Zacks Small-Cap Research

July 19, 2017
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Opiant Pharmaceuticals Inc. (OPNT-OTC)

OPNT: Encouraging Data From P1 Study of OPNT002 in Alcohol Use Disorder…

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

Current Price (07/19/17)	$9.75
Valuation	**$20.00**

OUTLOOK

On July 19, 2017, Opiant Pharmaceuticals Inc. (OPNT) announced results from a Phase 1 study of OPNT002, an intranasally (IN) dosed formulation of the opioid antagonist naltrexone hydrochloride. The study examined the effects of Intravail®, an absorption enhancer that was recently licensed by Opiant, on the pharmacokinetic properties of IN naltrexone.

Results of the study showed that Intravail® increased the maximal plasma concentration of IN naltrexone by three-fold compared to IN naltrexone alone and decreased the time to reach maximal plasma concentration from 30 minutes to 10 minutes. Importantly, these effects were seen with no safety or tolerability issues and no nasal irritation. Opiant has signed a contract manufacturing agreement with Renaissance to begin work on optimizing the formulation of OPNT002 for P2 studies.

SUMMARY DATA

52-Week High	**$9.75**
52-Week Low	**$5.35**
One-Year Return (%)	**27.45**
Beta	**1.10**
Average Daily Volume (sh)	**7,347**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$20**
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 A	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	-$1.55 A	-$0.87 E	$2.94 A
2018					-$4.83 E
2019					-$3.65 E

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

Encouraging Results From a Phase 1 Development Study of OPNT002

On July 19, 2017, Opiant Pharmaceuticals Inc. (OPNT) announced results from a Phase 1 study of OPNT002, an intranasally (IN) administered formulation of the opioid antagonist naltrexone hydrochloride. Opiant is developing OPNT002 for the treatment of Alcohol Use Disorder (AUD). The Phase 1 study 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.

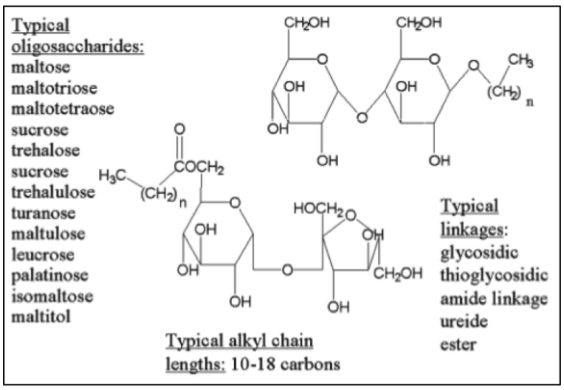
Results from the study showed that Intravail® both increased the maximal plasma concentration (Cmax) of IN naltrexone and decreased the time to reach Cmax from 30 minutes to 10 minutes. The median time to reach Cmax following administration of IN naltrexone with Intravail® was also more rapid than an 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 has 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.

Intravail®

The Intravail® technology was developed by Aegis Therapeutics, LLC and 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.

Intravail® excipients are members of a class of compounds known as alkylsaccharides, sugars that are covalently linked to one or more alkyl chains (Maggio *et al*., 2012). The following image shows a typical Intravail® alkylsaccharide structure, with sucrose and maltose as example saccharide moieties.

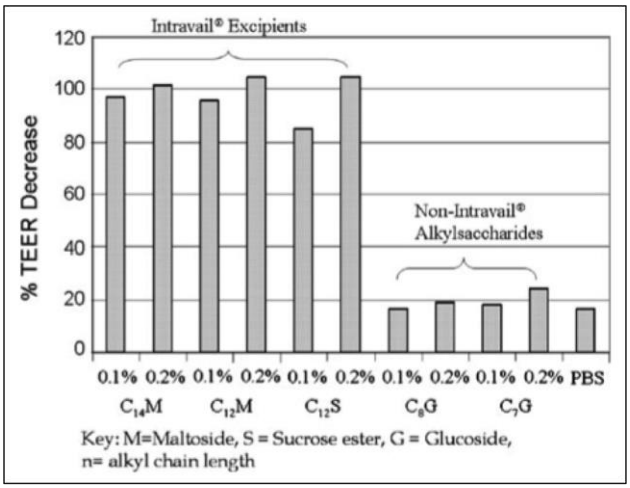


Source: Maggio *et al*., 2012

The excipients used in the Intravail® technology are safe to use. Following administration, the alkylsaccharides are quickly metabolized to the natural dietary components of a sugar and a fatty acid. The No Observed Effect Level (NOEL) for some of the excipients (sucrose esters) is as high as 2,000 mg/kg body weight (WHO, 1998), while the World Health Organization (WHO) oral allowable daily intake is approximately 10,000 times the amount used in a single nasal spray dose.

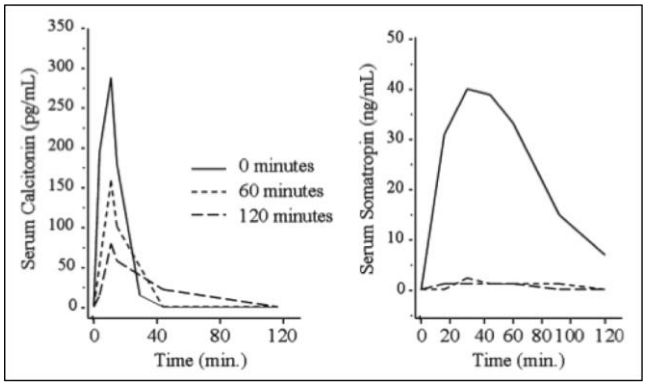
The effectiveness of alkylsaccharides in increasing transmucosal absorption is shown through an assay measuring the reduction in transepithelial electrical resistance (TEER). The assay involves growing human tracheal and bronchoepithelial cells to confluence in culture, which results in tight junctions between cells that prevents the flow

of ions when subjected to an electrical current. Thus, a reduction in TEER to ions flowing across the confluent cell layer is a way to measure openings in the tight junctions. The following graph shows the reduction in TEER that is seen for a number of alkylsaccharides used in the Intravail® technology along with those that are not. The Intravail® excipients show TEER decreases of close to 100%, while non-Intravail® alkylsaccharides are no more effective than saline (PBS).



Source: Maggio *et al.*, 2012

The opening of the tight junctions between cells is a reversible process, as shown in the following graphs. The "0 minutes" line indicates the pharmacokinetic profile for intranasal administration to rats of small proteins (calcitonin on the left and somatotropin on the right) along with an alkylsaccharide excipient. The next line shows the pharmacokinetic profile when the alkylsaccharide is separately administered intranasally to the animal followed 60 minutes later by the protein. The lower line shows the pharmacokinetic profile when the alkylsaccharide is administered 120 minutes before the protein. For the smaller molecule (calcitonin is 4 kDa), some absorption still takes place at the 60 and 120 minute mark following alkylsaccharide, although it is steadily decreasing with time. For the larger molecule (somatotropin is 22 kDa), no absorption is seen when it is administered 60 or 120 minutes after administration of the alkylsaccharide. In addition, these results show that the excipients work on the mucosal membrane, and not through direct interaction with the drugs being administered, since the alkylsaccharide can be administered separately and still result in absorption of the drug.



Source: Maggio *et al.*, 2012

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 for the treatment of 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®. Vivitrol® is an extended release version of naltrexone that is administered by injection once monthly. Sales of Vivitrol totaled $209 million in 2016 ($110 million for AUD), and it is expected to

generate approximately $300 million in revenue in AUD in 2022 (EvaluatePharma). OPNT002 is differentiated from Vivitrol® as it will be used on an “as needed” basis.

Conclusion

Opiant appears to be on track with the development of OPNT002 for the treatment of AUD with the encouraging Phase 1 data showing increased absorption of intranasally administered naltrexone with the use of the Intravail® technology. We look forward to learning more about the Phase 2 program and believe that AUD represents a sizeable market opportunity for Opiant with potential peak revenues of approximately $200 million.

In addition to AUD, Opiant is also targeting bulimia nervosa, for which it initiated a clinical trial earlier this year, and cocaine use disorder, each of which is a potential $300 million opportunity. Our currently valuation is $20 per share, and with a goal of uplisting later in 2017, now would be a good time for investors to take a closer look at Opiant.

PROJECTED FINANCIALS

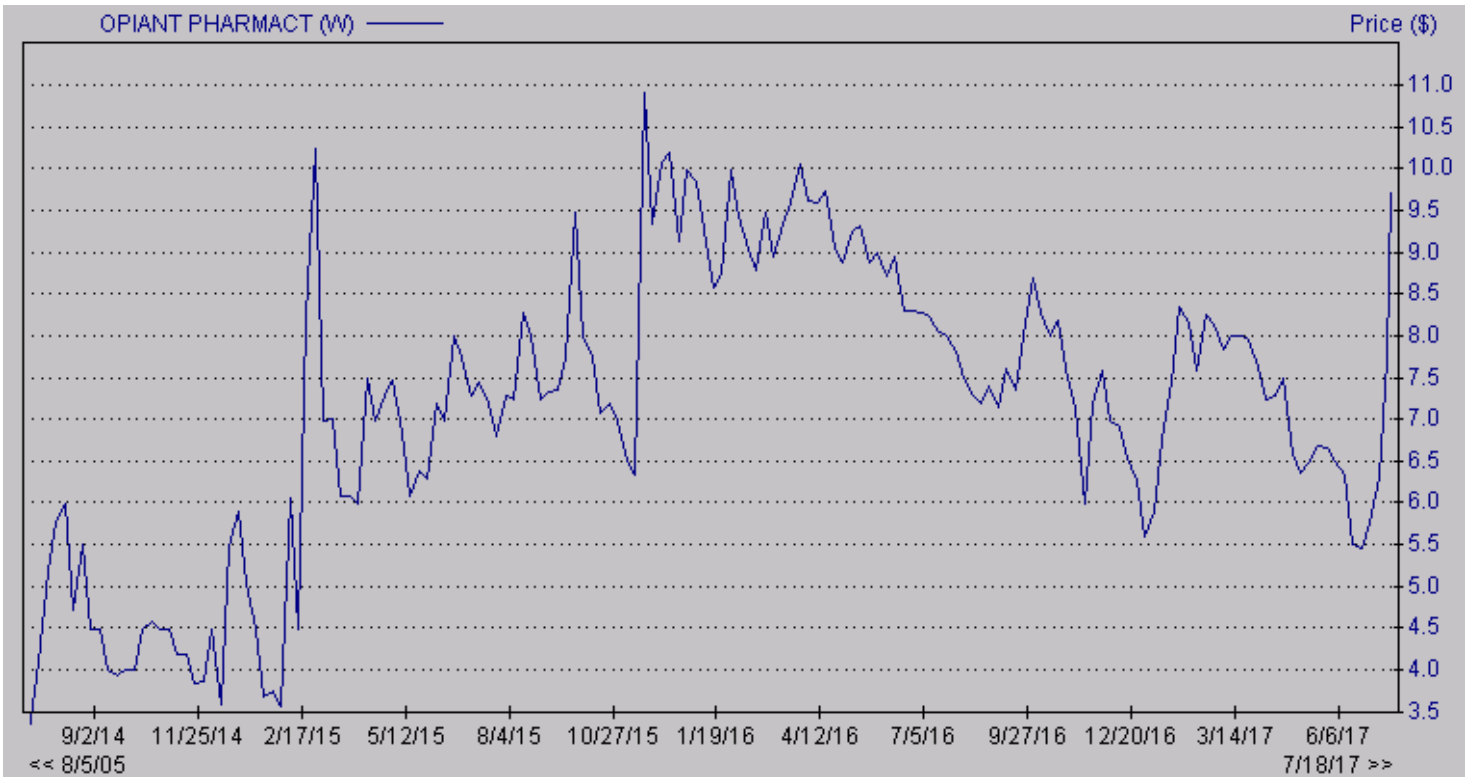
Opiant Pharmaceuticals, Inc.
Income Statement

Opiant Pharmaceuticals, Inc.	FY 2016 A	Oct-16 A	Jan-17 A	Apr-17 A	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	$14.1	$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	$1.1	$0.5	$2.4	$3.0	$3.0
General & Administrative	$15.6	$1.2	$1.4	$2.0	$1.4	$6.0	$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	($3.2)	($2.0)	$4.9	($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	($3.1)	($2.0)	$4.9	($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**	**($3.1)**	**($2.0)**	**$4.9**	**($14.5)**	**($14.6)**
Net Margin	-	-	-	-	-	-		
Reported EPS	**($4.09)**	**($0.30)**	**$5.31**	**($1.55)**	**($0.87)**	**$2.36**	**($4.83)**	**($3.65)**
YOY Growth	-	-	-	-	-	-		
Basic Shares Outstanding	1.9	2.0	2.0	2.0	2.3	2.1	3.0	4.0

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

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2017, 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.