

Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

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2022 Outlook Promises Multiple Catalysts; Reiterate Buy

Stock Data		01/14/2022	
Price		\$11.05	
Exchange		NASDAQ	
Price Target		\$32.00	
52-Week High		\$31.54	
52-Week Low		\$4.24	
Enterprise Value (M)		\$297	
Market Cap (M)		\$423	
Public Market Float (M)		37.0	
Shares Outstanding (M)		38.3	
3 Month Avg Volume		888,118	
Short Interest (M)		2.21	
Balance Sheet Metrics			
Cash (M)		\$125.8	
Total Debt (M)		\$0.0	
Total Cash/Share		\$3.29	
Book Value/Share		\$4.47	
EPS (\$) Diluted			
Full Year - Aug	2021A	2022E	2023E
1Q	(0.23)	(0.20)	(0.32)
2Q	(0.17)	(0.23)	(0.35)
3Q	(0.17)	(0.26)	(0.38)
4Q	(0.22)	(0.29)	(0.35)
FY	(0.81)	(0.98)	(1.41)
Revenue (\$M)			
Full Year - Aug	2021A	2022E	2023E
1Q	0.7	0.7	0.8
2Q	0.7	0.7	0.8
3Q	0.7	0.7	0.8
4Q	0.7	0.7	0.8
FY	2.7	2.8	3.2



Shareholder update provides color on various timelines. In a press release last week, Oramed provided an update on anticipated timelines for its various drug development programs. ORA-D-013-1, the larger of two concurrent Phase 3 oral insulin trials with the company's lead candidate ORMD-0801, has enrolled more than 75% of the planned 675 subjects. In addition, more than 25% of the planned 450 patients in Oramed's second Phase 3 trial, ORA-D-013-2, have been enrolled. The company expects six-month top-line efficacy results from the ORA-D-013-1 trial to be reported in 2022, while the ORA-D-013-2 trial is slated to complete enrollment in 2022 as well. More than 50% of patients have been enrolled in the U.S. and Israel in Oramed's double-blind Phase 2 trial of ORMD-0801 for the treatment of non-alcoholic steatohepatitis (NASH) in subjects with type 2 diabetes. Enrollment completion is slated for 1H22, with top-line data release in 2H22. The company is currently conducting a bioavailability trial for ORMD-0901, its oral glucagon-like peptide-1 (GLP-1) analog capsule, in subjects with type 2 diabetes. Bioavailability (PK and PD) data are expected in 1H22. Oramed also provided a timeline for the development of Oravax, its proprietary COVID-19 oral vaccine being developed through a joint venture with Premas Biotech and others. Oravax combines Oramed's POD oral delivery technology with Premas' proprietary virus like particle (VLP) triple antigen vaccine. Top-line data from a Phase 1 trial of Oravax currently under way in South Africa are slated for release in 1H22. Oramed expects to initiate a Phase 2/3 oral COVID-19 vaccine program during 2H22. We reiterate our Buy rating and 12-month price target of \$32.

COVID-19 vaccine could prove disruptive in the context of a continuing pandemic threat. We remind investors that Oravax's VLP vaccine technology targets three SARS-CoV-2 coronavirus surface proteins, including proteins less susceptible to mutation, thus making the vaccine potentially more effective against current and future variants of the COVID-19 virus. Oravax's VLP vaccine technology is highly scalable and easily transferable. In a pilot animal study, the oral COVID-19 vaccine promoted systemic immunity through both Immunoglobulin G (IgG), the most common antibody in blood and bodily fluids that protects against viral infections, and Immunoglobulin A (IgA). Commercialization of widely-used messenger RNA (mRNA)-based vaccines such as Spikevax from Moderna (MRNA; not rated) and COMIRNATY from Pfizer (PFE; not rated) and BioNTech SE (BNTX; Buy; Burns) has not succeeded in eradicating COVID-19. Furthermore, vaccination rates in various emerging countries are tiny fractions of the vaccination rates that have been achieved in developed nations. Some African nations have vaccination rates below 4%. The advent of novel variant strains of SARS-CoV-2, such as Delta and the heavily mutated Omicron, which emerged in South Africa just over a month ago but already accounts for the vast majority of new infections in the U.S., illustrate the continuing perils of the pandemic.


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Valuation methodology, risks and uncertainties. Factoring in a 12% discount rate, a 75% probability of approval for ORMD-0801, and peak annual sales of \$2.6B (on which we project double-digit percentage royalties), we derive a total risk-adjusted net present value (rNPV) of \$800M for this candidate within the diabetes indication alone. 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 and the Oravax program (total value of \$250M), to derive a total enterprise value of approximately \$1.2B. This yields a price objective of \$32, per share, assuming net cash of \$154M—resulting in a total firm value of \$1.3B—and roughly 40M fully diluted shares outstanding as of end-F2022. 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

	2021A				2021A	2022E				2022E	2023E
	1QA	2QA	3QA	4QA		1QE	2QE	3QE	4QE		
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	674	665	681	683	2,703	700	700	700	700	2,800	3,200
Total revenue	674	665	681	683	2,703	700	700	700	700	2,800	3,200
Expenses											
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-
Research & development	5,774	3,869	5,502	5,844	20,989	6,000	7,000	8,000	9,000	30,000	43,000
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-
General and administrative	727	1,664	1,297	2,249	5,937	2,300	2,500	2,800	3,000	10,600	15,000
Total expenses	6,501	5,533	6,799	8,093	26,926	8,300	9,500	10,800	12,000	40,600	58,000
Gain (loss) from operations	(5,827)	(4,868)	(6,118)	(7,410)	(24,223)	(7,600)	(8,800)	(10,100)	(11,300)	(37,800)	(54,800)
Other income/expense											
Financial income	257	260	493	232	1,242	160	140	300	260	860	860
Financial expense	-	-	-	(8)	(8)	-	-	-	-	-	-
Impairment of available-for-sale securities	-	-	-	-	-	-	-	-	-	-	-
Total investment income and other	257	260	493	224	1,234	160	140	300	260	860	860
Loss before provision for income taxes	(5,570)	(4,608)	(5,625)	(7,186)	(22,989)	(7,440)	(8,660)	(9,800)	(11,040)	(36,940)	(53,940)
Deferred income tax benefit	-	-	-	-	-	-	-	-	-	-	-
Net loss attributable to non-controlling interests	-	-	418	333	751	500	500	500	500	2,000	3,200
Net loss/income	(5,570)	(4,608)	(5,207)	(7,186)	(22,989)	(7,440)	(8,660)	(9,800)	(11,040)	(36,940)	(53,940)
Net loss per share (basic)	(0.23)	(0.17)	(0.17)	(0.22)	(0.81)	(0.20)	(0.23)	(0.26)	(0.29)	(0.98)	(1.41)
Net loss per share (diluted)	(0.23)	(0.17)	(0.17)	(0.22)	(0.81)	(0.20)	(0.23)	(0.26)	(0.29)	(0.98)	(1.41)
Weighted average number of shares outstanding (basic)	23,746	27,004	29,930	33,196	28,469	36,690	38,111	38,161	38,211	37,793	38,336
Weighted average number of shares outstanding (diluted)	23,746	27,004	29,930	33,196	28,469	36,690	38,111	38,161	38,211	37,793	38,336

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

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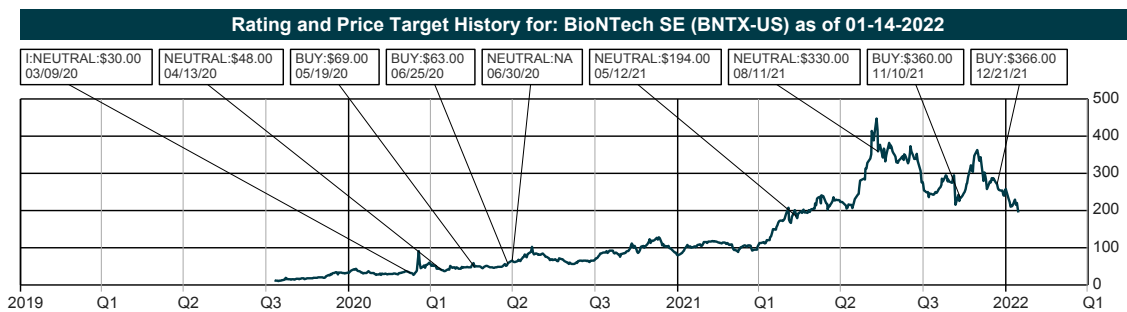
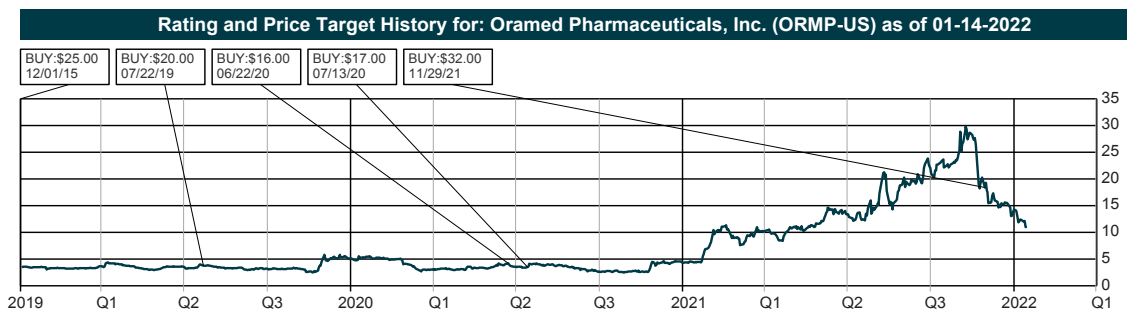
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Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

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Related Companies Mentioned in this Report as of Jan/14/2022

Company	Ticker	H.C. Wainwright Rating	12 Month Price Target	Price	Market Cap
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Ratings	Count	Percent	IB Service/Past 12 Months	
			Count	Percent
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Neutral	47	7.45%	13	27.66%
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Under Review	2	0.32%	1	50.00%

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