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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: PD Data for OPNT003 Expected 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 (08/06/21)	$15.78
Valuation	**$44.00**

OUTLOOK

On August 5, 2021, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the second quarter of 2021 and provided a business update. The company reported $11.3 million in revenue for the second quarter of 2021, which included $9.3 million in royalties from the sale of NARCAN® Nasal Spray. Emergent BioSolutions reported NARCAN revenues of $106.2 million, which was well above estimates, and Opiant is now forecasting for 2021 royalties of $28.9 million and expects to exit 2021 with approximately $42 to $44 million in cash, cash equivalents, and marketable securities. We anticipate results from the pharmacodynamic (PD) study of OPNT003 in the fourth quarter of 2021 and for the company to file an NDA for OPNT003 in late 2021 or the first quarter of 2022.

SUMMARY DATA

52-Week High	**$18.03**
52-Week Low	**$6.87**
One-Year Return (%)	**72.65**
Beta	**0.77**
Average Daily Volume (sh)	**52,210**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$68**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
Insider Ownership (%)	**29**
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-Blend**
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	11.3 A	9.0 E	9.0 E	35.6 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	$0.39 A	-$0.12 E	- $0.23 E	-$0.63 E
2022					-$1.11 E
2023					$1.36 E

WHAT'S NEW

Financial Update

On August 5, 2021, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the second quarter of 2021. The company reported $11.3 million in revenue for the second quarter of 2021, compared to $6.3 million in revenue for the second quarter of 2020. The revenue in the second quarter of 2021 consisted of approximately $9.3 million of royalty revenue from the licensing agreement with Adapt Pharma Operations Limited, a subsidiary of Emergent BioSolutions (EBS), for the sale of NARCAN® Nasal Spray and approximately $1.9 million from grant and contract revenue. Emergent reported $106.2 million in revenue from the sale of NARCAN in the second quarter of 2021 and is continuing to guide for full year 2021 NARCAN revenue of $305-$325 million. Opiant is now forecasting full year royalty revenue of $28.9 million based on the high end of Emergent's forecast.

Net income for the three months ending June 30, 2021 was approximately $1.7 million, or $0.39 per share, compared to a net loss of approximately $0.2 million, or $0.05 per share, for the comparable period in 2020. G&A expenses in the second quarter of 2021 were $2.7 million, compared to $2.8 million in the second quarter of 2020. The decrease was due to a decrease in legal and professional fees. R&D expenses were $3.2 million for the second quarter of 2021, compared to $0.6 million for the second quarter of 2020. The increase was primarily due to increased activity for OPNT003. Sales and marketing expenses for the three months ending June 30, 2021 were $1.0 million, compared to $1.7 million for the three months ending June 30, 2020. Sales and marketing expenses are related to pre-commercialization efforts for OPNT003. Royalty expense for the second quarter of 2021 was $2.1 million, compared to $1.4 million for the second quarter of 2020. The increase is due to increased royalties received from sales of NARCAN.

As of June 30, 2021, Opiant had approximately $48.5 million in cash, cash equivalents, and marketable securities. We estimate that the company will finish 2021 with approximately $42-$44 million in cash, cash equivalents, and marketable securities. As of August 2, 2021, Opiant had approximately 4.4 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 9.1 million.

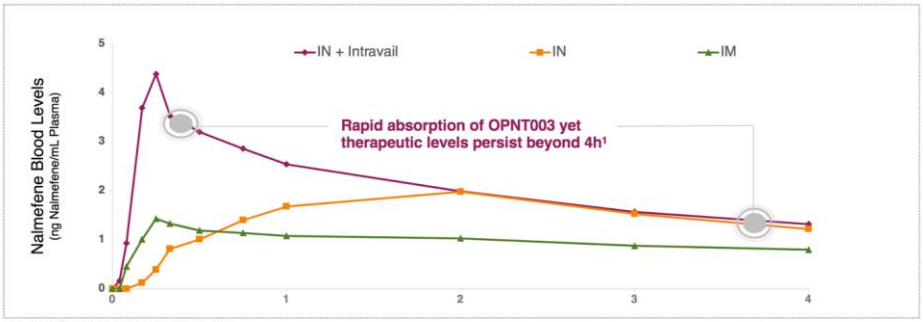
Business Update

Positive Results for OPNT003 PK Study

On July 6, 2021, Opiant announced positive topline results from the confirmatory pharmacokinetic (PK) study of OPNT003, an intranasal (IN) formulation of nalmefene, which is being developed as a treatment for opioid overdose. This was an open label, randomized, crossover study in 68 healthy volunteers and compared 3mg IN nalmefene with 1mg intramuscular (IM) nalmefene.

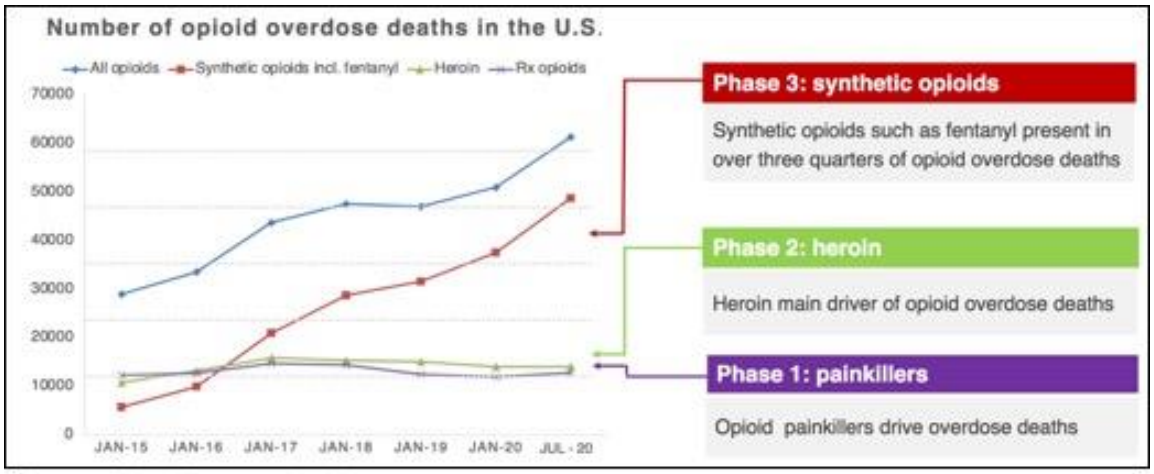
The topline results showed that IN nalmefene achieved significantly higher plasma concentrations compared to the IM injection ($P<0.0001$). In addition, the time for IN nalmefene the achieve maximum plasma concentrations (T_{max}) was consistent with what was seen in the previously completed pilot study, the maximum plasma concentration (C_{max}) was higher than seen in the pilot study, and the plasma half-life of IN nalmefene was consistent with what was seen following other routes of administration (oral and parenteral).

Opiant had previously conducted an initial PK study of IN nalmefene that showed rapid increases in plasma levels with an onset faster than an IM 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 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.

The following graph shows that the opioid epidemic currently ongoing in the U.S. is showing no signs of abating. The COVID-19 pandemic only exacerbated an already serious problem with opioid overdose deaths, which is now being fueled mostly by an increase in the use of synthetic opioids such as fentanyl, which has a half-life of more than seven hours (compared to 1-2 hours for heroin). For this reason, there is an urgent need for an opioid overdose therapy that is stronger and longer-acting than naloxone.



Source: Opiant Pharmaceuticals, Inc.

Compared to IN naloxone, IN 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.

Opiant is currently conducting a pharmacodynamic (PD) trial of OPNT003 that will compare its effectiveness with IN 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.), which 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.

Phase 1 Trial for OPNT004, Drinabant, in 2022

OPNT004 (drinabant), a novel CB-1 receptor antagonist, is being developed for the treatment of acute cannabinoid overdose (ACO). 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. 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.

Preclinical activities and formulation development are currently ongoing with a Phase 1 trial anticipated to begin in 2022 with the parenteral form of the drug.

Conclusion

The increase in sales of NARCAN are not too surprising given the continued escalation in opioid overdoses in the U.S., which has seen a significant increase due in part to the ongoing coronavirus pandemic. We would not be surprised to see Emergent raise full year sales estimates for NARCAN following the release of the third quarter 2021 numbers given how much higher they were than estimated in the second quarter of 2021. Regardless, Opiant remains in solid financial shape as the company awaits results from the PD trial in the fourth quarter of 2021 and the NDA filing either late in 2021 or the first quarter of 2022. With no changes to our model our valuation remains at $44.

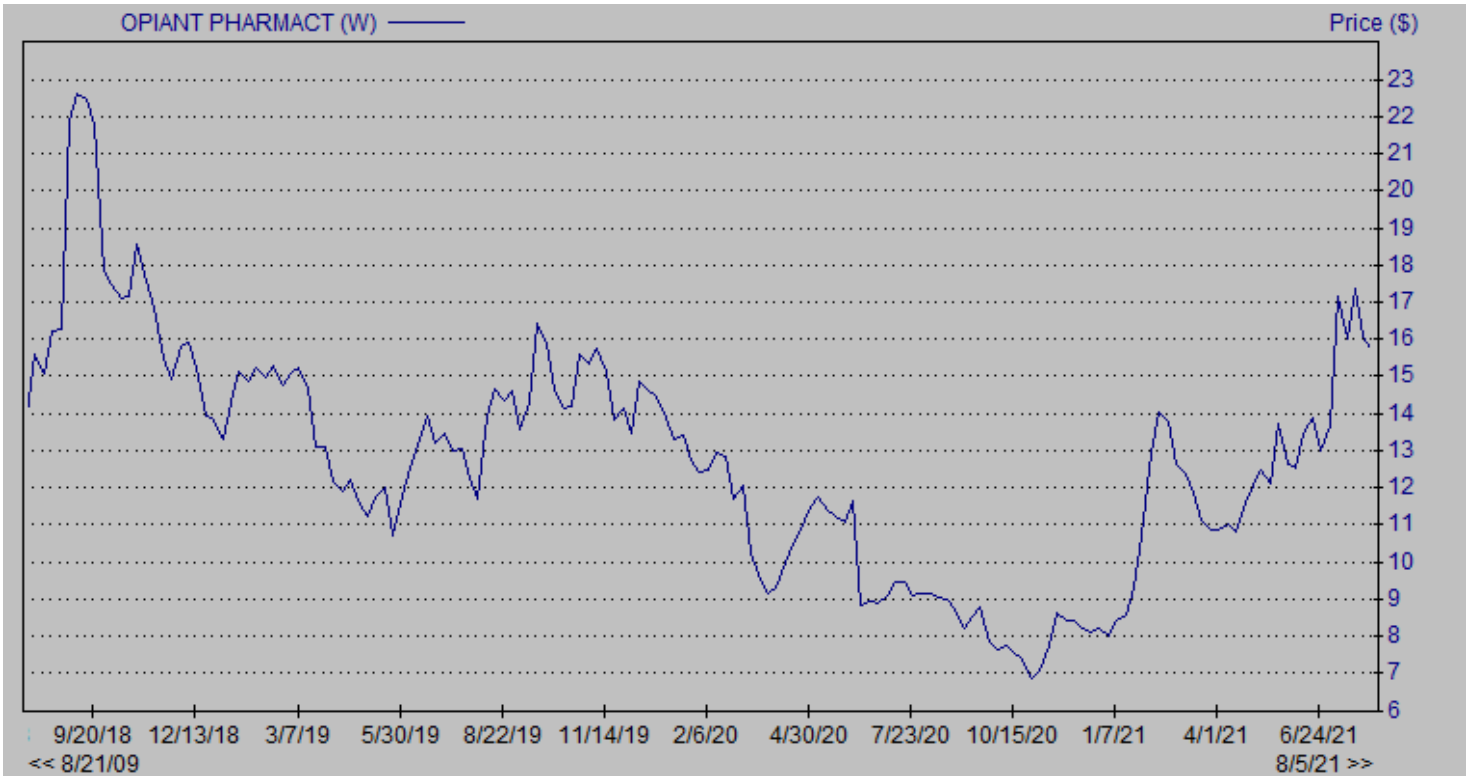
PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	2020 E	1Q A	2Q A	3Q E	4Q E	2021 E	2022 E	2023 E
NARCAN royalty	$27.4	$4.3	$9.3	$7.7	$7.6	$28.9	$31.6	$26.2
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	$1.9	$1.3	$1.4	$6.7	$0.0	$0.0
Total Revenues	**$29.6**	**$6.4**	**$11.3**	**$9.0**	**$9.0**	**$35.6**	**$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	$3.1	$2.8	$3.0	$13.0	$11.0	$12.0
General & Administrative	$11.7	$2.6	$2.7	$3.1	$3.2	$11.7	$13.0	$14.0
Sales and Marketing	$4.7	$1.0	$1.0	$1.8	$2.0	$5.8	$6.5	$6.5
Royalty Expenses	$6.2	$1.0	$2.1	$2.0	$1.9	$6.9	$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)	$2.2	($0.6)	($1.1)	($1.8)	($5.3)	$5.7
Non-Operating Expenses (Net)	($0.0)	($0.5)	($0.6)	$0.1	$0.1	($0.9)	$0.4	$0.4
Pre-Tax Income	($2.3)	($2.8)	$1.7	($0.5)	($1.0)	($2.7)	($4.9)	$6.1
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Net Income	**($1.9)**	**($2.8)**	**$1.7**	**($0.5)**	**($1.0)**	**($2.7)**	**($4.9)**	**$6.1**
Reported EPS	**($0.44)**	**($0.66)**	**$0.39**	**($0.12)**	**($0.23)**	**($0.63)**	**($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*

HISTORICAL STOCK PRICE



Source: Zacks SCR

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