

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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

Pivotal Development Pathway Promulgated for Oral Insulin; Reiterate Buy

Stock Data		10/04/2017	
Price		\$10.02	
Exchange		NASDAQ	
Price Target		\$25.00	
52-Week High		\$11.19	
52-Week Low		\$5.70	
Enterprise Value (M)		\$106.8	
Market Cap (M)		\$133	
Public Market Float (M)		9.7	
Shares Outstanding (M)		13.3	
3 Month Avg Volume		61,872	
Short Interest (M)		0.27	
Balance Sheet Metrics			
Cash (M)		\$26.20	
Total Debt (M)		\$0.00	
Total Cash/Share		\$1.97	
Book Value/Share		\$1.49	
EPS Diluted			
Full Year - Aug	2016A	2017E	2018E
1Q	(0.24)	(0.20)A	(0.27)
2Q	(0.14)	(0.24)A	(0.31)
3Q	(0.15)	(0.15)A	(0.33)
4Q	(0.38)	(0.23)	(0.34)
FY	(0.87)	(0.78)	(1.27)

Continuing coverage under the name H.C. Wainwright & Co. with a Buy rating. Effective October 5, 2017, research in the above titled name will now be published under H.C. Wainwright & Co. and no longer distributed in conjunction with “Rodman & Renshaw, a unit of H.C. Wainwright.”

Regulatory path clarified with FDA for ORMD-0801. Last month, Oramed reported that it had successfully concluded its formal meeting with the FDA to discuss the pivotal clinical development program for the company’s lead drug candidate, the oral insulin agent ORMD-0801. Among the principal elements defined at this meeting were the following: (1) ORMD-0801 would be submitted for approval according to the Biologics License Application (BLA) pathway, which we regard as a very positive development as it would provide a minimum of 12 years of market exclusivity for ORMD-0801 if approved under current legislation; (2) the FDA confirmed that the non-clinical toxicology, CMC and excipient qualification work required for ORMD-0801 would be defined by their published guidance documents, consistent with Oramed’s expectations; (3) specific guidance was given regarding the scope and design of the pivotal ORMD-0801 trial program, including the definition of reduction in HbA1c as the primary efficacy endpoint; (4) Oramed now plans—based on FDA feedback—to initiate a three-month trial in patients with type 2 diabetes to evaluate the effect of ORMD-0801 on HbA1c, the main FDA registrational endpoint, later this year; and (5) the FDA confirmed the company’s ability to use insulin from different suppliers like HTBT (Hefei Tianmai Biotechnology Development Co., Ltd., Hefei, China) in the Phase 3 program. We continue to expect that Oramed and its Chinese partner, Hefei Tianhui Incubator of Technologies Co. Ltd. (HTIT), would divide responsibilities for clinical testing of ORMD-0801, with Oramed taking the lead in conducting U.S.-based pivotal testing and HTIT assessing the drug in China. The two entities are slated to share data from one another’s trial programs to support regulatory filings on ORMD-0801 in China and the U.S. We reiterate our Buy rating and price target of \$25.00 per share.



Patent estate continues to strengthen. Investors should be aware that, just over the course of the past six months, Oramed has been granted patent claims covering a proprietary insulin and glucagon-like peptide 1 (GLP-1) analog combination capsule in both Europe and Japan; and claims covering its GLP-1 analog capsule in Canada. We anticipate further expansion of the company’s intellectual property (IP) estate in the coming months.

Solid financial base and low burn rate remain positives. In our view, Oramed—which, as of end-August 2017, had roughly \$26.2M in cash, short-term deposits and marketable securities—likely has an operational runway extending for over two years. We believe that the company has sufficient resources to conduct pivotal development of ORMD-0801.

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Vice President of Medical Affairs appointed. During the summer, Oramed also took steps to strengthen its development team, notably through the hiring of Dr. Simon Bruce as Vice President of Medical Affairs. Dr. Bruce is trained in Internal Medicine with sub-specialization in Endocrinology at the National Institutes of Health (NIH). At the NIH, he received training and conducted human patient-oriented clinical research. For the past 17 years, he has held positions of increasing responsibility in both large pharmaceutical and small to medium-sized biotechnology firms. He has broad experience across all phases of clinical development and has been responsible for clinical development strategy and execution from pre-IND to first-in-human and Phase 1/2 proof-of-concept trials through Phase 3 planning, execution and filing. Dr. Bruce has led clinical development of multiple compounds in the metabolic disorders and diabetes therapeutic areas including DPP4 and SGLT2 inhibitors, GLP-1 agonists, leptin and prandial insulins among others. Most recently, he served as Chief Medical Officer with Adocia Inc. (ADOC.PA; not rated), working on an ultra-rapid insulin in collaboration with Eli Lilly & Co. (LLY; not rated).

Valuation methodology, risks and uncertainties. Factoring in a 15% discount rate, a 70% probability of success for ORMD-0801, and peak annual sales of roughly \$2.1B (on which we project double-digit percentage royalties), we derive a total rNPV of \$150M. We add to this the value from Oramed's pipeline, mainly ORMD-0901, to which we ascribe a total valuation of \$210M, to derive a total firm value of \$385M. This translates into a price objective of \$25.00 per share, assuming net cash of ~\$25M and ~15M fully-diluted shares outstanding as of mid-F2018. Risks to our target include, but are not limited to: (1) delays in pivotal testing of ORMD-0801; (2) adverse results from future clinical trials; and (3) negative regulatory actions.

Table 1: Oramed Pharmaceuticals, Inc. (ORMP)—Historical Income Statements, Financial Projections

FY end August 31

\$ in thousands, except per share data

	2016A				2016A	2017E				2017E	2018E
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE		
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	125	163	353	641	610	611	617	617	2,455	2,800
Total revenue	-	125	163	353	641	610	611	617	617	2,455	2,800
Expenses											
Cost of product and service revenue	-	-	-	490	490	187	-	-	-	187	-
Research & development	1,901	1,307	1,718	2,783	7,709	2,353	3,125	2,267	3,000	10,745	16,300
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-
General and administrative	548	730	555	619	2,452	468	851	505	800	2,624	4,600
Total expenses	2,449	2,037	2,273	3,892	10,651	3,008	3,976	2,772	3,800	13,556	20,900
Gain (loss) from operations	(2,449)	(1,912)	(2,110)	(3,539)	(10,010)	(2,398)	(3,365)	(2,155)	(3,183)	(11,101)	(18,100)
Other income/expense											
Financial income	76	128	137	133	474	186	203	210	180	779	465
Financial expense	(17)	(34)	(23)	(19)	(93)	(24)	(21)	(20)	(20)	(85)	(120)
Impairment of available-for-sale securities	(406)	78	84	(208)	(452)	(63)	168	286	-	391	-
Total investment income and other	(347)	172	198	(94)	(71)	99	350	476	160	1,085	345
Loss before provision for income taxes	(2,796)	(1,740)	(1,912)	(3,633)	(10,081)	(2,299)	(3,015)	(1,679)	(3,023)	(10,016)	(17,755)
Deferred income tax benefit	-	-	-	(1,335)	(1,335)	(400)	-	-	-	(400)	-
Net loss/income	(2,796)	(1,740)	(1,912)	(4,968)	(11,416)	(2,699)	(3,015)	(1,679)	(3,023)	(10,416)	(17,755)
Net loss per share (basic)	(0.24)	(0.14)	(0.15)	(0.38)	(0.87)	(0.20)	(0.24)	(0.15)	(0.23)	(0.78)	(1.25)
Net loss per share (diluted)	(0.24)	(0.14)	(0.15)	(0.38)	(0.87)	(0.20)	(0.24)	(0.15)	(0.23)	(0.78)	(1.25)
Weighted average number of shares outstanding (basic)	11,573	12,653	13,119	13,157	12,624	13,206	13,280	13,301	13,367	13,288	14,242
Weighted average number of shares outstanding (diluted)	11,573	12,653	13,119	13,157	12,624	13,206	13,280	13,301	13,367	13,288	14,242

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.

Market Perform (Neutral): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

Market Underperform (Sell): The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.



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Distribution of Ratings Table as of October 4, 2017				
Ratings	Count	Percent	IB Service/Past 12 Months	
			Count	Percent
Buy	222	88.80%	75	33.78%
Neutral	10	4.00%	0	0.00%
Sell	0	0.00%	0	0.00%
Under Review	18	7.20%	3	16.67%
Total	250	100%	78	31.20%

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