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Company Update
Healthcare

November 25, 2020

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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ORMD-0801 Global Phase 3 Program Patient Screening Begins; Reiterate Buy

Stock Data	11/24/2020
Price	$2.78
Exchange	NASDAQ
Price Target	$17.00
52-Week High	$6.05
52-Week Low	$2.40
Enterprise Value (M)	$20
Market Cap (M)	$66
Public Market Float (M)	20.7
Shares Outstanding (M)	23.5
3 Month Avg Volume	145,993
Short Interest (M)	0.22
Balance Sheet Metrics	
Cash (M)	$45.6
Total Debt (M)	$0.0
Total Cash/Share	$1.94
Book Value/Share	$1.47

EPS ($) Diluted			
Full Year - Aug	2019A	2020E	2021E
1Q	(0.25)	(0.15)A	(0.16)
2Q	(0.21)	(0.21)A	(0.19)
3Q	(0.23)	(0.10)A	(0.19)
4Q	(0.13)	(0.12)	(0.19)
FY	(0.82)	(0.55)	(0.73)

Global ORMD-0801 pivotal program begins patient screening. In a press release yesterday, Oramed indicated that it had begun screening the first patients in its global Phase 3 trials of its oral insulin capsule ORMD-0801 for the treatment of type 2 diabetes (T2D). The patients were screened at U.S. sites participating in Oramed's ORA-D-013-1 trial, one of two Phase 3 trials being conducted in accordance with FDA-authorized protocols. Both Phase 3 trials—designated ORA-D-013-1 and ORA-D-013-2—shall treat T2D patients who have inadequate glycemic control over a period of six to 12 months. The double-blinded, placebo-controlled, multi-center randomized trials are slated to recruit a total of 1,125 patients to evaluate the efficacy and safety of ORMD-0801. Efficacy data should become available after all patients have completed the first six-month treatment period. We expect enrollment to be completed in early 2022, with data release later that year. ORMD-0801 could be the subject of a Biologics License Application (BLA) filing in 2023 and receive FDA approval in 2024. The BLA classification would provide a 12-year period of market exclusivity in the U.S. post-launch. We reiterate our Buy rating and 12-month price target of $17 per share.

Pivotal trials' design parameters disclosed. A geographically diverse patient population shall be recruited from multiple sites throughout the U.S., European Union countries, and Israel. As agreed with the FDA, the ORA-D-013-1 study shall treat T2D patients with inadequate glycemic control who are currently on one, two or three oral glucose-lowering agents. This U.S. study shall recruit 675 patients from 75 sites located throughout the U.S. Patients are to be randomized 1:1:1 in this double-dummy study into cohorts of: 8mg ORMD-0801 once-daily at night and placebo 45 mins before breakfast; 8mg ORMD-0801 twice-daily, at night and 45 mins before breakfast; and placebo twice-daily, at night and 45 mins before breakfast. The primary endpoint of the study is to evaluate the efficacy of ORMD-0801 vs. placebo in improving glycemic control as assessed by A1c, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks. The ORA-D-013-2 study shall include T2D patients with inadequate glycemic control who are managing their condition with either diet alone or with diet and metformin monotherapy. A total of 450 patients shall be recruited at 36 sites in the U.S. and 25 sites in Western Europe and Israel. Patients are to be randomized 1:1 into two cohorts dosed with: 8mg ORMD-0801 at night; and placebo at night. The primary endpoint is to evaluate the efficacy of ORMD-0801 vs. placebo in improving glycemic control as assessed by A1c over a 26-week period, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks.

ORMD-0901 slated to advance into bioavailability study next year. We note that ORMD-0901 (oral exenatide), Oramed's second pipeline candidate, has shown a >50% reduction in mean glucose (similar to subcutaneous delivery of exenatide). ORMD-0901 was tested in four healthy volunteers. ORMD-0901 formulations preserved the biological activity of exenatide when delivered orally and the drug was shown to successfully curb blood sugar excursions following glucose challenge. We expect Oramed to conduct and potentially complete a bioavailability study in T2D patients with ORMD-0901 next year, following a change in active pharmaceutical ingredient (API) supplier.

Valuation methodology, risks and uncertainties. Factoring in a 15% discount rate, a 75% probability of approval for ORMD-0801, and peak annual sales of $2.5B (on which we project double-digit percentage royalties), we derive a total rNPV of $200M within the diabetes indication. 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, to derive a total enterprise value of $450M. This yields a price objective of $17.00 per share, assuming net cash of $105M and 32.8M fully-diluted shares outstanding as of end-F3Q21. The fully-diluted projected shares outstanding assumes exercise of roughly 4.4M options and warrants and the issuance of an additional 5M shares. 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

	2019A					2020E					
	1QA	2QA	3QA	4QA	2019A	1QA	2QA	3QA	4QE	2020E	2021E
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	674	666	682	681	2,703	674	674	681	681	2,710	2,800
Total revenue	674	666	682	681	2,703	674	674	681	681	2,710	2,800
Expenses											
Cost of product and service revenue	35	55	-	-	90	-	-	-	-	-	-
Research & development	4,347	3,114	3,861	2,200	13,522	2,022	3,320	1,925	2,400	9,667	15,000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-
General and administrative	932	1,065	899	826	3,722	1,081	1,391	1,030	1,200	4,702	7,000
Total expenses	5,314	4,234	4,760	3,026	17,334	3,103	4,711	2,955	3,600	14,369	22,000
Gain (loss) from operations	(4,640)	(3,568)	(4,078)	(2,345)	(14,631)	(2,429)	(4,037)	(2,274)	(2,919)	(11,659)	(19,200)
Other income/expense											
Financial income	286	273	263	239	1,061	209	169	200	190	768	860
Financial expense	(8)	(19)	(14)	(174)	(215)	(20)	(2)	(8)	(8)	(38)	(120)
Impairment of available-for-sale securities	60	(87)	(243)	-	(270)	(303)	182	(202)	-	(323)	-
Total investment income and other	338	167	6	65	576	(114)	349	(10)	182	407	740
Loss before provision for income taxes	(4,302)	(3,401)	(4,072)	(2,280)	(14,055)	(2,543)	(3,688)	(2,284)	(2,737)	(11,252)	(18,460)
Deferred income tax benefit	-	(300)	-	-	(300)	-	-	-	-	-	-
Net loss/income	(4,302)	(3,701)	(4,072)	(2,280)	(14,355)	(2,543)	(3,688)	(2,284)	(2,737)	(11,252)	(18,460)
Net loss per share (basic)	(0.25)	(0.21)	(0.23)	(0.13)	(0.82)	(0.15)	(0.21)	(0.10)	(0.12)	(0.55)	(0.73)
Net loss per share (diluted)	(0.25)	(0.21)	(0.23)	(0.13)	(0.82)	(0.15)	(0.21)	(0.10)	(0.12)	(0.55)	(0.73)
Weighted average number of shares outstanding (basic)	17,449	17,454	17,457	17,383	17,454	17,472	17,818	23,215	23,302	20,452	25,302
Weighted average number of shares outstanding (diluted)	17,449	17,454	17,457	17,383	17,454	17,472	17,818	23,215	23,302	20,452	25,302

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

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RETURN ASSESSMENT

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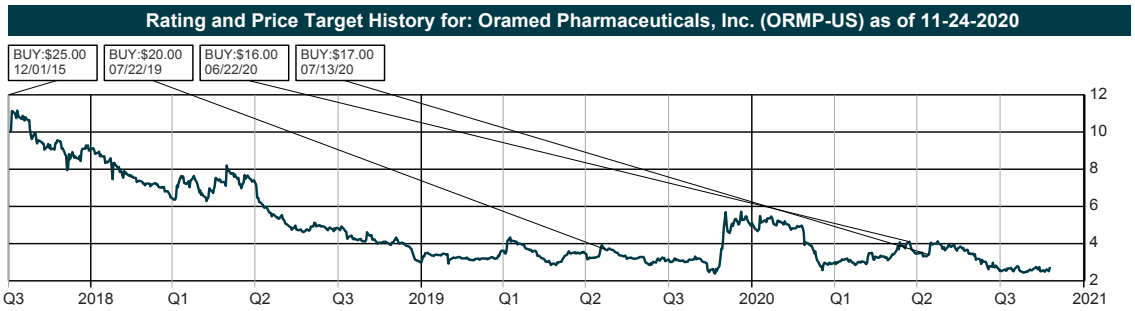

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Distribution of Ratings Table as of November 24, 2020

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	406	87.69%	164	40.39%
Neutral	37	7.99%	7	18.92%
Sell	0	0.00%	0	0.00%
Under Review	20	4.32%	7	35.00%

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