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Biotechnology
Company Update
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BUY
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Oramed Pharmaceuticals, Inc.

Oral Insulin Is Moving Forward with Phase 3 Design After End-of-Phase-2 Meeting

ORMP (NASDAQ)

Company & Market Data	
Closing Price (as of 07/15/2020):	$4.06
Rating:	BUY
Price Target:	$6.00
52 Week Range:	$2.32 - $6.05
Shares Outstanding (MM):	23.5
Market Capitalization (MM):	$96
Cash (MM):	$32.5
Fiscal Year End:	Aug

Estimates			
EPS	**2018A**	**2019A**	**2020E**
1Q	$(0.18)	$(0.25)	$(0.15)A
2Q	$(0.20)	$(0.21)	$(0.35)A
Prior			*$(0.21)*
3Q	$(0.30)	$(0.23)	$(0.44)A
Prior			*$(0.16)*
4Q	$(0.20)	$(0.15)	$(0.36)
Prior			*$(0.03)*
Full Year	$(0.86)	$(0.82)	$(1.28)
Prior			*$(0.51)*
Revenue (MM)	**2018A**	**2019A**	**2020E**
1Q	$0.6	$0.7	$0.6A
2Q	$0.6	$0.7	$1.3A
Prior			*$0.6*
3Q	$0.7	$0.7	$2.0A
Prior			*$0.6*
4Q	$0.6	$0.7	$3.7
Full Year	$2.6	$2.6	$7.7
Prior			*$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 announced that it has received positive feedback from an End-of-Phase-2 meeting with the FDA in which the agency reviewed the results of its oral insulin, ORMD-0801. The company plans to use the guidance from the meeting to design two Phase 3 studies. Following FDA trial design review and approval, we estimate these studies could begin treating patients in early 2021.

We see this as an important milestone, as we had been concerned about the statistical strength of the Phase 2b trial. The analysis was based on a small numbers of patients at different dose levels and administration schedules. We saw potential for the FDA to require additional patient data before allowing the company to start Phase 3. The positive feedback allows ORMD-0801 to advance to Phase 3 without additional testing and remains consistent with our expected timeframes.

Discussion: The ORMD-0801 Phase 2b study had two arms, each testing different dose levels and administration schedules. In the first arm, statistical significance was reached with a daily dose of 32mg. The second arm tested lower daily doses, with statistical significance at 8mg daily. However, we had been concerned that the small numbers of patients completing treatment at each dosage level might not have sufficient statistical strength for the FDA to allow moving into Phase 3. Based on the positive feedback from the FDA, the company can move forward and no additional data is required.

We have expected the design of Phase 3 program to follow design of the previous Phase 2b with a larger number of patients to prove efficacy and safety. The next step will be for Oramed to write the protocols, including the number of patients to be enrolled and the duration of treatment. These two factors are needed to predict the timing of the trial results and the timing of first revenues. Allowing three to six months for design and submission of the trials, we believe patient enrollment could begin in early 2021.

Conclusion: We see the positive FDA feedback from the End-of-Phase-2 meeting as an important milestone for the ORMD-0801 program. In our opinion, the risk of Phase 3 delays from additional data requirements was significant and could have delayed the start of Phase 3. The company can now move forward with Phase 3 design and begin the studies.

We look forward to the announcement of details of the trial design, patient enrollment, dose levels, and duration of treatment. These factors are needed to estimate the patient accrual time, likelihood of success, and timing of first revenues. While we had previously expected Phase 3 to begin in 4Q20, our valuation was based on FY2026 EPS of $1.92 per share discounted at 30% per year, with intentionally conservative timeframes and revenue estimates to allow for delays and uncertainties. We maintain our Buy rating and our price target of $6 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 is planning to design a Phase 3 study to support an application for FDA approval. The FDA must review and approve the trial design, a process that could results in revisions or delays. 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 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.

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.

Feb-20

Oramed: Income Statement (in thousands)												
Fiscal Year Ended August 31	**2019E**	**1Q20A**	**2Q20A**	**3Q20A**	**4Q20E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**
License and Milestone Payments	2,703	674	1,348	2,029	3,650	7,701	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**	**1,348**	**2,029**	**3,650**	**7,701**	**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	5,342	7,267	8,500	23,131	19,000	23,000	29,500	32,000	36,400	40,400
General and Administrative	3,722	1,081	2,472	3,502	3,750	10,805	5,200	7,500	11,000	16,000	22,000	24,000
Total expenses	**17,334**	**3,103**	**7,814**	**10,769**	**12,250**	**33,936**	**24,200**	**30,500**	**40,500**	**50,329**	**68,647**	**79,376**
Operating Income (Loss)	(14,631)	(2,429)	(6,466)	(8,740)	(8,600)	(26,235)	(18,250)	(23,550)	(33,550)	(34,804)	12,129	70,384
Financial income	1,061	209	369	569	175	1,322	805	730	820	910	915	950
Other financial expenses	(485)	(20)	(13)	(21)	(21)	(75)	(69)	(71)	(85)	(122)	(130)	(140)
Income from changes in fair value of investments		(303)	(121)	(323)								
Total other income	576	(114)	235	225	154	1,247	736	659	735	788	785	810
Pretax Income	**(14,055)**	**(2,543)**	**(6,231)**	**(8,515)**	**(8,446)**	**(24,988)**	**(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)	**(14,355)**	**(2,543)**	**(6,231)**	**(8,515)**	**(8,446)**	**(24,988)**	**(17,514)**	**(22,891)**	**(32,815)**	**(34,016)**	**12,914**	**64,075**
EPS (basic)	**($0.82)**	**($0.15)**	**($0.35)**	**($0.44)**	**($0.36)**	**($1.28)**	**($0.67)**	**($0.79)**	**($1.07)**	**($1.03)**	**$0.39**	**$1.92**
EPS (diluted)	**($0.82)**	**($0.15)**	**($0.35)**	**($0.44)**	**($0.36)**	**($1.28)**	**($0.67)**	**($0.79)**	**($1.06)**	**($1.03)**	**$0.39**	**$1.92**
Weighted Avg Shrs (Basic) - (thousands)	17,458	17,472	17,645	19,496	23,700	19,578	26,261	28,872	30,989	33,118	33,250	33,384
Weighted Avg Shrs (Diluted) - (thousands)	17,458	17,472	17,645	19,496	23,700	19,578	26,261	28,872	30,989	33,118	33,250	33,384

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:

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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 (July 16, 2020)

Rating	%	IB %
BUY	74.7	61.0
NEUTRAL	25.3	52.2
SELL	0.0	0.0

COMPANIES UNDER ROBERT'S COVERAGE

Benitec Biopharma Inc. (BNTC)
Jaguar Health, Inc. (JAGX)
OncoSec Medical, Inc. (ONCS)
Outlook Therapeutics, Inc. (OTLK)
Calyxt, Inc. (CLXT)
NeuroBo Pharmaceuticals (NRBO)
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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