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Oramed Pharmaceuticals Inc.

(ORMP-NASDAQ)

ORMP: Moving Oral Delivery Platform Forward, + Potential to Generate Royalties

Oramed believes it has the financial flexibility and balance sheet to continue development activities around its oral insulin program and other opportunities. The company also has access to capital for development efforts, reflecting, among other factors, an agreement under which ORMP is slated to receive quarterly loan repayments that are expected to bolster its balance sheet.

OUTLOOK

Having completed an analysis of data from its terminated ORA-D-013-1 Phase 3 trial, Oramed is optimistic about prospects for ORMD-0801, particularly for certain subpopulations of patients with specific parameters that match those of study participants who responded well to oral insulin. ORMP has initiated discussions with the FDA and plans to launch a Phase 3 oral insulin trial in the U.S. under a differentiated protocol aligned with the positive data. Separately, a recent licensing agreement with Genomma Lab could provide attractive royalty revenue, if Genomma can commercialize an OTC hemorrhoids treatment & other products for which ORMP had acquired the rights.

Current Price (5/28/2024) \$2.20
Valuation \$3.25

SUMMARY DATA

52-Week High \$4.36
52-Week Low \$1.67
One-Year Return (%) -46
Beta 1.86
Average Daily Volume (sh) 111,891

Shares Outstanding (mil) 41
Market Capitalization (\$mil) \$89
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 2024 Estimate N/A
P/E using 2025 Estimate N/A

Risk Level High
Type of Stock Small-Blend
Industry Med Tech

ZACKS ESTIMATES

Revenue

(in millions of \$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)*
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 A	1.3 A
2024	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2025					0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)*
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	\$0.33 A	\$0.14 A
2024	\$0.04 A	\$0.04 E	\$0.04 E	-\$0.03 E	\$0.08 E
2025					-\$0.30 E

Quarters might not sum due to round'g, share counts & FY chg
Disclosures page 9 *'22 FY changed to Dec. 31

LEVERAGING ORAL PROTEIN DELIVERY PLATFORM

Solid cash & equivalents position...

Earlier this month, Oramed Pharmaceuticals' (NASDAQ:ORMP) CFO David Silberman announced his intention to resign from the company effective July 12, 2024, citing personal reasons. Oramed has launched a search for a new CFO and notes that it believes it has the financial flexibility and balance sheet to continue development activities of its oral insulin program and other opportunities. The company also has access to capital for development efforts, reflecting, among other factors, an agreement with Scilex Holding Company, under which ORMP is slated to receive quarterly loan repayments that are expected to bolster its balance sheet.

Oramed 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.

Specifically, in September 2023, Oramed entered into a securities purchase agreement with Scilex under which among other measures, Scilex issued ORMP a roughly \$102 million promissory note collateralized by most of its assets, plus penny warrants to purchase Scilex shares. The note matures on March 21, 2025 and repayment of principal began on December 21, 2023. In 4Q23 and 1Q24, Scilex paid about \$5 million and \$15 million, respectively, per the terms of the agreement. At the end of 1Q24, Oramed had about \$177 million in cash and equivalents to advance its development efforts and other initiatives, including investments, up from about \$162 million at year-end 2023 and about \$175 million at the end of September 2023. The Scilex payment schedule is shown below. Scilex prepaid \$9.6 million towards a \$20 million payment due June 21, 2024, leaving a balance of about \$10.4 million due on that date.

Scilex Scheduled Principal Payments

	Payment schedule (\$mns)	Payments made (\$mns)
12/21/2023	\$5	\$5
3/21/2024	\$15	\$15
6/21/2024	\$20	\$9.6
9/21/2024	\$20	
12/21/2024	\$20	
3/21/2025	bal	

Blue highlight indicates prepayment

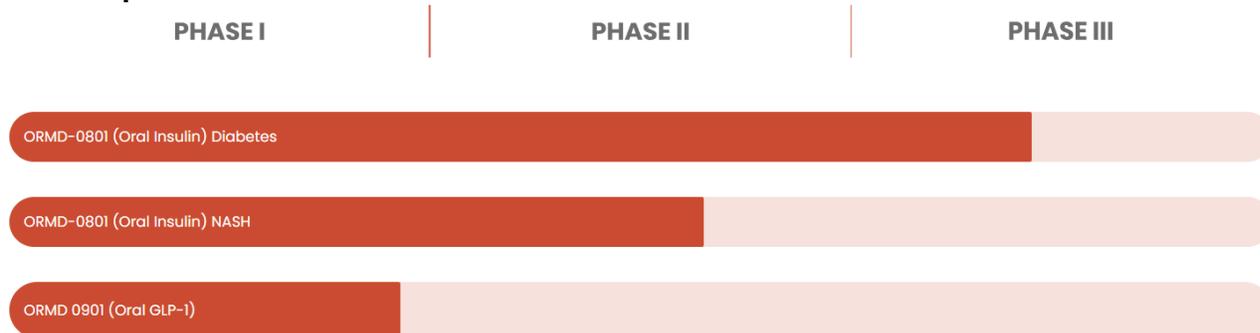
Source: [Company reports](#)

... As company continues development initiatives ...

The company also recently provided a business update, indicating important advances on a number of fronts. The company has assets in its portfolio in various stages of development. In addition to the payments noted above for R&D, via a joint venture (JV), JV partner HTIT (Hefei Tianhui Biotechnology) has committed a \$70 million investment to advance R&D activities (see below).

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 Pipeline



Source: [Company reports](#)

ORMP completed an analysis of data from a terminated U.S.-based Phase 3 trial of ORMD 0801 and learned that subpopulations of patients with pooled specific parameters responded well to oral insulin. The subpopulation included patients with specific parameters 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. As a result of this analysis, ORMP evaluated potential ways to advance its oral insulin candidate, as well as other assets in its existing pipeline. The company has initiated discussions with the FDA and plans to launch a Phase 3 oral insulin trial in the U.S. under a differentiated protocol aligned with this positive data and believes the trial could commence in 2024.

ORMP entered into a JV with HTIT as a strategic initiative to move assets forward. HTIT completed Phase 3 trials of oral insulin for type 2 diabetes 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 views these steps as positive for its ability to commercialize ORMD-0801 with HTIT.

Moreover, Oramed 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.”

The Oramed-HTIT JV is designed to focus on the development, marketing, and global commercialization of products leveraging Oramed's oral insulin and POD™ (Protein Oral Delivery) pipeline and HTIT's manufacturing capabilities and technologies. The company is also discussing other strategies with HTIT to leverage their combined capabilities and technologies and maximize prospects of the expected launch of oral insulin sales in China.

Potential opportunity to generate royalty revenues; recent PeriTech Pharma agreement

Separately, in December 2023, Oramed formed an agreement with PeriTech Pharma to acquire the rights to PeriTech's film-forming technology for the delivery of topical/dermatology agents, including a once-daily over-the-counter (OTC) treatment for hemorrhoids. We believe PeriTech had ceased operations prior to the agreement, suggesting that the economics for Oramed were attractive if any of the products in the PeriTech pipeline are commercialized.

PeriTech's pipeline includes, in addition to the OTC hemorrhoid treatment noted above, potential applications for indications such as pruritus ani, anal warts, anal fissures and herpes labialis. Oramed also has entered into an exclusive licensing agreement with an international consumer product and pharmaceutical group, Genomma Lab Internacional and granted Genomma Labs development and commercialization rights to the PeriTech pipeline in exchange for a royalty based on net sales if any of the assets are commercialized. Genomma Lab is a pharmaceutical company based in Mexico that also markets a broad variety of personal care products.

Over-the-counter products, including anti-hemorrhoids and pain relief products, made up 51% of Genomma total sales as of March 2024, according to its corporate presentation. Oramed had earlier entered into a 50/50 joint venture with Genomma when the Covid pandemic was raging to commercialize an oral COVID-19 vaccine candidate in Mexico and potentially other markets in South America.

Genomma: Select OTC Products



Source: [Genomma Lab presentation](#)

NASH studies...

In addition, Oramed is also studying potential opportunities to advance its assets for nonalcoholic steatohepatitis (NASH), and obesity, as an appetite suppressant. Earlier, a 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, showing a reduction of liver fat content in early clinical studies.

VALUATION

It would not surprise us if potential uncertainty around ORMP's development efforts continued to overhang ORMP shares in the near- to medium-term, as it has since the company terminated Phase 3 concurrent U.S. studies. Nevertheless, we believe the sizable population with or at risk for diabetes globally and analysis of data from the terminated concurrent ORMD-0801 trials support the company moving forward to potentially attain regulatory approval for lead asset ORMD-0801 and ORMD-0901 and commercializing these product in multiple markets.

It is difficult to know the revenue arc for ORMD-0801 at this early stage, but 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 use an 11% discount rate and 75% confidence rate. The latter reflects uncertainty that ORMD-0801 reaches this revenue in this timeframe. Given the expected economics of the HTIT JV, our NPV for ORMP shares is roughly \$3.25. Potential development and/or economics milestones could cause us to change our confidence metric or other valuation factors.

Prospects for the Genomma agreement 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.
- Scilex might not meet its loan repayment obligations.
- 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.
- Genomma might not be able to commercialize any PeriTech assets successfully.

RECENT NEWS

- On May 10, 2024, ORMP announced that its CFO would resign effective July 2024.
- On May 9, 2024, ORMP reported 1Q FY25 results.
- Scilex announced its repayment in full of the balance of convertible debentures and Early payment of the senior secured promissory note on March 19, 2024.
- Oramed issued a letter to shareholders on February 20, 2024.
- 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.

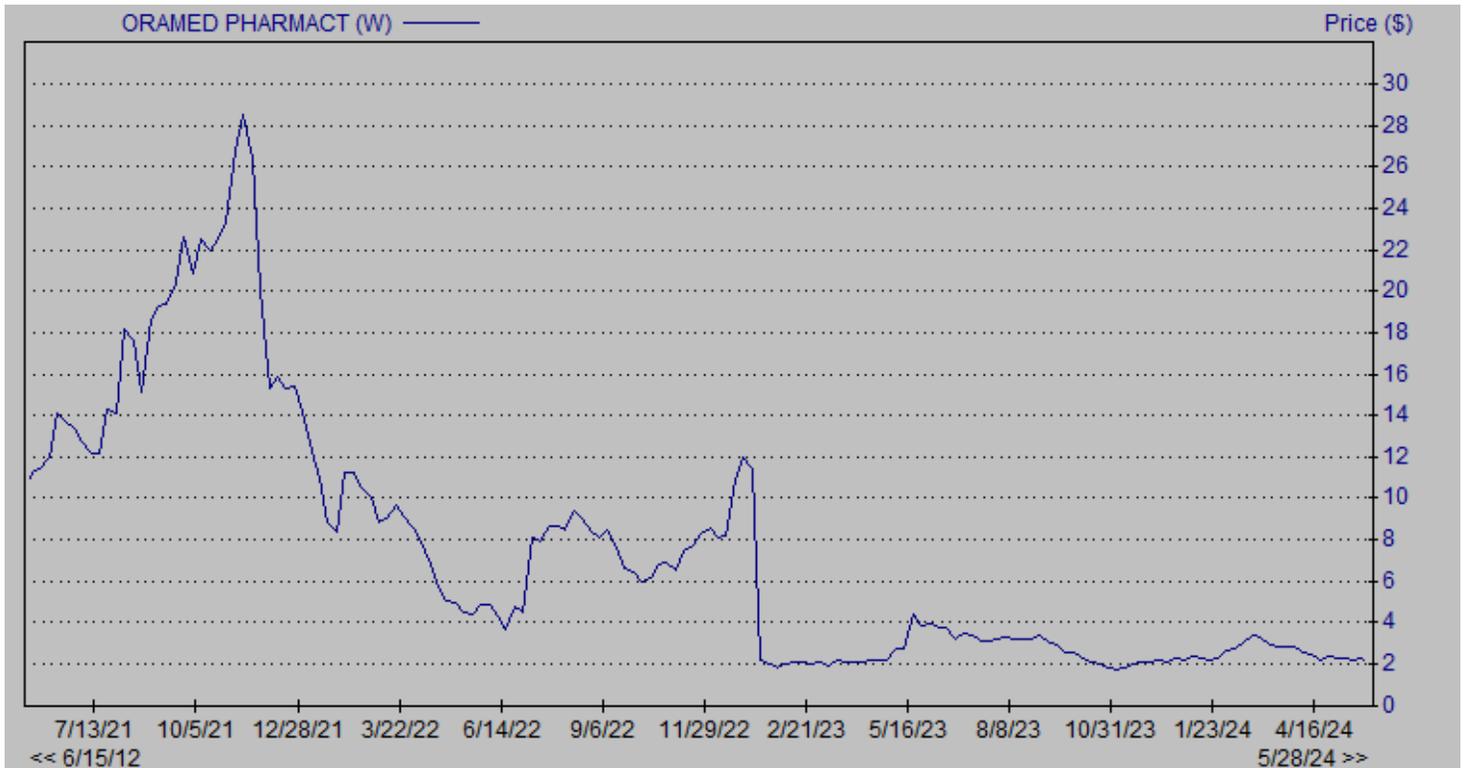
PROJECTED FINANCIALS

Oramed Pharmaceuticals Inc. (Fiscal Year ends Dec. 31*) \$Mns	FY 2020	FY 2021 A	FY 2022 A	Q1 A	Q2 A	Q3 A	Q4 A	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E
License Revenue	\$2.7	\$2.7	\$2.7	\$0.7	\$0.7	\$0.0	\$0.0	\$1.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<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	\$2.7	\$0.7	\$0.7	\$0.0	\$0.0	\$1.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>YOY Growth</i>	1%	-1%	0%	0%	0%	-100%	-100%	-50%					NM
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	\$2.7	\$0.7	\$0.7	\$0.0	\$0.0	\$1.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Gross Margin</i>	100.0%	100.0%	100.0%	100.0%	100.0%	NM	NM	NM	NM	NM	NM	NM	NM
Research & Development	\$10.2	\$21.0	\$27.6	\$4.4	\$1.8	\$1.0	\$1.8	\$9.0	\$1.2	\$1.2	\$1.2	\$3.5	\$7.1
General & Administrative	\$4.2	\$5.9	\$13.8	\$1.3	\$2.5	\$2.6	\$2.1	\$8.4	\$1.8	\$1.8	\$1.8	\$2.0	\$7.4
Other Expenses	\$0.0	\$0.0	\$1.9	\$0.2	\$0.2	\$0.7	\$0.0	\$0.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income / (loss)	(\$11.7)	(\$24.2)	(\$40.6)	(\$5.2)	(\$3.8)	(\$2.9)	(\$3.9)	(\$15.8)	(\$3.0)	(\$3.0)	(\$3.0)	(\$5.6)	(\$14.5)
<i>Operating Margin</i>	-	-	-										-
Other Income (Net)	\$0.2	\$1.2	\$2.9	\$1.6	\$2.5	\$0.4	\$17.2	\$20.9	\$4.5	\$4.5	\$4.5	\$4.5	\$18.0
Pre-Tax Income	(\$11.5)	(\$23.0)	(\$37.7)	(\$3.6)	(\$1.3)	(\$3.3)	\$13.3	\$5.1	\$1.5	\$1.5	\$1.5	(\$1.1)	\$3.5
Net Taxes (benefit)	\$0.0	\$0.0	\$0.1	\$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%	-0.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Minority interest / other		\$0.8	\$1.2	\$0.2	\$0.1	\$0.1	\$0.0	\$0.4	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Reported Net Income	(\$11.5)	(\$22.2)	(\$36.6)	(\$3.4)	(\$1.2)	(\$3.2)	\$13.3	\$5.5	\$1.5	\$1.5	\$1.5	(\$1.1)	\$3.5
<i>Net Margin</i>	-	-	-										-
Reported EPS	(\$0.56)	(\$0.78)	(\$0.94)	(\$0.08)	(\$0.03)	(\$0.08)	\$0.33	\$0.14	\$0.04	\$0.04	\$0.04	(\$0.03)	\$0.08
<i>YOY Growth</i>	-	-	-										-
Basic Shares Outstanding	20.5	28.5	39.0	40.0	40.2	40.4	40.6	40.6	41.6	41.6	41.6	41.6	41.6

Source: Zacks Investment Research, Inc.

*ORMP's fiscal year changed from ending on August 31 to ending on December 31. 2024E primarily noncash below the operating line income relates to Scilex, other financial agreements.

HISTORICAL STOCK PRICE



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