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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Data from NASH Phase 2 Study – Positive Takeaways

Oramed has multiple clinical development programs underway. ORMD-0801, ORMP's lead development candidate, is being tested in diabetes and NASH and in dual concurrent Phase 3 studies for the treatment of T2D. We believe the multiple studies currently being conducted underscore the potential versatility of the company's oral protein delivery platform technology.

OUTLOOK

The company's Phase 2 NASH study has 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. The company believes these results warrant further study of ORMD-0801 for NASH, particularly given the rising incidence of NASH worldwide and with no treatments currently approved by the FDA or EMA.

Current Price (11/18/2022)	$7.78
Valuation*	**$25.00**

SUMMARY DATA

52-Week High	**$26.45**
52-Week Low	**$3.59**
One-Year Return (%)	**-58.9**
Beta	**2.28**
Average Daily Volume (sh)	**269,428**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$305**
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**

*Excludes COVID-19 JV

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	0.7 A	0.7 A	0.7 A	0.7 A	2.7 A
2022	0.7 A	0.7 A	0.7 A	0.8 E	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	-$0.24 A	-$0.12 A	-$0.17 A	-$0.03 A	-$0.78 A
2022	-$0.22 A	-$0.27 A	-$0.18 A	-$0.16 E	-$0.83 E

Quarters might not sum due to round'g, share counts & FY
Disclosures begin on page 15 *'22 FY changed to Dec. 31

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KEY POINTS; POSITIVE TAKEAWAYS INITIAL NASH STUDY DATA

- Oramed has multiple clinical development programs underway for its lead development candidate, ORMD-0801. It is being tested both in type 1 (T1D) and T2D and NASH and recent results of the Phase 2 NASH study are encouraging. The company recently announced that the study had achieved primary endpoints of safety and tolerability in participants, with patients exhibiting no serious adverse events and no difference in the incidence rate of adverse events between ORMD-0801 and placebo.

- 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.

- Oramed believes that ORMD-0801 could become the first commercial oral insulin capsule for the treatment of diabetes. The company continues to advance ORMD-0801 in dual concurrent Phase 3 studies for the treatment of T2D. Earlier this month, the company signed an agreement with Medicox to distribute its oral insulin in South Korea, if it receives approval.

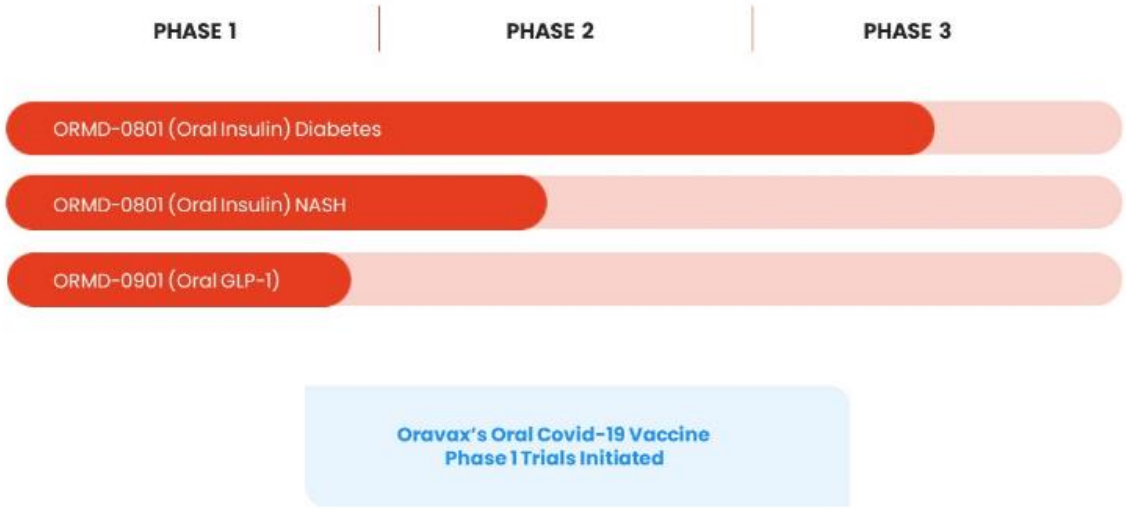
- ORMP had about $160 million of cash and equivalents at the end of 3Q22 to advance its clinical research and development activities.

NASH TRIAL

… NASH study - positive initial metrics

Oramed Pharmaceuticals Inc. (NASDAQ:ORMP) has multiple clinical development programs underway, as illustrated below. We believe these studies underscore the company's expectation that its oral protein delivery platform technology potentially can be used for a variety of indications. ORMD-0801 is the company's lead development candidate that concurrently is being tested both in type 1 (T1D) and T2D and NASH (nonalcoholic steatohepatitis).

Multiple Clinical Stage Programs

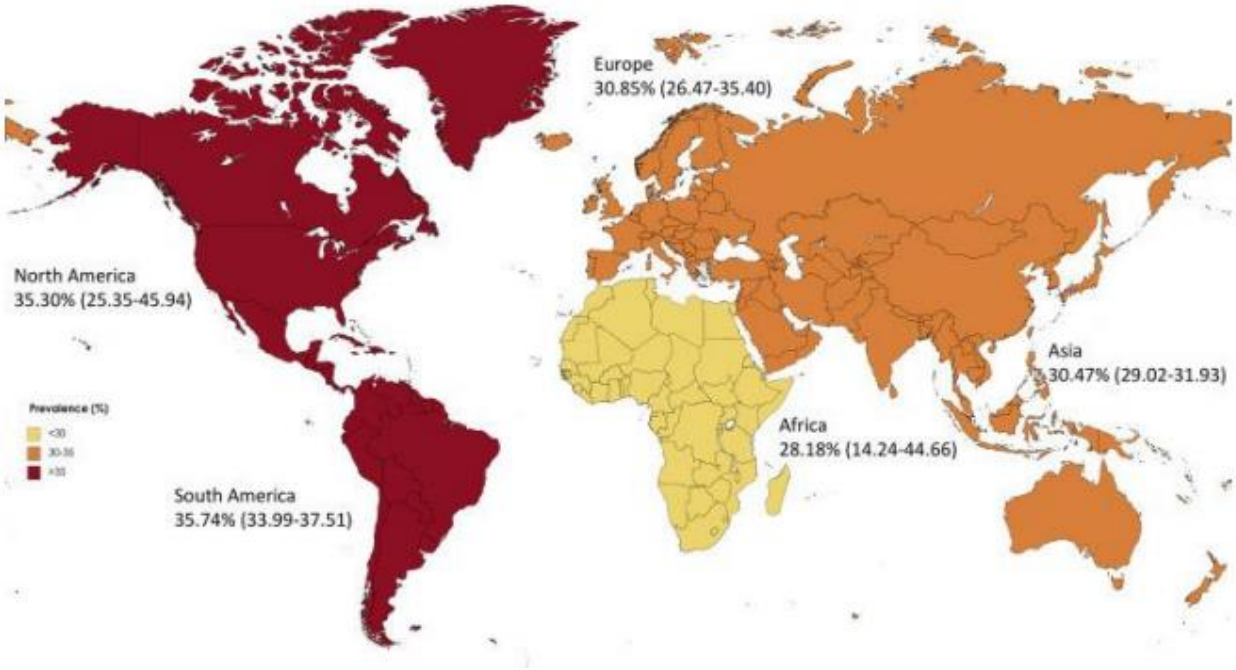


Source: Oramed presentation

In its Phase 2 global NASH trial, ORMP's oral insulin capsule ORMD-0801 is being studied for the treatment of patients with NASH assessing the safety and potential efficacy of ORMD-0801 in type 2 diabetes (T2D) patients with NASH. The study 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 at clinical locations in the U.S. (three locations), EU (three) and Israel (two).

According to Oramed, NASH is a global problem and the incidence of patients with NASH is increasing. This is consistent with NIH data indicating that NASH prevalence is expected to rise 63% from 2015 to 2030. Moreover, NASH puts T2D patients at increased risk of cirrhosis and liver cancer, according to company data. Currently there are no FDA or EMA (European Medicines Agency) approved medications to treat NASH. While the company's 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 (see below) and the company is optimistic that an expanded study will yield positive and statistically significant differences in treatment groups.

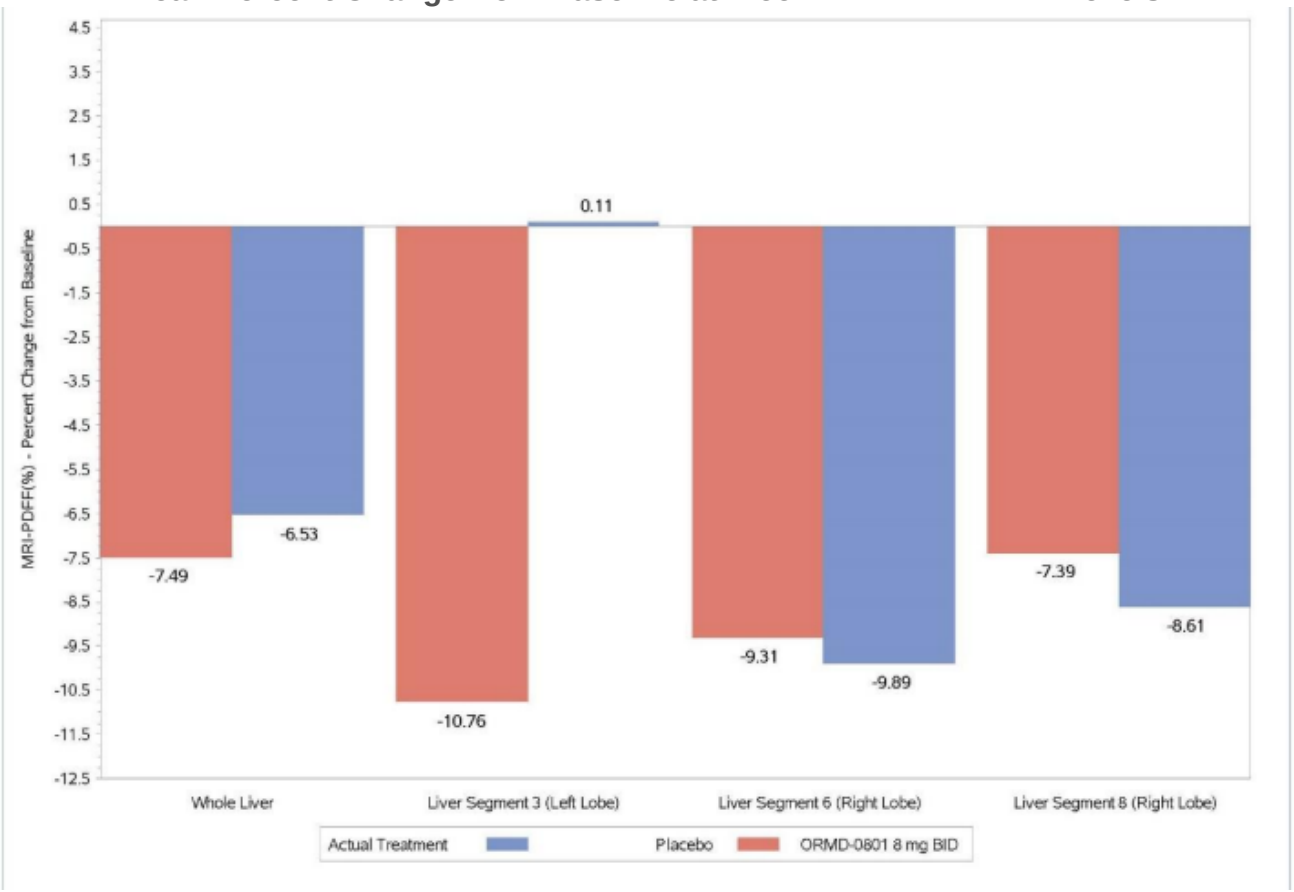
NASH Prevalence (%) in Global Markets



Source: Company's NASH presentation

The company recently announced that the study had achieved primary endpoints of safety and tolerability in participants – participants exhibited no serious adverse events and no difference in the incidence rate of adverse events between ORMD-0801 and the placebo. 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.



Source: Company's NASH presentation

Mean Levels at Baseline		
	Placebo	ORMD-0801
Whole Liver	21.558	15.683
Segment 3	20.617	14.560
Segment 6	22.174	15.828
Segment 8	22.565	16.071

12

Source: Company's NASH presentation

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.

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.

T2D DUAL STUDIES

Oramed believes that ORMD-0801 could become the first commercial oral insulin capsule for the treatment of diabetes. The company continues to advance ORMD-0801 in dual concurrent Phase 3 studies for the treatment of T2D.

- **ORA-D-013-1** - about 675 patients (enrollments were exceeded), 75 U.S. sites
- ORA-D-013-2 – about 450 patients, sites in the U.S., Europe and Israel

This dual study represents the world's first pivotal Phase 3 oral insulin trial conducted through an FDA approved protocol, underscoring Oramed's position as a pioneer in the study for oral insulin. Thus, ORMD-0801 is the first oral insulin capsule to achieve necessary FDA efficacy and safety data and the company's Phase 3 trial is the first worldwide FDA Phase 3 oral insulin trial. The studies follow positive feedback Oramed received during its end-of-Phase 2 meeting with the FDA and the FDA's review of its Phase 3 protocols and nonclinical documents.

To evaluate the efficacy and safety of ORMD-0801, ORMP intends to recruit an aggregate of about 1,160 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 recruited patients through 75 U.S. clinical centers who were on 1, 2 or 3 oral glucose-lowering agents.

The ORA-D-013-1 study – 100% enrolled

Anticipate topline results in January 2023 after the last patient's six months of treatment

The ORA-D-013-1 trial is a double blind, double dummy study randomizing patients 1:1:1 for: 8 mg ORMD-0801 once-daily at night and placebo 45 minutes before breakfast; or 8 mg ORMD-0801 twice-daily at night and 45 minutes before breakfast; or placebo twice-daily at night and 45 minutes before breakfast.

ORMP has fully enrolled and randomized 100% of the patients planned for the Phase 3 ORA-D-013-1 study. The company exceeded its target of 675 patients and ultimately, a total of 710 patients were randomized in the study. Efficacy data for ORA-D-013-1 will become available after all patients have completed the first 6-month treatment period. The company has indicated that it anticipates that topline results will be available in January 2023 after the last patient's six months of treatment. Depending on the results, we believe this could be a catalyst for the shares.

The ORA-D-013-2 study

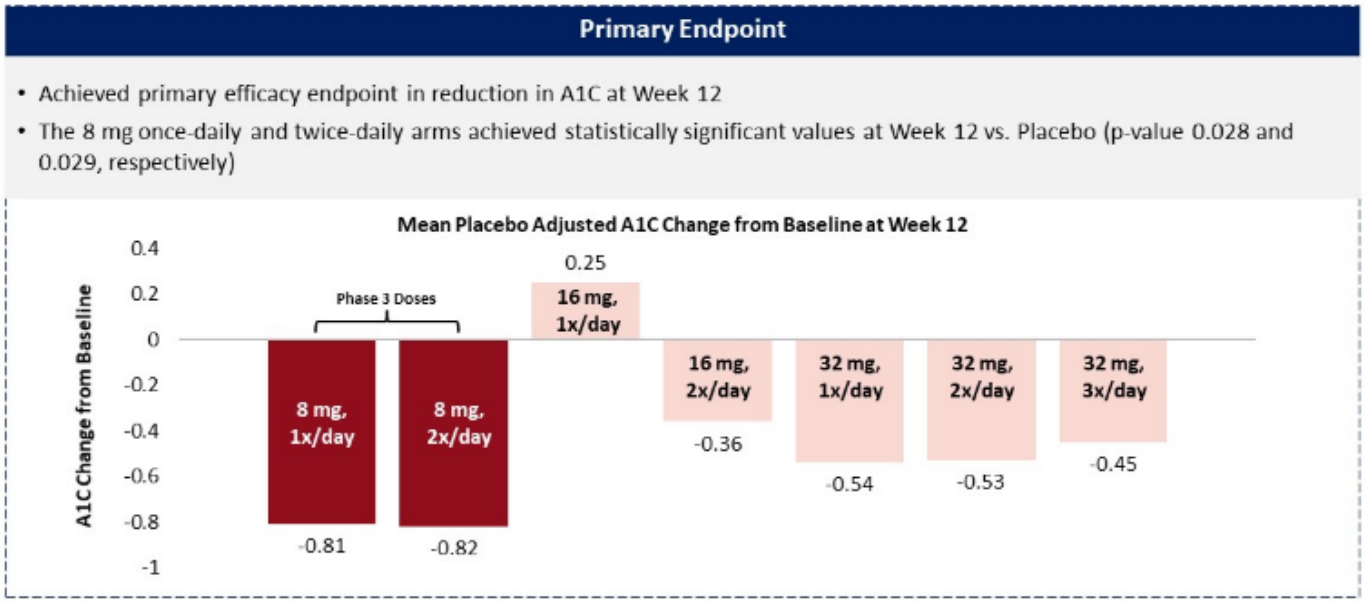
The ORA-D-013-2 study is planned to enroll 450 T2D patients through 36 U.S. sites, 25 in Western Europe and Israel. The ORA-D-013-2 trial is recruiting T2D patients with inadequate glycemic control who are managing their condition with either diet alone or with diet and metformin monotherapy. The double-blind trial will randomize patients 1:1 into two cohorts dosed with 8 mg of ORMD-0801 at night or placebo at night. The primary endpoint of the trial is to compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c over a 26-week treatment period, with a secondary endpoint of comparing ORMD-0801 to placebo in maintaining glycemic control over a 52-week treatment period.

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.

Given the importance of the study, we would expect efficacy data to become available shortly after all patients have completed the first six-month treatment period. As noted, topline results of ORA-D-013-1 are anticipated in January 2023. 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.

ORMD-0801 Phase 2b Achieved Safety and Primary Endpoints



Source: Oramed presentation

We believe demand for ORMD-0801 within the medical community and among patient populations could be significant, depending on the data from Oramed's Phase 3 trial in patients with T2D. 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.

Addressable Market metrics … recent distribution agreement

Earlier this month, the company signed an agreement with Medicox to distribute its oral insulin in South Korea, if it receives approval. The agreement grants Medicox an exclusive license to apply for regulatory approval for and distribute ORMD-0801 for ten years in the Republic of Korea. According to the terms of this agreement, Oramed will receive up to $18 million in developmental milestones and up to 15% in royalties on gross sales. The company views South Korea as a sizable addressable market, with one in seven adult Koreans over the age of 30 suffering with diabetes, according to company data.

… In the U.S.

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.

COVID-19 ORAL VACCINE

Oravax VLP COVID-19 vaccine Phase 1 clinical trial progressing in South Africa

The company also continues to advance its JV (joint venture) in the COVID-19 vaccine space with India-based Premas Biotech, Oravax Medical Inc., to advance an orally administered vaccine for the COVID-19 virus. Oramed is the largest shareholder of Oravax, which will leverage Oramed's proprietary POD™ oral delivery technology and Premas Biotech's novel vaccine technology. Oravax intends to launch and commercialize its oral COVID-19 vaccine following clinical trials. The Oravax vaccine represents a successful expansion of Oramed's POD™ oral protein delivery platform into the vaccine development market.

In addition to offering protection against current COVID-19 strains, Oramed also 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."

In fact, the vaccine currently is being tested against COVID-19 variants, including the Delta variant. The Phase 1 clinical trial of the Oravax VLP COVID-19 vaccine for COVID-naive participants is progressing in South Africa but, reflecting a number of factors – including that that many potential participants did not

qualify during screening because of prior asymptomatic COVID-19 infection – enrollments were slower than the company originally anticipated. 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.

Securing partnerships & pre-orders

Oravax also signed a licensing deal for VLP injectable vaccine technology with Premas Biotech for commercialization in India. Oravax intends to launch clinical trials for the oral COVID-19 vaccine, beginning in Israel, with additional international locations to follow. The Institutional Review Board (IRB) at Ichilov Hospital in Tel Aviv, Israel has approved the study protocol and it is pending approval from the Israeli Ministry of Health.

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 be necessary. The World Health Organization (WHO), which expects that people will require annual booster shots similar to their annual flu shots.

Moreover, given the difficulties involved in storing and distributing most COVID-19 vaccines currently being offered, the Oravax vaccine might also provide a more convenient way to provide wide-scale distribution and inoculation, as unlike most other vaccines that require freezing storage, the Oravax vaccine can be stored in standard refrigerators. A pill format would also enable people to fill a prescription and then take the pill vaccine in the comfort of their own homes, eliminating the inconvenience of seeking vaccine availability and then waiting at an external location to receive the dose. In turn, this might enable health agencies to boost inoculation rates. Currently, about 14% of people nationwide in the U.S. and less than 1% globally have been fully vaccinated, according to the New York Times, with a "striking divide" from one country to another. In turn, rising inoculation rates would allow commercial activity to resume towards pre-COVID-19 levels.

In addition, the company believes that a pill is probably also a greener vaccine option than a single or double dose injection solution that produces needles to be discarded. Depending on packaging of the Oravax oral vaccine, this could be an important differentiating factor from an environmental, social and corporate governance (ESG) investing perspective. We believe ESG is an increasingly important component of overall investment decision making.

Moving Oravax ahead in key global regions

Oravax has secured orders for its COVID-19 oral vaccine, closed a registered direct offering of about $50 million to continue advancing its goals and moved its Insulin study ahead. In November of 2021, Oramed formed a 50/50 joint venture with Genomma Lab Internacional, a pharmaceutical company based in Mexico, with an expanding international presence. Genomma Lab and Oravax will jointly develop and commercialize Oravax's oral COVID-19 vaccine candidate in Mexico and potentially other markets in South America.

Oravax will be able to leverage Genomma Lab's relationships in Latin America to support the development and expected vaccine roll-out of the oral COVI-19 vaccine in the region. Oramed and Genomma Lab entered into a US$20 million share swap, underscoring their aligned interests and Genomma Lab also committed to invest in Oravax.

Outside of Latin 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.

Vaccine has demonstrated efficacy in pre-clinical studies

In a preclinical study of its efficacy, the oral vaccine successfully produced antibodies after just one dose. It promoted systemic immunity through Immunoglobulin G (IgG), which is the most common antibody in the blood and bodily fluids protecting against viral infections, and through Immunoglobulin A (IgA), which are antibodies that are found in the lungs, sinuses, stomach, and intestines that protect the respiratory and gastrointestinal tracts against infection.

Oravax recently received clearance from the South African Health Products Regulatory Authority to begin enrolling patients in a first in human Phase 1 clinical trial for the COVID-19 oral vaccine. The company has already begun its preparations to begin the trials. If the Phase 1 trial data is positive, as the company anticipates, ORMP plans to advance with a Phase 2/3 trial for emergency use approval in target markets.

A Pill Might Help Overcome Vaccine Hesitancy

As noted with an oral insulin treatment, a COVID-19 pill could be particularly useful for patients with low tolerance for injections. The company particularly has focused on geographic markets where it believes a vaccine in pill form might help some people overcome *vaccine hesitancy*, or the fear of taking a relatively new vaccine. According to NCBI, vaccine hesitancy stems from a number of factors, including the lack of trust in public health agencies. Some people who are concerned about accepting a vaccine injection might be more willing to get a COVID-19 vaccine in oral pill format.

The several positive takeaways from this development include that Oramed has expanded its potential addressable commercial market into COVID-19 and potentially other viruses and has also expanded the technology behind its oral delivery platform, reflecting the potential versatility of the technology.

Other biotech companies are also researching and/or developing vaccines, including in oral format, as well as nasal sprays and precision transdermal (TDS) patch formats. However, there is still a tremendous global need for COVID-19 vaccines. Given the relatively early stage of inoculations at this point, we believe there is ample demand for vaccines and Oravax will be able to enjoy early mover advantage. Moreover, many in the medical community believe that a COVID-19 vaccine is likely to become recommended annually as the flu vaccine is, which further underscores the need for a greater number of vaccine manufacturers. Separately, Pfizer and Merck are pursuing early stage studies for a drug to *treat* the COVID-19 disease, not to inoculate against it.

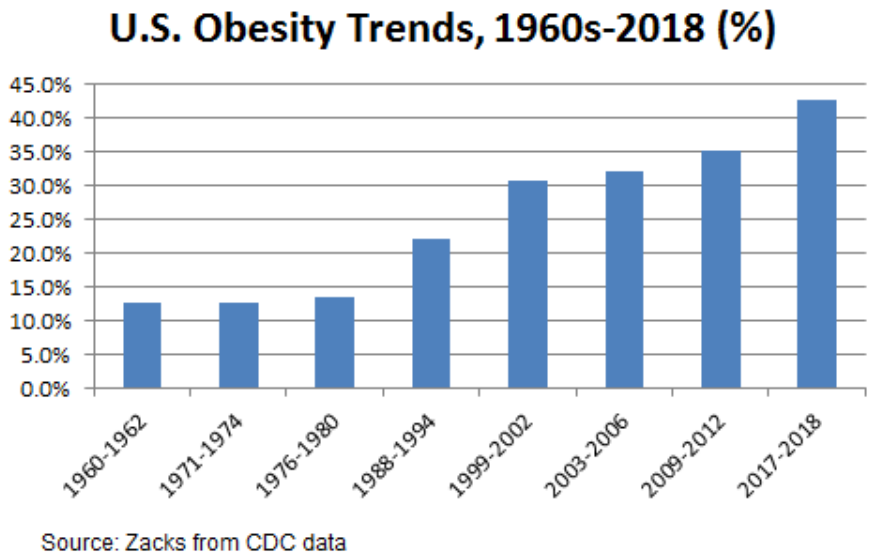
ORMD-0901 TECHNOLOGY PLATFORM

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

Oral GLP-1 and Leptin: Additional Studies Expected in 2021

ORMP reported positive first in human data from its oral leptin study on December 23, 2020. The company expects to commence a bigger double-blind, placebo-controlled study for oral leptin capsule in 2021. Specifically, Oramed expects to start a bioavailability study for ORMD-0901 in T2D patients. A prior Phase 1 pharmacokinetic (PK) study showed ORMD-0901, in healthy volunteers, preserved the biological activity of orally delivered GLP-1 and curbed blood sugar excursions following glucose challenge.

RECENT RESULTS – 3Q:22 HIGHLIGHTS

Oramed is largely pre-revenue at this stage. Its revenues primarily are related to its HTIT license agreement. ORMP's 3Q22 revenue of $682,000 matched that recognized in 3Q21. For the first nine months of both 2021 and 2022, revenue was $2.0 million. In 3Q22, R&D (Research and development) expenses were 12% lower, at $5.3 million, compared to $6.1 million in 3Q21, reflecting lower R&D expenses in ORMP's Oravax subsidiary. This was offset by higher sales and marketing and G&A expenses (respectively $463,000, compared to $172,000 and $3.1 million compared to $1.9 million). The company reported a loss per share of ($0.18).

Balance sheet / liquidity

ORMP had about $160 million of cash and equivalents at the end of 3Q22, reflecting just over $33 million of cash, about $121 million aggregate of short-term bank deposits and another roughly $5 million of marketable securities. ORMP can access these funds to advance its clinical studies and operations.

VALUATION

We value Oramed's original assets using a probability adjusted discounted cash flow model that takes into account potential future revenues from ORMD-0801 and ORMD-0901. Our 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. We note that the approval rates are highly sensitive to the timing of moving the assets forward. Moreover, the current interest rate environment could also mean that the discount rate might be too conservative. When including the current cash and dividing by the fully diluted share count, we obtain a NPV for Oramed on its initial focus lines of approximately $25 per share.

Over time and in success, we would also expect the shares to reflect the potential of the oral COVID-19 vaccine pill. Forecasts of the near-term size of the overall COVID-19 vaccine market range from $19 billion to $25 billion or higher, which suggests a large addressable – and growing – market opportunity for Oravax. If Oravax can commercialize the pill within the next few years and capture even a small fraction of the market, we estimate that the oral vaccine could add at least $10 to more than $15 per share to the company's total valuation, based on the NPV of this potential revenue stream.

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 and other regulatory approvals.
- Potential competitors might find a workaround vis-à-vis the company's IP.
- The price of ORMP shares could fluctuate, as the company advances its strategy.
- Competition in areas where ORMP has development efforts might intensify.

RECENT NEWS

- 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.
- The ORA-D-013-2 Phase 3 oral insulin study reached 50% enrollment on July 26, 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 completed patient enrollment in the ORA-D-013-1 Phase 3 oral insulin study on May 3, 2022.
- Oramed was granted a European patent for NASH on April 5, 2022.

PROJECTED FINANCIALS

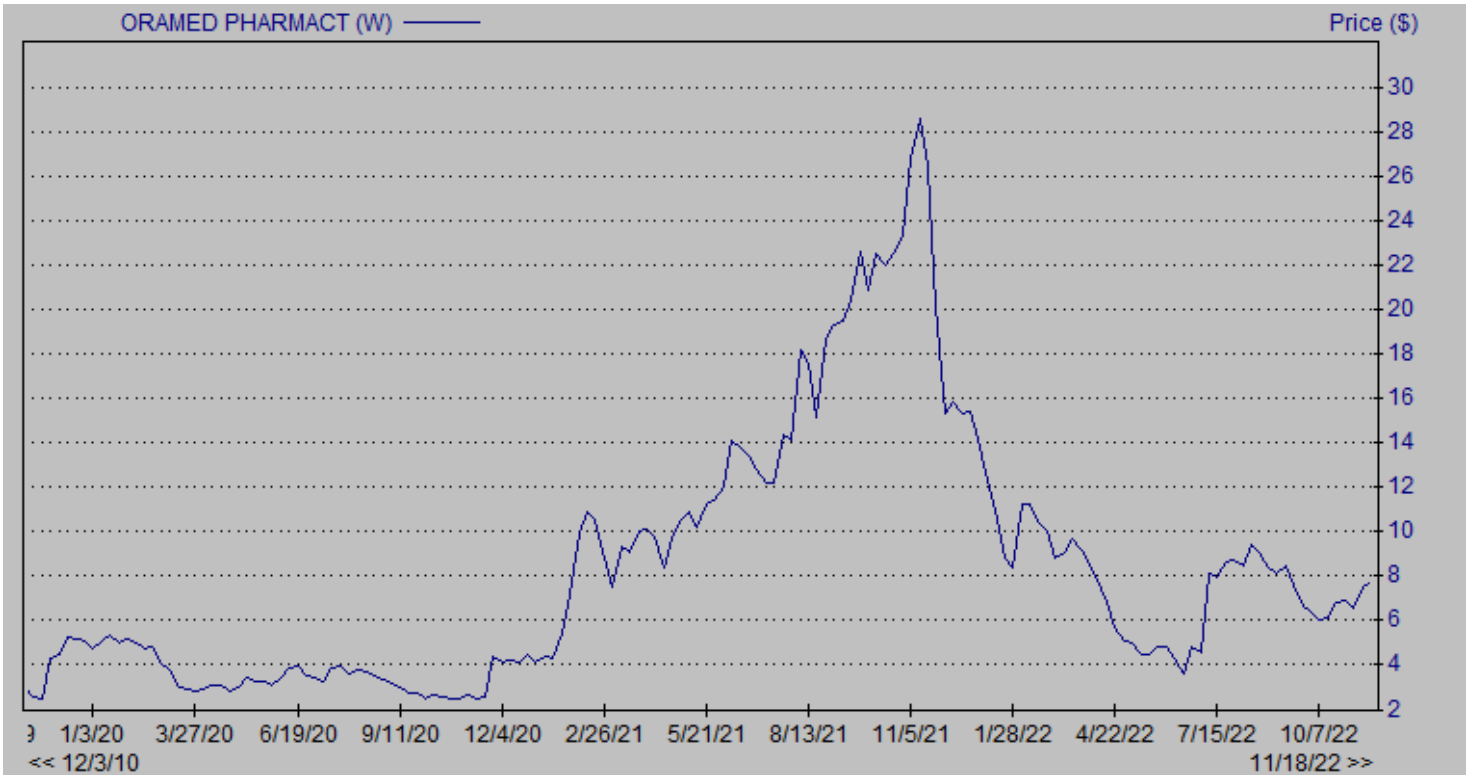
Oramed Pharmaceuticals Inc. (Fiscal Year ends Dec. 31*) $Mns	FY 2018 A	FY 2019 A	FY 2020	Q1 A	Q2 A	Q3 A	Q4 A	FY 2021 A	Q1 A	8/21-12/21*	Q2 A	Q3 A	Q4 E	FY 2022 E
License Revenue	$2.4	$2.7	$2.7	$0.7	$0.7	$0.7	$0.7	$2.7	$0.7	$0.9	$0.7	$0.7	$0.8	$2.8
YOY Growth	-	-	-					-						-
Grant/Contract Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$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	$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	$0.0
YOY Growth	-	-	-					-	-		-	-	-	-
Total Revenues	**$2.4**	**$2.7**	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$0.7**	**$0.9**	**$0.7**	**$0.7**	**$0.8**	**$2.8**
YOY Growth	*0%*	*10%*	*1%*	*0%*	*-1%*	*-3%*	*-2%*	*-1%*	*0%*	*0%*	*0%*	*0%*	*13%*	*4%*
Cost of Revenue	$0.1	$0.1	$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	**$2.5**	**$2.6**	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.7**	**$0.7**	**$0.9**	**$0.7**	**$0.7**	**$0.8**	**$2.8**
Gross Margin	*103.5%*	*96.7%*	*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	$12.0	$13.5	$10.2	$6.4	$3.2	$5.5	$0.7	$21.0	$6.4	$9.0	$9.2	$5.3	$0.5	$21.4
General & Administrative	$4.1	$3.7	$4.2	$0.5	$1.9	$1.3	$2.2	$5.9	$1.7	$3.3	$2.5	$3.1	$0.2	$7.5
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.6	$0.9	$0.4	$0.5	$0.4	$1.8
Operating Income	**($13.5)**	**($14.6)**	**($11.7)**	**($6.2)**	**($4.5)**	**($6.1)**	**($2.2)**	**($24.2)**	**($8.1)**	**($12.3)**	**($11.4)**	**($8.2)**	**($0.3)**	**($28.0)**
Operating Margin	-	-	-					-						-
Other Income (Net)	$1.1	$0.6	$0.2	$0.3	$0.5	$0.5	$1.0	$1.2	$0.0	$0.0	$0.4	$1.0	$0.9	$2.2
Pre-Tax Income	**($12.7)**	**($14.1)**	**($11.5)**	**($6.0)**	**($3.9)**	**($5.6)**	**($1.2)**	**($23.0)**	**($8.1)**	**($12.3)**	**($11.1)**	**($7.2)**	**$0.6**	**($25.7)**
Net Taxes (benefit)	$0.0	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$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%*	*0.0%*	*0.0%*	*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
Reported Net Income	**($12.7)**	**($14.4)**	**($11.5)**	**($6.0)**	**($3.8)**	**($5.2)**	**($0.8)**	**($22.2)**	**($7.9)**	**($11.7)**	**($10.5)**	**($7.1)**	**$1.0**	**($24.4)**
Net Margin	-	-	-					-						-
Reported EPS	**($0.86)**	**($0.82)**	**($0.56)**	**($0.25)**	**($0.12)**	**($0.17)**	**($0.03)**	**($0.78)**	**($0.22)**	**($0.31)**	**($0.27)**	**($0.18)**	**$0.03**	**($0.64)**
YOY Growth	-	-	-					-						-
Basic Shares Outstanding	14.9	17.5	20.5	23.7	30.7	29.9	30.3	28.5	36.7	37.1	38.8	39.1	39.5	38.5

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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