Zacks Small-Cap Research

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# Opiant Pharmaceuticals, Inc. (OPNT-NASDAQ)

## *OPNT: Increased Revenue Guidance for NARCAN® Nasal Spray…*

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 (08/13/19) | $15.16 |
| **Valuation** | **$44.00** |

## OUTLOOK

On May 9, 2019, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the second quarter of 2019. Royalties from the sale of NARCAN® Nasal Spray totaled $6.1 million due to higher than anticipated sales of the drug during the second quarter. Emergent BioSolutions (EBS) raised full year revenue guidance to $240-$260 million and we now anticipate full year royalty net revenues for Opiant to be approximately $22 million.

In the second half of 2019, we anticipate the company initiating a pivotal pharmacokinetic (PK) study for OPNT003, intranasal nalmafene, with results anticipated before the end of 2019. In addition, a Phase 2 trial of OPNT002 for the treatment of alcohol use disorder (AUD) is expected to commence before the end of 2019.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$23.43** |
| **52-Week Low** | **$10.25** |
| **One-Year Return (%)** | **-5.96** |
| **Beta** | **0.43** |
| **Average Daily Volume (sh)** | **25,302** |
| **Shares Outstanding (mil)** | **4** |
| **Market Capitalization ($mil)** | **$61** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **19** |
| **Insider Ownership (%)** | **31** |
| **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** | **Average** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Drugs** |

## ZACKS ESTIMATES

**Revenue**
(In millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2018 | 1.7 A | 3.2 A | 4.4 A | 4.8 A | 14.0 A |
| 2019 | 3.7 A | 6.8 A | 5.9 E | 7.1 E | 25.2 E |
| 2020 | | | | | 36.8 E |
| 2021 | | | | | 35.3 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2018 | -$3.68 A | $0.52 A | -$0.32 A | -$2.72 A | -$7.10 A |
| 2019 | -$0.44 A | $0.39 A | $0.21 E | $0.37 E | $0.47 E |
| 2020 | | | | | $3.21 E |
| 2021 | | | | | $2.51 E |

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## WHAT'S NEW

**Financial Update**

On August 8, 2019, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the second quarter of 2019. The company recorded a total of $6.8 million in revenue for the three months ending June 30, 2019, which consisted of $6.1 million in royalty revenue from the sale of NARCAN® Nasal Spray, $0.1 million from grant and contract revenue, and $0.6 million from treatment investment revenue. This compares to royalty revenue of $3.1 million for the three months ending June 30, 2018. The increase was attributable to an increase in sales of NARCAN® Nasal Spray by Emergent BioSolutions (EBS), which totaled $73 million in the second quarter of 2019. This was ahead of our estimate and according to Emergent was mainly the result of co-prescribing legislation, which is now active in nine states. Emergent raised full-year revenue guidance for NARCAN® Nasal Spray from $200 - $220 million to $240 - $260 million, implying that revenues in the third and fourth quarter will come down to the $55-$60 million range. We have raised our estimate for full year revenues for NARCAN® Nasal Spray to $260 million.

Opiant will receive a $13.5 million net milestone payment due to the company upon sales exceeding $200 million for the first time in a calendar year. We believe that sales will exceed $200 million in the fourth quarter of 2019, thus Opiant will receive the milestone payment in the first quarter of 2020. Due to a third-party license agreement entered into between Adapt Pharma and another company, Opiant will have $2.7 million deducted from the $13.5 million milestone payment, thus we anticipate the company receiving a net milestone payment of $10.8 million in the first quarter of 2020.

Net income for the second quarter of 2019 was approximately $1.6 million, or $0.39 per share, compared to a net loss of $1.4 million, or $0.52 per share, for the second quarter of 2019. R&D expenses in the second quarter of 2019 were $1.6 million, which was essentially the same as the second quarter of 2018. G&A expenses in the second quarter of 2019 were $3.7 million compared to $2.9 million for the second quarter of 2018. The increase was primarily due to an increase in legal, accounting, and professional fees along with an increase in royalty expenses partially offset by a decrease in stock-based compensation.

Opiant exited the second quarter of 2019 with approximately $23.9 million in cash and cash equivalents, which does not include the remaining amounts due from the NIDA grant and the BARDA contract. We forecast that the company will have approximately $17-$20 million in cash and cash equivalents at the end of 2019 and will likely receive the $10.8 million milestone payment during the first quarter of 2020.

**Business Update**

*OPNT003 Update*

OPNT003 is an intranasal (IN) formulation of nalmefene (a naltrexone derivative), which the company is developing as a long-lasting opioid antagonist for the treatment of opioid overdose. In 2018, Opiant received a $7.4 million grant from the National Institute on Drug Abuse (NIDA) to fund development of OPNT003. In addition, in September 2018 Opiant received a $4.6 million contract with the Biomedical Advanced Research and Development Authority (BARDA), which is part of the U.S. Health and Human Services Office of the Assistant Secretary for Preparedness and Response, which is intended to help fund development of OPNT003 through the new drug application (NDA) filing.

Of the approximately 48,000 opioid overdose deaths in 2017, approximately 55% of them were fentanyl related (CDC). This rapid rise in recent years of overdose deaths due to synthetic opioid (e.g., fentanyl) has led the National Institutes of Health (NIH) to call for improved opioid antagonists that are capable of counteracting their effects (Volkow *et al*., 2017). Synthetic opioids such as fentanyl and carfentanil are particularly problematic due to their potency and longer half-lives. For example, heroin has a half-life of approximately 30 minutes while fentanyl's half-life is two to four hours, thus necessitating opioid antagonism for an extended period of time. Naloxone has a half-life of approximately 1-2 hours and typically requires repeated administration during the treatment of someone suffering from a fentanyl overdose.

Nalmefene is an opioid antagonist with a much longer half-life than naloxone (7-9 hours). It was approved by the FDA in 1995 as an injectable treatment for opioid overdose sold under the brand name Revex®, however Baxter

discontinued it in the U.S. in 2008. Opiant has developed an intranasally administered nalmefene formulation using the Intravail® technology, which was developed by Aegis Therapeutics, LLC. It comprises a broad class of chemically synthesizable transmucosal absorption enhancement agents to allow the intranasal (although other routes of administration are available including oral, rectal, ocular, etc.) administration of therapeutics up to 30,000 Daltons molecular weight.

Opiant has successfully completed a Phase 1 study of intranasally administered 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 company is planning to conduct a pivotal pharmacokinetic study starting in the third quarter of 2019 with top-line data expected later this year. We believe Opiant will be in a position to file an NDA for OPNT003 in 2020.

Opiant owns all commercial rights to OPNT003 and the company's prospects for partnering remain wide open at this point. We believe that if the company were to enter into a commercialization partnership it would be able to command favorable terms given the commercial success of NARCAN® Nasal Spray and the company's strong financial position.

*OPNT002 Update*

OPNT002 is an intranasal formulation of naltrexone, which Opiant is developing for the treatment of alcohol use disorder (AUD). In April 2019, Opiant announced the publication of PK data for OPNT002 in *The Journal of Clinical Pharmacology*. The study involved 14 subjects who were each administered 4 mg IN naltrexone, 4 mg IN naltrexone with Intravail® (denoted as DDM in the publication), 2 mg intramuscular (IM) naltrexone, or 50 mg oral naltrexone on different days. The following table shows PK results from the study. The addition of Intravail® to IN naltrexone resulted in an approximately 3-fold increase in $C_{max}$ and a decrease in $T_{max}$, however the half-life of IN naltrexone was only 2.2 – 2.5 hours, which is very similar to naloxone, thus limiting the potential usefulness of IN naltrexone against longer-lived synthetic opioids such as fentanyl.

| 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)[f] | 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*: Krieter *et al.*, 2019

While IN naltrexone is likely not a good candidate to treat overdose from synthetic opioids, it is well-suited for "on demand" dosing to treat AUD. Multiple studies show that alcohol consumption results in release of endogenous opioids that bind to δ-opioid receptors with high affinities (Weerts *et al*., 2008; Mitchell *et al*., 2012). Since naltrexone is a high-affinity opioid antagonist, the ability to achieve high plasma concentrations of naltrexone through IN administration while an individual is craving alcohol may increase its efficacy compared to the oral or injectable form, for which it is currently approved to treat AUD.

Opiant will be currently preparing for a Phase 2 clinical trial, which we anticipate initiating later this year with results anticipated in the second half of 2020.

*OPNT004 Update*

In December 2018, Opiant announced the acquisition of drinabant (OPNT004), a novel CB-1 receptor antagonist, for the treatment of acute cannabinoid overdose (ACO). Opiant paid Sanofi an upfront payment of $500,000 and will be responsible for all development and commercialization activities. The company recently announced an agreement in which Sanofi will manufacture OPNT004.

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. This can ultimately result in severe effects if left untreated, including reports of suicide from marijuana-induced psychosis. 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 Δ-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. Following reformulation of the drug in 2019, we anticipate clinical studies commencing in 2020.

## Conclusion

Opiant is in strong financial shape with the incoming royalties from the sale of NARCAN® Nasal Spray, particularly with Emergent raising guidance for 2019 sales of NARCAN®. For the remainder of 2019, we anticipate results from the pivotal PK study of OPNT003 before the end of the year and the Phase 2 study for OPNT002 to initiate. Our valuation remains at $44 and we continue to see the potential for significant upside for investors as the stock continues to trade at a significant discount to that valuation.

## PROJECTED FINANCIALS

**Opiant Pharmaceuticals, Inc.**
Income Statement

| Opiant Pharmaceuticals, Inc. | 2018 A | 1Q A | 2Q A | 3Q E | 4Q E | 2019 E | 2020 E | 2021 E |
|---|---|---|---|---|---|---|---|---|
| NARCAN royalty | $13.3 | $3.7 | $6.1 | $5.4 | $6.6 | $21.9 | $33.8 | $20.8 |
| *YOY Growth* | - | - | - | - | - | *65%* | *54%* | *-38%* |
| 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 | $11.5 |
| OPNT004 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Licensing, Milestones, and Grants | $0.7 | $1.7 | $0.6 | $0.5 | $0.5 | $3.3 | $3.0 | $3.0 |
| **Total Revenues** | **$14.0** | **$5.4** | **$6.8** | **$5.9** | **$7.1** | **$25.2** | **$36.8** | **$35.3** |
| Cost of Sales | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Research & Development | $8.5 | $3.6 | $1.6 | $1.8 | $2.3 | $9.3 | $9.0 | $10.0 |
| General & Administrative | $11.3 | $3.7 | $3.7 | $3.3 | $3.3 | $14.0 | $14.0 | $14.0 |
| Selling Expenses | $0.2 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Royalty Expenses | $1.5 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| License Fees | $13.7 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Operating Income | ($21.2) | ($1.8) | $1.4 | $0.8 | $1.5 | $1.9 | $13.8 | $11.3 |
| Non-Operating Expenses (Net) | $0.0 | $0.1 | $0.1 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($21.1) | ($1.7) | $1.5 | $0.8 | $1.5 | $1.9 | $13.8 | $11.3 |
| Income Taxes Paid | $0 | $0 | ($0) | $0 | $0 | $0 | $0 | $0 |
| **Net Income** | **($21.2)** | **($1.7)** | **$1.6** | **$0.8** | **$1.5** | **$1.9** | **$13.8** | **$11.3** |
| **Reported EPS** | **($7.10)** | **($0.44)** | **$0.39** | **$0.21** | **$0.37** | **$0.47** | **$3.21** | **$2.51** |
| Basic Shares Outstanding | 3.0 | 3.9 | 4.0 | 4.0 | 4.1 | 4.0 | 4.3 | 4.5 |

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

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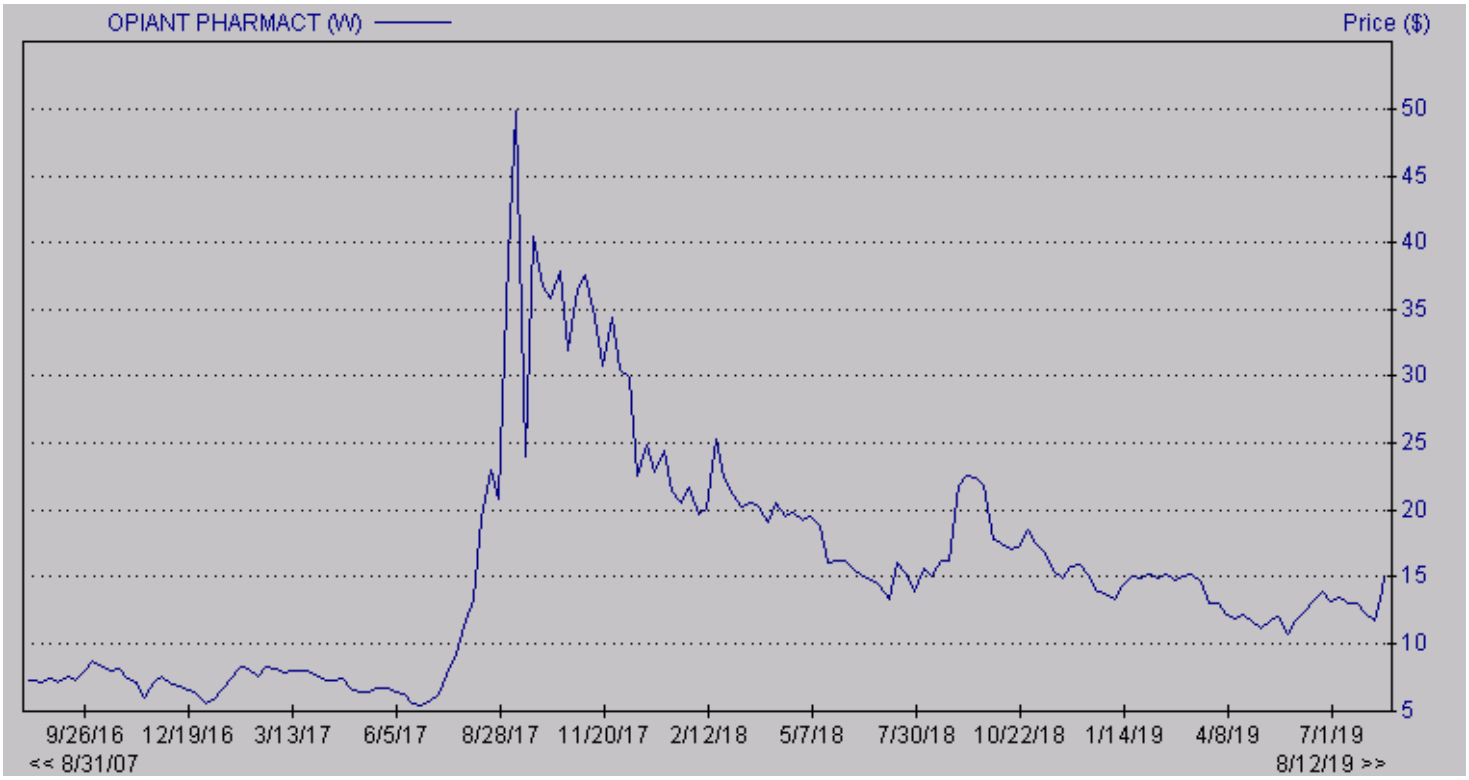
## HISTORICAL STOCK PRICE

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