

Oramed Pharmaceuticals

Biotechnology

US Equity Research

23 November 2021

Rating
BUY
unchanged

Price Target
US\$30.00
unchanged

ORMP-NASDAQ

Price
US\$17.40

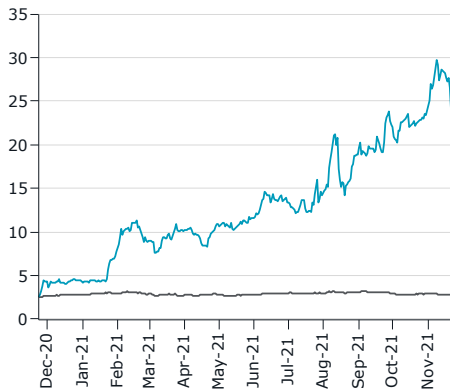
Market Data

52-Week Range (US\$) :	2.54 - 31.54
Market Cap (US\$M) :	661.8
Shares Out., Basic (M) :	38.0
Enterprise Value (US\$M) :	592
Cash (US\$M) :	69.6

FYE Aug	2020E	2021E	2022E
Revenue (US\$M)	2.7A	3.7	2.5
EPS GAAP (US\$)	(0.56)	(0.90)	(1.52)

Quarterly Revenue	Q1	Q2	Q3	Q4
2020E	0.7A	0.7A	0.7A	0.7A
2021E	0.7A	0.7A	0.7A	1.7
2022E	-	-	-	-

Quarterly EPS GAAP	Q1	Q2	Q3	Q4
2020E	(0.15)A	(0.21)A	(0.10)	(0.13)
2021E	(0.23)	(0.17)	(0.17)	(0.29)
2022E	-	-	-	-



— ORMP
— NASDAQ Biotechnology (NBI) (rebased)

Source: FactSet

Priced intraday 23 November 2021

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Negative, unauthored piece creates ideal buying opportunity on sell-off

Shares of ORMP closed down yesterday 28.5% and were down ~8% this morning. We attribute the sell-off to the online posting of a negatively-biased piece with no attribution to authorship. We spoke with management first thing this morning regarding the sell-off.

The CEO stated that the company has hired an outside firm to investigate the online posting in depth and to try to identify the author(s) of the report. The company will likely turn this over to the SEC for further investigation.

We do not believe the report has any merit. The factual points that were addressed in the report have been well known and were reviewed in our own due diligence efforts before initiating coverage on Oramed (see our [initiation of coverage](#)). The management team is compensated very much in line with the prevailing standards of most publicly traded biotech companies. Additionally, the clinical studies conducted by Oramed to-date for type 2 diabetes were, in our view, sufficiently designed with adequate dosing duration to deliver the signal and results needed to move into Phase III testing. The studies that were conducted were of the size expected from a biotech company and of course not of the size and magnitude in early studies that a large pharmaceutical company would conduct over multiple years. Importantly, both ongoing Phase III trials for type 2 diabetes have been designed with input from the FDA and are similar in design and powering to most approved drugs for type 2 diabetes.

ORMD-0801 Phase III enrollment remains strong

Additionally, this morning the company announced that the Phase III ORA-D-013-1 study of the oral insulin ORMD-0801 for type 2 diabetes (T2D) treatment has reached a patient enrollment of 75%. This trial is one of the two ongoing Phase III trials being conducted by Oramed in patients with type 2 diabetes.

ORA-D-013-1 is the larger study being conducted in the U.S. with T2D patients who are currently on two to three oral blood glucose-lowering medications and have inadequate glycemic control over a period of six to 12 months. The trial intends to enroll 675 patients. Top-line data is expected in 1H23.

The second Phase III study, ORA-D-013-2, is recruiting 450 T2D patients in the U.S., Western Europe, and Israel. Patients participating in this study are managing their diabetes with either diet alone or with diet and metformin. In August 2021, the company stated that this study had enrolled and randomized over 25% of the planned 450 patients.

We are pleased to see the fast enrollment of both Phase III trials. Oramed is also at the final stages of submitting data from the statistically significant second Phase IIb trial examining ORMD-0801's effect on HbA1c to a peer-reviewed journal.

We stand by our analyses and continue to maintain our BUY rating of the share and the \$30 price target.

Appendix: Important Disclosures

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Investment Recommendation

Date and time of first dissemination: November 23, 2021, 11:14 ET

Date and time of production: November 23, 2021, 11:14 ET

Target Price / Valuation Methodology:

Oramed Pharmaceuticals - ORMP

We value shares of Oramed by employing a sum-of-the-parts analysis that includes programs where we believe clinical data is available to fairly determine the overall probability of success, as well as net cash on hand. Our estimates solely for the T2D program in the U.S. are used to generate our \$30 12-month price target, and we view any additional programs such as T1D, NASH and T2D ex-U.S. as potential upside to our estimates.

Risks to achieving Target Price / Valuation:

Oramed Pharmaceuticals - ORMP

Clinical risk: Although ORMD-0801 has demonstrated clinical proof-of-concept in patients with T2D, the molecule is now being dosed in larger Phase III trials, and as more patients are exposed to drug over time there is the chance that issues could appear relating to efficacy, safety or both. While there is a significant amount of literature speaking to insulin use in treating T2D, ORMD-0801 is a unique orally delivered version of insulin and only through additional clinical trials can the molecule be further de-risked.

Regulatory risk: Given that there are currently no oral-insulin options approved for the treatment of T2D, the FDA is in new territory regarding the review of this type of molecule administration. The FDA continues to be unpredictable even with the review pathways, designations and outside panel reviews that can be employed during the review process.

Commercial risk: Given that there are currently no oral insulin therapeutics approved for the treatment of T1D and T2D, grasping the true commercial opportunity post-launch is difficult. The outcome of the two-Phase III trials and final labeling will be key to understanding the true market potential for ORMD-0801.

Competitive risk: The competitive landscape for T2D drug development is crowded. The opportunity to tap into a mature multi-billion-dollar market opportunity will result in the space remaining competitive. In addition to the overall T2D clinical landscape being competitive, specific to Oramed there are multiple players attempting to develop an oral delivery option for insulin.

Management risk: For a clinical stage biotech, stability in the C-suite roles is key as it is with any company. Turnover, especially in regulatory agency-facing roles such as CEO and CSO, could negatively impact share performance.

Distribution of Ratings:

Global Stock Ratings (as of 11/23/21)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	643	68.48%	45.10%
Hold	140	14.91%	25.71%
Sell	9	0.96%	33.33%
Speculative Buy	142	15.12%	61.97%
	939*	100.0%	

*Total includes stocks that are Under Review

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12-Month Recommendation History (as of date same as the **Global Stock Ratings** table)

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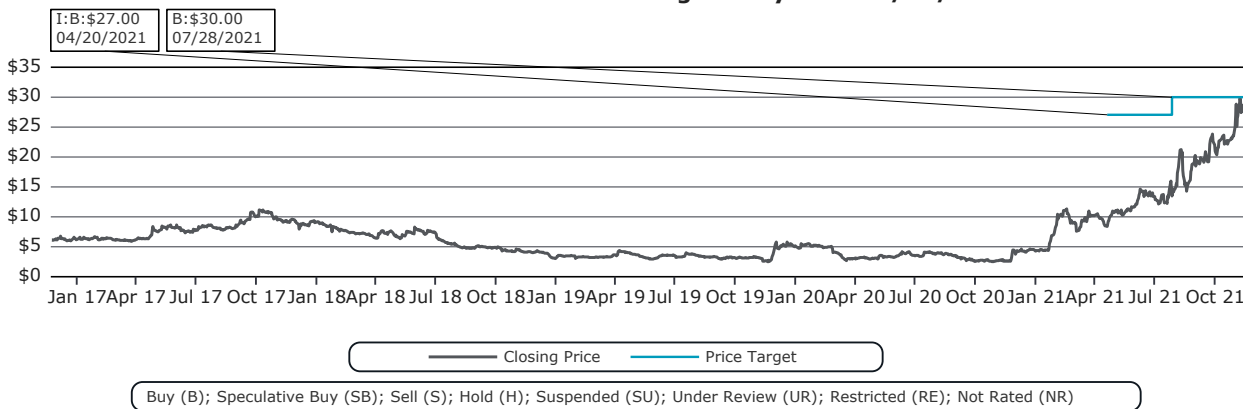
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Oramed Pharmaceuticals Rating History as of 11/19/2021



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