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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Distribution Deals, JVs in Anticipation of Commercializing ORMD-0801

As ORMP continues to advance its proprietary oral protein delivery technology potentially to treat diabetes, NASH and obesity and as an oral COVID vaccine, among other possible applications, Oramed has entered into multiple joint ventures (JVs) and / or distribution deals in recent quarters to maximize its R&D and anticipated commercialization efforts.

Current Price (10/4/2023)	$2.31
Valuation	**$4.30**

OUTLOOK

Oramed recently signed a non-binding term sheet with Hefei Tianhui Biotechnology Co. (HTIT) to establish a JV based on its oral drug delivery technology, focusing on development and commercialization of products based on its oral insulin and leveraging HTIT's manufacturing capabilities and technologies. Each of the JV partners is expected to own an initial 50% share in the JV and have equal representation on the JV board.

SUMMARY DATA

52-Week High	**$13.73**
52-Week Low	**$1.81**
One-Year Return (%)	**-65**
Beta	**1.79**
Average Daily Volume (sh)	**186,026**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$93**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**17**
Insider Ownership (%)	**11**
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 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)*
2020					2.7 A
2021					2.7 A
2022	0.7 A	0.7 A	0.7 A	0.7 A	2.7 A
2023	0.7 A	0.7 A	0.7 E	0.6 E	2.6 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)*
2020					-$0.56 A
2021					-$0.78 A
2022	-$0.27 A	-$0.27 A	-$0.18 A	-$0.36 A	-$0.94 A
2023	-$0.08 A	-$0.03 A	-$0.08 E	-$0.23 E	-$0.41 E

Quarters might not sum due to round'g, share counts & FY
Disclosures page 10 *'22 FY changed to Dec. 31

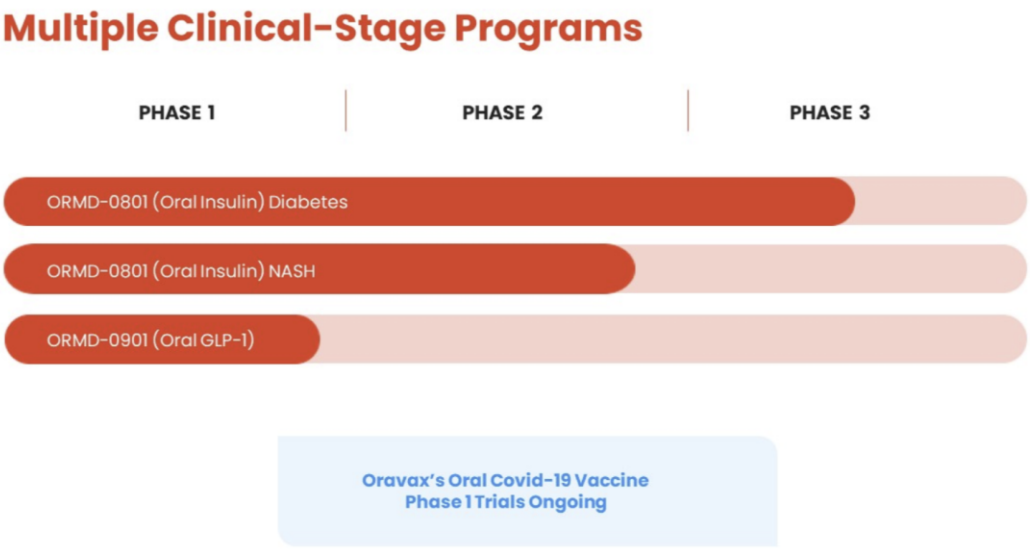
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JV'S, DISTRIBUTION DEALS IN ANTICIPATION OF ORMD-0801 COMMERCIALIZATION

JV with HTIT to help commercialize ORMD–0801 …

Oramed Pharmaceuticals' (NASDAQ:ORMP) continues to advance its proprietary oral protein delivery platform and is researching the technology potentially to treat diabetes, NASH (nonalcoholic steatohepatitis (NASH), and obesity, as an appetite suppressant, and a COVID vaccine, among other possible applications. To maximize its research and development and anticipated commercialization efforts, Oramed has entered into joint ventures (JVs) and distribution deals in recent quarters.

For example, Oramed has signed a non-binding term sheet with Hefei Tianhui Biotechnology Co. (HTIT) to establish a JV based on Oramed's oral drug delivery technology focusing on development and commercialization of innovative products based on Oramed's oral insulin and POD™ (Protein Oral Delivery) pipeline globally, leveraging HTIT's manufacturing capabilities and technologies. HTIT is a high-tech company focused on biopharmaceutical product manufacturing and R&D with an emphasis on the oral delivery of therapeutic macromolecules. HTIT operates an oral insulin manufacturing facility located in Hefei, China. Each of the JV partners would initially own a 50% share in the JV and have equal representation on the JV board. HTIT and Oramed are expected to make initial investments of $60 million and $10 million, respectively.



Source: Company presentation

ORMD–0801 potential treatment for diabetes, NASH …

Oramed's lead asset ORMD-0801 is being evaluated as an oral insulin treatment for Type 1 (T1D) and Type 2 (T2D) diabetes. The company believes that ORMD-0801 potentially could represent an innovative way to treat T2D through the oral delivery of insulin at an earlier stage of treatment than current delivery methods. In turn, providing earlier treatment could potentially slow the progression of the disease and delay late-stage complications. The company completed a Phase 2b, 90- day HbA1c trial of ORMD-0801, which met its primary endpoint achieving a statistically significant reduction of HbA1c.

HTIT has completed a Phase 3 oral insulin clinical trial in China and, based on the results, submitted a marketing authorization application to China's regulatory body, the National Medical Products Administration. The Phase 3 trials of oral insulin in type 2 diabetes (T2D) in China were conducted under a differentiated study protocol. The company believes these steps further its ability to commercialize ORMD-0801 in China with its partner. Separately, Oramed has also signed an exclusive distribution agreement with Medicox for ORMD-0801 in South Korea, where about one in seven adults suffers from diabetes, according to NIH. Both the Medicox and HTIT relationships have produced revenue for Oramed

in anticipation of ORMD-0801 commercialization. The company believes there is significant opportunities for an oral insulin treatment in China. About 10% of the adult population in China have diabetes, according to the World Health Organization (WHO), which noted in 2016 that:

"In 1980, less than 5% of Chinese men had diabetes. Now, more than 10% do. This increase has been largely driven by unhealthy lifestyles – diets that are too high in sugar and fat, and people not getting enough physical activity… Even more startling is the fact that almost half of all adults in China – close to 500 million people – have prediabetes. Not only does this pose a risk factor for developing Type 2 diabetes, but also for other conditions such as cardiovascular disease."

The company had about $150 million in cash and equivalents at the end of June 2023 to advance its development efforts and initiatives. Subsequently, Oramed entered into a roughly $102 million short-term senior secured note transaction with Scilex Holding Company. The notes bear interest at a rate of SOFR plus 8.5% (subject to a SOFR floor of 4.0%) per annum and have an 18-month maturity, with repayments set to begin in installments on December 21, 2023. Oramed also received warrants to purchase up to 17 million Scilex shares. Scilex is a biopharma company focused on acquiring, developing, and commercializing non-opioid management products to treat acute and chronic pain.

ORMD-0801 NASH DEVELOPMENT EFFORTS

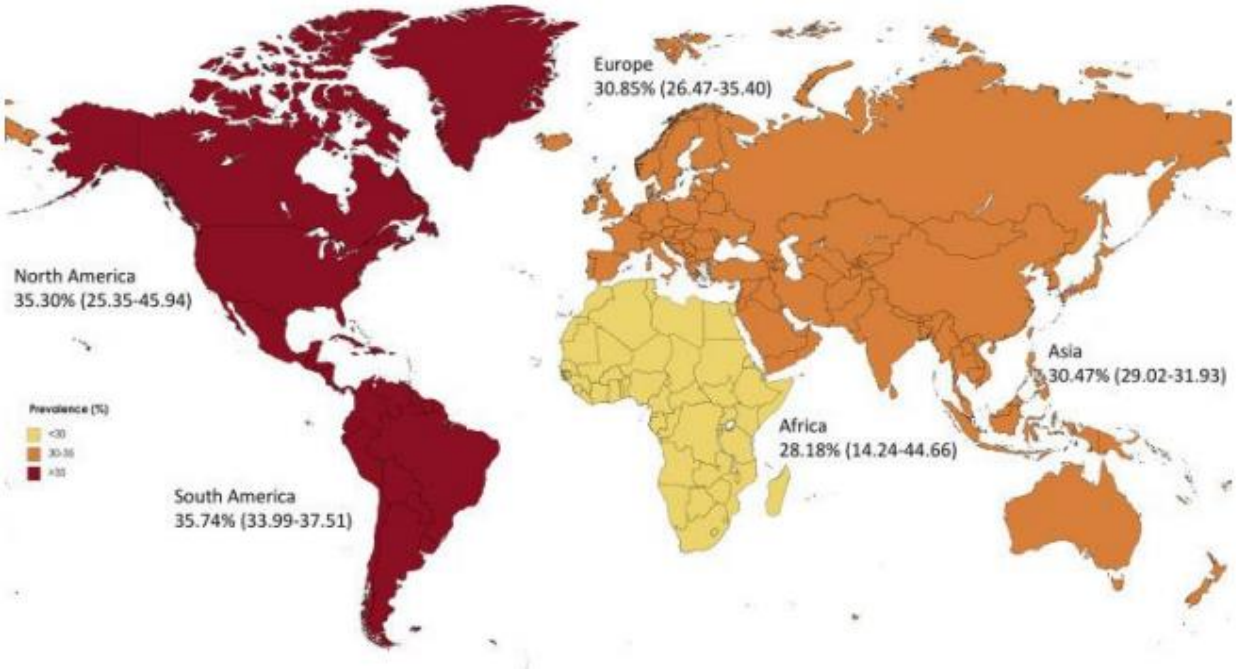
Oramed has multiple clinical development programs underway. For example, the company has completed a Phase 2 global NASH trial that was designed to test ORMD-0801's ability to reduce liver fat, inflammation, and fibrosis in NASH patients. The trial enrolled 32 patients and 30 patients completed. The trial measured efficacy endpoints via MRI-PDFF for 12-weeks dosing.

Currently there are no FDA or EMA approved medications to treat NASH. The disease often puts T2D patients at increased risk of cirrhosis and liver cancer, according to company data. 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. NASH can be severe and, as noted, 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. Oramed's earlier NASH study was not constructed to detect statistically significant differences between patients being treated with ORMD-0801 and those being dosed with placebo. The study achieved primary and secondary endpoints and Oramed has noted its optimism that an expanded study could yield statistically significant differences in treatment groups.

The Phase 2 NASH study demonstrated that ORMD-0801 was safe and well tolerated at 8 mg twice daily dosing, with no difference in adverse events for ORMD-0801 compared to placebo. The trial also evaluated the effectiveness of ORMD-0801 in reducing liver fat content over the 12-week treatment period by observing several independent measures, including MR PDFF (%) as measured by MRI, Steatosis and Fibrosis as measured by Fibroscan, Lipids and HbA1c. According to Oramed, the measurements showed a consistent clinically meaningful trend in favor of ORMD-0801. The company noted that the trial achieved the secondary objective of reducing liver fat content in patients with NASH and T2D (Percent Change from Baseline to Week 12 in MR PDFF (%): – Whole Liver showed a placebo adjusted mean decrease of 0.96 with a placebo adjusted median decrease of 6.0 for ORMD-0801. The company also has development efforts underway for another asset, ORMD-0901, and is also the majority partner in a JV that is developing an oral COVID vaccine (see below).

NASH Prevalence (%) in Global Markets



Source: Company's NASH presentation

ORAL COVID VACCINE

COVID-19 oral vaccine Phase 1 clinical trial in South Africa

Through a JV (joint venture) with India-based Premas Biotech, the company is developing an orally administered vaccine for the COVID-19 virus. Oramed is the largest shareholder of the JV, Oravax Medical, which will leverage Oramed's proprietary POD™ oral delivery technology and Premas Biotech's novel vaccine technology. If clinical trials are successful, Oravax intends to launch and commercialize its oral COVID-19 vaccine.

Oramed believes that the oral vaccine could protect against emerging coronavirus variants more than many other vaccines currently being administered because of its triple antigen targeting of three structural protein parts of the SARS CoV-2 virus: Spike (S), Membrane M, and coronavirus envelope E targets. Based on Premas' novel technology, the Oravax pill is a virus-like particle (VLP) triple antigen vaccine. VLPs are molecules that are similar to viruses but are not infectious. According to News Medical, using VLPs is "a very effective way of creating vaccines."

The oral VLP COVID-19 vaccine is being developed for use both as a standalone vaccine as well as a booster for people who have been previously vaccinated for COVID-19. With cases rising in many markets, including breakthrough cases of vaccinated individuals, healthcare professionals expect that booster shots will remain critical in controlling the disease. The World Health Organization (WHO), which expects that people will require annual booster shots similar to their annual flu shots.

Through a 50/50 joint venture with Genomma Lab Internacional, a pharmaceutical company based in Mexico, Oravax intends to commercialize the oral COVID-19 vaccine candidate in Mexico and potentially other markets in South America. Oravax also signed a cooperation and purchase agreement with Vietnam-based Tan Thanh Holdings to pre-purchase Oravax's oral COVID-19 vaccine. The agreement

grants Tan Thanh Holdings the right to sell Oravax's oral vaccine in development throughout the Association of Southeast Asian Nations (ASEAN) which encompasses some 660 million people, according to ORMP, in Vietnam, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore and Thailand. Tan Thanh Holdings placed an initial pre-order of 10 million doses and, in success, the potential for follow-on orders valued at hundreds of millions of dollars, according to ORMP. Tan Thanh Holdings has approval from Vietnam's Ministry of Health to conduct advanced stage clinical trials of Oravax's oral COVID-19 vaccine. Tan Thanh Holdings will also contribute to the funding and implementation of clinical development and regulatory approval.

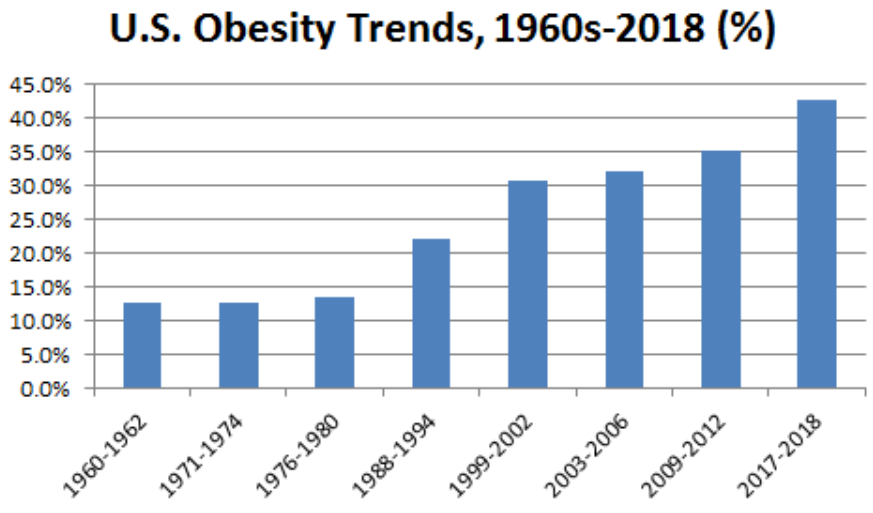
Oravax received clearance from the South African Health Products Regulatory Authority for an in-human Phase 1 clinical trial for the COVID-19 oral vaccine, although initial enrollments were slower than expected. The trial protocol calls for two cohorts that are each composed of 12 participants. Participants will be administered one dose of the oral vaccine at the beginning of the trial and a second dose three weeks later. The trial's endpoints will include safety and tolerability as well as efficacy by measuring the presence of an immunogenic response.

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. ORMD-0901 is designed for the treatment of obesity in patients with diabetes. Obesity is a growing problem worldwide.

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.



Source: Zacks from CDC data

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.

VALUATION

Oramed shares had been under pressure since the company terminated Phase 3 concurrent U.S. studies and it would not surprise us if potential uncertainty around ORMP's development efforts led to further share price volatility in the near- to medium-term. Nevertheless, we believe the sizable population with or at risk for diabetes globally and results of ongoing clinical trials support our valuation analysis, based on the company attaining regulatory approval for lead asset ORMD-0801 and ORMD-0901 and commercializing these product in multiple markets.

While it is difficult to know the revenue arc for ORMD-0801 at this early stage, given the growing incidence of diabetes worldwide, we believe it is not unreasonable to expect that ORMD-0801 could reach revenue of about $250 million to $300 million by the 2028-30 timeframe, depending on clinical trial results and commercialization milestones. We apply a 2x P/sales multiple, which is the low end of the range for other clinical companies at similar stages of development. We also maintain our estimate of peak U.S. sales of ORMD-0901 of approximately $500 million. Using a 12% discount rate and 45% and 70% respective confidence rates for ORMD-0901 and ORMD-0801 forecasts leads to a blended net present value (NPV) of roughly $4.30 per share.

Prospects for the COVID-19 vaccine pill could provide upside to our valuation. Moreover, we continue to view the versatility of the oral protein platform as a long-term positive and believe there could be additional opportunities for Oramed to apply its oral delivery technology. Studies indicate that many patients with a variety of diseases would prefer an oral treatment over injectable if the oral treatment proved as effective.

RISKS

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

- The company's partner in China might not attain regulatory approval in the timeline the partners anticipate or at all.
- ORMP might need to raise additional capital earlier than expected.
- Other of the company's clinical studies and potential commercialization timelines might be delayed.
- Other drug candidates might experience clinical failure and/or might not receive FDA and other regulatory approvals.
- The price of ORMP shares could continue to fluctuate, as the company advances its strategy.
- Competition in areas where ORMP has development efforts might intensify.

RECENT NEWS

- Oramed announced a roughly $102 million short-term senior secured note transaction with Scilex Holding Company on September 21, 2023.
- On August 2, 2023, Oramed signed a term sheet with HTIT to form a JV to advance the oral drug delivery technology globally.
- On May 15, 2023, the company announced that HTIT has successfully completed a Phase 3 oral insulin clinical trial and submitted a marketing authorization application in China.
- Oramed named Ben Shapiro to its board on May 1, 2023. He holds a 4% stake in the company.
- ORMP reported disappointing results of the T2D study on January 12, 2023.
- ORMP reported positive safety and efficacy NASH metrics on November 17, 2022.
- On November 14, 2022, Oramed signed a definitive deal with Medicox to commercialize oral insulin in South Korea.
- On June 1, 2022, the company announced that it had appointed Dr. Anne Peters to its Scientific advisory board.
- Oramed was granted a European patent for NASH on April 5, 2022.

PROJECTED FINANCIALS

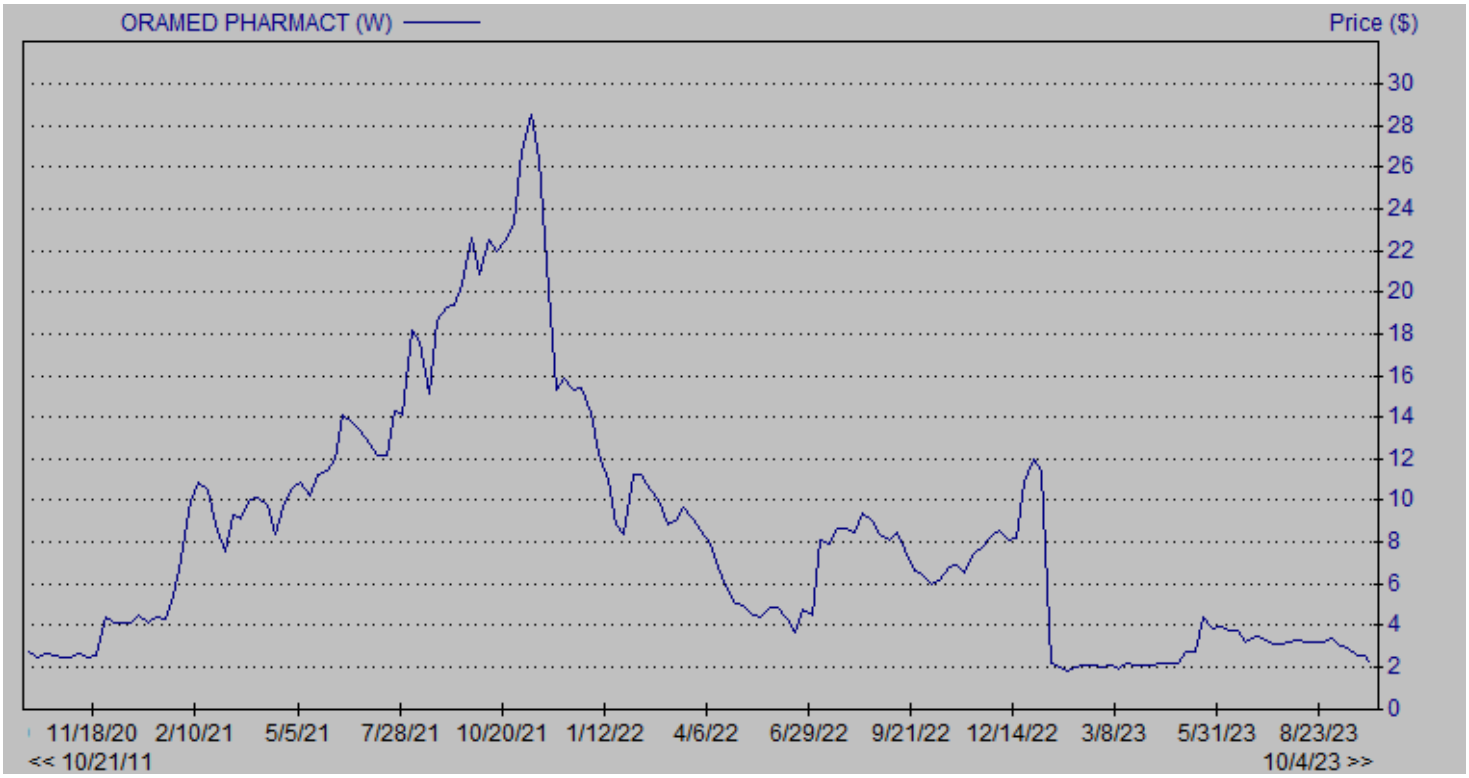
Oramed Pharmaceuticals Inc. (Fiscal Year ends Dec. 31*) $Mns	FY 2020	FY 2021 A	Q1 A	Q2 A	Q3 A	Q4 A	FY 2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E
License Revenue	$2.7	$2.7	$0.7	$0.7	$0.7	$0.7	$2.7	$0.7	$0.7	$0.7	$0.6	$2.6
YOY Growth	-	-					-					
Grant/Contract Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$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	$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	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-					-
Total Revenues	**$2.7**	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.6**	**$2.6**
YOY Growth	*1%*	*-1%*	*-1%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*-2%*	*-17%*	-5%
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	**$2.7**	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.6**	**$2.6**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
Research & Development	$10.2	$21.0	$5.8	$9.2	$5.3	$7.3	$27.6	$4.4	$1.8	$1.9	$11.0	$19.1
General & Administrative	$4.2	$5.9	$5.5	$2.5	$3.1	$2.7	$13.8	$1.3	$2.5	$2.5	$1.1	$5.1
Other Expenses	$0.0	$0.0	$0.6	$0.4	$0.5	$0.4	$1.9	$0.2	$0.2	$0.2	$0.4	$1.0
Operating Income / (loss)	**($11.7)**	**($24.2)**	**($11.3)**	**($11.4)**	**($8.2)**	**($9.7)**	**($40.6)**	**($5.2)**	**($3.8)**	**($3.9)**	**($9.8)**	**($22.6)**
Operating Margin	-	-					-					-
Other Income (Net)	$0.2	$1.2	$0.5	$0.4	$1.0	$4.9	$2.9	$1.6	$2.5	$0.4	$0.4	$4.9
Pre-Tax Income	**($11.5)**	**($23.0)**	**($10.7)**	**($11.1)**	**($7.2)**	**($14.6)**	**($37.7)**	**($3.6)**	**($1.3)**	**($3.5)**	**($9.4)**	**($17.8)**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*-0.3%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Minority interest / other		$0.8	$0.3	$0.5	$0.2	$0.4	$1.2	$0.2	$0.1	$0.2	$0.2	$1.0
Reported Net Income	**($11.5)**	**($22.2)**	**($10.4)**	**($10.5)**	**($7.1)**	**($14.2)**	**($36.6)**	**($3.4)**	**($1.2)**	**($3.2)**	**($9.2)**	**($16.8)**
Net Margin	-	-					-					-
Reported EPS	**($0.56)**	**($0.78)**	**($0.27)**	**($0.27)**	**($0.18)**	**($0.36)**	**($0.94)**	**($0.08)**	**($0.03)**	**($0.08)**	**($0.23)**	**($0.41)**
YOY Growth	-	-					-					-
Basic Shares Outstanding	20.5	28.5	38.7	38.8	39.1	39.5	39.0	40.0	40.2	40.3	40.3	40.5

Source: Zacks Investment Research, Inc.

*ORMP's board approved a change of the company's fiscal year from ending on August 31 to ending on December 31.

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