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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Upcoming Expected Milestones Include OraTech Spin-Off & IPO, Launch of Phase 3 Trial

ORMP intends to spin-off and IPO its JV with HTIT, OraTech, targeting a listing on Nasdaq. ORMP plans to distribute the majority of its OraTech holdings to ORMP shareholders via a dividend & potentially also pay a cash dividend of $0.25. OraTech will focus on developing and commercializing innovative products globally based on ORMP & HTIT's combined assets and capabilities.

Current Price (4/2/2025)	$2.20
Valuation	**$3.25**

OUTLOOK

OraTech will leverage HTIT's manufacturing capabilities and focus on developing and commercializing innovative products globally based on ORMP's technology & pipeline. 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 in China. Separately, with ORMP's strong balance sheet – ~$142m in cash, equivalents, ST investments & deposits at YE24 – capital allocations include share buybacks, a potential cash dividend and strategic investments in early stage companies designed to boost total returns to shareholders.

SUMMARY DATA

52-Week High	**$3.09**
52-Week Low	**$1.96**
One-Year Return (%)	**11**
Beta	**1.49**
Average Daily Volume (sh)	**252,431**
Shares Outstanding (mil)	**41**
Market Capitalization ($mil)	**$90**
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 2025 Estimate	**N/A**
P/E using 2026 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 A	0.0 A
2025	0.0 E	0.0 E	0.0 E	0.0 E	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	-$0.25 A	-$0.48 A
2025	-$0.01 E	-$0.01 E	-$0.01 E	-$0.03 E	-$0.07 E

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

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UPCOMING EXPECTED MILESTONES INCLUDE PLANNED IPO, PHASE 3 TRIAL

Planning Spin-off / IPO of JV Company

Oramed Pharmaceuticals (NASDAQ:ORMP) reported 4Q24/2024 results last week. The company's JV with Hefei Tianhui Biotech (HTIT), OraTech Pharmaceuticals, is a strategic initiative to move its assets forward. The JV partners recently made some amendments to their JV agreement to facilitate, among other goals, the planned spin-off and IPO of OraTech following the expected investments of $40.0 million and $7.5 million by HTIT and Oramed, respectively. When / if OraTech lists on Nasdaq, HTIT and ORMP intend to make respective additional $20.0 million and $7.5 million investments. Coincident with OraTech's launch on Nasdaq, Oramed plans to distribute the majority of expected 50% stake in OraTech to ORMP shareholders via a dividend.

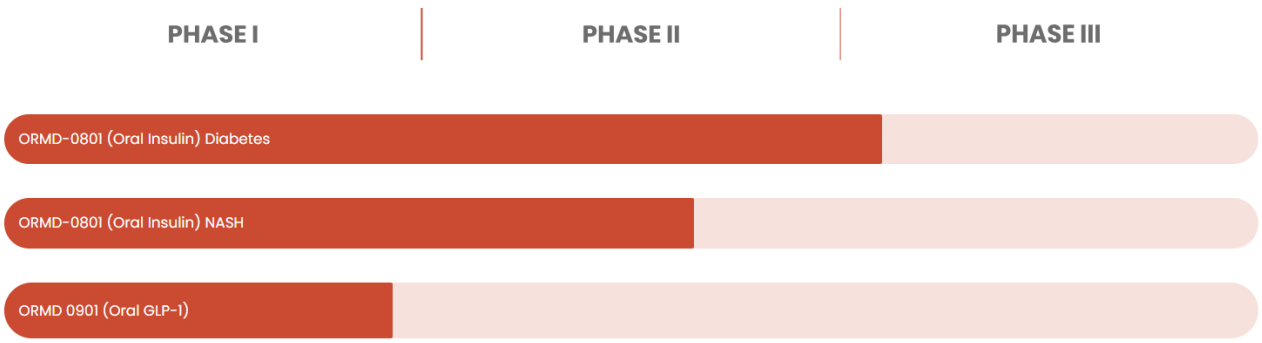
OraTech will leverage HTIT's manufacturing technologies and focus on developing and commercializing innovative products globally based on the combined assets and capabilities of the two JV partners. The company expects that the combination of their respective strengths – delivery technology and advanced manufacturing capabilities – will enable OraTech to develop, market and commercialize innovative treatments leveraging Oramed's oral insulin and POD™ (Protein Oral Delivery) pipeline and scale production with consistent, high-quality output.

ORMP's JV partner, 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. HTIT will receive an aggregate $30.0 million under a supply agreement with OraTech.

Phase 3 clinical oral insulin trial in the U.S. planned

OraTech intends to initiate a Phase 3 clinical trial in the U.S. that will be designed to incorporate takeaways from previous clinical studies in order to focus on key patient subpopulations that have responded in prior activities. 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. In prior clinical activities, a subpopulation of patients with specific parameters such as body mass index (BMI), baseline HbA1c, age, gender and body weight appeared to respond positively to the company's oral insulin. These subsets exhibited an over 1% placebo adjusted, statistically significant reduction in HbA1c. As a result, a differentiated protocol that is aligned with the positive subpopulation data and informed by feedback from discussions with the FDA is expected to guide the design of the planned Phase 3 trial.

Oramed Pipeline



Source: Company reports

Marketing Authorization Application submitted to regulators in China for the oral insulin

HTIT has also submitted a Marketing Authorization Application to regulators in China for the oral insulin capsule in that market, with commercialization preparations underway that are expected to result in royalties from sales in China to OraTech.

STRONG BALANCE SHEET; FINANCIAL FLEXIBILITY

Capital allocation strategy includes share buybacks, strategic investments & potential dividend

ORMP has a strong balance sheet that it is leveraging to support its initiatives and returns to shareholders via share buybacks and potential dividends. The company had $142 million in cash and equivalents and short-term investments at the end of 2024 and another roughly $11 million in long-term investments and no long term debt. Reflecting its sizable net cash position, ORMP potentially might issue cash dividends of about $0.25 per share to help offset any potential tax liabilities associated with its distribution of the OraTech stock to ORMP investors.

ORMP is also leveraging its balance sheet to make investments in other early stage companies, including Scilex Holding Company, a biopharma company focused on acquiring, developing, and commercializing non-opioid management products to treat acute and chronic pain. Scilex issued ORMP a roughly promissory note collateralized by most of its assets, plus penny warrants to purchase Scilex shares that have resulted in Oramed holding 12.25 million Scilex shares (slated to increase to 18.75 million shares) as a result of warrant vesting. ORMP also holds the right to receive 4% royalties from Scilex down the road. To date, ORMP has received $70 million in debt repayment and expects further payments of about $53 million over the next two years.

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.

In 2Q24, Oramed announced that its board has authorized a stock buyback program of up to $20 million of ORMP shares. During 2024, the company repurchased and retired 1.0 million ORMP shares for roughly $2.5 million. The company has indicated that it **is** actively pursuing additional strategic acquisitions and partnerships to leverage its expertise in technology development and has a pipeline of opportunities under consideration.

RECENT RESULTS

Oramed is pre-revenue at this stage. 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 in 2024, as it temporarily halted clinical trials. R&D expenses were about 30% lower at about $6 million in 2024 compared to $9 million in 2023. General and administrative (G&A) expenses fell about 23% to roughly $6.5 million compared to $8.4 million in 2023. However, reflecting a financial loss of $2.3 million, reflecting the revaluation of its investments in Scilex among other factors, compared to financial income of $22.9 million in 2023, Oramed reported a net loss of $19.1 million, or ($0.48) per share, compared to earnings of $5.1 million or $0.14 per share in 2023.

VALUATION

It would not surprise us if ORMP shares continued to trade in a range in the near- to medium-term, as the company moves toward Phase 3 launch and the OraTech IPO, particularly given current market dynamics. Nevertheless, we believe the sizable population with or at risk for diabetes globally and analysis of data from ORMP's 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., China 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 March 4, 2025, ORMP filed its 2024 10K.
- Oramed issued a letter to shareholders on March 4, 2025.
- Oramed announced updates to OraTech on February 11, 2025, intended to accelerate development and commercialization of oral insulin.
- 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

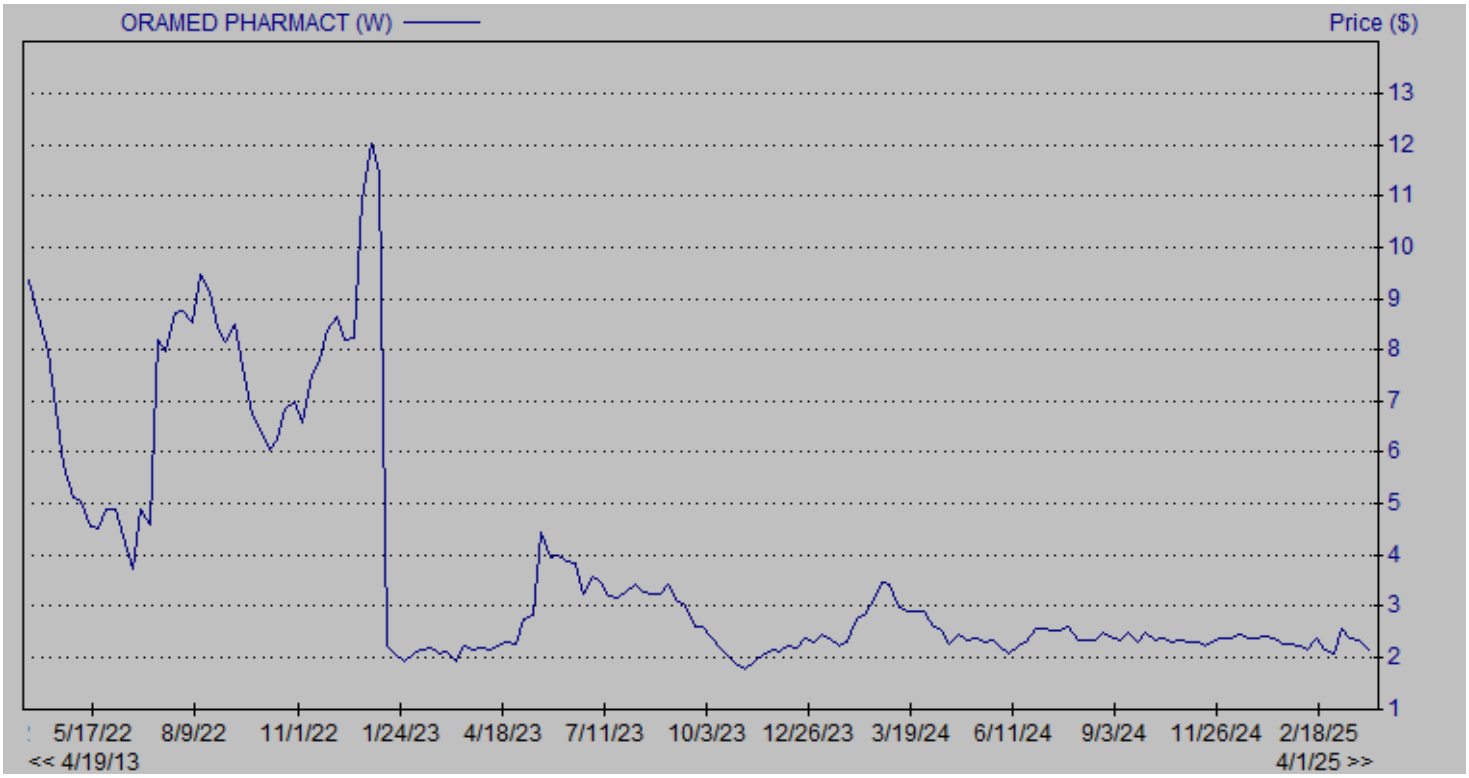
Oramed Pharmaceuticals Inc. (Fiscal Year ends Dec. 31*) $Mns	Q1 A	Q2 A	Q3 A	Q4 A	2024 A	Q1 E	Q2 E	Q3 E	Q4 E	2025 E
License Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth										
Grant/Contract Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth					-					-
ORMD-0801	$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
YOY Growth					-					-
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth					*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
Gross Income	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Gross Margin	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
Research & Development	$1.2	$1.4	$2.2	$1.5	$6.3	$1.5	$1.5	$1.5	$1.6	$6.0
General & Administrative	$1.8	$1.7	$0.8	$2.1	$6.5	$2.1	$2.1	$2.1	$2.5	$8.9
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income / (loss)	**($3.0)**	**($3.1)**	**($3.1)**	**($3.6)**	**($12.8)**	**($3.6)**	**($3.6)**	**($3.6)**	**($4.1)**	**($14.9)**
Operating Margin					-					-
Other Income (Net)	$4.5	$14.0	**($15.4)**	$6.2	$3.1	$3.0	$3.0	$3.0	$3.0	$12.0
Pre-Tax Income	**$1.5**	**$10.8**	**($18.5)**	**($9.8)**	**($15.9)**	**($0.6)**	**($0.6)**	**($0.6)**	**($1.1)**	**($2.9)**
Net Taxes (benefit)	$0.0	$1.6	$1.1	$0.4	$3.2					$0.0
Tax Rate	*0.0%*	*15.1%*	*-6.1%*	*nm*	*-20.0%*					*0.0%*
Minority interest / other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1
Reported Net Income	**$1.5**	**$9.2**	**($19.6)**	**($10.2)**	**($19.1)**	**($0.6)**	**($0.6)**	**($0.6)**	**($1.1)**	**($2.8)**
Net Margin										-
Reported EPS	**$0.04**	**$0.22**	**($0.48)**	**($0.25)**	**($0.48)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.07)**
YOY Growth										-
Basic Shares Outstanding	41.6	41.6	40.9	40.9	40.8	40.8	40.7	40.7	40.6	40.7

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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HISTORICAL STOCK PRICE



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