Zacks Small-Cap Research
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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: ORMD-0801 in Phase 3 TD2 and NASH Clinical Studies

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)	$4.32
Valuation	**$23.00**

OUTLOOK

ORMP has screened the first patients in its global TD2 Phase 3 trials and its global NASH trial for its proprietary oral insulin capsule, ORMD-0801, the company's lead development candidate. The company believes that ORMD-0801 could become the first commercial oral insulin capsule for the treatment of diabetes, a disease that is growing in prevalence and which registers an aggregate estimated national cost of $327 billion. Estimates of the global NASH drug treatment market range from about $20 billion to higher by the mid-2020's.

SUMMARY DATA

52-Week High	**$6.05**
52-Week Low	**$2.40**
One-Year Return (%)	**-13.25**
Beta	**1.99**
Average Daily Volume (sh)	**495,362**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$102**
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 A	0.7 A	2.7 A
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	-$0.15 A	-$0.56 A
2021					-$0.91 E
2022					-$0.95 E

Quarters might not sum due to rounding & share counts

Disclosures begin on page 11

KEY POINTS

- Oramed has screened the first patients in its global ORMD-0801 Phase 3 trials for the treatment of type 2 diabetes (T2D). ORMD-0801, the company's lead development candidate, is an oral insulin, that is being tested in both type 1 (T1D) and T2D.

- The company believes that ORMD-0801 could become the first commercial oral insulin capsule for the treatment of diabetes, a disease that is growing in prevalence and which puts the patient at increased risk for blindness and heart attack, among other diseases, and which results in significantly higher per patient (2.3x) healthcare costs and an aggregate estimated national annual cost of $327 billion.

- Oramed also has screened the first patients in its global NASH trial in which ORMD-0801 is being studied for the treatment of patients with nonalcoholic steatohepatitis (NASH).

- The number of NASH cases is 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.

- ORMP has renewed and extended its equity distribution agreement with Canaccord Genuity to issue up to $40 million of its shares from time to time to enhance its financial flexibility.

WHAT'S NEW? CLINICAL STUDIES MOVE FORWARD

ORMD-0801 Moves Into Phase 3 Program

Oramed Pharmaceuticals Inc. (Nasdaq: ORMP), a clinical-stage pharmaceutical company with a proprietary oral protein delivery platform technology, announced that it has screened the first patients in its global ORMD-0801 Phase 3 trials for the treatment of type 2 diabetes (T2D). ORMD-0801, the company's lead development candidate, is an oral insulin, that is being tested in both type 1 (T1D) and 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. Oramed is conducting two concurrent phase 3 trials:

- ORA-D-013-1 - about 675 patients, 75 U.S. sites
- ORA-D-013-2 – about 450 patients, sites in the U.S., Europe and Israel

Both ORA-D-013-1 and ORA-D-013-2 will treat T2D patients who have inadequate glycemic control over a six to 12 month period. To secure a geographically diverse patient population, ORMP is recruiting patients from multiple U.S., European and Israeli sites. The patients noted above were screened at U.S. sites that are participating in the ORA-D-013-1 trial. The U.S. study will recruit 675 patients from 75 clinical locations throughout the U.S.

These are double-blinded, placebo-controlled, multi-center randomized studies. To evaluate the efficacy and safety of ORMD-0801, ORMP intends to recruit an aggregate 1,125 patients. The company expects that efficacy data will be available after all patients enrolled have completed the first six-month treatment period. ORA-D-013-1 is recruiting 675 patients through 75 U.S. clinical centers. These patients currently are on 1, 2 or 3 oral glucose-lowering agents. The ORA-D-013-2 study will recruit about 450 patients through 36 U.S. sites, 25 in Western Europe and Israel.

The Phase 3 clinical trial is being conducted under an FDA Investigational New Drug (IND) application. Following positive feedback during its end-of-Phase 2 meeting with the FDA, ORMP initiated the two simultaneous Phase 3 clinical trials after the FDA had reviewed its Phase 3 protocols and nonclinical documents. The company has noted that, with ORMD-0801 as the first oral insulin capsule to achieve necessary FDA efficacy and safety data, the company's Phase 3 trial is the first worldwide FDA Phase 3 oral insulin trial.

Primary and Secondary Endpoints

- The primary endpoint of the Oramed study is to compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c

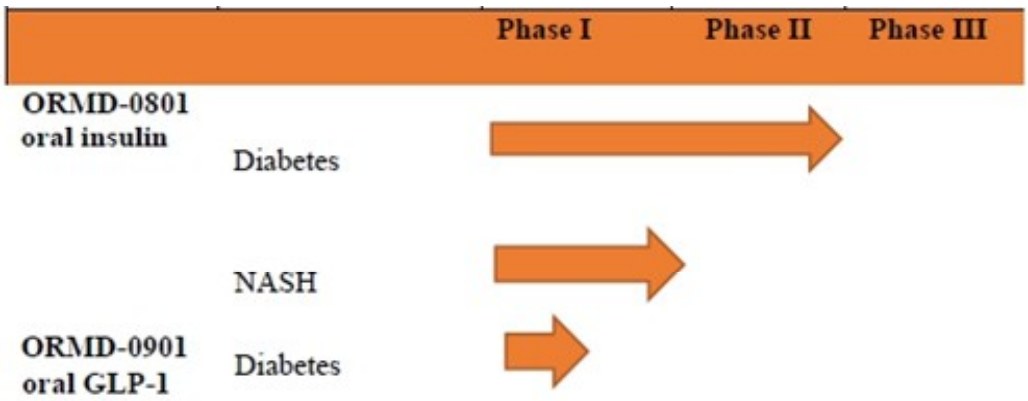
- The secondary endpoint is assessing the change from baseline in fasting plasma glucose at 26 weeks.

In preparing for the Phase 3 study, Oramed updated clinical research organization (CRO) services agreements with Integrium, LLC. Integrium, founded in 1998, has a long history of assisting biotech companies with their clinical trials.

The Phase 3 trial follows a successful Phase 2b trial that 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 in February 2020 for the above-noted end-of-Phase-2 meeting for feedback on the design for a Phase 3 trial. The company had announced earlier in July that the FDA had provided positive feedback during this meeting, as noted. The FDA outlined its expectations for the design of the ORMD-0801 Phase 3 trials.

We are optimistic about Oramed's Phase 3 trial in patients with T2D. 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.

Oramed Primary Product Pipeline



Source: Oramed 10-K

Diabetes, which affects how the body uses blood sugar (glucose), occurs when the body does not produce sufficient levels of or properly use insulin, which is a hormone that causes sugar to be absorbed into cells where it (the sugar) then is converted into energy. Diabetes is attributed to both hereditary and

environmental factors, including obesity and lack of exercise. As obesity rates rise globally (see below), the incidence of diabetes has also increased. For instance, the International Diabetes Federation (IDF) projects that 700 million adults (20-79 years) worldwide will suffer from diabetes by 2045, up from an estimated 463 million in 2019. The IDF also estimates that 4.2 million people died from diabetes in 2019.

Addressable Market

In its study, *Economic Costs of Diabetes in the U.S.,* the American Diabetes Association (ADA) estimates that in the U.S., roughly 34.2 million people, or 10.5% of the national population, suffer from diabetes (2018 data). Diabetes is a leading risk factor for blindness, kidney failure, heart attack, stroke and amputation. The ADA estimates that patients with diabetes incur 2.3x the cost of healthcare compared to those without diabetes and that the total cost of diagnosed diabetes in the U.S. aggregates to $327 billion, which represents a 26% increase over the five-year period ended 2017 (the year for which the most recent data is available). Most diabetes patients currently need to inject themselves with insulin and, according to studies conducted by ORMP and others, would prefer an oral delivery method to control their diabetes.

NASH TRIAL ALSO MOVING FORWARD

Earlier NASH Trial Showed Positive Signs of Treatment Using ORMD-0801

Last week Oramed announced that it had screened the first patients in its global NASH trial in which Oramed's oral insulin capsule ORMD-0801 is being studied for the treatment of patients with nonalcoholic steatohepatitis (NASH).

Oramed began an exploratory clinical study in October 2018 to evaluate ORMD-0801 in patients with NASH, testing the ability of ORMD-0801 to reduce liver fat, inflammation, and fibrosis in NASH patients. Oramed is expanding upon its earlier NASH trial to include up to 40 patients and additional sites. The Oramed trial is being conducted at clinical locations in the U.S. (three locations), EU (three) and Israel (two).

Patients in the NASH study were screened at a U.S. site that is participating in the Oramed trial, which is being conducted at clinical locations in the U.S. (three locations), EU (three) and Israel (two). The trial will measure efficacy endpoints via MRI-PDFF for 12-weeks dosing.

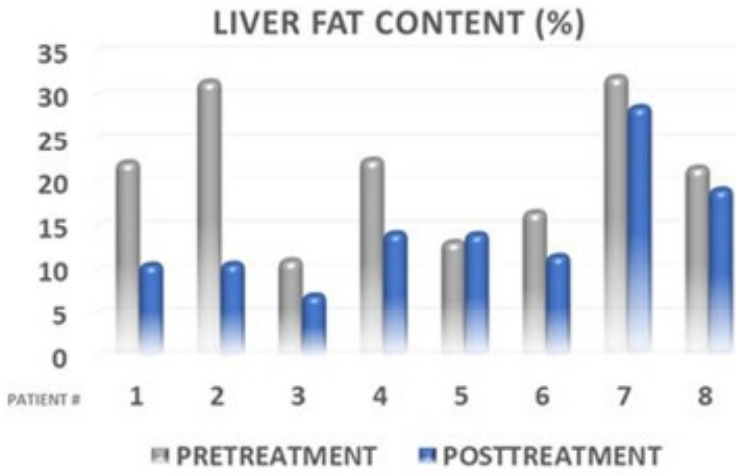
NASH is inflammation and damage to the liver reflecting a buildup of fat. It is the most severe form of nonalcoholic fatty liver disease (NAFLD). Moreover, many, if not most, people with NASH are relatively asymptomatic and therefore do not even realize that they have a liver problem. However, NASH can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

Based on the strong results from a previous study, where ORMD-0801 showed a 30% relative reduction in liver fat, the company appropriately felt it would be valuable to move clinical trials forward. The earlier study of the first eight patients in the Oramed 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.

In June 2020, the company presented preliminary data from the open-label study of the first 8 patients of the planned 40-patient multi-center pilot NASH study. When 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).



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.

ORMD-0901 TECHNOLOGY PLATFORM

Oral Glucagon-Like Peptide-1

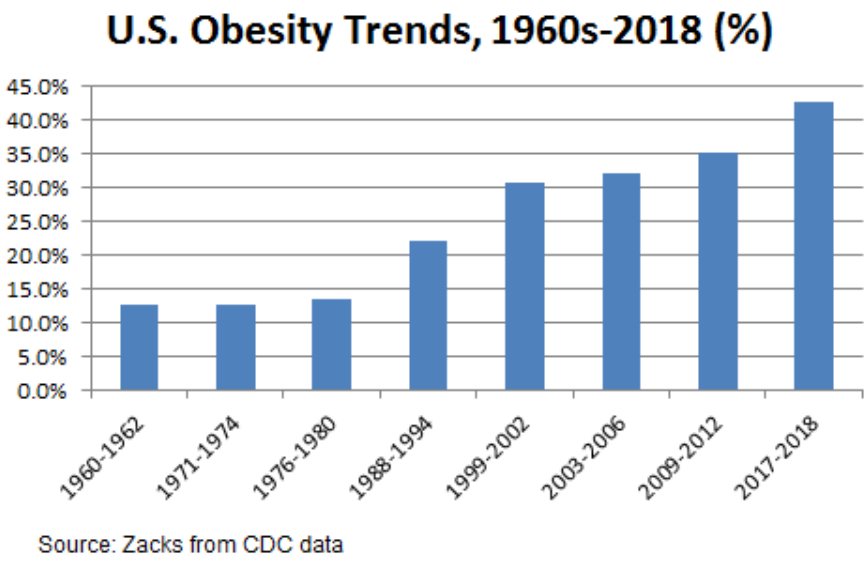
ORMP is also leveraging its technology for an orally ingestible glucagon-like peptide-1 (GLP-1) capsule, ORMP's second pipeline product, ORMD-0901. ORMD-0901 is an orally ingestible exenatide (GLP-1 analog) capsule designed to aid in the balance of blood-sugar levels and also to decrease appetite.

Glucagon-like peptide-1 (GLP-1) is an incretin hormone, which is a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. When it became evident that glucose ingested orally stimulated 2-3x more insulin release than the same amount of glucose administered intravenously, the incretin concept began to develop.

There are several positive attributes of GLP-1. In addition to stimulating insulin release, GLP-1 has been found to suppress pancreatic glucagon release, slow gastric emptying to, in turn, lower the rate of absorption of nutrients into the blood stream, and increase satiety to in turn lower appetite. Other important beneficial attributes of GLP-1 are its effects of increasing the number of beta cells (cells that manufacture and release insulin) in the pancreas and, possibly, protection of the heart.

The appetite suppressing attributes of GLP-1 could be an important factor in fighting obesity, as obesity rates in adults and children have more than doubled since the 1970's, according to the National Center

for Health Statistics. According to the CDC, over 42% of Americans are obese, up from 30.5% in 1999–2000. This pattern is evident globally, as well.



Source: Zacks from CDC data

Technology Platform Potential Delivery Mechanism for COVID-19 Vaccine, Among Other Uses

Separately, Oramed 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. The tremendous global need for COVID-19 vaccines is highly publicized, particularly as many markets head into new rounds of lockdowns or partial lockdowns. 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.

BALANCE SHEET - CAPITAL

At the end of its FY 2020 (fiscal year ends in August) ORMP had $19.3 million of cash, plus $20.6 million of deposit and marketable securities.

Earlier this month ORMP formed an equity distribution agreement with Canaccord Genuity to issue up to $40 million of its shares from time to time, extending their earlier agreement. From December 2, 2019 through December 1, 2020, ORMP sold 2.2 million shares under the agreement, raising an aggregate roughly $10.6 million, with $4.4 remaining under the prior agreement in addition to the $40 million under the new one.

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 $40 million at August 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.

RISKS

Risks to Oramed achieving its objectives, and to our valuation, include the following.

- ORMP might need to raise additional capital earlier than expected.
- The company's clinical studies and potential commercialization timelines might be delayed.
- The company's drug candidates might experience clinical failure and/or might not receive FDA approval.
- Potential competitors might find a workaround vis-à-vis the company's IP.

RECENT NEWS

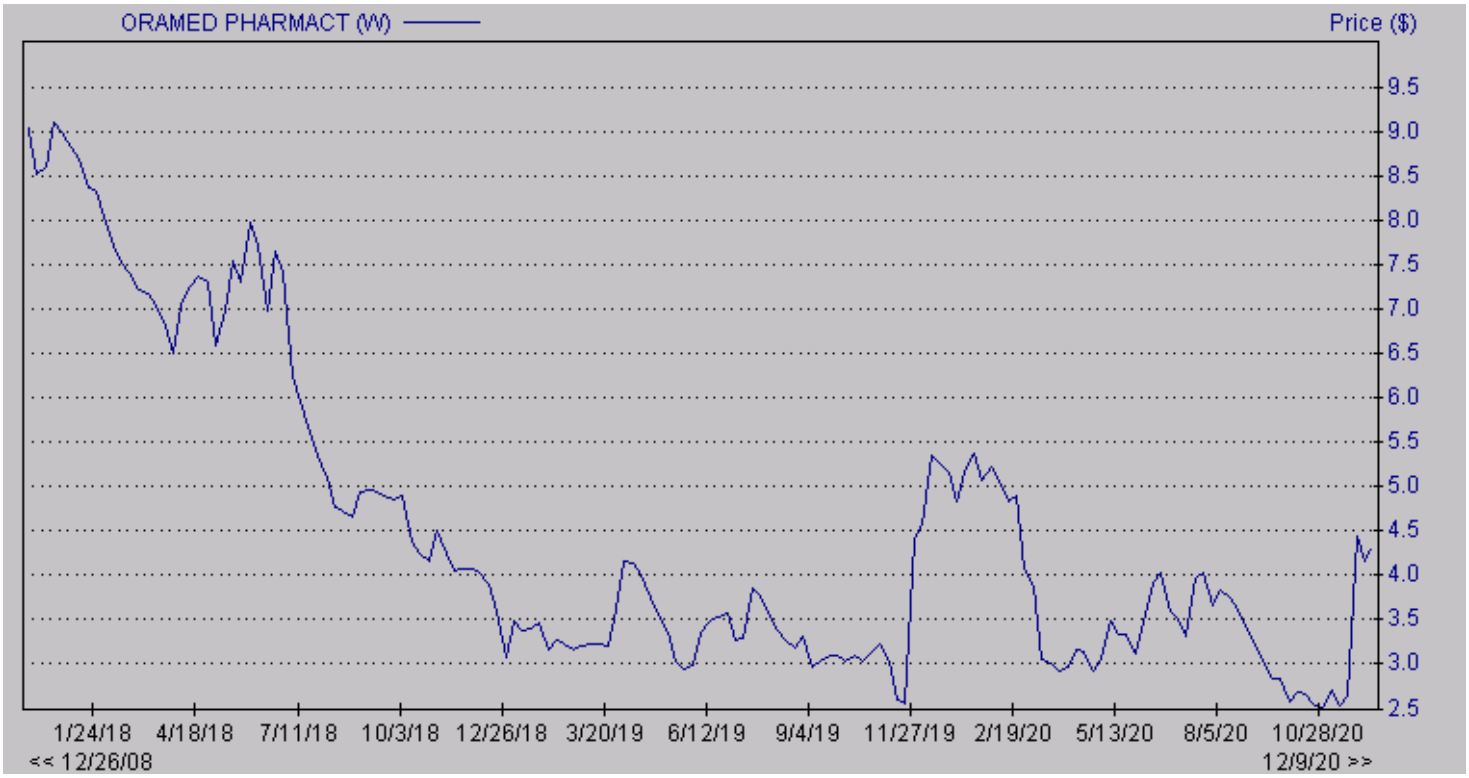
- On December 2, 2020, Oramed announced that it had initiated its Phase 2 NASH trial
- Oramed initiated the Phase 3 trial of ORMD-0801 on November, 24, 2020.
- Oramed presented Phase 2b ORMD-0801 data at the American Association of Pharmaceutical Scientists 2020 PharmSci 360 Conference on October 28, 2020.
- 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 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.

PROJECTED FINANCIALS

Oramed Pharmaceuticals Inc. (Fiscal Year ends Aug. 31)	FY2018 A	FY2019 A	Q1 A	Q2 A	Q3 A	Q4 A	FY2020 A	FY2021 E	FY2022 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	$3.0	$10.2	$18.0	$20.0
General & Administrative	$4.1	$3.7	$1.1	$1.4	$1.0	$0.7	$4.2	$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)	($3.0)	($11.7)	($22.7)	($24.7)
Operating Margin	-	-					-	-	-
Other Income (Net)	$1.1	$0.6	$0.1	($0.3)	($0.0)	$0.5	$0.2	$0.0	$0.0
Pre-Tax Income	**($12.7)**	**($14.1)**	**($2.5)**	**($3.7)**	**($2.3)**	**($3.5)**	**($11.5)**	**($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)**	**($3.5)**	**($11.5)**	**($22.7)**	**($24.7)**
Net Margin	-	-					-	-	-
Reported EPS	**($0.86)**	**($0.82)**	**($0.15)**	**($0.21)**	**($0.10)**	**($0.15)**	**($0.56)**	**($0.91)**	**($0.95)**
YOY Growth	-	-					-	-	-
Basic Shares Outstanding	14.9	17.5	17.5	17.8	23.2	23.5	20.5	25.0	26.0

Source: Zacks Investment Research, Inc.

HISTORICAL STOCK PRICE



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