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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Advancing Toward Phase 3 Program For ORMD-0801

Based on our probability adjusted DCF model that takes into account future revenues from ORMD-0801 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 (9/21/2020)	$2.79
Valuation	**$23.00**

OUTLOOK

ORMP plans to initiate two Phase 3 clinical trials for ORMD-0801 once the FDA review of protocols and nonclinical documents is complete. The company updated clinical research organization services agreements for the studies earlier this month. We believe demand for ORMD-0801 from the medical community and among T2D patient populations could be significant, given that ORMD-0801 is a less invasive oral treatment option that potentially does not cause hypoglycemia or weight gain.

SUMMARY DATA

52-Week High	**$6.05**
52-Week Low	**$2.43**
One-Year Return (%)	**-15.45**
Beta	**1.49**
Average Daily Volume (sh)	**117,000**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$66**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**16**
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 2020 Estimate	**N/A**
P/E using 2021 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	-$0.21 A	-$0.10 A	-$0.18 E	-$0.63 E
2021					-$0.91 E
2022					-$0.95 E

Quarters might not sum due to rounding & share counts

Disclosures begin on page 9

KEY POINTS

- Following positive feedback during its end of Phase 2 meeting with FDA representatives, ORMP tis getting ready to initiate two Phase 3 clinical trials after the FDA has reviewed its Phase 3 protocols and nonclinical documents.

- Earlier this month, Oramed updated clinical research organization services agreements with Integrium for the planned upcoming Phase 3 clinical trial to be conducted under an FDA Investigational New Drug (IND) application.

- Oramed's Phase 3 trial is designed to assess the safety of ORMD-0801 and evaluate its efficacy on about 675 patients with type 2 diabetes. Oramed plans to conduct two concurrent phase 3 trials in a double-blinded, placebo-controlled, double dummy, multi-center randomized, Phase 3 study.

- We believe demand for ORMD-0801 within the medical community and among patient populations could be significant, given that ORMD-0801 is a less invasive oral treatment option that potentially does not cause hypoglycemia or weight gain.

- In fact, findings from a recent study that Oramed commissioned from a third-party research firm shows strong potential support from health care providers for the use of oral insulin with T2D patients early in the treatment process through a primary care physician before the need for injectable insulin arises and before the patient must be seen by an endocrinologist for diabetes care. Health care providers saw the advantages of ORMD-0801's potential to not cause hypoglycemia or weight gain and as an oral medication that could avert the need for injections.

WHAT'S NEW: READYING FOR PHASE 3

Business Update

Phase 3 Program for ORMD-0801 to Initiate Shortly…

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.

CRO Agreement For Phase 3 Launch

Earlier this month, Oramed updated clinical research organization (CRO) services agreements with Integrium, LLC for its planned upcoming Phase 3 clinical trial to be conducted under an FDA Investigational New Drug (IND) application. Integrium has a long history of assisting biotech companies with their clinical trials, having been founded in 1998.

Oramed's Phase 3 trial is designed to assess the safety of ORMD-0801 and evaluate its efficacy on about 675 patients with type 2 diabetes. The study is a double-blinded, placebo-controlled, double dummy, multi-center randomized, Phase 3 study. Oramed plans to conduct the two concurrent phase 3 trials.

The company had announced earlier in July that the FDA had provided positive feedback (see below) during its end of Phase II meeting with FDA representatives. ORMP therefore intends to initiate two Phase III clinical trials after the FDA has reviewed its Phase 3 protocols and nonclinical documents. The FDA outlined its expectations for the design of the ORMD-0801 Phase 3 trials and of the submission of the Biologics License Application following successful trials.

Conclusion

We are optimistic as Oramed prepares for its upcoming Phase 3 trial in patients with T2D and we are eager to see enrollments begin. We believe demand for ORMD-0801 within the medical community and among patient populations could be significant. In fact, findings from a recent study that Oramed conducted through a third-party research firm supported that strong support exists among health care providers for use of oral insulin with T2D patients early in the treatment process through a primary care physician before injectable insulin is required and before the patient must be seen by an endocrinologist for diabetes care. Health care providers saw the advantages of ORMD-0801's potential to not cause hypoglycemia or weight gain and as an oral medication that could avert the need for injections.

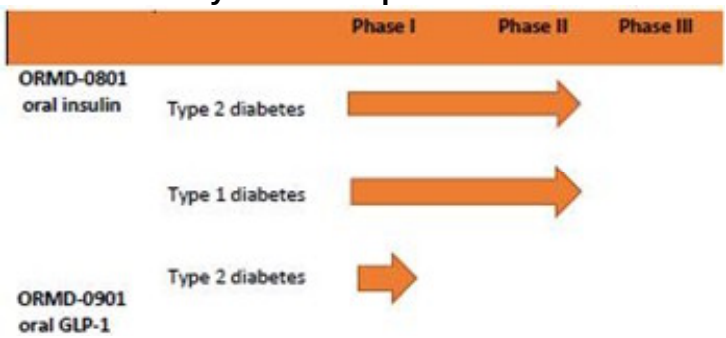
ENCOURAGED BY FDA FEEDBACK IN END-OF-PHASE 2 MEETING

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.

Oramed Primary Product Pipeline



Source: Oramed 10-Q

NASH TRIAL

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

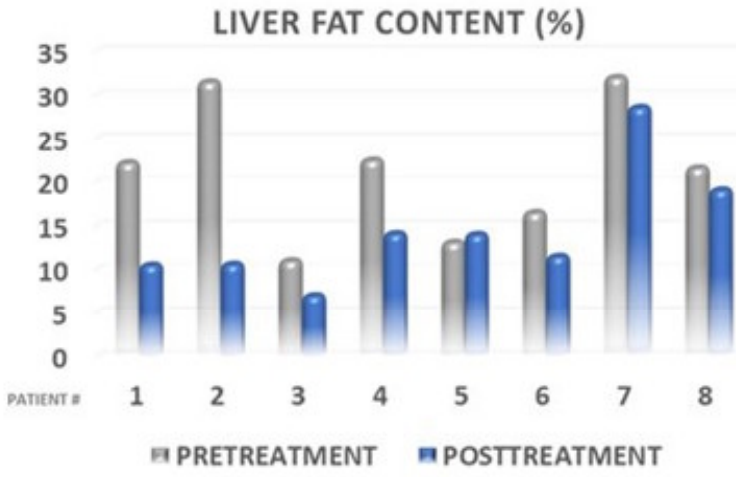
Separately, Oramed began an exploratory clinical study in October 2018 to evaluate ORMD-0801, its oral insulin candidate, in patients with nonalcoholic steatohepatitis (NASH), testing the ability of ORMD-0801 to reduce liver fat, inflammation, and fibrosis in NASH patients.

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.

ADDITIONAL POTENTIAL APPLICATIONS OF TECHNOLOGY

Potential COVID-19 Vaccine Delivery

Separately, in addition to the ORMD-0801 insulin capsule, ORMP''s leading drug candidate, the company is also studying the underlying technology for an orally ingestible GLP-1 capsule, ORMD-0901. Moreover, 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. With many markets heading into second rounds of lockdowns, there is still a tremendous global need for a COVID-19 vaccine.

In terms of ORMD-0901, ORMP completed a Phase 1 pharmacokinetics (PK) trial to evaluate the safety and PK of ORMD-0901 relative to placebo in February 2019. ORMP expects to conduct further studies on T2D patients in the U.S. under an IND.

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 (cash and equivalents plus long-term investments aggregated about $46 million at May 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

- On September 21, 2020, Oramed announced that it would present at the European Association for the Study of Diabetes (EASD) annual meeting.
- Oramed released an overview of its Diabetes Market Survey showing strong support for ORMD-0801 among physicians and patients on September 15, 2020.
- 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 A	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%*	*1%*	*3%*	*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	$1.9	$3.5	$10.8	$18.0	$20.0
General & Administrative	$4.1	$3.7	$1.1	$1.4	$1.0	$1.3	$4.8	$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)**	**($2.3)**	**($4.1)**	**($12.8)**	**($22.7)**	**($24.7)**
Operating Margin	-	-					-	-	-
Other Income (Net)	$1.1	$0.6	$0.1	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($12.7)**	**($14.1)**	**($2.5)**	**($3.7)**	**($2.3)**	**($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)**	**($2.3)**	**($4.1)**	**($12.8)**	**($22.7)**	**($24.7)**
Net Margin	-	-					-	-	-
Reported EPS	**($0.86)**	**($0.82)**	**($0.15)**	**($0.21)**	**($0.10)**	**($0.18)**	**($0.63)**	**($0.91)**	**($0.95)**
YOY Growth	-	-					-	-	-
Basic Shares Outstanding	14.9	17.5	17.5	17.8	23.2	23.1	20.4	25.0	26.0

Source: Zacks Investment Research, Inc.

HISTORICAL STOCK PRICE

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