Oramed Pharmaceuticals, Inc. (ORMP)
Rating: Buy

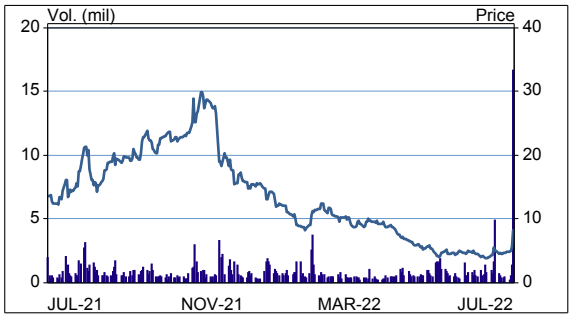
Raghuram Selvaraju, Ph.D.
212-916-3966
rselvaraju@hcwresearch.com

Pipeline Update Underscores Near-Term Catalysts; Reiterate Buy

Stock Data	07/08/2022
Price	$8.20
Exchange	NASDAQ
Price Target	$32.00
52-Week High	$31.54
52-Week Low	$3.59
Enterprise Value (M)	$147
Market Cap (M)	$316
Public Market Float (M)	37.0
Shares Outstanding (M)	38.6
3 Month Avg Volume	1,105,083
Short Interest (M)	3.70
Balance Sheet Metrics	
Cash (M)	$169.0
Total Debt (M)	$0.0
Total Cash/Share	$4.38
Book Value/Share	$4.21

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 trial readout early next year. Last week, Oramed provided a shareholder update that recapitulated the anticipated clinical development-related catalysts for the next few quarters. The most crucial of these, in our view, is the top-line data readout from the first of the company's two pivotal Phase 3 trials with its lead oral insulin candidate, ORMD-0801, in patients with Type 2 diabetes. This result is slated for January 2023. As a reminder, Oramed exceeded the number of planned participants in the first of its two oral insulin trials ORA-D-013-1, with 710 participants enrolled vs. the originally-envisaged 675 subjects. Concurrently, the company's second Phase 3 trial—ORA-D-013-2—has enrolled nearly 50% of the planned 450 patients. In our view, this second study could complete enrollment before the end of this year. We reiterate our Buy rating and 12-month target of $32. Investors should be aware that the company had $169M in cash and investments as of end-calendar 1Q22.

Liver disease data slated for release in the coming weeks. Oramed's other programs continue to advance. In March of this year, the company completed enrollment in a Phase 2 trial of ORMD-0801 for the treatment of non-alcoholic steatohepatitis (NASH). We expect the release of top-line results later this quarter. The double-blind, multi-center trial with sites in the U.S. and Israel assesses the safety and efficacy of ORMD-0801 in type 2 diabetes patients with NASH. There is currently no FDA-approved treatment for NASH, which is projected to become an $84B market by 2029.

Oravax clinical development continues to progress. The Phase 1 trial of Oravax's oral virus-like particle (VLP) COVID-19 vaccine for COVID-naive participants is underway in South Africa. The trial protocol calls for two cohorts, each comprising 12 participants. The South African Health Products Regulatory Authority (SAPHRA) requires a 42-day safety waiting period once the last patient in Cohort A completes enrollment and dosing, after which Cohort B may commence enrollment and dosing. Due to several factors, including the fact that many volunteers did not qualify during screening due to prior asymptomatic COVID-19 infection and other conditions, the enrollment rate was slower than anticipated. Oramed has added an additional site and since completed enrollment and dosing of Cohort A with no safety issues reported to date. The company anticipates sharing top-line data this quarter. We expect Cohort B to complete dosing this quarter as well, with data expected in 4Q22. Oramed is also positioning Oravax to address the broader global vaccine market and is currently exploring opportunities for additional vaccine indications. The vaccine market is projected to reach $125B by 2028.

Key addition to Scientific Advisory Board announced. We remind investors that early last month Oramed announced the addition of Anne Peters, M.D., to the company's Scientific Advisory Board (SAB). Dr. Peters is Professor of Medicine at the Keck School of Medicine of the University of Southern California (USC) and Director of the USC Clinical Diabetes Programs. Dr. Peters earned her medical degree from the Pritzker School of Medicine at the University of Chicago and performed an internal medicine residency at Stanford University and an endocrinology fellowship at Cedars-Sinai Medical Center. She previously directed the clinical diabetes programs at Cedars-Sinai and UCLA. Her research has focused on testing new approaches for diagnosing and treating diabetes and developing systems of care to improve outcomes in diabetic populations. In addition to being an investigator for more than 40 research studies, Dr. Peters has published over 200 articles, has written four books, and has given more than 500 lectures locally, nationally, and internationally. She has been on multiple guideline writing committees for the treatment of both type 1 and type 2 diabetes. She was a recipient of the American Diabetes Association (ADA) Outstanding Physician Clinician Award and received a 2021 Endocrine Society Laureate Award for Public Service. Currently, Dr. Peters is the chair of the Endocrine Society Committee on Diabetes Devices and is on the EASD/ADA Technology Safety Committee. In addition, she is a member of the Juvenile Diabetes Research Foundation (JDRF) Panel on Management of Exercise in type 1 diabetes (T1D) and a member of the ABIM Endocrinology Subspecialty Board. Dr. Peters has consulted for many entities, including the FDA, Optum Rx and CVS/Caremark to help guide treatments for diabetes.

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 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					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.

Important Disclaimers

This material is confidential and intended for use by Institutional Accounts as defined in FINRA Rule 4512(c). It may also be privileged or otherwise protected by work product immunity or other legal rules. If you have received it by mistake, please let us know by e-mail reply to unsubscribe@hcwresearch.com and delete it from your system; you may not copy this message or disclose its contents to anyone. The integrity and security of this message cannot be guaranteed on the Internet.

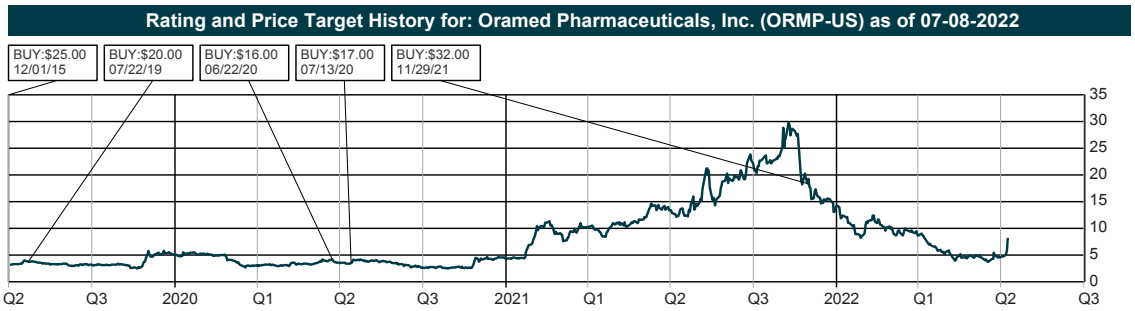
H.C. WAINWRIGHT & CO, LLC RATING SYSTEM: H.C. Wainwright employs a three tier rating system for evaluating both the potential return and risk associated with owning common equity shares of rated firms. The expected return of any given equity is measured on a RELATIVE basis of other companies in the same sector. The price objective is calculated to estimate the potential movements in price that a given equity could reach provided certain targets are met over a defined time horizon. Price objectives are subject to external factors including industry events and market volatility.

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.



Investment Banking Services include, but are not limited to, acting as a manager/co-manager in the underwriting or placement of securities, acting as financial advisor, and/or providing corporate finance or capital markets-related services to a company or one of its affiliates or subsidiaries within the past 12 months.

Distribution of Ratings Table as of July 8, 2022

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	560	88.33%	149	26.61%
Neutral	57	8.99%	13	22.81%
Sell	2	0.32%	0	0.00%
Under Review	15	2.37%	1	6.67%

H.C. Wainwright & Co, LLC (the “Firm”) is a member of FINRA and SIPC and a registered U.S. Broker-Dealer.

I, Raghuram Selvaraju, Ph.D. , certify that 1) all of the views expressed in this report accurately reflect my personal views about any and all subject securities or issuers discussed; and 2) no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report; and 3) neither myself nor any members of my household is an officer, director or advisory board member of these companies.

None of the research analysts or the research analyst’s household has a financial interest in the securities of Oramed Pharmaceuticals, Inc. (including, without limitation, any option, right, warrant, future, long or short position).

As of May 31, 2022 neither the Firm nor its affiliates beneficially own 1% or more of any class of common equity securities of Oramed Pharmaceuticals, Inc.. Affiliates of H.C. Wainwright beneficially own 1% or more of the common equity securities of Oravax Medical Inc., a joint-venture that is majority-owned by Oramed Pharmaceuticals Inc.

Neither the research analyst nor the Firm knows or has reason to know of any other material conflict of interest at the time of publication of this research report.

The research analyst principally responsible for preparation of the report does not receive compensation that is based upon any specific investment banking services or transaction but is compensated based on factors including total revenue and profitability of the Firm, a substantial portion of which is derived from investment banking services.

The firm or its affiliates received compensation from Oramed Pharmaceuticals, Inc. for non-investment banking services in the previous 12 months.

The Firm or its affiliates did receive compensation from Oramed Pharmaceuticals, Inc. for investment banking services within twelve months before, and will seek compensation from the companies mentioned in this report for investment banking services within three months following publication of the research report.

H.C. Wainwright & Co., LLC managed or co-managed a public offering of securities for Oramed Pharmaceuticals, Inc. during the past 12 months.

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

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. Past performance is no guarantee of future results. This report is offered for informational purposes only, and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. This research report is not intended to provide tax advice or to be used to provide tax advice to any person. Electronic versions of H.C. Wainwright & Co., LLC research reports are made available to all clients simultaneously. No part of this report may be reproduced in any form without the expressed permission of H.C. Wainwright & Co., LLC. Additional information available upon request.

H.C. Wainwright & Co., LLC does not provide individually tailored investment advice in research reports. This research report is not intended to provide personal investment advice and it does not take into account the specific investment objectives, financial situation and the particular needs of any specific person. Investors should seek financial advice regarding the appropriateness of investing in financial instruments and implementing investment strategies discussed or recommended in this research report.

H.C. Wainwright & Co., LLC's and its affiliates' salespeople, traders, and other professionals may provide oral or written market commentary or trading strategies that reflect opinions that are contrary to the opinions expressed in this research report.

H.C. Wainwright & Co., LLC and its affiliates, officers, directors, and employees, excluding its analysts, will from time to time have long or short positions in, act as principal in, and buy or sell, the securities or derivatives (including options and warrants) thereof of covered companies referred to in this research report.

The information contained herein is based on sources which we believe to be reliable but is not guaranteed by us as being accurate and does not purport to be a complete statement or summary of the available data on the company, industry or security discussed in the report. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Securities and other financial instruments discussed in this research report: may lose value; are not insured by the Federal Deposit Insurance Corporation; and are subject to investment risks, including possible loss of the principal amount invested.