

Zacks Small-Cap Research

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Oramed Pharmaceuticals Inc.

(ORMP-NASDAQ)

ORMP: Multiple Opportunities Advance; Senior Team Expands to Support Growth

Given ORMP's many opportunities in addition to its core diabetes studies, the company has expanded its senior management team to help facilitate the development and expected commercialization of its growing asset portfolio, with the appointment of an industry veteran to the newly created position of Chief Commercial Officer effective August 1, 2021, to oversee the overall commercial strategy and execution.

Current Price (8/25/2021) \$17.55
Valuation \$23.00

OUTLOOK

ORMP has enrolled and randomized 25+% of the planned 450 patients for the Phase 3 ORA-D-013-2 trial of ORMD-0801 for the treatment of type 2 diabetes and about 50% of the 675 patients planned in the Phase 3 ORA-D-013-1 study. 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. In addition to focusing on pursuing opportunities in its core diabetes space, Oramed has expanded the potential of its technology platform with a recent JV to develop an oral COVID-19 vaccine, underscoring the potential versatility of the company's oral protein delivery platform technology.

SUMMARY DATA

52-Week High \$23.57
52-Week Low \$2.48
One-Year Return (%) 400.00
Beta 1.91
Average Daily Volume (sh) 1,116,009

Shares Outstanding (mil) 33
Market Capitalization (\$mil) \$570
Short Interest Ratio (days) N/A
Institutional Ownership (%) 4
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 2021 Estimate N/A
P/E using 2022 Estimate N/A

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

ZACKS ESTIMATES

Revenue (in millions of \$)	Q1	Q2	Q3	Q4	Year
	(Nov)	(Feb)	(May)	(Aug)	(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	0.8 E	2.8 E
2022					2.8 E

Earnings per Share	Q1	Q2	Q3	Q4	Year
	(Nov)	(Feb)	(May)	(Aug)	(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	-\$0.17 A	-\$0.17 A	-\$0.10 E	-\$0.82 E
2022					-\$0.80 E

Quarters might not sum due to rounding & share counts
Disclosures begin on page 13

KEY POINTS

- This week ORMP announced that it has enrolled and randomized more than 25% of the planned 450 patients for the Phase 3 ORA-D-013-2 trial of ORMD-0801 for the treatment of type 2 diabetes (T2D). The company had earlier announced that it has enrolled and randomized about 50% of the 675 patients planned in the Phase 3 ORA-D-013-1 study of ORMD-0801. 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.
- In addition to focusing on pursuing opportunities in its core diabetes space, ORMP has also entered the COVID-19 vaccine space through a recently formed joint venture, Oravax Medical Inc., to advance an orally administered vaccine for the COVID-19 virus. The Oravax vaccine represents a successful expansion of Oramed's POD™ oral protein delivery platform into the vaccine development market.
- The vaccine currently is being tested against COVID-19 variants, including the Delta variant. Oravax intends to launch clinical trials for the oral COVID-19 vaccine, beginning in Israel, with additional international locations to follow. The many potential competitive advantage of a vaccine in pill form is easier and less expensive distribution and storage and the potential to overcome vaccine hesitancy.
- Separately, ORMP shares were recently included in the U.S. small cap Russell 2000® and broad-market Russell 3000® Index following the Russell annual reconstitution. We believe the addition to the Russell indices increases the pool of potential investors who can acquire ORMP shares, as the company continues to execute its growth strategy.
- The company has also expanded its senior management team to help facilitate the development and expected commercialization of its growing asset portfolio. Oramed appointed industry veteran Michael Rabinowitz to the newly created position of Chief Commercial Officer effective August 1, 2021. He is responsible for Oramed's overall commercial strategy and execution.

WHAT'S NEW? ORMP REACHES 25% ENROLLMENT IN T2D STUDY

25% of patients enrolled in ORA-D-013-2 study

Oramed Pharmaceuticals Inc. (NASDAQ:ORMP) announced that it has enrolled and randomized more than 25% of the planned 450 patients for the Phase 3 ORA-D-013-2 trial of ORMD-0801 for the treatment of type 2 diabetes (T2D). Oramed continues to advance its Oral Insulin in dual concurrent Phase 3 studies.

- 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

50% of patients enrolled in ORA-D-013-1 study

The company has also enrolled and randomized about 50% of the 675 patients planned in the Phase 3 ORA-D-013-1 study of ORMD-0801. 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.

Oramed has also screened the first patients in its ORA-D-013-2 study, the second of the two above-noted concurrent Phase 3 studies of ORMD-0801 for the treatment of T2D. The ORA-D-013-2 study is planned to enroll 450 T2D patients.

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.

ORMD-0801 is the company's lead development candidate 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.

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.

Primary and Secondary Endpoints

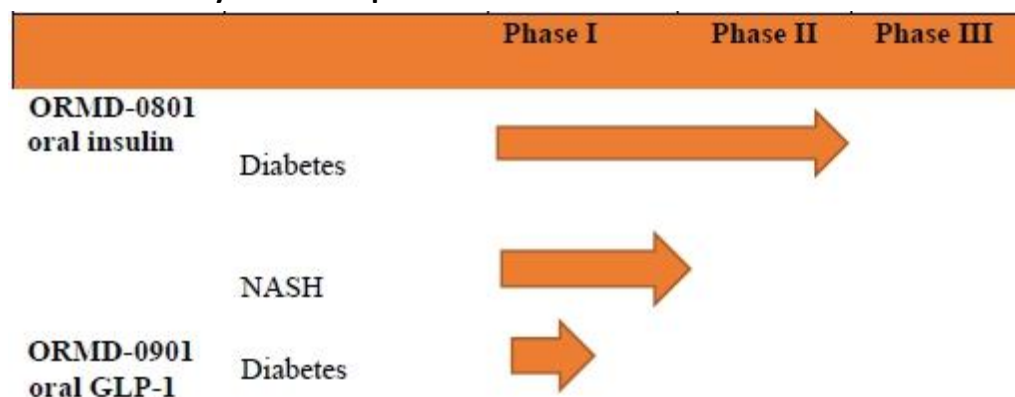
- The primary endpoint of the Oramed study is to compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c
- The secondary endpoint is assessing the change from baseline in fasting plasma glucose at 26 weeks.

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. 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.

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.

Oramed Primary Product Pipeline



Source: Oramed [10-K](#)

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.

Oral COVID-19 Vaccine: JV to Advance a pill vaccine

Many advantages include potential to overcome vaccine hesitancy; ease of storage and dosage

In addition to focusing on pursuing opportunities in its core diabetes space, ORMP has also entered the COVID-19 vaccine space through a recently formed joint venture, Oravax. Oramed formed a new joint venture 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, as noted. Simultaneously, Oramed continues

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.

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. Moreover, 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.

A Pill Might Help Overcome Vaccine Hesitancy

A vaccine in pill form might also 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.

Oravax expects to begin clinical trials in 2Q 2021. 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 has indicated that it is pursuing early stage oral studies for a drug to *treat* the COVID-19 disease, not to inoculate against it.

Expanding the pool of investors

Separately, ORMP shares were recently included in the U.S. small cap Russell 2000® and broad-market Russell 3000® Index following the Russell annual reconstitution. The Russell 2000 includes the smaller cap stocks in the Russell 3000.

As investment managers and institutional investors use Russell indices as benchmarks for investment strategies, about \$10.6 trillion in assets are benchmarked against the Russell U.S. indexes. According to FTSE Russell, Russell U.S. indices are the leading U.S. equity benchmarks for institutional investors. All sub-indexes roll-up to the Russell 3000 Index. We believe the addition to the Russell indices increases the pool of potential investors who can acquire ORMP shares, as the company continues to execute its growth strategy.

Enhanced financial flexibility & expanded senior team to support growth

Oramed has also increased its access to financing to help move its assets forward. Oramed recently extended a 2020 agreement to sell ORMP shares from time to time under its shelf registration, depending on company needs and market conditions. Under the prior 2020 agreement, ORMP sold just under 4.0 million shares from December 1, 2020, through June 14, 2021, raising gross proceeds of roughly \$38.5 million. In addition to the \$28.0 million under the new agreement, there is also roughly \$1.5 million remaining under the 2020 agreement that further augments the potential to raise funds.

With \$57.4 million of cash & equivalents at the end of 3Q21 (May 2021), plus \$12.2 million of short-term deposits and marketable securities, ORMP is well-positioned to advance its growth strategy, in our view. In addition, the flexibility of the shelf registration and extended broker agreement gives Oramed the ability to raise funds, as needed, to support its growth plans, which have multiplied with the recent entrance into the Oravax Medical JV.

Moreover, the company has also expanded its senior management team to help facilitate the development and expected commercialization of its growing asset portfolio. Oramed appointed industry veteran Michael Rabinowitz to the newly created position of Chief Commercial Officer effective August 1, 2021. He is responsible for Oramed's overall commercial strategy and execution.

NASH TRIAL ALSO MOVING FORWARD

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

Oramed has also screened the first patients in its global nonalcoholic steatohepatitis (NASH) trial in which Oramed's oral insulin capsule ORMD-0801 is being studied for the treatment of patients with NASH. Initial patients were screened in the U.S., with other clinical sites to commence in Europe and Israel.

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).

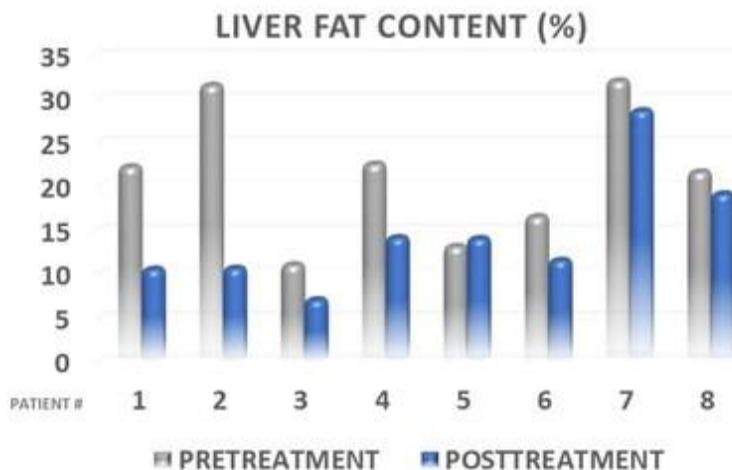
Patients in the NASH study were screened at a U.S. site that is participating in the Oramed trial, which is being conducted at clinical locations in the U.S. (three locations), EU (three) and Israel (two). The trial will measure efficacy endpoints via MRI-PDFF for 12-weeks dosing.

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 $6.9 \pm 6.8\%$ 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

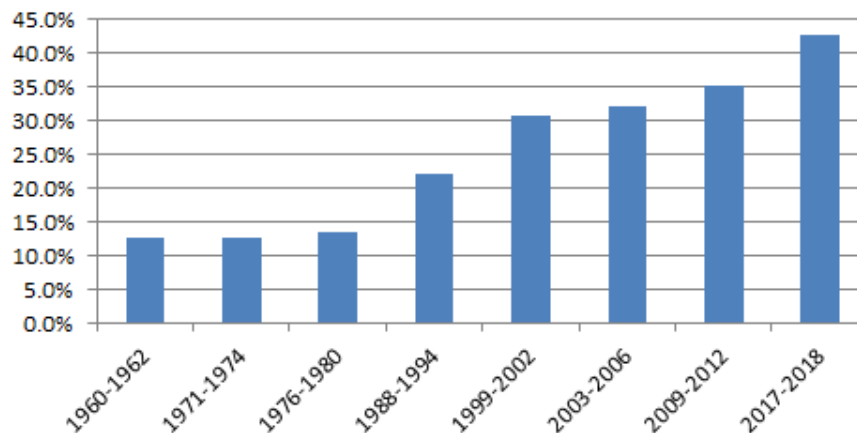
ORMP is also leveraging its technology for an orally ingestible glucagon-like peptide-1 (GLP-1) capsule, ORMP's second pipeline product, ORMD-0901. ORMD-0901 is an orally ingestible exenatide (GLP-1 analog) capsule designed to aid in the balance of blood-sugar levels and also to decrease appetite. ORMD-0901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

U.S. Obesity Trends, 1960s-2018 (%)



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.

We believe the multiple studies currently being conducted underscore the potential versatility of the company's oral protein delivery platform technology.

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, 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. Moreover, as the oral COVID-19 vaccine pills advances through clinical trials and to expected commercial launch, it could also imply upside to our valuation.

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 August 24, 2021, ORMP announced that it reached 25% enrollment in the 2nd of its two concurrent Phase 3 oral insulin trials.
- Oramed announced the publication of an oral insulin study in the journal *Diabetes, Obesity, and Metabolism* on August 16, 2021.
- Oramed appointed a Chief Commercial Officer on July 29, 2021.
- On June 22, 2021, the company announced the shares pending inclusion in the Russell 2000 and 3000 indices.

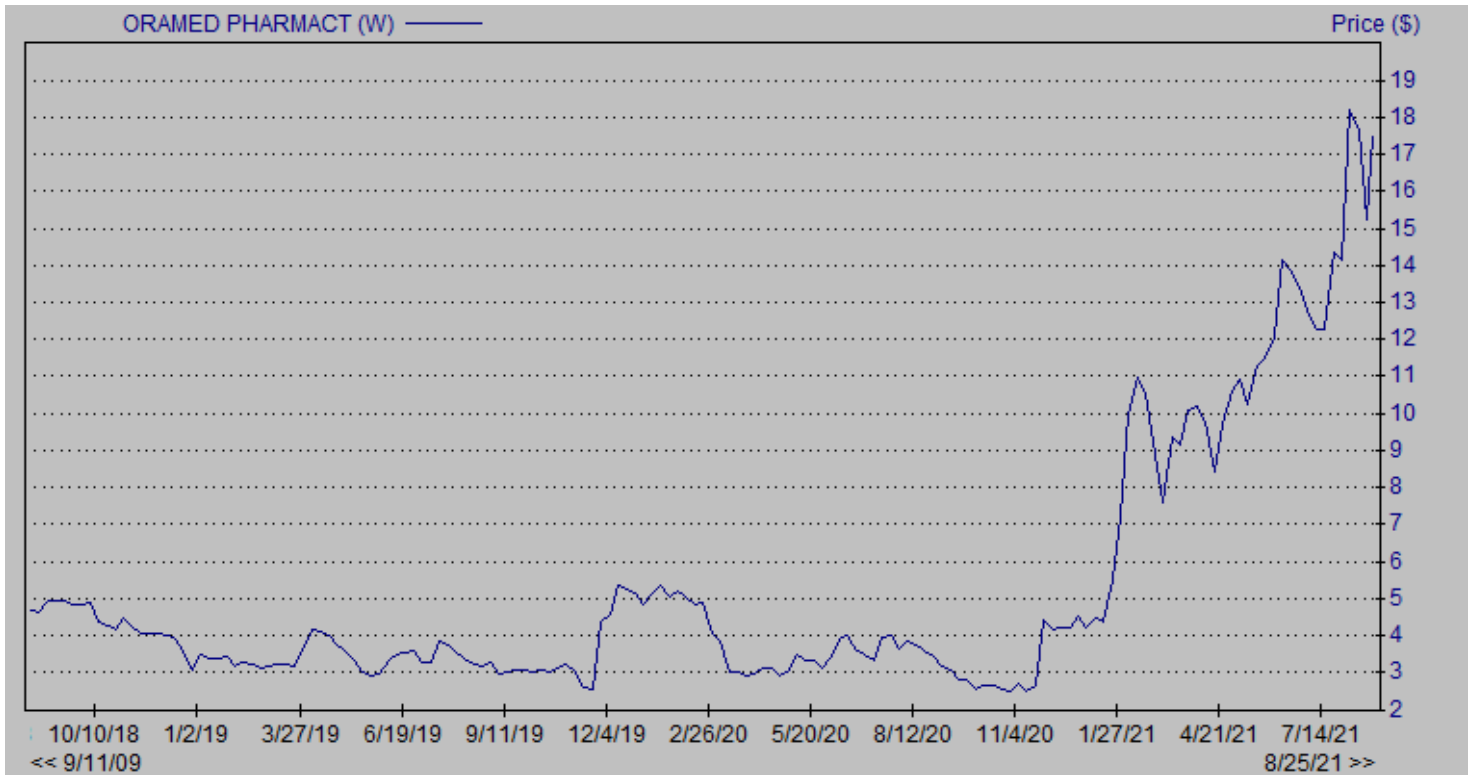
- On June 8, 2021, the company announced that it had reached 50% enrollment in its phase 3 oral insulin study being conducted under FDA approved protocol.
- ORMP initiated the second Phase 3 oral insulin study under the FDA's approved dual concurrent protocol on March 23, 2021.
- Oramed announced the formation of a JV, Oravax Medical Inc., to develop a novel oral COVID-19 vaccine on March 19, 2021.
- ORMP reported positive first in human data from its oral leptin study on December 23, 2020.
- On December 2, 2020, Oramed announced that it had initiated its Phase 2 NASH trial.
- Oramed announced positive initial clinical trial results for treatment of NASH with oral insulin on June 15, 2020.

PROJECTED FINANCIALS

Oramed Pharmaceuticals Inc. (Fiscal Year ends Aug. 31) \$Mns	FY 2018 A	FY 2019 A	Q1 A	Q2 A	Q3 A	Q4 A	FY 2020	Q1 A	Q2 A	Q3 A	Q4 E	FY 2021 E	FY 2022 E
License Revenue	\$2.4	\$2.7	\$0.7	\$0.7	\$0.7	\$0.7	\$2.7	\$0.7	\$0.7	\$0.7	\$0.8	\$2.8	\$2.8
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
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
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
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
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
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
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	\$2.4	\$2.7	\$0.7	\$0.7	\$0.7	\$0.7	\$2.7	\$0.7	\$0.7	\$0.7	\$0.8	\$2.8	\$2.8
<i>YOY Growth</i>	0%	10%	0%	1%	3%	3%	1%	0%	-1%	-3%	11%	3%	0%
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
Gross Income	\$2.5	\$2.6	\$0.7	\$0.7	\$0.7	\$0.7	\$2.7	\$0.7	\$0.7	\$0.7	\$0.8	\$2.8	\$2.8
<i>Gross Margin</i>	103.5%	96.7%	96.7%	96.7%	96.7%	96.7%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Research & Development	\$12.0	\$13.5	\$2.0	\$3.3	\$1.9	\$3.0	\$10.2	\$5.8	\$3.9	\$5.5	\$0.9	\$18.0	\$20.0
General & Administrative	\$4.1	\$3.7	\$1.1	\$1.4	\$1.0	\$0.7	\$4.2	\$0.7	\$1.7	\$1.3	\$3.8	\$7.5	\$7.5
Other Expenses	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	(\$13.5)	(\$14.6)	(\$2.4)	(\$4.0)	(\$2.3)	(\$3.0)	(\$11.7)	(\$5.8)	(\$4.9)	(\$6.1)	(\$3.9)	(\$22.7)	(\$24.7)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income (Net)	\$1.1	\$0.6	\$0.1	(\$0.3)	(\$0.0)	\$0.5	\$0.2	\$0.3	\$0.3	\$0.5	\$0.9	\$0.0	\$0.0
Pre-Tax Income	(\$12.7)	(\$14.1)	(\$2.5)	(\$3.7)	(\$2.3)	(\$3.5)	(\$11.5)	(\$5.6)	(\$4.6)	(\$5.6)	(\$3.0)	(\$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	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	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										\$0.4			
Reported Net Income	(\$12.7)	(\$14.4)	(\$2.5)	(\$3.7)	(\$2.3)	(\$3.5)	(\$11.5)	(\$5.6)	(\$4.6)	(\$5.2)	(\$3.0)	(\$22.7)	(\$24.7)
<i>Net Margin</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported EPS	(\$0.86)	(\$0.82)	(\$0.15)	(\$0.21)	(\$0.10)	(\$0.15)	(\$0.56)	(\$0.24)	(\$0.17)	(\$0.17)	(\$0.10)	(\$0.82)	(\$0.80)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-	-	-	-	-	-
Basic Shares Outstanding	14.9	17.5	17.5	17.8	23.2	23.5	20.5	23.7	27.0	29.9	30.3	27.7	30.7

Source: Zacks Investment Research, Inc.

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