H.C.WAINWRIGHT&CO.

Company Update
Healthcare

March 17, 2022

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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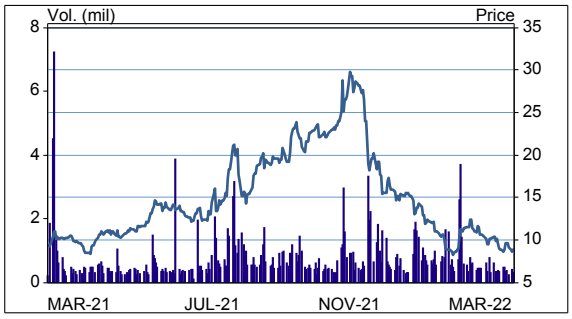
ORMD-0801 Phase 2 NASH Trial Completes Enrollment; Reiterate Buy

Stock Data	03/16/2022
Price	$9.48
Exchange	NASDAQ
Price Target	$32.00
52-Week High	$31.54
52-Week Low	$7.52
Enterprise Value (M)	$237
Market Cap (M)	$363
Public Market Float (M)	37.0
Shares Outstanding (M)	38.3
3 Month Avg Volume	754,252
Short Interest (M)	2.20
Balance Sheet Metrics	
Cash (M)	$125.8
Total Debt (M)	$0.0
Total Cash/Share	$3.29
Book Value/Share	$4.47

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



Enrollment completed on schedule in mid-stage NASH study. Yesterday, Oramed announced that it has completed enrollment of all patients in a Phase 2 trial of its oral insulin capsule ORMD-0801 for the treatment of non-alcoholic steatohepatitis (NASH). An estimated 1.5% to 6.5% of adults in the U.S.—roughly 4-17M people—have NASH. About half of these also have diabetes, according to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The double-blind, multi-center trial (n=36) with sites in the U.S. and Israel is assessing the safety and efficacy of ORMD-0801 in type 2 diabetes patients with NASH. Efficacy endpoints including safety and percentage change in liver fat content, liver fibrosis, and liver steatosis from baseline are being measured via magnetic resonance imaging-proton density fat fraction (MRI-PDFF) following 12 weeks of dosing. In our view, the potential applicability of oral insulin to treatment of NASH makes a great deal of sense, since Oramed's proprietary formulation was designed to exert control of night-time glucose production by the liver. Investors should be aware that our current valuation methodology only ascribes $50M to the potential utility of ORMD-0801 in NASH, which could prove a significant underestimate if this drug candidate demonstrates clear clinical utility in this trial. We await top-line data release in 2H22. Total worldwide annual sales for drugs to treat NASH are projected to reach $84B by 2029, according to a publication by Research and Markets on the global NASH drug market.

Multiple additional catalysts in the offing. We remind investors that Oramed's late-stage clinical programs continue to advance apace. ORA-D-013-1, the larger of two concurrent Phase 3 oral insulin trials with ORMD-0801, has enrolled more than 75% of the planned 675 subjects. In addition, more than 25% of the planned 450 patients in Oramed's second Phase 3 trial, ORA-D-013-2, have been enrolled. The company expects six-month top-line efficacy results from the ORA-D-013-1 trial to be reported in 2022, while the ORA-D-013-2 trial is slated to complete enrollment in 2022 as well. The company is currently conducting a bioavailability trial for ORMD-0901, its oral glucagon-like peptide-1 (GLP-1) analog capsule, in subjects with type 2 diabetes. Bioavailability (PK and PD) data are expected in 1H22. Oramed also provided a timeline for the development of Oravax, its proprietary COVID-19 oral vaccine being developed through a joint venture with Premas Biotech and others. Oravax combines Oramed's POD oral delivery technology with Premas' proprietary virus like particle (VLP) triple antigen vaccine. Top-line data from a South African Phase 1 trial of Oravax are slated for release in 1H22. Oramed expects to initiate a Phase 2/3 oral COVID-19 vaccine program in 2H22. We reiterate our Buy rating and 12-month price target of $32 per share.

For definitions and the distribution of analyst ratings, analyst certifications, and other disclosures, please refer to pages 4 - 5 of this report.

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 non-alcoholic steatohepatitis (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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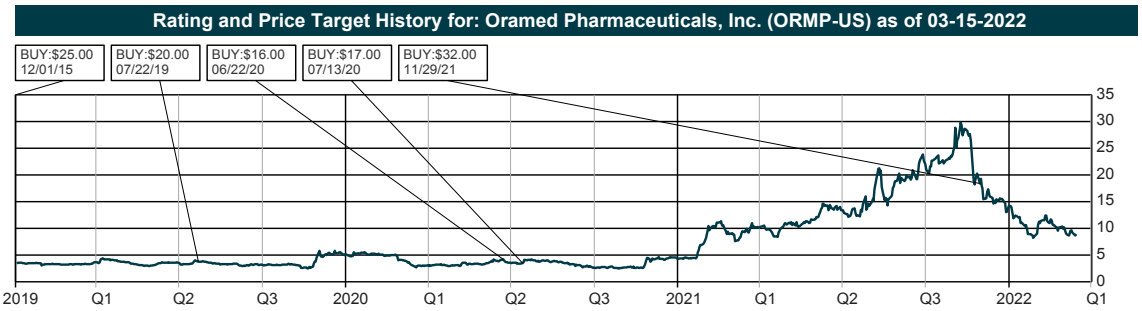

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Distribution of Ratings Table as of March 15, 2022

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	587	91.43%	184	31.35%
Neutral	46	7.17%	12	26.09%
Sell	1	0.16%	0	0.00%
Under Review	8	1.25%	1	12.50%

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