LADENBURG THALMANN
ESTABLISHED 1876

Biotechnology
Company Update
November 30, 2020
BUY
Robert M. LeBoyer; RLeBoyer@ladenburg.com
212.409.2031

Oramed Pharmaceuticals, Inc.

The First Phase 3 Trial Has Started on Schedule

ORMP (NASDAQ)

Company & Market Data	
Closing Price (as of 11/27/2020):	$4.45
Rating:	BUY
Price Target:	$6.00
52 Week Range:	$2.40 - $6.05
Shares Outstanding (MM):	23.7
Market Capitalization (MM):	$105
Cash (MM):	$32.5
Fiscal Year End:	Aug

Estimates			
EPS	**2019A**	**2020E**	**2021E**
1Q	$(0.25)	$(0.15)A	$(0.29)
2Q	$(0.21)	$(0.35)A	$(0.32)
3Q	$(0.23)	$(0.44)A	$(0.36)
4Q	$(0.15)	$(0.36)	$(0.23)
Full Year	$(0.82)	$(1.28)	$(1.19)
Revenue (MM)	**2019A**	**2020E**	**2021E**
1Q	$0.7	$0.6A	$0.6
2Q	$0.7	$1.3A	$0.6
3Q	$0.7	$2.0A	$0.6
4Q	$0.7	$3.7	$4.0
Full Year	$2.6	$7.7	$5.9

Ratios			
P/E	NA	NA	NA

Oramed Pharmaceuticals is developing products based on its Protein Oral Delivery technology (POD). Its lead product is ORMD-0801, an oral insulin capsule that recently began Phase 3 trials. Additional indications and products are in clinical development.

Summary: Oramed announced that it has begun screening patients for the first of the two Phase 3 trials of ORMD-0801, its oral insulin for treatment of type 2 diabetes (T2D). This meets the planned 4Q20 timeframe for the start of the trial. Patients receive six months of treatment, so that the first patients should be completing the study in mid-2021. First efficacy data could be available as soon as 3Q21.

Patients in the first study, ORA-013-1, will be taking up to three diabetes medications and have inadequate glucose control for 6 to 12 months. This study will test two dosage regimens against placebo.

The second study, ORA-013-2, will enroll patients who can control their blood glucose with either diet alone or diet with metformin. This trial will randomize patients into two arms, one with 8 mg active drug, the other with placebo.

The first study has a target enrollment of 675 patients, while the second has a target of 450 patients. The primary endpoint in both trials is an improvement in glucose control as measured by HbA1c at 26 weeks. Secondary endpoints include change from baseline in fasting glucose 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.

Dosing Regimen in the ORA-013-1 Study: The first study will randomize 675 patients who can be taking up to 3 diabetes drugs, randomized into three treatment groups. The first group will receive two active doses, with 8mg administered before bedtime and 8mg the next morning before breakfast. The second group will receive one active dose and one placebo, with 8 mg at night and placebo the next morning. The third group will receive two placebo doses, one at night and another the next morning. This "double-dummy" design is intended to determine the best dosing for glucose control. Patient recruitment will be at 75 sites in the US, Europe, and Israel.

Study ORA-013-2 Is Expected to Begin Shortly: The second study, ORA-013-2, will enroll 450 patients who can control their blood glucose with diet or diet plus metformin. Patients in this study will be randomized into a group receiving active drug once daily or placebo, both administered before bedtime. Patients will be treated at 61 sites in the US, Europe, and Israel.

Conclusion: The start of the first Phase 3 trial in 4Q20 meets our expected timeframe. With a planned enrollment of 1,125 patients in at least 75 sites in the US, Europe, and Israel, these two ORA-013 studies should provide a globally diverse population to justify approval around the world. If the studies are positive, the oral administration of insulin could change the way T2D is 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.

Oramed: Income Statement (in thousands)																
Fiscal Year Ended August 31	**2019A**	**1Q20A**	**2Q20A**	**3Q20A**	**4Q20E**	**2020E**	**1Q21E**	**2Q21E**	**3Q21E**	**4Q21E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**
License and Milestone Payments	2,703	674	1,348	2,029	3,650	7,701	650	650	650	4,000	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**	**650**	**650**	**650**	**4,000**	**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	8,500	9,500	10,500	11,000	39,500	47,000	46,000	43,000	42,000	40,400
General and Administrative	3,722	1,081	2,472	3,502	3,750	10,805	1,200	1,200	1,400	1,400	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**	**9,700**	**10,700**	**11,900**	**12,400**	**44,700**	**54,500**	**57,000**	**61,329**	**74,247**	**79,376**
Operating Income (Loss)	(14,631)	(2,429)	(6,466)	(8,740)	(8,600)	(26,235)	(9,050)	(10,050)	(11,250)	(8,400)	(38,750)	(47,550)	(50,050)	(45,804)	6,529	70,384
Financial income	1,061	209	369	569	175	1,322	225	215	190	175	805	730	820	910	915	950
Other financial expenses	(485)	(20)	(13)	(21)	(21)	(75)	(16)	(16)	(18)	(19)	(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	209	199	172	156	736	659	735	788	785	810
Pretax Income	**(14,055)**	**(2,543)**	**(6,231)**	**(8,515)**	**(8,446)**	**(24,988)**	**(8,841)**	**(9,851)**	**(11,078)**	**(8,244)**	**(38,014)**	**(46,891)**	**(49,315)**	**(45,016)**	**7,314**	**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)**	**(8,841)**	**(9,851)**	**(11,078)**	**(8,244)**	**(38,014)**	**(46,891)**	**(49,315)**	**(45,016)**	**7,314**	**64,075**
EPS (basic)	**($0.82)**	**($0.15)**	**($0.35)**	**($0.44)**	**($0.36)**	**($1.28)**	**($0.29)**	**($0.32)**	**($0.36)**	**($0.23)**	**($1.19)**	**($1.31)**	**($1.30)**	**($1.12)**	**$0.18**	**$1.58**
EPS (diluted)	**($0.82)**	**($0.15)**	**($0.35)**	**($0.44)**	**($0.36)**	**($1.28)**	**($0.29)**	**($0.32)**	**($0.36)**	**($0.23)**	**($1.19)**	**($1.31)**	**($1.30)**	**($1.12)**	**$0.18**	**$1.58**
Weighted Avg Shrs (Basic) - (thousands)	17,458	17,472	17,645	19,496	23,700	19,578	30,724	30,754	30,785	35,816	32,020	35,906	38,050	40,208	40,369	40,531
Weighted Avg Shrs (Diluted) - (thousands)	17,458	17,472	17,645	19,496	23,700	19,578	30,724	30,754	30,785	35,816	32,020	35,906	38,050	40,208	40,369	40,531

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 ORMD-0801, an oral insulin capsule that recently began Phase 3 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, 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.

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 30, 2020)

Rating	%	IB %
BUY	76.4	58.9
NEUTRAL	22.5	51.2
SELL	1.1	50.0

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

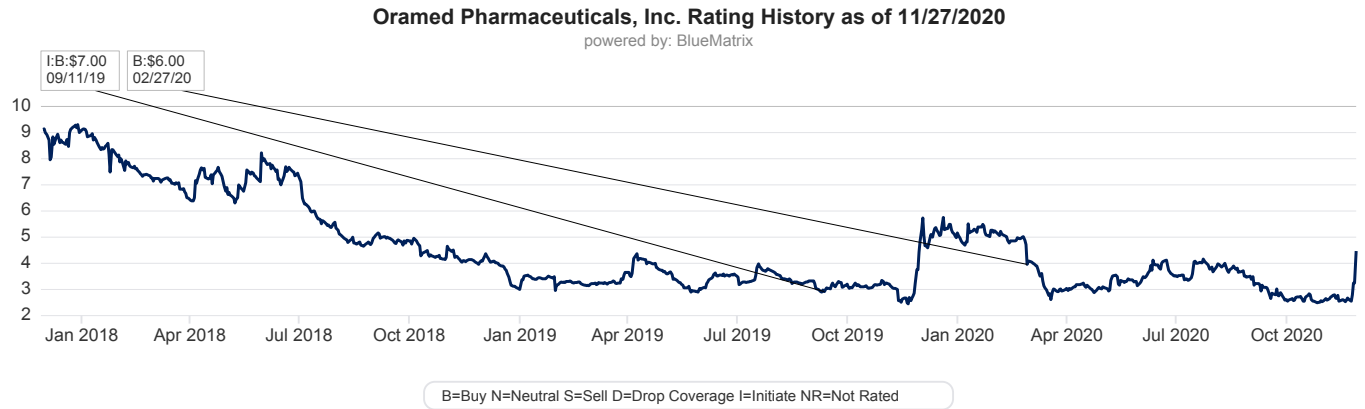
Ladenburg Thalmann & Co. Inc. makes a market in Oramed Pharmaceuticals, Inc..

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



GENERAL DISCLAIMERS

Information and opinions presented in this report have been obtained or derived from sources believed by Ladenburg Thalmann & Co. Inc. to be reliable. The opinions, estimates and projections contained in this report are those of Ladenburg Thalmann as of the date of this report and are subject to change without notice.

Ladenburg Thalmann & Co. Inc. accepts no liability for loss arising from the use of the material presented in this report, except that this exclusion of liability does not apply to the extent that such liability arises under specific statutes or regulations applicable to Ladenburg Thalmann & Co. Inc. This report is not to be relied upon in substitution for the exercise of independent judgment. Ladenburg Thalmann & Co. Inc. may have issued, and may in the future issue, other reports that are inconsistent with, and reach different conclusions from, the information presented in this report. Those reports reflect the different assumptions, views and analytical methods of the analysts who prepared them and Ladenburg Thalmann & Co. Inc. is under no obligation to ensure that such other reports are brought to the attention of any recipient of this report. Investors should consider this report as only a single factor in making their investment decisions.

Some companies that Ladenburg Thalmann & Co. Inc. follows are emerging growth companies whose securities typically involve a higher degree of risk and more volatility than the securities of more established companies. The securities discussed in Ladenburg Thalmann & Co. Inc. research reports may not be suitable for some investors. Investors must make their own determination as to the appropriateness of an investment in any securities referred to herein, based on their specific investment objectives, financial status and risk tolerance.

Past performance should not be taken as an indication or guarantee of future performance, and no representation or warranty, express or implied, is made regarding future performance. The price, value of and income from any of the securities mentioned in this report can fall as well as rise. The value of securities is subject to exchange rate fluctuation that may have a positive or adverse effect on the price or income of such securities. Investors in securities such as ADRs, the values of which are influenced by currency volatility, effectively assume this risk. Securities recommended, offered or sold by Ladenburg Thalmann & Co. Inc. (1) are not insured by the Federal Deposit Insurance Company; (2) are not deposits or other obligations of any insured depository institution; and (3) are subject to investment risks, including the possible loss of some or all of principal invested. Indeed, in the case of some investments, the potential losses may exceed the amount of initial investment and, in such circumstances; you may be required to pay more money to support these losses.

The information and material presented in this report are provided to you for information purposes only and are not to be used or considered as an offer or the solicitation of an offer to sell or to buy any securities mentioned herein. This publication is confidential for the information of the addressee only and may not be reproduced in whole or in part, copies circulated, or disclosed to another party, without the prior written consent of Ladenburg Thalmann & Co. Inc.

Investing in low priced securities is speculative and carries a high degree of risk. You should independently investigate and understand all risks before making any investment. The markets for small cap stocks are highly speculative and this level of risk may not be appropriate for all investors. Some of the companies listed may be subject to the “Penny Stock Rule”. Under this rule, the SEC has defined a “penny stock” to be an equity security which has a market price of less than $5.00 a share, subject to certain exemptions. Such exemptions include equity listed on NASDAQ and an equity security issued by an issuers which has (i) net tangible assets of at least $2,000,000, if such issuers has been in continuous operational for (3) years; (ii) net tangible assets of $5,000,000, if such issuer has been in continuous operation for less than (3) years; or (iii) average revenue of at least $6,000,000 for the preceding three (3) years. Unless such exemption is available, regulations require delivery of a risk disclosure document explaining the penny stock market and the risks associated therewith prior to any transaction involving a penny stock. For stock not quoted on NASDAQ or at any time that the company has less than $2,000,000 in net tangible assets, the trading in common stock is covered under Rule 15g-9 under the Securities Exchange Act of 1934 for non-NASDAQ and non-exchange listed securities. Under such rule, broker-dealers who recommend covered securities to persons other than established customers and accredited investors must make a written suitability determination for the purchaser and receive the purchaser’s written agreement to a transaction prior to sale. Some securities may not be cleared for sale in all states or other jurisdictions and LTCO assumes no responsibility to apprise you of individual states and jurisdictions’ regulatory restrictions. Stocks in the microcap segment of market have risks that are not as common in other segments of market. These risks include, but are not limited to, liquidity risk, which can lead to higher volatility and low trade volume, company specific risks that contribute to lower valuation, higher probability of financial default and distress.

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

Additional Information Available Upon Request

LADENBURG THALMANN
ESTABLISHED 1876

EQUITY RESEARCH

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