

Opiant Pharmaceuticals, Inc.

(OPNT-NASDAQ)

OPNT: Positive Results for Pharmacodynamic Trial of OPNT003...

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 \$40/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 (05/12/22) \$12.00
Valuation \$40.00

OUTLOOK

On May 10, 2022, Opiant Pharmaceuticals, Inc. (OPNT) announced financial results for the first quarter of 2022 and provided a business update. The company reported \$4.5 million in revenue for the first quarter of 2022, with \$2.2 million of that due to the license agreement with Emergent BioSolutions (EBS) for the sale of NARCAN® Nasal Spray. This was lower than anticipated due to EBS invoking the “Generic Reduction Clause” in the license agreement.

Opiant also provided additional insight into the positive topline results from the pharmacodynamic study of OPNT003, which met the primary endpoint of non-inferiority compared to nasal naloxone. The company is now poised to file a new drug application (NDA) with the FDA in the second half of 2022.

SUMMARY DATA

52-Week High \$36.79
52-Week Low \$12.00
One-Year Return (%) -4.08
Beta 0.65
Average Daily Volume (sh) 159,272

Shares Outstanding (mil) 5
Market Capitalization (\$mil) \$61
Short Interest Ratio (days) N/A
Institutional Ownership (%) 28
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 Above Avg.
Type of Stock Small-Value
Industry Med-Drugs

ZACKS ESTIMATES

Revenue

(In millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	6.4 A	11.3 A	16.3 A	13.8 A	47.8 A
2022	4.5 A	1.9 E	1.8 E	1.8 E	10.0 E
2023					55.0 E
2024					154.5 E

Earnings per Share

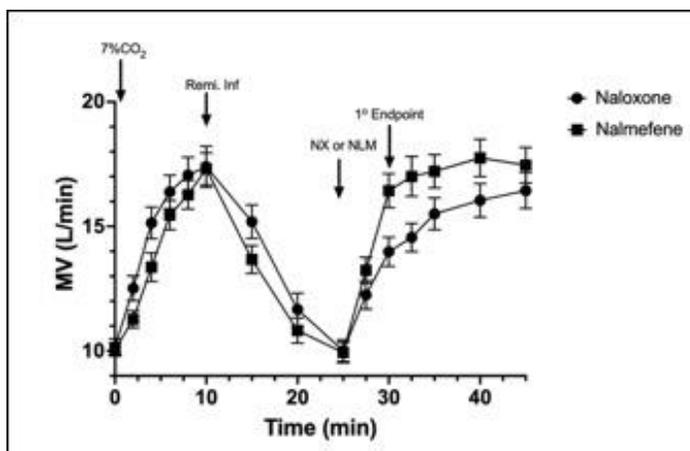
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-\$0.66 A	\$0.39 A	\$0.77 A	\$0.16 A	\$0.68 A
2022	-\$2.43 A	-\$1.48 E	-\$1.55 E	-\$1.73 E	-\$7.18 E
2023					-\$2.01 E
2024					\$10.40 E

WHAT'S NEW

Business Update

On May 10, 2022, Opiant Pharmaceuticals, Inc. (OPNT) provided additional details from the positive pharmacodynamic (PD) study of OPNT003, for which the company had [announced](#) results a couple of weeks ago. A copy of the company's presentation on the results can be found [here](#). This was a single center, randomized, open label study in healthy volunteers that was powered to demonstrate non-inferiority between nasal nalmeferene and nasal naloxone. The primary endpoint was the reversal of respiratory depression brought about by the synthetic opioid remifentanyl (measured by minute ventilation at five minutes), with additional secondary endpoints examining a range of other timepoints.

The following graph shows how the study was conducted. The y-axis is the change in minute ventilation (MV) over the course of the study. MV is the amount of air inhaled or exhaled per minute. At time 0 participants were given 7% CO₂ to increase their respiration rate. Remifentanyl was then administered, which resulted in a rapid decrease in MV. After 15 minutes, nasal nalmeferene or nasal naloxone was given and the primary outcome of the study was the change in MV after 5 minutes. The 5-minute mark was chosen since it is very important to counteract opioid induced respiratory depression as quickly as possible.

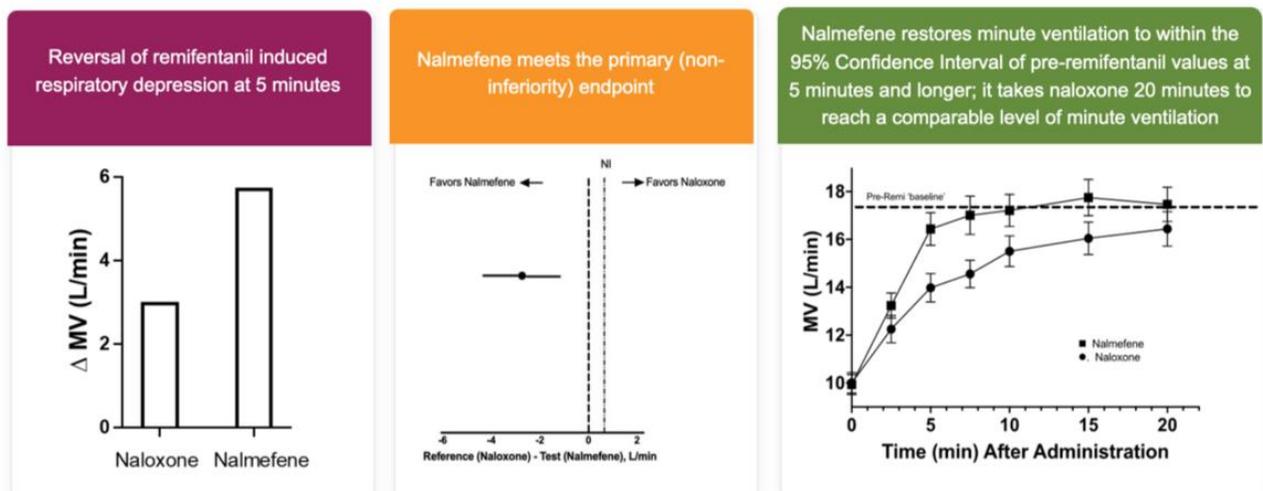


Source: Opiant Pharmaceuticals, Inc.

The following graphs give greater details regarding the data presented above. The first graph on the left shows the change in MV from the time nasal nalmeferene or nasal naloxone is given until five minutes later. The increase in MV was 5.7 L/min for nasal nalmeferene and 3.0 L/min for nasal naloxone, a difference that clearly favored nalmeferene. The middle graph represents the FDA criteria that were established to demonstrate non-inferiority. The filled circle represents the difference in MV between nasal nalmeferene and nasal naloxone (the lines to either side of the filled circle represent the 95% confidence interval). The dotted line at "0" represents no difference in MV between the two treatments. The dotted line to the right of "0" is the point that was proposed by Opiant to represent non-inferiority between nasal nalmeferene and nasal naloxone, where nasal nalmeferene could be no more than 20% lower than nasal naloxone. This graph shows that the trial clearly met the primary endpoint. The final graph on the right shows the first 20 minutes post dose of nasal nalmeferene or nasal naloxone. By 5 minutes, treatment with nasal nalmeferene results in MV returning to "pre-remifentanyl" levels, while it takes 20 minutes for the MV of those treated with nasal naloxone to return to "pre-remifentanyl" levels.

Positive Primary Endpoint

Study showed a mean difference in minute ventilation that clearly favors OPNT003



Source: Opiant Pharmaceuticals, Inc.

These data, together with the pharmacokinetic (PK) data collected from earlier studies, will form the clinical basis for the new drug application (NDA) of nasal nalmefene for the treatment of opioid overdose. We anticipate the NDA being submitted to the FDA in the second half of 2022 following completion of the pre-NDA meeting.

Financial Update

On May 10, 2022, Opiant Pharmaceuticals, Inc. (OPNT) [announced](#) financial results for the first quarter of 2022. Opiant reported revenue of \$4.5 million, including \$2.2 million of revenue from the licensing agreement with Adapt Pharma Operations Limited, a subsidiary of Emergent BioSolutions (EBS), for the sale of NARCAN® Nasal Spray, compared to approximately \$6.4 million in revenue, including \$4.3 million in royalty income, for the first quarter of 2022. Emergent BioSolutions reported revenue from the sale of NARCAN Nasal Spray of approximately \$93.1 million for the first quarter of 2022.

The decrease in the royalty revenue was due to EBS applying the “Generic Reduction Clause” of the licensing agreement. With the launch of a generic equivalent of NARCAN Nasal Spray by Teva Pharmaceuticals in the U.S. in December 2021, the royalty rate for Opiant can reduce to 2% if NARCAN revenues in the U.S., which includes its authorized generic, are less than 70% of the U.S. net NARCAN sales in the third quarter of 2021 (the quarter before the quarter that the first generic sales took place). The calculation is computed on a quarterly basis, thus the reduction of the royalty rate in the first quarter of 2022 has no bearing on whether it is triggered in the remaining quarters of 2022.

Net loss for the first quarter of 2022 was approximately \$12.2 million, or \$2.43 per share, compared to a net loss of approximately \$2.8 million, or \$0.66 per share, for the first quarter of 2021. G&A expenses for the first quarter of 2022 were approximately \$4.4 million, compared to approximately \$2.6 million for the first quarter of 2021. The increase was primarily due to increased employee costs and legal fees. R&D expenses for the first quarter of 2022 were \$8.8 million, compared to approximately \$4.1 million for the first quarter of 2021. The increase was related to expenses associated with the completion of clinical work for OPNT003. Sales and marketing expenses for the first quarter of 2022 were approximately \$2.7 million, which were related to pre-commercialization efforts related to OPNT003.

As of March 31, 2022, Opiant had approximately \$50.8 million in cash, cash equivalents, and marketable securities. In addition, there is up to \$30 million available from the Loan Agreement with Pontifax, if certain conditions are met. We believe the company is well capitalized to support the planned commercial and R&D activities planned for 2022. As of May 9, 2022, there were approximately 5.1 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 9.5 million.

Conclusion

We were glad to see the PD trial returned positive results and the company is now poised to submit the NDA for OPNT003 in the second half of 2022. The drop-off in royalty revenue from the sale of NARCAN Nasal Spray is unfortunate, and while we had not expected it in the current quarter we had factored it into subsequent quarters in our model. Our valuation has decreased slightly to \$40, however we remain positive on the prospects for OPNT003 and do not believe the recent selloff of the stock was warranted or is representative of Opiant's potential.

PROJECTED FINANCIALS

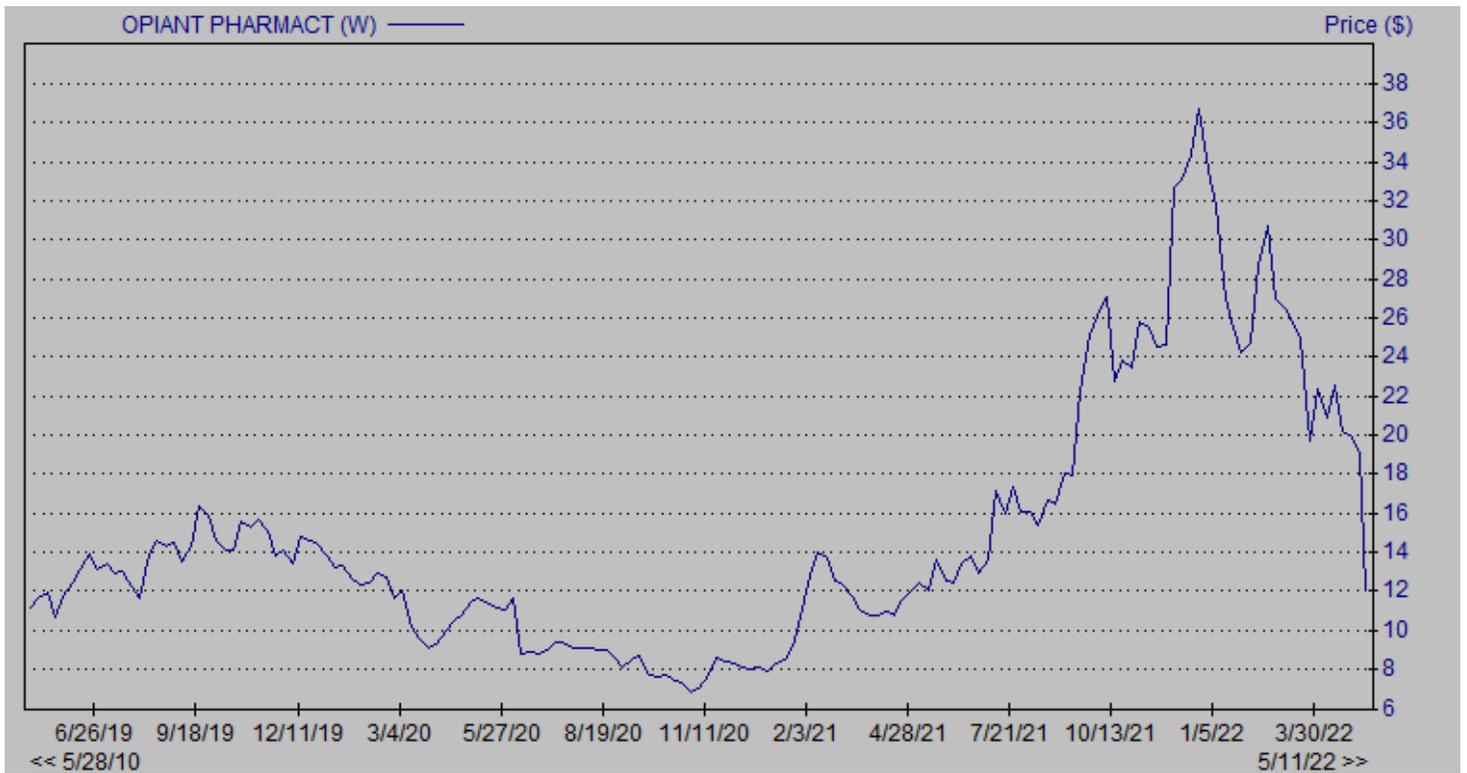
Opiant Pharmaceuticals, Inc. Income Statement

Opiant Pharmaceuticals, Inc.	2021 A	1Q A	2Q E	3Q E	4Q E	2022 E	2023 E	2024 E
NARCAN royalty	\$40.7	\$2.2	\$1.4	\$1.3	\$1.3	\$6.2	\$5.0	\$4.5
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	\$50.0	\$150.0
OPNT004	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Licensing, Milestones, and Grants	\$7.1	\$2.3	\$0.5	\$0.5	\$0.5	\$3.8	\$0.0	\$0.0
Total Revenues	\$47.8	\$4.5	\$1.9	\$1.8	\$1.8	\$10.0	\$55.0	\$154.5
Cost of Sales	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$5.0
Research & Development	\$16.8	\$8.8	\$4.4	\$4.5	\$4.6	\$22.3	\$18.2	\$20.0
General & Administrative	\$12.2	\$4.3	\$3.2	\$3.3	\$3.4	\$14.2	\$30.0	\$40.0
Sales and Marketing	\$4.6	\$2.7	\$1.0	\$1.1	\$2.0	\$6.8	\$15.0	\$25.0
Royalty Expenses	\$9.1	\$0.4	\$0.3	\$0.3	\$0.3	\$1.4	\$1.2	\$1.0
License Fees	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	\$5.2	(\$11.8)	(\$7.1)	(\$7.4)	(\$8.5)	(\$34.7)	(\$9.4)	\$63.5
Non-Operating Expenses (Net)	(\$2.1)	(\$0.4)	(\$0.5)	(\$0.5)	(\$0.5)	(\$1.9)	(\$2.1)	(\$2.1)
Pre-Tax Income	\$3.0	(\$12.2)	(\$7.6)	(\$7.9)	(\$9.0)	(\$36.7)	(\$11.5)	\$61.4
Income Taxes Paid	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net Income	\$3.0	(\$12.2)	(\$7.6)	(\$7.9)	(\$9.0)	(\$36.7)	(\$11.5)	\$61.4
Reported EPS	\$0.68	(\$2.43)	(\$1.48)	(\$1.55)	(\$1.73)	(\$7.18)	(\$2.01)	\$10.40
Basic Shares Outstanding	4.5	5.0	5.1	5.1	5.2	5.1	5.7	5.9

Source: Zacks Investment Research, Inc.

David Bautz, PhD

HISTORICAL STOCK PRICE



Source: Zacks SCR

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