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Biotechnology
Price Target Change
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BUY

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Oramed Pharmaceuticals, Inc.

Second Cohort from Phase 2b Reported; Lowering Price Target to $6

ORMP (NASDAQ)

Company & Market Data	
Closing Price (as of 02/26/2020):	$4.70
Rating:	BUY
Price Target:	$6.00
Prior Price Target:	*$7.00*
52 Week Range:	$2.32 - $6.05
Shares Outstanding (MM):	17.8
Market Capitalization (MM):	$84
Cash (MM):	$26.9
Fiscal Year End:	Aug

Estimates			
EPS	**2018A**	**2019A**	**2020E**
1Q	$(0.18)	$(0.25)	$(0.15)A
Prior			*$(0.23)*
2Q	$(0.20)	$(0.21)	$(0.21)
3Q	$(0.30)	$(0.23)	$(0.16)
Prior			*$(0.17)*
4Q	$(0.20)	$(0.15)	$(0.03)
Prior		*$(0.26)E*	
Full Year	$(0.86)	$(0.82)	$(0.51)
Prior		*$(0.88)*	*$(0.61)*
Revenue (MM)	**2018A**	**2019A**	**2020E**
1Q	$0.6	$0.7	$0.6
2Q	$0.6	$0.7	$0.6
3Q	$0.7	$0.7	$0.6
4Q	$0.6	$0.7	$3.7
Full Year	$2.6	$2.6	$5.6

Ratios			
P/E	NA	NA	NA

Oramed Pharmaceuticals is developing products based on its Protein Oral Delivery technology (POD). Its lead product is an oral insulin capsule, currently in Phase 2b trials. Additional indications and products are in clinical development.

Summary: Oramed reported data from the second cohort of its Phase 2b trial for ORMD-0801 in Type 2 Diabetes (T2D). This arm of the trial tested lower doses than the first trial cohort, reported in November 2019. The trial tested four doses against placebo, with the two lower doses showing efficacy. The lowest dose (8mg) showed the greatest effect on HbA1C lowering in both cohorts. Oramed now plans to use this lowest dose in its upcoming Phase 3 trial.

The company will present data from both cohorts when it meets with the FDA to finalize the design of the Phase 3 trial. Data from an additional Phase 2 study testing ORMD-0801 in Type 1 Diabetes is expected shortly, and could allow an additional arm with Type 1 Diabetes be included in the Phase 3 study. We await the results of the T1D data and the final design of the Phase 3 study before revisiting our revenue estimates.

Separately, the company also announced an offering of 5.25 million shares, raising $21 million. We have adjusted our estimates and price target to allow for the increased number of shares outstanding.

Discussion: Oramed reported the second patient cohort from its Phase 2b study testing ORMD-0801 in Type 2 Diabetes (T2D, insulin insufficient). This cohort enrolled 78 patients for treatment, of whom 65 were included in the primary analysis. The primary endpoint was a reduction in HbA1C at 12 weeks, the accepted measure of bloodstream glucose levels. Out of the 65 patients, 57 had week 12 results.

Patients were randomized into four treatment groups, 8mg once daily, 8mg twice daily, 16mg once daily, and 16 mg twice daily. These dosing levels were below the lowest dose of 32 mg tested in the first cohort, and were chosen to determine the minimum effective dosage and pharmacokinetics.

The results showed decreases in HbA1C levels in the groups dosed at 8 mg once and twice daily. In the group given 8mg one daily, HbA1C observed mean levels were 1.29% lower compared with 0.27% for placebo. This benefit of 1.02% was statistically significant (p=0.0276).

The observed mean values for the group receiving 8 mg twice daily (total dose of 16mg daily) showed a lowering of 0.71% compared with 0.27% for placebo. This benefit of 0.44% was also statistically significant (p=0.0292).

Observed mean values in the 16mg daily dose showed an increase in HbA1C levels of 0.13% compared with a decrease of 0.27% for placebo, indicating a worsening of HbA1C (p=0.4896). The 16mg twice daily group showed an HbA1C decrease of 0.85% which was not statistically significant (p=0.3603).

We had previously expected the Phase 3 trial to use the 32 mg dose from larger Phase 2b cohort. After finding a greater HbA1C lowering from placebo at the 8mg dose, the company may now use 8 mg in the study.

Conclusion: The data from second cohort gives Oramed the data it needs for an FDA meeting to finalize the Phase 3 design. We expect this meeting to take place during the March-April timeframe, allowing the Phase 3 to begin in late 3Q to 4Q2020. This is consistent with our expected timeframe and revenue projections.

(Continued)

We have adjusted our models to allow for the increase in shares outstanding from the offering. We are maintaining our Buy rating and have lowered our price target to $6 per share, based on our 2026 estimate of $1.93 per share discounted at 30% per year with a multiple of 15X.

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.

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.

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.

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	**2019E**	**1Q20A**	**2Q20E**	**3Q20E**	**4Q20E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**
License and Milestone Payments	2,703	674	650	650	3,650	5,624	5,950	6,950	6,950		-	-
Royalites												
ORMD-0801 Type 2 diabetes - China										15,525	80,775	117,000
ORMD-0801 Type 2 diabetes - US only												32,760
Total Product Revenues	**2,703**	**674**	**650**	**650**	**3,650**	**5,624**	**5,950**	**6,950**	**6,950**	**15,525**	**80,775**	**149,760**
Expenses												
Cost of Goods Sold	90						-			2,329	10,247	14,976
%COGS										*15%*	*13%*	*10%*
Research and Development	13,522	2,022	3,500	3,600	3,500	12,622	19,000	23,000	29,500	32,000	36,400	40,400
General and Administrative	3,722	1,081	1,100	960	1,074	4,215	5,200	7,500	11,000	16,000	22,000	24,000
Total expenses	**17,334**	**3,103**	**4,600**	**4,560**	**4,574**	**16,837**	**24,200**	**30,500**	**40,500**	**50,329**	**68,647**	**79,376**
Operating Income (Loss)	(14,631)	(2,429)	(3,950)	(3,910)	(924)	(11,213)	(18,250)	(23,550)	(33,550)	(34,804)	12,129	70,384
Financial income	1,061	209	215	200	175	799	805	730	820	910	915	950
Other financial expenses	(485)	(20)	(16)	(18)	(21)	(75)	(69)	(71)	(85)	(122)	(130)	(140)
Income from changes in fair value of investments		(303)										
Total other income	576	(114)	199	182	154	724	736	659	735	788	785	810
Pretax Income	**(14,055)**	**(2,543)**	**(3,751)**	**(3,728)**	**(770)**	**(10,489)**	**(17,514)**	**(22,891)**	**(32,815)**	**(34,016)**	**12,914**	**71,194**
Income Tax Provision (benefit)	300											7,119
Tax Rate												10%
Net income (loss)												
Unrealized gain (loss) on available for sale securities												
Net Income (loss)	**(14,355)**	**(2,543)**	**(3,751)**	**(3,728)**	**(770)**	**(10,489)**	**(17,514)**	**(22,891)**	**(32,815)**	**(34,016)**	**12,914**	**64,075**
EPS (basic)	**($0.82)**	**($0.15)**	**($0.21)**	**($0.16)**	**($0.03)**	**($0.51)**	**($0.67)**	**($0.80)**	**($1.07)**	**($1.03)**	**$0.39**	**$1.93**
EPS (diluted)	**($0.82)**	**($0.15)**	**($0.21)**	**($0.16)**	**($0.03)**	**($0.51)**	**($0.67)**	**($0.80)**	**($1.06)**	**($1.03)**	**$0.39**	**$1.93**
Weighted Avg Shrs (Basic) - (thousands)	17,458	17,472	17,492	23,547	23,570	20,520	26,130	28,741	30,857	32,986	33,118	33,251
Weighted Avg Shrs (Diluted) - (thousands)	17,458	17,472	17,492	23,547	23,570	20,520	26,130	28,741	30,857	32,986	33,118	33,251

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, 277 Park Avenue, 26th floor, New York, New York 10172 (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 an oral insulin capsule, currently in Phase 2b trials. Additional indications and products are in clinical development.

VALUATION METHODOLOGY

We value the company based on our 2026 discounted EPS, applying a discount rate of 30% with a multiple of 15X to derive our price target of $6.00 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, and regulatory failures. As novel therapies, the drugs also face risks with reimbursement and product adoption.

Industry risk. The company faces the risks of the drug development industry, including scientific, technical, clinical, regulatory failures. As novel therapies, its products also face risks with reimbursement and product adoption.

Company risk. 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.

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.

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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.

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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 licensing application cannot be assumed.

Exchange and market risk. ORMD 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.

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 (February 27, 2020)

Rating	%	IB %
BUY	72.9	56.1
NEUTRAL	27.1	45.5
SELL	0.0	0.0

COMPANIES UNDER ROBERT'S COVERAGE

Calyxt, Inc. (CLXT)
NeuroBo Pharmaceuticals (NRBO)
Outlook Therapeutics, Inc. (OTLK)
Jaguar Health, Inc. (JAGX)
Oramed Pharmaceuticals, Inc. (ORMP)
Yield10 Bioscience, Inc. (YTEN)

COMPANY SPECIFIC DISCLOSURES

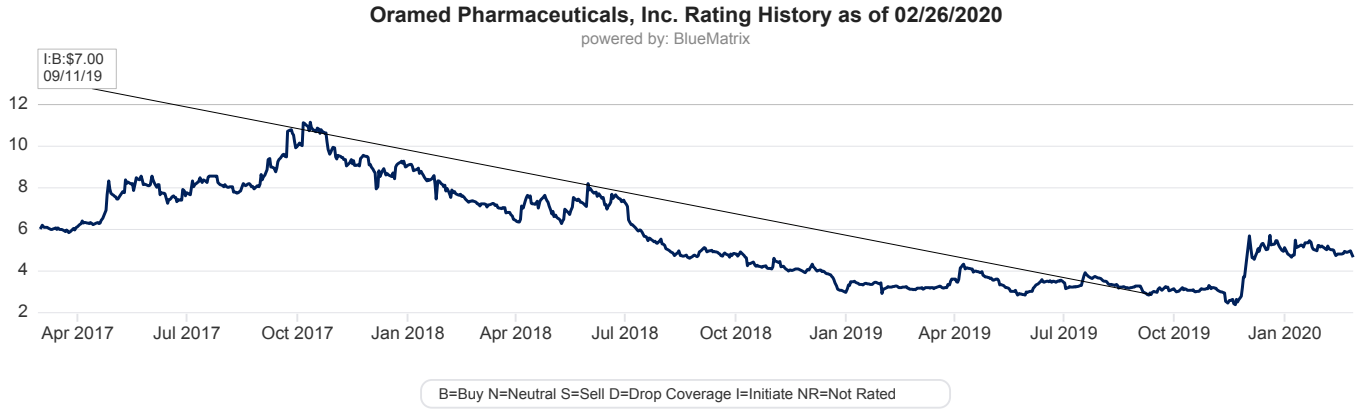
Ladenburg Thalmann & Co. Inc. makes a market in Oramed Pharmaceuticals, Inc..

Ladenburg Thalmann & Co. Inc received compensation for investment banking services from Oramed Pharmaceuticals, Inc. within the past 12 months.

Ladenburg Thalmann & Co. Inc had an investment banking relationship with Oramed Pharmaceuticals, Inc. within the last 12 months.

Ladenburg Thalmann & Co Inc. acted in an advisory capacity for Oramed Pharmaceuticals, Inc. in the last 12 months.

INVESTMENT RATING AND PRICE TARGET HISTORY



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