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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Transferring Coverage; Multiple Clinical Readouts for Oral Protein Delivery Technology Over Next 12-18 Months…

Based on our probability adjusted DCF model that takes into account future revenues from ORMD-0801 and ORMD-0901, ORMP is valued at $18.00 per share. This model is highly dependent on continued clinical success of ORMD-0801 and ORMD-0901 and will be adjusted accordingly based on future clinical results.

Current Price (11/15/18)	$4.09
Valuation	**$18.00**

OUTLOOK

We are transferring coverage of Oramed Pharmaceuticals Inc. (ORMP) with a valuation of $18. Oramed is developing multiple products based on the company's technology that allows for oral administration of proteins. The lead development product, ORMD-0801, is an oral insulin being tested in patients with both type 1 and type 2 diabetes. A Clamp Study and a phase IIb, pivotal, 90-day HbA1c study are currently ongoing in type 1 and type 2 diabetic patients, respectively. We anticipate readouts from these studies in 2019. The company also recently initiated a study of ORMD-0801 in NASH patients and will soon commence a Phase 1 study of ORMD-0901, an orally administered GLP-1.

SUMMARY DATA

52-Week High	**$9.56**
52-Week Low	**$4.03**
One-Year Return (%)	**-55.30**
Beta	**0.59**
Average Daily Volume (sh)	**23,509**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$71**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**28**
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 2019 Estimate	**-3.9**
P/E using 2020 Estimate	**-3.7**

Risk Level	**Average**
Type of Stock	**Small-Growth**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2017	0.6 A	0.6 A	0.6 A	0.6 A	2.5 A
2018	0.6 A	0.6 A	0.6 A	0.6 E	2.4 E
2019					2.5 E
2020					2.5 E

Earnings per Share

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2017	-$0.20 A	-$0.24 A	-$0.15 A	-$0.20 A	-$0.79 A
2018	-$0.18 A	-$0.20 A	-$0.31 A	-$0.25 E	-$0.95 E
2019					-$0.85 E
2020					-$0.88 E

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WHAT'S NEW

Business Update

Oramed Pharmaceuticals Inc. (ORMP) is a biotechnology company with a proprietary oral protein delivery platform technology. The lead development candidate is ORMD-0801, an oral insulin, that is currently being tested in both type 1 (T1D) and type 2 diabetics (T2D). The company is also developing ORMD-0901, an oral glucagon-like peptide-1 (GLP-1).

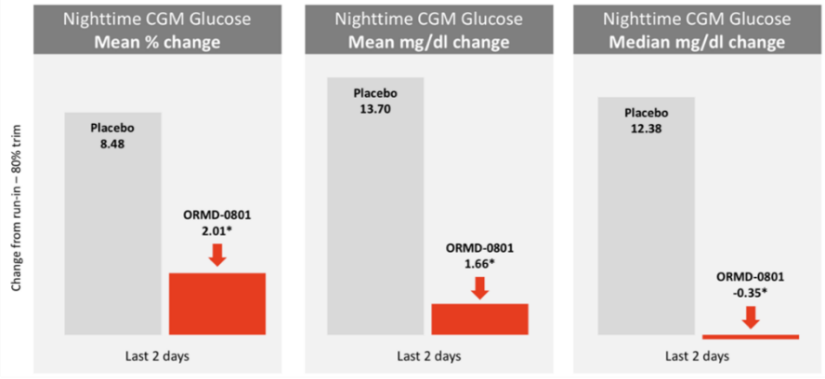
ORMD-0801 Update

Type 1 Diabetics: In June 2018, the company initiated both a clamp study and a food effect study, and while these studies are enrolling T1D patients and healthy controls, investors should be aware that the data gleaned from these studies will be equally applicable to an approval in T2D. The clamp study is enrolling T1D patients with HbA1c levels ≤ 10% between the ages of 18-70 The clamp study was originally developed in 1979 as a means of testing how well a patient metabolizes glucose and their insulin sensitivity (DeFronzo *et al*., 1979). A clamp study is a requirement of all regulatory agencies around the world for performing pharmacodynamic studies of diabetes drugs in development. We anticipate results from this study in the first half of 2019.

The food effect study is a single blind, five period, randomized, placebo controlled crossover study that is designed to evaluate the pharmacokinetics and pharmacodynamics of ORMD-0801 as a function of when the drug is administered in relation to meals. Up to 48 subjects (half healthy volunteers and half T1D patients) will be enrolled. We anticipate data from this study in mid-2019.

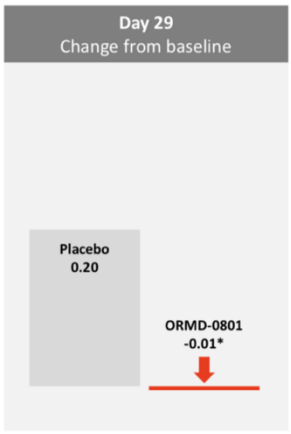
Type 2 Diabetics: In April 2018, Oramed initiated a 90-day dose-ranging Phase 2b clinical trial designed to measure the effect of ORMD-0801 on glycated hemoglobin (HbA1c). This is a prerequisite prior to initiating Phase 3 clinical trials. Recently, Oramed announced that the trial is over 50% enrolled. The company had previously found a statistically significant improvement in HbA1c following just 28 days of treatment in the company's prior Phase 2 clinical trial (discussed below). High levels of blood glucose results in its binding to hemoglobin (becoming glycated). Since red blood cells survive for an average of 90 days, it typically takes this amount of time to determine the true effect a drug may be having on reducing glycated hemoglobin. We anticipate approximately 260 patients being enrolled in the trial, which will test 16, 24, and 32 mg doses of ORMD-0801 given once, twice, or three times a day. Topline results should be available before the end of 2019.

ORA-D-007 Study: This was a 28-day Phase 2b clinical trial of ORMD-0801 in 180 T2D patients who were also on metformin. Patients were administered 16 mg ORMD-0801 (n=60), 24 mg ORMD-0801 (n=60), or placebo (n=60) once daily at bedtime. The following graphs show that nighttime blood glucose rose statistically significantly less in patients administered ORMD-0801 than in those administered placebo.



Source: Oramed Pharmaceuticals Inc.

In addition, the company examined a number of exploratory endpoints, including the change in HbA1c over the 28-day treatment period. As discussed above, a 90-day treatment period is required to get an accurate reading on any change in HbA1c, however there was a statistically significant difference in the change in HbA1c after 28 days of treatment when comparing the placebo and ORMD-0801 groups.



* Indicates comparison to placebo p-Value<0.05

Source: Oramed Pharmaceuticals Inc.

Importantly, ORMD-0801 was safe and well-tolerated, with a similar number of Adverse Events (AEs) reported for each treatment group. In addition, there was no significant differences in morning fasting serum insulin, c-peptide, or triglycerides between the treatment groups.

	Placebo	ORMD-0801	ORMD-0801
	N=64	460 IU	690 IU
	N (%)	N= 61	N= 63
		N (%)	N (%)
Total Adverse Events	34	34	42
TEAEs	19 (29.7)	19 (31.1)	19 (30.2)
Severe TEAE	0 (0)	1 (1.6)	0 (0)
Serious TEAE	0 (0)	1 (1.6)	0 (0)
Related TEAEs	2 (3.1)	0 (0)	0(0)
Related Severe TEAEs	0 (0)	0 (0)	0 (0)
Related Serious TEAEs	0 (0)	0 (0)	0 (0)
Withdrawal from treatment due to AE	0 (0)	1 (1.6)	0 (0)
Death due to AE	0 (0)	0 (0)	0 (0)

Source: Oramed Pharmaceuticals Inc.

NASH Study: On Oct. 4, 2018, Oramed announced the initiation of an exploratory proof-of-concept study to evaluate ORMD-0801 in patients suffering from nonalcoholic steatohepatitis (NASH). The study will test the ability of ORMD-0801 to reduce liver fat, inflammation, and fibrosis in NASH patients. NASH is inflammation and damage to the liver brought about by a buildup of fat and is the most severe form of nonalcoholic fatty liver disease (NAFLD). It is often a "silent" liver disease as most patients with NASH feel well and are not aware that they have a liver problem. However, NASH can be severe and ultimately lead to cirrhosis, liver failure, and hepatocellular carcinoma. NASH is currently estimated to affect two to five percent of the U.S. population (NIDDK) with the global market estimated to reach $20 billion by 2025 (Allied Market Research).

License Deal in China: In 2015, Oramed signed a Technology License Agreement with Hefei Tianhui (HTIT), a Chinese company that owns a GMP-certified API insulin manufacturing facility. The agreement gave HTIT exclusive commercialization rights for ORMD-0801 in China, Macau, and Hong Kong. HTIT purchased $12 million in restricted stock and will pay 10% royalties on net sales along with up to $37.5

million in milestone payments. Oramed has already received $30 million, with an anticipated $5 million expected over the next six months. China represents a vast potential opportunity as there are over 100 million diabetic individuals in the country and approximately 500 million that are pre-diabetic.

ORMD-0901 Update

On September 17, 2018, Oramed announced that the U.S. FDA has approved the company's investigational new drug application (IND) to initiate clinical trials for ORMD-0901, an oral formulation of the GLP-1 analog exenatide. GLP-1 analogs mimic the action of GLP-1 and are currently used in the treatment of T2D, with sales of this class of drugs totaling $6.9 billion in 2017 (EvaluatePharma).

The company is planning to conduct a randomized, single blind, placebo controlled, 4-way crossover Phase 1 study to evaluate the safety and pharmacokinetics of ORMD-0901 compared to Byetta® in up to 15 healthy subjects. We anticipate the study initiating before the end of the year, and a larger Phase 2 clinical trial of ORMD-0901 initiating in 2019.

Financial Update

In July 2018, Oramed announced an $18.1 million direct offering where the company sold a total of 2,892,000 Units for $6.25 each, with each Unit consisting of one share of common stock and one warrant to purchase a share of common stock at an exercise price of $7.25. Net proceeds to Oramed were approximately $16.5 million. The company exited the third fiscal quarter of 2018 ending May 31, 2018, with approximately $34.4 million in cash, cash equivalents, and marketable securities. Thus, we estimate that the company currently has approximately $45-$48 million, which should be enough to fund operations for at least the next 18 months.

Valuation

We value Oramed using a probability adjusted discounted cash flow model that takes into account potential future revenues from ORMD-0801 and ORMD-0901. We currently model for approval of ORMD-0801 in late 2023 with first sales in 2024 and approval of ORMD-0901 in late 2024 with first sales in 2025. We estimate for peak U.S. sales of ORMD-0801 of approximately $400 million and peak U.S. sales of ORMD-0901 of approximately $500 million. Using a 12% discount rate and a 60% probability of approval for ORMD-0801 and a 45% probability of approval for ORMD-0901 leads to a net present value for those two programs of $162 million and $136 million, respectively. When including the current cash total, potential cash from warrant exercises, and dividing by the fully diluted share count of 20.4 million, it leads to a net present value for Oramed of approximately $18 per share.

PROJECTED FINANCIALS

Oramed Pharmaceuticals Inc. (Fiscal Year ends Nov. 30)	FY 2017 A	FY 18 Q1 A	FY 18 Q2 A	FY 18 Q3 A	FY 18 Q4 E	FY 2018 E	FY 2019 E	FY 2020 E
License Revenue	$2.5	$0.6	$0.6	$0.6	$0.6	$2.4	$2.5	$2.5
YOY Growth	-	-	-	-	-	-	-	-
Grant/Contract Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-
ORMD-0801	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-
ORMD-0901	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$2.5**	**$0.6**	**$0.6**	**$0.6**	**$0.6**	**$2.4**	**$2.5**	**$2.5**
YOY Growth		*0%*	*-2%*	*0%*	*-2%*	*-1%*	*2%*	*0%*
Cost of Revenue	$0.2	$0.0	$0.0	$0.1	$0.0	$0.1	$0.1	$0.1
Gross Income	**$2.3**	**$0.6**	**$0.6**	**$0.5**	**$0.6**	**$2.4**	**$2.4**	**$2.4**
Gross Margin	*92.3%*	*100.0%*	*100.0%*	*86.1%*	*100.0%*	*96.5%*	*96.0%*	*96.0%*
Research & Development	$10.3	$2.3	$2.7	$4.2	$4.2	$13.4	$15.0	$18.0
General & Administrative	$2.8	$1.0	$1.0	$1.0	$1.0	$4.1	$5.0	$7.0
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($10.8)**	**($2.7)**	**($3.1)**	**($4.7)**	**($4.6)**	**($15.1)**	**($17.6)**	**($22.6)**
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$0.7	$0.2	$0.2	$0.2	$0.2	$0.8	$0.7	$0.5
Pre-Tax Income	**($10.1)**	**($2.5)**	**($2.9)**	**($4.5)**	**($4.4)**	**($14.3)**	**($16.9)**	**($22.1)**
Net Taxes (benefit)	$0.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*-4.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($10.5)**	**($2.5)**	**($2.9)**	**($4.5)**	**($4.4)**	**($14.3)**	**($16.9)**	**($22.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.79)**	**($0.18)**	**($0.20)**	**($0.31)**	**($0.25)**	**($0.95)**	**($0.85)**	**($0.88)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	13.3	14.2	14.4	14.5	17.4	15.1	20.0	25.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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