Healthcare

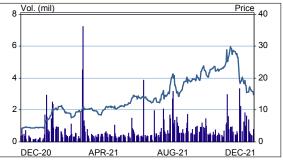
**December 15, 2021** 

## Oramed Pharmaceuticals, Inc. (ORMP) Rating: Buy

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## Oravax COVID-19 Vaccine Clinical Development Begins; Reiterate Buy

Stock Data			,	12/14/2021			
Price				\$14.63			
Exchange				NASDAQ			
Price Target		ŀ		\$32.00			
52-Week High				\$31.54			
52-Week Low				\$4.02			
Enterprise Valu	ıe (M)	i		\$431			
Market Cap (M		i		\$557			
Public Market F				36.7			
Shares Outstar	. ,		38.1				
3 Month Avg Vo	olume	İ		847,743			
Short Interest (	M)	İ		0.90			
Balance Sheet Metrics							
Cash (M)				\$125.8			
Total Debt (M)				\$0.0			
Total Cash/Sha	ire			\$3.30			
Book Value/Sh				\$3.28			
EPS (\$) Diluted							
Full Year - Aug	2021A	20	22E	2023E			
1Q	(0.23)	(0	.20)	(0.32)			
2Q	(0.17)	•	.23)	(0.35)			
3Q	(0.17)		.26)	(0.38)			
4Q	(0.22)	(0.29)		(0.35)			
FY	(0.81)	(0	.98)	(1.41)			
Revenue (\$M)							
Full Year - Aug	2021A		22E	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			0.8			
FY	2.7	2	2.8	3.2			



Oral COVID-19 vaccine enters clinic. In a press release yesterday, Oramed announced that its subsidiary, Oravax Medical Inc., has screened and enrolled the first participant in a Phase 1 clinical trial of its oral virus-like particle (VLP) COVID-19 vaccine in Johannesburg, South Africa. The open-label trial anticipates enrolling 24 participants who have not received either a COVID-19 vaccine or contracted the virus. Participants are to be administered one dose of the oral vaccine at the beginning of the trial and a second dose three weeks later. The trial's endpoints will include safety and tolerability as well as efficacy by measuring the presence of an immunogenic response. We reiterate our Buy rating and 12-month price target of \$32 per share.

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—responsible for 99.9% of new infections in the U.S.—and the heavily mutated Omicron, which emerged in South Africa only a few weeks ago, illustrate the continuing perils embodied by the pandemic.

Significant commercial potential remains, given low vaccination rates in emerging countries and persistent infection outbreaks. A total of over 270M people globally have been infected with SARS-CoV-2, according to official statistics, while roughly 5.3M people have been recorded as having died due to the disease since the pandemic began. Epidemiologists around the world consider these numbers to considerably underestimate the scope and scale of the public health disaster. Accordingly, we believe that there remains ample room for additional vaccine approaches—particularly those that offer both convenience and safety advantages as well as coverage of emergent variant strains, as could be achieved with Oravax. The total COVID-19 vaccine market could approach \$100B in 2022, in our view. Vaccination rates in emerging countries—particularly in Africa—considerably lag the rest of the world (below 5% in certain territories vs. >70% in various developed nations). Thus, we continue to see a healthy market opportunity for new COVID-19 vaccine technologies.

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 \$32.00 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.

Oramed Pharmaceuticals, Inc.

December 15, 2021

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

FY end August 31

\$ in thousands, except per share data

	2021A			2022E							
	1QA	2QA	3QA	4QA	2021A	1QE	2QE	3QE	4QE	2022E	2023E
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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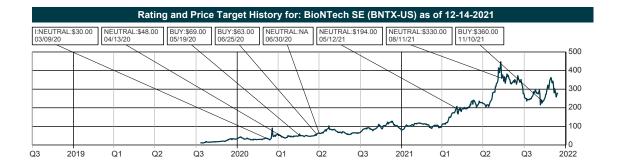
## **RETURN ASSESSMENT**

**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.

**Market Perform (Neutral):** The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

**Market Underperform (Sell):** The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.





Related Companies Mentioned in this Report as of Dec/14/2021						
Company	Ticker	H.C. Wainwright Rating	12 Month Price Target	Price	Market Cap	
BioNTech SE	BNTX	Buy	\$360.00	\$278.22	\$66846	

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Distribution of Ratings Table as of December 14, 2021							
			IB Se	rvice/Past 12 Months			
Ratings	Count	Percent	Count	Percent			
Buy	557	90.57%	200	35.91%			
Neutral	54	8.78%	12	22.22%			
Sell	1	0.16%	0	0.00%			
Under Review	3	0.49%	1	33.33%			

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The Firm does not make a market in Oramed Pharmaceuticals, Inc. and BioNTech SE as of the date of this research report.

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