approximately 7.6 million.

NARCAN® Nasal Spray Forecast for 2020

Emergent BioSolutions recently reaffirmed revenue guidance for 2020, which included an estimated $285 to $315 million in revenues for NARCAN® Nasal Spray. Emergent acquired Adapt Pharma, which markets NARCAN® Nasal Spray for the treatment of opioid overdose and for which Opiant receives tiered royalties, for $635 million in Aug. 2018. The royalty payments to Opiant are based on the agreement signed with Adapt in 2014 according to the following table. Opiant receives 90% of the royalty payment, with the other 10% going to SWK Holdings Corporation based on the agreement signed in 2016.

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 gross revenues of approximately $300 million in 2020, we estimate that Opiant would receive approximately $26.2 million in royalty payments.

U.S. District Court Rules in Favor of Teva Pharmaceuticals in Patent Litigation

In June 2020, the U.S. District Court for the District of New Jersey ruled in favor of Teva Pharmaceuticals in a patent litigation with Emergent BioSolutions, Opiant's commercial partner, regarding NARCAN® Nasal Spray. This could allow for Teva to market a generic version of NARCAN® Nasal Spray. Emergent intends to appeal the decision to the Court of Appeals for the Federal Circuit and has indicated that they don't anticipate any effect on NARCAN® sales this year.

Conclusion

The coronavirus epidemic continues to wreak havoc on people's lives, leading to a number of negative consequences including an increase in drug overdose deaths. This is a trend that unfortunately is likely to continue for the foreseeable future. The fact that such a large percentage of drug overdose deaths are caused by fentanyl supports the development of an improved opioid overdose treatment like OPNT003. We continue to anticipate an NDA filing for OPNT003 in 2021. With no changes to our model our valuation remains at $44.

PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	2019 A	1Q A	2Q A	3Q E	4Q E	2020 E	2021 E	2022 E
NARCAN royalty	$37.6	$4.2	$6.3	$7.3	$8.9	$26.7	$28.9	$31.6
YOY Growth	*183%*	-	-	-	-	*-29%*	*8%*	*9%*
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	$4.0
OPNT004	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Licensing, Milestones, and Grants	$2.9	$0.1	$0.1	$0.9	$0.9	$1.9	$0.0	$0.0
Total Revenues	**$40.5**	**$4.3**	**$6.3**	**$8.2**	**$9.8**	**$28.6**	**$28.9**	**$35.6**
Cost of Sales	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & Development	$9.1	$1.4	$0.6	$2.5	$2.5	$7.0	$10.0	$11.0
General & Administrative	$12.2	$2.6	$2.8	$3.2	$3.3	$11.9	$13.0	$14.0
Sales and Marketing	$0.6	$1.1	$1.7	$1.3	$1.4	$5.5	$0.0	$0.0
Royalty Expenses	$7.7	$0.9	$1.4	$1.5	$1.8	$5.6	$5.8	$6.4
License Fees	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	$10.9	($1.7)	($0.2)	($0.3)	$0.8	($1.4)	$0.1	$4.2
Non-Operating Expenses (Net)	$0.5	$0.1	$0.0	$0.1	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	$11.4	($1.6)	($0.2)	($0.2)	$0.8	($1.4)	$0.1	$4.2
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Net Income	**$11.6**	**($1.7)**	**($0.2)**	**($0.2)**	**$0.8**	**($1.4)**	**$0.1**	**$4.2**
Reported EPS	**$2.88**	**($0.40)**	**($0.05)**	**($0.04)**	**$0.18**	**($0.33)**	**$0.02**	**$0.89**
Basic Shares Outstanding	4.0	4.2	4.3	4.4	4.5	4.3	4.6	4.7

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

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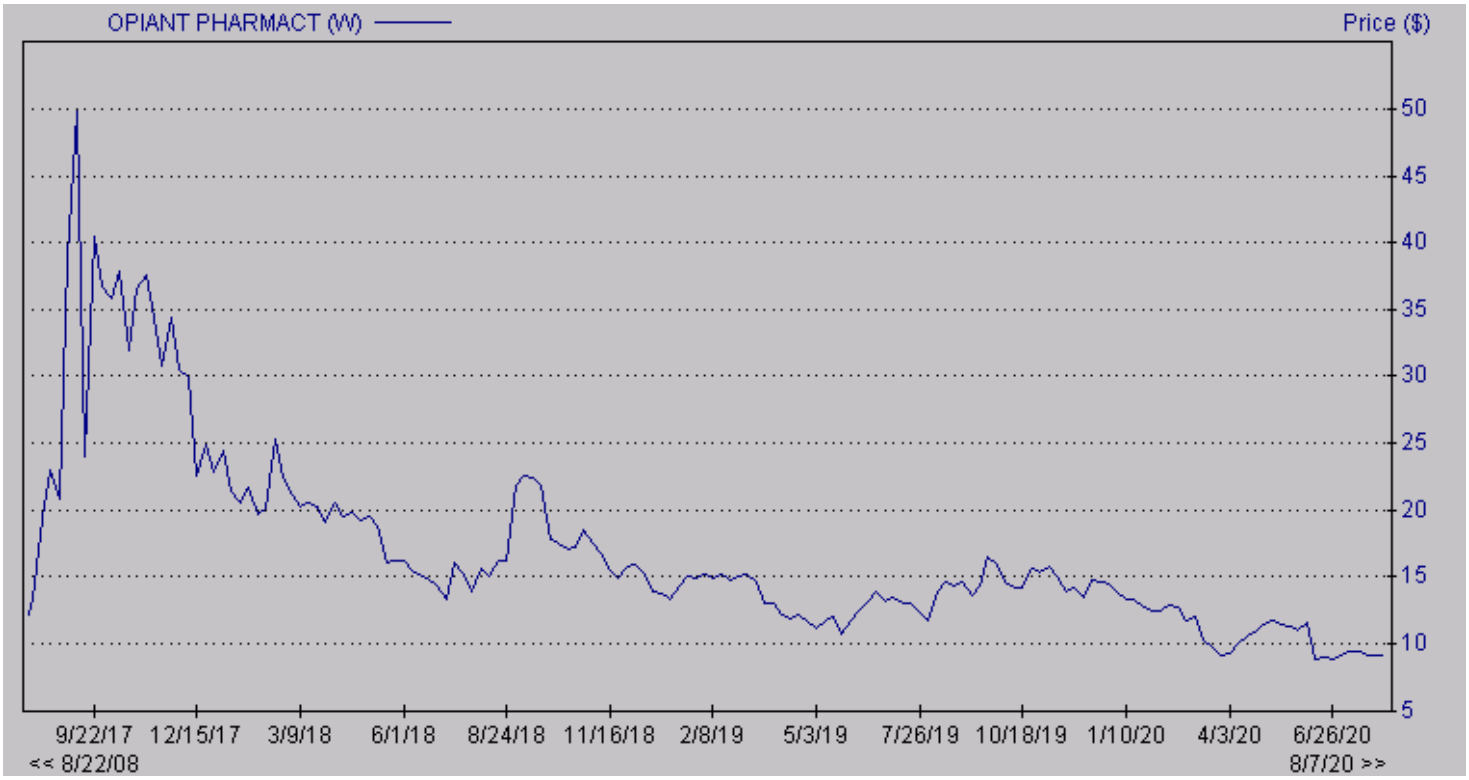

Source: Zacks SCR

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