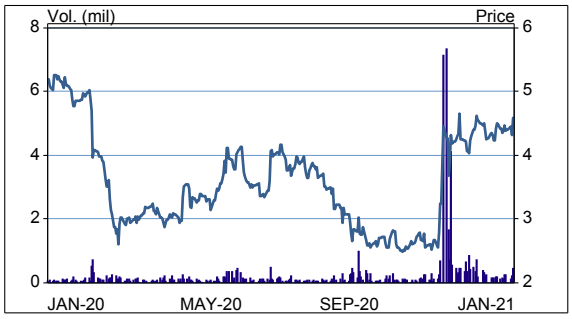
Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

Raghuram Selvaraju, Ph.D.
212-916-3966
rselvaraju@hcwresearch.com

ORMD-0801 Phase 3 Program Patient Dosing Initiated; Reiterate Buy

Stock Data	01/21/2021
Price	$4.58
Exchange	NASDAQ
Price Target	$17.00
52-Week High	$5.58
52-Week Low	$2.40
Enterprise Value (M)	$77
Market Cap (M)	$122
Public Market Float (M)	23.7
Shares Outstanding (M)	26.7
3 Month Avg Volume	559,340
Short Interest (M)	0.95
Balance Sheet Metrics	
Cash (M)	$45.6
Total Debt (M)	$0.0
Total Cash/Share	$1.71
Book Value/Share	$1.18

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)



Dosing under way in pivotal Phase 3 oral insulin program. In a press release yesterday, Oramed announced that randomization and dosing of patients in its first Phase 3 study of its oral insulin capsule ORMD-0801 for the treatment of type 2 diabetes (T2D) is under way. The Phase 3 program for ORMD-0801 consists of two trials. The first of these, ORA-D-013-1, is recruiting 675 patients who are on two or three oral glucose-lowering agents at 75 clinical sites throughout the U.S. The primary endpoint of the study is to compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c, with a secondary endpoint of assessing change from baseline in fasting plasma glucose at 26 weeks. Efficacy data will become available after all patients have completed the first six-month treatment period. The ORA-D-013-1 trial is a double-blinded, double-dummy study randomizing patients 1:1:1 for: 8mg ORMD-0801 once daily at night and placebo 45 minutes before breakfast; or 8mg ORMD-0801 twice daily at night and 45 minutes before breakfast; or placebo twice daily at night and 45 minutes before breakfast. We reiterate our Buy rating and 12-month price target of $17 per share.

Global ORMD-0801 pivotal trials constitute a landmark program. Both Phase 3 trials of ORMD-0801 will 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. 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.

ORMD-0901 slated to advance near term. 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 complete a bioavailability study in T2D patients with ORMD-0901 this year.

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. 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

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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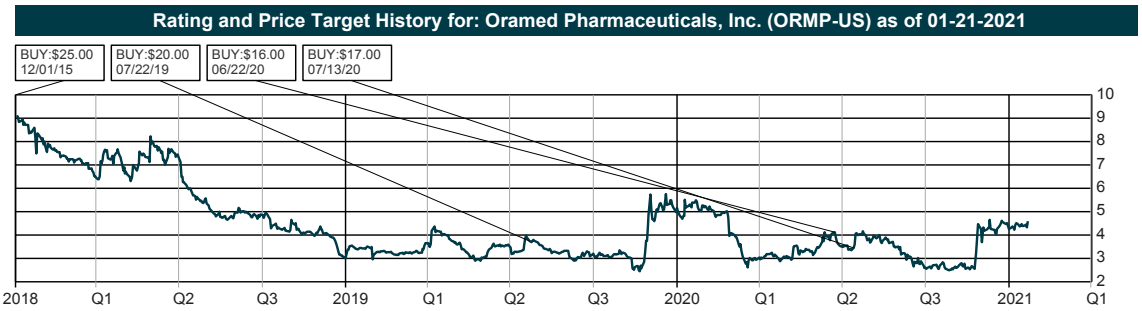

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Distribution of Ratings Table as of January 21, 2021

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	439	91.27%	170	38.72%
Neutral	38	7.90%	11	28.95%
Sell	0	0.00%	0	0.00%
Under Review	4	0.83%	2	50.00%

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