Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

August 10, 2018
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: Increasing Royalties from NARCAN® Nasal Spray…

Based on our probability adjusted DCF model that takes into account potential future revenues from opioid antagonists, eating disorder treatments, and alcohol use disorder (AUD) treatments, OPNT is valued at $55/share. This model is highly dependent upon the commercial and clinical success of opioid antagonists and clinical success in treating eating disorders and AUD.

Current Price (08/10/18)	$17.60
Valuation	**$55.00**

OUTLOOK

On August 9, 2018, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the second quarter of 2018 and provided a business update. The company reported revenue of $3.2 million, which included $3.1 million in royalty revenue from the sale of NARCAN® Nasal Spray. By our calculations, Adapt Pharma has sold approximately $80 million in NARCAN® Nasal Spray during the first half of 2018, and with sales increasing substantially from the first to the second quarter, we have raised our estimate for 2018 sales to $180 million, which would result in revenues of approximately $13.6 million to Opiant. The company exited the second quarter of 2018 with approximately $11.2 million, and with the expected royalty revenue and the $7.4 million grant to fund development of OPNT003, we believe Opiant has sufficient funding to get OPNT003 to an NDA filing and OPNT001 and OPNT002 through Phase 2 testing.

SUMMARY DATA

52-Week High	**$50.50**
52-Week Low	**$12.89**
One-Year Return (%)	**-1.95**
Beta	**-0.84**
Average Daily Volume (sh)	**27,269**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$46**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**64**
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-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0.0 A	0.0 A	0.0 A	11.8 A	11.8 A
2018	1.7 A	3.2 A	4.7 E	5.2 E	14.8 E
2019					37.8 E
2020					23.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.30 A	$5.31 A	-$1.55 A	-$0.17 A	$0.66 A
2018	-$3.68 A	-$0.52 A	-$0.11 E	-$0.10 E	-$2.20 E
2019					$6.32 E
2020					$0.33 E

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

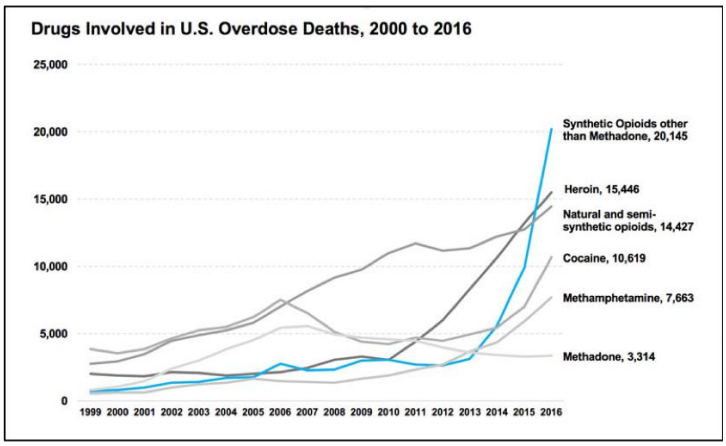
WHAT'S NEW

Business Update

OPNT003 Update

Earlier in 2018, Opiant announced the receipt of a $7.4 million grant from the National Institute on Drug Abuse (NIDA) to fund the development of OPNT003, a long-lasting opioid antagonist for the treatment of opioid overdose. OPNT003 is an intranasal formulation of nalmefene, a naltrexone derivative. Based on its favorable pharmacokinetic profile, we believe OPNT003 could become a novel opioid overdose treatment, particularly for overdoses caused by synthetic opioids such as fentanyl and its derivatives.

The following chart shows the number of overdose deaths in the U.S. from certain drugs, with the rapid rise in deaths from synthetic opioids just since 2013 particularly striking. This increase in synthetic opioid deaths 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).



Source: Centers for Disease Control

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). These data formed the basis for a meeting with the FDA regarding the planned development of OPNT003. Based on the guidance received from the FDA, Opiant believes it will be in a position to file an NDA 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.

OPNT001 Update

Last year, Opiant announced the initiation of a Phase 2 clinical trial evaluating OPNT001, nasally-delivered naloxone, 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.

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 of OPNT001 is expected to 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 will be announced in the first quarter of 2019.

OPNT002 Update

Earlier in 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, intranasally (IN) administered naltrexone, 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).

In July 2017, Opiant announced results from a Phase 1 study of OPNT002, which examined the effects of Intravail® on the pharmacokinetic properties of IN naltrexone in healthy volunteers. A total of 14 men and women between the ages of 18 to 55 participated in the study. Each subject received four naltrexone treatments.

Results from the study showed that Intravail® both increased the maximal plasma concentration (Cmax) of IN naltrexone and decreased the time to reach Cmax from 30 minutes to 10 minutes. The median time to reach Cmax following administration of IN naltrexone with Intravail® was also more rapid than an intramuscular (IM) injection of naltrexone. Oral administration of 50 mg of naltrexone resulted in a slower time to reach Cmax than either IN or IM administration. Importantly, the results with IN naltrexone seen without any identified safety or tolerability issues. There was also no evidence of nasal irritation.

To follow up on these results, Opiant signed a contract manufacturing agreement with Renaissance to develop an IN naltrexone formulation for Phase 2 studies. The company has previously worked with Renaissance for commercial manufacturing of NARCAN® Nasal Spray. We anticipate patient enrollment will begin for a Phase 2 study of OPNT002 in AUD in 2019.

Financial Update

On August 9, 2018, Opiant announced financial results for the second quarter of 2018. The company recorded approximately $3.2 million in revenue for the second quarter of 2018 compared to $3.8 million during the corresponding three months of 2017. The $3.8 million in revenue in 2017 was the result of the sale to SWK of the royalty rights for NARCAN® Nasal Spray. Based upon the agreement with Adapt and the fact that Opiant receives 90% of royalty income we estimate that Adapt sold approximately $49.5 million worth of NARCAN® Nasal Spray in the second quarter of 2018.

G&A expenses for the second quarter of 2018 were $2.9 million compared to approximately $1.9 million for the corresponding period of 2017. The increase was primarily due to increased stock-based compensation and professional fees. R&D expenses totaled $1.6 million for the second quarter of 2018 compared to $1.4 million for the corresponding period of 2017. The increase was primarily due to increased share-based compensation and personnel costs partially offset by a decrease in third party expenses. Net loss for the second quarter of 2018 was

$1.4 million, or $0.52 per share, compared to net income of $0.2 million, or $0.12 per share, for the comparable period of 2017.

As of June 30, 2018, Opiant had approximately $11.2 million in cash and cash equivalents, which we believe will be enough to fund operations for at least the next 12 months. As of Aug. 3, 2018, the company had approximately 2.8 million shares outstanding and when factoring in options and warrants a fully diluted share count of approximately 5.9 million.

Conclusion

We believe our estimates for 2018 sales of NARCAN® Nasal Spray were too conservative and we have increased our estimate to $180 million for the year. Based on the royalty agreement between Opiant and Adapt, we calculate Opiant would receive approximately $13.6 million based on $180 million in sales of NARCAN® Nasal Spray. As a reminder, Opiant will be due a $15 million milestone payment if sales of NARCAN® Nasal Spray exceed $200 million in a calendar year, which we currently estimate to occur in 2019. Between the expected royalties from NARCAN® Nasal Spray, the $7.4 million grant from NIDA for the development of OPNT003, and the company's current cash position, we believe Opiant is well financed to advance its pipeline forward, which includes an expected data read out from a Phase 2 trial of OPNT001 in BN in the first quarter of 2019 and initiation of a Phase 2 trial of OPNT002 in AUD in 2019.

Based on our probability adjusted discounted cash flow model that takes into account potential future revenues from royalties for NARCAN® Nasal Spray and revenues from OPNT003, OPNT001 in BN, and OPNT002 in AUD our current valuation stands at $55 per share.

PROJECTED FINANCIALS

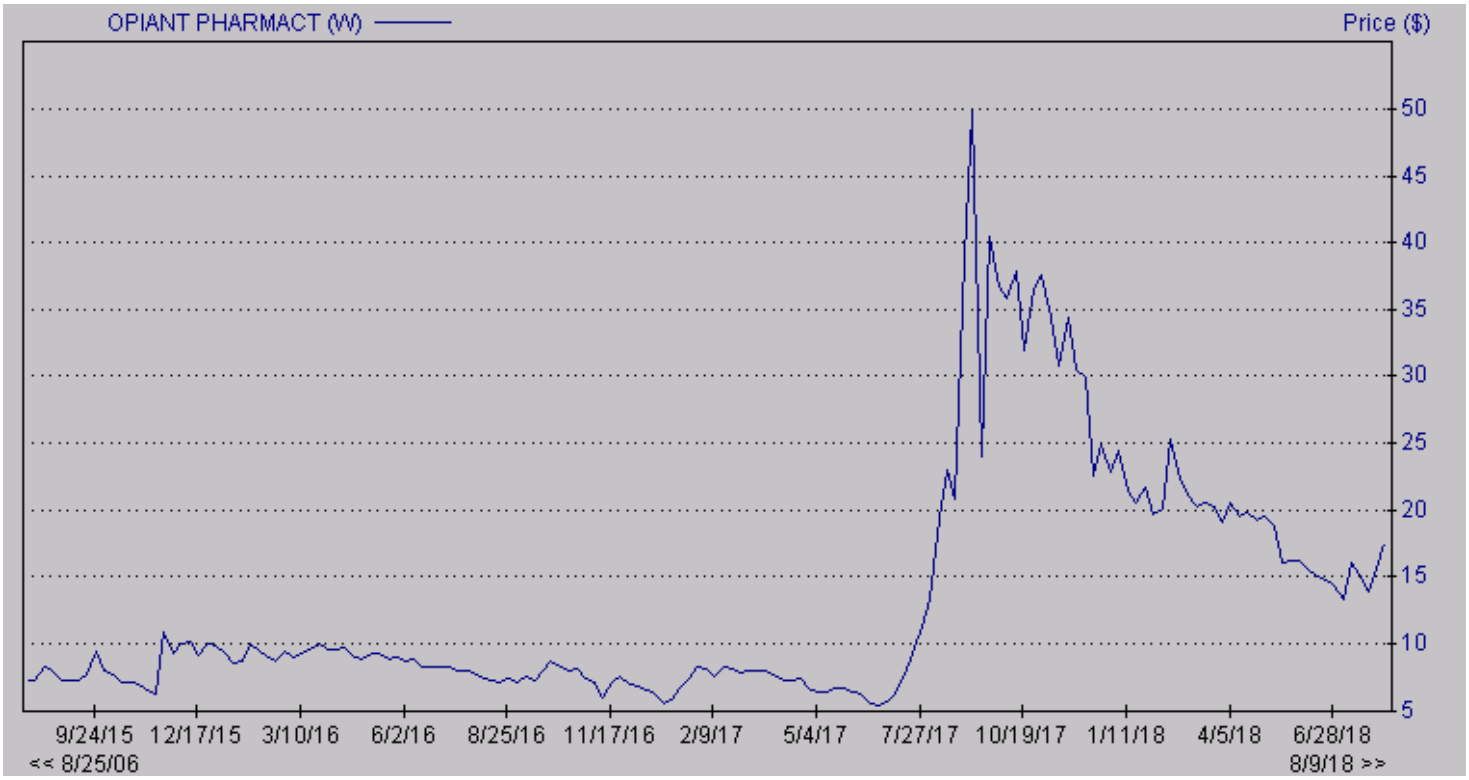
Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	Five Months Ending Dec-17	1Q18 A	2Q18 A	3Q18 E	4Q18 E	2018 E	2019 E	2020 E
NARCAN royalty	$11.7	$1.6	$3.1	$4.3	$4.6	$13.6	$31.6	$23.5
YOY Growth	-	-	-	-	-	-		
OPNT003	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$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	-	-	-	-	-	-		
Bulimia Nervosa	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-		
Licensing, Milestones, and Grants	$0.1	$0.1	$0.1	$0.4	$0.6	$1.2	$6.2	$0.0
YOY Growth	-	-	-	-	-	-		
Total Revenues	**$11.8**	**$1.7**	**$3.2**	**$4.7**	**$5.2**	**$14.8**	**$37.8**	**$23.5**
YOY Growth	-	-	-	-	-	-		
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-		
Research & Development	$2.5	$2.4	$1.6	$2.0	$2.5	$8.5	$10.0	$10.0
General & Administrative	$5.9	$3.0	$2.9	$3.0	$3.0	$11.8	$12.0	$12.5
Selling Expenses	$0.4	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0	$1.0
Other Expenses	$1	$5.6	$0	$0	$0	$0	$0	$0
Operating Income	$1.5	($9.3)	($1.3)	($0.3)	($0.3)	($5.6)	$14.8	$0.0
Operating Margin	-	-	-	-	-	-		
Non-Operating Expenses (Net)	$0.0	($0.0)	($0.1)	$0.0	$0.0	($0.1)	$0.0	$0.0
Pre-Tax Income	$1.5	($9.3)	($1.4)	($0.3)	($0.3)	($5.7)	$14.8	$0.0
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**$1.4**	**($9.3)**	**($1.4)**	**($0.3)**	**($0.3)**	**($5.7)**	**$14.8**	**$0.0**
Net Margin	-	-	-	-	-	-		
Reported EPS	**$0.66**	**($3.68)**	**($0.52)**	**($0.11)**	**($0.10)**	**($2.20)**	**$5.92**	**$0.00**
YOY Growth	-	-	-	-	-	-		
Basic Shares Outstanding	2.1	2.5	2.7	2.8	2.9	2.6	2.5	3.0

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

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2018, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.