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Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: PK and PD Trials for OPNT003 Underway…

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 (05/13/21)	$12.51
Valuation	**$44.00**

OUTLOOK

On May 11, 2021, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the first quarter of 2021 and provided a business update. The company reported approximately $6.4 million in revenue for the first quarter of 2021 ($4.3 million from NARCAN Nasal Spray royalties). Emergent BioSolutions is estimating full year 2021 sales of NARCAN Nasal Spray of $305 - $325 million, which takes into account at least one generic competitor in the second half of 2021. We forecast royalties of approximately $28 million for Opiant in 2021. The company has initiated the confirmatory PK trial of OPNT003 with topline data expected in the third quarter of 2021 and has initiated a comparator PD trial with topline data expected in the fourth quarter of 2021. An NDA filing for OPNT003 is expected in late 2021 or early 2022.

SUMMARY DATA

52-Week High	**$14.49**
52-Week Low	**$6.87**
One-Year Return (%)	**13.98**
Beta	**0.75**
Average Daily Volume (sh)	**18,318**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$54**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**19**
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	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	4.3 A	6.3 A	9.1 A	9.9 A	29.6 A
2021	6.4 A	7.3 E	9.2 E	10.4 E	31.4 E
2022					31.6 E
2023					44.2 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.40 A	$0.05 A	$0.17 A	-$0.16 A	$0.44 A
2021	-$0.66 A	-$0.26 E	-$0.08 E	$0.08 E	-$0.91 E
2022					-$1.11 E
2023					$1.36 E

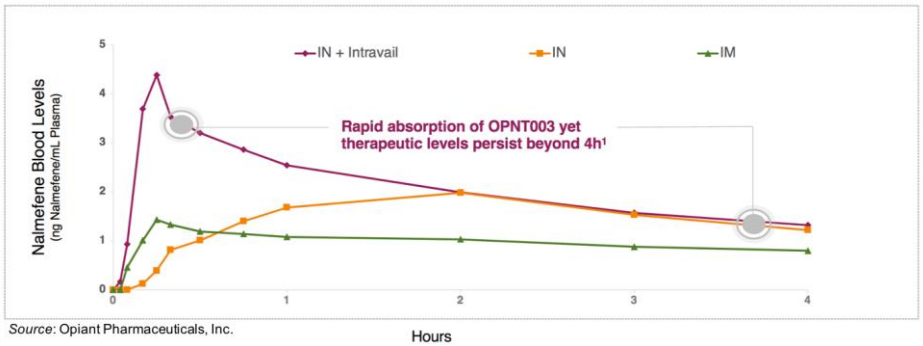
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Business Update

OPNT003 PD and PK Studies Ongoing

In February 2021, Opiant Pharmaceuticals, Inc. (OPNT) announced that the confirmatory pharmacokinetic (PK) study for OPNT003, an intranasal (IN) formulation of nalmefene, is underway. The open label, randomized, crossover study will enroll 68 healthy volunteers and will compare the PK profile of IN nalmefene to intramuscularly administered nalmefene. The trial is close to completing enrollment and we anticipate topline results in the third quarter of 2021.

Opiant had previously conducted an initial PK study of IN 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 following graph shows a rapid increase in nalmefene concentration following IN administration of nalmefene with and without INTRAVAIL®, which is a broad class of chemically synthesizable transmucosal absorption enhancement agents to allow the intranasal administration of therapeutics up to 30,000 Daltons molecular weight.



Source: Opiant Pharmaceuticals, Inc.

Compared to intranasal naloxone, intranasal nalmefene has a number of characteristics that make it superior as a treatment for fentanyl overdose, 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.

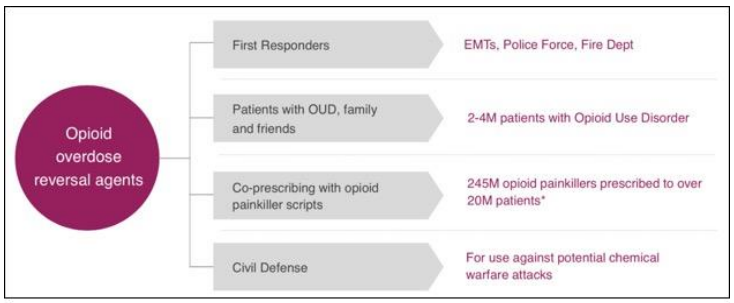
Parameter	OPNT003	Naloxone	Why this is important
K_i (nM) (Binding affinity to Mu opioid receptor)	1.0[1]	5.4[1]	**Higher binding affinity** at the opioid receptors gives OPNT003 higher potency
$t_{1/2}$ (h) (Half-life)	7.11[2]	2.08[3]	**Longer half-life** reduces the potential for renarcotization
t_{max} (h) (Amount of time after administration to reach peak plasma levels)	0.25[2]	0.5[3]	**Faster action** necessary due to shorter window to save a life from fentanyl
C_{max} (ng/mL) (Peak plasma concentration after administration)	4.45[2]	4.83[3]	

Source: Opiant Pharmaceuticals, Inc.

On April 5, 2021, Opiant announced the first subject was dosed in a pharmacodynamic (PD) trial that will compare the effectiveness of OPNT003 with nasal naloxone. It is a single center, randomized, open label study in healthy volunteers that will test 3 mg nasal nalmefene to 4 mg nasal naloxone with the primary outcome examining the reversal of respiratory depression brought about by the synthetic opioid remifentanil (NCT04828005). We anticipate topline results from the trial in the fourth quarter of 2021.

The potential market opportunity for OPNT003 is substantial. Opiant is focused on four addressable markets: 1) the first responder market (EMTs, police force, fire dept.) is key as they are typically the first person at the scene of an overdose; 2) both patients with opioid use disorder as well as their family members; 3) co-prescribing with opioid

painkillers; and 4) civil defense, in which the government is concerned about the potential use of fentanyl as a chemical weapon and thus could stockpile nalmefene for use in the event of an attack.



Source: Opiant Pharmaceuticals, Inc.

With topline results from the PK study in the third quarter in 2021 and results from the PD study in the fourth quarter of 2021, Opiant will be in a position to file a New Drug Application (NDA) for OPNT003 at year-end 2021 or early 2022.

Financial Update

On May 11, 2021, Opiant announced financial results for the first quarter of 2021. For the first quarter of 2021, Opiant reported revenue of $6.4 million, compared to $4.3 million in the first quarter of 2020. The company received approximately $4.3 million in royalty 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 $4.2 million in the first quarter of 2020. Emergent is continuing to guide for full year 2021 NARCAN revenues of $305 to $325 million, which at the mid-range of $315 million would equate to approximately $28 million in royalties for Opiant in 2021.

Net loss for the first quarter of 2021 was $2.8 million, or $0.66 per share, compared to a net loss of $1.7 million, or $0.40 per share, for the first quarter of 2020. G&A expenses in the first quarter of 2021 and 2020 were both approximately $2.6 million. R&D expenses for the first quarter of 2021 were approximately $4.1 million, compared to approximately $1.4 million for the first quarter of 2020. The increase was primarily due to external development expenses for OPNT003. Sales and marketing expenses for the first quarter of 2021 were approximately $1.0 million, primarily for pre-commercialization efforts related to OPNT003, compared to approximately $1.1 million in the first quarter of 2020. Royalty expense in the first quarter of 2021 was approximately $1.0 million, compared to approximately $0.9 million in the first quarter of 2020.

As of March 31, 2021, Opiant had approximately $50.6 million in cash, cash equivalents, and marketable securities. In December 2020, Opiant announced a $50 million convertible note purchase and security agreement with a syndicate of Pontifax Medison Finance and Kreos Capital. The first tranche of $20 million has been funded, with a second tranche of $10 million being available upon submission of an NDA to the FDA and the third tranche of $20 million will be funded upon FDA approval of an opioid overdose product. In March 2021, the company received the third and final tranche of $1.8 million from the $7.4 million grant from the National Institute on Drug Abuse (NIDA).

As of May 3, 2021, Opiant had approximately 4.3 million in shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 9.0 million.

Conclusion

We look forward to the results of the PK and PD trials later in 2021 and for Opiant to file the NDA for OPNT003 by the end of 2021 or early 2022. The company is continuing to evaluate when the best time would be to initiate the Phase 2 clinical trial of OPNT002 for the treatment of alcohol use disorder, and we expect additional information on when this trial will get underway later in the year. Our valuation remains at $44, and with the stock continuing to trade considerably below our valuation and multiple catalysts ahead this year, we believe there is the potential for considerable upside for investors.

PROJECTED FINANCIALS

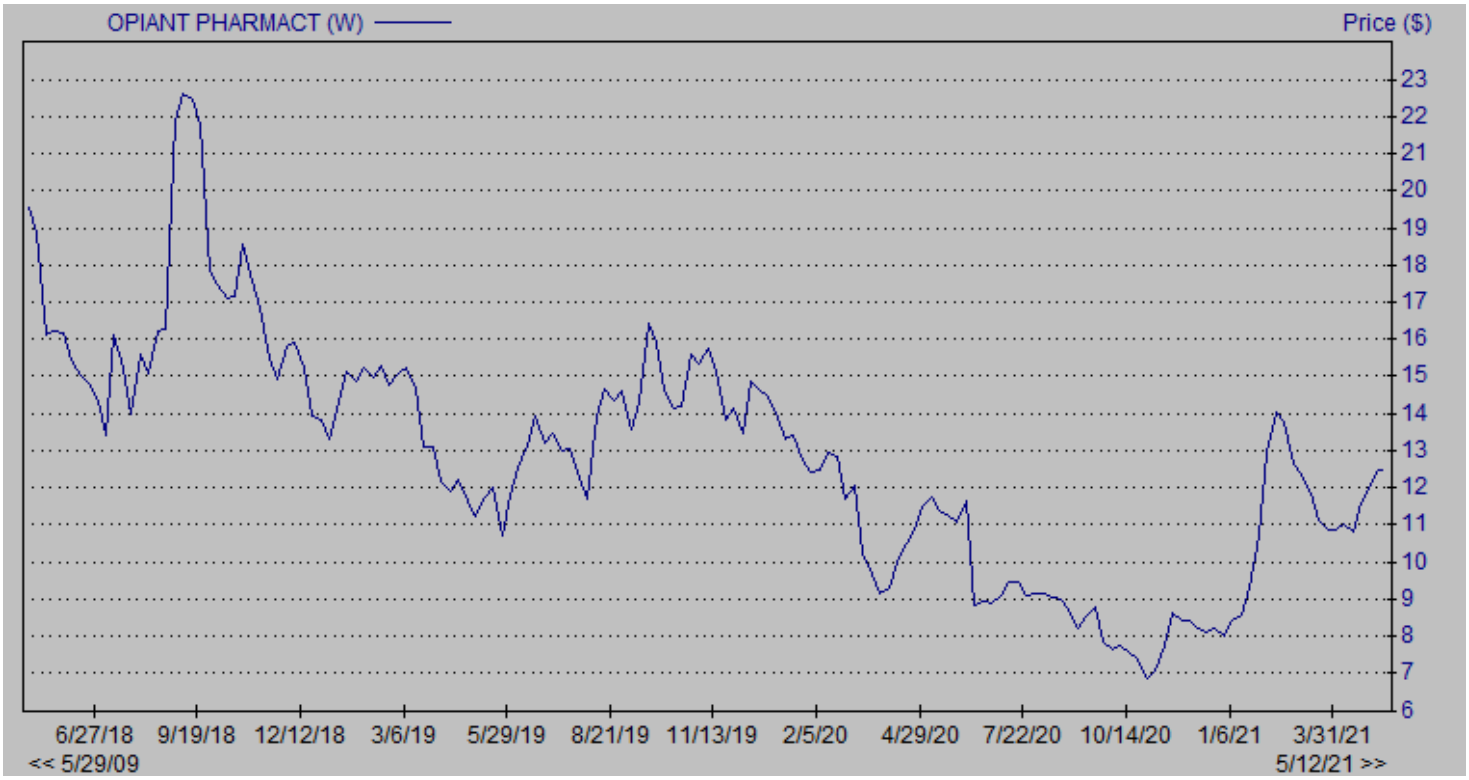
Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	2020 E	1Q A	2Q E	3Q E	4Q E	2021 E	2022 E	2023 E
NARCAN royalty	$27.4	$4.3	$6.8	$7.9	$9.0	$28.0	$31.6	$26.2
YOY Growth	*-27%*	-	-	-	-	*2%*	*13%*	*-17%*
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	$18.0
OPNT004	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Licensing, Milestones, and Grants	$2.2	$2.1	$0.5	$1.3	$1.4	$5.3	$0.0	$0.0
Total Revenues	**$29.6**	**$6.4**	**$7.3**	**$9.2**	**$10.4**	**$33.2**	**$31.6**	**$44.2**
Cost of Sales	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & Development	$9.2	$4.1	$2.6	$2.8	$3.0	$12.5	$11.0	$12.0
General & Administrative	$11.7	$2.6	$3.0	$3.1	$3.2	$11.9	$13.0	$14.0
Sales and Marketing	$4.7	$1.0	$1.5	$1.8	$2.0	$6.3	$6.5	$6.5
Royalty Expenses	$6.2	$1.0	$1.4	$2.0	$1.9	$6.2	$6.4	$6.0
License Fees	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($2.2)	($2.3)	($1.2)	($0.4)	$0.3	($3.7)	($5.3)	$5.7
Non-Operating Expenses (Net)	($0.0)	($0.5)	$0.1	$0.1	$0.1	($0.2)	$0.4	$0.4
Pre-Tax Income	($2.3)	($2.8)	($1.1)	($0.3)	$0.4	($3.9)	($4.9)	$6.1
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Net Income	**($1.9)**	**($2.8)**	**($1.1)**	**($0.3)**	**$0.4**	**($3.9)**	**($4.9)**	**$6.1**
Reported EPS	**($0.44)**	**($0.66)**	**($0.26)**	**($0.08)**	**$0.08**	**($0.91)**	**($1.11)**	**$1.36**
Basic Shares Outstanding	4.2	4.3	4.3	4.3	4.3	4.3	4.4	4.5

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

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Source: Zacks SCR

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