

Oramed Pharmaceuticals, Inc.

Breakthrough oral drug delivery technology for diabetes, drugs and vaccines

Initiating Report

| November 5, 2014

Key data	
Sector	Biotechnology
Rating	BUY
Target Price	\$45.00
Current Market Price	\$7.25
52 Week Low/52 Week High	\$6.28/\$31.73
Nasdaq Composite Index	4,624
3-mth avg. daily volume	47,495
Market Cap (in mn)	\$72.2
Shares Outstanding (in mn)	10.0
Cash & Investments (in mn)	Approx. \$20.0*
Debt	0

Source: Yahoo Finance as of November 4, 2014 and publicly available company documents

*ORMP announced on Nov. 3 that it entered into a Stock Purchase Agreement to raise approximately an additional \$5 million in a deal slated to close by November 28. This would increase cash and investments to \$25 million.

Company Description: Oramed Pharmaceuticals has a breakthrough platform technology that allows for the oral delivery of drugs and vaccines that are presently available only via injection. Oramed's pipeline is currently focused on diabetes and has potential for a variety of additional treatment indications to address markets worth roughly \$50 billion. The Company has \$15 million in cash which it is efficiently using to advance its Phase 2 U.S. FDA trial of its oral insulin capsule ORMD-0801 for the treatment of Type 2 diabetes. The Company's product pipeline includes three indications: ORMD-0801 in Phase 2 for Type 2 diabetes as a new, early treatment option before insulin injections become necessary; ORMD-0801 in Phase 2 for Type 1 diabetes to eliminate insulin injections prior to meals; and ORMD-0901, an oral GLP-1 analog, in Phase 1 for the treatment of Type 2 diabetes. Oramed is led by a management team, directors, and scientific advisors who are recognized as unparalleled leaders in their field.

Investment Summary

We initiate coverage of Oramed Pharmaceuticals, Inc. (NASDAQ: ORMP) with a BUY rating and a \$45.00 per share fair value estimate, based on our Discounted Cash Flow valuation methodology. Accordingly, ORMP's shares should trade at a 510% premium to its current valuation. Our BUY rating is based on the following:

- On November 3, 2014 ORMP announced very favorable top-line results from a Phase 2a trial for its oral insulin capsule in ORMD-0801 for Type 1 diabetes, addressing the multi-billion dollar diabetes market.
- ORMP's unique Protein Oral Delivery (POD™) technology is a breakthrough in medical science that enables small proteins to travel through the gastrointestinal tract, via the liver, and into the bloodstream to treat a broad number of indications including diabetes.
- POD technology addresses a market of roughly \$50 billion worth of drugs and vaccines that are currently delivered via injections. This includes diabetes, the first indication pursued by ORMP, a market where \$20 billion worth insulin was sold globally in 2013.
- The Company's ORMD-0801 oral insulin capsule has the potential to create a new paradigm in the treatment of Type 2 diabetes by treating the disease at an earlier stage, thereby slowing its progression. Having completed a successful FDA Phase 2a trial in Type 2 diabetes, ORMP is now planning its Phase 2b trial for Type 2 diabetes.
- ORMD-0901, an oral GLP-1 analog, addressing an annual \$2 billion market is expected to enter Phase 1b trials in Israel by the end of 2014. In Q3 of 2013 ORMP submitted a Pre-IND package to the U.S. FDA. ORMP expects to begin a Phase II multi-center study for ORMD-0901 in Q3-2015.

Major Risks to our valuation include the following:

- ORMP is in relatively early stages for its human clinical trials. Although clinical results have been favorable to date, there is no guarantee that results will continue to be favorable in later stage trials that include larger patient populations.
- Other small and large pharmaceutical companies are currently working on oral insulin and other oral delivery technologies. One or more of these may come to market with an oral insulin drug before ORMP does.

Diabetes Market: Key Data	
Total insulin market, 2013	\$20 Billion
Total projected insulin market, 2018	\$32.3 Billion
Global economic burden, 2012	\$471 Billion
Diabetics worldwide, 2012	371 Million
Diabetics in the U.S., 2012	25.8 Million

Source: Company Reports

Investment Merits

ORMP's proprietary platform allows oral delivery of drugs that are now only available via injection....

Greater patient compliance and better treatment...

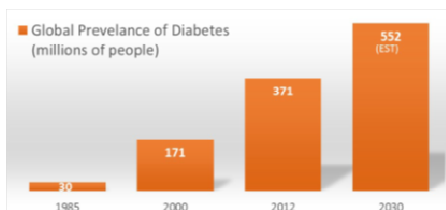
ORMP's first indication pursued is injectable oral insulin, which was a \$20 billion market in 2013 and is projected to grow to \$40 billion by 2020....

Oral insulin is expected to capture a large part of this market...

Oral insulin can be given at an earlier stage of the disease and slow its progression...

Oral insulin is released into the body in a more natural physiological way, through the digestive system, as compared to injections which directly enter the bloodstream. Oral insulin reduces systemic impact and side effects...

Diabetes has become an epidemic...



Very favorable Phase 2a trial results for oral insulin reported on November 3, 2014 in Type 1 diabetes are valuable data for trials and for potential partnerships...

Oral GLP-1 analog addresses \$2 billion injectable market expected to grow to \$6.6 billion by 2018...

POD™ Technology is Platform for Oral Delivery of Drugs & Vaccines: ORMP's unique Protein Oral Delivery (POD™) technology is a breakthrough in medical science that enables small proteins to travel through the gastrointestinal tract, via the liver, and into the bloodstream. This method of protein passage through the digestive system is more natural and should therefore eliminate the many side effects of delivery via needle directly into the bloodstream. Oral administration of current injection-only therapies for conditions including diabetes offers clear benefits including fewer side effects and greater comfort for patients. This can result in increased patient compliance and earlier treatment to slow disease progression.

ORMP Addresses \$50 Billion Market: Roughly \$50 billion worth of drugs and vaccines are currently delivered via injections. This includes the diabetes market where \$20 billion worth of injectable insulin was sold in 2013. This is expected to grow to \$40 billion by 2020. Oral insulin, for which ORMP is now in Phase 2, is expected to gain a significant share of the injectable market. Oral insulin can be delivered as a treatment in the early stages of the disease, thus potentially reducing the global economic cost of diabetes which is now \$500 billion. In addition, in 2012 there was a \$2 billion market for GLP-1 agonists, a drug used to treat diabetes and for which ORMP is in Phase 1. Other injectables include \$24 billion worth of vaccines which were sold in 2013; and interferon, which is used in the treatment of a number of diseases, a \$6.3 billion global market in 2011.

Phase 2 for Type 2 Diabetes - A New Paradigm for Treating an Epidemic: ORMD-o8o1 has the potential to create a new paradigm in the treatment of Type 2 diabetes by oral delivery of insulin at an earlier stage of treatment. Earlier treatment can potentially slow disease progression and delay late-stage complications. The oral insulin tablet is indicated for early stage Type 2 diabetes, before the disease advances to a stage when the patient becomes insulin-dependent for life. ORMP announced successful results from its completed ORMD-o8o1 Phase 2a study for Type 2 diabetes with the U.S. FDA. The Company is now preparing its multi-site Phase 2b study. The proposed study will enroll 180 patients through 30 U.S. sites, for 28 days of treatment in a double blind, randomized study.

Phase 2 for Type 1 Diabetes – New Data Important for Future Trials and Potential Pharma Partnership: On November 3, 2014 ORMP announced top line results in its Phase 2a US FDA trial for ORMD-o8o1 for Type 1 diabetes. The specific indication was the replacement of pre-meal injections for Type 1 diabetics with ORMD-o8o1 as an oral alternative. In patients treated with ORMP-o8o1 the data showed a decrease in the amount of exogenous insulin required (injectable synthetic insulin), with the treatment impact increasing in each of the seven days of treatment. The data also showed favorable lower fasting blood glucose levels in the treated group. These data are applicable to both Type 1 and Type 2 diabetes and are valuable for future clinical study design as well as to inform potential big pharma partners.

Phase I for Oral GLP-1 Analog in Type 2 Diabetes: Glucagon-like peptide-1 (GLP-1), a gastrointestinal hormone that stimulates the secretion of insulin from the pancreas, has shown to be beneficial for Type 2 diabetic patients in several ways including promoting weight loss. GLP-1 analogs are

currently available only via injection and accounted for \$2 billion in global sales in 2012. In Q3 of 2013 ORMP submitted a Pre-IND package to the FDA for ORMD-0901 its oral GLP-1 analog. A Phase 2 multi-center study is estimated to begin in Q2 of 2015.

Investment Risks

Clinical risk: ORMP is now in Phase 1 and Phase 2 trials for its platform technology. These are still fairly early, smaller trials. Although clinical results have been favorable to date, there is no guarantee that results will continue to be favorable in later stage trials that include larger patient populations. ORMP is also heavily concentrated on its POD platform technology. If the technology does not produce the desired clinical results, the Company does not have a diversified portfolio of technologies to fall back upon.

Regulatory risk: Even if ORMP advances into and completes Phase III trials, there is no guarantee that the FDA or other regulatory bodies will grant marketing rights for its drugs.

Competitive risk: The value of oral delivery of insulin and other drugs and vaccines currently delivered via injection is clearly recognized by the marketplace. Therefore, several small and large pharmaceutical companies are currently working on oral insulin and other oral delivery technologies. Other companies may develop oral insulin in the form of a tablet or capsule faster and reach market sooner than ORMP. Insulin via inhalers is already on the market and if ORMP's oral insulin capsules are approved, they would compete with inhalers, needles and pumps.

Financing risk: ORMP now has over \$15 million in cash, which may be sufficient to carry the Company through its trials to a point where it can execute a favourable partnership deal with a big pharma partner. If ORMP does not find a suitable larger partner, the Company may need to raise further capital to fund trials.

Active Clinical Programs

Product	Indication	Phase 1	Phase 2	Phase 3
ORMD-0801 Oral insulin	Type 2 Diabetes			
ORMD-0801 Oral insulin	Type 1 Diabetes			
ORMD-0901 Oral GLP-1	Type 2 Diabetes			

Results From Phase 2a ORMD-0801 Trial



Oramed ORA-D-010 – Key Top Line Results Total Exogenous Insulin

Total Exogenous Insulin – ITT – All Subjects

Placebo

Run-in Period Average – 87.34 IU

Day 6 and 7 Average – 90.17 IU

Change → 2.83 IU

Active Treatment

Run-in Period Average – 67.78 IU

Day 6 and 7 Average – 65.68 IU

Change → -2.09 IU

Favorable results in early stage trials may not pan out in later stage, larger studies...

As with all biotech products currently in clinical trials, the FDA and other global regulatory bodies may not grant marketing rights...

The clear value of oral delivery technologies means there are several other companies in the marketplace also developing oral delivery technologies...

To fund larger Phase III trials, ORMP will either need to fund raise or execute an agreement with a big-pharma partner ...

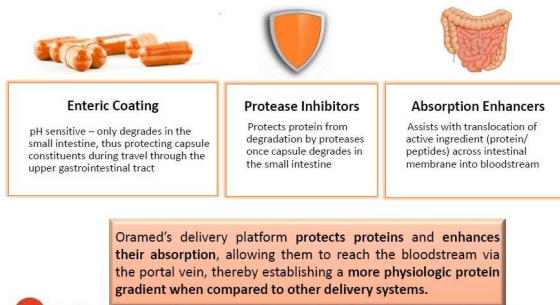
Current clinical programs targeting \$22 billion market for diabetes...

Phase 2a results published November 3, 2014 show the amount of insulin injections required by the treated group declined, as compared to the an increase in insulin injections for the placebo group...

POD Platform Technology

ORMP's 5 patent families for its platform oral delivery technology are pending or have been granted in numerous countries...

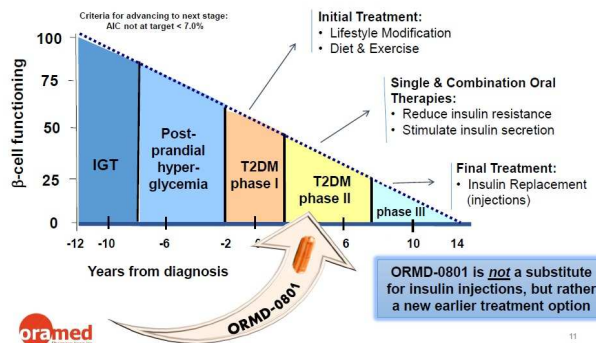
Oramed POD™ Technology: Oral Protein and Peptide Delivery and Absorption



Treating Diabetes Sooner

Designed to treat diabetes earlier and slow down disease progression...

ORMD-0801 Treats Diabetes Sooner: Type 2 Diabetes Stages & Treatment Options



Outlook

To reach a target price for ORMP, we began with a projected revenue model based on current and future estimates of the global diabetes market, as published by Transparency Market Research, who predicts a compound annual growth rate of almost 10% over the next four years to reach \$98.4 billion by 2018. Our market penetration figures were kept moderate to low and operating expenses, that include research and development, were kept high, in accordance with the stage of commercialization we expect ORMP to attain by the terminal date of our projections. Resulting EPS are \$2.62 in 2018 and \$4.39 in 2019.

...so our verdict is a BUY on this one

Valuation

Our discounted cash flow analysis used a discount rate of approximately 15%, based on the present risk-free rate, in addition to market risk and size risk premiums. A forward P/E of 18x was chosen, slightly lower than several publicly traded biotechs, to be conservative. In sum, we arrive at a fair value of \$45.00/share for ORMP – a 510% gain over the current price. Based on these analyses, we initiate coverage of ORMP with a BUY rating.

Oramed Pharmaceuticals Inc.
Discounted Cash Flow Valuation

	<u>2018</u>	<u>2019</u>	Discount rate	15%
EPS	\$2.62	\$4.39	P/E multiple	18 x

$$\text{Price} = \frac{\text{EPS}}{\text{P/E multiple}} = \frac{\$4.39}{18 \text{ x}}$$

$$\text{Price} = \$78.70$$

Discounted to 2015:

$$\text{PV} = \frac{\$78.70}{(1.15)^4} = \frac{\$78.70}{1.749} \quad \text{Price in 2015} = \$45.00$$

Disclosures:

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Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months. **Sell:** A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months. **Under Review [UR]:** A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

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