Healthcare

October 1, 2018

Oramed Pharmaceuticals, Inc. (ORMP) Rating: Buy

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

OWL833 Transaction Provides Benchmark for ORMD-0901; Reiterate Buy

Stock Data				09/28/2018				
Price		\$4.87						
Exchange	NASDAQ							
Price Target	\$25.00							
52-Week High	\$11.34							
52-Week Low	\$4.60							
Enterprise Valu	\$61.6							
Market Cap (M	\$85							
Public Market F	10.9							
Shares Outstar	17.4							
3 Month Avg Vo	44,860							
Short Interest (0.28						
Balance Sheet Metrics								
Cash (M)		\$23.4						
Total Debt (M)		\$0.0						
Total Cash/Sha		\$1.34						
Book Value/Sha		\$1.15						
EPS Diluted								
Full Year - Aug	2017A	2	018E	2019E				
1Q	(0.20)	`	.18)A	(0.29)				
2Q	(0.24)	•	.20)A	(0.28)				
3Q	(0.15)	•	0.30)	(0.25)				
4Q	(0.21)	((0.30)	(0.25)				
FY	(0.79)	(((0.96) (1.06)					
Vol. (mil)				Price				



Preclinical licensing transaction shows value of oral delivery. Last month, Tokyo-based Chugai Pharmaceutical—a division of Roche (RHHBY; not rated) via its Genentech division—licensed the global rights to OWL833, an oral, non-peptide GLP-1 receptor agonist that has completed preclinical development and is now slated to enter a Phase 1 study. The licensee, Eli Lilly & Co. (LLY; not rated), paid \$50M upfront and is also slated to pay additional development-, regulatory-, and sales-based milestones that remain undisclosed. In our view, the upfront payment alone—quite large for such an early-stage candidate -underscores the value of oral delivery for well-known agents with validated mechanisms of action in chronic diabetes treatment. We remind investors that various injectable versions of GLP-1 receptor agonists are already on the market, including drugs like Byetta (exenatide), Bydureon, Victoza (liraglutide) and Trulicity (dulaglutide). The licensing transaction that Lilly—which already markets Trulicity -has completed may be considered indicative of the value of ORMD-0901, Oramed's own orally-deliverable GLP-1 receptor agonist. ORMD-0901 is already in the clinic. Given the modest enterprise value of Oramed at this juncture—roughly \$60M—we consider it appropriate to highlight the fact that ORMD-0901 alone could easily account for the entirety of this valuation. We reiterate our Buy rating and price target of \$25.00 per share on ORMP.

Largest trial yet with ORMD-0801 now in progress. In May 2018, Oramed launched its largest and most advanced clinical trial to date for its oral insulin candidate ORMD-0801, involving 240 patients with type 2 diabetes in multiple centers throughout the U.S., including the CHEAR Center in the Bronx. This study was designed with input from the FDA and is aimed at providing a robust indication of the oral insulin candidate's therapeutic impact on a longer-term basis. Trial participants are to take the oral pill for 90 days, with different groups following different dosing regimens at varying times throughout the day. The study is designed to show ORMD-0801's effectiveness at lowering glycated hemoglobin, a determinant of average blood sugar levels over three months and is considered the fundamental standard endpoint by the FDA in evaluating the drug's efficacy. In our view, favorable data from this trial could position ORMD-0801 in a highly differentiated manner within the oral insulin space.

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 ~\$37M and ~16M fully-diluted shares outstanding as of mid-F2019. 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.

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

FY end August 31

\$ in thousands, except per share data

	2017A				2018E							
-	1QA	2QA	3QA	4QA	2017A	1QA	2QA	3QA	4QE	2018E	2019E	2020E
Revenue												
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-
Research and other	610	611	617	618	2,456	611	604	617	617	2,449	2,800	2,800
Total revenue	610	611	617	618	2,456	611	604	617	617	2,449	2,800	2,800
Expenses												
Cost of product and service revenue	187	-	-	-	187	-	-	(86)	-	(86)	-	-
Research & development	2,353	3,125	2,267	2,536	10,281	2,327	2,724	4,194	4,250	13,495	18,500	20,000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-	-
General and administrative	468	851	505	935	2,759	1,016	991	1,043	1,200	4,250	6,000	7,500
Total expenses	3,008	3,976	2,772	3,471	13,227	3,343	3,715	5,151	5,450	17,659	24,500	27,500
Gain (loss) from operations	(2,398)	(3,365)	(2,155)	(2,853)	(10,771)	(2,732)	(3,111)	(4,534)	(4,833)	(15,210)	(21,700)	(24,700)
Other income/expense												
Financial income	186	203	210	193	792	222	217	209	105	753	465	465
Financial expense	(24)	(21)	(20)	(36)	(101)	(21)	(22)	(29)	(29)	(101)	(120)	(120)
Impairment of available-for-sale securities	(63)	168	286	(96)	295	326	-	-	- 1	326	-	-
Total investment income and other	99	350	476	61	986	527	195	180	76	978	345	345
Loss before provision for income taxes	(2,299)	(3,015)	(1,679)	(2,792)	(9,785)	(2,205)	(2,916)	(4,354)	(4,757)	(14,232)	(21,355)	(24,355)
Deferred income tax benefit	(400)	-	-	-	(400)	-	-	-	-	-	-	-
Net loss/income	(2,699)	(3,015)	(1,679)	(2,792)	(10,185)	(2,205)	(2,916)	(4,354)	(4,757)	(14,232)	(21,355)	(24,355)
Net loss per share (basic)	(0.20)	(0.24)	(0.15)	(0.21)	(0.79)	(0.18)	(0.20)	(0.30)	(0.30)	(0.96)	(1.06)	(1.04)
Net loss per share (diluted)	(0.20)	(0.24)	(0.15)	(0.21)	(0.79)	(0.18)	(0.20)	(0.30)	(0.30)	(0.96)	(1.06)	(1.04)
Weighted average number of shares outstanding (basic)	13,206	13,280	13,301	13,505	13,309	14,239	14,357	14,519	15,940	14,764	20,069	23,353
Weighted average number of shares outstanding (diluted)	13,206	13,280	13,301	13,505	13,309	14,239	14,357	14,519	15,940	14,764	20,069	23,353

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

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Distribution of Ratings Table as of September 28, 2018							
			IB Se	IB Service/Past 12 Months			
Ratings	Count	Percent	Count	Percent			
Buy	286	93.77%	114	39.86%			
Neutral	16	5.25%	4	25.00%			
Sell	1	0.33%	0	0.00%			
Under Review	2	0.66%	0	0.00%			
Total	305	100%	118	38.69%			

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