CANTOR Fitzgerald

Biotechnology

Oramed Pharmaceuticals Inc. (ORMP)

EQUITY RESEARCH
January 4, 2023

Price: $12.40
Price Target: $20.00

Rating: Overweight

Key Statistics:

Symbol	NASDAQ: ORMP
52-Week Range	$3.59 - $14.77
Market Cap ($M)	485.0
ADV (3 mo)	311,035
Shares Out (M)	39.1

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REV ($M)

FYE Dec	2022E	2023E	2024E
1Q	$0.7A	$0.7	-
2Q	$0.7A	$0.7	-
3Q	$0.7A	$0.7	-
4Q	$0.7E	$0.7	-
Year	$2.7E	$2.7	$56.8

EPS

FYE Dec	2022E	2023E	2024E
1Q	$(0.27)A	$(0.20)	-
2Q	$(0.27)A	$(0.19)	-
3Q	$(0.18)A	$(0.20)	-
4Q	$(0.19)E	$(0.22)	-
Year	$(0.91)E	$(0.80)	$(0.07)

Company Update

Alpha-Hunting Expedition with '801 in T2D – What to Look for from P3 Results Even Yet in January

Investment Summary. We reiterate our OW rating and 12-month $20 PT on ORMP shares. Oramed (ORMP) recently announced the European Patent Office granted a patent supporting the company's POD (Protein Oral Delivery) tech platform. We find the additional IP protection incrementally positive as it adds to an already growing, some would say sizable, patent estate (88 granted and 35 pending). That said, we remain focused on the near-term value driver, the topline readout of the P3 ORA-D-013-1 study of ORMD-0801 ('0801) in type 2 diabetes (T2D), guided for January 2023.

The primary efficacy endpoint of the trial is the mean change from baseline in HbA1C (hemoglobin A1c) at week 26 and the key secondary efficacy endpoint is the mean change from baseline in fasting plasma glucose at week 26. We believe that the study enrolled 710 patients (over target of n=675) with inadequate glycemic control on two or three oral glucose-lowering agents.

Based on prior diligence, we believe that '0801 (oral insulin) may show a differentiated and superior clinical profile relative to injected insulin driven in part by its potential to mimic a more physiological response. In our view, this route of administration allows the absorbed insulin to travel through the hepatic portal vein and target the liver directly. Additionally, adherence drives treatment benefit, and we believe an oral administration compared to injections could result in heightened patient compliance and thus, improved glycemic control and reduced complications of long-term T2D.

Regarding our gauge of "results that would be 'good'", consistent with our previously published thesis (note here), we would like to see ≥0.5% pbo-adjusted reduction in HbA1c, which we project to be a clinically relevant change that may lead to lowered cardiovascular disease risk in patients with T2D (N Am J Med Sci. 2012 Aug; 4(8): 336–343). Based on prior data from a 12-week P2b study, we believe this result is possible as most of the '0801 dosing regimens were directionally positive in reducing HbA1C levels (note here, slide 27). However, due to the small sample size of its Cohort B as well as an unclear dose response relationship seen in the P2 data available, we consider the totality of the earlier clinical studies database to be "only" provocative and remain cautiously optimistic on the P3 results.

If the readout of this study and the second P3 trial ORA-D-013-2 (in T2DM patients with inadequate glycemic control on diet control alone or diet control and metformin monotherapy - we expect in 2H23) are clearly positive, we believe the results could be sufficient to support an NDA filing for a broad T2D patient population. Considering T2D has become a pervasive global health issue, even with low penetration into the US and EU5 markets, we project ~$981M in un-adjusted revenue by 2030 (note here).

The Disclosure Section may be found on pages 3 - 4.

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% and do not assume a terminal value. The resulting NPV of free cash flow is ~$1003M, based on our analysis, which drives our 12-month price target of $20/share based on shares outstanding as of end-2Q23E. Our model assumes an equity raise in 2Q23.

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

Analyst Certification

The analyst primarily responsible for this research report, and whose name appears on the front cover, certifies that: (i) all of the views expressed in this research report accurately reflects his or her personal views about any and all of the subject securities or issuers featured in this report; and (ii) no part of any of the research analyst's compensation was, is, or will be, directly or indirectly related to the specific recommendations or views expressed by the research analyst in this report.

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Cantor Fitzgerald's rating system

Overweight/OW: We expect the stock's total return to exceed 15% over the next 12 months. For the purpose of calculating the percentage of subject companies within the Buy, Hold, and Sell categories for whom Cantor Fitzgerald has provided investment banking services within the previous 12 months, an Overweight rating equates to a Buy rating.

Neutral/N: We expect the stock's total return to be between -10% and 15% over the next 12 months. For the purpose of calculating the percentage of subject companies within the Buy, Hold, and Sell categories for whom Cantor Fitzgerald has provided investment banking services within the previous 12 months, a Neutral rating equates to a Hold rating.

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Not Rated/NR: We are not currently carrying a rating on this stock. Rating and estimates are under review. The NR rating does not equate to an Overweight, Neutral, or Underweight rating and thus is not counted in the calculation of the percentage of subject companies within these three categories for whom Cantor Fitzgerald has provided investment banking services within the previous 12 months.

Performance parameters should be interpreted flexibly as general guidelines relating to performance over a twelve-month period and are not intended to be influenced by short-term share price volatility. Performance in this context is evaluated in terms of total absolute return.

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.

Other Disclosures

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Distribution of Ratings/Investment Banking Services (IB) as of 01/04/23

	Cantor		IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [1/B]	**239**	**85.66**	**176**	**73.64**
HOLD [2]	**40**	**14.34**	**20**	**50.00**
SELL [SL/3]	**0**	**0.00**	**0**	**0.00**

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