



## Oramed Pharmaceuticals Inc. (ORMP)

## EQUITY RESEARCH

November 15, 2022

Price: \$7.89

Price Target: \$20.00

Rating: Overweight

## Key Statistics:

Symbol	NASDAQ: ORMP
52-Week Range	\$3.59 - \$29.24
Market Cap (\$M)	308.6
ADV (3 mo)	275,385
Shares Out (M)	39.1

## Research Analysts:

Charles C. Duncan, Ph.D.

212-915-1236

Charles.Duncan@cantor.com

Pete Stavropoulos, Ph.D.

212-915-1966

Pete.Stavropoulos@cantor.com

Avraham Novick

212-359-8723

Avraham.Novick@cantor.com

## REV (\$M)

FYE Dec	2022E	2023E	2024E
1Q	\$0.7A	\$0.7	-
2Q	\$0.7A	\$0.7	-
3Q	\$0.7A	\$0.7	-
4Q	\$0.7E	\$0.7	-
Year	\$2.7E	\$2.7	\$56.8

## EPS

FYE Dec	2022E	2023E	2024E
1Q	\$(0.27)A	\$(0.20)	-
Prev	-	\$(0.33)	-
2Q	\$(0.27)A	\$(0.19)	-
Prev	-	\$(0.32)	-
3Q	\$(0.18)A	\$(0.20)	-
Prev	\$(0.30)E	\$(0.35)	-
4Q	\$(0.19)E	\$(0.22)	-
Prev	\$(0.31)E	\$(0.37)	-
Year	\$(0.91)E	\$(0.80)	\$(0.07)
Prev	\$(1.15)E	\$(1.37)	\$(0.59)

## Company Update

## 3Q Postview: Good Cash and Two Possible P3 Reads Could Make 2023 a Sweet Year

**Investment Summary.** We reiterate our OW rating and 12-month \$20 PT on ORMP shares. Oramed (ORMP) press released financial results ending the quarter with cash/equivalents of ~\$160M. Current cash/equivalents should provide runway through key value-creating milestones including: 1) P3 ORA-D-013-1 study of ORMD-0801 ('0801) in type 2 diabetes (T2D) top-line data in January 2023 and 2) P3 ORA-D-013-2 study of '0801 in T2D top-line data in 2H23 (our estimate). We believe that '0801 (oral insulin) may show a differentiated and superior clinical profile relative to injected insulin because of its potential to mimic a more physiological response. In our view, this route of administration allows the absorbed insulin to travel through the hepatic portal vein and target the liver directly. We look forward to the January readout, which will allow us to gauge possibilities and probabilities for potential approval and commercialization prospects.

**P3 ORA-D-013-1 top-line data in January 2023 a key near-term potential value driver.**

We are interested in the outcome of the P3 ORA-D-013-1 study of '0801 in T2D, which is guided to read out in January. The primary efficacy endpoint is the mean change from baseline in HbA1C (hemoglobin A1c) at Week 26. If this P3 readout is clearly positive, it may enable '0801 to become a second/third line of treatment in place of DPP4s (dipeptidyl-peptidase 4) inhibitors, GLP-1 (glucagon-like peptide 1) receptor agonists, and SGLT2 (sodium-glucose transport protein 2) inhibitors.

The second P3, ORA-D-013-2, for which the company disclosed was 50% enrolled in July 2022, is being conducted in T2D patients with inadequate glycemic control on diet control alone or on diet control and metformin monotherapy, for which we estimate a data readout in 2H23. Similar to the first study, the primary efficacy endpoint is mean change from baseline in HbA1c at week 26. Importantly, approximately 30% of subjects will be naïve to first line of therapy, metformin. With the enrollment criteria of this study, if the readout is clearly positive, there is the potential that '0801 may become first-line monotherapy or used in combination with metformin.

**Changes to our model.** We adjusted our model to reflect 3Q22 actual earnings. The company reported a net loss of (\$0.18) per basic and diluted shares for the quarter. In addition, we updated 3Q22 operating expenses. Furthermore, our model assumes an equity raise in 2Q23; we believe the company may initiate additional studies as well as start commercialization activity for ORMD-0801 if the P3 ORA-D-013-1 study reads out positively, which will increase the burn rate. Therefore, we increased the size of the assumed equity raise to ~\$113M from ~\$71M in 2Q23. These factors resulted in changes to our EPS estimates.

**Exhibit 1: ORMP Income Statement**

	1Q22A	2Q22A	3Q22A	4Q22E	2022E	1Q23E	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E
ORMD-0801 in Type 2 Diabetes Mellitus	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$56,771	\$117,767
<b>US Sales</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$56,771</b>	<b>\$117,767</b>
ORMD-0801 in Type 2 Diabetes Mellitus	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$9,145
<b>EU Sales</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$9,145</b>
<b>Product sales</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$56,771</b>	<b>\$126,912</b>
Other revenues	\$666	\$674	\$682	\$674	\$2,696	\$674	\$674	\$674	\$674	\$2,696	\$0	\$0
<b>Total revenues</b>	<b>\$666</b>	<b>\$674</b>	<b>\$682</b>	<b>\$674</b>	<b>\$2,696</b>	<b>\$674</b>	<b>\$674</b>	<b>\$674</b>	<b>\$674</b>	<b>\$2,696</b>	<b>\$56,771</b>	<b>\$126,912</b>
<b>COGS</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$5,677</b>	<b>\$12,691</b>
as % of product revenues			10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
% growth												
<b>R&amp;D expenses (GAAP)</b>	<b>\$5,836</b>	<b>\$9,179</b>	<b>\$5,347</b>	<b>\$5,614</b>	<b>\$25,976</b>	<b>\$5,895</b>	<b>\$6,190</b>	<b>\$6,499</b>	<b>\$6,824</b>	<b>\$25,408</b>	<b>\$31,761</b>	<b>\$38,113</b>
% growth		57%	-42%	5%		5%	5%	5%	5%	-2%	25%	20%
% of sales												
<b>SG&amp;A expenses (GAAP)</b>	<b>\$6,082</b>	<b>\$2,912</b>	<b>\$3,524</b>	<b>\$3,700</b>	<b>\$16,218</b>	<b>\$3,885</b>	<b>\$4,079</b>	<b>\$4,691</b>	<b>\$5,395</b>	<b>\$18,051</b>	<b>\$27,077</b>	<b>\$37,907</b>
% growth		-52%	5%	5%		5%	5%	15%	15%			40%
% of sales												
<b>Operating expenses (GAAP)</b>	<b>\$11,918</b>	<b>\$12,091</b>	<b>\$8,871</b>	<b>\$9,315</b>	<b>\$42,195</b>	<b>\$9,780</b>	<b>\$10,269</b>	<b>\$11,191</b>	<b>\$12,219</b>	<b>\$43,460</b>	<b>\$64,514</b>	<b>\$88,711</b>
<b>Operating Income (GAAP)</b>	<b>(\$11,252)</b>	<b>(\$11,417)</b>	<b>(\$8,189)</b>	<b>(\$8,641)</b>	<b>(\$39,499)</b>	<b>(\$9,106)</b>	<b>(\$9,595)</b>	<b>(\$10,517)</b>	<b>(\$11,545)</b>	<b>(\$40,764)</b>	<b>(\$7,743)</b>	<b>\$38,201</b>
<i>Operating Margin</i>												
Loss on remeasurement of redeemable convertible preferred stock liability	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Other income, net	\$544	\$350	\$1,036	\$1,036	\$2,966	\$1,036	\$1,036	\$1,036	\$1,036	\$4,144	\$4,144	\$4,144
Loss (gain) from changes in fair value of investment	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Total other income (expense), net</b>	<b>\$544</b>	<b>\$350</b>	<b>\$1,036</b>	<b>\$1,036</b>	<b>\$2,966</b>	<b>\$1,036</b>	<b>\$1,036</b>	<b>\$1,036</b>	<b>\$1,036</b>	<b>\$4,144</b>	<b>\$4,144</b>	<b>\$4,144</b>
<b>Pre-tax income</b>	<b>(\$10,708)</b>	<b>(\$11,067)</b>	<b>(\$7,153)</b>	<b>(\$7,605)</b>	<b>(\$36,533)</b>	<b>(\$8,070)</b>	<b>(\$8,559)</b>	<b>(\$9,481)</b>	<b>(\$10,509)</b>	<b>(\$36,620)</b>	<b>(\$3,599)</b>	<b>\$42,345</b>
Income tax expense	\$0	\$0	\$100	\$0	\$100	\$0	\$0	\$0	\$0	\$0	\$0	\$0
tax rate %	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Net Income</b>	<b>(\$10,708)</b>	<b>(\$11,067)</b>	<b>(\$7,253)</b>	<b>(\$7,605)</b>	<b>(\$36,633)</b>	<b>(\$8,070)</b>	<b>(\$8,559)</b>	<b>(\$9,481)</b>	<b>(\$10,509)</b>	<b>(\$36,620)</b>	<b>(\$3,599)</b>	<b>\$42,345</b>
% growth												
Accretion on redeemable preferred stock	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Deemed dividend - beneficial conversion feature on redeemable convertible preferred stock	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Non-controlling interests	\$283	\$534	\$193		\$1,010							
<b>Net loss attributable to common stockholders</b>	<b>(\$10,425)</b>	<b>(\$10,533)</b>	<b>(\$7,060)</b>	<b>(\$7,605)</b>	<b>(\$35,623)</b>	<b>(\$8,070)</b>	<b>(\$8,559)</b>	<b>(\$9,481)</b>	<b>(\$10,509)</b>	<b>(\$36,620)</b>	<b>(\$3,599)</b>	<b>\$42,345</b>
<b>GAAP EPS</b>	<b>(\$0.27)</b>	<b>(\$0.27)</b>	<b>(\$0.18)</b>	<b>(\$0.19)</b>	<b>(\$0.91)</b>	<b>(\$0.20)</b>	<b>(\$0.19)</b>	<b>(\$0.20)</b>	<b>(\$0.22)</b>	<b>(\$0.80)</b>	<b>(\$0.07)</b>	<b>\$0.78</b>
Shares outstanding - Basic (M)	38.88	38.80	39.10	39.30	38.97	39.49	45.49	48.49	48.73	45.55	53.73	54.00

Source: Cantor Fitzgerald Research, Company Presentation and SEC Filings

**Valuation**

We use a probability-adjusted DCF analysis to value ORMP shares. We forecast cash flows out to 2036. We apply a discount rate of 14% & do not assume a terminal value. The resulting NPV of free cash flow is ~\$1003M, based on our analysis, which drives our 12-month price target of \$20/share based on shares outstanding as of end-2Q23E. Our model assumes an equity raise in 2Q23.

**Risks**
**Development, regulatory & commercial risks**

ORMD-0801 may not show efficacy as a sole agent and/or in combination with other medications in Type 2 diabetes mellitus patients in P3 studies. ORMD-0801 may not show efficacy in additional indications it is being evaluated in, such as Type 1 diabetes mellitus or NASH. Studies may reveal unforeseen safety and/or tolerability issues for ORMD-0801. If ORMD-0801 is approved, new, more-efficacious products may enter the market and may compete for market share.

The company may fail to secure financing for additional studies or commercialization of ORMD-0801, should it be approved. The oral SARS-CoV-2 vaccine may fail to stimulate a suitable immune response for protection against COVID-19. ORMD-0901, an orally delivered GLP-1 analog, may fail to show efficacy in Type 2 diabetes mellitus. Preclinical programs may fail to receive an IND or to enter the clinic.

## Company Description

*Oramed is developing drugs using its Protein Oral Delivery (POD) technology, which protects proteins from proteolysis in the gastrointestinal (GI) tract & enhances absorption.*

## Disclosures Appendix

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*Total return is defined as the sum of (1) the percentage difference between the target price and the current price and (2) the expected dividend yield of the stock.*

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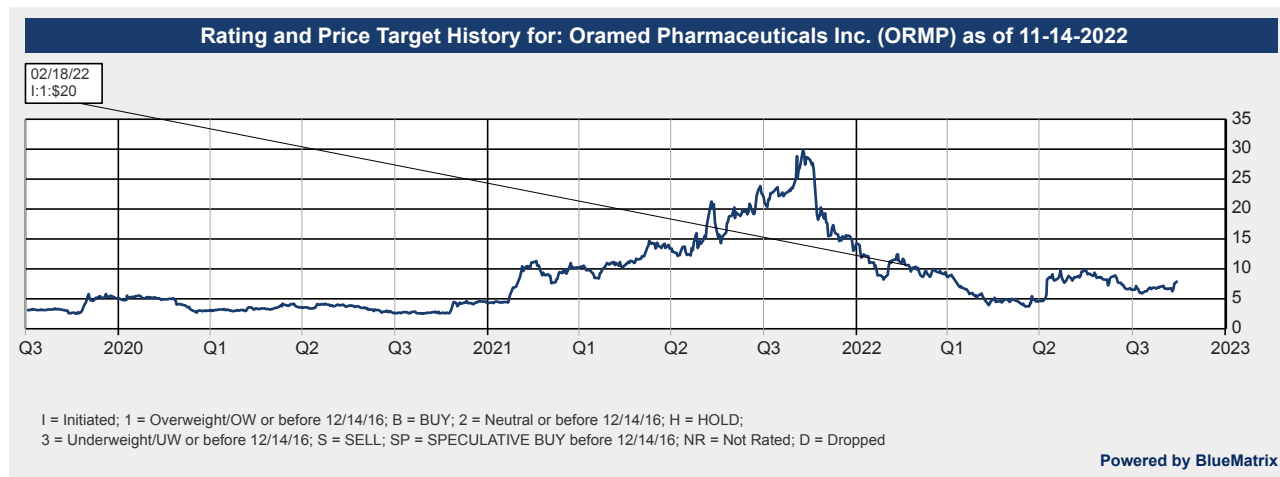
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Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [1/B]	232	84.98	171	73.71
HOLD [2]	41	15.02	21	51.22
SELL [SL/3]	0	0.00	0	0.00



## U.S. Equity Research Analysts & Management

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### Director of Equity Research

David Siffringer  
212-829-7091  
[David.Siffringer@cantor.com](mailto:David.Siffringer@cantor.com)

### BIOTECH/HEALTHCARE

#### Biopharma & Biotech

Brandon Folkes, CFA  
212-294-8081  
[Brandon.Folkes@cantor.com](mailto:Brandon.Folkes@cantor.com)

#### Biotechnology

Prakhar Agrawal  
212-610-3614  
[Prakhar.Agrawal@cantor.com](mailto:Prakhar.Agrawal@cantor.com)

#### Olivia Brayer

(212) 428-5907  
[Olivia.Brayer@cantor.com](mailto:Olivia.Brayer@cantor.com)

#### Charles C. Duncan, Ph.D.

212-915-1236  
[Charles.Duncan@cantor.com](mailto:Charles.Duncan@cantor.com)

#### Avraham Novick

212-359-8723  
[Avraham.Novick@cantor.com](mailto:Avraham.Novick@cantor.com)

#### Kristen Kluska

212-915-1927  
[Kristen.Kluska@cantor.com](mailto:Kristen.Kluska@cantor.com)

#### Rick Miller, Ph.D.

212-915-1803  
[Rick.Miller@cantor.com](mailto:Rick.Miller@cantor.com)

#### Pete Stavropoulos, Ph.D.

212-915-1966  
[Pete.Stavropoulos@cantor.com](mailto:Pete.Stavropoulos@cantor.com)

#### Li Watsek

212-915-1221  
[Li.Watsek@cantor.com](mailto:Li.Watsek@cantor.com)

### Large Cap Pharma, Biopharma & Biotech

Louise Chen  
212-915-1794  
[Louise.Chen@cantor.com](mailto:Louise.Chen@cantor.com)

#### Carvey Leung

212-915-1917  
[Carvey.Leung@cantor.com](mailto:Carvey.Leung@cantor.com)

#### Wayne Wu

212-294-7879  
[Wayne.Wu@cantor.com](mailto:Wayne.Wu@cantor.com)

#### Jennifer Kim

212-829-4860  
[Jennifer.Kim@cantor.com](mailto:Jennifer.Kim@cantor.com)

### Life Science Tools & Diagnostics

Ross Osborn  
212-915-1806  
[Ross.Osborn@cantor.com](mailto:Ross.Osborn@cantor.com)

### Medical Devices & Supplies

Brandon Folkes, CFA  
212-294-8081  
[Brandon.Folkes@cantor.com](mailto:Brandon.Folkes@cantor.com)

#### Ross Osborn

212-915-1806  
[Ross.Osborn@cantor.com](mailto:Ross.Osborn@cantor.com)

### CANNABIS

#### Cannabis

#### Cannabis Services

#### Wellness

Pablo Zuanic  
212.915.1057  
[Pablo.Zuanic@cantor.com](mailto:Pablo.Zuanic@cantor.com)

### TECHNOLOGY

#### Alternative Energy & Industrial Technology

Andres Sheppard  
212-428-5983  
[Andres.Sheppard@cantor.com](mailto:Andres.Sheppard@cantor.com)

#### Clean Tech

Derek Soderberg  
212-359-8721  
[Derek.Soderberg@cantor.com](mailto:Derek.Soderberg@cantor.com)

#### Consumer Internet

#### Software

Brett Knoblauch  
212-610-2221  
[Brett.Knoblauch@cantor.com](mailto:Brett.Knoblauch@cantor.com)

#### Alex Medow

212-294-8016  
[Alex.Medow@cantor.com](mailto:Alex.Medow@cantor.com)

### Crypto & Blockchain

#### Financial Technology

Josh Siegler  
212-428-5960  
[Josh.Siegler@cantor.com](mailto:Josh.Siegler@cantor.com)

#### Keeler Patton

212-829-5457  
[Keeler.Patton@cantor.com](mailto:Keeler.Patton@cantor.com)

#### Will Carlson

212-829-4709  
[Will.Carlson@cantor.com](mailto:Will.Carlson@cantor.com)

### Security & Infrastructure Software

Jonathan Ruykhaver, CFA  
617-443-4473  
[Jonathan.Ruykhaver@cantor.com](mailto:Jonathan.Ruykhaver@cantor.com)

#### Yi Fu Lee, CFA, CPA, CMT, CAIA

212-915-1235  
[YiFu.Lee@cantor.com](mailto:YiFu.Lee@cantor.com)