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Company Update
Healthcare

October 26, 2020

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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Phase 3 Program Poised to Advance; Reiterate Buy

Stock Data	10/23/2020
Price	$2.55
Exchange	NASDAQ
Price Target	$17.00
52-Week High	$6.05
52-Week Low	$2.32
Enterprise Value (M)	$14
Market Cap (M)	$60
Public Market Float (M)	20.7
Shares Outstanding (M)	23.5
3 Month Avg Volume	133,642
Short Interest (M)	0.18
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)

Pivotal trials' design parameters disclosed. Earlier this month, Oramed provided a shareholder update in which the company disclosed several details regarding its proposed pivotal trial program with ORMD-0801. As a reminder, the company previously held a successful End-of-Phase 2 (EOP2) meeting with the FDA, in which many of the protocol details and trial parameters were discussed. Oramed intends to conduct two Phase 3 studies concurrently in patients with type 2 diabetes (T2D). These studies involve about 1,125 patients to provide evidence of ORMD-0801's safety and efficacy in T2D patients over a treatment period of six to 12 months. 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. We expect these trials to begin enrollment this quarter and yield data in 2022. ORMD-0801 could be the subject of a Biologics License Application (BLA) filing in 2023 and receive regulatory approval in 2024. The BLA classification ought to provide a 12-year period of market exclusivity in the U.S. We reiterate our Buy rating and 12-month target of $17 per share.

Market research supports oral insulin target product profile. Last month, Oramed released data from a diabetes market survey conducted by a third-party research firm. The survey included qualitative interviews with healthcare providers as well as type 1 (T1D) and type 2 (T2D) diabetes patients regarding ORMD-0801. A total of 41 health care providers, including 22 endocrinologists and 19 primary care physicians, nurse practitioners, physician assistants and certified diabetes educators were surveyed. There was strong support among these health care providers for use of oral insulin with T2D patients early in the treatment process through a primary care physician before the need for injectable insulin and before the patient is moved to an endocrinologist for diabetes care.

Survey results appear promising across multiple metrics. Overall, health care providers stated they would "strongly recommend oral insulin" for T2D patients currently on oral medication; T2D patients who are candidates for insulin; and T2D patients who are candidates for basal insulin. A total of 40 T1D and T2D patients were surveyed and responded with a high degree of interest, stating oral administration of insulin is "extremely important" or "very important." Overall, 91% of T1D patients surveyed stated they were "extremely likely" or "very likely" to ask their doctors about ORMD-0801; 85% of T2D patients surveyed stated they were "extremely likely" or "very likely" to ask their doctors about ORMD-0801; and 80% of T2D patients surveyed stated that oral administration is "extremely important" or "very important", in particular to delay the necessity for use of injectable insulin. From our vantage point, these data underscore the market opportunity for ORMD-0801 and indicate that the drug could achieve substantial market uptake if successful in the pivotal trial program. We note that ORMD-0801 resonated well with health care providers because of the potential to avoid hypoglycemia or weight gain when using the product, as well as the advantage of oral administration without the requirement for needles.

ORMD-0801 poised to enter mid-stage development in NASH. We remind investors that initial data from eight patients treated with ORMD-0801 in the context of non-alcoholic steatohepatitis (NASH) were presented at the American Diabetes Association (ADA) 2020 meeting. Safety was favorable over a 12-week period, with no serious adverse events (SAEs). There was a 30% relative fat reduction in the liver measured by magnetic resonance imaging proton density fat fraction (MRI-PDFF), while a 6.9+/-6.8% mean reduction in liver fat content (p=0.035) was also observed. The company is currently recruiting an additional 10 patients in Europe and is also slated to initiate a double-blind, placebo-controlled Phase 2 trial in 30 subjects to be enrolled in both the U.S. and Israel within the coming weeks.

ORMD-0901 slated to advance into bioavailability study. 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 before the end of this year. Investors should take note of the fact that glucagon-like peptide 1 (GLP1) receptor agonists like exenatide—also known as incretin mimetics—represent a well-established anti-diabetic drug class. Seven GLP1 receptor agonist drugs have been approved in the U.S.—Byetta or Bydureon (exenatide) from AstraZeneca (AZN; not rated), Victoza (liraglutide) from Novo Nordisk (NVO; not rated), Lyxumia (lixisenatide) from Sanofi S.A. (SNY; not rated), Tanzeum (albiglutide)—withdrawn from the market for economic reasons—from GlaxoSmithKline (GSK; not rated), Trulicity (dulaglutide) from Eli Lilly & Co. and Ozempic (semaglutide) from Novo Nordisk. All of these products are formulated for subcutaneous delivery via injection under the aforementioned brand names. An orally-bioavailable tablet formulation of semaglutide was approved in the U.S. in 2019 under the trade name Rybelsus. To date, this is the only oral GLP-1 receptor agonist drug to be made available; thus, we believe that Oramed's oral exenatide candidate could constitute an attractive commercial opportunity. The GLP-1 receptor agonist class represents a target market of several million prescriptions annually.

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

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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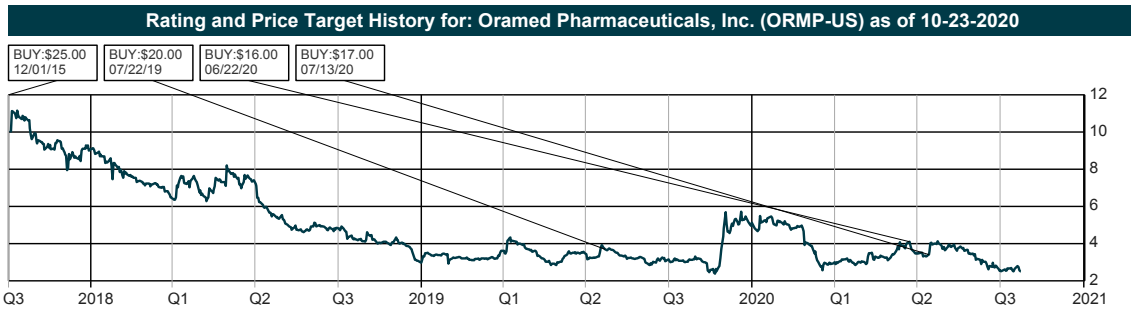

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Distribution of Ratings Table as of October 23, 2020

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	402	87.20%	159	39.55%
Neutral	36	7.81%	5	13.89%
Sell	0	0.00%	0	0.00%
Under Review	23	4.99%	8	34.78%

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