H.C.WAINWRIGHT&CO.

Company Update
Healthcare

August 2, 2022

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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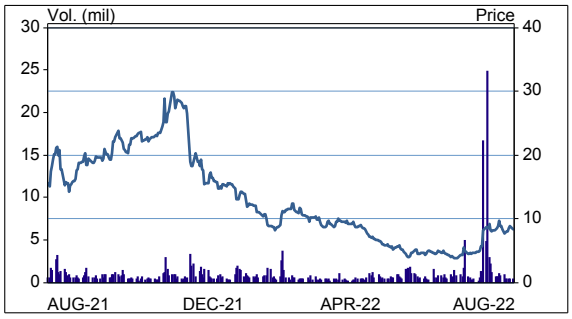
Second Pivotal Oral Insulin Trial Reaches 50% Enrollment; Reiterate Buy

Stock Data	08/01/2022
Price	$8.36
Exchange	NASDAQ
Price Target	$32.00
52-Week High	$31.54
52-Week Low	$3.59
Enterprise Value (M)	$153
Market Cap (M)	$322
Public Market Float (M)	37.0
Shares Outstanding (M)	38.6
3 Month Avg Volume	1,615,970
Short Interest (M)	3.59
Balance Sheet Metrics	
Cash (M)	$169.0
Total Debt (M)	$0.0
Total Cash/Share	$4.38
Book Value/Share	$4.21

EPS ($) Diluted			
Full Year - Aug	2021A	2022E	2023E
1Q	(0.23)	(0.20)	(0.32)
2Q	(0.17)	(0.23)	(0.35)
3Q	(0.17)	(0.26)	(0.38)
4Q	(0.22)	(0.29)	(0.35)
FY	(0.81)	(0.98)	(1.41)

Revenue ($M)			
Full Year - Aug	2021A	2022E	2023E
1Q	0.7	0.7	0.8
2Q	0.7	0.7	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. Last week, Oramed announced that it had enrolled and randomized over 50% of the planned 450 patients for its international multicenter 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 per share. Investors should be aware that the company had $169M in cash and investments as of end-calendar 1Q22.

Liver disease data slated for release in the coming weeks. 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.

Oravax initial clinical data readout later this year. The Phase 1 trial of Oravax's oral virus-like particle (VLP) COVID-19 vaccine for COVID-naive participants is underway in South Africa. The trial protocol calls for two cohorts, each comprising 12 participants. Oramed anticipates sharing top-line data from Cohort A this quarter. We expect Cohort B to complete dosing this quarter as well, with data expected in 4Q22. Oramed is also positioning Oravax to address the broader global vaccine market and is exploring opportunities for additional vaccine indications. The vaccine market may reach $125B by 2028.

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 $800M 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 $1.2B. This yields a price objective of $32 per share, assuming net cash of $154M—resulting in a total firm value of $1.3B—and roughly 40M fully diluted shares outstanding as of end-F2022. 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					2022E					
	1QA	2QA	3QA	4QA	2021A	1QE	2QE	3QE	4QE	2022E	2023E
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	674	665	681	683	2,703	700	700	700	700	2,800	3,200
Total revenue	674	665	681	683	2,703	700	700	700	700	2,800	3,200
Expenses											
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-
Research & development	5,774	3,869	5,502	5,844	20,989	6,000	7,000	8,000	9,000	30,000	43,000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-
General and administrative	727	1,664	1,297	2,249	5,937	2,300	2,500	2,800	3,000	10,600	15,000
Total expenses	6,501	5,533	6,799	8,093	26,926	8,300	9,500	10,800	12,000	40,600	58,000
Gain (loss) from operations	(5,827)	(4,868)	(6,118)	(7,410)	(24,223)	(7,600)	(8,800)	(10,100)	(11,300)	(37,800)	(54,800)
Other income/expense											
Financial income	257	260	493	232	1,242	160	140	300	260	860	860
Financial expense	-	-	-	(8)	(8)	-	-	-	-	-	-
Impairment of available-for-sale securities	-	-	-	-	-	-	-	-	-	-	-
Total investment income and other	257	260	493	224	1,234	160	140	300	260	860	860
Loss before provision for income taxes	(5,570)	(4,608)	(5,625)	(7,186)	(22,989)	(7,440)	(8,660)	(9,800)	(11,040)	(36,940)	(53,940)
Deferred income tax benefit	-	-	-	-	-	-	-	-	-	-	-
Net loss attributable to non-controlling interests	-	-	418	333	751	500	500	500	500	2,000	3,200
Net loss/income	(5,570)	(4,608)	(5,207)	(7,186)	(22,989)	(7,440)	(8,660)	(9,800)	(11,040)	(36,940)	(53,940)
Net loss per share (basic)	(0.23)	(0.17)	(0.17)	(0.22)	(0.81)	(0.20)	(0.23)	(0.26)	(0.29)	(0.98)	(1.41)
Net loss per share (diluted)	(0.23)	(0.17)	(0.17)	(0.22)	(0.81)	(0.20)	(0.23)	(0.26)	(0.29)	(0.98)	(1.41)
Weighted average number of shares outstanding (basic)	23,746	27,004	29,930	33,196	28,469	36,690	38,111	38,161	38,211	37,793	38,336
Weighted average number of shares outstanding (diluted)	23,746	27,004	29,930	33,196	28,469	36,690	38,111	38,161	38,211	37,793	38,336

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

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RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

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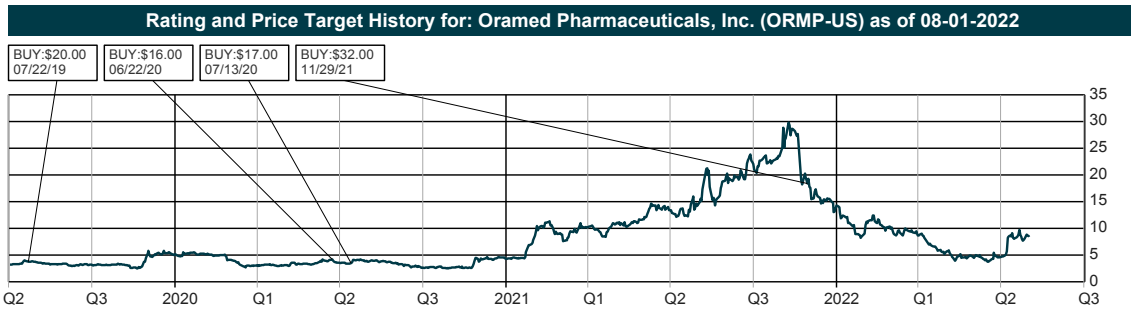

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Distribution of Ratings Table as of August 1, 2022

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	565	88.01%	144	25.49%
Neutral	59	9.19%	12	20.34%
Sell	2	0.31%	0	0.00%
Under Review	16	2.49%	1	6.25%

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