Healthcare

**September 18, 2019** 

## Oramed Pharmaceuticals, Inc. (ORMP) Rating: Buy

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

## Last Patient Dosed in ORMD-0801 Phase 2b Trial; Top-Line Readout Next Month; Reiterate Buy

Price Exchange Price Target 52-Week High 52-Week Low Enterprise Value (M) Market Cap (M) Public Market Float ( Shares Outstanding	M) (M)			\$3.15 NASDAQ \$20.00 \$4.99 \$2.78 \$29 \$55 14.5			
Exchange Price Target 52-Week High 52-Week Low Enterprise Value (M) Market Cap (M) Public Market Float (	M) (M)			NASDAQ \$20.00 \$4.99 \$2.78 \$29 \$55			
Price Target 52-Week High 52-Week Low Enterprise Value (M) Market Cap (M) Public Market Float (	M) (M)			\$20.00 \$4.99 \$2.78 \$29 \$55			
52-Week High 52-Week Low Enterprise Value (M) Market Cap (M) Public Market Float (	M) (M)			\$4.99 \$2.78 \$29 \$55			
52-Week Low Enterprise Value (M) Market Cap (M) Public Market Float (	M) (M)			\$2.78 \$29 \$55			
Enterprise Value (M) Market Cap (M) Public Market Float (	M) (M)			\$29 \$55			
Market Cap (M) Public Market Float (	M) (M)			\$55			
Public Market Float (	(M)						
	(M)			14.5			
Shares Outstanding	` '						
			17.4				
3 Month Avg Volume	44,333						
Short Interest (M)	0.04						
Balance Sheet Metrics							
Cash (M)	\$26.2						
Total Debt (M)	\$0.0						
Total Cash/Share				\$1.51			
Book Value/Share				\$1.24			
EPS Diluted							
Full Year - Aug 20	)18A	2	019E	2020E			
1Q (0	).18)	(0	.25)A	(0.26)			
2Q (0	).20)		.21)A	(0.25)			
3Q (0	).30)	(0	.23)A	(0.24)			
4Q (0	).18)	((	(0.23) (0.23)				
FY (C	).86)	((	0.92)	(0.97)			



Final patient dosed in key clinical study. Yesterday, Oramed reported that it has dosed the last patient in the primary cohort of the Phase 2b HbA1c trial evaluating Oramed's lead oral insulin candidate. ORMD-0801, which has the potential to be the first commercial oral insulin capsule for the treatment of type 2 diabetes. As a reminder, this Phase 2b, double-blinded, randomized, 90-day dose-ranging trial is assessing the impact of ORMD-0801 therapy on the primary efficacy endpoint of reduction in HbA1c, as well as safety endpoints. Top-line data from the primary cohort of the Phase IIb trial are slated to be released during 4Q19; in our view, this data could become available by the end of next month. From our vantage point, statistically significant impact in this study should clearly validate Oramed's approach to type 2 diabetes therapy with an orally-administered insulin formulation, while making the ORMD-0801 candidate more attractive to potential licensees. We reiterate our Buy rating and 12-month price target of \$20.00.

Other clinical data catalysts approaching. Multiple additional clinical trial programs involving candidates from Oramed's pipeline comprise the following: (1) top-line data from the low-dose cohort in the Phase 2b trial of ORMD-0801, which could be released in 1Q20; (2) top-line data from the first cohort in an exploratory three-month study assessing ORMD-0801 in non-alcoholic steatohepatitis (NASH), which may be reported early next year assuming the first cohort completes enrollment before the end of 2019; (3) potential release of top-line pharmacokinetic (PK) data from the recently-completed Phase 1 trial of the company's second pipeline candidate, the oral exenatide designated ORMD-0901, which could occur once the analysis has been completed within the next several weeks; and (4) top-line data from a single-dose exploratory study involving an oral leptin candidate, which may be released within the next several months, either in late 2019 or early 2020.

Valuation methodology, risks and uncertainties. Factoring in a 15% discount rate, a 75% 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 \$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 \$100M, as well as our current anticipated value for Oramed's pipeline, mainly ORMD-0901, to derive a total enterprise value of \$520M. This yields a price objective of \$20.00 per share, assuming net cash of ~\$82M and ~30M fully-diluted shares outstanding as of end-F3Q20. The fully-diluted projected shares outstanding assumes exercise of roughly 4.4M options and warrants and the issuance of an additional 7.9M shares. Risks include, but are not limited to: (1) delays in pivotal testing of ORMD-0801; (2) adverse results from future clinical trials, particularly the Phase 2b trial of ORMD-0801; (3) negative regulatory actions, including refusal of permission to advance ORMD-0801 into pivotal clinical studies; and (4) possible medium- to long-term dilution risk.

Oramed Pharmaceuticals, Inc. September 18, 2019

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

FY end August 31

\$ in thousands, except per share data

	2018A			2019E							
	1QA	2QA	3QA	4QA	2018A	1QA	2QA	3QA	4QE	2019E	2020E
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	611	604	617	617	2,449	674	666	682	700	2,722	2,800
Total revenue	611	604	617	617	2,449	674	666	682	700	2,722	2,800
Expenses											
Cost of product and service revenue	-	-	(86)	-	(86)	35	55	-	-	90	-
Research & development	2,327	2,724	4,194	2,734	11,979	4,347	3,114	3,861	4,000	15,322	20,000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-
General and administrative	1,016	991	1,043	1,033	4,083	932	1,065	899	1,200	4,096	7,000
Total expenses	3,343	3,715	5,151	3,767	15,976	5,314	4,234	4,760	5,200	19,508	27,000
Gain (loss) from operations	(2,732)	(3,111)	(4,534)	(3,150)	(13,527)	(4,640)	(3,568)	(4,078)	(4,500)	(16,786)	(24,200)
Other income/expense											
Financial income	222	217	209	255	903	286	273	263	250	1,072	1,320
Financial expense	(21)	(22)	(29)	(31)	(103)	(8)	(19)	(14)	(14)	(55)	(120)
Impairment of available-for-sale securities	326	-	-	(25)	301	60	(87)	(243)	-	(270)	-
Total investment income and other	527	195	180	199	1,101	338	167	6	236	747	1,200
Loss before provision for income taxes	(2,205)	(2,916)	(4,354)	(2,951)	(12,426)	(4,302)	(3,401)	(4,072)	(4,264)	(16,039)	(23,000)
Deferred income tax benefit	-	-	-	-	-	-	(300)	-	-	(300)	-
Net loss/income	(2,205)	(2,916)	(4,354)	(2,951)	(12,426)	(4,302)	(3,701)	(4,072)	(4,264)	(16,339)	(23,000)
Net loss per share (basic)	(0.18)	(0.20)	(0.30)	(0.18)	(0.86)	(0.25)	(0.21)	(0.23)	(0.23)	(0.92)	(0.97)
Net loss per share (diluted)	(0.18)	(0.20)	(0.30)	(0.18)	(0.86)	(0.25)	(0.21)	(0.23)	(0.23)	(0.92)	(0.97)
Weighted average number of shares outstanding (basic)	14,239	14,357	14,519	16,412	14,882	17,449	17,454	17,457	18,854	17,803	23,800
Weighted average number of shares outstanding (diluted)	14,239	14,357	14,519	16,412	14,882	17,449	17,454	17,457	18,854	17,803	23,800

Source: Company reports and H.C. Wainwright & Co. estimates.

## **Important Disclaimers**

This material is confidential and intended for use by Institutional Accounts as defined in FINRA Rule 4512(c). It may also be privileged or otherwise protected by work product immunity or other legal rules. If you have received it by mistake, please let us know by e-mail reply to unsubscribe@hcwresearch.com and delete it from your system; you may not copy this message or disclose its contents to anyone. The integrity and security of this message cannot be guaranteed on the Internet.

**H.C. WAINWRIGHT & CO, LLC RATING SYSTEM:** H.C. Wainwright employs a three tier rating system for evaluating both the potential return and risk associated with owning common equity shares of rated firms. The expected return of any given equity is measured on a RELATIVE basis of other companies in the same sector. The price objective is calculated to estimate the potential movements in price that a given equity could reach provided certain targets are met over a defined time horizon. Price objectives are subject to external factors including industry events and market volatility.

## 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.



Investment Banking Services include, but are not limited to, acting as a manager/co-manager in the underwriting or placement of securities, acting as financial advisor, and/or providing corporate finance or capital markets-related services to a company or one of its affiliates or subsidiaries within the past 12 months.

Distribution of Ratings Table as of September 17, 2019								
			IB Se	IB Service/Past 12 Months				
Ratings	Count	Percent	Count	Percent				
Buy	358	92.27%	123	34.36%				
Neutral	30	7.73%	3	10.00%				
Sell	0	0.00%	0	0.00%				
Under Review	0	0.00%	0	0.00%				
Total	388	100%	126	32.47%				

H.C. Wainwright & Co, LLC (the "Firm") is a member of FINRA and SIPC and a registered U.S. Broker-Dealer.

I, Raghuram Selvaraju, Ph.D., certify that 1) all of the views expressed in this report accurately reflect my personal views about any and all subject securities or issuers discussed; and 2) no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report; and 3) neither myself nor any members of my household is an officer, director or advisory board member of these companies.

None of the research analysts or the research analyst's household has a financial interest in the securities of Oramed Pharmaceuticals, Inc. (including, without limitation, any option, right, warrant, future, long or short position).

As of August 31, 2019 neither the Firm nor its affiliates beneficially own 1% or more of any class of common equity securities of Oramed Pharmaceuticals. Inc..

Neither the research analyst nor the Firm knows or has reason to know of any other material conflict of interest at the time of publication of this research report.

The research analyst principally responsible for preparation of the report does not receive compensation that is based upon any specific investment banking services or transaction but is compensated based on factors including total revenue and profitability of the Firm, a substantial portion of which is derived from investment banking services.

The firm or its affiliates received compensation from Oramed Pharmaceuticals, Inc. for non-investment banking services in the previous 12 months.

The Firm or its affiliates did not receive compensation from Oramed Pharmaceuticals, Inc. for investment banking services within twelve months before, but will seek compensation from the companies mentioned in this report for investment banking services within three months following publication of the research report.

The Firm does not make a market in Oramed Pharmaceuticals, Inc. as of the date of this research report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. Past performance is no guarantee of future results. This report is offered for informational purposes only, and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. This research report is not intended to provide tax advice or to be used to provide tax advice to any person. Electronic versions of H.C. Wainwright & Co., LLC research reports are made available to all clients simultaneously. No part of this report may be reproduced in any form without the expressed permission of H.C. Wainwright & Co., LLC. Additional information available upon request.

- H.C. Wainwright & Co., LLC does not provide individually tailored investment advice in research reports. This research report is not intended to provide personal investment advice and it does not take into account the specific investment objectives, financial situation and the particular needs of any specific person. Investors should seek financial advice regarding the appropriateness of investing in financial instruments and implementing investment strategies discussed or recommended in this research report.
- H.C. Wainwright & Co., LLC's and its affiliates' salespeople, traders, and other professionals may provide oral or written market commentary or trading strategies that reflect opinions that are contrary to the opinions expressed in this research report.
- H.C. Wainwright & Co., LLC and its affiliates, officers, directors, and employees, excluding its analysts, will from time to time have long or short positions in, act as principal in, and buy or sell, the securities or derivatives (including options and warrants) thereof of covered companies referred to in this research report.

The information contained herein is based on sources which we believe to be reliable but is not guaranteed by us as being accurate and does not purport to be a complete statement or summary of the available data on the company, industry or security discussed in the report. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Securities and other financial instruments discussed in this research report: may lose value; are not insured by the Federal Deposit Insurance Corporation; and are subject to investment risks, including possible loss of the principal amount invested.