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Opiant Pharmaceuticals, Inc.

(OPNT-NASDAQ)

OPNT: NDA Filing for OPNT003 in Early 2021…

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 (05/14/20)	$10.98
Valuation	**$44.00**

OUTLOOK

On May 12, 2020, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the first quarter of 2020 and provided a business update. Opiant reported $4.2 million in net royalties from the sale of NARCAN® Nasal Spray in the first quarter of 2020. Emergent BioSolutions has reiterated their 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.

The FDA has lifted the clinical hold on OPNT003 and we anticipate Opiant conducting a PK and PD study this year with an anticipated NDA filing in early 2021.

SUMMARY DATA

52-Week High	**$16.48**
52-Week Low	**$9.01**
One-Year Return (%)	**-11.91**
Beta	**0.86**
Average Daily Volume (sh)	**20,073**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$47**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
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	**Low**
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	6.6 E	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	-$0.24 E	-$0.04 E	$0.18 E	-$0.54 E
2021					$0.02 E
2022					$0.89 E

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Business Update

NDA Filing for OPNT003 in Early 2021

Opiant Pharmaceuticals, Inc. (OPNT) is developing OPNT003, an intranasal (IN) formulation of nalmefene (a naltrexone derivative), which the company is developing 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.

Earlier in 2020, the FDA placed a clinical hold on the development of OPNT003 so it could review certain characteristics of the drug delivery device and the confirmatory PK study. Following a review of Opiant's response the FDA has lifted the hold and agreed to the protocol for the PK study. In addition, Opiant and the FDA have come to an agreement on 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.

Given the changes to the OPNT003 program, as well as taking into consideration travel restrictions that will impact the equipment engineers in Europe, we now estimate for an NDA filing in early 2021.

Update on OPNT002

Opiant is developing OPNT002 (intranasal naltrexone) for the treatment of alcohol use disorder (AUD). Approximately 16-17 million individuals in the U.S. suffer from AUD, but only a very small percentage of them receive any type of pharmacotherapy (<5%). The company believes that a more effective pharmacotherapy would increase the number of patients on medication.

Just as with intranasal nalmefene, Opiant is developing intranasal naltrexone with INTRAVAIL® to rapidly increase the plasma concentration of the drug following dosing. The following table shows that intranasally administered naltrexone with INTRAVAIL® has a Cmax that is approximately 50% higher than orally administered naltrexone along with a Tmax of approximately 12 minutes, and a short half-life. All of these characteristics are suitable for developing OPNT002 for 'as needed' intranasal dosing.

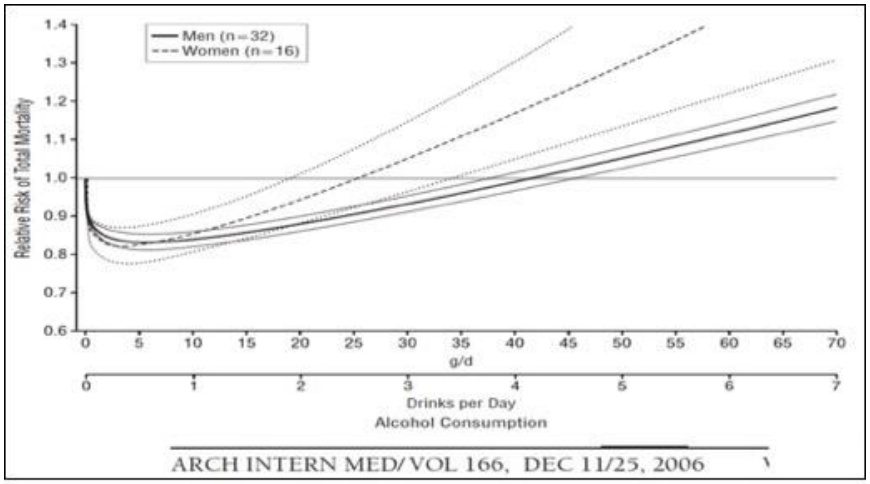
Table 2. Pharmacokinetics of Naltrexone Following Intranasal, Intramuscular, and Oral Administration

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)[c]	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: Opiant Pharmaceuticals, Inc.

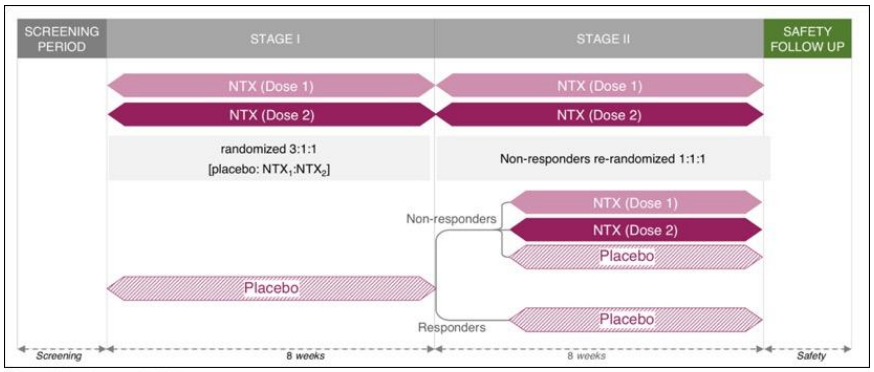
The FDA has changed its stance on endpoints for treating AUD. Whereas previously the agency would require an endpoint that examined abstinence (0 drinks), research shows that is an unrealistic expectation given how many different signaling pathways alcohol affects. Thus, the FDA now considers a "harm reduction" endpoint acceptable in AUD trials. For example, a decrease in 'heavy drinking days', defined as ≥ 4 drinks in one day for women or ≥5 drinks in one day for a man, as an acceptable endpoint. This is based on a meta analysis showing a couple of

drinks a day actually reduces overall mortality and that the decreased risk of mortality effect is lost at approximately 4 drinks per day for women and 5 drinks per day for men, as shown in the following figure.



Source: Opiant Pharmaceuticals, Inc.

One of the biggest issues with AUD trials is the high placebo response. In an effort to mitigate this effect, Opiant will be utilizing a Sequential Parallel Comparison Study Design for the Phase 2 trial of OPNT002 in AUD. An overview of the trial design is shown below. During stage 1, two doses of the drug are tested along with placebo. At the midpoint, the trial is unblinded and those that were administered placebo are re-randomized. Subjects that responded are maintained on placebo, while non-responders to placebo are randomized between placebo and active.



Source: Opiant Pharmaceuticals, Inc.

In summary, OPNT002 is being developed for dosing “as needed” when a patient anticipates drinking or is craving alcohol. Patients enrolled into the study will not be abstinent drinkers, making it both easier to enroll patients and to meet the primary endpoint of reduction in heavy drinking days. Lastly, the Sequential Parallel Comparison Study Design should help to reduce the placebo response, which is a known issue in AUD studies.

Due to the ongoing coronavirus pandemic, initiation of the Phase 2 trial is being postponed and when the trial can initiate will depend upon when conditions allow for it. When it commences, we anticipate approximately 300 patients being enrolled into the randomized, double blind, placebo controlled trial, which will be taking place in a number of countries in Europe.

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.

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 May 12, 2020, Opiant announced financial results for the first quarter of 2020. The company reported total revenue in the first quarter of 2020 of approximately $4.3 million, compared to approximately $5.4 million in the first quarter of 2019. The difference is primarily due to the company recording $1.7 million in revenue from the NIDA grant and BARDA contract during the first quarter of 2019. In the first quarter of 2020, $4.2 million in revenue was a result of the licensing agreement with Emergent BioSolutions (EBS) for the sale of NARCAN® Nasal Spray, compared to approximately $3.7 million in the first quarter of 2019. EBS reported first quarter 2020 sales of NARCAN® Nasal Spray of approximately $72.2 million.

R&D expenses in the first quarter of 2020 were approximately $1.4 million, compared to approximately $3.6 million in the first quarter of 2019. The decrease was primarily due to a reduction in third-party clinical trial and development expenses. G&A expenses in the first quarter of 2020 were approximately $2.6 million, compared to approximately $3.4 million for the first quarter of 2019. The decrease was primarily due to a decrease in stock-based compensation and legal expenses. Sales and marketing expenses were approximately $1.1 million in the first quarter of 2020 while there were no such expenses in the first quarter of 2019. Sales and marketing expenses are expected to continue to increase as the company moves closer to commercializing OPNT003.

As of Mar. 31, 2020, Opiant had approximately $32.2 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. Since those grants cover the development of OPNT003 through the NDA filing, we anticipate the remainder of the NIDA grant and BARDA contract revenue to be recognized over the next 12 months.

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.

Conclusion

We are glad to see that the FDA has lifted the clinical hold on OPNT003 and those studies will be able to be completed this year such that an NDA filing can occur in early 2021. The coronavirus epidemic has resulted in a number of areas experiencing a large increase in opioid overdoses, which serves as a harsh reminder that the opioid epidemic is continuing to enact a deadly toll in the country. Since fentanyl is involved in approximately 2/3rd of opioid overdoses, we believe OPNT003 is well positioned to make a positive impact in treating those situations. Due to the slight delays in the timeline for OPNT003 our valuation has decreased to $44, however the stock continues to trade at a significant discount to our valuation, thus we see the potential for significant upside for investors.

PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	2019 A	1Q A	2Q E	3Q E	4Q E	2020 E	2021 E	2022 E
NARCAN royalty	$37.6	$4.2	$5.8	$7.3	$8.9	$26.2	$28.9	$31.6
YOY Growth	*183%*	-	-	-	-	*-30%*	*10%*	*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	$0.8	$0.9	$0.9	$2.7	$0.0	$0.0
Total Revenues	**$40.5**	**$4.3**	**$6.6**	**$8.2**	**$9.8**	**$28.9**	**$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	$2.3	$2.5	$2.5	$8.7	$10.0	$11.0
General & Administrative	$12.2	$2.6	$3.0	$3.2	$3.3	$12.1	$13.0	$14.0
Sales and Marketing	$0.6	$1.1	$1.2	$1.3	$1.4	$5.0	$0.0	$0.0
Royalty Expenses	$7.7	$0.9	$1.3	$1.5	$1.8	$5.4	$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)	($1.1)	($0.3)	$0.8	($2.3)	$0.1	$4.2
Non-Operating Expenses (Net)	$0.5	$0.1	$0.1	$0.1	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	$11.4	($1.6)	($1.0)	($0.2)	$0.8	($2.3)	$0.1	$4.2
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Net Income	**$11.6**	**($1.7)**	**($1.0)**	**($0.2)**	**$0.8**	**($2.4)**	**$0.1**	**$4.2**
Reported EPS	**$2.88**	**($0.40)**	**($0.24)**	**($0.04)**	**$0.18**	**($0.54)**	**$0.02**	**$0.89**
Basic Shares Outstanding	4.0	4.2	4.3	4.4	4.5	4.4	4.6	4.7

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

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