

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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Positive End-of-Phase 2 Meeting With FDA; Reiterate Buy

Stock Data		07/17/2020	
Price			\$3.98
Exchange		NASDAQ	
Price Target			\$17.00
52-Week High			\$6.05
52-Week Low			\$2.32
Enterprise Value (M)			\$48
Market Cap (M)			\$94
Public Market Float (M)			20.7
Shares Outstanding (M)			23.5
3 Month Avg Volume			137,950
Short Interest (M)			0.21
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)

Clear path to registration via agreed-upon pivotal program. Last week, Oramed announced that the FDA had provided positive feedback based on the previously-conducted End-of-Phase 2 (EOP2) meeting on the company's oral insulin candidate (ORMD-0801). Based on agency commentary, Oramed intends to initiate two Phase 3 trials following FDA review of those Phase 3 protocols and non-clinical documents. The FDA outlined its expectations for the design of the ORMD-0801 Phase 3 trials as well as submission of the Biologics License Application (BLA) that would follow successful trials. Oramed plans to conduct the two Phase 3 trials concurrently. In our view, these trials could begin enrollment later this year and yield data in 2022. ORMD-0801 could be the subject of a BLA filing in 2023 and receive regulatory approval in 2024. We note that 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 price target of \$17 per share.

Pivotal entry based on proof-of-concept clinical data. We anticipate that Oramed should obtain final agency input on the proposed clinical protocols for the ORMD-0801 Phase 3 program in the coming months. As a reminder, ORMD-0801 has generated proof-of-concept clinical activity data from a previously-completed Phase 2b trial and has shown a favorable safety and tolerability profile to date. The Phase 2b trial of ORMD-0801 met its primary endpoint, achieving a reduction in mean A1C of 0.60% from baseline, or a reduction of 0.54% adjusted for placebo (p=0.036). The trial was a 90-day dose-ranging study in type 2 diabetes patients with inadequate glycemic control on oral anti-hyperglycemic agents (i.e., the efficacy seen with ORMD-0801 was demonstrated on top of existing therapy).

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.

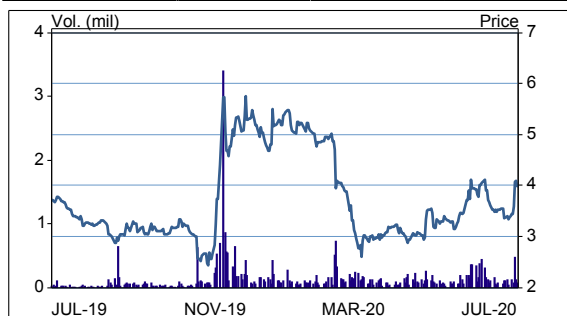



Table 1: Oramed Pharmaceuticals, Inc. (ORMP)—Historical Income Statements, Financial Projections

FY end August 31

\$ in thousands, except per share data

	2019A				2019A	2020E				2020E	2021E
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE		
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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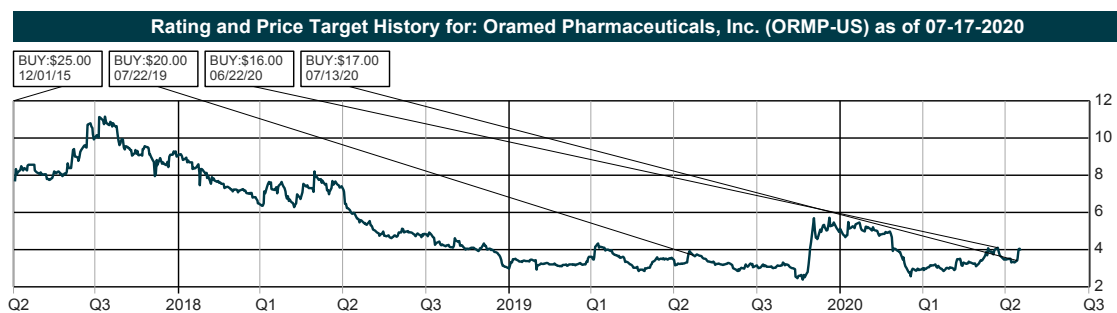
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RETURN ASSESSMENT

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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Distribution of Ratings Table as of July 17, 2020

Ratings	Count	Percent	IB Service/Past 12 Months	
			Count	Percent
Buy	397	89.82%	151	38.04%
Neutral	42	9.50%	9	21.43%
Sell	0	0.00%	0	0.00%
Under Review	3	0.68%	3	100.00%

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