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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com 10 S. Riverside Plaza, Chicago, IL 60606

Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Phase 2b Trial of ORMD-0801 Fully Enrolled; Data Expected 4Q19…

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 (06/25/19)	$3.50
Valuation	**$18.00**

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 that the 90-day, dose-ranging Phase 2b clinical trial of ORMD-0801 has completed enrollment. The primary efficacy endpoint is reduction in HbA1c. We anticipate topline results being reported in the fourth quarter of 2019. 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.

SUMMARY DATA

52-Week High	**$7.61**
52-Week Low	**$2.78**
One-Year Return (%)	**-53.27**
Beta	**1.28**
Average Daily Volume (sh)	**77,190**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$61**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
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	**-3.5**
P/E using 2020 Estimate	**-3.6**

Risk Level	**Above Avg.**
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	0.6 E	0.6 E	2.5 E
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	-$0.22 E	-$0.34 E	-$1.02 E
2020					-$0.98 E
2021					-$0.90 E

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WHAT'S NEW

Business Update

Oramed Pharmaceuticals Inc. 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), and an oral leptin for the treatment of obesity in patients with T1D.

Phase 2b HbA1c Trial Fully Enrolled

On May 21, 2019, Oramed announced that the Phase 2b clinical trial of ORMD-0801 has completed enrollment. The double blind, randomized 90-day dosing trial is designed to evaluate the efficacy of ORMD-0801 in decreasing glycated hemoglobin (HbA1c), a key clinical measure of blood sugar. 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.

Approximately 300 patients have been enrolled in the Phase 2b trial and 242 (over 80%) have completed treatment. The trial has three arms (once a day, twice a day, or three times a day dosing with ORMD-0801), 80 patients in each arm, and approximately 1/3rd of patients in each arm assigned to placebo. We anticipate topline results in the fourth quarter of 2019.

The company has also initiated a secondary cohort of patients in the study to evaluate the potential efficacy of lower doses of ORMD-0801. Those results are expected to be announced in the first quarter of 2020.

Following release of the data from the first cohort of patients in the fourth quarter of 2019, the company hopes to be able to meet with the FDA soon thereafter for an 'end-of-Phase-2' meeting for feedback on the design for a Phase 3 trial. We believe that the company will most likely look to partner with a larger pharmaceutical company prior to initiating a Phase 3 trial.

Exploratory NASH Trial Ongoing

In Oct. 2018, 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 before the end of 2019.

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 Soon

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 third quarter of 2019. 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).

Oral Leptin Trial to Initiate in 3Q19

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. The single-dose safety trial is scheduled to begin in the third quarter of 2019 in 10 patients with T1D and we anticipate topline results in the fourth quarter of 2019. The ultimate goal of the project is to address weight loss in T1D patients.

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). Research shows there has been a dramatic increase in T1D patients who are overweight and obese over the past 30 years (Conway *et al*., 2010).

Conclusion and Valuation

We're glad to see that Oramed has completed enrollment for the Phase 2b HbA1c trial in patients with T2D and we are eager to see the results. 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. Success in that trial is likely to 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 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 $181 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 $18 per share.

PROJECTED FINANCIALS

Oramed Pharmaceuticals Inc. (Fiscal Year ends Aug. 31)	FY 2018 A	FY 19 Q1 A	FY 19 Q2 A	FY 19 Q3 E	FY 19 Q4 E	FY 2019 E	FY 2020 E	FY 2021 E
License Revenue	$2.4	$0.7	$0.7	$0.6	$0.6	$2.5	$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**	**$0.6**	**$0.6**	**$2.5**	**$2.4**	**$2.4**
YOY Growth	*0%*	*10%*	*11%*	*-3%*	*-3%*	*3%*	*-6%*	*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**	**$0.6**	**$0.6**	**$2.5**	**$2.4**	**$2.4**
Gross Margin	*103.5%*	*94.8%*	*91.7%*	*100.0%*	*100.0%*	*96.5%*	*100.0%*	*100.0%*
Research & Development	$12.0	$4.3	$3.1	$3.5	$5.0	$16.0	$16.0	$18.0
General & Administrative	$4.1	$0.9	$1.1	$1.2	$1.8	$5.0	$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)	($6.2)	($18.5)	($20.1)	($23.1)
Operating Margin	-	-	-	-	-	-	-	-
Other Income (Net)	$1.1	$0.3	$0.2	$0.2	$0.2	$0.9	$0.5	$0.5
Pre-Tax Income	($12.7)	($4.302)	($3.4)	($3.9)	($6.0)	($17.6)	($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%*	*-1.7%*	*0.0%*	*0.0%*
Reported Net Income	($12.7)	($4.3)	($3.7)	($3.9)	($6.0)	($17.9)	($19.6)	($22.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	($0.86)	($0.25)	($0.21)	($0.22)	($0.34)	($1.02)	($0.98)	($0.90)
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	14.9	17.4	17.5	17.6	17.7	17.6	20.0	25.0

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

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