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Biotechnology
Company Update
November 12, 2019
BUY
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ORAMED PHARMACEUTICALS, INC.

ORMD: Oramed Announces Successful Phase 2b Study Results for ORMD-0801

ORMP (NASDAQ)

Company & Market Data	
Closing Price (as of 11/11/2019):	$2.99
Rating:	BUY
Price Target:	$7.00
52 Week Range:	$2.78 - $4.50
Shares Outstanding (MM):	17.4
Market Capitalization (MM):	$52
Cash (MM):	$37.0
Fiscal Year End:	Aug

Estimates			
EPS	**2018A**	**2019E**	**2020E**
1Q	$(0.18)	$(0.25)A	$(0.23)
2Q	$(0.20)	$(0.21)A	$(0.21)
3Q	$(0.30)	$(0.23)A	$(0.17)
4Q	$(0.20)	$(0.26)	$(0.03)
Full Year	$(0.86)	$(0.88)	$(0.61)
Revenue (MM)	**2018A**	**2019E**	**2020E**
1Q	$0.6	$0.7A	$0.6
2Q	$0.6	$0.7A	$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 announced successful results of its Phase 2b clinical trial testing ORMD-0801, its proprietary oral insulin. The study met its primary efficacy endpoint, the change in HbA1c at 90 days for the once and twice daily dosage groups. We expect the company to move forward to Phase 3 with either once or twice daily dosing. Oramed will host an investor meeting on November 18 to fully discuss the data.

Discussion: Oramed has developed ORMD-0801 as an oral insulin capsule using its proprietary oral delivery technology for delivering large proteins through the GI system. ORMD-0801 had completed a Phase 2 study showing that the drug lowered overnight bloodstream glucose and had statistically significant changes in HbA1c after 28 days of treatment. The Phase 2b study announced today had a primary endpoint of HbA1C levels after 90 days of treatment to meet FDA approval requirements.

Two Dose Levels Met the Primary Endpoint: The Phase 2b trial enrolled 268 patients with Type 2 diabetes. Patients were randomized into three dose levels or placebo. The treatment groups received 32mg doses given either once a day, twice a day, or three times a day. The primary endpoint was a reduction in HbA1C, an accepted measure of bloodstream glucose levels.

The once daily treatment arm showed an HbA1C reduction from baseline of 0.60%, or 0.54% with placebo adjustment, and statistical significance ($p<0.036$). The twice daily treatment group had a reduction of 0.059%, or 0.053% with placebo adjustment, and statistical significance ($p<0.042$). The three times daily group did not meet statistical significance ($p<0.093$).

Interpretation: We see the data from the two lower dose arms as clinically successful and consistent with the previous Phase 2a study. The lack of statistical significance for the three times daily dosing group could be due to physiologic feedback related to normal glucose control. We await additional data analysis, but do not see the high dose group as a contradictory result.

A second cohort treated with a 16 mg dose administered once, twice, or three times daily is also in progress. This study has overlapping total daily doses with the first cohort that should provide interesting comparisons.

Conclusion: We see the Phase 2b as a successful trial that shows a positive effect of ORMD-0801 on glucose control. While the effect may seem numerically small, the long term impact of ORMD-0801 on the progression of diabetes is clinically meaningful. As an orally administered insulin it could be added to existing diabetes regimens for better glucose control and reduction in the many co-morbidities caused by high glucose levels.

We reiterate our Buy rating and $7 price target, based on our 2026 discounted EPS estimate of $2.26 applying a discount rate of 30% 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	**2017A**	**2018A**	**1Q19A**	**2Q19A**	**3Q19A**	**4Q19E**	**2019E**	**1Q20E**	**2Q20E**	**3Q20E**	**4Q20E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**
License and Milestone Payments	2,456	2,535	674	666	682	650	2,672	650	650	650	3,650	5,600	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	**2,456**	**2,535**	**674**	**666**	**682**	**650**	**2,672**	**650**	**650**	**650**	**3,650**	**5,600**	**5,950**	**6,950**	**6,950**	**15,525**	**80,775**	**149,760**
Expenses																		
Cost of Goods Sold	187	-	35	55			90						-			2,329	10,247	14,976
%COGS																*15%*	*13%*	*10%*
Research and Development	10,281	11,979	4,347	3,114	3,861	4,100	15,422	3,700	3,500	3,600	3,500	14,300	18,500	23,000	28,000	31,000	35,000	37,750
General and Administrative	2,759	4,083	932	1,065	899	950	3,846	1,200	1,100	960	1,074	4,334	5,200	7,500	11,000	14,500	16,000	17,000
Total expenses	**13,227**	**16,062**	**5,314**	**4,234**	**4,760**	**5,050**	**19,358**	**4,900**	**4,600**	**4,560**	**4,574**	**18,634**	**23,700**	**30,500**	**39,000**	**47,829**	**61,247**	**69,726**
Operating Income (Loss)	(10,771)	(13,527)	(4,640)	(3,568)	(4,078)	(4,400)	(16,686)	(4,250)	(3,950)	(3,910)	(924)	(13,034)	(17,750)	(23,550)	(32,050)	(32,304)	19,529	80,034
Financial income	792	903	286	273	263	250	1,072	225	215	200	175	815	805	730	820	910	915	950
Other financial expenses	(101)	(103)	(8)	(19)	(14)	(15)	(56)	(14)	(16)	(18)	(21)	(69)	(69)	(71)	(85)	(122)	(130)	(140)
Income from changes in fair value of investments			60	(87)	(243)		(270)											
Total other income	691	800	338	167	6	235	746	211	199	182	154	746	736	659	735	788	785	810
Pretax Income	**(10,080)**	**(12,727)**	**(4,302)**	**(3,401)**	**(4,072)**	**(4,165)**	**(15,940)**	**(4,039)**	**(3,751)**	**(3,728)**	**(770)**	**(12,288)**	**(17,014)**	**(22,891)**	**(31,315)**	**(31,516)**	**20,314**	**80,844**
Income Tax Provision (benefit)	400			300		350	650											8,084
Tax Rate																		10%
Net income (loss)	(10,480)	(12,727)																
Unrealized gain (loss) on available for sale securities	295	301																
Net Income (loss)	**(10,185)**	**(12,426)**	**(4,302)**	**(3,701)**	**(4,072)**	**(4,515)**	**(15,290)**	**(4,039)**	**(3,751)**	**(3,728)**	**(770)**	**(12,288)**	**(17,014)**	**(22,891)**	**(31,315)**	**(31,516)**	**20,314**	**72,760**
EPS (basic)	**($0.79)**	**($0.86)**	**($0.25)**	**($0.21)**	**($0.23)**	**($0.26)**	**($0.88)**	**($0.23)**	**($0.21)**	**($0.17)**	**($0.03)**	**($0.61)**	**($0.68)**	**($0.83)**	**($1.06)**	**($0.99)**	**$0.63**	**$2.26**
EPS (diluted)	**($0.79)**	**($0.86)**	**($0.25)**	**($0.21)**	**($0.23)**	**($0.26)**	**($0.88)**	**($0.23)**	**($0.21)**	**($0.17)**	**($0.03)**	**($0.61)**	**($0.68)**	**($0.83)**	**($1.05)**	**($0.99)**	**$0.63**	**$2.26**
Weighted Avg Shrs (Basic) - (thousands)	13,309	14,882	17,449	17,454	17,457	17,474	17,458	17,492	17,509	22,527	22,549	20,019	25,107	27,714	29,826	31,950	32,078	32,207
Weighted Avg Shrs (Diluted) - (thousands)	13,309	14,882	17,449	17,454	17,457	17,474	17,458	17,492	17,509	22,527	22,549	20,019	25,107	27,714	29,826	31,950	32,078	32,207

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 $7.00 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.

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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 (November 12, 2019)

Rating	%	IB %
BUY	73.1	56.5
NEUTRAL	26.9	42.6
SELL	0.0	0.0

COMPANIES UNDER ROBERT'S COVERAGE

Jaguar Health, Inc. (JAGX)
Outlook Therapeutics, Inc. (OTLK)
Oramed Pharmaceuticals, Inc. (ORMP)

COMPANY SPECIFIC DISCLOSURES

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

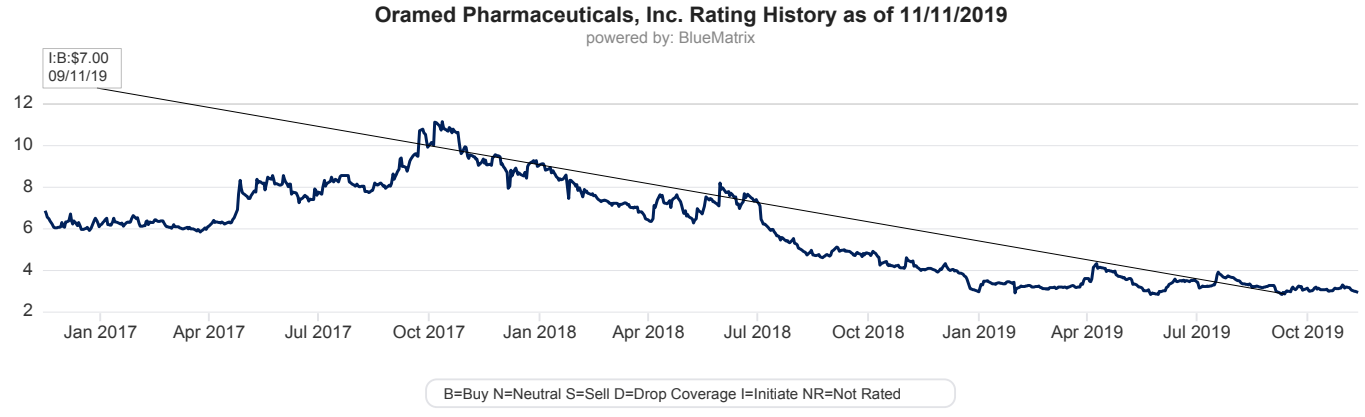
Ladenburg Thalmann & Co. Inc. expects to receive compensation for investment banking and/or advisory services from Oramed Pharmaceuticals, Inc. within the next 3 months.

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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Additional Information Available Upon Request

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