Zacks Small-Cap Research
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Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: NDA Filing on Track for 4Q21…

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 (03/09/21)	$11.58
Valuation	**$44.00**

OUTLOOK

On March 4, 2021, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the fourth quarter and full year 2020 and provided a business update. The company reported approximately $10 million in revenue for the fourth quarter of 2020 ($8.3 million from NARCAN Nasal Spray royalties) and $29.6 million for the full year 2020 ($27.4 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 $28 million for Opiant in 2021. The company has initiated the confirmatory PK study of OPNT003 with topline data expected in June 2021 and an NDA filing before the end of 2021.

SUMMARY DATA

52-Week High	**$14.49**
52-Week Low	**$6.87**
One-Year Return (%)	**4.32**
Beta	**0.79**
Average Daily Volume (sh)	**40,659**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$50**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**24**
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	4.6 E	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	-$0.65 E	-$0.26 E	-$0.08 E	$0.08 E	-$0.90 E
2022					-$1.11 E
2023					$1.36 E

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WHAT'S NEW

Financial Update

On March 4, 2021, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the fourth quarter and full year 2020. For the fourth quarter of 2020, Opiant reported revenue of $10.0 million, including $8.3 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 $7.2 million for the fourth quarter of 2019. Emergent BioSolutions reported revenue from the sale of NARCAN Nasal Spray of approximately $77.4 million for the fourth quarter of 2020.

For the full year 2020, Opiant recorded approximately $29.6 million in revenue, compared to approximately $40.5 million for 2019. For 2020, the company reported $27.6 million of revenue from the licensing agreement with Adapt Pharma for the sale of NARCAN Nasal Spray compared to approximately $37.6 million for 2019. The total in 2019 included a onetime milestone payment of $13.5 million due to NARCAN Nasal Spray sales exceeding $200 million for 2019. Emergent BioSolutions reported revenue from the sale of NARCAN Nasal Spray of approximately $311.2 million for 2020.

Net loss for 2020 was $1.9 million, or $0.44 per share, compared to a net gain of $11.6 million, or $2.88 per share, for 2019. G&A expenses for 2020 were approximately $11.7 million, compared to approximately $12.2 million for 2019. The decrease was primarily due to decreased legal, investor relations, and professional fees along with lower stock-based compensation partially offset by increased expenses associated with OPNT003. R&D expenses for 2020 were $9.2 million, compared to approximately $9.1 million for 2019. The increase was related to increased third party expenses for external R&D programs. Sales and marketing expenses were approximately $4.7 million in 2020, compared to approximately $0.6 million for 2019. The increase was primarily due to initial pre-commercialization market research for OPNT003 along with increased stock-based compensation. Royalty expenses in 2020 were approximately $6.2 million, compared to approximately $7.7 million for 2019. The decrease was due to lower net royalty revenue in 2020 compared to 2019.

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 $50 million will be available to Opiant in three tranches: the first tranche of $20 million was funded at the closing of the deal; a second tranche of $10 million will be available upon submission of an NDA to the FDA; the third tranche of $20 million will be funded upon FDA approval of an opioid overdose product. Each tranche matures over five years and has an interest-only period of 30 months at an average rate of 8.75%. The agreement allows for Pontifax and Kreos to convert up to half of their outstanding loan into shares of Opiant stock at a conversion price of $19.64 per share, which could result in a maximum of approximately 1.27 million shares being issued.

As of December 31, 2020, Opiant had approximately $48.3 million in cash and cash equivalents, which includes the first tranche of $20 million from the December 2020 convertible note agreement but does not include the remainder of the National Institute on Drug Abuse (NIDA) grant or the BARDA contract. In December 2020, the company announced an additional commitment of up to $3.5 million from BARDA for OPNT003.

NARCAN® Nasal Spray Forecast for 2020

Emergent BioSolutions Inc. (EBS) recently announced revenue guidance for 2021, that included an estimated $305 to $325 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

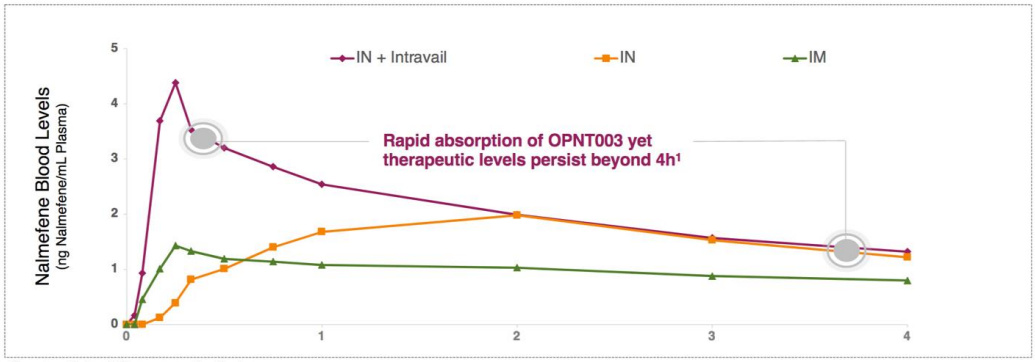
Based on gross revenues of approximately $315 million in 2021, we estimate that Opiant would receive approximately $28.0 million in royalty payments.

Business Update

OPNT003 Confirmatory PK Study Underway

On February 8, 2021, Opiant 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. We anticipate results in June 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 naloxone, intranasal nalmefene has a number of characteristics that make it superior to intranasal naloxone 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.

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.

In addition to the PK study for OPNT003, Opiant will also be conducting a pharmacodynamic (PD) study. The purpose of this study is to generate data to support the notion that OPNT003 is a fully differentiated product from other opioid overdose reversal treatments. The company has received Institutional Review Board (IRB) approval and we anticipate dosing initiating in mid-March 2021 with topline data expected in the beginning of the fourth quarter of 2021. Opiant remains on track to file a New Drug Application (NDA) for OPNT003 before the end of 2021.

Conclusion

We are glad to see that Opiant has initiated the confirmatory PK study for OPNT003 and we anticipate it running smoothly with topline results available in June 2021. The $50 million financing could allow the company to launch OPNT003 without any further financings, particularly with the expected continued strong sales of NARCAN® Nasal Spray and the royalties Opiant receives from it. 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 E	2Q E	3Q E	4Q E	2021 E	2022 E	2023 E
NARCAN royalty	$27.4	$4.4	$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	$0.2	$0.5	$1.3	$1.4	$3.4	$0.0	$0.0
Total Revenues	**$29.6**	**$4.6**	**$7.3**	**$9.2**	**$10.4**	**$31.4**	**$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	$2.4	$2.6	$2.8	$3.0	$10.8	$11.0	$12.0
General & Administrative	$11.7	$2.8	$3.0	$3.1	$3.2	$12.1	$13.0	$14.0
Sales and Marketing	$4.7	$1.3	$1.5	$1.8	$2.0	$6.6	$6.5	$6.5
Royalty Expenses	$6.2	$0.9	$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)	($2.8)	($1.2)	($0.4)	$0.3	($4.2)	($5.3)	$5.7
Non-Operating Expenses (Net)	($0.0)	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Pre-Tax Income	($2.3)	($2.7)	($1.1)	($0.3)	$0.4	($3.8)	($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)**	**($0.65)**	**($0.26)**	**($0.08)**	**$0.08**	**($0.90)**	**($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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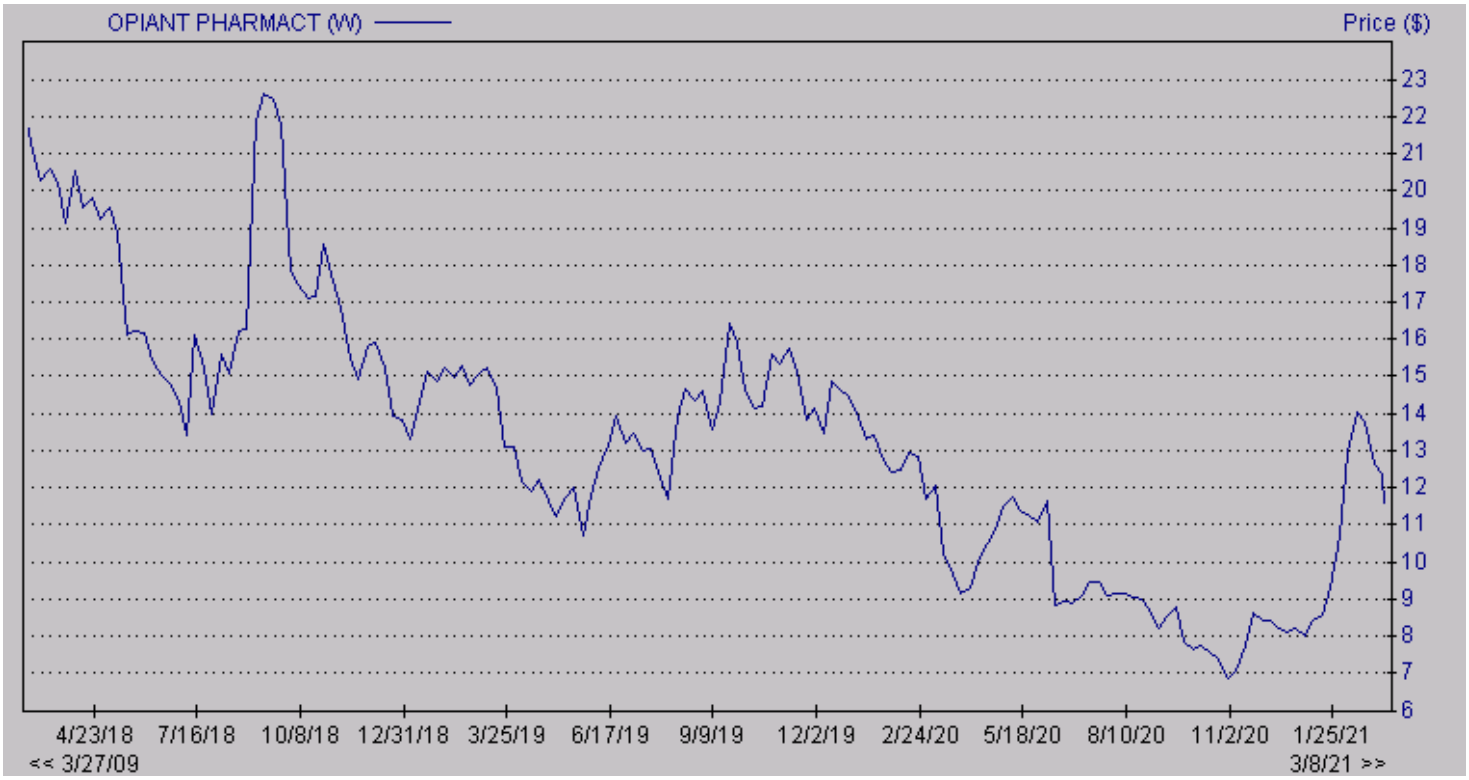

Source: Zacks SCR

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