

Oramed Pharmaceuticals Biotechnology

US Equity Research
17 November 2022

Rating BUY <i>unchanged</i>	Price Target US\$30.00 <i>unchanged</i>
ORMP-NASDAQ	Price US\$8.02

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Oramed remains on track to release Phase III top-line data in T2D in January

Oramed reported financial results for 3Q22. The company will host a conference call today Nov. 17th at 11:00 a.m. EST to highlight safety and efficacy data from the Phase II NASH trial for ORMD-0801, the company's oral insulin drug candidate.

Market Data

52-Week Range (US\$) :	3.59 - 28.54
Market Cap (US\$M) :	313.7
Shares Out., Basic (M) :	39.1
Enterprise Value (US\$M) :	154
Cash (US\$M) :	133.9

FYE Dec	2021A	2022E	2023E
Revenue (US\$M)	2.7	2.7	2.7
EPS (US\$)	(0.78)	(1.05)↑	(0.93)↑
<i>Previous</i>	-	(1.07)	(0.94)

Quarterly Revenue	Q1	Q2	Q3	Q4
2021A	0.7	0.7	0.7	0.7
2022E	0.7A	0.7A	0.7A	0.7
2023E	0.7	0.7	0.7	0.7

Quarterly EPS	Q1	Q2	Q3	Q4
2021A	(0.23)	(0.17)	(0.17)	(0.24)
2022E	(0.27)A	(0.27)A	(0.18)A	(0.32)
2023E	(0.28)	(0.22)	(0.22)	(0.24)

Oramed Pharmaceuticals 3Q22 snapshot

	3Q22A	CG 3Q22E	Var (A:E)	% Var	3Q22 Consensus	Var (A:C)	% Var
GAAP EPS (diluted)	-0.18	-0.22	0.04	22.2%	-0.25	0.07	38.9%
Product Sales Revenue (\$MM)	0.0	0.0	0.0		0.0	0.0	
R&D	5.3	6.7	-1.4	-26.4%	7.9	-2.6	-49.1%
G&A	3.1	3.0	0.1	3.2%	2.3	0.8	25.8%

BALANCE SHEET

	3Q22
Cash (\$MM)	\$159.5
LTD (\$MM)	\$0.0

EXPECTED UPCOMING CLINICAL / COMMERCIAL MILESTONES

ORMD-0801	Jan-23	Top-line data read-out from Phase III T2D trial (ORA-D-013-1)
VLP oral COVID-19 vaccine	4Q22	Top-line data read-out from Cohort B of the Phase I study (South Africa)
ORMD-0801	2H22	Enrollment completion of Phase III T2D trial (ORA-D-013-2)
ORMD-0901	2H22	Data read-out on bioavailability study (T2D)

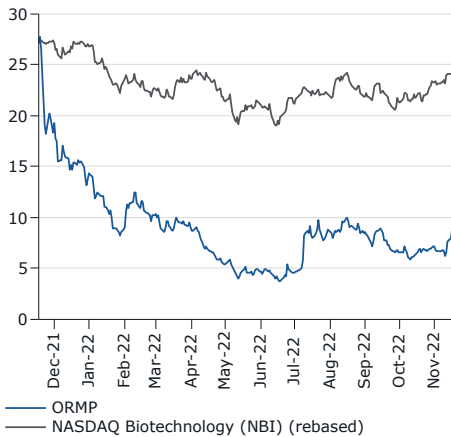
CHANGES MADE TO FINANCIAL PROJECTIONS

Updated model to reflect companies latest financial results

Source: Company reports and Canaccord Genuity estimates

Financial results for 3Q22

Oramed booked a net loss of \$7.1M, or (\$0.18) per share, for 3Q22, compared to a net loss of \$7.3M for three months ended September 30, 2021. The company ended 3Q22 with cash, cash equivalents, and marketable securities of \$159.5M. R&D expense was \$5.3M for 3Q22, compared to \$6.1M for 3Q21. The decrease was mainly due to lower research and development expenses in the subsidiary Oravax Inc. ("Oravax") in 3Q22. G&A expense was \$3.1M for 3Q22, compared to \$1.9M for 3Q21. The increase was mainly due to higher stock-based compensation expenses and salary expenses and stock-based compensation expenses.



Source: FactSet

Priced intraday 17 November 2022

Oramed Pharmaceuticals (ORMP) income statement

	2019	2020	2021	FY transition		2022E					2023E					2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	
	Aug-19	Aug-20	Aug-21	Nov-21 3 months	Dec-21 4 months	1Q	2Q	3Q	4QE	Year	1QE	2QE	3QE	4QE	Year														
ORMD-0801 T2D product sales	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	0.0	0.0	11.6	24.5	77.9	206.0	485.5	700.4	988.1	1,394.0	1,680.1	2,172.6	2,507.8	3,095.6	3,552.6	
Collaboration revenue	2.7	2.7	2.7	0.7	0.9	0.7	0.7	0.7	0.7	2.7	0.7	0.7	0.7	0.7	2.7	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	0.0
Total Revenue	2.7	2.7	2.7	0.7	0.9	0.7	0.7	0.7	0.7	2.7	0.7	0.7	0.7	0.7	2.7	11.6	24.5	77.9	206.0	485.5	700.4	988.1	1,394.0	1,680.1	2,172.6	2,507.8	3,095.6	3,552.6	
Cost of U.S. product sales (10%)	0.1	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	0.0	1.2	2.5	7.8	20.6	48.5	70.0	98.8	139.4	168.0	217.3	250.8	309.6	355.3	
Gross profit	2.6	2.7	2.7	0.7	0.9	0.7	0.7	0.7	0.7	2.7	0.7	0.7	0.7	0.7	2.7	10.4	22.1	70.1	185.4	436.9	630.4	889.3	1,254.6	1,512.1	1,955.4	2,257.0	2,786.0	3,197.3	
R&D	13.5	10.2	21.0	6.4	9.0	5.8	9.2	5.3	8.0	28.4	7.0	7.0	8.0	8.0	30.0	31.5	33.1	34.7	36.5	38.3	40.2	42.2	44.3	46.5	48.9	51.3	53.9	56.6	
G&A	3.7	4.2	5.9	1.7	3.3	5.5	2.5	3.1	4.0	15.1	5.0	4.0	3.0	4.0	16.0	16.5	17.0	17.5	18.0	18.5	19.1	19.7	20.3	20.9	21.5	22.1	22.8	23.5	
Sales expense	0.0	0.0	0.0	0.6	0.8	0.6	0.4	0.5	0.0	1.4	0.0	0.0	0.0	0.0	0.0	18.8	31.3	37.5	38.6	39.8	43.0	42.2	43.5	44.8	46.1	47.5	48.8	50.4	
Operating expense	17.2	14.5	26.9	8.7	13.2	11.9	12.1	8.9	12.0	44.9	12.0	11.0	11.0	12.0	46.0	66.7	81.3	89.7	93.1	96.6	100.3	104.1	108.1	112.7	116.5	121.0	125.8	130.5	
Operating Profit (Loss)	(14.6)	(11.8)	(24.2)	(8.1)	(12.3)	(11.3)	(11.4)	(8.2)	(11.3)	(42.2)	(11.3)	(10.3)	(10.3)	(11.3)	(43.3)	(56.3)	(59.2)	(19.6)	92.3	340.3	530.1	785.2	1,146.6	1,399.9	1,838.9	2,136.0	2,660.4	3,066.9	
Interest income	1.1	0.7	1.2	(0.1)	(0.2)	0.5	0.4	1.0	(1.1)	0.8	0.2	0.2	0.2	0.2	0.8	0.8	0.8	0.9	3.4	5.3	7.9	11.5	14.0	18.4	21.4	26.6	30.7		
Interest expense	0.5	(0.4)	(0.0)	0.2	0.1	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Loss (gain) fair value of investments	0.0	0.0	0.0	0.2	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net loss attributable to non-controlling interests	0.0	0.0	(0.8)	0.0	0.6	0.3	0.5	0.2	(1.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax profit (loss)	(14.1)	(11.5)	(22.2)	(7.9)	(11.7)	(10.4)	(10.5)	(7.0)	(13.5)	(41.4)	(11.1)	(10.1)	(10.1)	(11.1)	(42.5)	(55.5)	(58.4)	(18.8)	93.2	343.7	535.4	793.1	1,158.0	1,413.9	1,857.3	2,157.4	2,687.0	3,097.5	
Income Tax	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.2	92.8	144.6	214.1	312.7	381.7	501.5	582.5	725.5	836.3		
Tax rate	-2.1%	0.0	0.0%	0.0%	0.0%	0.0%	0.0%	-1.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	27.0%	27.0%	27.0%	27.0%	27.0%	27.0%	27.0%	27.0%	27.0%	27.0%	27.0%	
Net Income (Loss)	(14.4)	(11.5)	(22.2)	(7.9)	(11.7)	(10.4)	(10.5)	(7.1)	(13.5)	(41.5)	(11.1)	(10.1)	(10.1)	(11.1)	(42.5)	(55.5)	(58.4)	(18.8)	68.0	250.9	390.9	579.0	845.4	1,032.1	1,355.8	1,574.9	1,961.5	2,261.2	
EPS - basic	(\$0.82)	(\$0.56)	(\$0.78)	(\$0.22)	(\$0.31)	(\$0.27)	(\$0.27)	(\$0.18)	(\$0.32)	(\$1.05)	(\$0.28)	(\$0.22)	(\$0.22)	(\$0.24)	(\$0.93)	(\$1.12)	(\$1.15)	(\$0.37)	\$1.34	\$4.95	7.7	11.4	16.7	20.4	26.8	31.1	38.7	44.6	
EPS - diluted	(\$0.82)	(\$0.56)	(\$0.78)	(\$0.22)	(\$0.31)	(\$0.27)	(\$0.27)	(\$0.18)	(\$0.32)	(\$1.05)	(\$0.28)	(\$0.22)	(\$0.22)	(\$0.24)	(\$0.93)	(\$1.12)	(\$1.15)	(\$0.37)	\$1.34	\$4.95	7.7	11.4	16.7	20.4	26.8	31.1	38.7	44.6	
Weighted average basic shares	17.5	20.5	28.5	36.7	37.1	38.7	38.8	39.1	42.1	39.5	39.5	45.1	45.1	46.8	45.5	49.6	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	
Weighted average diluted shares	17.5	20.5	28.5	36.7	37.1	38.7	38.8	39.1	42.1	39.5	39.5	45.1	45.1	46.8	45.5	49.6	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	50.7	

Source: Company Reports, Canaccord Genuity estimates. A more detailed financial model, including balance sheet, income statement, and cash flow projections, if available, may be obtained by contacting your Canaccord Genuity Sales Person or the Authoring Analyst, whose contact information appears on the front page of this report.

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Investment Recommendation

Date and time of first dissemination: November 17, 2022, 11:05 ET

Date and time of production: November 17, 2022, 11:05 ET

Target Price / Valuation Methodology:

Oramed Pharmaceuticals - ORMP

We value shares of Oramed by employing a sum-of-the-parts analysis that includes programs where we believe clinical data is available to fairly determine the overall probability of success, as well as net cash on hand. Our estimates solely for the T2D program in the U.S. are used to generate our \$30 12-month price target, and we view any additional programs such as T1D, NASH and T2D ex-U.S. as potential upside to our estimates.

Risks to achieving Target Price / Valuation:

Oramed Pharmaceuticals - ORMP

Clinical risk: Although ORMD-0801 has demonstrated clinical proof-of-concept in patients with T2D, the molecule is now being dosed in larger Phase III trials, and as more patients are exposed to drug over time there is the chance that issues could appear relating to efficacy, safety or both. While there is a significant amount of literature speaking to insulin use in treating T2D, ORMD-0801 is a unique orally delivered version of insulin and only through additional clinical trials can the molecule be further de-risked.

Regulatory risk: Given that there are currently no oral-insulin options approved for the treatment of T2D, the FDA is in new territory regarding the review of this type of molecule administration. The FDA continues to be unpredictable even with the review pathways, designations and outside panel reviews that can be employed during the review process.

Commercial risk: Given that there are currently no oral insulin therapeutics approved for the treatment of T1D and T2D, grasping the true commercial opportunity post-launch is difficult. The outcome of the two-Phase III trials and final labeling will be key to understanding the true market potential for ORMD-0801.

Competitive risk: The competitive landscape for T2D drug development is crowded. The opportunity to tap into a mature multi-billion-dollar market opportunity will result in the space remaining competitive. In addition to the overall T2D clinical landscape being competitive, specific to Oramed there are multiple players attempting to develop an oral delivery option for insulin.

Management risk: For a clinical stage biotech, stability in the C-suite roles is key as it is with any company. Turnover, especially in regulatory agency-facing roles such as CEO and CSO, could negatively impact share performance.

Distribution of Ratings:

Global Stock Ratings (as of 11/17/22)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	636	65.77%	29.40%
Hold	148	15.31%	18.92%
Sell	14	1.45%	0.00%
Speculative Buy	161	16.65%	40.99%
	967*	100.0%	

*Total includes stocks that are Under Review

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BUY: The stock is expected to generate risk-adjusted returns of over 10% during the next 12 months.

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Risk Qualifier

SPECULATIVE: Stocks bear significantly higher risk that typically cannot be valued by normal fundamental criteria. Investments in the stock may result in material loss.

12-Month Recommendation History (as of date same as the **Global Stock Ratings** table)

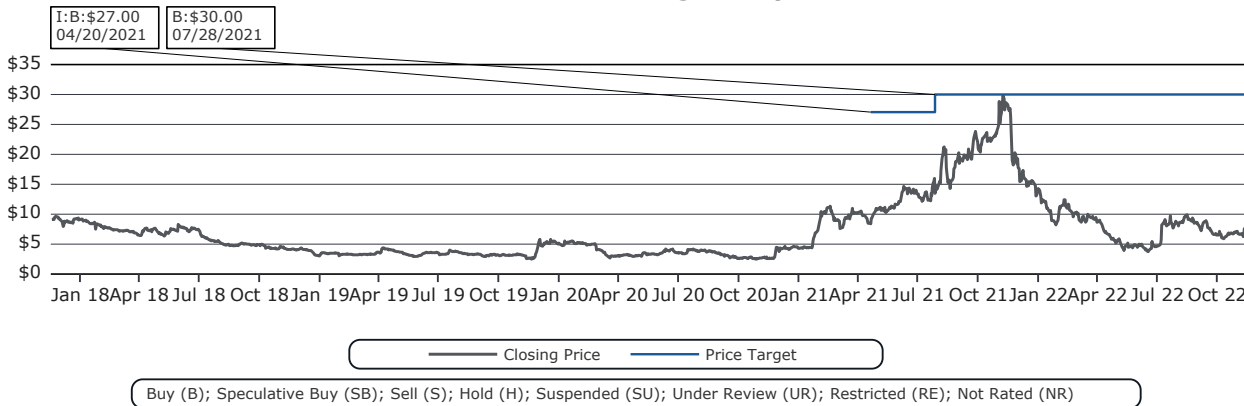
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Oramed Pharmaceuticals Rating History as of 11/16/2022



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