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Biotechnology
Price Target Change
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BUY

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Oramed Pharmaceuticals, Inc.

Raising Price Target to $15 as Clinical Progress Continues

ORMP (NASDAQ)

Company & Market Data	
Closing Price (as of 01/25/2021):	$6.85
Rating:	BUY
Price Target:	$15.00
Prior Price Target:	*$6.00*
52 Week Range:	$2.40 - $7.43
Shares Outstanding (MM):	26.7
Market Capitalization (MM):	$183
Cash (MM):	$25.5
Fiscal Year End:	Aug

Estimates			
EPS	**2020A**	**2021E**	**2022E**
1Q	$(0.15)	$(0.23)A	$(0.31)
Prior		*$(0.29)*	
2Q	$(0.35)	$(0.28)	$(0.31)
Prior		*$(0.32)*	
3Q	$(0.10)	$(0.32)	$(0.33)
Prior	*$(0.44)*	*$(0.36)*	
4Q	$(0.02)	$(0.19)	$(0.18)
Prior	*$(0.36)E*	*$(0.23)*	
Full Year	$(0.56)	$(1.00)	$(1.15)
Prior	*$(1.28)*	*$(1.19)*	
Revenue (MM)	**2020A**	**2021E**	**2022E**
1Q	$0.6	$0.7A	$0.7
Prior		*$0.6*	
2Q	$1.3	$0.7	$0.1
Prior		*$0.6*	
3Q	$0.6	$0.7	$0.1
Prior	*$2.0*	*$0.6*	
4Q	$0.1	$4.0	$5.0
Prior	*$3.7E*		
Full Year	$2.7	$6.0	$6.9
Prior	*$7.7*	*$5.9*	

Ratios			
P/E	NA	NA	NA

Oramed Pharmaceuticals is developing products based on its Protein Oral Delivery technology (POD). Its lead product is ORMD-0801, an oral insulin capsule that recently began Phase 3 trials. Additional indications and products are in clinical development.

Summary: Oramed announced that it has begun treating patients for the first of the two Phase 3 trials of ORMD-0801, its oral insulin for treatment of type 2 diabetes (T2D). This follows the start of patient screening and clinical progress of other pipeline products in late 2020. In view of these milestones, we are raising our price target to $15 per share.

Discussion: Oramed recently began treatment in its Phase 3 program for ORMD-0801. The program has two Phase 3 studies with total planned enrollment for 1,125 patients over 75 sites in the US, Europe, and Israel. These two ORA-013 studies are designed with different entry criteria that we believe could support a broad approval for insulin therapy. Its globally diverse population is designed to support approval around the world.

The primary endpoint in both trials is an improvement in glucose control, as measured by HbA1c, at 26 weeks. Secondary endpoints include change from baseline in fasting glucose at 26 weeks.

Trial Designs: The first study, ORA-013-1, will enroll patients with inadequate glucose control for 6 to 12 months and can be taking up to three diabetes medications. This study will test two dosage regimens against placebo.

The first group will receive two active doses, with 8mg administered before bedtime and 8mg the next morning before breakfast. The second group will receive one active dose and one placebo, with 8 mg at night and placebo the next morning. The third group will receive two placebo doses, one at night and another the next morning. This "double-dummy" design is intended to determine the best dosing for glucose control.

The second study, ORA-013-2, will enroll 450 patients who can control their blood glucose with either diet alone or diet with metformin. This trial will randomize patients into two arms, one with 8 mg active drug, the other with placebo.

Pipeline Indications Are Making Progress: In December 2020, the company reported the start of a trial in NASH, a liver condition that has high association with diabetes. While we are not including NASH as a separate indication at this time, we believe 30% reduction in liver fat could further support use of ORMD-0801 in diabetes.

Oramed also reported results from a proof-of-concept study in leptin, a hormone that regulates appetite and body weight. The drug was formulated using Oramed's oral delivery technology, and was able to decrease blood glucose levels after administration. We believe this study justifies moving forward to a placebo-controlled trial to explore dosing and efficacy.

Conclusion: The start of the trial allows us to project timeframes for patient accrual, treatment, and regulatory review. Using conservative timeframes, we project first revenues in 2026. Our estimates are based on small market penetration of the Type 2 Diabetes population similar to the clinical trials, although we believe it could be used more broadly to change the way diabetes is treated.

We have adjusted our EPS estimates for 2021 onward, and value ORMD based on our 2026 EPS estimate of $3.70, discounted at 30% with a 15X multiple for a price target of $15 per share.

Risk Factors

Risks to our rating and price target include but are not limited to:

Drug development risk: Oramed is a development stage company conducting clinical trials for its lead product. The company faces the risks of the drug development industry, including scientific, technical, clinical, regulatory failures. As novel therapies, the drugs also face risks with reimbursement and product adoption.

Oramed has started two Phase 3 studies to support an application for FDA approval. The FDA has approved the trial design, but the company must prove safety and efficacy before submitting an application for marketing approval. The trial is subject to numerous risks and may not duplicate results in its Phase 2b earlier studies.

Company risks: The company has a limited operating history and has incurred significant losses and negative cash flow operations since inception and expects to incur losses and negative cash flows for at least the next 12 months. Its independent registered public accounting firm has expressed doubt about their ability to continue as a going concern. Because certain of their stockholders control a significant number of shares of their common stock, they may have effective control over actions requiring stockholder approval.

International risks: The international aspects of their business expose the company to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the US. Oramed also has a collaboration covering China, with country with its own risks and uncertainties.

Foreign Company Risk. The company is affected by the political, economic, and military risks of having operations in Israel, as well as fluctuations in currency exchange rates. It may be difficult to enforce a U.S. judgment against the company or its officers and directors and to assert U.S. securities laws claims in Israel. The company received grants from the Israel Innovation Authority of the Israeli Ministry of Economy & Industry and may be subject to ongoing restrictions.

Intellectual property risk: The field of patents and intellectual property involves complex scientific and legal issues that are subject to change by legislation or judicial action. Other companies with greater resources may challenge the company through the legal system or in the marketplace. Oramed's patent estate is important to its ability to generate revenue from its products.

Clinical supplies and manufacturing risk: Oramed leases its operating facilities and depends on clinical trial managers and third party suppliers for its clinical trial grade materials, including the active pharmaceutical ingredients. We believe the supply of clinical materials is sufficient to conduct the trials, but third party manufacturing still carries a risk of problems or disagreements that could cause delays.

Regulatory risk: The company has conducted Phase 2 trials, and although we believe the pre-clinical and early clinical data indicate efficacy, further testing is needed before market approval. The findings from clinical trials must be reviewed by the FDA before the company receives approval to continue clinical testing. Analysis by the FDA may not agree with the analysis presented by the company. Approval of the application cannot be assumed.

Exchange and market risk: ORMP shares trade on the NASDAQ exchange with relatively small daily volume. The company is expected to raise additional capital to fund operations before its products reach the market, which is subject to market conditions.

Legislation and policy changes: Laws for drug approval are established by Congress and administered by the FDA. Reimbursement by third-party payors often follows policies established by the Center for Medicaid/Medicare. Both agencies are divisions of the Department of Health and Human Services, run by Commissioners appointed by the President and confirmed by the Senate. Changes in policies or political agendas could have broad effects on the environment for drug development and reimbursement.

Oramed: Income Statement (in thousands)												
Fiscal Year Ended August 31	**2019A**	**2020A**	**1Q21A**	**2Q21E**	**3Q21E**	**4Q21E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**
License and Milestone Payments	2,703	2,710	674	650	650	4,000	5,974	6,950	6,950		-	-
Royalites												
ORMD-0801 Type 2 diabetes - China										14,625	76,275	114,300
ORMD-0801 Type 2 diabetes - US only												111,420
Total Product Revenues	**2,703**	**2,710**	**674**	**650**	**650**	**4,000**	**5,974**	**6,950**	**6,950**	**14,625**	**76,275**	**225,720**
Expenses												
Cost of Goods Sold	90						-			2,194	9,707	22,572
%COGS										*15%*	*13%*	*10%*
Research and Development	13,522	10,235	5,774	6,750	7,250	8,250	28,024	34,500	37,500	39,000	41,000	43,600
General and Administrative	3,722	4,232	727	727	1,100	1,300	3,854	6,200	11,000	16,000	18,000	23,000
Total expenses	**17,334**	**14,467**	**6,501**	**7,477**	**8,350**	**9,550**	**31,878**	**40,700**	**48,500**	**57,194**	**68,707**	**89,172**
Operating Income (Loss)	(14,631)	(11,757)	(5,827)	(6,827)	(7,700)	(5,550)	(25,904)	(33,750)	(41,550)	(42,569)	7,569	136,548
Financial income	1,061	690	257	215	190	175	837	730	820	910	915	950
Financial expenses	(485)	(444)		(16)	(18)	(19)	(53)	(71)	(85)	(122)	(130)	(140)
Income from changes in fair value of investments												
Total other income	576	246	257	199	172	156	784	659	735	788	785	810
Pretax Income	**(14,055)**	**(11,511)**	**(5,570)**	**(6,628)**	**(7,528)**	**(5,394)**	**(25,120)**	**(33,091)**	**(40,815)**	**(41,781)**	**8,354**	**137,358**
Income Tax Provision (benefit)	300											13,736
Tax Rate												10%
Net Income (loss)	**(14,355)**	**(11,511)**	**(5,570)**	**(6,628)**	**(7,528)**	**(5,394)**	**(25,120)**	**(33,091)**	**(40,815)**	**(41,781)**	**8,354**	**123,622**
EPS (basic)	**($0.82)**	**($0.56)**	**($0.23)**	**($0.28)**	**($0.32)**	**($0.19)**	**($1.00)**	**($1.15)**	**($1.33)**	**($1.26)**	**$0.25**	**$3.70**
EPS (diluted)	**($0.82)**	**($0.56)**	**($0.23)**	**($0.28)**	**($0.32)**	**($0.19)**	**($1.00)**	**($1.15)**	**($1.32)**	**($1.26)**	**$0.25**	**$3.70**
Weighted Avg Shrs (Basic) - (thousands)	17,458	20,532	23,746	23,770	23,793	28,817	25,032	28,889	31,006	33,135	33,268	33,401
Weighted Avg Shrs (Diluted) - (thousands)	17,458	20,532	23,746	23,770	23,793	28,817	25,032	28,889	31,006	33,135	33,268	33,401

Source: Company reports and Ladenburg Thalmann estimates

APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

ANALYST CERTIFICATION

I, Robert M. LeBoyer, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, 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, provided, however, that:

The research analyst primarily responsible for the preparation of this research report has or will receive compensation based upon various factors, including the volume of trading at the firm in the subject security, as well as the firm's total revenues, a portion of which is generated by investment banking activities.

Additional information regarding the contents of this publication will be furnished upon request. Please contact Ladenburg Thalmann, Compliance Department, 640 Fifth Avenue, 4th floor, New York, New York 10019 (or call 212-409-2000) for any information regarding current disclosures, and where applicable, relevant price charts, in regard to companies that are the subject of this research report.

COMPANY BACKGROUND

Oramed Pharmaceuticals is developing products based on its Protein Oral Delivery technology (POD). Its lead product is ORMD-0801, an oral insulin capsule that recently began Phase 3 trials. Additional indications and products are in clinical development.

VALUATION METHODOLOGY

We value the company based on our 2026 discounted EPS of $3.70, applying a discount rate of 30% with a multiple of 15X to derive our price target of $15.00 per share.

RISKS

Risks to our rating and price target include but are not limited to:

Drug development risk: Oramed is a development stage company conducting clinical trials for its lead product. The company faces the risks of the drug development industry, including scientific, technical, clinical, regulatory failures. As novel therapies, the drugs also face risks with reimbursement and product adoption.

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Company risks: The company has a limited operating history and has incurred significant losses and negative cash flow operations since inception and they expect to incur losses and negative cash flows for at least the next 12 months. Their independent registered public accounting firm has expressed doubt about their ability to continue as a going concern. Because certain of their stockholders control a significant number of shares of their common stock, they may have effective control over actions requiring stockholder approval.

Emerging growth company: The company is considered an emerging growth company and due to the reduced operating requirements applicable to emerging growth companies, certain investors may find investing in their securities less attractive.

International risks: The international aspects of their business expose the company to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the US. Oramed also has a collaboration covering China, with its owns risks and uncertainties.

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STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 12.5% over the next twelve months.

Neutral: The stock's return is expected to be plus or minus 12.5% over the next twelve months.

Sell: The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

RATINGS DISPERSION AND BANKING RELATIONSHIPS AS OF (January 26, 2021)

Rating	%	IB %
BUY	76.2	58.3
NEUTRAL	22.8	37.2
SELL	1.1	50.0

COMPANIES UNDER ROBERT'S COVERAGE

Anavex Life Sciences Corp. (AVXL)
Calyxt, Inc. (CLXT)
Jaguar Health, Inc. (JAGX)
OncoSec Medical, Inc. (ONCS)
Outlook Therapeutics, Inc. (OTLK)
Yield10 Bioscience, Inc. (YTEN)
Benitec Biopharma Inc. (BNTC)
CNS Pharmaceuticals Inc. (CNSP)
NeuroBo Pharmaceuticals (NRBO)
Oramed Pharmaceuticals, Inc. (ORMP)
Plus Therapeutics Inc. (PSTV)

COMPANY SPECIFIC DISCLOSURES

Ladenburg Thalmann & Co. Inc. makes a market in Oramed Pharmaceuticals, Inc..

INVESTMENT RATING AND PRICE TARGET HISTORY

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