Biotechnology

Oramed Pharmaceuticals Inc. (ORMP)

EQUITY RESEARCH
May 3, 2022

Price: $5.63
Price Target: $20.00

Rating: Overweight

Key Statistics:

Symbol	NASDAQ: ORMP
52-Week Range	$5.13 - $31.54
Market Cap ($M)	215.5
ADV (3 mo)	598,518
Shares Out (M)	38.3

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One-Year Price History

Quick Take

Increased Visibility on '0801 Whets Our Appetite for More — First P3 in T2DM Completes Enrollment

Takeaways

- Oramed completed enrollment for its P3 ORA-D-013-1 study of ORMD-0801 ('0801) for type 2 diabetes (T2D) – data guided for January 2023
- Enrollment exceeded target of 675 patients with 710 – should increase statistical powering and signal-to-noise of study
- Study focused on T2DM patients with inadequate glycemic control on two or three oral glucose-lowering agents – positive results may enable '0801 to become a second/third line of treatment
- Second P3 study, ORA-D-013-2, conducted in T2DM patients with inadequate glycemic control on diet control alone or on diet control and metformin – we estimate a data readout in 2H23
- Results from these two trials could support NDA filing for a broad T2DM patient population

Summary

Oramed announced that it completed enrollment for its P3 ORA-D-013-1 study of its oral insulin candidate, '0801, for T2DM, with data guided for January 2023. Importantly, the study over-enrolled with 710 patients, exceeding the target of 675 patients. We believe the larger sample size increases powering of the study as well as the signal-to-noise, and perhaps increase the PoS, depending on dropout rates being consistent with trial design assumptions.

In our view '0801 may show a differentiated and superior clinical profile relative to injected insulin because of its potential to mimic a more physiological response as this route of administration allows the absorbed insulin to travel through the hepatic portal vein and target the liver directly. We note that oral insulin may have additional advantages to injected insulin by avoiding/reducing frequent needle encounters, such as increased compliance and adherence by patients, potentially leading to better outcomes in terms of glycemic control and complications of long term T2DM.

The P3 ORA-D-013-1 study is in T2DM patients with inadequate glycemic control on two or three oral glucose-lowering agents. The primary efficacy endpoint is the mean change from baseline in HbA1C (hemoglobin A1c) at week 26. If this P3 readouts clearly positive, it may enable '0801 to become a leading second/third line of treatment in place of DPP4s (dipeptidyl-peptidase 4) inhibitors, GLP-1 (glucagon-like peptide 1) receptor agonists, and SGLT2 (sodium-glucose transport protein 2) inhibitors.

The company is conducting a second P3, ORA-D-013-2, in T2DM patients with inadequate glycemic control on diet control alone or on diet control and metformin monotherapy, for which we estimate a data readout in 2H23. Like the first P3 study, the primary efficacy endpoint is mean change from baseline in HbA1c at week 26. Importantly, approximately 30% of subjects will be naïve to first line of therapy, metformin. With the enrollment criteria of this study, if the readout is clearly positive, there is the potential '0801 may become first line monotherapy or used in combination with metformin.

We highlight that the T2DM is a large market as it has become a major global public health concern, with the International Diabetes Federation estimating that in 2013 382M adults aged 20–70 years worldwide had T2DM and this prevalence is expected to rise to 592M

The Disclosure Section may be found on pages 4 - 5.

by 2035 (Nat Rev Dis Primers. 2015 Jul 23;1:15019). We believe an approval of ‘0801 that generates even low penetration into the US and EU5 markets can yield substantial revenue, and possibly strategic interest, as we model ~$981M in un-adjusted revenue by 2030.

Valuation

We use a probability-adjusted DCF analysis to value ORMP shares. We forecast cash flows out to 2036. We apply a discount rate of 14% & do not assume a terminal value. The resulting NPV of free cash flow is ~$876M, based on our analysis, which derives our 12-month price target of $20/share based on shares outstanding as of end-FY2Q23E. Our model assumes an equity raise in FY2Q23.

Risks

ORMD-0801 may not show efficacy as a sole agent and/or in combination with other medications in type 2 diabetes mellitus patients in P3 studies. ORMD-0801 may not show efficacy in additional indications it is being evaluated in, such as type 1 diabetes mellitus or NASH. Studies may reveal unforeseen safety and/or tolerability issues for ORMD-0801. If ORMD-0801 is approved, new, more-efficacious products may enter the market and may compete for market share.

The company may fail to secure financing for additional studies or commercialization of ORMD-0801, should it be approved. The oral SARS-CoV-2 vaccine may fail to stimulate a suitable immune response for protection against COVID-19. ORMD-0901, an orally delivered GLP-1 analog, may fail to show efficacy in type 2 diabetes mellitus. Preclinical programs may fail to receive an IND or to enter the clinic.

Company Description

Oramed is developing drugs using its Protein Oral Delivery (POD) technology, which protects proteins from proteolysis in the gastrointestinal (GI) tract & enhances absorption.

Disclosures Appendix

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Total return is defined as the sum of (1) the percentage difference between the target price and the current price and (2) the expected dividend yield of the stock.

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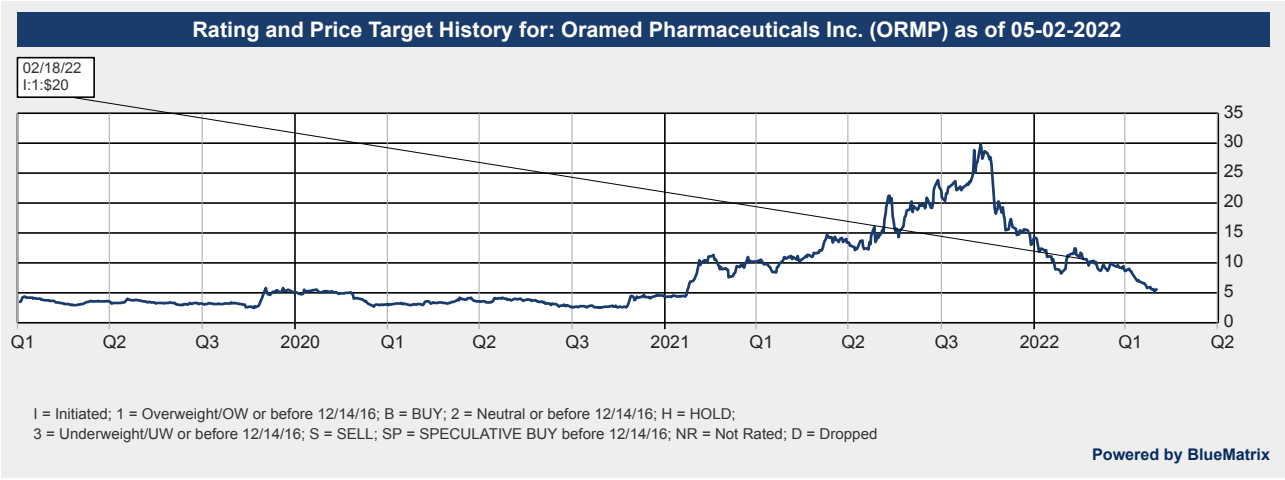

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			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [1/B]	**223**	**88.84**	**172**	**77.13**
HOLD [2]	**28**	**11.16**	**15**	**53.57**
SELL [SL/3]	**0**	**0.00**	**0**	**0.00**

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