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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Multiple Data Readouts on the Horizon…

Based on our probability adjusted DCF model that takes into account future revenues from ORMD-0801 and ORMD-0901, ORMP is valued at $23.00 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 (1/6/20)	$4.68
Valuation	**$23.00**

OUTLOOK

Oramed Pharmaceuticals Inc. (ORMP) 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. The company recently announced successful results from the 90-day, dose-ranging Phase 2b clinical trial. The company has also initiated a second low dose cohort in the same trial to evaluate the efficacy of lower doses of ORMD-0801. Results from that portion of the study will be available in the first quarter of 2020. In addition, results from a pharmacokinetic study of an oral GLP-1 analog of exenatide and the first cohort in an exploratory study of ORMD-0801 in NASH patients are anticipated in the first quarter of 2020.

SUMMARY DATA

52-Week High	**$5.74**
52-Week Low	**$2.43**
One-Year Return (%)	**38.18**
Beta	**1.42**
Average Daily Volume (sh)	**177,323**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$84**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**21**
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	**-4.9**
P/E using 2020 Estimate	**-5.4**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2018	0.6 A	0.6 A	0.6 A	0.6 A	2.4 A
2019	0.7 A	0.7 A	0.7 A	0.7 A	2.7 A
2020					2.4 E
2021					2.4 E

Earnings per Share

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2018	-$0.18 A	-$0.20 A	-$0.30 A	-$0.20 A	-$0.86 A
2019	-$0.25 A	-$0.21 A	-$0.23 A	-$0.12 A	-$0.82 A
2020					-$0.98 E
2021					-$0.90 E

WHAT'S NEW

Financial Update

On November 27, 2019, Oramed Pharmaceuticals, Inc. (ORMP) filed form 10-K with financial results for the fiscal year 2019 ending August 31, 2019.

The company reported revenues of $2.7 million for the fiscal year 2019 compared to $2.4 million for 2018. The revenues are related to the license agreement with Hefei Tianhui Incubator of Technologies Co., Ltd. (HTIT) singed in 2015. The revenues originating from that license agreement are recognized through June 2023. The increase in revenues was primarily due to additional milestone payments received during the second quarter of fiscal year 2019.

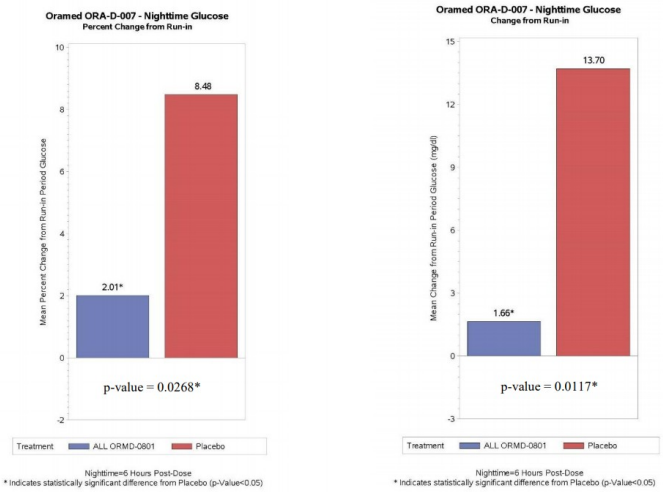
R&D expenses for the fiscal year 2019 were $13.5 million compared to ~$12 million in 2018. The increase was primarily due to expenses related to the Phase IIb three-month dose-ranging clinical trial and the oral leptin development and is partially offset by a decrease in expenses related to toxicology studies and scale-up process development and production of the oral capsule ingredients. The expense was partially offset by the stock-based compensation. G&A expenses were $ 3.7 million in 2019 compared to $4.1 million in 2018. The decrease was primarily attributable to a decrease in stock-based compensation costs partially offset by an increase in salaries and related expenses. Net loss for the fiscal year 2019 was $14.3 million, or $0.82 per share, compared to a net loss of $12.7 million, or $0.86 per share in 2018.

Close to $13 million of cash was used in operating activities and $11.2 million in investing activities. As of August 31, 2019, Oramed had approximately $33.0 million in cash, cash equivalents, and short-term and long-term deposits and marketable securities. We estimate the company has sufficient capital to fund operations for the near term. As of November 26, 2019, Oramed had approximately 17.4 million common shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 21.6 million.

Business Update

New addition to the Board of Directors: In the beginning of December, the company strengthened its Board with the addition of Arie Mayer, Ph.D. Dr. Arie Mayer is currently the Managing Director and Chairman of the Board of Merck Life Science Israel (formerly Sigma-Aldrich Israel Ltd.,) and has held that position since January 2010. Dr. Mayer has held various roles with Sigma-Aldrich Israel Ltd. since 1995 and was instrumental in introducing and developing the Cell Culture and Molecular Biology business for Sigma Aldrich Israel. Dr. Mayer holds a Bachelor of Science in chemistry from Hebrew University and a Ph.D. in biochemistry from Israel Institute of Technology. In addition, he has publications as a main author in the following journals: Science, Journal of Biological Chemistry, New Scientist and the Journal of Cell Sciences.

ORA-D-007 Phase 2 Trial: 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 (ORA-D-007 Study). In this randomized, double-blind, placebo-controlled study, ORMD-0801 was evaluated 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 with ORMD-0801 than in those administered with placebo.



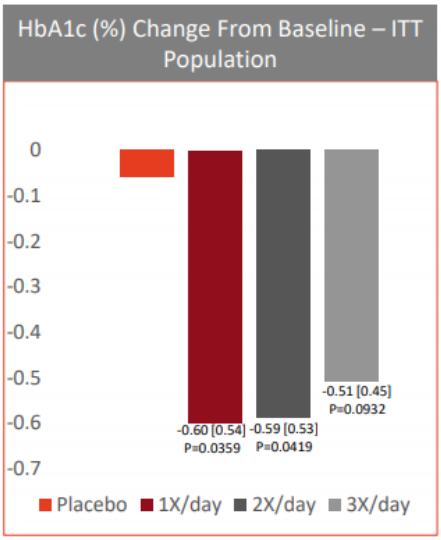
(Source: Oramed.com)

In addition, the company examined a number of exploratory endpoints, including the change in glycated hemoglobin, 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.

Results of the Phase 2b Trial

In order to prepare for a pivotal Phase 3 trial, a Phase 2b study was conducted. On September 17, 2019, Oramed announced that the last patient from the first cohort of the Phase 2b clinical trial of ORMD-0801 had completed treatment. The double blind, randomized 90-day dosing trial, which was funded by ORMD, was designed to evaluate the efficacy of ORMD-0801 in decreasing HbA1c levels, a key clinical measure of blood sugar.

A total of 269 U.S.- based patients with more than 6-months history of T2D and HbA1c levels between 7.5% and 9.6%, were enrolled in the Phase 2b trial. Approximately 70% of the randomized patients were on metformin alone, or metformin with up to two additional oral antihyperglycemic agents. Patients were randomized into three groups (~80 patients in each arm) to assess dosing frequency: once-daily (32 mg/day), twice-daily (64 mg/day), thrice-daily (96 mg/day). Approximately 1/3rd of patients in each treatment arm were assigned to placebo. Two hundred nine (209) patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment). In addition, due to evidence of treatment-by-center interaction, two sites (36 patients (13.4% of enrolled subjects)) were excluded from the statistical analysis. The key outcomes were reduction in HbA1c levels and safety. As expected, topline results were released on November 12th 2019.



Approximately 70% of the randomized patients were on 2 or more glucose lowering drugs

All Patients were on Metformin.
Glucose lowering agents taken in addition to Metformin included: Glibenclamide, Glipizide, Empagliflozin, Pioglitazone, Glimepiride, Dapagliflozin, Sitagliptin, Glibomet, Ertugliflozin

(Source: oramed.com)

Results demonstrated that an optimal dosing of once and twice daily resulted in HbA1c reduction of 0.60% (0.54% with placebo adjustment, p-value 0.036) and 0.59% (0.53% with placebo adjustment, p-value 0.042) by 12 weeks. The thrice-daily arm did not meet statistical significance (p-value 0.093). ORMD-0801 demonstrated an excellent safety profile with no serious drug-related adverse events. Results also demonstrated no increase in hypoglycemic events and no weight gain when compared to placebo.

In normal patients, glucose homeostatis is maintained. A transient increase in insulin secretion occurs just before dawn to control hepatic glucose production and prevent hyperglycemia. A major challenge T2D patients face is that they experience abrupt increases in fasting levels of plasma glucose or insulin requirements or both at dawn. One of the goals in treating T2D patients is to reestablish normal glycemic levels in the morning to lower the mean daily blood glucose and HbA1c levels. By improving night-time glucose levels, a person with diabetes can start the day with improved metabolic condition, which enables better control of blood glucose levels throughout the day. ORMD-0801 has demonstrated an excellent safety profile, specifically with regards to hypoglycemic events.

The company has also initiated a second cohort of patients in the study to evaluate the potential efficacy of multiple lower doses of ORMD-0801 with once daily higher dosing. The study is designed with a sample size of 15 subjects per treatment group to identify the optimal dose of ORMD-0801 for the Phase 3 trial. In the low-dose second cohort, 75 patients have been randomized into five groups: 8 mg dosed once-daily; 8 mg dosed twice-daily; 16 mg dosed once-daily; 16 mg dosed twice-daily; and placebo dosed twice-daily. Oramed expects to announce the results from the second cohort in the first quarter of 2020.

The company hopes to be able to meet with the FDA soon for an ‘end-of-Phase-2’ meeting for feedback on the design for a Phase 3 trial. We believe that the company may look to partner with a larger pharmaceutical company prior to initiating a Phase 3 trial.

Exploratory NASH Trial Ongoing
Oramed initiated 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. We anticipate data from the first safety cohort of 10 patients in the first quarter 2020.

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).

ORMD-0901 PK Study Results in the near term
Oramed has completed a Phase 1 pharmacokinetic (PK) study of ORMD-0901, an oral formulation of the GLP-1 analog exenatide. The randomized, single blind, placebo controlled crossover study is evaluating the safety of ORMD-0901 along with its PK compared to placebo and open label Byetta® in 16 healthy subjects. The company is continuing to evaluate the data and we anticipate topline results in the first quarter 2020.

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 $8.5 billion in 2018 (EvaluatePharma). On Sep. 20, 2019, the FDA announced the approval of Rybelus®, the first approved oral GLP-1 receptor agonist. We believe the approval of Rybelus® is likely to spur interest in partnering other oral GLP-1 analogs, including ORMD-0901.

Oral Leptin Trial to Initiate in 1Q20
Oramed is planning to conduct an exploratory, proof-of-concept trial to evaluate an oral leptin product for the reduction of glucagon in patients with T1D. Leptin is a 16-kDa peptide hormone that is primarily produced by adipose tissue. It is an essential hormone for maintaining energy homeostasis and body weight, with leptin resistance identified as a key risk factor for obesity (Zhou *et al*., 2013).

The single-dose safety trial is scheduled to begin in the first quarter of 2020 in 10 patients with T1D and we anticipate topline results in the same quarter. The ultimate goal of the project is to address weight loss in overweight patients.

Conclusion and Valuation

We're glad to see the results for the Phase 2b HbA1c trial in patients with T2D. While we anticipate data from a couple of other studies before the end of 2019, we view the data from the Phase 2b study of ORMD-0801 as the most important for the company. It seems likely that the company might jumpstart partnership negotiations since we believe Oramed will seek a development partner before moving into a Phase 3 trial.

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 2024 with first sales in 2025 and approval of ORMD-0901 in 2025 with first sales in 2026. 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 64% 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 $213 million and $152 million, respectively. When including the current cash total, potential cash from warrant exercises, and dividing by the fully diluted share count leads to a net present value for Oramed of approximately $23 per share.

PROJECTED FINANCIALS

Oramed Pharmaceuticals Inc. (Fiscal Year ends Aug. 31)	FY2018 A	FY19 Q1 A	FY19 Q2 A	FY19 Q3 A	FY19 Q4 A	FY2019 A	FY2020 E	FY2021 E
License Revenue	$2.4	$0.7	$0.7	$0.7	$0.7	$2.7	$2.4	$2.4
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	**$2.4**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$2.4**	**$2.4**
YOY Growth	*0%*	*10%*	*11%*	*10%*	*10%*	*10%*	*-11%*	*0%*
Cost of Revenue	$0.1	$0.0	$0.1	$0.0	$0.0	$0.1	$0.0	$0.0
Gross Income	**$2.5**	**$0.6**	**$0.6**	**$0.7**	**$0.7**	**$2.6**	**$2.4**	**$2.4**
Gross Margin	*103.5%*	*94.8%*	*91.7%*	*100.0%*	*100.0%*	*96.7%*	*100.0%*	*100.0%*
Research & Development	$12.0	$4.3	$3.1	$3.9	$2.2	$13.5	$16.0	$18.0
General & Administrative	$4.1	$0.9	$1.1	$0.9	$0.8	$3.7	$6.5	$7.5
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($13.5)	($4.6)	($3.6)	($4.1)	($2.3)	($14.6)	($20.1)	($23.1)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$1.1	$0.3	$0.2	$0.0	$0.2	$0.6	$0.5	$0.5
Pre-Tax Income	**($12.7)**	**($4.302)**	**($3.4)**	**($4.1)**	**($2.1)**	**($14.1)**	**($19.6)**	**($22.6)**
Net Taxes (benefit)	$0.0	$0.0	$0.3	$0.0	$0.0	$0.3	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*-8.8%*	*0.0%*	*0.0%*	*-2.1%*	*0.0%*	*0.0%*
Reported Net Income	**($12.7)**	**($4.3)**	**($3.7)**	**($4.1)**	**($2.1)**	**($14.4)**	**($19.6)**	**($22.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.86)**	**($0.25)**	**($0.21)**	**($0.23)**	**($0.12)**	**($0.82)**	**($0.98)**	**($0.90)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	14.9	17.4	17.5	17.5	17.7	17.5	20.0	25.0

Source: Zacks Investment Research, Inc. *Anita Dushaynth, PhD*

HISTORICAL STOCK PRICE

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