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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: ORA-D-013-1 Failed To Meet Endpoints; Ending T2D Oral Insulin Efforts

Recently released top-line results from Oramed's ORA-D-013-1 Phase 3 study comparing the efficacy of ORMD-0801 to placebo in patients with T2D at 26 weeks failed to meet primary and secondary endpoints. Oramed expects to discontinue its oral insulin clinical activities for T2D. This likely pushes out the company's potential commercialization timeline, although Oramed has multiple clinical development programs underway.

Current Price (1/24/2025)	$2.04
Valuation	**$2.80**

OUTLOOK

We expect the company to pivot to other development programs. If Oramed continues clinical efforts around ORMD-0801 for the treatment of T2D patients with NASH, for example, an earlier small Phase 2 NASH study demonstrated that ORMD-0801 was safe and well tolerated. The company also has development efforts underway for ORMD-0901, an orally ingestible capsule designed to aid in the balance of blood-sugar levels and also to decrease appetite. ORMP is also developing an oral COVID vaccine with a JV partner. The company has cash of roughly $4 per share, as of September 2022, to advance development activities.

SUMMARY DATA

52-Week High	**$13.72**
52-Week Low	**$1.81**
One-Year Return (%)	**-76**
Beta	**2.17**
Average Daily Volume (sh)	**1,322,370**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$80**
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 2022 Estimate	**N/A**
P/E using 2023 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	0.8 E	2.8 E
2023	0.7 E	0.7 E	0.7 E	0.7 E	2.7 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)*
2020					-$0.56 A
2021					-$0.78 A
2022	-$0.22 A	-$0.27 A	-$0.18 A	-$0.16 E	-$0.83 E
2023	-$0.23 E	-$0.23 E	-$0.22 E	-$0.19 E	-$0.87 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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KEY POINTS; POSITIVE TAKEAWAYS INITIAL NASH STUDY DATA

- Recently released top-line results from Oramed's ORA-D-013-1 Phase 3 study comparing the efficacy of ORMD-0801 to placebo in patients with T2D at 26 weeks failed to meet primary and secondary endpoints. Oramed expects to discontinue its oral insulin clinical activities for T2D, which represents a setback even though Oramed has multiple clinical development programs underway.

- We expect the company's focus to pivot to other programs. If Oramed continues clinical efforts around ORMD-0801 for the treatment of T2D patients with NASH, for example, an earlier small 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 company also has development efforts underway for ORMD-0901, an orally ingestible capsule designed to aid in the balance of blood-sugar levels and also to decrease appetite. ORMP is also developing an oral COVID vaccine with a JV partner.

- ORMD-0901 is designed for the treatment of obesity in patients with T1D. In general, obesity is a growing problem worldwide. Regarding the COVID-19 oral vaccine, the JV has received clearance from the South African Health Products Regulatory Authority for an in-human Phase 1 clinical trial.

ORA-D-013-1 STUDY FAILED TO MEET ENDPOINTS

Oramed discontinuing clinical activities for T2D…

Oramed Pharmaceuticals Inc. (NASDAQ:ORMP) had been conducting dual concurrent Phase 3 studies of ORMP's oral insulin capsule ORMD-0801 for the treatment of Type 2 Diabetes (T2D). Recently released top-line results from the **ORA-D-013-1** Phase 3 study comparing the efficacy of ORMD-0801 to placebo in patients with T2D at 26 weeks failed to meet the primary and secondary endpoints. The primary endpoint compared ORMD-0801 to placebo in improving glycemic control as assessed by the mean change from baseline in A1C at 26 weeks. The secondary endpoint assessed the mean change from baseline in fasting plasma glucose at 26 weeks. Given the disappointing results, Oramed has indicated that it expects to discontinue its oral insulin clinical activities for T2D.

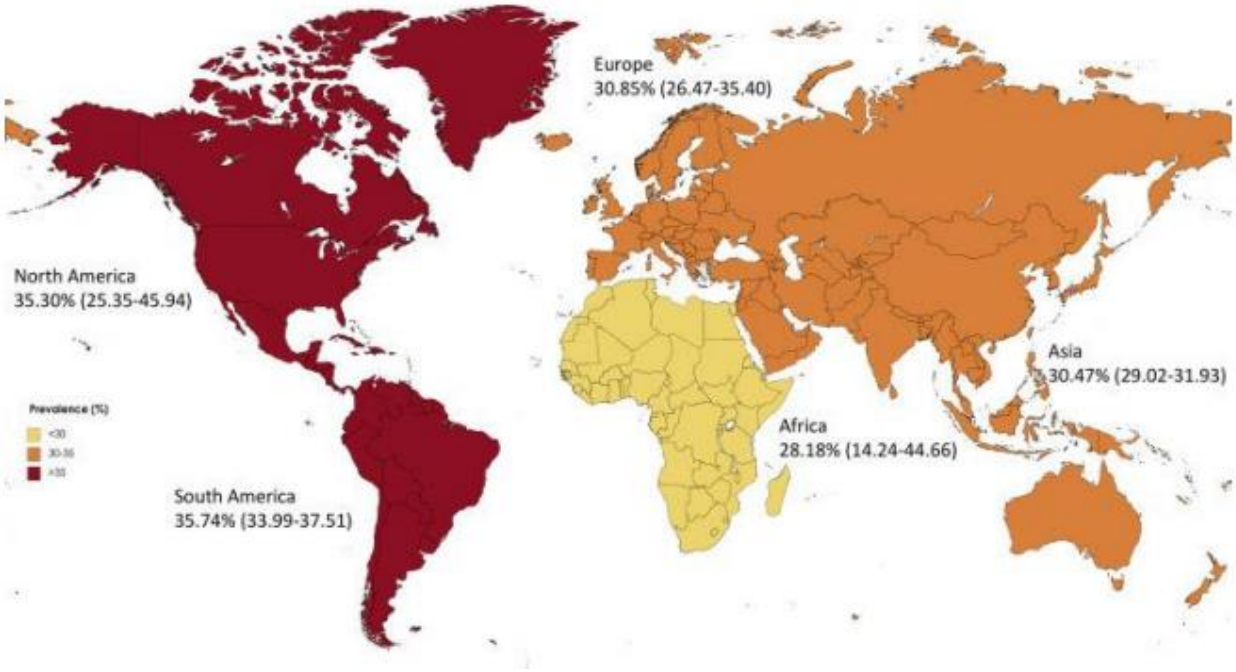
This represents a setback for the company even though Oramed has multiple clinical development programs underway. We expect the company's focus to pivot to other programs. If Oramed continues its clinical efforts around ORMD-0801 for the treatment of T2D patients with NASH, for example, the company has 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.

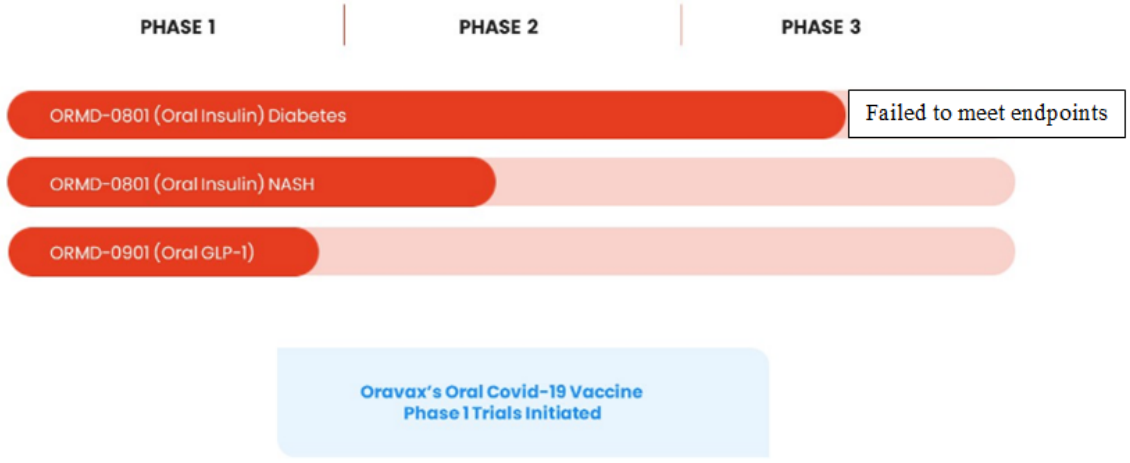
NASH Prevalence (%) in Global Markets



Source: Company's NASH presentation

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.

Additional Development Efforts



Source: Oramed presentation

… ***Terminating T2D efforts likely pushes back timeframe of commercializing ORMD-0801…***

The company also has development efforts underway for another asset, ORMD-0901, and is the majority partner in a JV that is developing an oral COVID vaccine (see below). However, ORMP's T2D program was more advanced than other clinical efforts. Thus, pivoting away from these development efforts to focus on others in the pipeline likely also pushes out the potential timeline for Oramed commercializing ORMD-0801, in our view.

COMPANY HAS OTHER DEVELOPMENT EFFORTS ONGOING

COVID-19 oral vaccine
Phase 1 clinical trial progressing 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.

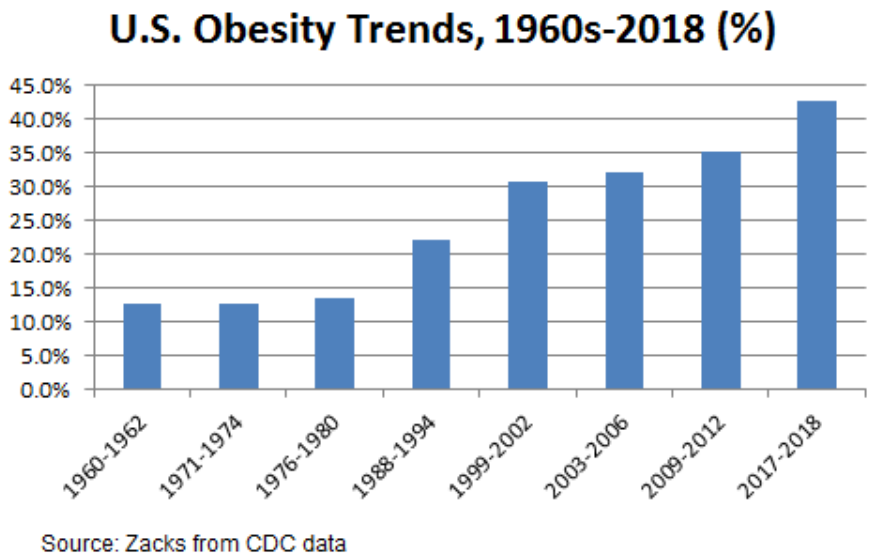
ORMD-0901 TECHNOLOGY PLATFORM

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 T1D. 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.

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

VALUATION

On the back of the Phase 2 ORMD-0801 T2D results, we lower our expected valuation for ORMP shares. The overall diabetes treatment market is estimated at about $966 billion annually. We had estimated peak U.S. sales of ORMD-0801 of approximately $400 million, including expected revenue for treatment for T2D. We lower the forecast to $80 million. We had incorporated a 64% probability of approval for ORMD-0801 and now lower that probability forecast to 20%. We maintain our estimate of peak U.S. sales of ORMD-0901 of approximately $500 million and 45% probability of approval forecast. Reflecting delayed clinical trial timelines generally in recent quarters due to the pandemic and other factors, we model approval timelines for both candidates in the 2028-30 time period.

Using a 12% discount rate leads to a net present value (NPV) for those two programs combined of about $269 million. Applying our probability forecasts for their respective approvals leads to a valuation of about $2.80 per share. We note that the company has a cash balance of roughly $4 per share as of September 2022 to advance clinical development efforts. 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.

Since the company reported disappointing results of the T2D study on January 12, 2023, the shares have declined 80+% (compared to a 2% advance for the NASDAQ). Separately, over 2021 the shares rose from the roughly $4 level to above $28, largely (we believe) on the oral COVID initiative as the pandemic raged and subsequently gave back those gains as vaccination rates climbed. We expect uncertainty around ORMP's pivoting its development efforts to weigh on the shares in the near- to medium-term.

RISKS

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

- 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

- 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.
- ORMP reported 3Q22 results on November 10, 2022.
- ORMP issued a letter to shareholders on July 7, 2022.
- 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	Q1 A	Q2 A	Q3 A	Q4 A	FY 2021 A	Q1 A	8/21-12/21*	Q2 A	Q3 A	Q4 E	FY 2022 E	2023 E
License Revenue	$2.7	$0.7	$0.7	$0.7	$0.7	$2.7	$0.7	$0.9	$0.7	$0.7	$0.8	$2.8	$2.7
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	$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	$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	$0.0
YOY Growth	-					-	-		-	-	-	-	-
Total Revenues	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$0.7**	**$0.9**	**$0.7**	**$0.7**	**$0.8**	**$2.8**	**$2.7**
YOY Growth	*1%*	*0%*	*-1%*	*-3%*	*-2%*	*-1%*	*0%*	*0%*	*0%*	*0%*	*13%*	*4%*	*-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	$0.0
Gross Income	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$0.7**	**$0.9**	**$0.7**	**$0.7**	**$0.8**	**$2.8**	**$2.7**
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%*	*100.0%*
Research & Development	$10.2	$6.4	$3.2	$5.5	$0.7	$21.0	$6.4	$9.0	$9.2	$5.3	$5.1	$26.0	$26.8
General & Administrative	$4.2	$0.5	$1.9	$1.3	$2.2	$5.9	$1.7	$3.3	$2.5	$3.1	$2.9	$10.2	$10.3
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.6	$0.9	$0.4	$0.5	$0.4	$1.9	$1.9
Operating Income	**($11.7)**	**($6.2)**	**($4.5)**	**($6.1)**	**($2.2)**	**($24.2)**	**($8.1)**	**($12.3)**	**($11.4)**	**($8.2)**	**($7.7)**	**($35.3)**	**($36.4)**
Operating Margin	-					-						-	-
Other Income (Net)	$0.2	$0.3	$0.5	$0.5	$1.0	$1.2	$0.0	$0.0	$0.4	$1.0	$0.9	$2.2	$0.0
Pre-Tax Income	**($11.5)**	**($6.0)**	**($3.9)**	**($5.6)**	**($1.2)**	**($23.0)**	**($8.1)**	**($12.3)**	**($11.1)**	**($7.2)**	**($6.8)**	**($33.1)**	**($36.4)**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$0.1	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*-0.3%*	*0.0%*
Minority interest / other			$0.1	$0.4	$0.4	$0.8	$0.2	$0.6	$0.5	$0.2	$0.4	$1.4	$1.0
Reported Net Income	**($11.5)**	**($6.0)**	**($3.8)**	**($5.2)**	**($0.8)**	**($22.2)**	**($7.9)**	**($11.7)**	**($10.5)**	**($7.1)**	**($6.4)**	**($31.9)**	**($35.4)**
Net Margin	-					-						-	-
Reported EPS	**($0.56)**	**($0.25)**	**($0.12)**	**($0.17)**	**($0.03)**	**($0.78)**	**($0.22)**	**($0.31)**	**($0.27)**	**($0.18)**	**($0.16)**	**($0.83)**	**($0.87)**
YOY Growth	-					-						-	-
Basic Shares Outstanding	20.5	23.7	30.7	29.9	30.3	28.5	36.7	37.1	38.8	39.1	39.5	38.5	40.5

Source: Zacks Investment Research, Inc. **Transition period*

*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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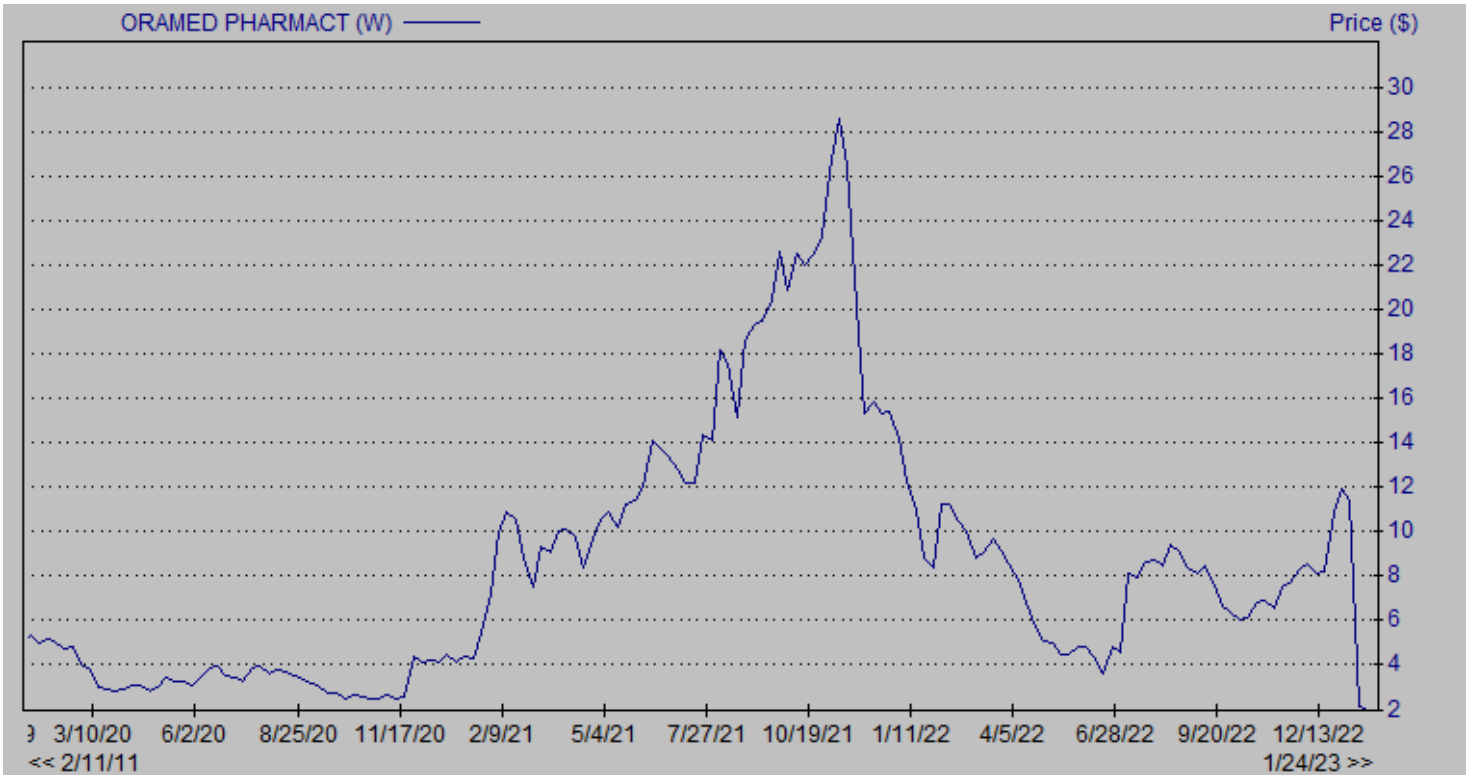
HISTORICAL STOCK PRICE



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