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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Preparations for New Phase 3 Trial Advance, While ORMP Leverages Balance Sheet Through Recent Agreements

ORMP has pivoted its clinical R&D focus to prioritize studying ORMD-0801 for subpopulations of patients with pooled specific parameters who responded well to oral insulin in its prior trial. ORMP intends to launch a Phase 3 oral insulin trial in the U.S. under a differentiated protocol that is aligned with the positive subpopulation data and informed by feedback from discussions with the FDA.

OUTLOOK

ORMP is leveraging its strong balance sheet – ~$142m in cash, equivalents, ST investments & deposits, no LT debt – to optimize its cash position. The company is augmenting its cash position with repayments / interest from collateralized loans issued to Scilex & to a domestic real estate project. Management expects its resources are sufficient to maintain planned activities for roughly at least the next year as clinical activities pick-up and as it maintains strategic share repurchases under its 2024 share buyback plan.

Current Price (11/29/2024)	$2.37
Valuation	**$3.25**

SUMMARY DATA

52-Week High	**$3.67**
52-Week Low	**$2.00**
One-Year Return (%)	**11**
Beta	**1.77**
Average Daily Volume (sh)	**98,352**
Shares Outstanding (mil)	**40**
Market Capitalization ($mil)	**$96**
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 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (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 A	0.0 A	0.0 E	0.0 E
2025					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (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	$0.22 A	-$0.48 A	$0.02 E	-$0.24 E
2025					-$0.12 E

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

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PREPARATIONS FOR NEW PHASE 3 TRIAL ADVANCE

Planning Phase 3 Oral Insulin study under revised protocol while leveraging balance sheet to optimize cash

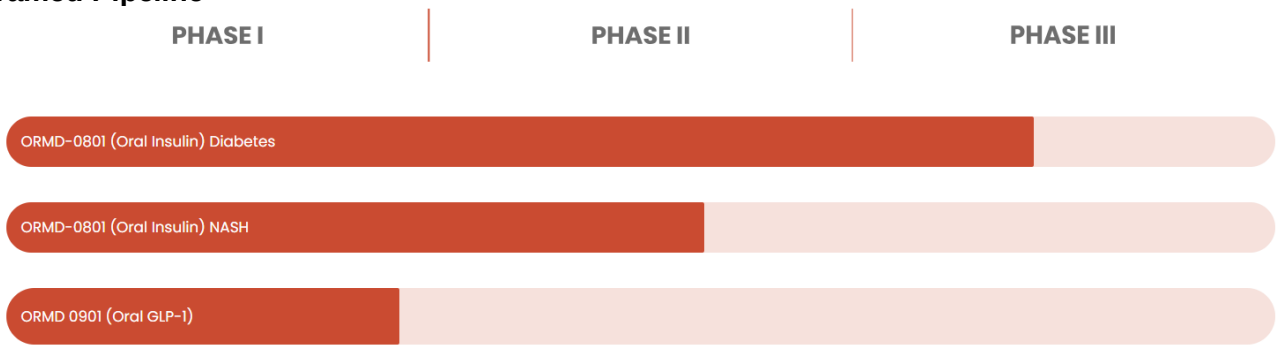
Oramed Pharmaceuticals (NASDAQ:ORMP) has pivoted its clinical R&D focus to prioritize studying ORMD 0801 for subpopulations of patients with pooled specific parameters who responded well to oral insulin in its prior trial. The subpopulation included patients with specific parameters such as body mass 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, in conjunction with JV partner HTIT, ORMP intends to launch a Phase 3 oral insulin trial in the U.S. under a differentiated protocol that is aligned with the positive subpopulation data and informed by feedback from discussions with the FDA. ORMP entered into a JV with Hefei Tianhui Biotech Co., Ltd. (HTIT) as a strategic initiative to move assets forward. HTIT is a high-tech company focused on biopharmaceutical product manufacturing and R&D with an emphasis on the oral delivery of therapeutic macromolecules. It operates an oral insulin manufacturing facility located in Hefei, China. The ORMP-HTIT JV will focus on developing, marketing, and commercializing innovative products from Oramed's oral insulin and POD™ (Protein Oral Delivery) pipeline leveraging HTIT's manufacturing technologies. Their JV will focus on developing and commercializing innovative products worldwide based on their combined assets and capabilities worldwide.

ORMP entered into a services agreement with a CRO (Clinical Research Organization) on September 23, 2024, for services including strategic planning, expert consultation, data processing, regulatory, clerical and project management, among other R&D related services for the Phase 3 clinical trial.

The protocol for the planned new Phase 3 study would represent a fine-tuned approach strategically focused on the specific patient subgroups identified as significant responders following the company's analysis of prior Phase 2 and Phase 3 data. ORMP hopes to leverage its analysis in order to optimize the potential for successful outcomes of a new Phase 3 trial to advance its oral insulin therapy in diabetes management.

Oramed Pipeline



Source: Company reports

ORMD–0801 potential treatment for NASH, as well as diabetes…

Moreover, ORMP's R&D activities include potentially developing an orally ingestible capsules for delivery of other polypeptides, as well as an orally ingestible insulin capsule for the treatment of diabetes. ORMP has evaluated potential opportunities to advance ORMD–0801 for nonalcoholic steatohepatitis (NASH), and obesity as an appetite suppressant in earlier studies. 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.

LEVERAGING STRONG BALANCE SHEET

Cash position strengthened by various agreements, including with Scilex…

ORMP has a strong balance sheet that it is leveraging to optimize its cash position. The company had $42.1 million in cash and equivalents at the end of 3Q24, short-term deposits of $42.7 million, Investments of $57.5 million and no long term debt. Based on its commitments and cash and equivalents, management expects its resources will be sufficient to maintain planned activities for at least roughly the next year.

At the same time, ORMP is also leveraging its balance sheet to optimize its cash position, augmenting its cash position with debt repayments from Scilex Holding Company following a September 2023 agreement and repayment schedule. Scilex is a biopharma company focused on acquiring, developing, and commercializing non-opioid management products to treat acute and chronic pain. In September 2023, Oramed entered into a securities purchase agreement with Scilex under which Scilex issued ORMP a roughly $102 million promissory note (the Tranche A Note) collateralized by most of its assets, plus penny warrants to purchase Scilex shares. The notes bear interest at a rate of SOFR plus 8.5% (subject to a SOFR floor of 4.0%) per annum. Repayment of principal began on December 21, 2023.

On October 24, 2024, Oramed received a repayment of about $1.0 million on the Tranche A note. As of September 30, 2024, Scilex had repaid $41.7 million due under the Tranche A note out of the total $102 million principal, which excludes interest and exit fees. Earlier, on October 7, 2024, ORMP entered into an agreement to refinance a portion of the Tranche A Note; Scilex issued ORMP a new tranche B of senior secured convertible notes and warrants to purchase Scilex shares. ORMP exchanged and reduced $2.5 million of the principal balance under the Tranche A note, implying that an aggregate $80.2 million of the original principal under the Tranche A note has been repaid or refinanced.

Moreover, on September 4, 2024, Oramed entered into a loan agreement with Rabi Binyamin 4 Tama 38 Ltd. to finance a real estate project that is essentially collateralized by the project. Originally TAMA 38 was designed to offer real estate developers incentives to accelerate construction of approved projects. ORMP agreed to loan US$1.5 million to the project subject to certain milestones being reached in 1H 2025. Upon completion of the real estate project, ORMP is entitled to receive repayment of principal and the greater of either 20% annual interest on the principal loaned or 40% of the profits from the real estate project.

Company purchased shares in 3Q24 under buyback, cash runway ~a year or more

In 2Q24, Oramed announced that its board has authorized a stock buyback program of up to $20 million of ORMP shares. The company has indicated that it might repurchase shares at times, depending on market conditions. Through the end of 3Q24, Oramed had repurchased and retired 539,452 ORMP shares for roughly $1.3 million (at an average price of $2.401 per share). Given the cash balance noted above, we expect the company has sufficient capital to maintain share repurchases and continue to advance its strategy.

OTHER RECENT INITIATIVES AIMED AT DRIVING REVENUE

Potential opportunity to generate royalty revenues; recent PeriTech Pharma agreement

Genomma: Select OTC Products



Source: Genomma Lab presentation

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*, which we believe has not occurred to-date. We view this as a long-term potential opportunity.

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.

Separately, the company is currently evaluating a potential path forward subsidiary Oravax's oral vaccines for COVID-19. The backdrop of COVID-19 has changed considerably since Oramed initially entered into a JV (ORMP holds a 63% stake in Oravax) to develop an oral vaccine for COVID in 2021.

RECENT RESULTS

Following the termination of its ORA-D-013-1 and ORA-D-013-2 Phase 3 trials last year, ORMP incurred lower R&D and sales and marketing expenses through 1H 2024, as it conducted a strategic review and temporarily halted clinical trials. However, in 3Q24, R&D activities related to preparation for the company's planned new Phase 3 clinical trial increased. As a result, R&D expenses more than doubled (up 134% year-over-year) to $2.2 million in 3Q24 compared to 3Q23.

General and administrative (G&A) expenses were impacted by a reversal of previously recognized expenses following a change in the management team. As noted in a prior report, David Silberman announced his intention to resign as CFO effective July 12, 2024 citing personal reasons. He was replaced by former ORMP CFO Avraham Gabay, who served as ORMP's CFO from 2019 until 2021 and as CFO at Oravax Inc., a 63% owned subsidiary of Oramed, from 2021 until 2023.

In 3Q24, the company recorded a financial loss of $15.4 million, primarily reflecting the revaluation of its investments in Scilex. Tax expenses were $1.1 million in 3Q24 and were primarily attributable to anticipated gains from the company's agreement with Scilex. Reflecting the anticipated gains, Oramed expects to fully utilize its NOLs and incur tax expenses.

ORMP reported a 3Q24 net loss of $19.6 million, or ($0.48) per share, compared to a net loss of $3.2 million or ($0.08) per share in last year's 3Q. We estimate that on a pro forma basis excluding the above-noted Scilex revaluation and taxes related to the anticipated gain on the Scilex transactions, the company would have recorded 3Q24 EPS of roughly $0.02 to $0.04.

VALUATION

In the near- to medium-term, it would not surprise us if potential uncertainty around ORMP's development efforts continued to overhang ORMP shares, 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 perhaps ORMD-0901 down the road) and commercializing it in the U.S. and potentially other 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.

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.
- The Rabi Binyamin 4 Tama 38 Ltd. project might not generate sufficient returns to cover ORMP's principal / interest repayment or a percent of project profits.
- 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 November 7, 2024, ORMP reported 3Q results.
- On October 7, 2024, the company refinanced $25.0 million of the Scilex Tranche A note.
- Oramed received aggregate payments of about $1,400 on the Scilex Tranche A note on October 24, 2024 and November 5, 2024.
- Oramed entered into a Clinical Research Organization Services agreement on September 23, 2024.
- On September 20, 2024, the company entered into an extension agreement with Scilex on the Tranche A note.
- On September 4, 2024, ORMP entered into a loan agreement with Rabi Binyamin 4 Tama 38 Ltd.
- Oramed announced its share buyback plan on June 26, 2024.
- Oramed announced its new CFO on June 6, 2024.
- On January 22, 2024, Oramed entered into a JV with Hefei Tianhui Biotech based on Oramed's oral drug delivery technology.

PROJECTED FINANCIALS

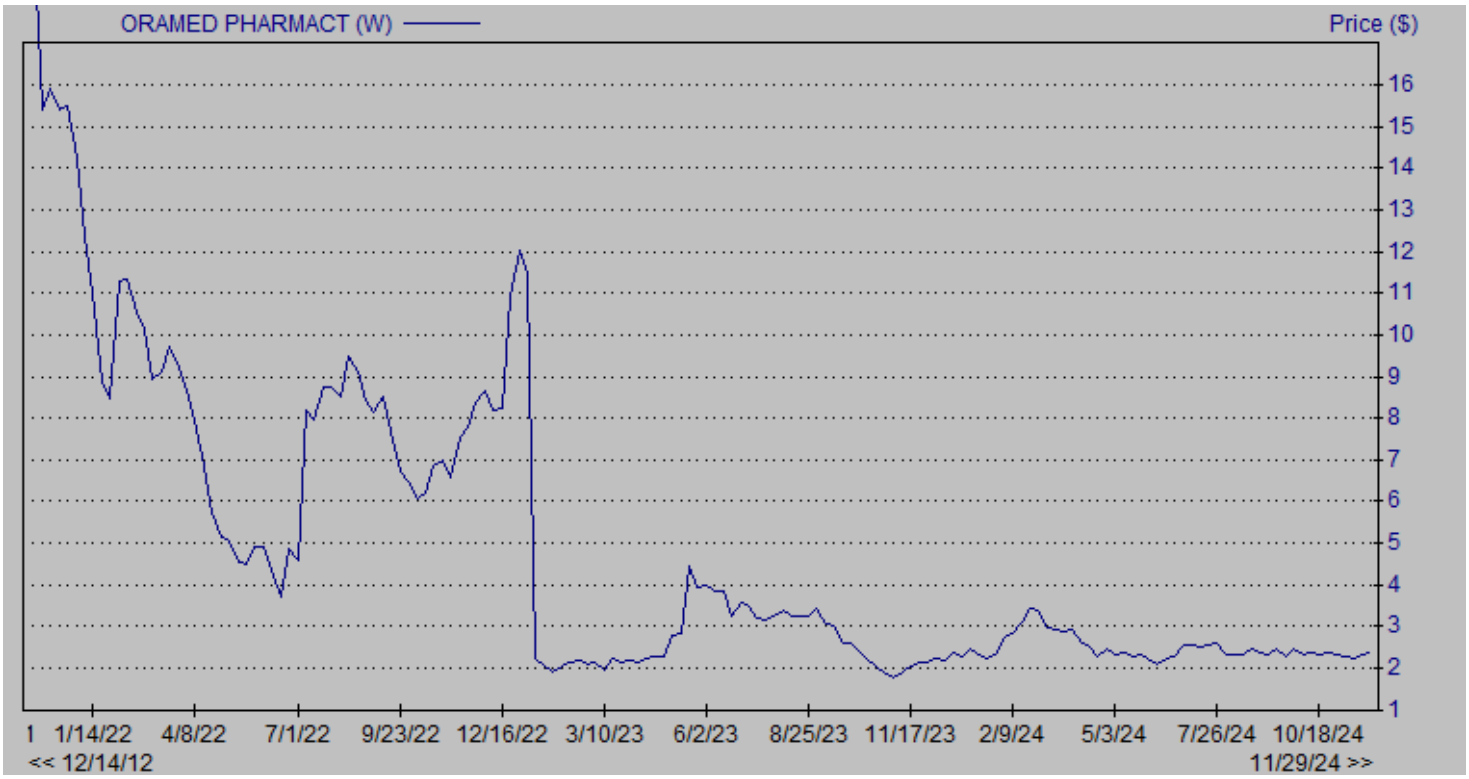
Oramed Pharmaceuticals Inc. (Fiscal Year ends Dec. 31*) $Mns	Q1 A	Q2 A	Q3 A	Q4 A	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E
License Revenue	$0.7	$0.7	$0.0	$0.0	$1.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth											
Grant/Contract Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth					-					-	-
ORMD-0801	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth					-					-	-
ORMD-0901	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth					-					-	-
Total Revenues	**$0.7**	**$0.7**	**$0.0**	**$0.0**	**$1.3**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	*0%*	*0%*	*-100%*	*-100%*	*-50%*					*NM*	*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
Gross Income	**$0.7**	**$0.7**	**$0.0**	**$0.0**	**$1.3**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Gross Margin	*100.0%*	*100.0%*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
Research & Development	$4.4	$1.8	$1.0	$1.8	$9.0	$1.2	$1.4	$2.2	$2.4	$7.2	$9.7
General & Administrative	$1.3	$2.5	$2.6	$2.1	$8.4	$1.8	$1.7	$0.8	$1.7	$6.0	$7.1
Other Expenses	$0.2	$0.2	$0.7	$0.0	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income / (loss)	**($5.2)**	**($3.8)**	**($2.9)**	**($3.9)**	**($15.8)**	**($3.0)**	**($3.1)**	**($3.1)**	**($4.1)**	**($13.2)**	**($16.8)**
Operating Margin					-					-	-
Other Income (Net)	$1.6	$2.5	$0.4	$17.2	$20.9	$4.5	$14.0	**($15.4)**	$4.0	$7.0	$12.0
Pre-Tax Income	**($3.6)**	**($1.3)**	**($3.3)**	**$13.3**	**$5.1**	**$1.5**	**$10.8**	**($18.5)**	**($0.1)**	**($6.2)**	**($4.8)**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.6	$1.1	$0.8	$3.6	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.1%*	*-6.1%*	*nm*	*-57.6%*	*0.0%*
Minority interest / other	$0.2	$0.1	$0.1	$0.0	$0.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1
Reported Net Income	**($3.4)**	**($1.2)**	**($3.2)**	**$13.3**	**$5.5**	**$1.5**	**$9.2**	**($19.6)**	**($0.9)**	**($9.7)**	**($4.7)**
Net Margin					-					-	-
Reported EPS	**($0.08)**	**($0.03)**	**($0.08)**	**$0.33**	**$0.14**	**$0.04**	**$0.22**	**($0.48)**	**($0.02)**	**($0.24)**	**($0.12)**
YOY Growth					-					-	-
Basic Shares Outstanding	40.0	40.2	40.4	40.6	40.6	41.6	41.6	40.9	40.3	41.1	40.1

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.

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