

## Oramed Pharmaceuticals Inc.

(ORMP-NASDAQ)

### ORMP: Broadening IP Protection, Positive Physician Indicators & Studies Advancing

The European Patent Office granted Oramed a patent for NASH. The patent has been granted to Oramed in the U.S. & is also pending in several other markets, as well. ORMP recently announced that it had achieved 100% enrollment in its Phase 2 global NASH trial in which ORMD-0801 (its oral insulin capsule) is being studied for the treatment of T2D diabetes patients with NASH.

### OUTLOOK

Oramed has multiple clinical development programs underway, which we believe underscores the potential versatility of the company's oral protein delivery platform technology. The company believes that ORMD-0801 could become the first commercial oral insulin capsule for the treatment of diabetes. Results from a diabetes market survey Oramed commissioned indicate the potential for positive endorsements of ORMD-0801, following further clinical studies. Of 170 doctors surveyed, 76% indicated an inclination to prescribe it for T2D patients, depending on data from advanced trials. These positive results are consistent with a KOL webinar Oramed hosted last month on the need for oral insulin in T2D.

Current Price (4/26/2022) **\$5.55**  
Valuation **\$38.00**

### SUMMARY DATA

52-Week High **\$31.54**  
52-Week Low **\$5.48**  
One-Year Return (%) **-49.41**  
Beta **1.88**  
Average Daily Volume (sh) **594,739**

Shares Outstanding (mil) **38**  
Market Capitalization (\$mil) **\$213**  
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  
Type of Stock Industry  
Average Small-Blend 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 E	0.7 E	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	-\$0.17 A	-\$0.17 A	-\$0.03 A	-\$0.78 A
2022	-\$0.22 A	-\$0.15 E	-\$0.23 E	-\$0.15 E	-\$0.75 E

Quarters might not sum due to rounding & share counts  
Disclosures begin on page 15 ^FY will change to Dec. 31

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## KEY POINTS

- The European Patent Office granted Oramed a patent for NASH. The patent, which has been granted to Oramed in the U.S., is also pending in several additional markets, as well.
- The company recently announced that it had achieved 100% enrollment in its Phase 2 global NASH trial in which its oral insulin capsule ORMD-0801 is being studied for the treatment of patients with NASH assessing the safety and potential efficacy of ORMD-0801, ORMP's lead product, oral insulin, in type 2 diabetes (T2D) patients with NASH.
- In a previous study, ORMD-0801 showed a 30% relative reduction in liver fat, supporting the company's moving NASH clinical trials forward.
- Oramed has multiple clinical development programs underway, which we believe underscores the potential versatility of the company's oral protein delivery platform technology. The company believes that ORMD-0801 could become the first commercial oral insulin capsule for the treatment of diabetes.
- Results from a diabetes market survey Oramed commissioned indicate the potential for positive endorsements of ORMD-0801. Following their review of the existing data from ORMD-0801 studies, 76% of 170 doctors surveyed indicated their inclination to prescribe it for T2D patients.
- These positive results are consistent with a KOL (Key Opinion Leader) webinar Oramed recently hosted on the need for oral insulin in T2D. The KOL speakers appeared receptive to and positive about the prospects for ORMD-0801, if the results of the company's clinical efforts are successful.
- 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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## NASH PATENT - TRIAL

### *Broadening patent IP protection...*

Oramed Pharmaceuticals Inc. (NASDAQ:ORMP) announced that the European Patent Office has granted it a patent, *Methods and Compositions for Treating NAFLD, Hepatic Steatosis, and Sequelae Thereof*. The patent, which has been granted to Oramed in the U.S., is pending in several additional markets, as well. This brings the company's patent portfolio to nearly 90 patents granted and over 30 additional patents pending.

### *... NASH study completes enrollment*

The patent comes as Oramed continues to move its global nonalcoholic steatohepatitis (NASH) study forward. The company recently announced that it had achieved 100% enrollment in its [Phase 2](#) global NASH trial in which its oral insulin capsule ORMD-0801 is being studied for the treatment of patients with NASH assessing the safety and potential efficacy of ORMD-0801, ORMP's lead product, oral insulin, in type 2 diabetes (T2D) patients with NASH. The study is testing ORMD-0801's ability to reduce liver fat, inflammation, and fibrosis in NASH patients. It 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.

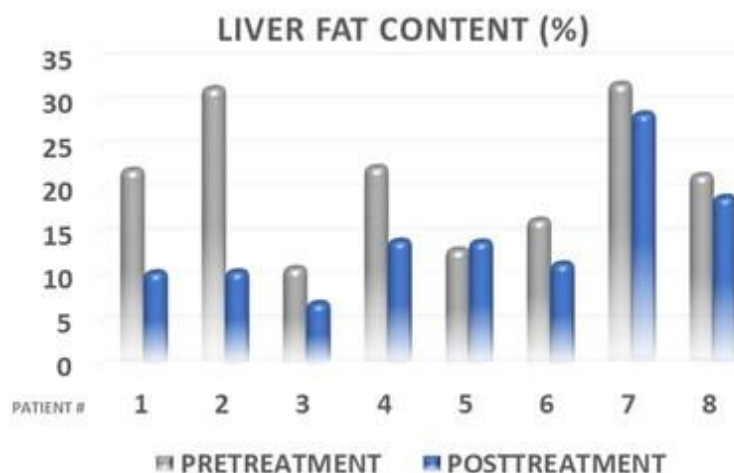
NASH is inflammation and damage to the liver reflecting a buildup of fat. It is the most severe form of nonalcoholic fatty liver disease (NAFLD). Moreover, many, if not most, people with NASH are relatively

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.

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).

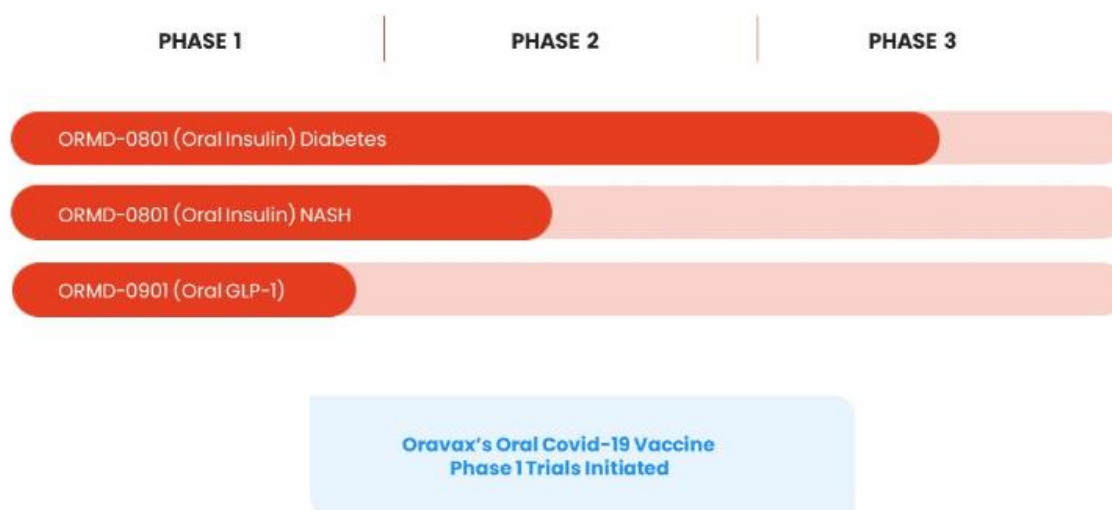


Source: oramed.com

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. Forecasts of the size of the NASH [treatment market](#) from several market research firms vary, with some forecasting that it could be as large as \$84 billion globally by 2029.

ORMD-0801 is the company's lead development candidate that is being tested both in type 1 (T1D) and T2D and NASH. Oramed has multiple clinical development programs underway, as illustrated below. We believe the multiple studies currently being conducted underscore the potential versatility of the company's oral protein delivery platform technology. The company believes that ORMD-0801 could become the first commercial oral insulin capsule for the treatment of diabetes.

## Multiple Clinical Stage Programs



Source: [Oramed presentation](#)

## T2D DUAL STUDIES MOVING FORWARD

Oramed also continues to advance ORMD-0801 in dual concurrent Phase 3 studies for the treatment of T2D.

- 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

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. 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.

ORMP has enrolled and randomized over 75% of the 675 patients planned for the Phase 3 ORA-D-013-1 study. Efficacy data for ORA-D-013-1 will become available after all patients have completed the first 6-month treatment period. The concurrent study, ORA-D-013-2, commenced enrollment in March for a planned 450 patients. The company is nearing the end of enrollment and anticipates announcing topline results in 2022.

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

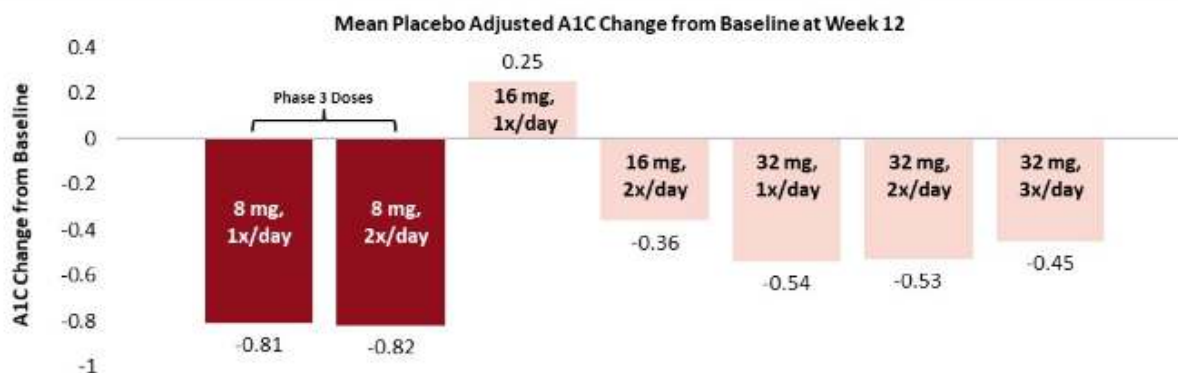
- The primary endpoint of the Oramed study is to compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c
- The secondary endpoint is assessing the change from baseline in fasting plasma glucose at 26 weeks.

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.

## ORMD-0801 Phase 2b Achieved Safety and Primary Endpoints

### Primary Endpoint

- Achieved primary efficacy endpoint in reduction in A1C at Week 12
- The 8 mg once-daily and twice-daily arms achieved statistically significant values at Week 12 vs. Placebo (p-value 0.028 and 0.029, respectively)



Source: [Oramed presentation](#)

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.

## Positive survey results & KOL feedback

In fact, results from a diabetes market survey Oramed commissioned IQVIA to conduct indicate the potential for positive endorsements of ORMD-0801. IQVIA is a global provider of advanced analytics and other services to the life sciences industry, with operations in more than 100 countries. IQVIA conducted a survey of relevant physicians in the U.S. and Europe, including 88 endocrinologists and 82 primary care physicians. Following their review of the existing data from ORMD-0801 studies, 76% responded that they “definitely would” or “probably would” prescribe it for T2D patients. With only 2% indicating they would not prescribe it, respondents appear receptive to prescribing oral insulin, if it receives regulatory approval.

### IQVIA Survey Responses (170 respondents)

	Willingness to prescribe oral insulin (A)	Willingness to prescribe Product X (B)
Definitely would NOT prescribe	0%	0%
Probably would NOT prescribe	2%	1%
Might or might not prescribe	20%	22%
Probably WOULD prescribe	53%	57%
Definitely WOULD prescribe	23%	20%

Source: [Oramed presentation](#)

These positive results are consistent with a KOL (Key Opinion Leader) webinar Oramed recently hosted on the need for oral insulin in T2D. The KOL speakers appeared receptive to and positive about the prospects for ORMD-0801, if the results of the company’s clinical efforts are successful. One KOL speaker noted that ORMD-0801 could be particularly useful for patients with a low tolerance to injections. Overall, the results suggest that the initial data provides clinical proof of concept on ORMD-0801, supporting moving forward with further clinical studies.

Diabetes, which affects how the body uses blood sugar (glucose), occurs when the body does not produce sufficient levels of or properly use insulin, which is a hormone that causes sugar to be absorbed into cells where it (the sugar) then is converted into energy. Diabetes is attributed to both hereditary and environmental factors, including obesity and lack of exercise. As obesity rates rise globally (see below), the incidence of diabetes has also increased. For instance, the International Diabetes Federation (IDF) projects that 700 million adults (20-79 years) worldwide will suffer from diabetes by 2045, up from an estimated 463 million in 2019. The IDF also estimates that 4.2 million people died from diabetes in 2019.

## Addressable Market

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

## COVID-19 ORAL VACCINE

### Securing partnerships and pre-orders

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. 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.

## 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 COVID-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, moving trials forward

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.

In another key region, Oravax has screened and enrolled the first participant in a Phase 1 clinical trial of its oral virus-like particle (VLP) COVID-19 vaccine in Johannesburg, South Africa. The open-label trial anticipates enrolling 24 participants who have not received either a COVID-19 vaccine or contracted the virus. 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.

## 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.

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## **ORMD-0901 TECHNOLOGY PLATFORM**

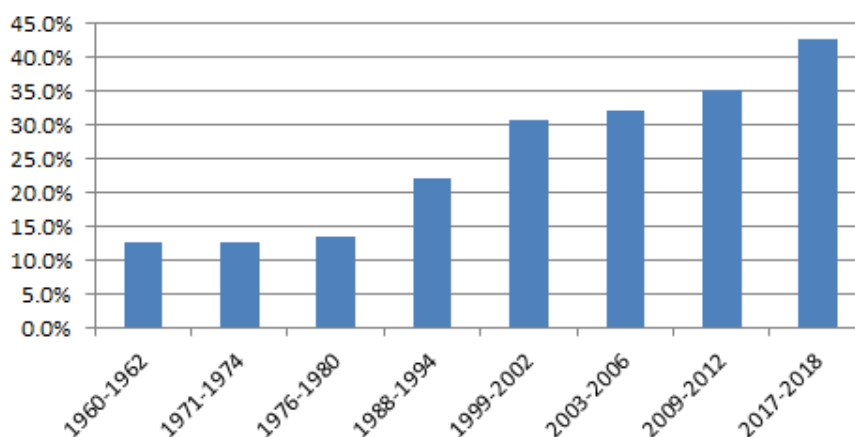
### ***Oral Glucagon-Like Peptide-1***

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.

## VALUATION

We believe ORMP's prospects have multiplied with the company's recent entrance into the COVID-19 space. 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.

### ORMD-0801

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 following the recent offering, potential cash from warrant exercises, and dividing by the fully diluted share count, we obtain a NPV for Oramed on its initial focus lines of approximately \$25 per share.

### COVID-19 vaccine pill

We also expect the shares to reflect the potential of the oral COVID-19 vaccine pill. It is still early to ascertain the revenue arc for Oravax at this stage because of many variables, including potential regulatory approval and commercial launch timelines, consumer adoption of an oral vaccine and whether recurring administration of a vaccine becomes standard, as we expect. Nevertheless, 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. The expected competitive advantages of a vaccine in a pill format, particularly in certain markets where freezing refrigeration requirements make it difficult to transport, store and distribute an injectable vaccine include that Oravax's VLP vaccine technology targets three SARS CoV-2 virus surface proteins, as noted, including proteins that are less susceptible to mutation. The company believes this potentially could make its vaccine more effective against a range of variants of the COVID-19 virus. Moreover, it is also scalable, according to management, and easier to transfer and transport, as noted. The company also believes its pill could be a good solution as a booster for people who have already been vaccinated.

Including the prospects for the COVID-19 vaccine pill, we derive a combined valuation of about \$38 per share. We also believe the company's entrance into the COVID-19 vaccine space underscores the versatility – and economic potential – of the company's oral drug delivery technology. Although the shares have appreciated significantly recently, we believe the current ORMP share price does not reflect the company's ability to further expand its focus, which also could imply upside to the above-noted valuation, in our view.

### **Expanding investor pool; positive implications**

Separately, we also believe the recent inclusion of ORMP shares in the U.S. small cap Russell 2000® and broad-market Russell 3000® Index following the Russell annual reconstitution is positive for the liquidity of the shares. 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 and has positive implications, in our view, for the shares. The shares were also recently added to the MSCI USA Small Cap Index, which is designed to measure the performance of the small cap segment of the U.S. equity market.

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## **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

- Oramed was granted a European patent for NASH on April 5, 2022.
- Oramed appointed Yadin Rozov to its board on April 4, 2022, as an independent director.
- Oramed announced the results of its diabetes market survey on March 29, 2022, showing strong Interest for ORMD-0801 among physicians.
- Oramed hosted a KOL (Key Opinion Leader) webinar on the need for oral insulin in T2D on March 30, 2022.
- Oramed was granted a European patent for the oral delivery of proteins on January 5, 2022.
- Oravax Medical signed a cooperation and purchase agreement with Tan Thanh Holdings on December 29, 2021.
- On December 14, 2021, Oravax announced the first participant enrolled in its Phase 1 Oral COVID-19 vaccine trial in South Africa.
- Oramed appointed a Chief Legal Officer on December 8, 2021.
- ORMP shares were added to the MSCI USA Small Cap Index in November of 2021.
- On November 23, 2021, ORA-D-013-1 of Oramed's Phase 3 oral insulin study reached 75% enrollment.
- Oravax Medical and Genomma Lab Internacional announced their JV on November 18, 2021.
- The company closed a \$50 million equity offering on November 8, 2021.
- On August 24, 2021, ORMP announced that it reached 25% enrollment in the 2nd of its 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.
- 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.

## PROJECTED FINANCIALS

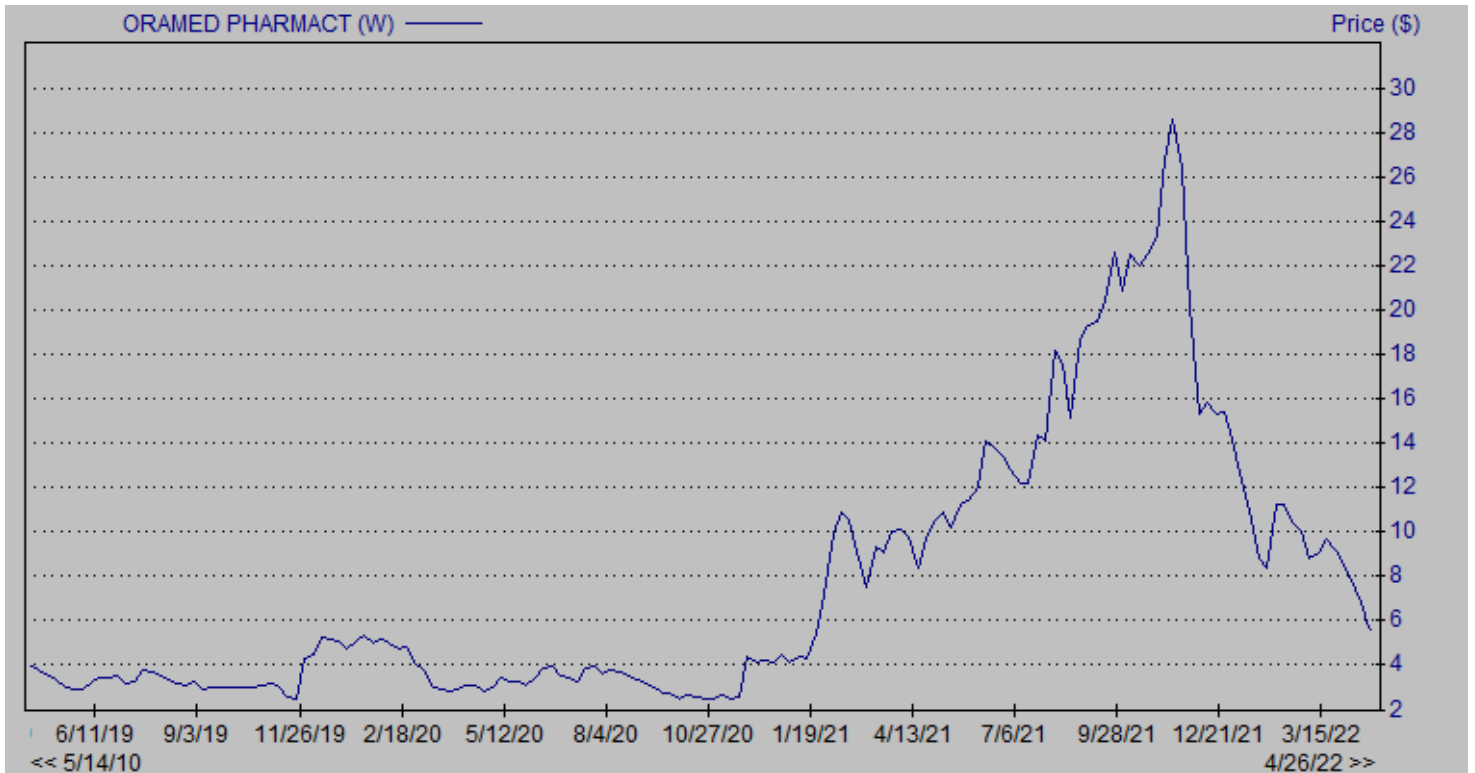
Oramed Pharmaceuticals Inc. (Fiscal Year ends Dec. 31*) \$Mns	FY 2018 A	FY 2019 A	FY 2020	Q1 A	Q2 A	Q3 A	Q4 A	FY 2021 A	Q1 A	8/21- 12/21*	Q2 E	Q3 E	Q4 E	FY 2022 E
License Revenue	\$2.4	\$2.7	\$2.7	\$0.7	\$0.7	\$0.7	\$0.7	\$2.7	\$0.7	\$0.9	\$0.7	\$0.7	\$0.8	\$2.8
<i>YOY Growth</i>	-	-	-					-						-
Grant/Contract 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	\$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	\$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	\$0.0
<i>YOY Growth</i>	-	-	-					-						-
<b>Total Revenues</b>	<b>\$2.4</b>	<b>\$2.7</b>	<b>\$2.7</b>	<b>\$0.7</b>	<b>\$0.7</b>	<b>\$0.7</b>	<b>\$0.7</b>	<b>\$2.7</b>	<b>\$0.7</b>	<b>\$0.9</b>	<b>\$0.7</b>	<b>\$0.7</b>	<b>\$0.8</b>	<b>\$2.8</b>
<i>YOY Growth</i>	0%	10%	1%	0%	-1%	-3%	-2%	-1%	0%	0%	1%	-1%	14%	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
<b>Gross Income</b>	<b>\$2.5</b>	<b>\$2.6</b>	<b>\$2.7</b>	<b>\$0.7</b>	<b>\$0.7</b>	<b>\$0.7</b>	<b>\$0.7</b>	<b>\$2.7</b>	<b>\$0.7</b>	<b>\$0.9</b>	<b>\$0.7</b>	<b>\$0.7</b>	<b>\$0.8</b>	<b>\$2.8</b>
<i>Gross Margin</i>	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	\$5.8	\$3.9	\$5.5	\$0.7	\$21.0	\$6.4	\$9.0	\$5.0	\$5.0	\$3.6	\$20.0
General & Administrative	\$4.1	\$3.7	\$4.2	\$0.7	\$1.7	\$1.3	\$2.2	\$5.9	\$1.7	\$3.3	\$1.5	\$1.5	\$2.8	\$7.5
Other Expenses	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.6	\$0.9	\$0.0	\$0.0	\$0.6	\$0.0
Operating Income	(\$13.5)	(\$14.6)	(\$11.7)	(\$5.8)	(\$4.9)	(\$6.1)	(\$2.2)	(\$24.2)	(\$8.1)	(\$12.3)	(\$5.8)	(\$5.8)	(\$5.0)	(\$24.7)
<i>Operating Margin</i>	-	-	-					-						-
Other Income (Net)	\$1.1	\$0.6	\$0.2	\$0.3	\$0.3	\$0.5	\$1.0	\$1.2	\$0.0	\$0.0	\$0.0	\$3.3	\$1.2	\$0.0
<b>Pre-Tax Income</b>	<b>(\$12.7)</b>	<b>(\$14.1)</b>	<b>(\$11.5)</b>	<b>(\$5.6)</b>	<b>(\$4.6)</b>	<b>(\$5.6)</b>	<b>(\$1.2)</b>	<b>(\$23.0)</b>	<b>(\$8.1)</b>	<b>(\$12.3)</b>	<b>(\$5.8)</b>	<b>(\$9.2)</b>	<b>(\$6.2)</b>	<b>(\$24.7)</b>
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	\$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%	0.0%
Minority interest / other						\$0.4	\$0.4	\$0.8	\$0.2	\$0.6	\$0.4	\$0.4	\$0.4	\$1.5
<b>Reported Net Income</b>	<b>(\$12.7)</b>	<b>(\$14.4)</b>	<b>(\$11.5)</b>	<b>(\$5.6)</b>	<b>(\$4.6)</b>	<b>(\$5.2)</b>	<b>(\$0.8)</b>	<b>(\$22.2)</b>	<b>(\$7.9)</b>	<b>(\$11.7)</b>	<b>(\$5.4)</b>	<b>(\$8.7)</b>	<b>(\$5.8)</b>	<b>(\$23.2)</b>
<i>Net Margin</i>	-	-	-					-						-
<b>Reported EPS</b>	<b>(\$0.86)</b>	<b>(\$0.82)</b>	<b>(\$0.56)</b>	<b>(\$0.24)</b>	<b>(\$0.17)</b>	<b>(\$0.17)</b>	<b>(\$0.03)</b>	<b>(\$0.78)</b>	<b>(\$0.22)</b>	<b>(\$0.31)</b>	<b>(\$0.15)</b>	<b>(\$0.23)</b>	<b>(\$0.15)</b>	<b>(\$0.75)</b>
<i>YOY Growth</i>	-	-	-					-						-
Basic Shares Outstanding	14.9	17.5	20.5	23.7	27.0	29.9	30.3	28.5	36.7	37.1	37.0	37.4	37.7	37.2

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.

# HISTORICAL STOCK PRICE



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