Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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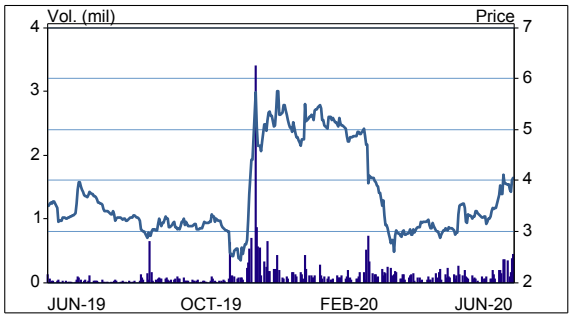
Initial Fatty Liver Trial Data; Reiterate Buy; Lowering PT to $16

Stock Data	06/19/2020
Price	$4.05
Exchange	NASDAQ
Price Target	$16.00
52-Week High	$6.05
52-Week Low	$2.32
Enterprise Value (M)	$65
Market Cap (M)	$94
Public Market Float (M)	20.2
Shares Outstanding (M)	23.3
3 Month Avg Volume	121,641
Short Interest (M)	0.23
Balance Sheet Metrics	
Cash (M)	$28.9
Total Debt (M)	$0.0
Total Cash/Share	$1.24
Book Value/Share	$0.70

EPS Diluted			
Full Year - Aug	2019A	2020E	2021E
1Q	(0.25)	(0.15)A	(0.20)
2Q	(0.21)	(0.21)A	(0.22)
3Q	(0.23)	(0.18)	(0.22)
4Q	(0.13)	(0.19)	(0.22)
FY	(0.82)	(0.72)	(0.87)



Initial data in fatty liver appear encouraging—modulating price target based on dilution. Last week, Oramed reported that the pilot study of its oral insulin candidate ORMD-0801 in type 2 diabetes patients with non-alcoholic steatohepatitis (NASH) has thus far shown ORMD-0801 to be safe and well-tolerated. There was also encouraging reduction seen in fatty liver content, as shown via magnetic resonance imaging (MRI)-derived proton density fat fraction (MRI-PDFF). While this is very early data, generated from the first eight patients in the study, we note that several patients showed substantial reductions in liver fat and none showed an increase. The pilot, open-label assessment of the first eight patients of a planned 40-patient multi-center study aimed to assess the safety, tolerability, and early effects of a 16mg dose of ORMD-0801 (two 8mg capsules) on liver fat in type 2 diabetes patients with NASH. The 12-week, once-daily treatment had no serious adverse events, and induced an observed mean 6.9±6.8% reduction in liver fat content (sign test p=0.035); the relative reduction was 30% as measured by MRI-PDFF. In parallel, gamma-glutamyltransferase (GGT) concentrations—a key marker of chronic hepatitis—were significantly lower after 12 weeks of treatment vs. baseline (-14.6±13.1 U/L; sign test p=0.008), as were fasting insulin levels (-96.5±206.0 pmol/L; sign test p=0.035). We reiterate our Buy rating, while lowering our 12-month target to $16 vs. the prior $20 per share to account for recent dilution.

ORMD-0801 moving ahead in diabetes. We remind investors that Oramed held an end-of-Phase 2 (EOP2) meeting with the FDA in February of this year to discuss the ORMD-0801 program in type 2 diabetes treatment. The agency provided feedback on key items related to drug product manufacturing and expressed support for advancement into pivotal testing. Oramed is slated to initiate the Phase 3 program upon receipt of additional agency feedback regarding its design. 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 $530M. This yields a price objective of $16.00 per share, assuming net cash of ~ $80M and ~32.7M 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	3QE	4QE	2020E	2021E
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	674	666	682	681	2,703	674	674	674	674	2,696	2,800
Total revenue	674	666	682	681	2,703	674	674	674	674	2,696	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	3,500	3,600	12,442	18,000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-
General and administrative	932	1,065	899	826	3,722	1,081	1,391	1,500	1,600	5,572	7,400
Total expenses	5,314	4,234	4,760	3,026	17,334	3,103	4,711	5,000	5,200	18,014	25,400
Gain (loss) from operations	(4,640)	(3,568)	(4,078)	(2,345)	(14,631)	(2,429)	(4,037)	(4,326)	(4,526)	(15,318)	(22,600)
Other income/expense											
Financial income	286	273	263	239	1,061	209	169	205	190	773	860
Financial expense	(8)	(19)	(14)	(174)	(215)	(20)	(2)	(2)	(2)	(26)	(120)
Impairment of available-for-sale securities	60	(87)	(243)	-	(270)	(303)	182	-	-	(121)	-
Total investment income and other	338	167	6	65	576	(114)	349	203	188	626	740
Loss before provision for income taxes	(4,302)	(3,401)	(4,072)	(2,280)	(14,055)	(2,543)	(3,688)	(4,123)	(4,338)	(14,692)	(21,860)
Deferred income tax benefit	-	(300)	-	-	(300)	-	-	-	-	-	-
Net loss/income	(4,302)	(3,701)	(4,072)	(2,280)	(14,355)	(2,543)	(3,688)	(4,123)	(4,338)	(14,692)	(21,860)
Net loss per share (basic)	(0.25)	(0.21)	(0.23)	(0.13)	(0.82)	(0.15)	(0.21)	(0.18)	(0.19)	(0.72)	(0.87)
Net loss per share (diluted)	(0.25)	(0.21)	(0.23)	(0.13)	(0.82)	(0.15)	(0.21)	(0.18)	(0.19)	(0.72)	(0.87)
Weighted average number of shares outstanding (basic)	17,449	17,454	17,457	17,383	17,454	17,472	17,818	23,119	23,169	20,395	25,169
Weighted average number of shares outstanding (diluted)	17,449	17,454	17,457	17,383	17,454	17,472	17,818	23,119	23,169	20,395	25,169

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

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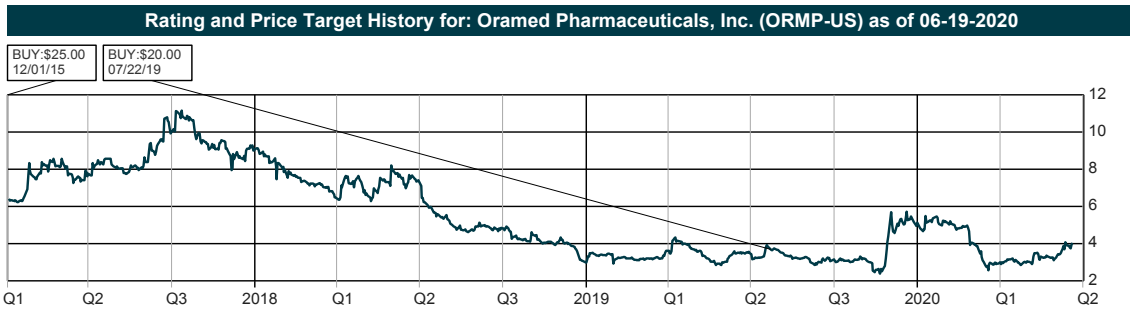

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Distribution of Ratings Table as of June 19, 2020				
			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	388	90.44%	140	36.08%
Neutral	38	8.86%	8	21.05%
Sell	0	0.00%	0	0.00%
Under Review	3	0.70%	3	100.00%

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