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Biotechnology
Company Update
October 19, 2020
BUY

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Oramed Pharmaceuticals, Inc.

ORMD-0801 Phase 3 Design Finalized with Enrollment Expected to Start During 4Q20

ORMP (NASDAQ)

Company & Market Data	
Closing Price (as of 10/16/2020):	$2.68
Rating:	BUY
Price Target:	$6.00
52 Week Range:	$2.32 - $6.05
Shares Outstanding (MM):	23.5
Market Capitalization (MM):	$63
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
3Q	$(0.30)	$(0.23)	$(0.44)A
4Q	$(0.20)	$(0.15)	$(0.36)
Full Year	$(0.86)	$(0.82)	$(1.28)
Revenue (MM)	**2018A**	**2019A**	**2020E**
1Q	$0.6	$0.7	$0.6A
2Q	$0.6	$0.7	$1.3A
3Q	$0.7	$0.7	$2.0A
4Q	$0.6	$0.7	$3.7
Full Year	$2.6	$2.6	$7.7

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 completed the design of its Phase 3 clinical development program of ORMD-0801, its oral insulin for the treatment of type 2 diabetes (T2D). Patient enrollment is expected to begin in 4Q20, slightly ahead of our expected 1Q21 starting date.

There are two large Phase 3 trials (n=1,225) with clinically meaningful endpoints and dosing regimens that we believe will be sufficient to show efficacy and safety for approval with a broad product label. Their trial will be conducted at clinical sites in the US, Europe, and Israel.

Discussion: Oramed has announced that the Phase 3 protocol for ORMS-0801 has been completed and submitted to the FDA. The design follows the guidance from the End-of-Phase 2 meetings with the FDA that were announced in March and June 2020.

The two studies will test blood glucose control with ORMD-0801 in type 2 diabetes patients. The first study will include patients who are taking up to three diabetes medications, while the second study will be in patients who can control their diabetes with diet or diet plus metformin. These two populations should show glucose control in patients with different severities of diabetes.

The primary endpoint for both studies is an improvement in glycemic control as measured by HbA1c at 26 weeks. The secondary endpoint is the change in fasting plasma glucose from baseline at 26 weeks. If the endpoints are met, we believe the clinical benefit, length of treatment, and size of the studies could justify product approval with a broad label for use in diabetes.

The two studies also differ by dosing regimen:

-- The first study, ORA-013-1, will enroll 675 patients who are taking up to 3 glucose-lowering agents. Patients will be randomized into three treatment groups. The first group will receive 8 mg at night and 8 mg the next morning before breakfast (two doses daily). The second group will receive 8mg at night and placebo the next morning before breakfast (one dose, one placebo daily). The third group will receive placebo taken at night and placebo the next morning before breakfast (two placebos daily). This “double-dummy” study will be conducted at 75 sites in the US, Europe, and Israel.

-- The second study, ORA-013-2, will enroll 450 patients who can control their blood glucose with either diet alone or diet and metformin. The study will have two arms, an active arm with patients receiving 8mg at night and a control arm with patients receiving placebo at night. Patients will be recruited at 36 sites in the US and 25 sites in Europe and Israel.

The planned total enrollment of 1,125 patients will be treated at least 75 clinical sites in the US, Europe, and Israel, providing a study population with ethnic and geographical diversity to reflect the diabetic population throughout the world.

Conclusion: We see the announcement of the two Phase 3 study designs and start of the trial as an important milestone for ORMD-0801. We view the enrollment numbers, treatment duration, and allowable medications in Phase 3 studies as important criteria that should demonstrate the effect of ORMD-0801 on measures of blood glucose in patients with ether mild or severe diabetes. If successful in meeting the trial endpoints, ORMD-0801 could change the way millions of T2D patients are treated. We maintain our Buy rating and 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 start 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

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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 (October 19, 2020)

Rating	%	IB %
BUY	77.1	59.3
NEUTRAL	22.3	47.6
SELL	0.5	100.0

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)
Benitec Biopharma Inc. (BNTC)
CNS Pharmaceuticals Inc. (CNSP)
NeuroBo Pharmaceuticals (NRBO)
Oramed Pharmaceuticals, Inc. (ORMP)
Yield10 Bioscience, Inc. (YTEN)

COMPANY SPECIFIC DISCLOSURES

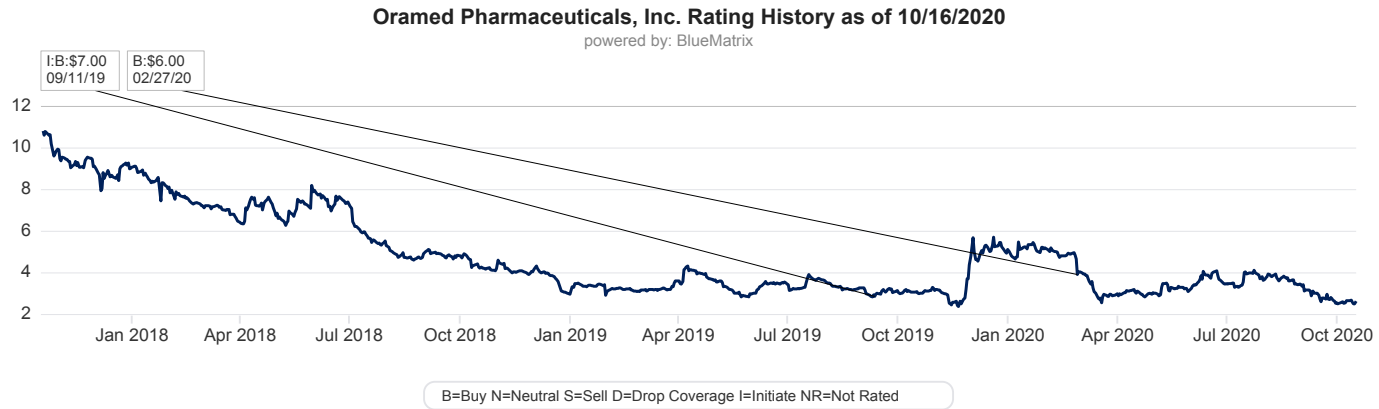
Ladenburg Thalmann & Co. Inc. makes a market in Oramed Pharmaceuticals, Inc..

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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Member: NYSE, NYSE American, NYSE Arca, FINRA, all other principal exchanges and SIPC

Additional Information Available Upon Request

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