

Oramed Pharmaceuticals

Biotechnology

Rating BUY unchanged	Price Target US\$30.00 unchanged
ORMP-NASDAQ	Price US\$8.26

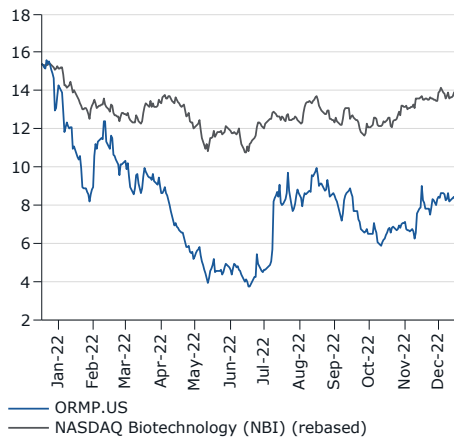
Market Data

52-Week Range (US\$) :	3.59 - 15.80
Market Cap (US\$M) :	323.1
Shares Out., Basic (M) :	39.1
Enterprise Value (US\$M) :	139
Cash (US\$M) :	159.6

FYE Dec	2021A	2022E	2023E
Revenue (US\$M)	2.7	2.7	2.7
EPS (US\$)	(0.78)	(1.05)	(0.93)

Quarterly Revenue	Q1	Q2	Q3	Q4
2021A	0.7	0.7	0.7	0.7
2022E	0.7A	0.7A	0.7A	0.7
2023E	0.7	0.7	0.7	0.7

Quarterly EPS	Q1	Q2	Q3	Q4
2021A	(0.23)	(0.17)	(0.17)	(0.24)
2022E	(0.27)A	(0.27)A	(0.18)A	(0.32)
2023E	(0.28)	(0.22)	(0.22)	(0.24)



Source: FactSet

Priced as of close of business 16 December 2022

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Investor meetings underscore significant potential underlying January Phase III read-out in T2D

We hosted several investor meetings last week with the management of BUY-rated Oramed Pharmaceuticals. These meetings were conducted as the company is just weeks away from announcing top-line data from the first of two Phase III trials for ORMD-0801 in type 2 diabetes (T2D). Oramed is the first company, biotech or pharma, to have successfully advanced clinically this far with an oral insulin candidate for T2D.

We remain bullish on shares of ORMD and would be strong buyers in front of the first Phase III read-out. We project a positive read-out from the first Phase III in January and the second Phase III in mid-2023 followed by a BLA filing in 2023 and an approval and launch in 2024. We project U.S. sales revenue of \$3.5B in the out-year of our model, 2036 with a modest 15% penetration of the target market. Our pricing assumptions are in-line with current branded injectable insulins.

Our take on a positive read-out remains strong

Management reiterated that the top-line read-out from the first Phase III, ORA-D-013-1 will be in January 2023.

This trial is a double-blind, randomized trial testing ORMD-0801 in 710 patients with T2D that have inadequate glycemic control on two or three oral glucose-lowering agents. The study is being conducted solely in the U.S. Patients have been randomized 2:2:1:1 to receive:

- 8mg once daily at night and placebo 45min before breakfast
- 8mg twice daily at night and 45min before breakfast
- Placebo twice daily at night and 45min before breakfast

The primary endpoint is improvement in glycemic control as compared to placebo at 26 weeks. Safety will be evaluated over 52 weeks.

Phase IIb at 8mg once daily was statistically significant

Given the robust, statistically significant results observed from the Phase IIb on reduction in HbA1c, we believe, in the larger Phase III trials, ORMD-0801 will replicate these results.

In the 8mg once daily dose at 12 weeks ORMD-0801 demonstrated a 0.95 (0.81 placebo adjusted) reduction in HbA1c as compared to baseline. This reduction is in line with what the injectable insulin Lantus demonstrated in pivotal trials for approval of what became a Blockbuster product. Results from the second Phase III trial, ORA-D-013-2 in T2D patients with inadequate glycemic control on diet control alone or on diet control and metformin is expected in mid-2023. This study is being conducted 450 subjects in the U.S., Europe and Israel and has completed 50% randomization. The primary endpoint is again glycemic control as compared to placebo at 26 weeks.

Phase III program follows an FDA path to success

The clinical trial program that Oramed has followed is what has been typical and the tried and true path to FDA approval when successful. The company demonstrated success on HbA1c reduction vs placebo in a Phase IIb and then designed two Phase III trials with one focused on treatment experienced patients and one on treatment naive patients. We believe Oramed's success has been its proprietary delivery technology that allows recombinant human insulin to be delivered orally to the gut where it then is able to travel to the liver directly by means of the portal vein. This gets the insulin in high concentration where it needs to be as opposed to injectable insulin that ends up delivering a fraction of its payload to site of activity, the liver.

Appendix: Important Disclosures

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Investment Recommendation

Date and time of first dissemination: December 18, 2022, 23:35 ET

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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 12/18/22)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	639	66.36%	26.60%
Hold	148	15.37%	17.57%
Sell	14	1.45%	7.14%
Speculative Buy	154	15.99%	40.91%
	963*	100.0%	

*Total includes stocks that are Under Review

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Risk Qualifier

SPECULATIVE: Stocks bear significantly higher risk that typically cannot be valued by normal fundamental criteria. Investments in the stock may result in material loss.

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

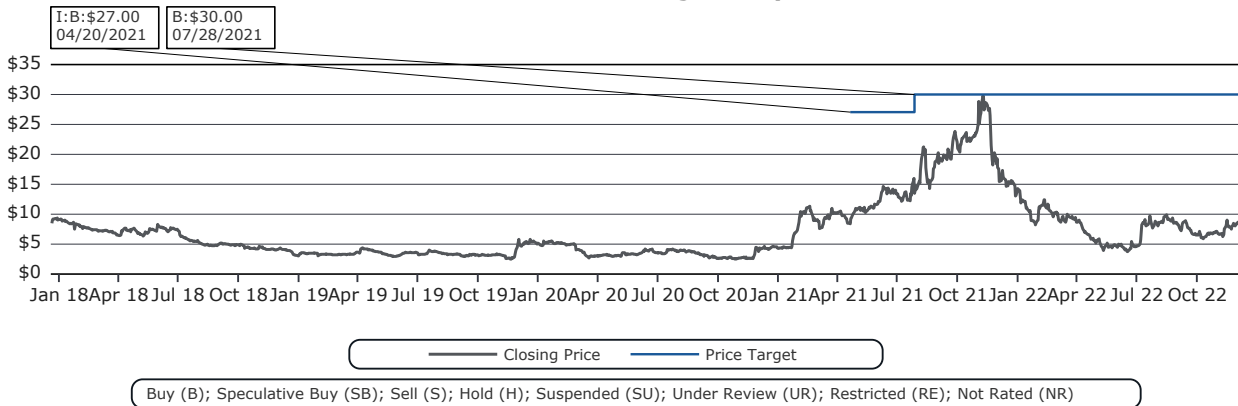
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Oramed Pharmaceuticals Rating History as of 12/16/2022



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