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March 9, 2020
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Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: Pivotal PK Study for OPNT003 to Initiate in 2Q20…

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 $46/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 (03/09/20)	$12.00
Valuation	**$46.00**

OUTLOOK

On March 4, 2020, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the fourth quarter and full year 2019 and provided a business update. Opiant reported $37.6 million in net royalties from the sale of NARCAN® Nasal Spray in 2019. For 2020, Emergent BioSolutions is forecasting between $285 and $315 million in NARCAN® revenues, and we are estimating approximately $26.2 million in royalties to Opiant.

Opiant will be initiating a pivotal PK study of OPNT003 in the second quarter of 2020 and we anticipate an NDA being filed before the end of 2020. In addition, the company will be initiating patient recruitment for a Phase 2 trial of OPNT002 for the treatment of alcohol use disorder in the next few weeks.

SUMMARY DATA

52-Week High	**$16.48**
52-Week Low	**$10.25**
One-Year Return (%)	**-20.93**
Beta	**0.40**
Average Daily Volume (sh)	**21,110**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$51**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**23**
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-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	4.7 E	7.0 E	8.3 E	9.6 E	29.6 E
2021					35.4 E
2022					45.1 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	-$0.23 E	$0.13 E	$0.26 E	$0.47 E	$0.58 E
2021					$1.43 E
2022					$2.91 E

WHAT'S NEW

Financial Update

On March 4, 2020, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the fourth quarter and full year 2019. For the fourth quarter of 2019, Opiant reported total revenue of $7.7 million, including $7.2 million of revenue from the licensing agreement with Adapt Pharma Operations Limited, a subsidiary of Emergent BioSolutions (EBS), for the sale of NARCAN® Nasal Spray, compared to approximately $4.8 million for the fourth quarter of 2018. Emergent BioSolutions reported revenue from the sale of NARCAN® Nasal Spray of approximately $66.8 million for the fourth quarter of 2019.

For the full year 2019, Opiant recorded approximately $40.5 million in revenue compared to approximately $14.0 million for the full year 2018. In 2019, the company recognized approximately $37.6 million in revenue from the licensing agreement with Adapt Pharma for the sale of NARCAN® Nasal Spray compared to approximately $13.3 million for 2018. The increase was due to increased royalties received in 2019 from an increase in sales of NARCAN® Nasal Spray to approximately $280 million along with a $13.5 million one-time milestone payment resulting from sales of NARCAN® Nasal Spray exceeding $200 million through the third quarter of 2019.

Net income for the year ending Dec. 31, 2019 was approximately $11.6 million, or $2.88 per share, compared to a net loss of $21.2 million, or $7.10 per share, for the year ending Dec. 31, 2018. G&A expenses in 2019 were approximately $12.2 million compared to approximately $11.5 million for 2018. The increase was primarily due to increased personnel and legal expenses partially offset by a decrease in stock-based compensation. R&D expenses in 2019 were approximately $9.1 million compared to $8.5 million in 2018. The increase was primarily due to increased third-party and compensation expenses partially offset by a decrease in stock-based compensation. Sales and marketing expense in 2019 was approximately $0.6 million compared to none in 2018. The increase was due to compensation-related expense and third-party consulting expense. Royalty expense in 2019 was approximately $7.7 million, compared to approximately $1.5 million in 2018. The increase was due to increased payments due to Net Profit Partners for the royalties and sales milestone received from the net sales of NARCAN® Nasal Spray and payments made to buyout the net profit interests in nasal nalmefene held by investors who supported the development of NARCAN® Nasal Spray.

As of Dec. 31, 2019, Opiant had approximately $31.9 million in cash and cash equivalents, however this does not include the remainder of the National Institute on Drug Abuse (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, if the company is able to file an NDA this year for OPNT003 we anticipate the remainder of the NIDA grant and BARDA contract revenue to be recognized this year.

NARCAN® Nasal Spray Forecast for 2020

Emergent BioSolutions Inc. (EBS) recently announced revenue guidance for 2020, that 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.

Business Update

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.

Update on OPNT003

OPNT003 is 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. In Dec. 2019, Opiant announced the receipt of $2.4 million from the BARDA grant, and has thus far received approximately $3.0 million of the $4.6 million contract.

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 starting in the second quarter of 2020 following an FDA review of certain characteristics of the nasal delivery device. We believe Opiant will be in a position to file an NDA for OPNT003 before the end 2020.

Phase 2 AUD Trial for OPNT002 to Initiate Soon

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.

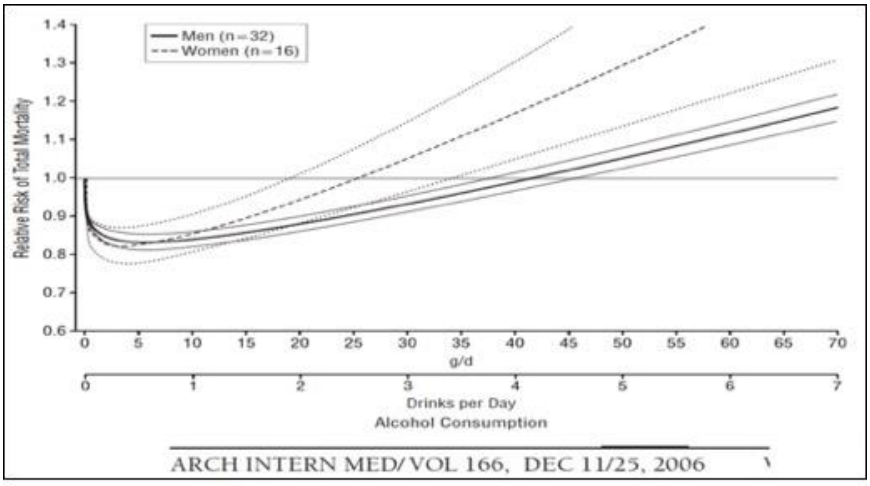
Just as with intranasal nalmefene, Opiant is developing intranasal naltrexone with INTRAVAIL® to rapidly increase the plasma concentration of the drug following dosing. The following table shows that intranasally administered naltrexone with INTRAVAIL® has a Cmax that is approximately 50% higher than 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)

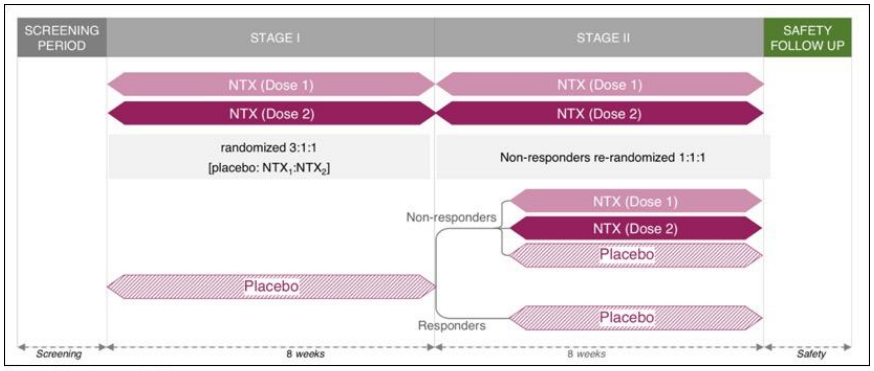
Source: Opiant Pharmaceuticals, Inc.

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. We anticipate patient enrollment initiating in the next few weeks and the company's goal is to have the study fully enrolled by the end of 2020.

Conclusion

Opiant is in very strong financial shape with the incoming royalties from the sale of NARCAN® Nasal Spray, and the drug continues to perform ahead of expectations. Now that the company has earned the final milestone payment from Emergent, attention turns to the pivotal PK study for OPNT003 that will likely initiate in the second quarter of 2020. With the rate of deaths attributable to fentanyl continuing to rise, there is an urgent need for an easy to administer, potent, and long-lasting opioid overdose reversal agent, and we believe OPNT003 is exactly what is needed to combat the increasing prevalence of fentanyl in the country. We look forward to hearing the results from the PK study of OPNT003 and are glad to hear that the company remains on track to file an NDA before the end of 2020. Our valuation has increased slightly to $46 due to moving our DCF model ahead a year and we continue to see the potential for significant upside for investors as the stock continues to trade at a deep discount to that valuation.

PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	2019 A	1Q A	2Q A	3Q A	4Q A	2020 E	2021 E	2022 E
NARCAN royalty	$37.6	$3.9	$6.2	$7.4	$8.7	$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	$6.5	$13.5
OPNT004	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Licensing, Milestones, and Grants	$2.9	$0.8	$0.8	$0.9	$0.9	$3.4	$0.0	$0.0
Total Revenues	**$40.5**	**$4.7**	**$7.0**	**$8.3**	**$9.6**	**$29.6**	**$35.4**	**$45.1**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Research & Development	$9.1	$2.2	$2.3	$2.5	$2.5	$9.5	$10.0	$11.0
General & Administrative	$12.2	$2.8	$3.0	$3.2	$3.3	$12.3	$13.0	$14.0
Sales and Marketing	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Royalty Expenses	$7.7	$0.8	$1.3	$1.5	$1.8	$5.3	$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	($1.1)	$0.4	$1.1	$2.1	$2.5	$6.6	$13.7
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	($1.0)	$0.5	$1.2	$2.1	$2.5	$6.6	$13.7
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Net Income	**$11.6**	**($1.0)**	**$0.5**	**$1.2**	**$2.1**	**$2.5**	**$6.6**	**$13.7**
Reported EPS	**$2.88**	**($0.23)**	**$0.13**	**$0.26**	**$0.47**	**$0.58**	**$1.43**	**$2.91**
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*

HISTORICAL STOCK PRICE

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