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Biotechnology
Company Update
February 19, 2020
BUY
Robert M. LeBoyer; RLeBoyer@ladenburg.com
212.409.2031

Oramed Pharmaceuticals, Inc.

Looking Forward to Additional Data in 1Q20 and Phase 3 in 2H20

ORMP (NASDAQ)

Company & Market Data	
Closing Price (as of 02/18/2020):	$4.87
Rating:	BUY
Price Target:	$7.00
52 Week Range:	$2.32 - $6.05
Shares Outstanding (MM):	17.8
Market Capitalization (MM):	$87
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: During the remaining weeks of 1Q20, we expect the release of the second patient cohort of the Phase 2b study testing ORMD-0801 in Type 2 Diabetes (T2D, insulin insufficient). This arm of the study tested a lower dose than the first cohort. We expect the study to more fully characterize the dose-response and provide additional data for dose selection in the upcoming Phase 3 trial.

Type 1 Diabetes Study: A separate study testing ORMD-0801 in Type 1 Diabetes (T1D, insulin dependent) is also expected to be announced in 1Q20. This could be used to design a T1D arm in the Phase 3 study that would run in parallel with the T2D arms.

FDA Meetings: The company held a meeting with the FDA earlier in February to review its manufacturing processes. While the meeting minutes have not been received and the results are not final yet, the company expects that the manufacturing and testing controls meet requirements for commercial manufacturing and can be included in an application for approval.

Following the data analysis, we expect the company to meet with the FDA to present these additional studies to finalize the protocols for the Phase 3. This would be within our expected time frame for Phase 3 to begin in 2H20.

Discussion: In November 2019, Oramed reported results from the first cohort of its Phase 2b trial for ORMD-0801. This cohort enrolled 268 patients with Type 2 diabetes, 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 (for total dosages of 32mg, 64mg, or 96 mg).

The primary endpoint was a reduction in HbA1C, the accepted measure of bloodstream glucose levels. The once-daily (32mg) treatment arm showed an HbA1C reduction from baseline of 0.60%, or 0.54% difference from placebo, and statistical significance ($p<0.036$). The twice-daily (64mg) treatment group had a reduction of 0.59% from baseline, or 0.53% difference from placebo, and statistical significance ($p<0.042$).

The second cohort tested ORMD-0801 at lower doses than the first cohort. Data from these lower dosage regimens is intended to better characterize the pharmacokinetics of ORMD-0801 in the body and determine the lowest effective dose. This second cohort enrolled 75 patients administered at a dosage of 8mg or 16mg once or twice a day for 12 weeks (total dosages of 8mg, 16 mg, or 32 mg per day).

We do not expect all of the dosage groups to reach statistically significant reductions, and see the pharmacokinetic and dose-response as the key measures. This data is intended to support the choice of dosage for Phase 3, which we expect to be the regimens from the first cohort (32mg or 64mg). We therefore see little downside to the results.

Type 1 Diabetes Patient Data May Allow an Additional Arm to Phase 3: In the coming weeks, the company also expects to announce data from a Phase 2 study in T1D patients that could allow an additional arm of the Phase 3 study to be run in parallel with the T2D arms.

If the Phase 3 study is successful in both T1D and T2D, it could lead to a product label with approval in both types of diabetes. At this time, our models and price target are based

(Continued)

only on the portion of Type 2 diabetes population included in the first Phase 2b cohort. A successful outcome in T1D would add an estimated 1.2 million patients in the US alone. This could represent a substantial potential upside to our models.

Additional Trial Data: One of the observations in the Phase 2b trial was the reduction in liver fat after treatment with ORMD-0801. Although the company is not developing the drug as a treatment for NASH, it is running a study to determine the effect of the drug on accumulation of fat in the liver. Since diabetes, liver fat, and development of NASH are correlated, this could become an additional endpoint in the Phase 3 trial. Separately, a study using leptin, the body weight regulatory hormone, is also expected to report data in 1Q20. This study will explore the link between leptin, obesity, diabetes, and insulin levels.

Conclusion: We expect these clinical data announcements to be reported in the remaining weeks of 1Q20, meeting the expected timeframes. The Type 1 Diabetes data and the Phase 2b low-dose cohort data should allow finalization of the Phase 3 design, which we expect to be highly similar to Phase 2b. In our opinion, following the Phase 2b design with larger numbers lowers clinical risk and has the best probability of repeating the previous outcome for efficacy and safety, leading to FDA approval. We are maintaining our Buy rating and price target of $7 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.

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.

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.

International risk. 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.

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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 19, 2020)

Rating	%	IB %
BUY	73.8	55.7
NEUTRAL	26.2	43.4
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

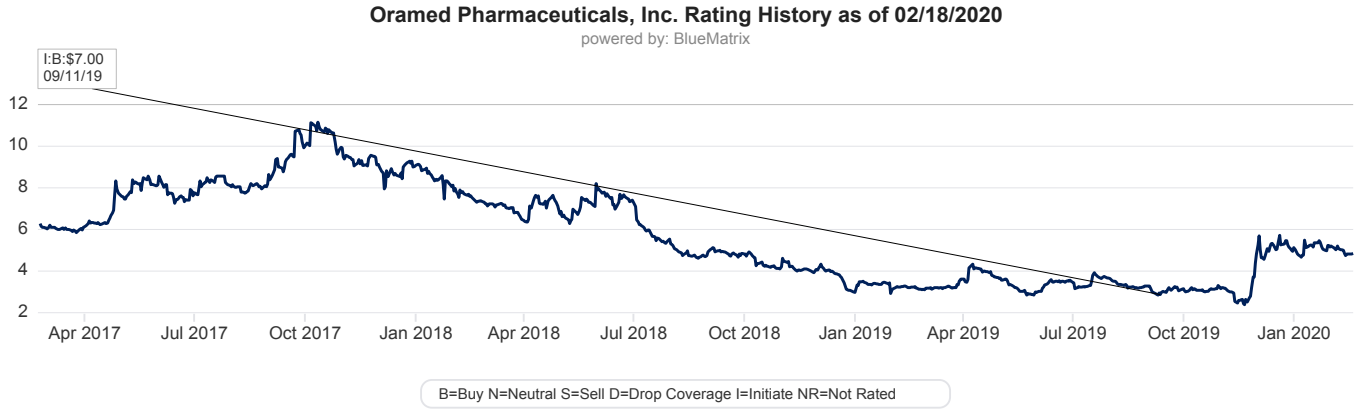
Ladenburg Thalmann & Co. Inc. makes a market in Oramed Pharmaceuticals, Inc..

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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Additional Information Available Upon Request

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EQUITY RESEARCH

ENERGY, POWER & INFRASTRUCTURE

Energy Exploration & Production, Upstream
Michael Schmitz, CFA (212) 409-2028 mschmitz@ladenburg.com

Master Limited Partnerships, Midstream
Michael Schmitz, CFA (212) 409-2028 mschmitz@ladenburg.com

HEALTHCARE

Biotechnology
Matthew L. Kaplan (212) 891-5247 mkaplan@ladenburg.com

Biotechnology
Robert M. LeBoyer (212) 409-2031 rleboyer@ladenburg.com

Biotechnology
Wangzhi Li, PhD (212) 409-2051 wli@ladenburg.com

Biopharmaceuticals
Michael Higgins (212) 409-2074 mhiggins@ladenburg.com

Healthcare & Medical Technologies
Jeffrey S. Cohen (561) 620-2049 jcohen@ladenburg.com

FINANCIAL INSTITUTIONS

Financial Services – Business Development Co. & Specialty Finance
Mickey M. Schleien, CFA (305) 572-4131 mschleien@ladenburg.com

Financial Services – Business Development Co. & Specialty Finance
Christopher Nolan, CFA (212) 409-2068 cnolan@ladenburg.com

Financial Services – Equity REITs
John J. Massocca (212) 409-2543 jmassocca@ladenburg.com

SPECIALTY CONSUMER/CANNABIS

Specialty Consumer/Cannabis
Glenn G. Mattson (212) 409-2073 gmattson@ladenburg.com

TECHNOLOGY

Internet & Software Services
Jon R. Hickman (510) 918-4045 jhickman@ladenburg.com

Software and Services
Glenn G. Mattson (212) 409-2073 gmattson@ladenburg.com

ADDITIONAL CONTACTS

Kenneth Brush, Head of Trading (212) 409-2011 kbrush@ladenburg.com
Eric Novotny (212) 409-2011 enovotny@ladenburg.com