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Oramed Pharmaceuticals Inc.

(ORMP-NASDAQ)

ORMP: Multiple Potential Applications for Proprietary Oral Protein Delivery Platform

Earlier this month, Oramed entered into a pact with Hefei Tianhui Biotech to establish a 50%/50% JV based on Oramed's oral drug delivery technology focused on developing and commercializing innovative products based on Oramed's oral insulin and POD™ (Protein Oral Delivery) pipeline globally, leveraging HTIT's manufacturing capabilities and technologies.

OUTLOOK

ORMP recently completed an analysis of the data from its terminated ORA-D-013-1 Phase 3 trial. Oramed learned that subpopulations of patients with pooled specific parameters, responded well to oral insulin. The subpopulation included patients , such as body mass index (BMI), baseline HbA1c, age, gender and body weight. These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c. Following these results, ORMP is evaluating if there is a path to continue to advance its oral insulin candidate, as well as other assets in its existing pipeline. The HTIT JV is a strategic initiative to move assets forward.

Current Price (1/23/2024) \$2.29
Valuation \$4.25

SUMMARY DATA

52-Week High \$5.25
52-Week Low \$1.67
One-Year Return (%) 11
Beta 1.77
Average Daily Volume (sh) 207,906

Shares Outstanding (mil) 40
Market Capitalization (\$mil) \$93
Short Interest Ratio (days) N/A
Institutional Ownership (%) 17
Insider Ownership (%) 11

Annual Cash Dividend \$0.00
Dividend Yield (%) 0.00

5-Yr. Historical Growth Rates
Sales (%) N/A
Earnings Per Share (%) N/A
Dividend (%) N/A

P/E using TTM EPS N/A
P/E using 2023 Estimate N/A
P/E using 2024 Estimate N/A

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

ZACKS ESTIMATES

Revenue

(in millions of \$)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec)* |
|------|-------------|-------------|-------------|-------------|----------------|
| 2021 | | | | | 2.7 A |
| 2022 | 0.7 A | 0.7 A | 0.7 A | 0.7 A | 2.7 A |
| 2023 | 0.7 A | 0.7 A | 0.0 A | 0.0 E | 1.3 E |
| 2024 | | | | | 0.6 E |

Earnings per Share

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec)* |
|------|-------------|-------------|-------------|-------------|----------------|
| 2021 | | | | | -\$0.78 A |
| 2022 | -\$0.27 A | -\$0.27 A | -\$0.18 A | -\$0.36 A | -\$0.94 A |
| 2023 | -\$0.08 A | -\$0.03 A | -\$0.08 A | -\$0.23 E | -\$0.42 E |
| 2024 | | | | | -\$0.41 E |

Quarters might not sum due to round'g, share counts & FY
Disclosures page 8 **22 FY changed to Dec. 31

ORAL PROTEIN DELIVERY PLATFORM: EXPLORING CERTAIN INDICATIONS

Multiple potential applications for proprietary oral protein delivery platform...

Oramed Pharmaceuticals (NASDAQ:ORMP) continues to advance its proprietary oral protein delivery platform. Earlier this month, Oramed entered into an agreement with Hefei Tianhui Biotech to establish a joint venture (JV) based on Oramed's oral drug delivery technology focused on developing and commercializing innovative products based on Oramed's oral insulin and POD™ (Protein Oral Delivery) pipeline globally, leveraging HTIT's manufacturing capabilities and technologies.

HTIT is a high-tech company focused on biopharmaceutical product manufacturing and R&D with an emphasis on the oral delivery of therapeutic macromolecules. HTIT operates an oral insulin manufacturing facility located in Hefei, China. Oramed and HTIT will be 50%/50% JV partners and have equal representation on the JV board. HTIT and Oramed are expected to make initial investments of \$70 million and \$20 million, respectively. Oramed's contribution will consist of \$10 million in cash and \$10 million in ORMP shares. HTIT has an option to increase its investment in the JV by an incremental up to \$20 million and increase its stake and board representation. In exchange for contributing the assets under developing in its pipeline, Oramed will be entitled to a 3% royalty on gross revenues of these assets.

... include oral insulin diabetes treatment...

As we have indicated in previous reports, the Company announced on January 11, 2023, that the ORA-D-013-1 Phase 3 trial did not meet its primary and secondary endpoints and terminated this trial and a parallel Phase 3, ORA-D-013-2 clinical trial. However, Oramed recently completed an analysis of the data from its terminated ORA-D-013-1 Phase 3 trial. Oramed learned that subpopulations of patients with pooled specific parameters, responded well to oral insulin. The subpopulation included patients, such as body mass index (BMI), baseline HbA1c, age, gender and body weight. These subsets exhibited an over 1% placebo adjusted, statistically significant, reduction in HbA1c. Following these results, ORMP is evaluating if there is a path to continue to advance its oral insulin candidate, as well as other assets in its existing pipeline. The HTIT JV is a strategic initiative to move assets forward.

The Oramed / HTIT JV is expected to launch a Phase 3 oral insulin trial in the U.S. HTIT has completed a Phase 3 oral insulin clinical trial in China and, based on the results, submitted a marketing authorization application to China's regulatory body, the National Medical Products Administration. The Phase 3 trials of oral insulin in type 2 diabetes (T2D) in China were conducted under a differentiated study protocol. The company believes these steps further its ability to commercialize ORMD-0801 in China with HTIT.

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

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

... and COVID-19 oral vaccine...

In addition, Oramed is also studying potential opportunities to advance its assets for (nonalcoholic steatohepatitis (NASH), and obesity, as an appetite suppressant, and a COVID vaccine, among other possible applications. In terms of COVID vaccines, through a JV (joint venture) with India-based Premas Biotech, the company is developing an orally administered vaccine for the COVID-19 virus. Oramed is

the largest shareholder of the JV, [Oravax](#) Medical, which will leverage Oramed's proprietary POD™ oral delivery technology and Premas Biotech's novel vaccine technology. If clinical trials are successful, Oravax intends to launch and commercialize its oral COVID-19 vaccine. Public health organizations have indicated that people are likely to require a booster on a regular basis. The [CDC](#) notes that,

“Vaccination remains the best protection against COVID-19-related hospitalization and death. Vaccination also reduces your chance of suffering the effects of Long COVID, which can develop during or following acute infection and last for an extended duration....”

The virus that causes COVID-19 is always changing, and protection from COVID-19 vaccines declines over time. Receiving an updated COVID-19 vaccine can restore protection and provide enhanced protection against the variants currently responsible for most infections and hospitalizations in the United States.”

While the company had previously indicated that the oral COVID vaccine would primarily be earmarked for markets outside the U.S., depending on receiving regulatory approvals, the need for ongoing vaccinations against the disease is a global one. The [World Health Organization](#) (WHO), which expects that people will require annual booster shots similar to their annual flu shots. In fact, the National Bureau of Economic Research ([NBER](#)) notes that,

“The global COVID-19 vaccination campaign is the largest public health campaign in history, with over 2 billion people fully vaccinated within the first 8 months. Nevertheless, the impact of this campaign on all-cause mortality is not well understood. Leveraging the staggered rollout of vaccines, we find that the vaccination campaign across 141 countries averted 2.4 million excess deaths, valued at \$6.5 trillion.”

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

The oral VLP COVID-19 vaccine is being developed for use both as a standalone vaccine as well as a booster for people who have been previously vaccinated for COVID-19. With cases rising in many markets, including breakthrough cases of vaccinated individuals, healthcare professionals expect that booster shots will remain critical in controlling the disease.

The company had about \$175 million in cash and equivalents and short-term investments at the end of September 2023 to advance its development efforts and initiatives. Oramed also entered into a roughly \$102 million short-term senior secured note transaction with Scilex Holding Company. The notes bear interest at a rate of SOFR plus 8.5% (subject to a SOFR floor of 4.0%) per annum and have an 18-month maturity, with repayments set to begin in installments on December 21, 2023. Oramed also received warrants to purchase up to 17 million Scilex shares. Scilex is a biopharma company focused on acquiring, developing, and commercializing non-opioid management products to treat acute and chronic pain.

VALUATION

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

While it is difficult to know the revenue arc for ORMD-0801 at this early stage, given the growing incidence of diabetes worldwide, we believe it is not unreasonable to expect that ORMD-0801 could reach revenue of about \$250 million to \$300 million by the 2028-30 timeframe, depending on clinical trial results and commercialization milestones. We apply a 2x P/sales multiple, which is the low end of the range for other clinical companies at similar stages of development. We also maintain our estimate of peak U.S. sales of ORMD-0901 of approximately \$500 million. Using a 12% discount rate and 45% and 70% respective confidence rates for ORMD-0901 and ORMD-0801 forecasts leads to a blended net present value (NPV) of roughly \$4.25 per share.

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

RISKS

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

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

RECENT NEWS

- On January 22, 2024, Oramed entered into a JV with Hefei Tianhui Biotech based on Oramed's oral drug delivery technology.
- Oramed announced a roughly \$102 million short-term senior secured note transaction with Scilex Holding Company on September 21, 2023.
- On August 2, 2023, Oramed signed a term sheet with HTIT to form a JV to advance the oral drug delivery technology globally.
- On May 15, 2023, the company announced that HTIT has successfully completed a Phase 3 oral insulin clinical trial and submitted a marketing authorization application in China.
- Oramed named Ben Shapiro to its board on May 1, 2023. He holds a 4% stake in the company.
- ORMP reported disappointing results of the T2D study on January 12, 2023.
- ORMP reported positive safety and efficacy NASH metrics on November 17, 2022.
- Oramed was granted a European patent for NASH on April 5, 2022.

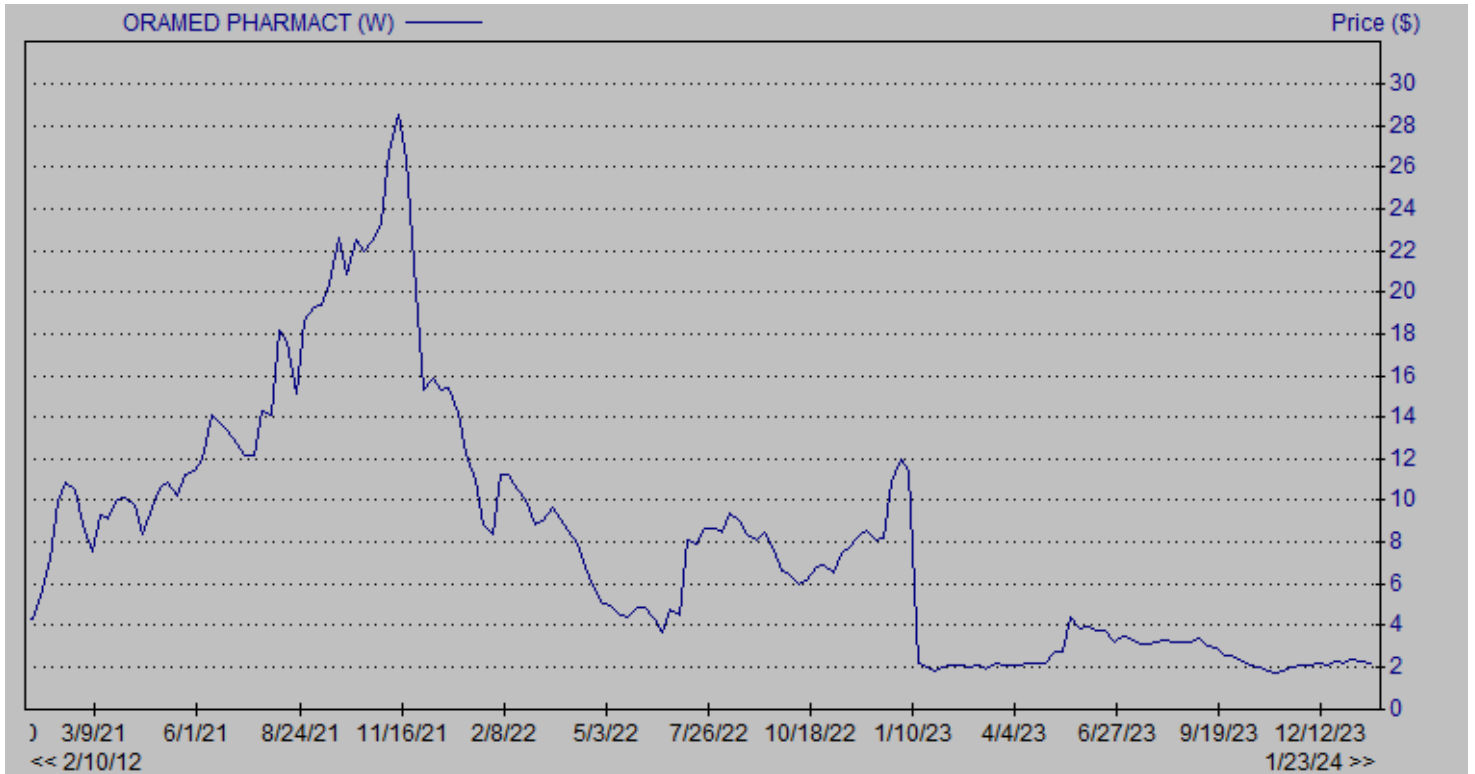
PROJECTED FINANCIALS

| Oramed Pharmaceuticals Inc. (Fiscal Year ends Dec. 31*) \$Mns | FY 2020 | FY 2021 A | Q1 A | Q2 A | Q3 A | Q4 A | FY 2022 A | Q1 A | Q2 A | Q3 A | Q4 E | 2023 E | 2024 E |
|--|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| License Revenue | \$2.7 | \$2.7 | \$0.7 | \$0.7 | \$0.7 | \$0.7 | \$2.7 | \$0.7 | \$0.7 | \$0.0 | \$0.0 | \$1.3 | \$0.6 |
| <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 | \$2.7 | \$2.7 | \$0.7 | \$0.7 | \$0.7 | \$0.7 | \$2.7 | \$0.7 | \$0.7 | \$0.0 | \$0.0 | \$1.3 | \$0.6 |
| <i>YOY Growth</i> | 1% | -1% | -1% | 0% | 0% | 0% | 0% | 0% | 0% | -100% | -100% | -50% | -53% |
| Cost of Revenue | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 |
| Gross Income | \$2.7 | \$2.7 | \$0.7 | \$0.7 | \$0.7 | \$0.7 | \$2.7 | \$0.7 | \$0.7 | \$0.0 | \$0.0 | \$1.3 | \$0.6 |
| <i>Gross Margin</i> | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | NM | #DIV/0! | 100.0% | 100.0% |
| Research & Development | \$10.2 | \$21.0 | \$5.8 | \$9.2 | \$5.3 | \$7.3 | \$27.6 | \$4.4 | \$1.8 | \$1.0 | \$1.0 | \$8.2 | \$19.1 |
| General & Administrative | \$4.2 | \$5.9 | \$5.5 | \$2.5 | \$3.1 | \$2.7 | \$13.8 | \$1.3 | \$2.5 | \$2.6 | \$2.6 | \$8.9 | \$5.1 |
| Other Expenses | \$0.0 | \$0.0 | \$0.6 | \$0.4 | \$0.5 | \$0.4 | \$1.9 | \$0.2 | \$0.2 | \$0.7 | \$0.4 | \$0.1 | \$1.0 |
| Operating Income / (loss) | (\$11.7) | (\$24.2) | (\$11.3) | (\$11.4) | (\$8.2) | (\$9.7) | (\$40.6) | (\$5.2) | (\$3.8) | (\$2.9) | (\$4.0) | (\$15.9) | (\$24.6) |
| <i>Operating Margin</i> | - | - | | | | | - | | | | | - | - |
| Other Income (Net) | \$0.2 | \$1.2 | \$0.5 | \$0.4 | \$1.0 | \$4.9 | \$2.9 | \$1.6 | \$2.5 | \$0.4 | \$0.4 | \$4.1 | \$6.6 |
| Pre-Tax Income | (\$11.5) | (\$23.0) | (\$10.7) | (\$11.1) | (\$7.2) | (\$14.6) | (\$37.7) | (\$3.6) | (\$1.3) | (\$3.3) | (\$3.6) | (\$11.8) | (\$18.0) |
| Net Taxes (benefit) | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.1 | \$0.0 | \$0.1 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 |
| <i>Tax Rate</i> | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | -0.3% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Minority interest / other | | \$0.8 | \$0.3 | \$0.5 | \$0.2 | \$0.4 | \$1.2 | \$0.2 | \$0.1 | \$0.1 | \$0.2 | \$0.6 | \$1.0 |
| Reported Net Income | (\$11.5) | (\$22.2) | (\$10.4) | (\$10.5) | (\$7.1) | (\$14.2) | (\$36.6) | (\$3.4) | (\$1.2) | (\$3.2) | (\$9.2) | (\$17.0) | (\$17.0) |
| <i>Net Margin</i> | - | - | | | | | - | | | | | - | - |
| Reported EPS | (\$0.56) | (\$0.78) | (\$0.27) | (\$0.27) | (\$0.18) | (\$0.36) | (\$0.94) | (\$0.08) | (\$0.03) | (\$0.08) | (\$0.23) | (\$0.42) | (\$0.41) |
| <i>YOY Growth</i> | - | - | | | | | - | | | | | - | - |
| Basic Shares Outstanding | 20.5 | 28.5 | 38.7 | 38.8 | 39.1 | 39.5 | 39.0 | 40.0 | 40.2 | 40.4 | 40.6 | 40.3 | 41.5 |

Source: Zacks Investment Research, Inc.

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

HISTORICAL STOCK PRICE



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