Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

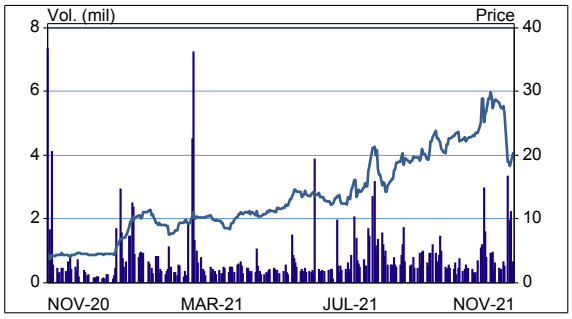
Raghuram Selvaraju, Ph.D.
212-916-3966
rselvaraju@hcwresearch.com

ORMD-0801 Phase 3 Trial Progress; F2021 Financials; Raising PT to $32

Stock Data	11/26/2021
Price	$20.21
Exchange	NASDAQ
Price Target	$32.00
52-Week High	$31.54
52-Week Low	$3.55
Enterprise Value (M)	$644
Market Cap (M)	$770
Public Market Float (M)	36.9
Shares Outstanding (M)	38.1
3 Month Avg Volume	817,560
Short Interest (M)	0.93
Balance Sheet Metrics	
Cash (M)	$125.8
Total Debt (M)	$0.0
Total Cash/Share	$3.30
Book Value/Share	$3.28

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



Pivotal insulin program continues to achieve key milestones. Last week, Oramed announced that it has enrolled and randomized over 75% of the 675 patients planned for its Phase 3 ORA-D-013-1 study of its oral insulin capsule ORMD-0801 for type 2 diabetes (T2D). The ORMD-0801 Phase 3 program consists of two trials. The first of these, ORA-D-013-1, is recruiting patients on two or three oral glucose-lowering agents at 75 sites throughout the U.S. The primary endpoint is comparison of the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c, with a secondary endpoint of assessing change from baseline in fasting plasma glucose at 26 weeks. Efficacy data will become available after all patients have completed the first six-month treatment period. The ORA-D-013-1 trial is a double-blinded, double-dummy study randomizing patients 1:1:1 for: 8mg ORMD-0801 once-daily at night and placebo 45 minutes before breakfast; or 8mg ORMD-0801 twice-daily at night and 45 minutes before breakfast; or placebo twice-daily at night and 45 minutes before breakfast. The second study, ORA-013-2, is designed to evaluate the efficacy and safety of ORMD-0801 in 450 subjects in the U.S., Europe, and Israel who have inadequate glycemic control and are on diet modification without medication, or on metformin monotherapy. Both Phase 3 trials of ORMD-0801 should complete enrollment in 2022, with data release later that year. A Biologics License Application (BLA) could be filed in 2023, with FDA approval of ORMD-0801 in 2024. The BLA classification would provide 12 years of U.S. market exclusivity post-launch. We continue to expect Oramed to seek a partner to efficiently commercialize ORMD-0801 outside China. As a reminder, our valuation assessment currently does not include any contribution from Chinese sales of ORMD-0801, where this candidate is already partnered with Hefei Tianhui Incubator of Technologies (HTIT). China may represent the world's largest diabetes market in terms of patient population size, with over 100M diabetes sufferers. Revenue to Oramed derived from sales of ORMD-0801 could thus drive meaningful upside to our forecasts.

Key model assumptions revised—raising price target. We revise our market model assumptions for Oramed's lead anti-diabetic drug candidates, ORMD-0801 and ORMD-0901. Currently, we expect ORMD-0801 to be launched in both the U.S. and Europe in 2024, while we anticipate that ORMD-0901 could be launched in the U.S. in 2025 and in Europe in 2026. Our probability of approval assumptions for both candidates remain unchanged at 75% for ORMD-0801 and 40% for ORMD-0901. We reduce our discount rate to 12% from the prior 15% to reflect the maturation of Oramed's pipeline and the established nature of the global diabetes market. Our valuation of ORMD-0801 rises to $800M from the previous $200M, while our valuation of ORMD-0901 remains at $150M since we have pushed back the anticipated launch timeframe. We include a $50M contribution from use of ORMD-0801 in treatment of NASH, as well as a $100M contribution from Oramed's ownership stake in Oravax, a COVID-19 vaccine candidate. These changes result in an increase in our valuation to $1.3B vs. the previous $555M. We thus reiterate our Buy rating, while raising our 12-month price target to $32 vs. the previous $17 per share.

Oral COVID-19 vaccine could prove disruptive in the context of a continuing pandemic threat. Oramed's majority-owned subsidiary, Oravax Medical Inc., received clearance in late October 2021 from the South African Health Products Regulatory Authority to commence patient enrollment in a first-in-human (FIH) Phase 1 clinical trial for its oral COVID-19 vaccine and preparations to begin the trials are now underway. Previously, Institutional Review Board (IRB) approval to begin testing Oravax clinically was received at Ichilov Hospital in Tel Aviv, Israel. Oravax's virus-like particle (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. A total of 260M people globally have been infected with SARS-CoV-2, according to official statistics, while roughly 5.2M people have been recorded as having died due to the disease. 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.

Mexican joint venture may provide rapid path to market access. Earlier this month, Oramed and Genomma Lab Internacional, S.A.B. de C.V. (BMV: LABB; not rated), a leading pharmaceutical and personal care product company in Latin America with an expanding international presence, announced the formation of a 50/50 joint venture between Genomma Lab and Oramed's majority-owned subsidiary Oravax Medical Inc. to develop and commercialize Oravax's oral COVID-19 vaccine candidate in Mexico. Genomma Lab is slated to contribute resources to the joint venture's oral COVID-19 vaccine development, as well as clinical, regulatory, and commercial activities in Mexico. In addition, Genomma Lab shall leverage its extensive supply chain capabilities, partnerships and market presence in Latin America to support the business development process and vaccine roll-out throughout the region. Oramed and Genomma Lab also intend to enter into a $20M share swap based on the average closing price of their respective shares during the past 15 trading days. Genomma Lab has committed to participate in a future investment in Oravax. We believe that this arrangement may facilitate clinical development, regulatory approval and efficient commercialization of the Oravax candidate in Mexico—a country of roughly 130M people that is one of the most populous in Latin America, which has been hard-hit by the COVID-19 pandemic with almost 4M reported infections and nearly 300K officially recorded deaths. The Latin American vaccine market comprises over 660M people.

Financial results reported—by the numbers. Oramed closed fiscal 2021 with approximately $126M in cash, cash equivalents, marketable securities and long- and short-term deposits. Subsequently, earlier this month the company completed a $50M equity financing transaction that involved the sale of 2M shares of common stock at $25 per share. We believe that Oramed could end the fiscal first quarter of 2022 with over $170M in cash and equivalents on its balance sheet, which would represent the strongest-ever financial position that the company has achieved since inception. Thus, we consider Oramed amply financed to complete pivotal development of ORMD-0801, continue the advancement of pipeline candidates such as ORMD-0901 and Oravax, and possibly identify business development opportunities with which to broaden its product candidate portfolio. We forecast total operating expenses of $37.8M in fiscal 2022, rising to $54.8M in fiscal 2023. In our view, Oramed has sufficient resources to fund operations into calendar 2025, possibly past U.S. approval of ORMD-0801.

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.

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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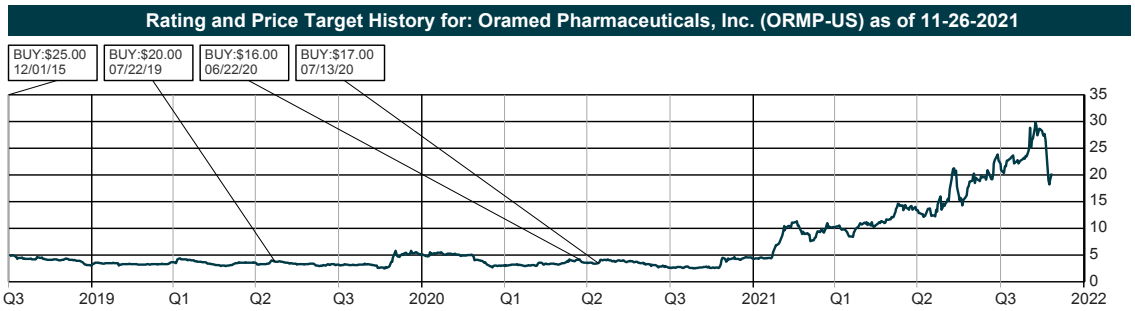
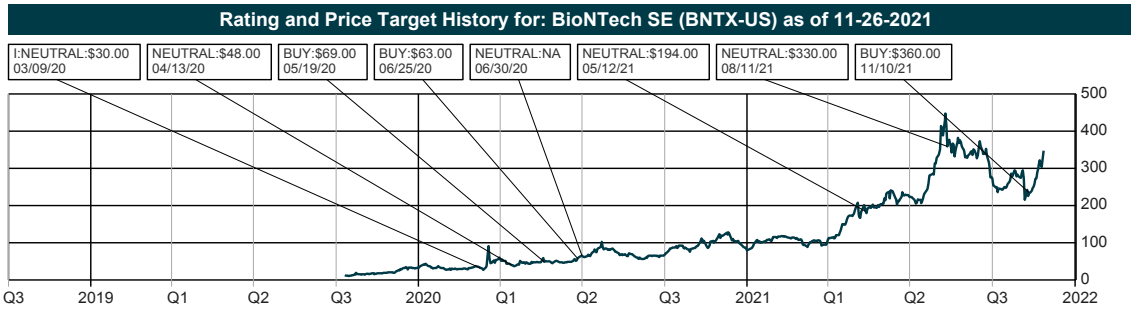
RETURN ASSESSMENT

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 Nov/26/2021

Company	Ticker	H.C. Wainwright Rating	12 Month Price Target	Price	Market Cap
BioNTech SE	BNTX	Buy	$360.00	$348.00	$84049

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Distribution of Ratings Table as of November 26, 2021				
			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	552	90.49%	203	36.78%
Neutral	54	8.85%	12	22.22%
Sell	1	0.16%	0	0.00%
Under Review	3	0.49%	1	33.33%

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