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Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

OPNT: Raises 2021 Full-Year Revenue and Cash Guidance…

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 $49/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 (11/15/21)	$25.64
Valuation	**$49.00**

OUTLOOK

On November 11, 2021, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the third quarter of 2021 and provided a business update. The company reported $16.3 million in revenue for the third quarter of 2021, which included $14.0 million in royalties from the sale of NARCAN® Nasal Spray. Emergent BioSolutions reported NARCAN revenues of $133.3 million, which was well above estimates, and Opiant is now forecasting for 2021 royalties of $38 million and expects to exit 2021 with approximately $50 to $52 million in cash, cash equivalents, and marketable securities. We anticipate results from the pharmacodynamic (PD) study of OPNT003 in the first quarter of 2022 and for the company to file an NDA for OPNT003 in the first half of 2022.

SUMMARY DATA

52-Week High	**$28.42**
52-Week Low	**$7.24**
One-Year Return (%)	**229.14**
Beta	**0.39**
Average Daily Volume (sh)	**36,349**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$113**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
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	**High**
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	16.3 A	14.6 E	48.6 E
2022					31.6 E
2023					76.2 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	$0.77 A	$ 0.64 E	$1.18 E
2022					-$2.71 E
2023					-$1.12 E

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WHAT'S NEW

Financial Update

On November 11, 2021, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the third quarter of 2021. The company reported $16.3 million in revenue for the third quarter of 2021, compared to $9.1 million in revenue for the third quarter of 2020. The revenue in the third quarter of 2021 consisted of approximately $14 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 $2.3 million from grant and contract revenue. Emergent reported $133.3 million in revenue from the sale of NARCAN in the third quarter of 2021 and has raised guidance for full year 2021 NARCAN revenues to $400-$420 million. Opiant is now forecasting full year royalty revenue of $38 million.

Net income for the three months ending September 30, 2021 was approximately $3.4 million, or $0.77 per share, compared to net income of approximately $0.7 million, or $0.17 per share, for the comparable period in 2020. G&A expenses in the third quarter of 2021 were $3.4 million, compared to $2.7 million in the third quarter of 2020. The increase was primarily due to increased legal and professional fees. R&D expenses were $4.9 million for the third quarter of 2021, compared to $2.8 million for the third quarter of 2020. The increase was primarily due to increased activity for OPNT003. Sales and marketing expenses for the three months ending September 30, 2021 were $1.1 million, compared to $0.9 million for the three months ending September 30, 2020. Sales and marketing expenses are related to pre-commercialization efforts for OPNT003. Royalty expense for the third quarter of 2021 was $3.1 million, compared to $2.0 million for the third quarter of 2020. The increase is due to increased royalties received from sales of NARCAN.

As of September 30, 2021, Opiant had approximately $50.3 million in cash, cash equivalents, and marketable securities. We estimate that the company will finish 2021 with approximately $50-$52 million in cash, cash equivalents, and marketable securities. As of November 9, 2021, Opiant had approximately 4.7 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 9.1 million.

Business Update

Fast Track Designation for OPNT003; PD Results in 1Q22

On November 4, 2021, Opiant announced that the U.S. FDA has granted Fast Track designation for OPNT003, the company's intranasal (IN) formulation of nalmefene, which is being developed as a treatment for opioid overdose. Fast Track designation was established to help expedite the review of therapeutics for serious conditions with an unmet medical need and allows for more frequent communication with the FDA along with the potential for a rolling submission of the NDA.

In July 2021, the company announced positive topline results for the confirmatory pharmacokinetic (PK) study of OPNT003. The 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 is currently conducting a pharmacodynamic (PD) trial of OPNT003 that will compare its effectiveness to IN naloxone. It is a single center, randomized, open label study in healthy volunteers that is powered to demonstrate non-inferiority between nalmefene and naloxone. The primary endpoint is the reversal of respiratory depression brought about by the synthetic opioid remifentanil (measured by minute ventilation at five minutes), with additional secondary endpoints examining a range of other timepoints.

This is a two-part trial; Part 1 is determining the optimal dose of remifentanil that will allow a safe and meaningful comparison in the study and Part 2 is the head-to-head comparison of nalmefene and naloxone. The company has completed Part 1 of the study and is expecting to complete recruitment and dosing in Part 2 by the end of 2021. While we had originally anticipated topline data before the end of 2021, during Part 1 of the study the company

decided to alter the dose of remifentanil, which was reviewed by the FDA and subsequently approved by the Institutional Review Board (IRB). We now anticipate topline results in the first quarter of 2022.

OPNT002 Phase 2 Trial to Initiate 4Q21

Following a delay due to the COVID-19 pandemic, Opiant is planning to initiate a Phase 2 clinical trial of OPNT002 (intranasal naltrexone) for the treatment of alcohol use disorder (AUD) in the fourth quarter of 2021. It will be a randomized, double blind, placebo controlled trial of approximately 300 individuals

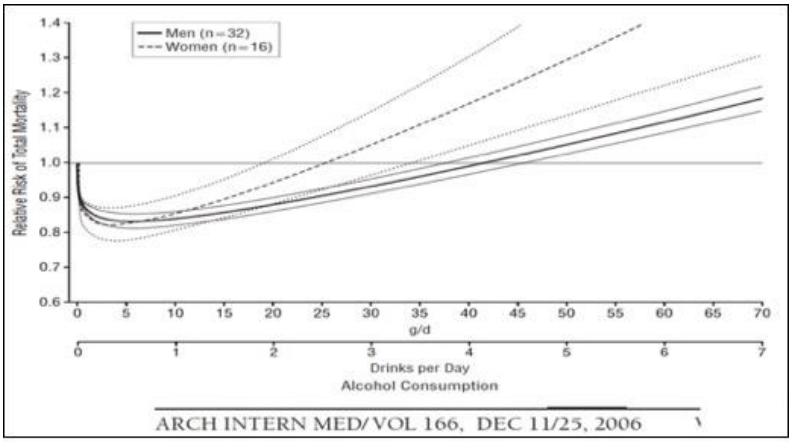
Just as with intranasal nalmefene, Opiant is developing intranasal naltrexone with INTRAVAIL® to rapidly increase the plasma concentration of the drug following dosing. The following table shows that intranasally administered naltrexone with INTRAVAIL® has a Cmax that is approximately 50% higher than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

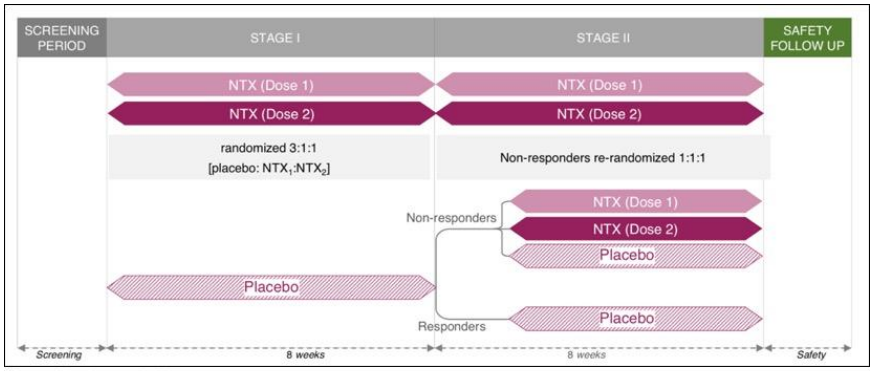
Source: Opiant Pharmaceuticals, Inc.

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.

The primary endpoint of the trial will examine whether OPNT002 reduces heavy drinking in patients as measured by the World Health Organization (WHO) drinking risk levels (WHO, 2000), which are defined by alcohol consumed per day (low risk: 1-40 g for males/1-20 g for females; medium risk: 41-60 g for males/21-40 g for females; high risk: 61-100 g for males/41-60 g for females; very high risk: 101+ g for males/61+ g for females). A recent study showed that at least one- and two-level reductions in WHO risk levels were associated with improved health parameters and quality of life (Witkiewitz *et al*., 2018), with another study showing one- and two-level reductions in WHO risk levels by the end of treatment being associated with WHO risk level reductions at the 1-year follow-up assessment (Witkiewitz *et al*., 2019).

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

Following a very large increase in NARCAN sales for the third quarter of 2021, we believe Opiant is in a fantastic financial position to advance the company to the next stage. We are looking forward to the results of the PD trial in the first quarter of 2022, which could help to differentiate OPNT003 from NARCAN, which combined with the recent addition of Matt Ruth (who helped to launch NARCAN Nasal Spray at Adapt Pharma) as Chief Commercial Officer should set up OPNT003 to be a successful opioid overdose treatment, if approved. Now that it looks like Opiant is going to commercialize OPNT003 on its own, we have adjusted our model to account for how OPNT003 revenues/expenses will be recorded, which has resulted in an increase in our valuation to $49.

PROJECTED FINANCIALS

Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	2020 E	1Q A	2Q A	3Q A	4Q E	2021 E	2022 E	2023 E
NARCAN royalty	$27.4	$4.3	$9.3	$14.0	$13.2	$40.9	$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	$50.0
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	$2.3	$1.4	$7.7	$0.0	$0.0
Total Revenues	**$29.6**	**$6.4**	**$11.3**	**$16.3**	**$14.6**	**$48.6**	**$31.6**	**$76.2**
Cost of Sales	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.0
Research & Development	$9.2	$4.1	$3.1	$4.9	$3.0	$15.1	$17.0	$20.0
General & Administrative	$11.7	$2.6	$2.7	$3.4	$3.2	$12.0	$13.0	$34.0
Sales and Marketing	$4.7	$1.0	$1.0	$1.1	$2.0	$5.1	$6.5	$15.0
Royalty Expenses	$6.2	$1.0	$2.1	$3.1	$2.9	$9.0	$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	$4.0	$3.5	$7.4	($11.3)	($3.8)
Non-Operating Expenses (Net)	($0.0)	($0.5)	($0.6)	($0.5)	($0.5)	($2.1)	($2.0)	($2.0)
Pre-Tax Income	($2.3)	($2.8)	$1.7	$3.4	$3.0	$5.3	($13.3)	($5.8)
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Net Income	**($1.9)**	**($2.8)**	**$1.7**	**$3.4**	**$3.0**	**$5.3**	**($13.3)**	**($5.8)**
Reported EPS	**($0.44)**	**($0.66)**	**$0.39**	**$0.77**	**$0.64**	**$1.18**	**($2.71)**	**($1.12)**
Basic Shares Outstanding	4.2	4.3	4.3	4.5	4.7	4.4	4.9	5.2

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

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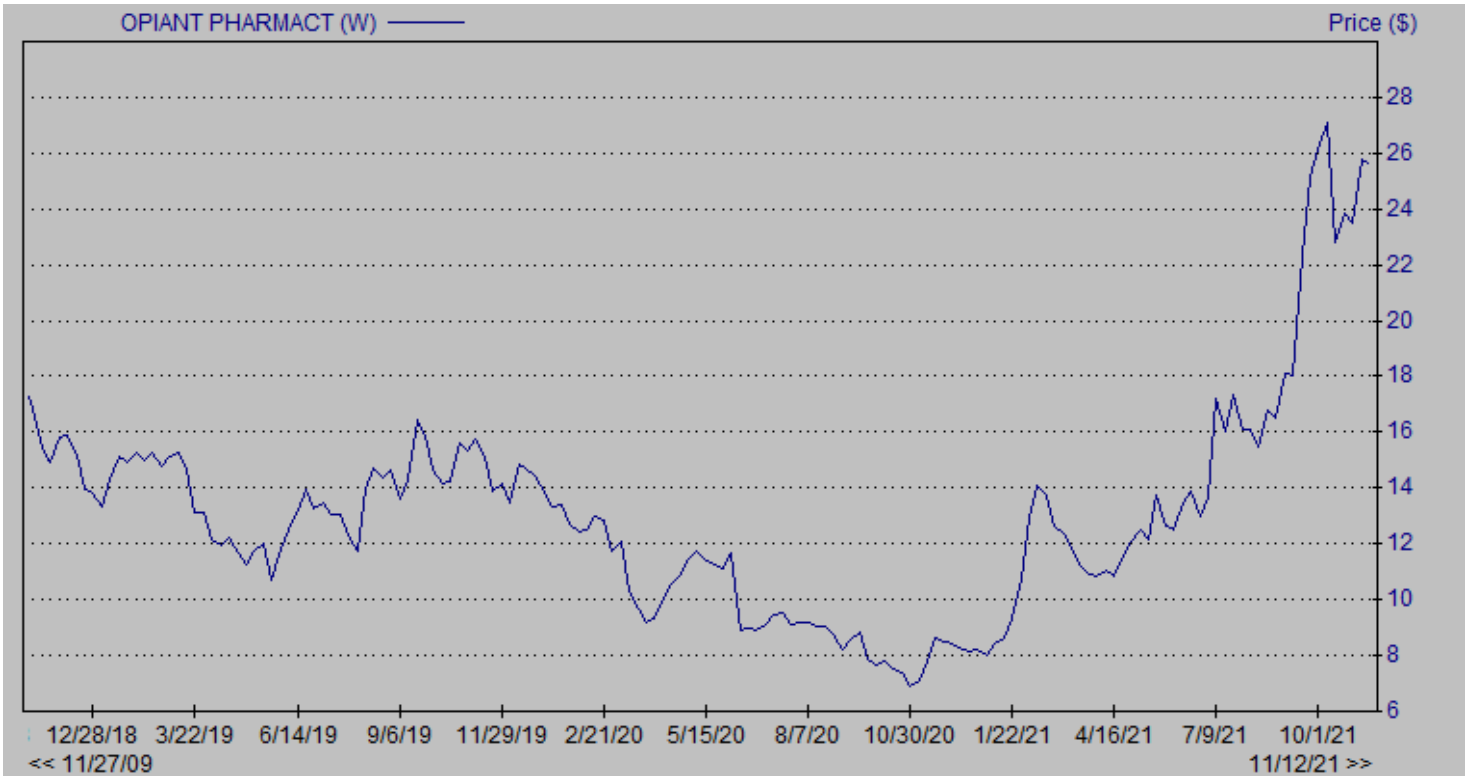
HISTORICAL STOCK PRICE



Source: Zacks SCR

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