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June 18, 2020
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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Positive Takeaways of Preliminary NASH Study Findings

Based on our probability adjusted DCF model that takes into account future revenues from ORMD0801 and ORMD-0901, the value of ORMP shares could reach $23.00/share as the company advances these candidates towards commercialization. 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 (6/18/2020)	$4.00
Valuation	**$23.00**

OUTLOOK

This week Oramed presented findings from its Nonalcoholic Steatohepatitis (NASH) study at the 2020 American Diabetes Association (ADA) Scientific Sessions, along with two other posters on ORMD-0801.

NASH is currently estimated to affect about 3% to 12% of adults in the U.S., according to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

SUMMARY DATA

52-Week High	**$6.06**
52-Week Low	**$2.32**
One-Year Return (%)	**11.73**
Beta	**1.61**
Average Daily Volume (sh)	**114,228**
Shares Outstanding (mil)	**23**
Market Capitalization ($mil)	**$92**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**21**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-34.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**

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)
2019	0.7 A	0.7 A	0.7 A	0.7 A	2.7 A
2020	0.7 A	0.7 A	0.7 E	0.7 E	2.7 E
2021					2.8 E
2022					2.8 E

Earnings per Share

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2019	-$0.25 A	-$0.21 A	-$0.23 A	-$0.12 A	-$0.82 A
2020	-$0.15 A	-$0.16 A	-$0.11 E	-$0.18 E	-$0.64 A
2021					-$0.91 E
2022					-$0.95 E

Quarters might not sum due to rounding & share counts

Disclosures begin on page 9

KEY POINTS

- This week, Oramed presented preliminary data findings from its NASH study at the American Diabetes Association Scientific Session 2020. The company announced that its NASH study has shown ORMD-0801 to be safe and well tolerated thus far, with an encouraging lowering of fatty liver content. NASH is currently estimated to affect 3%-12% of the U.S. adult population, according to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

- The study of the first eight patients showed that the 12-week, once-daily treatment had no serious adverse events, and induced an observed mean 6.9±6.8% reduction in liver fat content. The relative reduction, as measured by MRI-PDFF, was 30%.

- Concentrations of gamma-glutamyltransferase (GGT), a key marker of chronic hepatitis, were significantly lower after 12 weeks of treatment as compared to baseline.

- We are glad to see that these early results are positive. The company believes that the preliminary observations suggest a positive effect of oral insulin on NASH in people with type 2 diabetes, as shown by reductions in liver fat content.

WHAT'S NEW: POSITIVE UPDATE ON NASH TRIAL

Oramed Pharmaceuticals Inc. (NASDAQ:ORMP) is a clinical-stage pharmaceutical company with a proprietary oral protein delivery platform technology. The company's lead development candidate is ORMD-0801, an oral insulin, that is being tested in both type 1 (T1D) and type 2 diabetics (T2D). The company is also developing ORMD0901, an oral glucagon-like peptide-1 (GLP-1), and an oral leptin for the treatment of obesity in patients with T1D. The company believes that ORMD-0801 could become the first commercial oral insulin capsule for the treatment of diabetes.

NASH Trial Shows Early Positive Signs of Treatment Using ORMD-0801

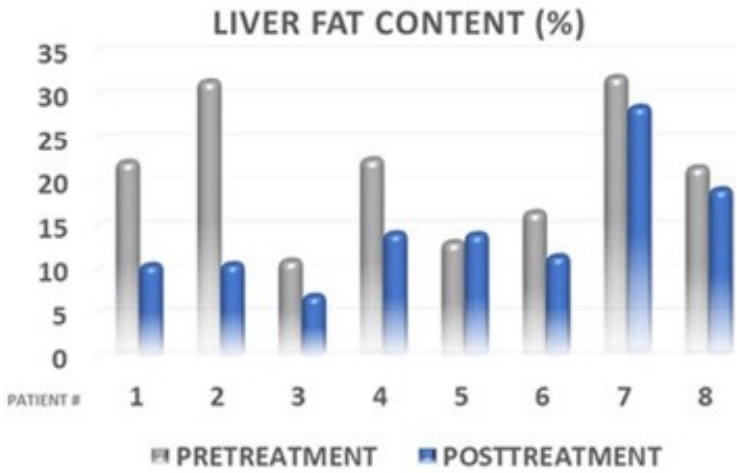
In October 2018, Oramed began an exploratory clinical study to evaluate ORMD-0801, its oral insulin candidate, in patients with nonalcoholic steatohepatitis (NASH), testing the ability of ORMD-0801 to reduce liver fat, inflammation, and fibrosis in NASH patients.

NASH is inflammation and damage to the liver reflecting a buildup of fat. It is the most severe form of nonalcoholic fatty liver disease (NAFLD). Moreover, many, if not most, people with NASH are relatively asymptomatic and therefore do not even realize that they have a liver problem. However, NASH can be severe and put patients at higher risk to develop cirrhosis, liver failure and hepatocellular carcinoma.

According to the National Institutes of Health (NIH), NAFLD is currently estimated to affect up to one billion people globally. It is estimated to be the most common cause of chronic liver disease in the U.S., with 80 to 100 million people affected and some 25% of afflicted patients progressing to NASH. The number of NASH cases is also expected to increase by as much as 63% from 2015 to 2030, according to NIH, driven by rising obesity rates, unmet medical needs and sedentary lifestyles, among other factors. Estimates of the global NASH drug treatment market range from about $20 billion to higher by the mid-2020's.

The study of the first eight patients in Oramed's NASH trial showed that the 12-week, once-daily treatment had no serious adverse events, and induced an observed mean 6.9±6.8% reduction in liver fat content. The relative reduction, as measured by MRI-PDFF, was 30%. The data suggests that ORMD-0801 can have a positive effect in people with type 2 diabetes.

This week, Oramed presented its preliminary data findings at the American Diabetes Association Scientific Session 2020. The company announced that its NASH study has shown ORMD-0801 to be safe and well tolerated thus far, with an encouraging lowering of fatty liver content, as seen by MRI-derived proton density fat fraction (MRI-PDFF). Oramed is expanding its NASH trial to 30 patients and intends to have additional sites in Israel, Europe and potentially the U.S., as well. The study is planned ultimately to enroll 40 patients.



Source: oramed.com

Concentrations of gamma-glutamyltransferase (GGT) were also significantly lower after 12 weeks of treatment as compared to baseline. GGT levels generally are elevated in most diseases that cause damage to the liver or bile ducts and GGT is a key marker of chronic hepatitis.

ADA SCIENTIFIC SESSION 2020 PRESENTATIONS

With the preliminary NASH results in-hand, Oramed presented the results at the ADA meeting. In addition to the NASH data, Oramed also presented two additional posters illustrating the potential benefits of ORMD-0801 from a study exploring its therapeutic efficacy in patients at different dosing levels. A double blind, randomized 90-day dosing trial (Phase 2b), which was funded by ORMD, was designed to evaluate the efficacy of ORMD- 0801 in decreasing glycated hemoglobin A1c (HbA1C) levels, a key clinical measure of blood sugar. Oramed announced on September 17, 2019, that the last patient from the first cohort of the Phase 2b clinical trial of ORMD-0801 had completed treatment.

Oramed scientific advisory board member Dr. Julio Rosenstock presented the other posters. Earlier this year, Oramed bolstered its scientific advisory board with the addition of Dr. Rosenstock and Dr. Alexander Fleming, who both have relevant experience that deepens the board's expertise.

Objective of the Study

- Oral Insulin (ORMD-0801) Effects on Glucose Parameters in Uncontrolled T2DM on Oral Antibiotic Drugs (OADs)
  - Presented by Dr. Julio Rosenstock
  - Director of the Dallas Diabetes Research Center
  - Member of Oramed scientific advisory board

The objective of ORMP's study of oral insulin effects on glucose parameters in uncontrolled type 2 diabetes on oral anti-diabetes (OADs) treatment aimed to assess the efficacy of 12-weeks of 32 mg of ORMD-0801, administered once, twice or three times daily in 272 patients with type 2 diabetes.

Outcome and Conclusion

The 12-week 32 mg ORMD-0801 once or twice daily treatments elicited clinically significant HbA1c reductions among type 2 diabetes patients who were inadequately controlled on standard therapies. Continuous glucose monitoring and serum glucose measures showed similar trends.

ORMD-0801 also was not associated with an increased risk of hypoglycemia or with severe or serious side effects. Moreover, patients did not exhibit any significant weight gain and there were no postprandial glucose parameters recorded over the 12-week treatment period.

The company's conclusion is that the study clearly demonstrated that when considering changes in 12-week HbA1c levels, there is no significant benefit derived from dosing more than once a day at night and that once daily dosing enhances subject compliance and reduces overall treatment costs.

Objective of the Study

- Evening Oral Insulin (ORMD-0801) Glycemic Effects in Uncontrolled T2DM Patients
  - Presented by Dr. Julio Rosenstock
  - Director of the Dallas Diabetes Research Center
  - Member of Oramed scientific advisory board

The objective of ORMP's study of evening oral insulin (ORMD-0801) glycemic effects In uncontrolled type 2 diabetes patients aimed to assess the efficacy of 12-weeks of 8 mg, 16 mg and 32 mg of ORMD-0801, administered once, twice or three times daily in 419 patients with type 2 diabetes. It was a randomized, placebo-controlled, multi-center study in phase 2b.

Outcome and Conclusion

The 12-week 8 mg to 32 mg of ORMD-0801 once daily and twice daily treatments elicited clinically significant HbA1c reductions among patients with type 2 diabetes inadequately controlled on standard therapies and with mean HbA1c levels >8% versus the normal HbA1c range of 4% to 5.6% in people who do not have diabetes. Continuous glucose monitoring and serum glucose measures showed similar trends.

ORMD-0801 was not associated with an increased risk of hypoglycemia or with severe or serious side effects. Patients exhibited no significant weight gain and no postprandial glucose parameters were recorded over the 12-week treatment period. The company's conclusion is that the study demonstrated that when considering changes in 12-week HbA1c levels, there is no significant benefit derived from dosing more than once daily, at night. Daily dosing will enhance subject compliance and reduce treatment costs.

ENCOURAGED BY FDA FEEDBACK IN END-OF-PHASE 2 MEETING

On May 21, 2019, Oramed announced that the Phase 2b clinical trial of ORMD-0801 had completed enrollment. The double blind, randomized 90-day dosing trial was 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 its prior Phase 2 clinical trial.

The Phase 2b trial noted above achieved its primary endpoint, which was the reduction in HbA1c compared to placebo at week 12. Following release of the data from the first cohort of patients in 4Q19, the company met with the FDA for an end-of-Phase-2 meeting for feedback on the design for a Phase 3 trial.

The meeting was held in February 2020. The company received feedback from the FDA on key issues relating to Drug Product manufacture and supported continuing to Phase 3 clinical development. The company was encouraged by the feedback it received. We believe that Oramed will most likely look to partner with a larger pharmaceutical company prior to initiating a Phase 3 trial.

Potential COVID-19 Vaccine Delivery

Separately, given the potential versatility of the company's oral protein delivery platform technology, ORMP believes that the platform could also be effective for protein-based vaccines for the COVID-19 virus caused by SARS-CoV-2 novel coronavirus and is monitoring developments for the possibility of forming potential partnerships with regard to a COVID-19 vaccine.

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. Our current model has ORMD- 0801 receiving approval in 2024, with first commercial sales in 2025. We model ORMD-0901 receiving approval in 2025, with commercial sales commencing the following year.

We estimate 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 (NPV) for those two programs of $213 million and $152 million, respectively.

When including the current cash total (pro forma cash was estimated at about $50 million in April 2020), potential cash from warrant exercises, and dividing by the fully diluted share count, we obtain a NPV for Oramed of approximately $23 per share. As the company moves these assets closer to commercialization, we would expect to see their anticipated future value begin to be reflected in the share price.

RECENT NEWS

- Oramed announced positive initial clinical trial results for treatment of NASH with oral insulin on June 15, 2020.
- The Canadian Patent Office indicated its intention to grant Oramed a patent for oral delivery of proteins on April 7, 2020.
- Oramed issued a shareholder letter and business update, noting the impact of COVID-19 on its business, on April 1, 2020.
- Oramed announced that it had received positive feedback from its end-of-Phase 2 Oral Insulin CMC meeting with the FDA on March 19, 2020.

- The company raised $20 million in an offering of about 5.3 million shares in a transaction that closed on February 26, 2020.

- Oramed reported positive results in the final cohort of Its Phase 2b Oral Insulin Trial on February 26, 2020.

- Oramed appointed Dr. Julio Rosenstock to Its Scientific Advisory Board on January 30, 2020.

PROJECTED FINANCIALS

Oramed Pharmaceuticals Inc. (Fiscal Year ends Aug. 31)	FY 2018 A	FY 2019 A	Q1 A	Q2 A	Q3 E	Q4 E	FY 2020 E	FY 2021 E	FY 2022 E
License Revenue	$2.4	$2.7	$0.7	$0.7	$0.7	$0.7	$2.7	$2.8	$2.8
YOY Growth	-	-	-	-	-	-		-	-
Grant/Contract Revenue	$0.0	$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	$0.0
YOY Growth	-	-	-	-	-	-		-	-
ORMD-0901	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-		-	-
Total Revenues	**$2.4**	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$2.8**	**$2.8**
YOY Growth	*0%*	*10%*	*0%*	*1%*	*3%*	*3%*	*2%*	*2%*	*0%*
Cost of Revenue	$0.1	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	**$2.5**	**$2.6**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$2.8**	**$2.8**
Gross Margin	*103.5%*	*96.7%*	*96.7%*	*96.7%*	*96.7%*	*96.7%*	*100.0%*	*100.0%*	*100.0%*
Research & Development	$12.0	$13.5	$2.0	$3.3	$2.0	$3.5	$10.8	$18.0	$20.0
General & Administrative	$4.1	$3.7	$1.1	$1.4	$1.2	$1.3	$5.0	$7.5	$7.5
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($13.5)	($14.6)	($2.4)	($4.0)	($2.5)	($4.1)	($13.1)	($22.7)	($24.7)
Operating Margin	-	-						-	-
Other Income (Net)	$1.1	$0.6	$0.1	$0.3	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	**($12.7)**	**($14.1)**	**($2.5)**	**($3.7)**	**($2.5)**	**($4.1)**	**($12.8)**	**($22.7)**	**($24.7)**
Net Taxes (benefit)	$0.0	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($12.7)**	**($14.4)**	**($2.5)**	**($3.7)**	**($2.5)**	**($4.1)**	**($12.8)**	**($22.7)**	**($24.7)**
Net Margin	-	-						-	-
Reported EPS	**($0.86)**	**($0.82)**	**($0.15)**	**($0.21)**	**($0.11)**	**($0.18)**	**($0.64)**	**($0.91)**	**($0.95)**
YOY Growth	-	-							
Basic Shares Outstanding	14.9	17.5	17.5	17.8	23.1	23.1	20.4	25.0	26.0

Source: Zacks Investment Research, Inc.

HISTORICAL STOCK PRICE

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