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Company Update
Healthcare

December 28, 2020

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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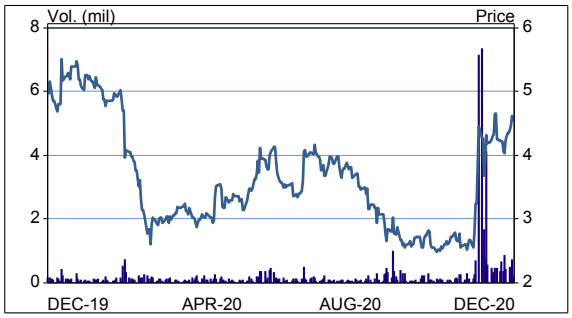
Leptin Candidate Initial Clinical Data Reported; Reiterate Buy

Stock Data	12/24/2020
Price	$4.54
Exchange	NASDAQ
Price Target	$17.00
52-Week High	$5.88
52-Week Low	$2.40
Enterprise Value (M)	$62
Market Cap (M)	$107
Public Market Float (M)	21.0
Shares Outstanding (M)	23.7
3 Month Avg Volume	536,588
Short Interest (M)	1.11
Balance Sheet Metrics	
Cash (M)	$45.6
Total Debt (M)	$0.0
Total Cash/Share	$1.93
Book Value/Share	$1.39

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)



Initial leptin candidate clinical data reported. Last week, Oramed reported results from a proof-of-concept study approved by Israel's Ministry of Health for its oral leptin drug candidate. The single dose study evaluated oral leptin's safety and pharmacodynamics (glucagon and glucose reduction) in type 1 diabetic (T1DM) patients. A total of 10 patients were enrolled, with seven randomized to receive one capsule of leptin and three randomized to receive a placebo. Patients who received leptin on average had a decrease in glucose vs. the placebo group during the first 30-180 minutes following dosing. At different time periods, the leptin-treated patients on average had glucagon values that were either lower than, or similar to, those in the placebo group. Oramed management intends to utilize these data to advance the leptin candidate into a Phase 2 study in roughly 30 patients next year. Our valuation assessment does not include any contribution from this candidate; its future successful clinical development could transform Oramed into a true triple threat—with ORMD-0801 (oral insulin), ORMD-0901 (oral exenatide) and oral leptin all in clinical trials in 2021—going forward.

Global ORMD-0801 pivotal program ongoing. Both Phase 3 trials of ORMD-0801, Oramed's lead clinical-stage candidate—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.

ORMD-0901 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, after changing its 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 assume 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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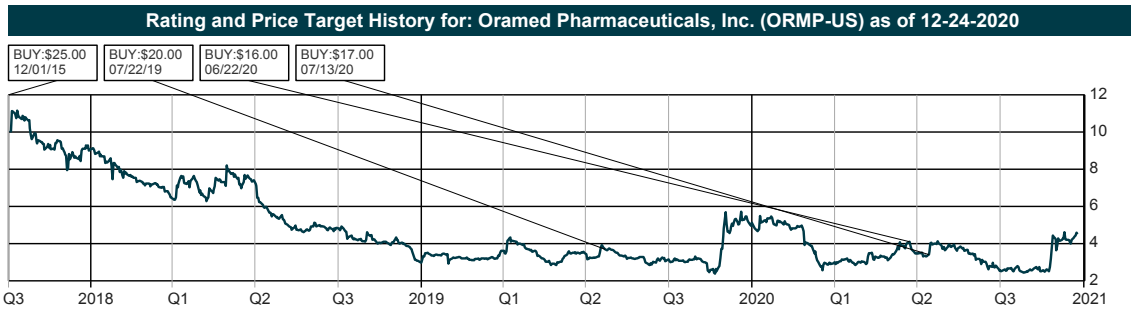

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Distribution of Ratings Table as of December 24, 2020

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	436	90.64%	170	38.99%
Neutral	37	7.69%	9	24.32%
Sell	0	0.00%	0	0.00%
Under Review	8	1.66%	6	75.00%

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