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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: OPNT003 PK Study 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 (02/12/21)	$13.87
Valuation	**$44.00**

OUTLOOK

On February 8, 2020, Opiant Pharmaceuticals, Inc. (OPNT) announced that the confirmatory pharmacokinetic (PK) study for OPNT003, intranasal nalmefene, is underway. The open label, randomized, crossover study will enroll 68 healthy volunteers and will compare the PK profile of intranasally administered nalmefene to intramuscularly administered nalmefene. We anticipate results in June 2021. Prior PK results showed that OPNT003 has the potential for a rapid onset of action with a longer duration of activity compared to currently available opioid overdose therapies, thus it could provide another effective weapon in the fight against the ongoing opioid epidemic. The development of OPNT003 is being supported by grants from both NIDA and BARDA, and we anticipate a 505(b)(2) NDA being filed for OPNT003 before the end of 2021.

SUMMARY DATA

52-Week High	**$14.49**
52-Week Low	**$6.87**
One-Year Return (%)	**12.49**
Beta	**0.78**
Average Daily Volume (sh)	**69,519**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$59**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
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)
2019	3.7 A	6.8 A	20.6 A	7.7 A	40.5 A
2020	4.3 A	6.3 A	9.1 A	9.8 E	29.5 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	$0.07 A	$0.09 E	-$0.09 E
2021					$0.02 E
2022					$0.89 E

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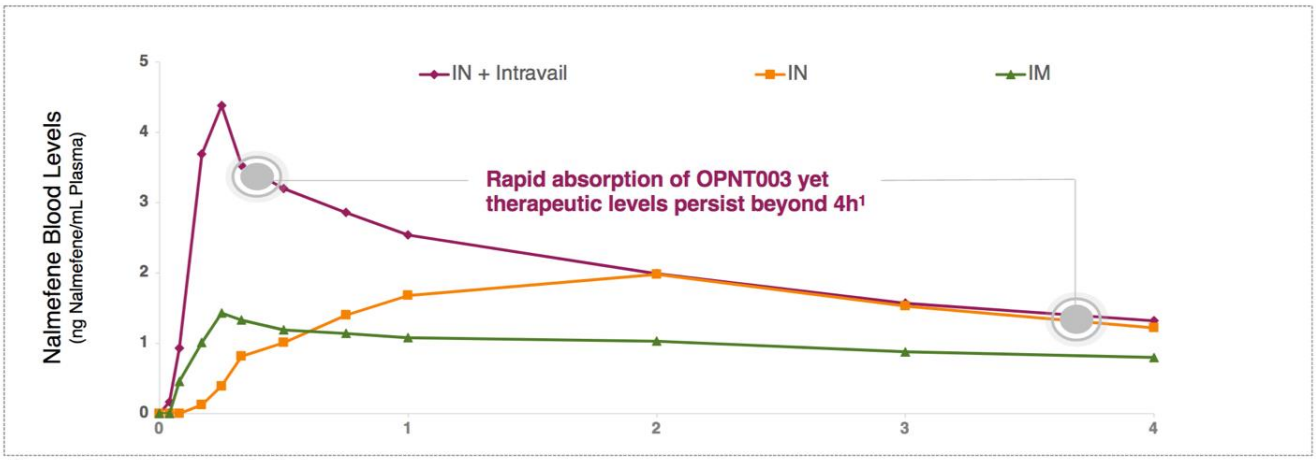
Business Update

OPNT003 Confirmatory PK Study Underway

On February 8, 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. 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.

The development of OPNT003 is being supported by a $7.4 million grant from the National Institute on Drug Abuse (NIDA) and $8.1 million in total from the Biomedical Advanced Research and Development Authority (BARDA). The company had previously received a $4.6 million contract from BARDA, and recently announced an additional $3.5 million to support a planned pharmacodynamic study in healthy volunteers and development work associated with the use of Aptar Pharma's Unit Dose System.

Financial Update

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.

Opiant had approximately $31 million in cash and cash equivalents as of September 30, 2020 and with this financing and the expected royalties from the sale of NARCAN® Nasal Spray the company is in a position to potentially launch OPNT003 without any additional financing.

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 should 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.	2019 A	1Q A	2Q A	3Q A	4Q E	2020 E	2021 E	2022 E
NARCAN royalty	$37.6	$4.2	$6.3	$8.6	$8.9	$28.0	$28.9	$31.6
YOY Growth	*183%*	-	-	-	-	*-26%*	*3%*	*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	$0.5	$0.9	$1.5	$0.0	$0.0
Total Revenues	**$40.5**	**$4.3**	**$6.3**	**$9.1**	**$9.8**	**$29.5**	**$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	$2.8	$2.5	$7.3	$10.0	$11.0
General & Administrative	$12.2	$2.6	$2.8	$2.7	$3.3	$11.4	$13.0	$14.0
Sales and Marketing	$0.6	$1.1	$1.7	$0.9	$1.4	$5.1	$0.0	$0.0
Royalty Expenses	$7.7	$0.9	$1.4	$2.0	$1.8	$6.0	$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)	$0.7	$0.9	($0.3)	$0.1	$4.2
Non-Operating Expenses (Net)	$0.5	$0.1	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	$11.4	($1.6)	($0.2)	$0.7	$0.9	($0.3)	$0.1	$4.2
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Net Income	**$11.6**	**($1.7)**	**($0.2)**	**$0.7**	**$0.9**	**($0.4)**	**$0.1**	**$4.2**
Reported EPS	**$2.88**	**($0.40)**	**($0.05)**	**$0.17**	**$0.21**	**($0.09)**	**$0.02**	**$0.89**
Basic Shares Outstanding	4.0	4.2	4.3	4.3	4.3	4.3	4.5	4.7

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

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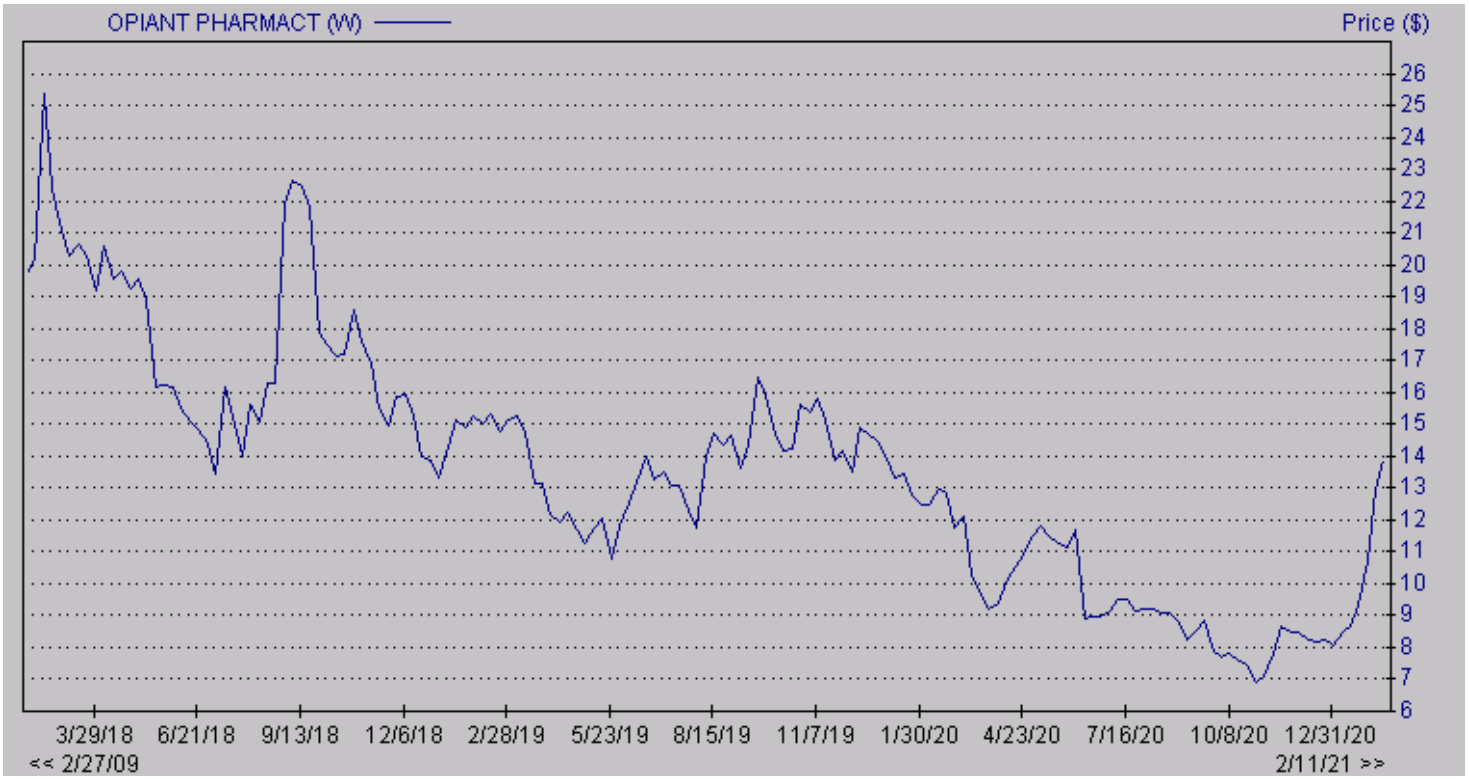
HISTORICAL STOCK PRICE



Source: Zacks SCR

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