

**Transferring Coverage / Price Target Change** 

### January 5, 2016

#### **Key Metrics**

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ORMP - NASDAQ	\$8.49
Pricing Date	Jan 4 2016
Price Target	\$18.00
52-Week Range	\$10.74 - \$3.11
Shares Outstanding (mm)	11.5
Market Capitalization (mm)	\$97.6
3-Mo Average Daily Volume	147,302
Institutional Ownership	13%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	\$3.02
Price/Book	2.8x
Dividend Yield	NM
LTM EBITDA Margin	NM

### **EPS FY: August**

		Prior	Curr.	Prior	Curr.
	2015A	2016E	2016E		
1Q-Nov	(0.19)		0.07E		
2Q-Feb	(0.15)		(0.16)E		
3Q-May	(0.14)		(0.18)E		
4Q-Aug	(0.15)		0.35E		
FY	(0.66)		0.07E		
P/E	NM		NM		

Fiscal Year Ends August 31Quarters may not add due to changes in shares outstanding

### REVENUE

		Prior	Curr.	Prior	Curr.
	2015A	2016E	2016E		
1Q-Nov			3.0E		
2Q-Feb			NM		
3Q-May			NM		
4Q-Aug			8.0E		
FY			11.0E		

#### **Company Description:**

Oramed Pharmaceuticals, Inc. is an emerging firm in the diabetes sector based in Givat Ram, Israel.

# Oramed Pharmaceuticals, Inc. Rating: Buy

### **Oral Proteins Could Begin With Oral Insulin**

### **Investment Highlights:**

We are transferring coverage of Oramed and changing our price target to \$18. Oramed has developed proprietary technology for oral delivery of large molecules currently administered by injection. The lead product, ORMD-0801, is a formulation of insulin in Phase IIb development for Type 1 and Type 2 diabetes. Its second product, ORMD-0901, is an oral GLP-1 analogue in preclinical development with an IND planned for mid-2016.

**Oral Insulin Could Have Many Benefits:** Insulin is currently used by diabetics as an injection several times a day or by intravenous pumps. Oramed's technology combines enteric coating, protease inhibitors, and absorption enhancers to deliver insulin from the intestine to the bloodstream. An oral version could improve compliance and glucose control for these patients. This could reduce the long-term secondary morbidities of diabetes, including cardiovascular disease, renal nephropathy, and nerve damage. Delivering insulin without injections could also enable treatment for patients that could benefit from insulin but avoid self-injection.

**Phase IIb Results Expected In 2016:** The company has an ongoing Phase IIb study testing ORMD-0801 in Type 2 Diabetes. We expect the enrollment of 180 patients to be completed in 1Q2016. Allowing for the 28 day treatment period, safety and efficacy results could be announced around mid-year 2016.

**Marketing Agreement For China Was Recently Completed:** Oramed recently completed a marketing agreement for ORMD-0801 covering China. The agreement included a \$3.0 million payment upon signing, \$12 million in equity purchase at \$10.39 per share (34% premium at time of closing) and \$8 million in near-term milestone payments. Oramed can get a total of \$50 million in payments and 10% royalties on sales upon introduction. We see this as a positive sign for the product.

**Worldwide Marketing Agreement Could Follow:** Assuming Phase IIb trials in diabetes are positive, we would expect the company to form a development partnership that would provide expertise in Phase III trials and regulatory approval in exchange for marketing rights, milestones, and royalties on sales. The patient population in diabetes is so large that we believe a marketing collaboration with a company that has a sales force selling diabetes products would be the best way to reach prescribing doctors. We also believe this would be the best way to include patients with early stage Type II diabetes that could benefit from insulin but do not take it due to the self-injection required.

**Valuation:** We value the company based on our 2022 discounted EPS of \$5.94 per share, applying a discount rate of 30% with a multiple of 15X to derive our price target of \$18 per share. This would correlate with a projected market valuation of about \$230 million, in comparison to the company's current market valuation of about \$100 million. We estimate cash at December 31, 2015 at \$32 million, (\$2.54 per share), leaving a technology value of roughly \$70 million. We believe the valuation for a breakthrough technology platform for oral protein delivery that serves the diabetes market would have substantial upside if successful.

**Investment Thesis:** We are transfering coverage of Oramed with a Buy rating and a new price target of \$18 per share.

Oramed has developed drug delivery technology that enables large proteins to be given orally. These molecules are currently given by injection to avoid the effect of digestive enzymes as they pass through the digestive tract. Oramed's proprietary method shields the molecules from destruction and facilitates their absorption from the intestine to the bloodstream. Its lead molecule is ORMP-0801, an oral insulin for Type I and Type II diabetes. ORMP-0901 is a GLP-1 analogue, a second product for diabetes. Additional preclinical work has been completed in vaccines and interferons.

**Two Phase IIb studies are in progress for ORMP-0801 in both Type I and Type 2 diabetes.** These trials are designed to show that ORMD-0801 can be delivered orally, be absorbed through the intestine, and reach the liver through the portal vein. These Phase IIb trials are designed to give data on pharmacokinetics and safety, and will be used to design the Phase III program. The Phase III trials will be designed to show efficacy in various stages of diabetes and potential use in different clinical indications.

If ORMD-0801 can simply reduce the number of daily insulin injections, it could help patients maintain their target glucose levels. Many diabetic patients are hospitalized each year due to poor glucose control, often attributed to difficulty complying with insulin regimens. Even a combination of oral and injectable administration could be beneficial in slowing the progression of the disease and reducing its long-term effects and mortality. If ORMD-0801 were able to partially or completely replace insulin injections, it would be a substantial medical breakthrough for both Type 1 and Type 2 insulindependent patients.

In addition to replacing injectable insulin, there is a large population of early stage and pre-diabetic patients that could benefit from insulin but do not use it due to their aversion to daily injections. Use in these populations could slow the progression to diabetes and avoid its many morbidities. ORMD-0801 could allow earlier use of insulin and have a significant clinical impact on the way diabetes is treated.

Our financial projections allow for large Phase III trials, and expect the company to use the data to seek a partnership for clinical and regulatory support. We expect the Phase III trials to require clinical endpoints such as hemoglobin A1c (HbA1c, glycated hemoglobin), consistent with the current standards of diabetes product approvals from the FDA. The company plans to file an IND in 2016 to start US clinical trials for ORMD-0901, its oral GLP-1 analogue, a second diabetes drug that is also currently administered by injection. Avoiding daily GLP-1 injections could replace the current sales and enlarge the market, estimated at over \$3 billion in 2015 sales. Type I diabetes and Type II diabetes are both very large markets, with about 30 million patients in the US and over 387 million worldwide.

In December 2015, the company completed its marketing agreement with Hefei Tianhui Incubator Technologies (HTIT) to cover marketing in China. The partnership included \$15 million upon signing, with \$3 million in cash plus an equity investment of \$12 million (1,155,367 shares at \$10.39 per share). Additional milestones are worth up to \$8 million are payable in the short-term, with up to \$38 million upon milestone completion. Oramed will also receive 10% royalties on sales. We see this as a strong positive that adds cash for FY2016 and could lead to a large stream of royalties to the company.

We expect the stock to be driven by data from the Phase IIb trial in Type 2 diabetes. The Phase IIb trial is expected to complete treatment in 1Q16, with results announced shortly afterward. An ex-US human trial is in progress with GLP-1 to collect data for in an IND, expected in 2016. We anticipate these trial results and development milestones to be important inflection points for the stock in the coming year.

**Investment Conclusion:** In our view, oral insulin products using Oramed's technology could expand the market and/or replace products with several billions in current sales, change treatment of early-stage diabetes, and improve compliance for injection-averse patients. The high cost of caring for diabetes and its long-term consequences have been attributed to the high pricing of the current products, so that our models are close to current insulin price levels. Oral insulin products

have been attempted and failed in the past, so that the high discount to fair value is to be expected. If Phase IIb is successful, we expect a substantial increase in technology value.

We value the company based on our 2022 discounted EPS, applying a discount rate of 30% with a multiple of 15X to derive our price target of \$18 per share. This would correlate with a projected market valuation of \$230 million, in comparison to the company's current market valuation of about \$100 million. We estimate cash to be about \$32 million (\$2.54 per share) at December 31, 2015, leaving a technology value of roughly \$70 million for products that could generate billions in sales. We believe the valuation for breakthrough technology platform for oral protein delivery that serves the diabetes market would have substantial upside if successful.

### **Investment Risks**

Oramed is developing a new technology that would make large proteins deliverable with oral capsules. The oral route of delivery requires modifying the drug to pass through the mouth and stomach without being denatured or destroyed by digestive enzymes. Once in the intestine, it must be able to resist additional proteases, then be absorbed through the wall of the intestine and enter the circulation. The company has developed proprietary methods to solve these problems, but technology is in clinical testing and has not yet been shown to be effective. Diabetes is a complicated disease, with many clinical and regulatory concerns that must be addressed. The upcoming clinical trial results will be important data to assess the viability and practicality of the products.

Phase IIa studies were encouraging, but had short treatment period and a small number of patients. The current Phase IIb studies are enrolling a larger number of patients that we expect to have enough statistical power to determine the pharmacokinetics and potential success of the technology. The data from these studies is crucial to the future of the company.

Diabetes has been treated with injectable insulin for almost 100 years, and attempts to make versions that avoid injection have had numerous failures in clinical development. We believe the company's current valuation reflects a low probability of success in comparison to its revenue potential.

Oramed does not have its own manufacturing facilities and its clinical supplies are produced by contract manufacturers. The Phase IIa trial was affected by a formulation problem causing part of the drug dosage to be ineffective and, in our opinion, some of the data to be unreliable. The clinical trials are being conducted by a contract research organization. Although outsourcing to third party manufacturers and CROs is common in the drug development industry, the company relies on these third parties. Disagreements or problems with these companies can have effects on the company's clinical supplies, timelines, or integrity of the data.

### **Exhibit 1. Oramed Product Pipeline**

Product	Description	Indication	Research	Phase I	Phase lla	Phase IIb	Phase III
ORMD-0801	Oral insulin	Type 2 diabetes					
ORMD-0801	Oral insulin	Type 1 diabetes					
ORMD-0901	Oral GLP-1 analogue	Type 2 diabetes					
ORMD-0801 and 0901	Combination studies	Type 2 diabetes					

Source: Oramed Pharmaceuticals

Product	Indication	Event	Timeline
ORMD-0801	Type 2 diabetes	Phase IIb initiated	2Q15
ORMD-0801	Type 2 diabetes	Marketing agreement covering China	1Q16
ORMD-0801	Type 2 diabetes	Phase IIb enrollment completion	1Q16
ORMD-0801	Type 2 diabetes	Phase IIb trial results announcement	2H16
ORMD-0801	Type 2 diabetes	Glucose clamp studies completion	2H16
ORMD-0901	Type 2 diabetes	File IND	2H16
ORMD-0901	Type 2 diabetes	Initiate Phase II studies	4Q16
ORMD-0801	Type 2 diabetes	Initiate Phase III studies	2017
ORMD-0801	Type 1 diabetes	Initiate Phase III studies	2017

### **Exhibit 2. Oramed Milestones and Events**

Source: Company reports and Aegis Capital estimates

### **Recent Financial Results**

The company reported fiscal 2015, ended August 31, 2015, with a loss of \$7.2 million, or \$(0.67) per share. The loss was attributable to R&D expense of \$4.8 million and SG&A expense of \$2.6 million. Cash on hand at the end of the fiscal year was \$17.2 million, or \$1.58 per share.

On November 20, 2015, Oramed announced the marketing agreement with HTIT. The agreement was finalized on December 30, so the signing fee of \$3 million in cash plus the \$12 million equity purchase should be recognized in 1Q16. The share purchase at \$10.39 was for 1,155,367 shares, or about 10% of the 11.5 million shares outstanding at the time the deal was signed. We expect 1Q16 expenses of \$2.2 to be offset by the recognition of the \$3 million milestone, with net income of about \$0.9 million. We estimate the HTIT milestone and equity additions will bring the cash level to about \$32 million and shares outstanding to 12.6 million, or about \$2.54 per share, at December 31, 2015. With additional milestones of \$8 million in the near-term, we believe the company has sufficient cash on hand to fund operations. Due to the funding requirements for the next stage of clinical development and pipeline projects, we expect the company to raise additional capital in the coming years.

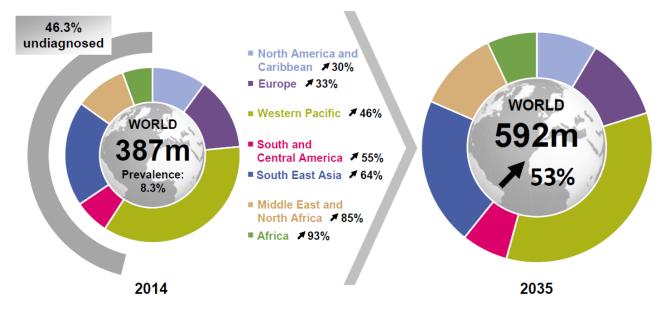
### **Company Background**

Oramed is developing a proprietary technology to make drugs that are currently administered by injection into capsules that can be taken orally. The technology platform, known as Protein Oral Delivery or "POD", protects the proteins and enhances their absorption. This allows them to be swallowed, pass through the stomach, and be absorbed through the intestine to the portal vein, which transports it directly to the liver. Passing directly from the intestine via the portal vein to the liver is closer to the physiological mechanism than injection through the circulatory system.

Insulin is a large protein that is injected to avoid the enzymes of the digestive tract that easily denature, inactivate, or destroy it. Many attempts have been made to develop insulin that can be swallowed, inhaled, or avoid the injections necessary for large proteins. Oramed's technology shields insulin in the stomach and intestine, then helps its adsorption in the intestine to the bloodstream. Many oral insulin products have failed clinical development, while inhaled versions of insulin have reached the market but had limited use. None have achieved both clinical and commercial success.

The Company's lead product is ORMD-0801, oral insulin capsule currently in Phase IIb trials. ORMD-0901 is an oral version of exenatide, also known as glucagon-like protein 1 or GLP-1, also in development for Type 2 diabetes. A combination study of both ORMD-0801 and ORMD-0901 is in early stage testing, pending the results of the Phase IIb studies. Other applications for interferons and vaccines, including the influenza vaccine, are in research stages.

**Exhibit 3. Diabetes Is A Worldwide Problem** There are an estimated 387 million people with diabetes today, expected to increase by 53% to 592 million people by 2035.



Source: International Diabetes Federation, Diabetes Atlas 6<sup>th</sup> Edition, 2014

### **Trials Are On Going In Type 1 and Type 2 Diabetes**

Type 2 diabetes is the form in which the body does not use insulin properly (insulin resistant), causing high blood glucose and insufficient transport of glucose into cells. This is the form typically associated with aging or obesity. In contrast, Type 1 diabetes is an autoimmune disease in which the insulin-producing cells of the pancreas are destroyed. This is often associated with juvenile-onset in which patients quickly become insulin dependent.

Type 2 diabetes has a gradual onset, beginning with insulin resistance. In the pre-diabetic stages, it can be treated with diet and exercise to balance sugar intake and energy use. As the resistance increases, metformin is used to increase insulin sensitivity. As the disease progresses, insulin injections are used to control blood glucose levels. The high glucose levels in the bloodstream affect the circulatory system, nerves, and tissues, and can lead to blindness, kidney failure, heart attack, stroke and amputation. There are an estimated 30 million people in the US with diabetes, divided between about 10 million Type 1 patients and 20 million Type 2 patients. The International Diabetes Federation estimates that 387 million people have diabetes today.

One of the first objectives in ORMD-0801 development is to control the excess glucose production and high blood sugar that is common while Type 2 diabetic patients are sleeping. A Phase IIa study to determine pharmacokinetics and establish safety administered ORMD-0801 before bedtime, and tested fasting blood sugar 8 hours later. The FDA had requested a safety trial before initiating a statistically powered efficacy study due to concerns that dosing before bedtime could cause hypoglycemic (low blood glucose) events while the patient was asleep.

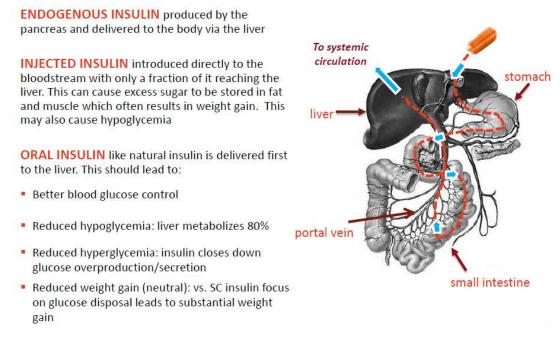
The trial enrolled 30 patients and tested the drug for 7 days. The study compared two dosing levels with a placebo group, 10 patients in each arm. The low dose group received 460 IU insulin as 16 mg of ORMD-0801 (two 8 mg capsules) and a high does group received 690 IU insulin as 24 mg (an 8mg and a 16 mg capsule). A manufacturing/dissolution problem with the 16 mg capsule caused it to lose potency, so that the 24 mg group effectively received only 8 mg of active drug, turning the arm into a low-dose group. The dose-response data was consistent with what would be expected, but the trial was criticized for the manufacturing problem and the lack of 24 mg dosing group.

The results of the Phase IIa study showed meaningful data in the nighttime glucose levels (determined using a continuous glucose monitor). The drug showed a reduction in mean daytime and nighttime glucose readings, as well as lowering the fasting blood glucose concentrations in comparison to the placebo group. There were no serious adverse events, and the results allowed moving to a larger statistically-powered Phase IIb study.

The Phase IIb trial began in June 2015. The study has two treatment groups, receiving either 16 mg (with two 8 mg capsules and one placebo capsule) or 24 mg (three 8 mg capsules) for a 28-day treatment period. The planned enrollment is 180 patients at over 30 sites. By September 2015, the trial had enrolled 98 patients, with full enrollment expected around early 2016 and results expected in mid-2016. The endpoints are designed show safety and pharmacokinetics of ORMD-0801.

In addition to the Phase IIb, the company began a glucose clamp study with Type 2 diabetic patients in April 2015. The glucose clamp is a method for quantifying insulin absorption in order to measure a patient's insulin sensitivity and how well a patient metabolizes glucose. We expect the study to be completed around mid-2016, in time to contribute to the design of Phase III. The study is being performed at The University of Texas Health Science Center at San Antonio and University Health System's Texas Diabetes Institute.

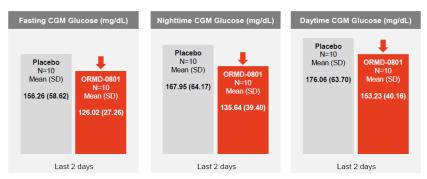
**Exhibit 4. ORMD-0801 Travels Directly To The Liver For Release** Oramed's oral insulin is absorbed through the intestine, then travels directly through the liver through the portal vein, where it can be stored for release as needed. This is closer to the natural mechanism of action than having insulin travel through the circulatory system.



Source: Oramed Pharmaceuticals

**Exhibit 5. The Phase IIa Trial Showed Safety With Evidence Of Efficacy** The Phase IIa Study was designed to show basic safety and tolerability. No hypoglycemic events were reported, and sustained reduction in glucose was seen at night, day, and mean fasting glucose test. It was not powered to show efficacy, but some evidence of its effect on lowering glucose was detected. There were no serious side effects.

- 30 T2DM patients
- Primary objective: Safety and tolerability
- Secondary objective: Pharmacodynamic effects on mean nighttime glucose



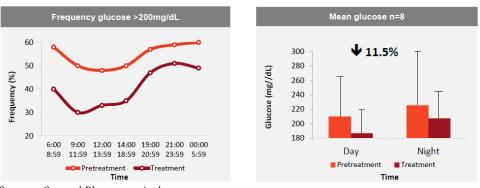
Source: Oramed Pharmaceuticals

**Type 1 Diabetes** In 2014, Oramed conducted a Phase IIa trial in Type 1 diabetics to establish basic safety. ORMD-0801 was given to 25 patients for seven days before meals to test safety and tolerability. The study treated 25 patients for seven days, but was not powered to show efficacy. During the seven day treatment period, patients showed a decrease in exogenous insulin use, a decrease in post-prandial glucose, a decrease in daytime glucose by continual glucose monitoring and an increase in post-prandial hypoglycemia in the active group. We consider the results sufficient to justify moving forward to a Phase IIb study.

Exhibit 6. Preliminary Results In Type 1 Diabetes Patients Lowered Glucose Levels and shows promise for futher development.

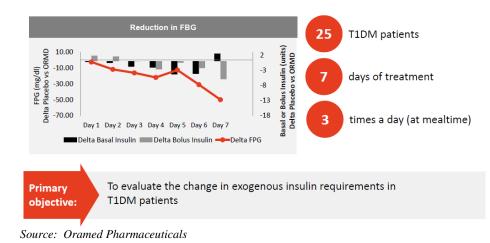
### Design:

- Monitor glycemic stability of orally administered ORMD-0801
- Uncontrolled T1DM patients
- 1 capsule of 8 mg insulin administered before meals, three times daily at mealtime
- Continuous glucose monitoring



Source: Oramed Pharmaceuticals

### Exhibit 7. Phase IIa Study in Type I Diabetes Showed Consistent and Accumulative Effect of ORMD-0801



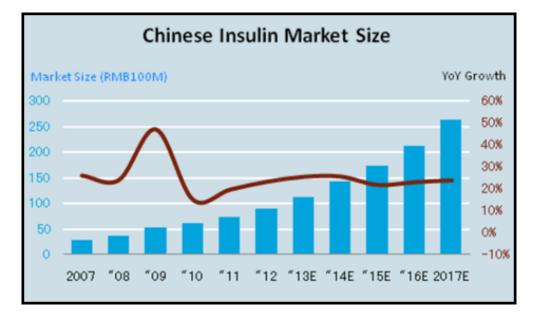
Blood glucose levels are lower, day and night, compared to control group

### **ORMD-0801** Partnerships and Marketing Agreements

In December 2015, the company finalized its agreement covering China with Hefei Tianhui Incubator of Technologies, known as HTIT. The agreement gives HTIT marketing rights for ORMD-0801 throughout China, Hong Kong and Macau in exchange for \$38 million in milestone payments, \$12 million equity purchase, and 10% royalties on sales. Oramed received a \$3 million payment on signing, plus the equity investment of \$12 million for 1,155,367 shares at \$10.39 per share. This was a premium of 34% to the previous day's \$7.75 market price before the deal was announced in November. Oramed can receive additional milestones of \$38 million, plus a 10% royalty on sales. Upon issuance, HTIT will own about 9% of the estimated 12.4 million shares to be outstanding.

We see HTIT as a strong partner for the Asian countries, with a growing diabetes business and insulin production facilities in Hefei, China. HTIT is partially owned by Sinopharm Group, a private equity firm that develops early-stage technologies for the Chinese health care market. In addition to being the largest country in the world, the Chinese people have an inherently high rate of diabetes. This has been worsened by adoption of Western diets that include processed foods, salt, cigarettes, and inactivity. An estimated 8% to 9% of its 1.4 billion people are diagnosed with diabetes.

**Exhibit 8.** Chinese Insulin Market An estimated 8% to 9% of the Chinese population has diabetes, implying population of over 100 million diabetic patients.



Source: Global and China Insulin Industry Report 2013-2017, ResearchInChina LLC.

**We Expect An Agreement For Late Stage Testing and Marketing For the US and ROW** Oramed has stated that it plans to seek a commercial partner if the Phase IIb trial is successful. The partnership could include clinical, regulatory, and marketing responsibilities for each company. We believe this is a good strategy, since the Phase III program will require a large trial with development expertise and funding that is beyond the company's current capacity. Trials for regulatory approval are likely to require a large number of patients with a substantial treatment period.

We also point out the oral insulin and exenatide applications are the first applications of the Oramed technology. Additional applications or the oral protein delivery technology have not been disclosed, although vaccines and interferons have been mentioned. Other companies could be interested in applying the technology to other injectable drugs, and form a collaborative agreements covering additional products either including or separate from ORMD-0801 and ORMD-0901.

There are many companies that have their own sales organization for diabetes drugs that could be leveraged by marketing Oramed's oral insulin or GLP-1. The market is highly competitive and the number of prescriber is quite large, so that experience in developing and marketing diabetes products would be critical to the success of the product. We believe bidding would be competitive, and could result in a deal that has a combination of Phase III and regulatory support as well as marketing rights.

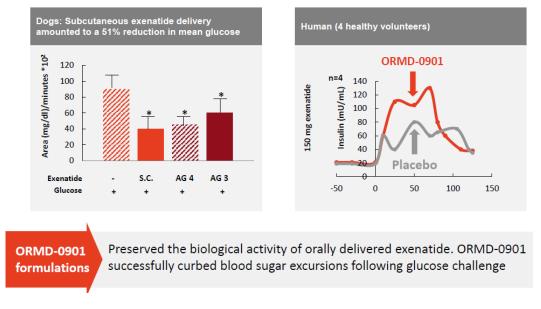
### **GLP-1 Analogue Could Be A Large Opportunity**

Exenatide, also known as glucagon-like peptide-1 or GLP-1, is a hormone produced in the intestine that has several actions in regulating glucose. Exenatide stimulates the beta cells to secrete insulin after a meal or when glucose is high, lowering blood glucose. It also suppresses pancreatic glucagon secretion and helps lower hepatic glucose output. In addition, it slows gastric emptying, effectively slowing the digestive process and the rate that glucose enters the blood after meals. This causes a feeling of fullness faster and increases satiety, causing users to eat less and lose weight. Another benefit of GLP-1 is that it increases the number of beta cells (cells that manufacture and release insulin) in the pancreas and, possibly, protecting the heart.

There are several GLP-1 analogue drugs on the market. Victoza/Saxenda (from Novo Nordisk) is once-daily injection that had 2014 sales of about \$2.4 billion, and nearly \$2 billion in the first nine months of 2015. AstraZeneca has two GLP-1 drugs that differ by injection frequency. Byetta is injected with meals, while Bydureon is injected once a week. The two drugs reported 2014 sales of about \$767 million.

ORMD-0901 is an oral exenatide GLP-1 analog-based preparation designed with Oramed's oral formulation technology. Oramed has completed pilot clinical trials of ORMP-0901 in healthy volunteers that demonstrated ORMD-0901 was able to reach the bloodstream and show biological activity after oral administration, then tested with an oral glucose load. These data are encouraging, although we point out that only six subjects were analyzed for safety, with just four subjects considered for the efficacy evaluations. The study was performed in Israel with human volunteers to obtain the data to file an IND to begin human studies in the US. This filing and start of a Phase 1b study with ORMD-0901 is planned for 2016.

**Exhibit 9. Preclinical and Phase I Studies of ORMD-0901 Are Encouraging** Oramed has conducted preclinical studies and has tested ORMD-0901 in Israel with Type 2 diabetes patients. An IND submission for human clinical trials is planned for 2016.



Source: Oramed Pharmaceuticals

**Combination Study:** In February 2013, Oramed conducted a clinical trial on Type 2 diabetic volunteers with ORMD-0801 in combination with the oral exenatide capsule, ORMD-0901. The company is focusing on the ORMD-0801 Phase IIb studies in Type 1 and Type 2 diabetes before moving forward with combination studies. Once the efficacy data from the single-agent trials is available, the company will design a combination study for the combination. At this point, we do not include any valuation for either ORMD-0901 or the combination of ORMD-0801 and ORMD-0901.

**Undisclosed Early Stage Products:** In August 2015, Oramed made a licensing agreement with an unnamed pharmaceutical company to perform a feasibility study to evaluate the combination of Oramed technology with one of the Pharma Company's propriety injectable compounds. This is aimed at determining the ability if the compound can be delivered orally, and could provide data that would lead to a collaborative agreement. While we consider this too early to value, it is a potential indication that could result in future fees, milestones, and royalties. We include this in the technology value of the stock price of roughly \$70 million.

**Valuation** Our models are based on Oramed successfully completing Phase IIb trials in 2016, then moving to Phase III trials in late 2017. This allows about 12 to 18 months for design of the Phase III trial, as well as forming a partnership to fund and conduct the Phase III trial. We allow two years for the Phase III trial, then another 12 months for NDA submission and about 12 more months for approval with product launch in late 2020. Our estimates include the remaining milestones from the HTIT agreement based on Phase III trials, approval, and sales levels. We have not included milestone revenues from future collaborative agreements, although they could be substantial.

We have assumed a small pricing premium over the current injectable insulin products, with modest market penetration. In our models, the first revenues begin in 2021, and assume Oramed receives 10% royalties on sales by a partner. We base our price target on the first full year of sales in 2022. Our price target of \$18 per share is based on our estimated FY2022 EPS of \$5.94, discounted at 30% with a multiple of 15X.

This 12-month price target correlates with a market capitalization of about \$210 million, which we consider relatively low for a platform technology that allows oral delivery of large proteins such as insulin and GLP-1. We have not included any of the milestones from a potential partnership for the Phase III trials that would include US or European marketing rights, although an agreement could be worth millions of dollars at each stage of development.

### **Exhibit 10. Oramed Valuation Table**

Current Year	2016
Year of EPS	2022
Earnings Multiple	15
Discount Factor	30%
Selected Year EPS	\$ 5.94
NPV	\$ 18
Source: Aegis Capital estimates	

		Discount	Rate and Earnir	ngs Multiple Va 2022 E		s Constant	
	18.5	5%	10%	15%	20%	25%	30%
Earnings	0	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00 \$	-
	5	\$22.16	\$16.76	\$12.84	\$9.94	\$7.78 \$	6.15
	10	\$44.31	\$33.52	\$25.67	\$19.89	\$15.57 \$	12.30
	15	\$66.47	\$50.28	\$38.51	\$29.83	\$23.35 \$	18.45
	20	\$88.62	\$67.04	\$51.34	\$39.77	\$31.13 \$	24.60
	25	\$110.78	\$83.80	\$64.18	\$49.72	\$38.92 \$	30.76
	30	\$132.93	\$100.55	\$77.01	\$59.66	\$46.70 \$	36.91
	35	\$155.09	\$117.31	\$89.85	\$69.60	\$54.48 \$	43.06

Oramed: Income Statement (\$000)																			
Fiscal YE August 31	2014A	1Q15A	2Q15A	3Q15A	4Q15A	2015E	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
License and Milestone Payments							3,000			8,000	11,000	-	2,000	10,000	10,000		5,000	-	-
Product sales																			
ORMD-0801 Type 2 diabetes															-	39,813	79,625	119,438	119,438
ORMD-0801 Type 1 diabetes															-	8,085	32,340	60,638	60,638
ORMD-0901 Type 2 diabetes															-	-	315	525	1,050
Total Product Sales	-	-	-	-	-	-	3,000	-	-	8,000	11,000	-	2,000	10,000	10,000	47,898	117,280	180,600	181,125
Expenses																			
Cost of Goods Sold													-	-	-	-	-	-	-
%COGS																			
Research and Development	3,277	1,302	1,136	915	1,428	4,781	1,500	1,700	1,900	2,100	7,200	8,000	10,000	12,000	15,000	17,500	20,000	23,000	26,000
%R&D																			
General and Administrative	2,629	600	538	719	745	2,602	765	750	850	1,000	3,365	3,500	4,500	5,500	6,500	8,000	9,000	11,000	12,500
%SG&A																			
Financial income	(225)	(27)	(38)	(51)	(52)	(168)	(65)	(50)	(50)	(50)	(215)	(215)	(250)						
Other financial expenses	11	21	1		(4)	18	(5)	(10)	(10)	(10)	(35)	(50)	(50)						
Total expenses	5,692	1,896	1,637	1,583	2,117	7,233	2,195	2,390	2,690	3,040	10,315	11,235	14,200	17,500	21,500	25,500	29,000	34,000	38,500
Operating Income (Loss)	(5,692)	(1,896)	(1,637)	(1,583)	(2,117)	(7,233)	805	(2,390)	(2,690)	4,960	685	(11,235)	(12,200)	(7,500)	(11,500)	22,398	88,280	146,600	142,625
Describes of some involvements	(0.4)	9		(1)	(11)	(0)	(0)				(0)								
Recapture of value of previously written	(34)	9		(1)	(11)	(3)	(2)				(2)								
Reclassification adjustment for gains in	80	050	-	(22)	(00.4)	(100)	(50)	(100)	(100)	(100)	(050)								
Unrealized gain on available for sale se	(194)	350	(7)	(62)	(384)	(103)	(50)	(100)	(100)	(100)	(350)								
Total other income	(148)	359	(7)	(63)	(395)	(106)	(52)	(100)	(100)	(100)	(352)					_			_
Pretax Income	(5,544)	(2,255)	(1,630)	(1,520)	(1,722)	(7,127)	857	(2,290)	(2,590)	5,060	1,037	(11,235)	(12,200)	(7,500)	(11,500)	22,398	88,280	146,600	142,625
	(0,011)	(2,200)	(1,000)	(1,020)	(1,1==)	(,,,,,,)		(2,200)	(2,000)	0,000	1,001	(11,200)	(12,200)	(1,000)	(11,000)	22,000	00,200	110,000	112,020
Income Tax Benefit (Provision)	4				(1)	(1)	1	2	5	3	11	-		-	_	_	_	29,320	35,656
Tax Rate	-				(1)	(1)		2	5	0								20%	25%
Net Income (loss)	(5,548)	(2,255)	(1,630)	(1,520)	(1,721)	(7,126)	856	(2,292)	(2,595)	5,057	1,026	(11,235)	(12,200)	(7,500)	(11,500)	22.398	88.280	117,280	106.969
	(0,010)	(=;=00)	(1,000)	(1)0=0)	(1,1=1)	(1,120)		(=,=v=)	(2,000)	0,001	1,020	(11,200)	(12,200)	(1,000)	(11,000)	22,000	00,200	111,200	100,000
EPS (basic)	(0.60)	(0.19)	(0.15)	(0.14)	(0.15)	(0.66)	0.07	(0.16)	(0.18)	0.35	0.07	(0.79)	-	-	-	-	-	-	-
EPS (basic) EPS (diluted)	(0.60)	(0.19) (0.19)	(0.15) (0.15)	(0.14) (0.14)	(0.15)			(0.16) (0.16)	(0.18) (0.18)	0.35	<b>0.07</b>	(0.79) (0.77)							- 7.14
EPS (basic) EPS (diluted) Wqtd Avq Shrs (Basic) - '000s	<b>(0.60)</b> (0.60) 9,244	(0.19) (0.19) 10,142	(0.15) (0.15) 10.826	(0.14) (0.14) 10.828	(0.15) (0.15) 11.484	(0.66) (0.66) 10.820	0.07 0.07 11,496	(0.16) (0.16) 14,507	(0.18) (0.18) 14,522	0.35 0.35 14,536	0.07 0.07 13,765	(0.79) (0.77) 14.573	(0.83) 14.631	- (0.51) 14,690	- (0.78) 14.749	- 1.51 14.808	- 5.94 14.867	- 7.86 14,927	- 7.14 14,986

Source: Company reports and Aegis Capital estimates

### **Required Disclosures**

### **Price Target**

Our 12-month price target is \$30.00 per share.

### Valuation Methodology

We utilize a discounted cash flow-based risk-adjusted Net Present Value (rNPV) approach to value the shares. Using this methodology, we derive a total firm value of roughly \$400 million, which translates into a price objective of \$30.00 per share, assuming ~\$20 million in cash and approximately 13 million shares outstanding (fully-diluted) at the end of 2015.

### **Risk Factors**

Issues that could prevent the achievement of our price objective include, but are not limited to, clinical, regulatory, competitive, reimbursement and financial risks. Drugs in clinical development may not advance due to inadequate safety, efficacy, or tolerability. Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a drug candidate at all. The firm may require substantial funding to complete the clinical development of its candidates and establish commercial infrastructure, which could be dilutive to current shareholders. We expect competition for the company's drugs from several public and private companies developing pharmaceuticals. Sales of the firm's drugs could depend upon reimbursement from private, as well as public, reimbursement agencies.

### For important disclosures go to www.aegiscap.com.

Research analyst compensation is dependent, in part, upon investment banking revenues received by Aegis Capital Corp.

Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.



		vestment Banking ices/Past 12 Mos.
Rating	Percent	Percent
BUY [BUY]	88.33	60.38
HOLD [HOLD]	11.67	42.86
SELL [SELL]	0.00	0.00

Meaning of Ratings

A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

### **Other Disclosures**

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