

**Oramed Pharmaceuticals, Inc. (ORMP)**  
**Rating: Buy**

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**ORMD-0801 Pivotal Top-Line Data Approaches; 2Q22 Financials; Reiterate Buy**

Stock Data		08/12/2022		
Price		\$9.48		
Exchange		NASDAQ		
Price Target		\$32.00		
52-Week High		\$31.54		
52-Week Low		\$3.59		
Enterprise Value (M)		\$206		
Market Cap (M)		\$366		
Public Market Float (M)		37.1		
Shares Outstanding (M)		38.8		
3 Month Avg Volume		1,523,783		
Short Interest (M)		3.21		
Balance Sheet Metrics				
Cash (M)		\$159.8		
Total Debt (M)		\$0.0		
Total Cash/Share		\$4.12		
Book Value/Share		\$3.99		
EPS (\$) Diluted				
Full Year - Aug		2021A	2022E	2023E
1Q		(0.23)	(0.28)A	(0.33)
2Q		(0.17)	(0.29)A	(0.36)
3Q		(0.17)	(0.29)	(0.38)
4Q		(0.22)	(0.31)	(0.34)
FY		(0.81)	(1.17)	(1.42)
Revenue (\$M)				
Full Year - Aug		2021A	2022E	2023E
1Q		0.7	0.7A	0.8
2Q		0.7	0.7A	0.8
3Q		0.7	0.7	0.8
4Q		0.7	0.7	0.8
FY		2.7	2.8	3.2

**Key enrollment milestone reached in late-stage program.** Oramed recently announced that it had enrolled and randomized more than 50% of the planned 450 patients for its international multi-center Phase 3 ORA-D-013-2 trial of its oral insulin capsule, ORMD-0801, for the treatment of type 2 diabetes (T2D). As a reminder, ORA-D-013-2 is the second of Oramed's two Phase 3 trials being conducted under an FDA-authorized Investigational New Drug Application (IND) filing to treat T2D patients who have inadequate glycemic control over a period of six to 12 months. This double-blind trial is randomizing patients 1:1 into two cohorts dosed with 8mg of ORMD-0801 at night or placebo at night. The primary endpoint is comparison of ORMD-0801 to placebo in improving glycemic control as assessed by A1c over a 26-week evaluation period, with a secondary endpoint of comparing ORMD-0801 to placebo in maintaining glycemic control over a 52-week evaluation period. We expect completion of enrollment by the end of 2022.

**Pivotal trial readout early next year.** We continue to expect the top-line data readout in January 2023 from the first of the two pivotal Phase 3 trials with Oramed's lead oral insulin candidate, ORMD-0801, in patients with T2D. As a reminder, Oramed exceeded the number of planned participants in the first of its two oral insulin trials ORA-D-013-1, with 710 participants enrolled vs. the originally-envisaged 675 subjects. We reiterate our Buy rating and 12-month target of \$32. Investors should be aware that the company had \$159.8M in cash and investments as of end-calendar 2Q22.

**Liver disease data remains slated for imminent release.** Oramed's other programs continue to advance. In March of this year, the company completed enrollment in a Phase 2 trial of ORMD-0801 for the treatment of non-alcoholic steatohepatitis (NASH). We expect the release of top-line results later this quarter. The double-blind, multi-center trial with sites in the U.S. and Israel assesses the safety and efficacy of ORMD-0801 in type 2 diabetes patients with NASH. There is currently no FDA-approved treatment for NASH, which is projected to become an \$84B market by 2029.

**Financial results reported**—by the numbers. Oramed reported a 2Q22 net loss of \$0.29 per share vs. our estimate of a net loss of \$0.23 per share. While G&A spending was in-line with our expectations at roughly \$2.5M, R&D spending was substantively higher, coming in at roughly \$9.2M vs. our projection of only \$7M. We expect R&D expenditures to continue to trend higher through both 2H22 and 1H23, as multiple clinical programs mature. In our view, Oramed's current resources should be sufficient to facilitate completion of ORMD-0801 pivotal clinical development in T2D and support regulatory submission for approval of the drug in the U.S.



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**Valuation methodology, risks and uncertainties.** Factoring in a 12% discount rate, a 75% probability of approval for ORMD-0801, and peak annual sales of \$2.6B (on which we project double-digit percentage royalties), we derive a total risk-adjusted net present value (rNPV) of ~\$820M for this candidate within the diabetes indication alone. We add to this the value from ORMD-0801 in the NASH indication, to which we ascribe an rNPV of \$50M, as well as our anticipated value for Oramed's pipeline, mainly ORMD-0901 and the Oravax program (total value of \$250M), to derive a total enterprise value of approximately \$1.3B. This yields a price objective of \$32 per share, assuming net cash of ~\$129M—resulting in a total firm value of \$1.3B—and roughly 41M fully diluted shares outstanding as of end-2Q23. Risks include, but are not limited to: (1) delays in pivotal testing of ORMD-0801; (2) adverse results from future clinical trials; (3) negative regulatory actions; and (4) medium- to long-term dilution risk.

**Table 1: Oramed Pharmaceuticals, Inc. (ORMP)—Historical Income Statements, Financial Projections**

FY end August 31

\$ in thousands, except per share data

	2021A				2021A	2022E				2022E	2023E
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE		
<b>Revenue</b>											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	674	665	681	683	2,703	666	674	700	750	2,790	3,200
<b>Total revenue</b>	674	665	681	683	2,703	666	674	700	750	2,790	3,200
<b>Expenses</b>											
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-
Research & development	5,774	3,869	5,502	5,844	20,989	5,836	9,179	9,500	10,000	34,515	44,000
Selling and marketing	-	-	-	-	-	590	380	-	-	970	-
General and administrative	727	1,664	1,297	2,249	5,937	5,492	2,532	2,800	3,000	13,824	15,000
<b>Total expenses</b>	6,501	5,533	6,799	8,093	26,926	11,918	12,091	12,300	13,000	49,309	59,000
<b>Gain (loss) from operations</b>	(5,827)	(4,868)	(6,118)	(7,410)	(24,223)	(11,252)	(11,417)	(11,600)	(12,250)	(46,519)	(55,800)
Other income/expense											
Financial income	257	260	493	232	1,242	544	350	300	260	1,454	860
Financial expense	-	-	-	(8)	(8)	-	-	-	-	-	-
Impairment of available-for-sale securities	-	-	-	-	-	-	-	-	-	-	-
<b>Total investment income and other</b>	257	260	493	224	1,234	544	350	300	260	1,454	860
<b>Loss before provision for income taxes</b>	(5,570)	(4,608)	(5,625)	(7,186)	(22,989)	(10,708)	(11,067)	(11,300)	(11,990)	(45,065)	(54,940)
Deferred income tax benefit	-	-	-	-	-	-	-	-	-	-	-
Net loss attributable to non-controlling interests	-	-	418	333	751	283	534	534	534	1,885	3,200
<b>Net loss/income</b>	(5,570)	(4,608)	(5,207)	(7,186)	(22,989)	(10,708)	(11,067)	(11,300)	(11,990)	(45,065)	(54,940)
<b>Net loss per share (basic)</b>	(0.23)	(0.17)	(0.17)	(0.22)	(0.81)	(0.28)	(0.29)	(0.29)	(0.31)	(1.17)	(1.42)
Net loss per share (diluted)	(0.23)	(0.17)	(0.17)	(0.22)	(0.81)	(0.28)	(0.29)	(0.29)	(0.31)	(1.17)	(1.42)
Weighted average number of shares outstanding (basic)	23,746	27,004	29,930	33,196	28,469	38,680	38,795	38,589	38,639	38,676	38,764
Weighted average number of shares outstanding (diluted)	23,746	27,004	29,930	33,196	28,469	38,680	38,795	38,589	38,639	38,676	38,764

Source: Company reports and H.C. Wainwright &amp; Co. estimates.

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Distribution of Ratings Table as of August 12, 2022				
Ratings	Count	Percent	IB Service/Past 12 Months	
			Count	Percent
Buy	564	87.58%	135	23.94%
Neutral	62	9.63%	12	19.35%
Sell	2	0.31%	0	0.00%
Under Review	16	2.48%	1	6.25%

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