Zacks Small-Cap Research

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# Opiant Pharmaceuticals Inc. (OPNT-OTC)

## *OPNT: Looking to Have a Transformative 2017…*

Based on our probability adjusted DCF model that takes into account potential future revenues from treating opioid abuse, bulimia nervosa, and cocaine use disorder, OPNT is valued at $20/share. This model is highly dependent upon the commercial success of NARCAN® Nasal Spray and clinical success in treating bulimia nervosa and cocaine use disorder.

| | |
|---|---|
| Current Price (03/22/17) | $8.50 |
| **Valuation** | **$20.00** |

## OUTLOOK

Opiant Pharmaceuticals, Inc. (OPNT) is looking to have a transformative 2017. The company has outlined a number of goals for the year and has already begun to execute on a number of them. Following the monetization of the royalty for NARCAN Nasal Spray that resulted in an initial payment of $13.7 million, Opiant has plenty of capital to move additional research products forward in the clinic. The company recently initiated a clinical trial of OPNT001 in patients with bulimia nervosa and has received supportive feedback from the FDA in regards to moving OPNT002 forward in development as a treatment for alcohol use disorder. A new In addition, during 2017 Opiant is planning to pursue an uplisting to a major stock exchange.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$10.15** |
| **52-Week Low** | **$5.60** |
| **One-Year Return (%)** | **N/A** |
| **Beta** | **N/A** |
| **Average Daily Volume (sh)** | **2,780** |
| **Shares Outstanding (mil)** | **2** |
| **Market Capitalization ($mil)** | **$17** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **0** |
| **Insider Ownership (%)** | **34** |
| **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 2016 Estimate** | **N/A** |
| **P/E using 2017 Estimate** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High,** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Biomed/Gene** |

## ZACKS ESTIMATES

### Revenue

(In millions of $)

| | Q1 (Oct) | Q2 (Jan) | Q3 (Apr) | Q4 (Jul) | Year (Jul) |
|---|---|---|---|---|---|
| 2016 | 0.1 A | 6.9 A | 2.6 A | 0.3 A | 9.9 A |
| 2017 | 1.1 A | 13.5 A | 0.0 E | 0.0 E | 14.7 A |
| 2018 | | | | | 0.0 E |
| 2019 | | | | | 0.0 E |

### Earnings per Share

(EPS is operating earnings before non-recurring items)

| | Q1 (Oct) | Q2 (Jan) | Q3 (Apr) | Q4 (Jul) | Year (Jul) |
|---|---|---|---|---|---|
| 2016 | -$6.00 A | $2.11 A | $0.22 A | -$0.42 A | -$4.09 A |
| 2017 | -$0.30 A | $5.31 A | -$0.82 E | -$0.87 E | $2.94 A |
| 2018 | | | | | -$4.83 E |
| 2019 | | | | | -$3.65 E |

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## WHAT'S NEW

**Financial Update**

On March 16, 2017, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the fiscal second quarter ending January 31, 2017. During the quarter, the company signed an agreement with SWK Holdings Corporation whereby SWK acquired the rights to certain royalty and milestone payments related to the sale of NARCAN® Nasal Spray for an initial payment of $13.7 million and the potential for an additional $3.75 million if certain future net sales milestones are met. Once SWK receives back 1.5 times their investment, Opiant will receive at least 90% of future NARCAN® royalties and milestone payments.

Total revenue for the fiscal second quarter was $13.535 million, compared to $6.86 million during the three months ending Jan. 31, 2016. The increase was due to the sale of royalty rights to SWK partially offset by revenue accrued in October 2016 that was assigned to SWK. Net profit for the quarter was $10.6 million, or $5.31 per share. General and administrative expenses for the quarter were $1.4 million compared to $2.4 million for the quarter ending Jan. 31, 2016. The decrease was a result of a decrease in management compensation and consulting expenses. Research and development expenses for the quarter were $0.34 million compared to $0.25 million for the prior year's corresponding quarter. Selling expenses totaled $1.2 million for the quarter ended Jan. 31, 2017 compared to $0.2 million for the quarter ended Jan. 31, 2016. The increase related to the sale of royalties to SWK under the purchase agreement.

Opiant exited the fiscal second quarter with $12.9 million, which we anticipate will be enough to fund operations through at least March of 2018. The company currently has 2.0 million shares outstanding, and when factoring in the 4.8 million vested and 0.2 million unvested stock options has a fully diluted share count of 7.0 million.

**Business Update**

Opiant is a specialty pharmaceutical company developing treatments for substance use, addictive, and eating disorders using the company's expertise in opioid antagonists. Opiant has developed a novel nasal spray formulation of naloxone as a treatment for opioid overdose, which was approved by the U.S. Food and Drug Administration (FDA) in November 2015. The company is also working on treatments for eating disorders, alcohol and cocaine use disorder, and has recently licensed the rights to a preclinical heroin vaccine from the National Institute on Drug Abuse.

***Clinical Trial of OPNT001 in Bulimia Nervosa Underway***

On March 20, 2017, Opiant announced the initiation of a Phase 2 clinical trial evaluating OPNT001, a novel nasally-delivered opioid antagonist, in bulimia nervosa (BN). BN is a serious and potentially life-threatening eating disorder characterized by a cycle of binge eating and purging. BN affects approximately 1-2% of the adult population with 80% of those affected being female. Complications of BN include dehydration, heart problems, severe tooth decay and gum disease, anxiety and depression, and increased risk of suicide.

Cognitive behavior therapy (CBT) has been shown to be effective in those suffering from BN. CBT encompasses numerous specific approaches for various psychiatric disorders, with the unifying theme being a combination of both cognitive and behavioral adaptations to change unhelpful thinking and actions. The only pharmacological agent approved to treat BN is fluoxetine (Prozac®). Two multicenter, double blind, placebo controlled randomized clinical trials of fluoxetine found that a 60 mg dose resulted in a statistically significant reduction in binge eating and vomiting episodes compared to placebo regardless of whether a patient was also suffering from depression, while a 20 mg dose of fluoxetine was only effective in those that did not also have depression (Goldstein *et al.*, 1999). While effective, fluoxetine has a number of potential adverse side effects including increased suicidal thoughts, sleep problems, headache, dizziness, and gastrointestinal issues.

The randomized, double blind, placebo controlled Phase 2 clinical trial will enroll up to 80 patients in the United Kingdom who have been diagnosed with BN. The study will evaluate OPNT001's safety and tolerability as well as its impact on various clinical outcomes, including change in eating behavior. We anticipate topline data from this study in the first half of 2018.

***FDA Gives Supportive Feedback for OPNT002 in Alcohol Use Disorder***

On February 28, 2017, Opiant announced that the U.S. Food and Drug Administration (FDA) gave supportive feedback from a Type B meeting in regards to the proposed development plan for OPNT002, an intranasally-dosed opioid antagonist, for the treatment of Alcohol Use Disorder (AUD).

The SAMHSA 2015 National Survey on Drug Use and Health reported approximately 17.3 million people in the U.S. with alcohol dependence or abuse. There are three FDA approved medicines to treat alcohol dependence including Antabuse®, Vivitrol®, and Campral®. However, there is still a pressing need for a safe and effective treatment for alcohol addiction as the FDA approved compounds have limited efficacy (Witkiewitz *et al*., 2012).
Opiant is planning to move OPNT001 into a Phase 2 trial in AUD later in 2017, and we anticipate learning more details about the trial as the company gets closer to initiating it. OPNT001 is differentiated from currently available AUD treatment's as it will be used on an "as needed" basis, and the company has Phase 1 data showing rapid intranasal absorption.

***Pre-Clinical Research on Heroin Vaccine to Continue***

On October 28, 2016, Opiant announced the signing of an agreement for exclusive rights to a heroin vaccine being developed by the Walter Reed Army Institute of Research (WRAIR) and the National Institute on Drug Abuse (NIDA). The vaccine is currently in pre-clinical development and works through the induction of anti-heroin antibodies in the bloodstream by immunization with "heroin-like" haptens (Li *et al*., 2014). The antibodies bind to heroin and prevent the drug from crossing the blood-brain barrier, thereby preventing the subsequent euphoric and addictive effects. Opiant's plan for 2017 is to continue to work with researchers at WRAIR to determine the viability of using the vaccine in a heroin-addict population.

***Additional Patents Granted for NARCAN® Nasal Spray***

On March 9, 2017, Opiant announced that two recently issued patents covering the methods of use for NARCAN® Nasal Spray are now listed in the U.S. FDA "Orange Book".

- U.S. Patent No. 9,480,644 claims nasal spray formulations, devices, and methods of treatment covering the 2 mg dose of NARCAN®. It also provides for methods for treating opioid overdose or its symptoms with the 2 mg formulation of NARCAN®.

- U.S. Patent No. 9,561,177 provides for formulations with particular spray plume characteristics and for methods of treating opioid overdose or narcotic-induced respiratory depression with the 4 mg dose of NARCAN®.

Opiant now has four patents listed in the "Orange Book" covering the 4 mg dose of NARCAN® Nasal Spray: U.S. Patent Nos. 9,211,253; 9,468,747; 9,561,177; and 9,561,177.

***New Chief Scientific Officer***

On February 6, 2017, Opiant announced an expansion of the the senior management team with the appointment of Dr. Phil Skolnick as Chief Scientific Officer, who will lead the company's research and development activities. Dr. Skolnick was previously at the National Institute of Health (NIH), where he served as Director of the Division of Therapeutics and Medical Consequences at the National Institute of Drug Abuse. Previous to the NIH, Dr. Skolnick was President and Chief Scientific Officer of DOV Pharmaceutical, Inc.

**Valuation and Conclusion**

We were glad to see the deal announced between Opiant and SWK as it gives Opiant immediate access to non-dilutive capital, thus removing any overhang for the stock from the need for financing in the near term, and allows the company to advance the pipeline candidates further along in development. We believe the terms of the deal were quite fair and Opiant retains long-term potential upside on NARCAN® sales.

Opiant has laid out an ambitious plan for 2017, and we are pleased to see that the company is already executing on a number of those goals, including initiating the clinical trial in BN. Uplisting to a major exchange is another very important milestone for the company this year, and we believe it could represent an inflection point for the shares when it occurs, as it will allow for greater trading liquidity and the chance to increase the shareholder base to

include funds that are limited from owning stocks traded on the OTC.

We now incorporate BN into our model as the clinical trial in BN has initiated. Our estimates are for an NDA in 2021 and potential peak revenues of approximately $300 million. For AUD, a clinical trial may get underway in 2017, which would lead to eventual approval in 2021 and potential peak revenues of approximately $200 million. For cocaine use disorder, we model for an NDA filing in 2021, approval in 2022, and potential peak revenues of approximately $300 million. All told, using a 12% discount rate, our model leads to a valuation of approximately $20 per share. Even with the recent influx of cash, the stock price has not moved and the company continues to trade at just over 1x cash, thus we believe now is the time for investors to take a closer look at Opiant.

## PROJECTED FINANCIALS

**Opiant Pharmaceuticals, Inc.**
Income Statement

| Opiant Pharmaceuticals, Inc. | FY 2016 A | Oct-16 A | Jan-17 A | Apr-17 E | Jul-17 E | FY 2017 E | FY 2018 E | FY 2019 E |
|---|---|---|---|---|---|---|---|---|
| **NARCAN royalty** | $0.1 | $0.6 | $0.0 | $0.0 | $0.0 | $0.6 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | | |
| **Binge Eating Disorder** | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | | |
| **Cocaine Use Disorder** | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | | |
| **Licensing and Milestones** | $9.8 | $0.5 | $13.5 | $0.0 | $0.0 | $14.0 | $0.0 | $0.0 |
| *YOY Growth* | - | - | - | - | - | - | | |
| **Total Revenues** | **$9.9** | **$1.1** | **$13.5** | **$0.0** | **$0.0** | **$14.7** | **$0.0** | **$0.0** |
| *YOY Growth* | - | - | - | - | - | - | | |
| Cost of Sales | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Product Gross Margin* | - | - | - | - | - | - | | |
| Research & Development | $1.7 | $0.4 | $0.3 | $0.4 | $0.5 | $1.7 | $3.0 | $3.0 |
| General & Administrative | $15.6 | $1.2 | $1.4 | $1.3 | $1.4 | $5.3 | $11.0 | $11.0 |
| Selling Expenses | $0.3 | $0.0 | $1.2 | $0.1 | $0.1 | $1.4 | $0.4 | $0.5 |
| Other Expenses | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Operating Income | ($7.7) | ($0.6) | $10.6 | ($1.8) | ($2.0) | $6.3 | ($14.4) | ($14.5) |
| *Operating Margin* | - | - | - | - | - | - | | |
| Non-Operating Expenses (Net) | ($0.1) | ($0.0) | $0.0 | ($0.0) | ($0.0) | ($0.0) | ($0.1) | ($0.1) |
| Pre-Tax Income | ($7.8) | ($0.6) | $10.6 | ($1.8) | ($2.0) | $6.2 | ($14.5) | ($14.6) |
| Income Taxes Paid | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **Net Income** | **($7.8)** | **($0.6)** | **$10.6** | **($1.8)** | **($2.0)** | **$6.2** | **($14.5)** | **($14.6)** |
| *Net Margin* | - | - | - | - | - | - | | |
| **Reported EPS** | **($4.09)** | **($0.30)** | **$5.31** | **($0.82)** | **($0.87)** | **$2.94** | **($4.83)** | **($3.65)** |
| *YOY Growth* | - | - | - | - | - | - | | |
| Basic Shares Outstanding | 1.9 | 2.0 | 2.0 | 2.2 | 2.3 | 2.1 | 3.0 | 4.0 |

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

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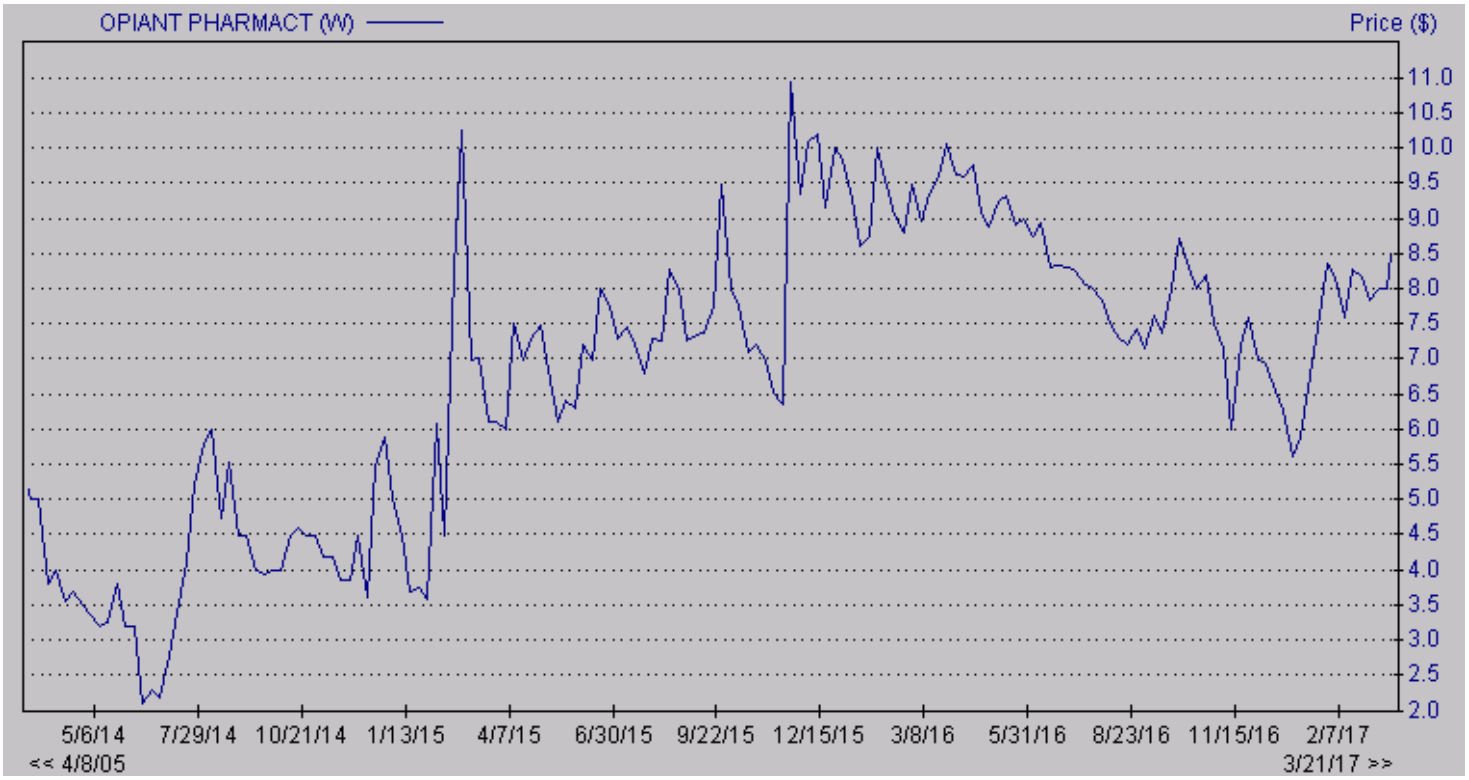
## HISTORICAL STOCK PRICE

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