

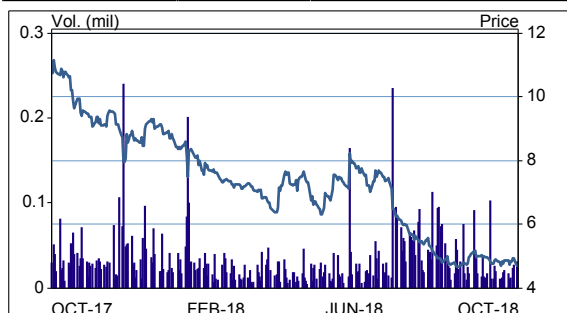
Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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First Patient Enrolled in Oral Insulin NASH Study; Reiterate Buy

Stock Data		10/08/2018	
Price		\$4.70	
Exchange		NASDAQ	
Price Target		\$25.00	
52-Week High		\$11.34	
52-Week Low		\$4.60	
Enterprise Value (M)		\$59	
Market Cap (M)		\$82	
Public Market Float (M)		12.8	
Shares Outstanding (M)		17.4	
3 Month Avg Volume		39,918	
Short Interest (M)		0.28	
Balance Sheet Metrics			
Cash (M)		\$23.4	
Total Debt (M)		\$0.0	
Total Cash/Share		\$1.34	
Book Value/Share		\$1.15	
EPS Diluted			
Full Year - Aug	2017A	2018E	2019E
1Q	(0.20)	(0.18)A	(0.29)
2Q	(0.24)	(0.20)A	(0.28)
3Q	(0.15)	(0.30)	(0.25)
4Q	(0.21)	(0.30)	(0.25)
FY	(0.79)	(0.96)	(1.06)

Assessment of oral insulin for liver disease advances. Last week, Oramed announced that it had enrolled the first patient in an exploratory clinical study of its oral insulin capsule, ORMD-0801, in the treatment of nonalcoholic steatohepatitis (NASH). The three-month treatment study, recently approved by Israel's Ministry of Health, is designed to assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH. Data from preclinical studies and clinical studies of ORMD-0801 demonstrate Oramed's oral insulin capsule has the potential to reduce inflammation of the liver. The company's management team has noted that the prevalence of NASH is accelerating rapidly and correlates directly with the rising incidence of type 2 diabetes. Given the potential for ORMD-0801 to control excessive glucose production by the liver, there may be therapeutic activity for the drug in NASH. A chronic liver disease caused by excessive fat in the liver, NASH can lead to fibrosis, cirrhosis, liver failure and death. According to the *Journal of Hepatology*, prevalent NASH cases are expected to increase 63% from 16M in 2015 to 27M cases in 2030. We remind investors that commercial potential for ORMD-0801 in NASH is not factored into our valuation at this time, and thus we believe that any future favorable clinical efficacy data for the drug in this indication would constitute a driver of upside to our projections. 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.



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

FY end August 31

\$ in thousands, except per share data

	2017A				2017A	2018E				2018E	2019E	2020E
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE			
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	-	-	-	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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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 October 8, 2018				
Ratings	Count	Percent	IB Service/Past 12 Months	
			Count	Percent
Buy	287	93.79%	113	39.37%
Neutral	16	5.23%	4	25.00%
Sell	1	0.33%	0	0.00%
Under Review	2	0.65%	0	0.00%
Total	306	100%	117	38.24%

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