

Oramed Pharmaceuticals

Biotechnology

US Equity Research
28 July 2021

Rating
BUY
unchanged

Price Target
US\$30.00↑
from US\$27.00

ORMP-NASDAQ

Price
US\$13.42

Market Data

52-Week Range (US\$) :	2.40 - 16.63
Market Cap (US\$M) :	436.3
Shares Out., Basic (M) :	32.5
Enterprise Value (US\$M) :	368
Cash (US\$M) :	56.8

FYE Aug 2020A 2021E 2022E

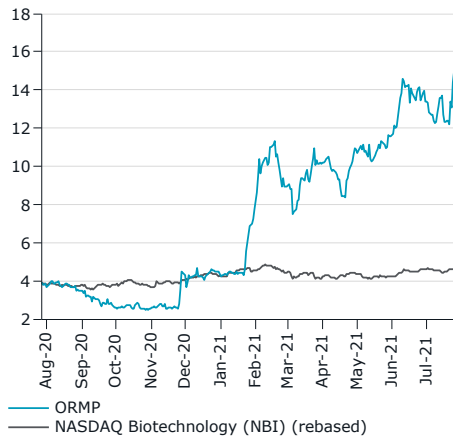
Revenue (US\$M)	2.7	3.7	2.5
EPS GAAP (US\$)	(0.56)	(0.90)↑	(1.52)↓
Previous	-	(1.56)	(1.41)

Quarterly Revenue Q1 Q2 Q3 Q4

2020A	0.7	0.7	0.7	0.7
2021E	0.7A	0.7A	0.7A	1.7
2022E	-	-	-	-

Quarterly EPS GAAP Q1 Q2 Q3 Q4

2020A	(0.15)	(0.21)	(0.10)	(0.13)
2021E	(0.23)A	(0.17)A	(0.17)A	(0.29)
2022E	-	-	-	-



Priced as of close of business 27 July 2021

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ORMP share performance continues to underscore pent-up value; increasing price target from \$27 to \$30

Oramed Pharmaceuticals, Inc. 3Q21 snapshot

	3Q21A	CG 3Q21E	3Q21 Consensus
GAAP EPS (diluted)	-0.17	-0.39	-0.20
REVENUE (\$MM)	0.7	1.8	1.0

BALANCE SHEET	3Q21	2Q21
Cash and cash equivalents (\$MM)	57.4	56.8
LTD (\$MM)	10.0	10.0

UPCOMING CLINICAL / COMMERCIAL MILESTONES

Oral COVID-19 vaccine	2H21	Initiate oral COVID-19 vaccine trial through Oravac Medical
ORMD-0801	YE2021	Complete enrollment of ongoing U.S. Phase III trial (ORA-D-013-1) for T2D
ORMD-0801	YE2023	Top-line data read-out of Phase III trial (ORA-D-013-1)

CHANGES MADE TO FINANCIAL PROJECTIONS

Reduced YE2021 R&D expense projections based on previous nine-month actuals

Added \$11M and corresponding shares from ATM activity in current FY4Q

Source: Company reports and Canaccord Genuity estimates

Based on Oramed's fiscal 3Q21 results we have updated our model accordingly and reiterate our BUY rating and are increasing our 12-month target price from \$27 to \$30. Shares of Oramed continue to demonstrate strong momentum. We believe the current valuation is 100% attributed to the company's Phase III oral insulin program. Recall this is the first oral insulin program to enter Phase III clinical development, and based on previous studies, including the most recent Phase IIb trial, we believe investors are beginning to see the true value and upside potential of this program. We believe shares remain undervalued and would be strong buyers at current levels.

Oramed is currently running a Phase III clinical study in the U.S. (ORA-D-013-1) of its oral insulin candidate ORMD-0801 for the treatment of T2D. The Phase III study has two parts (see [our initiation of coverage](#) for a detailed introduction), and the company anticipates a top-line data read-out in early 2023 with the completion of enrollment expected in 2021. Patient screening for the second part of Phase III started in March 2021. We project a BLA filing and subsequent FDA approval in 2024 under a normal review timeline of ten months.

Figure: Oramed Pharmaceuticals, Inc. (ORMP) - income statement (\$MM) - August Fiscal

	2019	2020					2021E					2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	
		1Q	2Q	3Q	4Q	Year	1Q	2Q	3Q	4Q	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	11.6	24.5	77.9	206.0	485.5	1,089.6	1,482.2	1,916.8	2,426.8	2,962.7	3,134.7	3,316.7	3,552.6	
Collaboration revenue	2.7	0.7	0.7	0.7	0.7	2.7	0.7	0.7	0.7	1.7	3.7	2.5	2.5	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	0.7	0.7	0.7	0.7	2.7	0.7	0.7	0.7	1.7	3.7	2.5	2.5	11.6	24.5	77.9	206.0	485.5	1,089.6	1,482.2	1,916.8	2,426.8	2,962.7	3,134.7	3,316.7	3,552.6	
Cost of U.S. product sales	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	1.2	2.5	7.8	20.6	48.5	109.0	148.2	191.7	242.7	296.3	313.5	331.7	355.3	
Gross profit	2.6	0.7	0.7	0.7	0.7	2.7	0.7	0.7	0.7	1.7	3.7	2.5	2.5	10.4	22.1	70.1	185.4	436.9	980.6	1334.0	1725.1	2184.1	2666.4	2821.2	2985.0	3197.3	
R&D	13.5	2.0	3.3	1.9	3.0	10.2	5.8	3.9	5.5	9.9	25.0	50.0	55.0	60.0	58.0	59.7	61.5	63.4	65.3	67.2	69.3	71.3	73.5	75.7	77.9	80.3	
G&A	3.7	1.1	1.4	1.0	0.7	4.2	0.7	1.7	1.3	1.0	4.7	5.0	6.5	8.0	8.4	8.8	9.3	9.7	10.2	10.7	11.3	11.8	12.4	13.0	13.7	14.4	
Sales expense	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	18.8	31.3	37.5	38.6	39.8	41.0	42.2	43.5	44.8	46.1	47.5	48.9	50.4	
Operating expense	17.2	3.1	4.7	3.0	3.7	14.5	6.5	5.5	6.8	10.9	29.7	55.0	61.5	86.8	97.7	106.1	109.4	112.9	116.5	120.2	124.0	127.9	132.0	136.2	140.6	145.0	
Operating Profit (Loss)	(14.6)	(2.4)	(4.0)	(2.3)	(3.0)	(11.8)	(5.8)	(4.9)	(6.1)	(9.2)	(26.0)	(52.5)	(59.0)	(76.3)	(75.6)	(36.0)	75.9	324.0	864.1	1213.8	1601.1	2056.2	2534.4	2685.0	2844.5	3052.3	
Interest income	1.1	0.2	(0.2)	0.2	0.5	0.7	0.3	0.3	0.5	0.2	1.2	0.8	0.8	0.8	0.8	0.8	0.8	3.2	8.6	12.1	16.0	20.6	25.3	26.9	28.4	30.5	
Interest expense	0.5	0.0	0.0	0.0	0.4	0.4	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	(0.3)	(0.2)	0.2	0.3	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	0.0	0.0	0.0	0.0	0.0	0.0	0.4	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)	(2.5)	(3.7)	(2.3)	(3.0)	(11.5)	(5.6)	(4.6)	(5.2)	(9.0)	(24.8)	(51.7)	(58.2)	(75.5)	(74.8)	(35.2)	76.7	327.3	872.8	1226.0	1617.1	2076.7	2559.8	2711.9	2872.9	3082.8	
Income Tax	0.3	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	20.7	88.4	235.7	331.0	436.6	560.7	691.1	732.2	775.7	832.4		
Tax rate	-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%	27.0%	27.0%	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	
Net Income (Loss)	(14.4)	(2.5)	(3.7)	(2.3)	(3.0)	(11.5)	(5.6)	(4.6)	(5.2)	(9.0)	(24.8)	(51.7)	(58.2)	(75.5)	(74.8)	56.0	238.9	637.1	895.0	1180.5	1516.0	1868.6	1979.7	2097.2	2250.4		
EPS - basic	(\$0.82)	(\$0.15)	(\$0.21)	(\$0.10)	(\$0.13)	(\$0.56)	(\$0.23)	(\$0.17)	(\$0.17)	(\$0.29)	(\$0.90)	(\$1.52)	(\$1.43)	(\$1.57)	(\$1.46)	(\$0.69)	\$1.09	\$4.64	12.4	17.3	22.8	29.2	36.0	38.0	40.2	43.1	
EPS - diluted	(\$0.82)	(\$0.15)	(\$0.21)	(\$0.10)	(\$0.13)	(\$0.56)	(\$0.23)	(\$0.17)	(\$0.17)	(\$0.29)	(\$0.90)	(\$1.52)	(\$1.43)	(\$1.57)	(\$1.46)	(\$0.69)	\$1.09	\$4.64	12.4	17.3	22.8	29.2	36.0	38.0	40.2	43.1	
Weighted average basic shares	17.5	17.5	17.8	23.2	23.7	20.5	23.7	27.0	29.9	31.0	27.6	34.0	40.8	48.0	51.1	51.2	51.3	51.4	51.5	51.6	51.7	51.8	51.9	52.0	52.1	52.2	
Weighted average diluted shares	17.5	17.5	17.8	23.2	23.7	20.5	23.7	27.0	29.9	31.0	27.6	34.0	40.8	48.0	51.1	51.2	51.3	51.4	51.5	51.6	51.7	51.8	51.9	52.0	52.1	52.2	

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: July 28, 2021, 08:24 ET

Date and time of production: July 28, 2021, 08:24 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 07/28/21)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	632	66.74%	43.99%
Hold	143	15.10%	23.78%
Sell	11	1.16%	36.36%
Speculative Buy	152	16.05%	64.47%
	947*	100.0%	

*Total includes stocks that are Under Review

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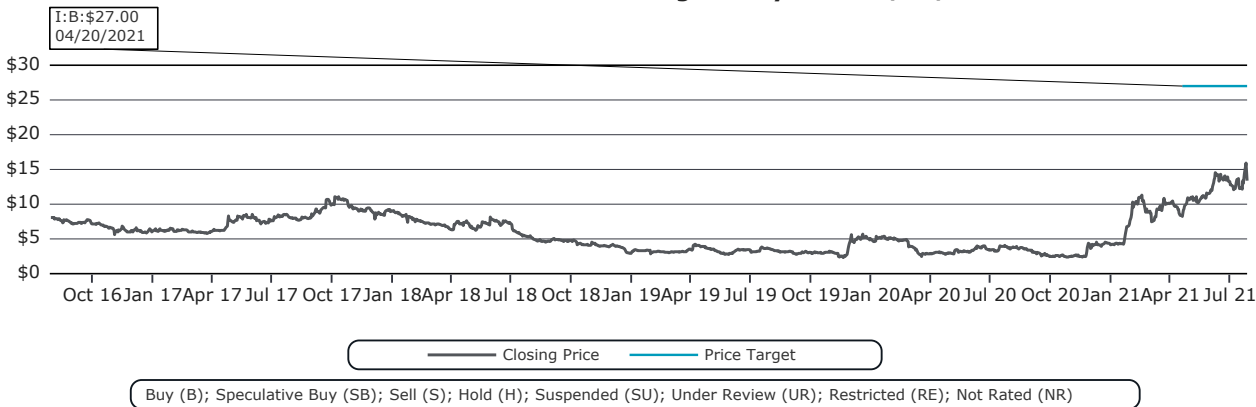
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Oramed Pharmaceuticals Rating History as of 07/27/2021



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