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Company Update
Healthcare

January 29, 2021

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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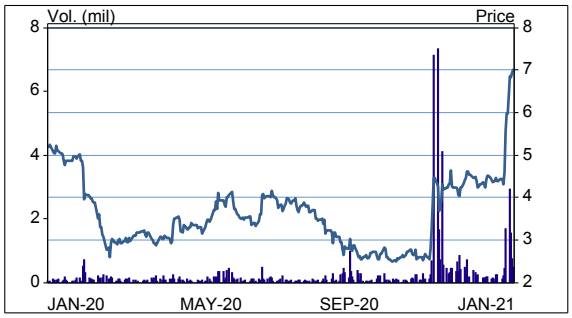
Pipeline Advancing on Multiple Fronts; Reiterate Buy

Stock Data	01/28/2021
Price	$6.99
Exchange	NASDAQ
Price Target	$17.00
52-Week High	$7.60
52-Week Low	$2.40
Enterprise Value (M)	$141
Market Cap (M)	$186
Public Market Float (M)	23.7
Shares Outstanding (M)	26.7
3 Month Avg Volume	672,730
Short Interest (M)	0.81
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)



Pivotal oral insulin program in progress. We remind investors that Oramed has commenced patient dosing in its pivotal program for ORMD-0801, the company's oral insulin candidate. This Phase 3 program consists of two trials. The first of these, ORA-D-013-1, is recruiting 675 patients on two or three oral glucose-lowering agents at 75 sites throughout the U.S. The primary endpoint is comparison of 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. The second study, ORA-013-2, is designed to evaluate the efficacy and safety of ORMD-0801 in 450 subjects in the U.S., Europe, and Israel who have inadequate glycemic control and are on diet modification without medication, or on metformin monotherapy. The company looks forward to sharing recruitment numbers later this quarter and plans to provide updates as enrollment milestones are achieved. We reiterate our Buy rating and 12-month price target of $17 per share.

ORMD-0801 pivotal trials could culminate in an approvable drug. Both Phase 3 trials of ORMD-0801 should complete enrollment in early 2022, with data release later that year. A Biologics License Application (BLA) could be filed in 2023, with FDA approval of ORMD-0801 in 2024. The BLA classification would provide 12 years of U.S. market exclusivity post-launch.

A second high-profile shot on goal in fatty liver disease. Oramed is currently enrolling patients in a global Phase 2 non-alcoholic steatohepatitis (NASH) study, which was initiated in December 2020 when the first patients were screened in the U.S. Other sites in Europe and Israel are slated to begin recruitment later this quarter. The trial will measure efficacy endpoints via MRI- derived proton density fat fraction (MRI-PDFF) for 12 weeks, as well as percent change in liver fibrosis and liver steatosis. We anticipate completion of this NASH study in 2021. Data from Oramed's pilot study of ORMD-0801 in diabetic patients with NASH showed a 30% relative reduction in fatty liver content, as measured by MRI-PDFF. Gamma-glutamyltransferase (GGT), a key marker of chronic hepatitis, and fasting insulin levels were both significantly lower after 12 weeks of treatment vs. baseline. ORMD-0801 was safe and well tolerated in this patient population.

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.

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Leptin program entering mid-stage development this year. In 2020, Oramed conducted an exploratory oral leptin trial to evaluate glucagon reduction in type 1 diabetes (T1D). Leptin is a protein that regulates hunger and is of interest to Oramed as a potential addition to the company's portfolio of clinical-stage candidates aimed at treatment of metabolic disease. The proof-of-concept study evaluated the pharmacokinetic and pharmacodynamics (PK/PD) of Oramed's oral leptin drug candidate in adult T1D patients and showed that patients who received leptin, on average, had a decrease in glucose vs. the placebo group during the first 30-180 minutes following dosing. We expect Oramed to initiate a larger double-blind, placebo-controlled study for its oral leptin capsule later this year. Investors should note that we do not currently ascribe any value to the leptin candidate; accordingly, positive data from the placebo-controlled trial may drive upside to our current assumptions.

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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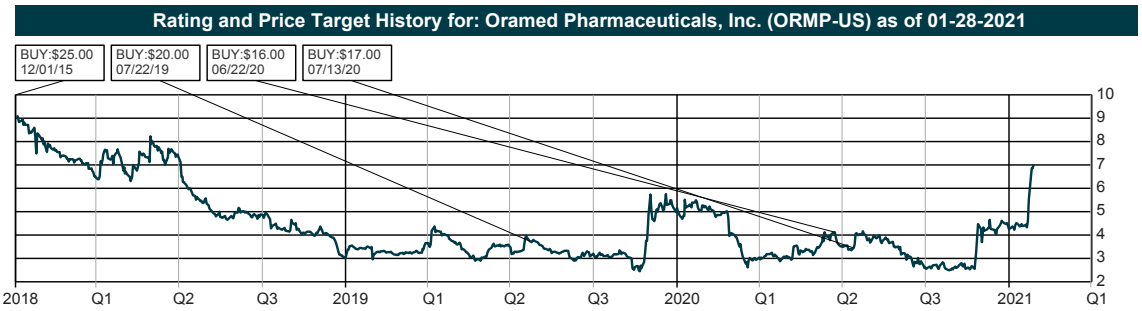

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Distribution of Ratings Table as of January 28, 2021

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	437	90.85%	173	39.59%
Neutral	41	8.52%	12	29.27%
Sell	0	0.00%	0	0.00%
Under Review	3	0.62%	1	33.33%

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