# Oramed Pharmaceuticals, Inc. (ORMP)
**Rating: Buy**

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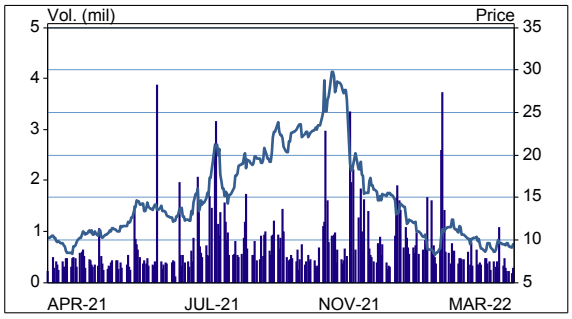
## KOL Event Underscores ORMD-0801 Value Proposition; Reiterate Buy

| Stock Data | 03/30/2022 |
|---|---|
| Price | $9.02 |
| Exchange | NASDAQ |
| Price Target | $32.00 |
| 52-Week High | $31.54 |
| 52-Week Low | $7.52 |
| Enterprise Value (M) | $220 |
| Market Cap (M) | $345 |
| Public Market Float (M) | 37.0 |
| Shares Outstanding (M) | 38.3 |
| 3 Month Avg Volume | 663,808 |
| Short Interest (M) | 2.26 |
| **Balance Sheet Metrics** | |
| Cash (M) | $125.8 |
| Total Debt (M) | $0.0 |
| Total Cash/Share | $3.29 |
| Book Value/Share | $4.47 |

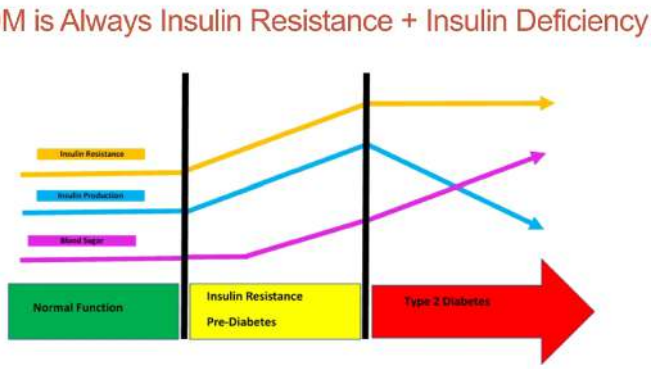
| EPS ($) Diluted | | | |
|---|---|---|---|
| Full Year - Aug | 2021A | 2022E | 2023E |
| 1Q | (0.23) | (0.20) | (0.32) |
| 2Q | (0.17) | (0.23) | (0.35) |
| 3Q | (0.17) | (0.26) | (0.38) |
| 4Q | (0.22) | (0.29) | (0.35) |
| FY | (0.81) | (0.98) | (1.41) |

| Revenue ($M) | | | |
|---|---|---|---|
| Full Year - Aug | 2021A | 2022E | 2023E |
| 1Q | 0.7 | 0.7 | 0.8 |
| 2Q | 0.7 | 0.7 | 0.8 |
| 3Q | 0.7 | 0.7 | 0.8 |
| 4Q | 0.7 | 0.7 | 0.8 |
| FY | 2.7 | 2.8 | 3.2 |



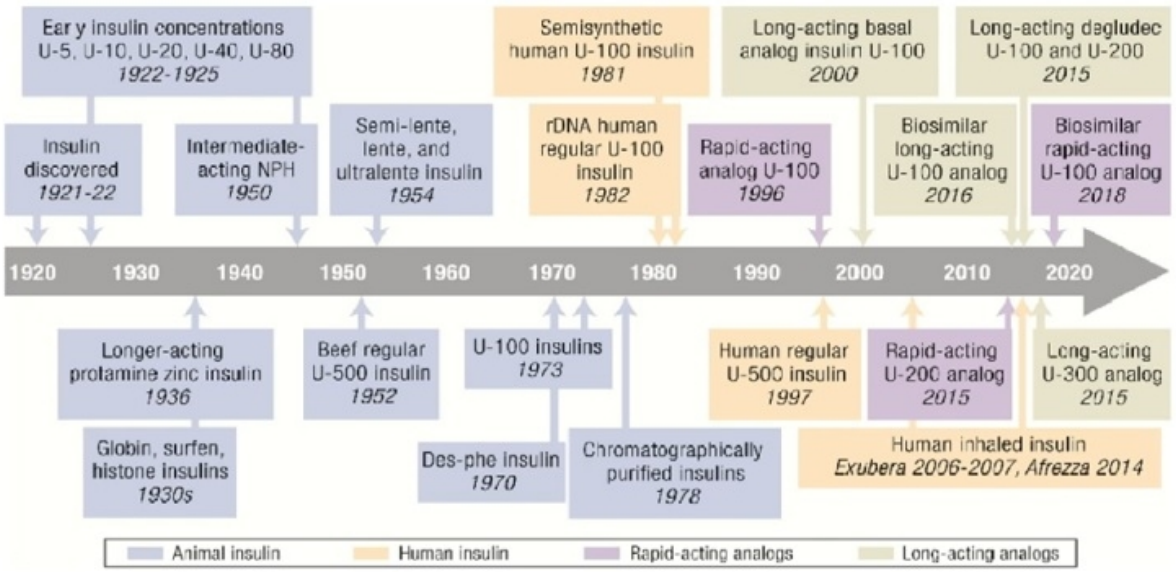

**Experts attest to importance of effective night-time glucose production control.** Yesterday, Oramed held a key opinion leader (KOL) event to discuss its lead candidate ORMD-0801 and the potential role of this candidate in effective disease management for type 2 diabetes (T2D) patients. T2D remains an area of serious unmet need, despite the availability of a plethora of medications beyond insulin—e.g. dipeptidyl peptidase IV (DPP-4) inhibitors and sodium-glucose co-transporter 2 (SGLT2) inhibitors—and constitutes a principal cause of ill-health. Every five seconds, at least one adult dies from the impact of diabetes globally. Patients with diabetes have significantly higher cardiovascular and kidney disease rates. The first KOL participating in Oramed's event, Anne Peters, M.D., is Professor of Medicine at the Keck School of Medicine of the University of Southern California (USC) and Director of the USC Clinical Diabetes Programs. Dr. Peters earned her medical degree from the Pritzker School of Medicine at the University of Chicago and performed an internal medicine residency at Stanford University and an endocrinology fellowship at Cedars-Sinai Medical Center. She previously directed the clinical diabetes programs at Cedars-Sinai and UCLA. Her research has focused on testing new approaches for diagnosing and treating diabetes and developing systems of care to improve outcomes in diabetic populations. Dr. Peters indicated that: (1) there is strong demand for oral insulin, which would reduce reliance on injections; (2) the ability to reduce reliance on other medications that carry substantial side effect burden, such as sulfonylureas, DPP-4 inhibitors and SGLT2 inhibitors, is highly desirable; and (3) night-time glucose over-production is one of the key drivers of worsening disease pathology in T2D patients. We reiterate our Buy rating and 12-month price target of $32 per share.

**Insulin resistance and insulin deficiency go hand-in-hand.** Dr. Peters explained that T2D develops as insulin resistance increases and is accompanied by rising insulin production. Subsequently, insulin production starts to decline, which is when the disease becomes firmly established, as illustrated below. Both insulin resistance and insulin deficiency need to be managed in order to effectively address T2D.




*Source: Anne Peters, M.D., USC Keck School of Medicine.*

**Product profile appears directly aligned with T2D population needs.** As a reminder, ORMD-0801 utilizes Oramed's drug delivery platform to enable the molecule—a peptide that typically cannot be administered orally without being degraded in the gastrointestinal (GI) tract—to be delivered intact from the stomach into the hepatic portal vein. This facilitates entry into the liver, permitting effective control of glucose production during the night. Dr. Peters indicated that an orally bioavailable insulin formulation could be positioned higher in the T2D treatment continuum, allowing for more efficient management of hyperglycemia. This would be a meaningful change in the overall use of insulin, which is currently deployed once most of the other drugs have stopped working and typically when endogenous insulin production has declined significantly. As shown below, despite a century of insulin formulation advances, the current lineup of insulin products is solely based on delivery via injection. Insulin delivery through the skin (i.e., subcutaneously) is far from ideal, since it is supposed to be secreted by the pancreas and sent into portal circulation. Thus, it is impossible to approximate natural insulin action using subcutaneous delivery. In our view, Oramed's approach is far more capable of recapitulating natural insulin action.




*Source: Vanita Aroda, M.D.*

Most of those on insulin do not reach the required glycemic control target, as measured via glycated hemoglobin (HbA1c) values. Two-thirds of patients are above the 7.5% threshold and one-third are above the 9% threshold. Continuous blood glucose monitoring (CBGM) technology has enabled detailed insight into the extent to which glucose control differs between non-diabetic and diabetic patients. One of the key issues with many T2D patients is their unwillingness to take insulin injections, even though their glucose levels are not properly controlled. Over time, uncontrolled glucose production causes a host of health issues, mostly related to cardiovascular and renal function. Oral insulin delivery may prevent such problems, while also eliminating weight gain by blocking cells from absorbing excess glucose, which gets converted into fat. Alexander Fleming, M.D., was the second participating KOL. He spent over a decade at the FDA, where he was responsible for the therapeutic areas of diabetes, other metabolic and endocrine disorders, growth and development, nutrition, lipid-lowering compounds, and reproductive indications. Dr. Fleming received his M.D. degree and internal medicine training from Emory University. He completed fellowship training in endocrinology at Vanderbilt University and metabolism at the National Institutes of Health (NIH), where he was a senior fellow. In assessing the Phase 2b data with ORMD-0801, Dr. Fleming characterized the efficacy profile as indicative of "very meaningful glycemic control without any increase in hypoglycemia—something that cannot be achieved with existing injected insulin products." In a survey conducted by IQVIA (IQV; not rated) for Oramed, 76% of healthcare practitioners (HCPs) indicated a willingness to prescribe oral insulin and only 1% stating that they would not prescribe a product with the target profile associated with the ORMD-0801 Phase 2b data set.

**Multiple additional catalysts in the offing.** Oramed's late-stage clinical programs continue to advance apace. ORA-D-013-1, the larger of two concurrent Phase 3 oral insulin trials with ORMD-0801, has enrolled more than 75% of the planned 675 subjects. In addition, more than 25% of the planned 450 patients in Oramed's second Phase 3 trial, ORA-D-013-2, have been enrolled. The company expects six-month top-line efficacy results from the ORA-D-013-1 trial to be reported in 2022, while the ORA-D-013-2 trial is slated to complete enrollment in 2022 as well.

**Valuation methodology, risks and uncertainties.** Factoring in a 12% discount rate, a 75% probability of approval for ORMD-0801, and peak annual sales of $2.6B (on which we project double-digit percentage royalties), we derive a total risk-adjusted net present value (rNPV) of $800M for this candidate within the diabetes indication alone. We add to this the value from ORMD-0801 in the non-alcoholic steatohepatitis (NASH) indication, to which we ascribe an rNPV of $50M, as well as our anticipated value for Oramed's pipeline, mainly ORMD-0901 and the Oravax program (total value of $250M), to derive a total enterprise value of approximately $1.2B. This yields a price objective of $32 per share, assuming net cash of $154M —resulting in a total firm value of $1.3B—and roughly 40M fully diluted shares outstanding as of end-F2022. Risks include,

but are not limited to: (1) delays in pivotal testing of ORMD-0801; (2) adverse results from future clinical trials; (3) negative regulatory actions; and (4) medium to long-term dilution risk.

**Table 1: Oramed Pharmaceuticals, Inc. (ORMP)—Historical Income Statements, Financial Projections**

FY end August 31
$ in thousands, except per share data

| | 2021A | | | | | 2022E | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1QA | 2QA | 3QA | 4QA | 2021A | 1QE | 2QE | 3QE | 4QE | 2022E | 2023E |
| **Revenue** | | | | | | | | | | | |
| Product revenue | - | - | - | - | - | - | - | - | - | - | - |
| Research and other | 674 | 665 | 681 | 683 | 2,703 | 700 | 700 | 700 | 700 | 2,800 | 3,200 |
| **Total revenue** | 674 | 665 | 681 | 683 | 2,703 | 700 | 700 | 700 | 700 | 2,800 | 3,200 |
| **Expenses** | | | | | | | | | | | |
| Cost of product and service revenue | - | - | - | - | - | - | - | - | - | - | - |
| Research & development | 5,774 | 3,869 | 5,502 | 5,844 | 20,989 | 6,000 | 7,000 | 8,000 | 9,000 | 30,000 | 43,000 |
| Selling and marketing | - | - | - | - | - | - | - | - | - | - | - |
| General and administrative | 727 | 1,664 | 1,297 | 2,249 | 5,937 | 2,300 | 2,500 | 2,800 | 3,000 | 10,600 | 15,000 |
| **Total expenses** | 6,501 | 5,533 | 6,799 | 8,093 | 26,926 | 8,300 | 9,500 | 10,800 | 12,000 | 40,600 | 58,000 |
| **Gain (loss) from operations** | (5,827) | (4,868) | (6,118) | (7,410) | (24,223) | (7,600) | (8,800) | (10,100) | (11,300) | (37,800) | (54,800) |
| Other income/expense | | | | | | | | | | | |
| Financial income | 257 | 260 | 493 | 232 | 1,242 | 160 | 140 | 300 | 260 | 860 | 860 |
| Financial expense | - | - | - | (8) | (8) | - | - | - | - | - | - |
| Impairment of available-for-sale securities | - | - | - | - | - | - | - | - | - | - | - |
| **Total investment income and other** | 257 | 260 | 493 | 224 | 1,234 | 160 | 140 | 300 | 260 | 860 | 860 |
| **Loss before provision for income taxes** | (5,570) | (4,608) | (5,625) | (7,186) | (22,989) | (7,440) | (8,660) | (9,800) | (11,040) | (36,940) | (53,940) |
| Deferred income tax benefit | - | - | - | - | - | - | - | - | - | - | - |
| Net loss attributable to non-controlling interests | - | - | 418 | 333 | 751 | 500 | 500 | 500 | 500 | 2,000 | 3,200 |
| **Net loss/income** | (5,570) | (4,608) | (5,207) | (7,186) | (22,989) | (7,440) | (8,660) | (9,800) | (11,040) | (36,940) | (53,940) |
| **Net loss per share (basic)** | (0.23) | (0.17) | (0.17) | (0.22) | (0.81) | (0.20) | (0.23) | (0.26) | (0.29) | (0.98) | (1.41) |
| Net loss per share (diluted) | (0.23) | (0.17) | (0.17) | (0.22) | (0.81) | (0.20) | (0.23) | (0.26) | (0.29) | (0.98) | (1.41) |
| Weighted average number of shares outstanding (basic) | 23,746 | 27,004 | 29,930 | 33,196 | 28,469 | 36,690 | 38,111 | 38,161 | 38,211 | 37,793 | 38,336 |
| Weighted average number of shares outstanding (diluted) | 23,746 | 27,004 | 29,930 | 33,196 | 28,469 | 36,690 | 38,111 | 38,161 | 38,211 | 37,793 | 38,336 |

*Source: Company reports and H.C. Wainwright & Co. estimates.*

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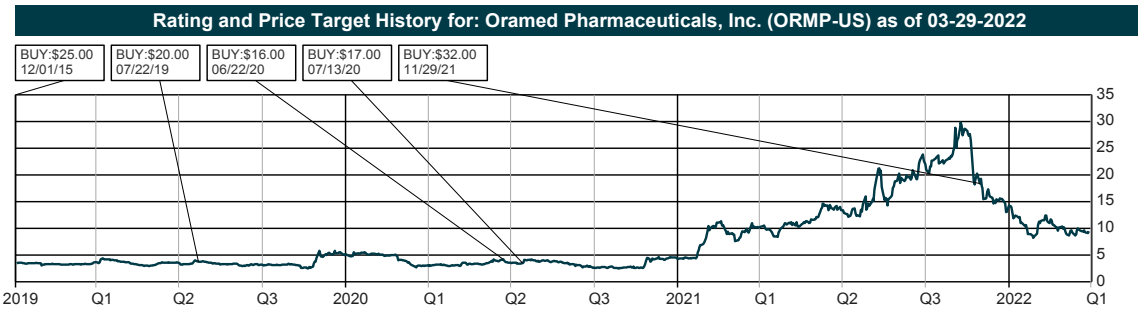
**RETURN ASSESSMENT**

**Market Outperform (Buy):** The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

**Market Perform (Neutral):** The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

**Market Underperform (Sell):** The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.

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**Distribution of Ratings Table as of March 29, 2022**

| | | | IB Service/Past 12 Months | |
|---|---|---|---|---|
| Ratings | Count | Percent | Count | Percent |
| Buy | 589 | 91.32% | 183 | 31.07% |
| Neutral | 47 | 7.29% | 12 | 25.53% |
| Sell | 1 | 0.16% | 0 | 0.00% |
| Under Review | 8 | 1.24% | 1 | 12.50% |

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