Zacks Small-Cap Research

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Oramed Pharma (ORMP-NASDAQ)

ORMP: New drug candidate nominated; Positive data from Phase IIb ORMD-0801 and Phase Ib ORMD-0901 reported, a significant de-risk event for the company.

Our relative valuation metrics indicates a fair value of $25/share.

Current Price (01/26/18)	$8.34
Valuation	**$25.00**

OUTLOOK

Oramed has a unique, proprietary protein oral delivery (POD™) platform technology with a mid-stage pipeline. The company's lead candidate ORMD-0801 is an oral insulin targeting the huge insulin market. The company just reported positive data from the Phase IIb ORMD-0801 study for type 2 diabetes. The company's second lead candidate ORMD-0901 is an oral formulation of GLP-1 analog exenatide, which will enter Phase IIb study in 2017. We estimate ORMD-0801/0901 to reach the market in 2019.

We are optimistic about the prospect of the company and value its shares at $25 per share.

SUMMARY DATA

52-Week High	**$11.15**
52-Week Low	**$5.87**
One-Year Return (%)	**25.41**
Beta	**0.34**
Average Daily Volume (sh)	**41,181**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$120**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-7.4**
P/E using 2019 Estimate	**-9.9**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Products**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2016	0.00 A	0.13 A	0.16 A	0.35 A	0.64 A
2017	0.61 A	0.61 A	0.61 A	0.62 A	2.46 A
2018					2.00 E
2019					2.50 E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2016	-$0.21 A	-$0.14 A	-$0.15 A	-$0.37 A	-$0.87 A
2017	-$0.20 A	-$0.24 A	-$0.15 A	-$0.20 A	-$0.79 A
2018					-$1.20 E
2019					-$1.65 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

Update on Oral Insulin Program ORMD-0801

The FDA Meeting

In early September 2017, Oramed concluded a meeting with the US FDA regarding ORMD-0801, the Company's novel **oral insulin** formulation.

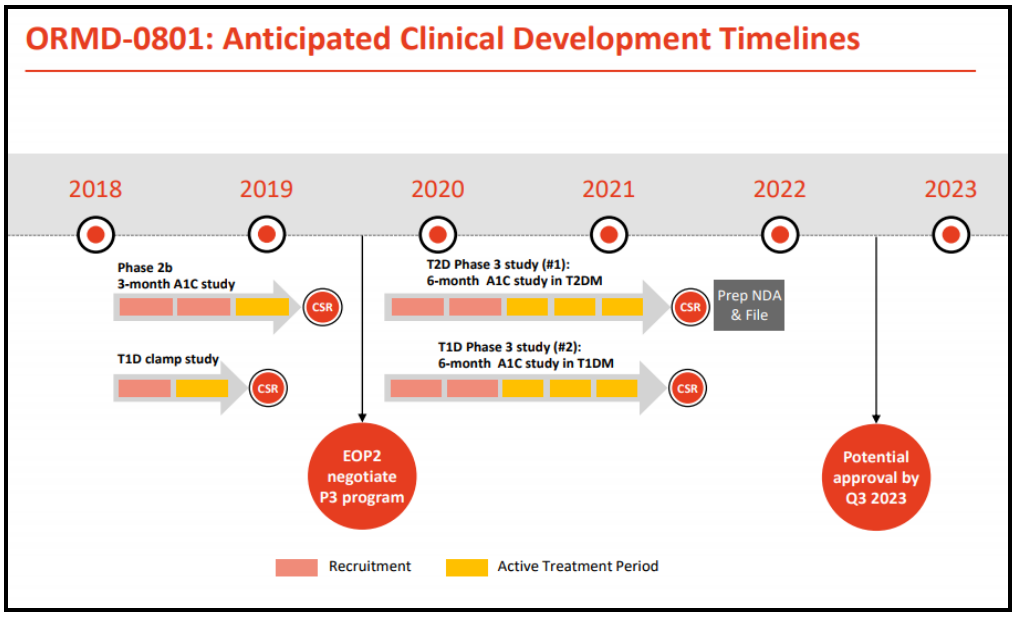
Here are some highlights from the meeting:

- the FDA gave ORMD-0801 a clear guidance that the regulatory pathway for submission would be a Biologics License Application (BLA).
- Such a pathway would grant a full 12 years of marketing exclusivity for ORMD-0801 if approved. On top of this, an additional six months of exclusivity can be granted if the product also receives approval for use in pediatric patients.
- The FDA also confirmed at the meeting that the approach to nonclinical toxicology, CMC and qualification of excipients would be driven by their published guidance documents, consistent with the Company's expectations.
- The FDA also made specific recommendations for clinical trials designed to provide pivotal data prior to registration.

Since oral insulin may have a positive more physiologic first-pass effect on the liver with less systemic insulin exposure compared to traditional injectable insulin, at the suggestion of the FDA, Oramed plans to initiate **a three-month trial** in patients with type 2 diabetes to evaluate the effect of ORMD-0801 on HbA1c, the main FDA registrational endpoint, later this year.

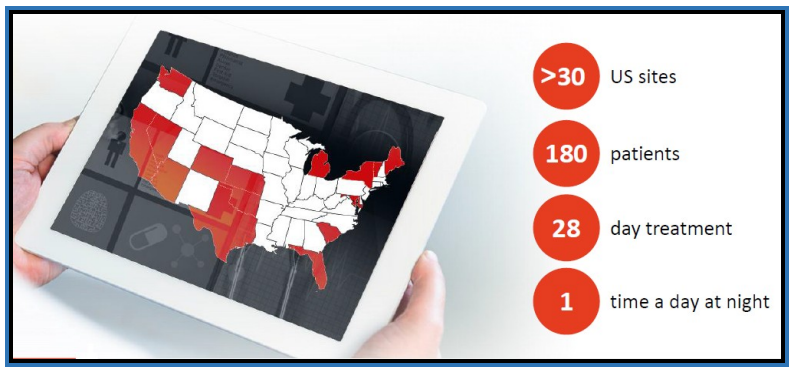
In addition, the FDA confirmed the Company's ability to use insulin from different suppliers like HTBT (Hefei Tianmai Biotechnology Development Co., Ltd., Hefei, China) in the **Phase III** study.

Oramed plans on implementing the FDA's feedback in the coming months which should facilitate the confirmatory Phase III study and registration of ORMD-0801.



Initial Top Line Phase IIb Data

ORA-D-007 is a double-blind, randomized, 28-day **Phase IIb** clinical trial designed to assess the safety and efficacy of **ORMD-0801** in **type II** diabetics. The trial will evaluate ORMD-0801 over a longer treatment period (28-day vs 7-day in the Phase IIa study) and will have statistical power to give greater insight into the drug's efficacy.



The Phase IIb trial was initiated on June 30, 2015 and conducted at 33 clinical sites in the United States.

Primary Objectives:

- To evaluate the pharmacodynamics effects of ORMD-0801 on mean nighttime glucose (determined using continuous glucose monitoring (CGM)).
- To evaluate the safety of ORMD-0801, including incidence of hypoglycemia.

Secondary Objectives:

- To evaluate changes from baseline in fasting blood glucose (FBG), morning fasting serum insulin, c-peptide, and triglycerides.

Exploratory Objectives:

- To evaluate the immunogenicity of ORMD-0801 through quantitation of anti-insulin antibodies.
- To evaluate changes from baseline in HbA1c, 24-hour, fasting and daytime glucose levels on CGM, weight, and C-Reactive Protein (CRP).

On May 18, 2016, Oramed announced **positive top-line data** from the **Phase IIb** study of ORMD-0801. The study achieved its primary objective: a significant reduction of weighted mean night-time glucose in patients treated with oral insulin ORMD-0801.

This study showed a statistically significant decrease in the primary endpoint, pooled night-time glucose mean percentage change of 6.47% from run-in, between placebo and active cohorts (p=0.0268).

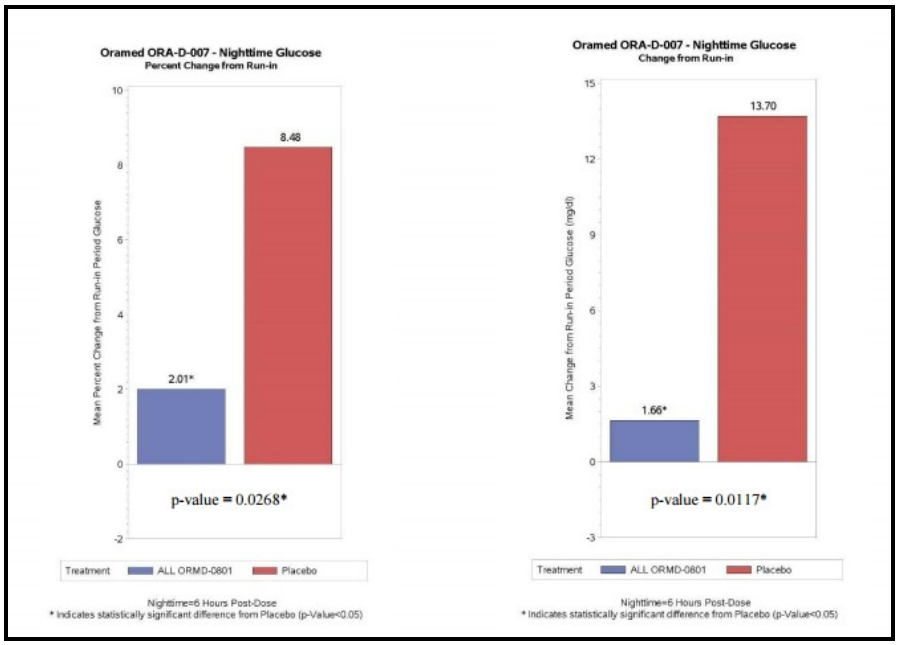
Further, the study demonstrated a good safety profile of ORMD-0801 with no drug related serious adverse events.

Additional Data

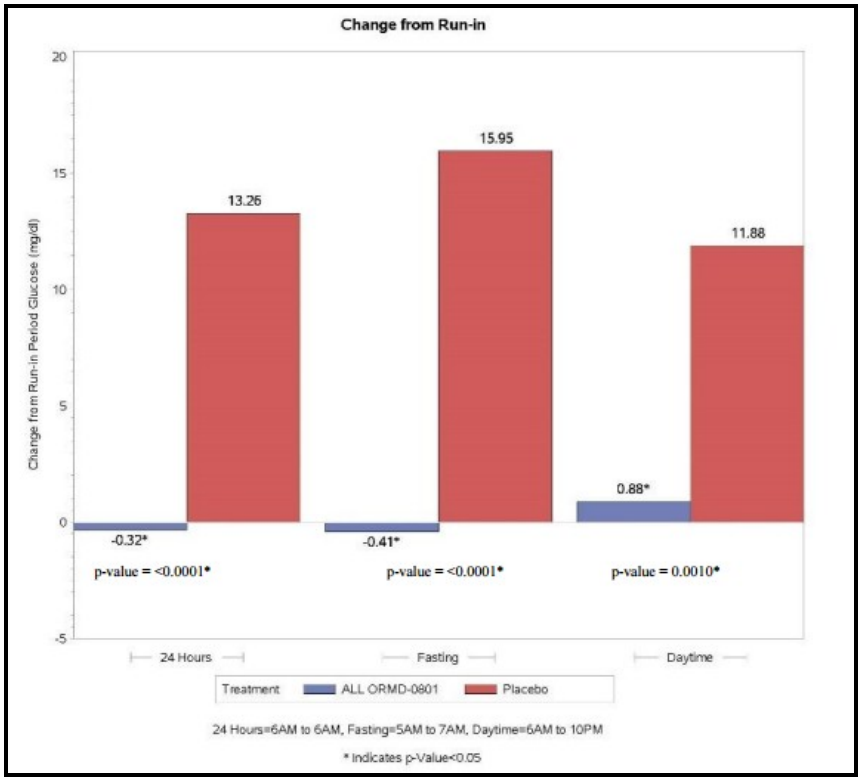
On July 28, Oramed reported **additional data** from the Phase IIb trial. In addition to positive topline data showing the study successfully met its primary efficacy and safety endpoints announced on May 18, the new data indicated a statistically significant lowering of glucose relative to placebo **across several endpoints.**

Due to technical inaccuracies that can occur in any diabetes study, measuring glucose changes with continuous glucose monitors (CGM), data can include extreme outliers. To reduce variability, trimming of unlocked, fully blinded information was conducted. In the current summary, the 80% trimmed data (data excluding the 10% highest and lowest values) is presented.

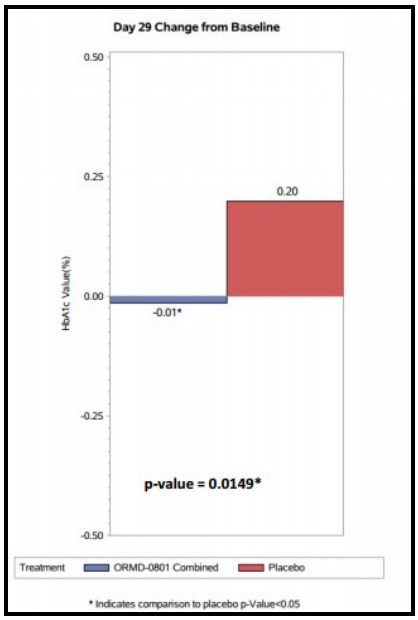
In the study, the mean nighttime glucose showed a significant difference in mean change from run-in (13.70 mg/dL for placebo vs. 1.66 mg/dL for the pooled ORMD-0801 arms with a p= 0.0117). ORMD-0801 was safe and well tolerated, with no drug related serious or severe adverse events and no statistically significant differences in laboratory values or vital signs.



Other secondary and exploratory objectives of the study included evaluating the effect of ORMD-0801 on mean 24-hour glucose, fasting glucose, and daytime glucose. The mean 24-hour glucose showed a highly significant difference in mean change from run-in (13.26 mg/dL for placebo vs. -0.32 mg/dL for ORMD-0801, p <0.0001). The mean fasting glucose showed a highly significant difference in mean change from run-in (15.95 mg/dL for placebo vs. -0.41 mg/dL for ORMD-0801, p <0.0001). The mean daytime CGM glucose showed a highly significant difference in mean change from run-in (11.88 for placebo vs. 0.88 for ORMD-0801, p= 0.0010).



There was a statistically significant difference in change in HbA1c at Day 29 (0.20% for placebo vs.-0.01% for ORMD-0801, p= 0.0149). It is important to note that due to the kinetics of change of HbA1c, a four-week study is insufficient to fully appreciate the potential positive impact of ORMD-0801 on HbA1c.



ORMD-0801 did not show a significant difference in change in morning fasting serum insulin, C-Peptide, or triglycerides.

The study demonstrated a good safety profile of ORMD-0801 with no drug related serious adverse events.

Adverse Events

	Placebo (N=64)	ORMD-0801 460IU (N=61)	ORMD-0801 690IU (N=63)
Number of Reported Adverse Events:	34	34	42
Number (%) of Subjects With at Least One:			
Treatment Emergent Adverse Event (TEAE)	19 (29.7)	19 (31.1)	19 (30.2)
Severe TEAE	0 (0.0)	1 (1.6)	0 (0.0)
Serious TEAE	0 (0.0)	1 (1.6)	0 (0.0)
Drug-related TEAE	2 (3.1)	0 (0.0)	0 (0.0)
Drug-related severe TEAE	0 (0.0)	0 (0.0)	0 (0.0)
Drug-related serious TEAE	0 (0.0)	0 (0.0)	0 (0.0)
TEAE leading to withdrawal of study drug	0 (0.0)	1 (1.6)	0 (0.0)
TEAE with outcome of death	0 (0.0)	0 (0.0)	0 (0.0)

Hypoglycemic Events

	Placebo (N=64)	ORMD-0801 460IU (N=61)	ORMD-0801 690IU (N=63)
Number (%) of Subjects with a Hypoglycemic Event:	1 (1.6)	1 (1.6)	1 (1.6)

Our Takeaways from the Phase IIb Study

The positive data from the Phase IIb trial is a significant **de-risk event** for Oramed in our opinion. The top line data further confirm the efficacy and safety of ORMD-0801, an orally delivered intestinally absorbed insulin, from previously reported results including the Phase IIa study.

With the positive top line data from the Phase IIb trial, we believe the company will move forward with a pivotal Phase III trial when they get some feedback from the FDA. We estimate a Phase III trial could start as early as in 2Q2017.

The positive top line results also triggered some milestone payments from HTIT.

On June 21 2016, Oramed received $6.5 million milestone payment from Hefei Tianhui Incubator of Technologies Co. Ltd. (HTIT). The payment follows Oramed's positive top-line results from its Phase IIb trial.

On August 2 2016, Oramed received another milestone payment of $4 million from HTIT, following Oramed's report of additional positive efficacy and safety data from the Phase IIb trial.

Per the terms of the agreement signed in December 2015, Oramed granted HTIT exclusive rights for commercialization of ORMD-0801 in Greater China. The up to $50 million license deal includes multiple milestone payments aggregating $38 million, with a $3 million upfront payment received by Oramed upon execution of the agreement, plus a $12 million investment made by HTIT in Oramed at $10.39 per share in December 2015. Oramed will receive a 10% royalty on net sales of ORMD-0801 and related commercialized products in Greater China.

With the guidance from the FDA, we believe the Company will accelerate the initiation of a pivotal **Phase III** study of ORMD-0801.

Oramed to Initiate Clinical Study of ORMD-0801 in NASH

In November 2017, Oramed received the approval from Israel's Ministry of Health to initiate an **exploratory clinical study** of ORMD-0801 in patients with nonalcoholic steatohepatitis **(NASH).** The three-month clinical study will assess the effectiveness of ORMD-0801 in reducing liver fat content, inflammation and fibrosis in patients with NASH.

Oramed plans on initiating the study **in the coming month**.

New Drug Candidate to Enter Clinic

In early May 2017, Oramed announced that the Company is developing a **new drug candidate**, a weight loss treatment in the form of an **oral leptin** capsule.

Leptin, commonly known as the obesity, fat or satiety hormone, is a protein that is produced in fat cells which regulates and alters long-term food intake and energy expenditure. Leptin helps to inhibit hunger and regulate energy balance. But obese individuals generally exhibit a higher concentration of leptin in their blood than normal weight individuals. These people show resistance to leptin, similar to resistance of insulin in type II diabetes. Leptin has additionally been shown to suppress glucagon secretion and improve glucose levels in type I diabetes.

In the news release, the company explained that the decision to expand into obesity market is based on **positive preclinical data** from Leptin. But the news release did not include the detailed data.

Israel's Ministry of Health has approved Oramed's commencement of a **proof of concept** single dose study for its oral leptin drug candidate to evaluate its pharmacokinetic and pharmacodynamics (glucagon reduction) in ten type I diabetic patients.

We think the expansion into obesity market is a natural expansion of the company's pipeline using its protein oral delivery **(POD) technology**.

The overall obesity market is a multibillion-dollar market which is expected to grow rapidly worldwide. Since Leptin's role in obesity is well defined and it's our belief that an oral leptin capsule may help control and reduce obesity. Also an oral leptin capsule is an appropriate fit in the company's portfolio of drug candidates which is focused on diabetes. Obesity and diabetes are highly correlated and insulin resistance has been found to generate leptin resistance.

The company plans to initiate the study later this year. We will update investors once we have detailed information about this study.

Phase IIb Trial to be Initiated for ORMD-0901

Oramed has successfully concluded a **Phase Ib** study of ORMD-0901, the Company's proprietary oral GLP-1 analog.

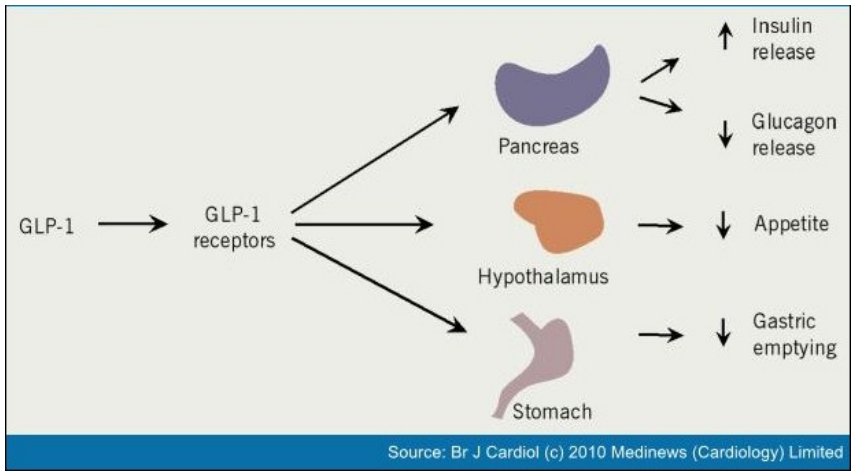
This **ex-US Phase Ib** study of ORMD-0901 was conducted in Israel. It's a small study to look at proof of concept (POC) and to glean some small dosing information. Data from this small study will help the company design the Phase II study.

The study on **type 2 diabetic** patients showed ORMD-0901 to be safe and well tolerated, having no serious adverse events, adverse events or abnormal laboratory findings during the study. In addition, the active oral GLP-1 arms of the study showed encouraging **trending efficacy**.

Currently Oramed is preparing to submit an IND with the FDA and anticipate initiating a **Phase IIb** study in **2018**.

Background of ORMD-0901 (GLP-1 Analog) Program

Glucagon-like peptide 1 **(GLP-1)** belongs to the hormonal family of **incretins** that enhance the secretion of insulin. The major sources of GLP-1 are the L-cells in the lining of small intestine. The pancreas and the central nervous system (CNS) also secrete this hormone in smaller quantities. GLP-1 stimulates the release of insulin from the pancreas; it also increases the volume of cells in the pancreas which produces insulin (beta cells) and regulates and controls the release of glucagon. GLP-1 acts on appetite centers in brain, slowing the emptying process in stomach and increasing the feeling of fullness during and between the meals.

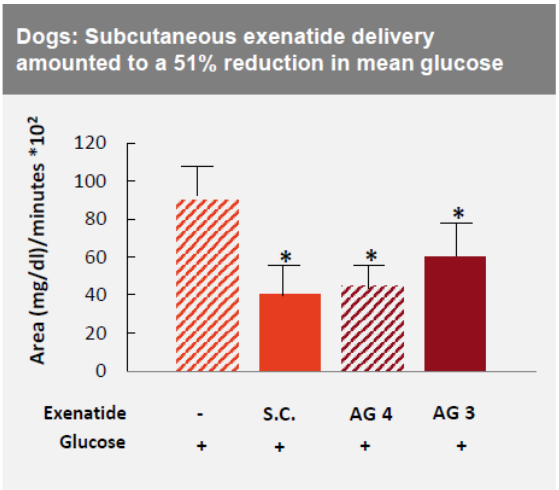


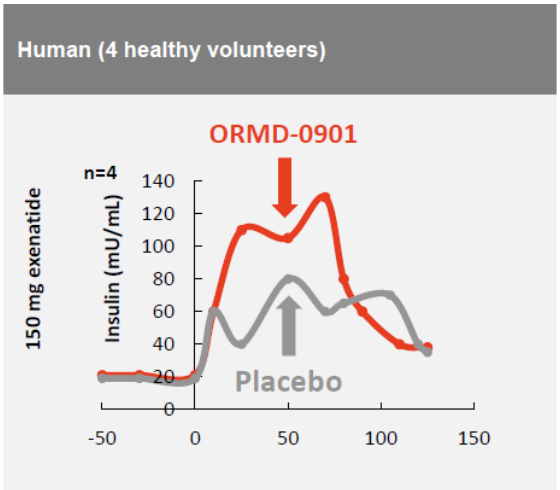
ORMD-0901 is oral GLP-1 analog (**oral exenatide**). Exenatide, a GLP-1 analog, is currently marketed in injectable form only, and is indicated for treatment of type 2 diabetes. Exenatide induces insulin release at increased glucose levels and causes a feeling of satiety, which results in reduced food intake and weight loss.

ORMD-0901, based on the company's POD™ technology, could significantly increase compliance and become a valuable tool in the treatment of diabetes.

In a **small scale preliminary proof of concept** study, ORMD-0901 demonstrated excellent glucose reduction efficacy in both animals (dogs) and human healthy volunteers.

In the following graph, the left showed a couple formulations of ORMD-0901 seemed to have similar efficacy to the injectable GLP-1 (lowering glucose). The right showed increase insulin in humans after taking ORMD-0901– as GLP-1 promotes insulin production/secretion.





Oramed is currently conducting IND-enabling toxicity studies. The company hopes to finish off the 90-day toxicity studies soon, and files an IND and start a **Phase II** study **in 2017**. The company may pursue the **505(b)(2) pathway**.

The 505(b)(2) regulatory pathway may reduce the drug development risks and costs by using prior findings of safety and/or efficacy for an approved product. In ORMD-0901 case, part of the safety and efficacy data from the injectable exenatide formulation may be used for the filing of a NDA for ORMD-0901.

We Continue to be Bullish on Oramed Shares

We continue to be bullish on the Oramed story and our fair valuation stands at $25 per share based on the strong fundamentals.

Oramed is a mid-stage development biotech company with a current focus on diabetes. Over the years, the company has developed a unique, proprietary protein oral delivery (POD) platform technology. This is the core value for the company and differentiates the company from other biotech companies in our view.

Base on its POD platform, Oramed has built a pipeline with focus on oral insulin **(ORMD-0801**) and oral GLP-1 analog (**ORMD-0901**).

Oral insulin mimics the role of natural insulin, therefore has many advantages over injectable insulins including better control of blood glucose and less side effects. The company has completed a **Phase IIa** study of ORMD-0801 for T2DM and reported positive data. The positive data from the **Phase IIb** study is a significant de-risk event for the company. We estimate a pivotal **Phase III** trial could start **in 2019**.

Based on the company's current development plan, we estimate ORMD-0801 to be approved by the FDA in late calendar 2020 for both type 1 and type 2 diabetes. Peak sales could be over $1 billion in 5 years after approval.

The company's second candidate is ORMD-0901, an oral formulation of exenatide (Byetta) for T2DM. The company expects to initiate a **Phase IIb** study in 2018. Oramed plans to pursue the **505(b)(2) pathway for** ORMD-0901. If everything goes Oramed's way, ORMD-0901 could be approved in late 2020. Peak sales should be in the neighborhood of $500 million.

The company recently announced a new drug candidate for the treatment of obesity and will enter clinic later this year.

We are very pleased to see that the company has been pursuing collaboration opportunities for its clinical programs. The recent deal with China based Hefei Tianhui Incubator of Technologies Co.is especially encouraging. The deal not only boosts the company's balance sheet in a non-dilutive way, but further validates the company's POD technology and its clinical program ORMD-0801. We should be able to see more deals in the near future when data from the Phase IIb trial prove to be positive.

Furthermore, we see great potential of the company's POD platform for other indications. Oral delivery of protein is a breakthrough technology and has great potential for oral delivery of other biologics. Therefore, pipeline expansion should be easy once the work for oral insulin/GLP-1 has been validated in clinical studies. Actually, the company has a feasibility study currently running with a big pharma company using this pharma's proprietary peptide with Oramed POD delivery technology.

With respect to valuation, we think current share price does not reflect the intrinsic value of the company. Currently, Oramed shares are trading at about $8.30, which values the company at $120 million in market capitalization based on 14.4 million outstanding shares. This is a discount compared to its peers. Based on our above discussions, ORMD-0801 and ORMD-0901 could be approved by the FDA in 2020.

We assign a probability of 75% for ORMD-0801 and 30% for ORMD-0901 for approval at this time. Based on our financial model, Oramed will become cash flow positive in 2020 with an EPS of $0.49 based on revenue of $78 million. EPS will grow to $2.50 in fiscal 2021 based on total revenue of $180 million. A 30x P/E multiple and 30% discount rate are used to arrive at our fair value of $25.00 per share. Our price target values the company at $360 million in market cap, which is still conservative in our view.

But keep in mind **the risks**. As we discussed, Oramed is still a mid-stage development biotech company. Our valuation assumes the final approval of either ORMD-0801 or ORMD-0901 or both, which we only assign 75% and 30% probability at this time. In order for the two candidates to reach the market, the company still needs to overcome both clinical and regulatory hurdles which have proven to be high. But the reward is also apparent. Once the company moves further with the two candidates, value will be created for shareholders with a higher probability of approval. Generally speaking, we think the stock has a typical high risk/high return profile, which could be appropriate for investors with a high-risk tolerance and relatively long investment horizon.

PROJECTED INCOME STATEMENT

	2016 (Aug)					2017 (Aug)					2018 (Aug)	2019 (Aug)	2020 (Aug)	2021 (Aug)
$ in million except per share data	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Grant revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
License/Royalties	$0.00	$0.13	$0.16	$0.35	$0.64	$0.61	$0.61	$0.62	$0.62	$2.46	$2.00	$2.50	$3.00	$5.00
Product revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$75.00	$175.00
Total Revenues	**$0.00**	**$0.13**	**$0.16**	**$0.35**	**$0.64**	**$0.61**	**$0.61**	**$0.62**	**$0.62**	**$2.46**	**$2.00**	**$2.50**	**$78.00**	**$180.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CoGS	0.00	0.00	0.00	0.49	0.49	0.19	0.00	0.01	(0.01)	0.19	0.00	0.50	15.60	36.00
Gross Income	**$0.00**	**$0.13**	**$0.16**	**($0.14)**	**$0.15**	**$0.42**	**$0.61**	**$0.61**	**$0.63**	**$2.27**	**$2.00**	**$2.00**	**$62.40**	**$144.00**
Gross Margin	-	-	100.0%	-38.8%	23.6%	69.3%	100.0%	98.1%	101.9%	92.4%	100.0%	80.0%	80.0%	80.0%
R&D	$1.90	$1.31	$1.72	$2.78	$7.71	$2.35	$3.13	$2.27	$2.54	$10.28	$15.00	$25.00	$30.00	$40.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$0.55	$0.73	$0.56	$0.62	$2.45	$0.47	$0.85	$0.51	$0.94	$2.76	$5.00	$10.00	$20.00	$45.00
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Expenses	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Operating Income	**($2.4)**	**($1.9)**	**($2.1)**	**($3.5)**	**($10.0)**	**($2.4)**	**($3.4)**	**($2.2)**	**($2.8)**	**($10.8)**	**($18.0)**	**($33.0)**	**$12.4**	**$59.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	32.78%
Other Net	$0.1	$0.1	$0.2	$0.0	$0.4	$0.2	$0.2	$0.2	$0.2	$0.7	$0.0	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($2.4)**	**($1.8)**	**($1.9)**	**($3.5)**	**($9.6)**	**($2.2)**	**($3.2)**	**($2.0)**	**($2.7)**	**($10.1)**	**($18.0)**	**($33.1)**	**$12.3**	**$58.9**
Income taxes(benefit)	$0.0	$0.0	$0.0	$1.3	$1.3	$0.4	$0.0	$0.0	$0.0	$0.4	$0.0	$0.0	$0.0	$2.9
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($2.4)**	**($1.8)**	**($1.9)**	**($4.8)**	**($11.0)**	**($2.6)**	**($3.2)**	**($2.0)**	**($2.7)**	**($10.5)**	**($18.0)**	**($33.1)**	**$12.3**	**$56.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	11.6	12.7	13.1	13.2	12.6	13.2	13.3	13.3	13.5	13.3	15.0	20.0	25.0	30.0
Reported EPS	**($0.21)**	**($0.14)**	**($0.15)**	**($0.37)**	**($0.87)**	**($0.20)**	**($0.24)**	**($0.15)**	**($0.20)**	**($0.79)**	**($1.20)**	**($1.65)**	**$0.49**	**$1.87**
One-time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non- GAAP Net Income	**($2.4)**	**($1.8)**	**($1.9)**	**($4.8)**	**($11.0)**	**($2.6)**	**($3.2)**	**($2.0)**	**($2.7)**	**($10.5)**	**($18.0)**	**($33.1)**	**$12.3**	**$56.0**
Non- GAAP EPS	**($0.21)**	**($0.14)**	**($0.15)**	**($0.37)**	**($0.87)**	**($0.20)**	**($0.24)**	**($0.15)**	**($0.20)**	**($0.79)**	**($1.20)**	**($1.65)**	**$0.49**	**$1.87**

Source: company filings and Zacks estimates

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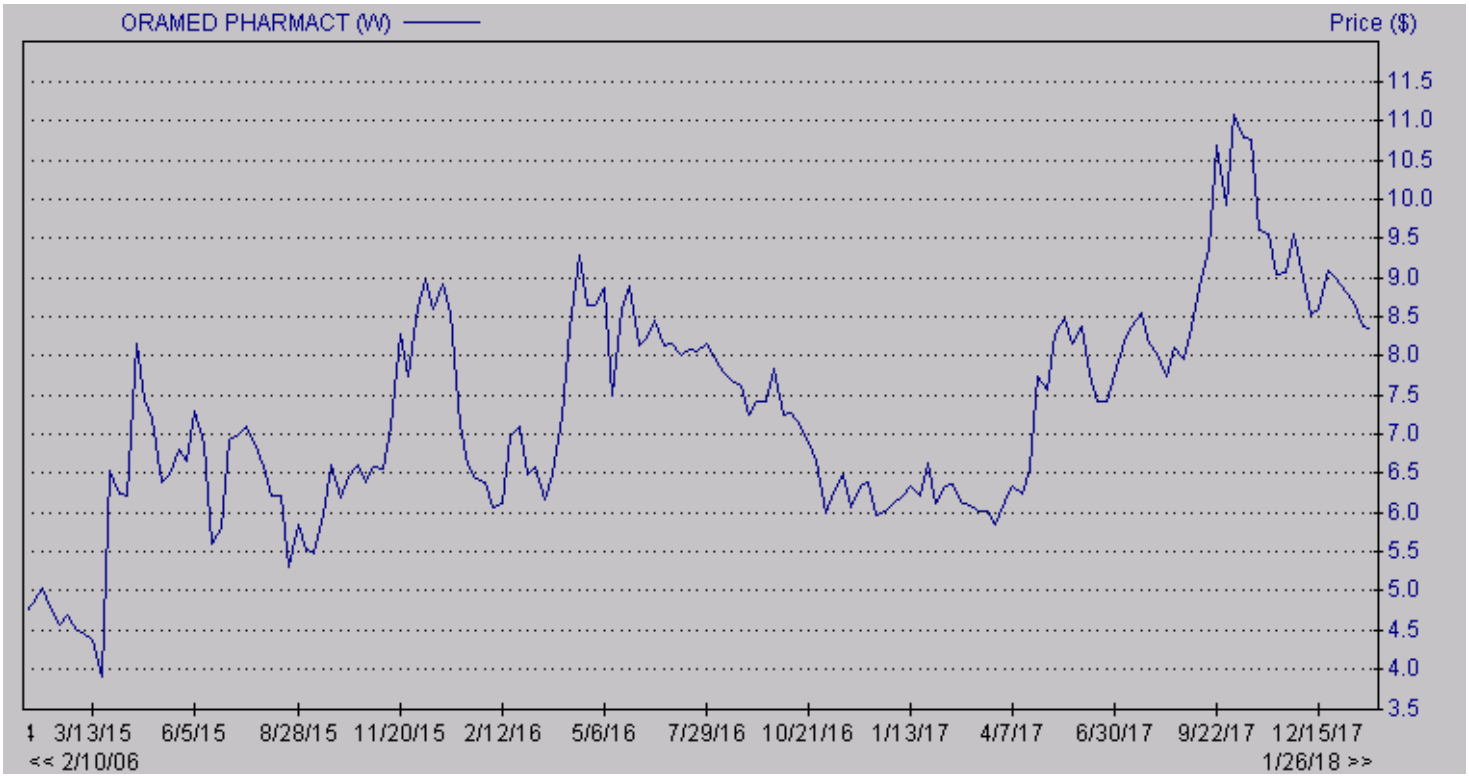
HISTORICAL STOCK PRICE



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