Canaccord Genuity Capital Markets

Estimates Revised

Oramed Pharmaceuticals

Biotechnology

US Equity Research
7 April 2022

Rating	Price Target
BUY *unchanged*	**US$30.00** *unchanged*
ORMP-NASDAQ	Price **US$8.25**

Market Data

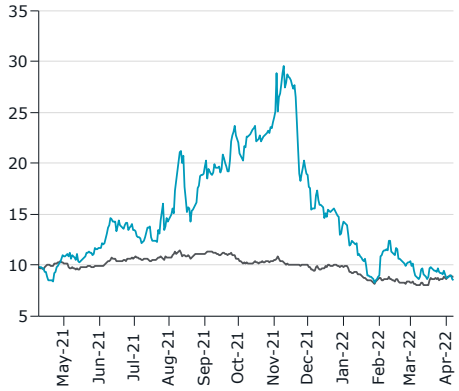
52-Week Range (US$) :	7.52 - 31.54
Market Cap (US$M) :	318.2
Shares Out., Basic (M) :	38.3
Enterprise Value (US$M) :	182
Cash (US$M) :	146.3

FYE Dec	2020A	2021A	2022E
Revenue[1] (US$M)	2.7	2.7	2.7↑
Previous	-	-	*2.5*
EPS GAAP (US$)	(0.56)	(0.78)	(1.13)↑
Previous	-	-	*(1.52)*

[1] : Years prior to 2022 reflect August fiscal year

Quarterly Revenue	Q1	Q2	Q3	Q4
2020A	0.7	0.7	0.7	0.7
2021A	0.7	0.7	0.7	0.7
2022E	0.7	0.7	0.7	0.7

Quarterly EPS GAAP	Q1	Q2	Q3	Q4
2020A	(0.15)	(0.21)	(0.10)	(0.13)
2021A	(0.23)	(0.17)	(0.17)	(0.24)
2022E	(0.27)	(0.35)	(0.33)	(0.25)



Source: FactSet

Priced as of close of business 7 April 2022

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KOL call gives greater insight into major treatment shifts with an oral insulin; Phase III data on track for 2H22

Oramed Pharmaceuticals, Inc. 4Q21* snapshot

	4Q21*A	
GAAP EPS (diluted)	-0.31	
REVENUE ($MM)	0.9	
BALANCE SHEET	**4Q21***	
Cash and cash equivalents ($MM)	146.3	
LTD ($MM)	9.6	
UPCOMING CLINICAL / COMMERCIAL MILESTONES		
ORMD-0801	2H22	Top-line data read-out of Phase III T2D trial (ORA-D-013-1)
ORMD-0801	2H22	Top-line data read-out of Phase II NASH trial
ORMD-0901	1H22	Update on bioavailability (PK and PD) study
ORMD-0901	YE2022	Initiation of oral GLP-1 analog Phase II T2D trial
ORMD-0801	YE2022	Enrollment completeion of Phase III T2D trial (ORA-D-013-2)
CHANGES MADE TO FINANCIAL PROJECTIONS		
Updated model to reflct companies latest financial results		
Estimated a $75M capital raise in 4Q22 assuming positive T2D trial results		
*: The company filed for the transition period from September 1, 2021 to December 31, 2021 and this table reflects the new fiscal schedule for a four-month period.		

Phase III oral insulin data on track for 2H22

Oramed hosted a KOL call discussing the need for oral insulin in type-2 diabetes (T2D) management. We found the call extremely useful and timely given the planned 2H22 top-line readout of the company's first of two Phase III trials for ORMD-0801 oral insulin. The presenters were Dr. Anne Peters, MD, Professor of Medicine at the USC Keck School of Medicine and Director of the USC Clinical Diabetes Program, and Dr. Alexander Fleming, MD, founder and executive chairman of Kinexum, a strategic advisory firm.

Insulin therapy has always been available only in an injectable form. This mode of administration has been an obstacle in optimizing patient treatment for the following reasons:

1. Lack of patient compliance.

2. Inability of physicians to optimize patient treatment because of patient resistance to an injectable.

3. Both patient and physician fear of hypoglycemia, which is a risk associated with injectable insulin.

An oral insulin could open up physician treatment options

Another key issue associated with exogenous insulin is that this is not how our body would normally regulate glycemic levels. In a healthy non-diabetic, the insulin produced by the pancreas enters the liver through the portal vein and is then released as needed throughout the body. Injections, however, have insulin entering directly into the blood circulation, thereby by-passing the regulatory control of the liver. This creates significant shifts in blood glucose, specifically hypoglycemia.

Both KOLs stated that they believe an oral insulin, if approved, would be a very meaningful addition to the treatment protocol for T2D patients and also potentially T1D patients. Many patients who should be on insulin or would benefit from its use earlier in the treatment cycle are currently not due to the difficulties mentioned above. The KOLs believe that if patients could be given insulin at an earlier period in their treatment, the control and progression of the disease would be largely improved.

Prior to the KOL call, Oramed also reported results from a diabetes market survey commissioned by the company from IQVIA. The survey included 88 endocrinologists and 82 primary care physicians in the U.S. and Europe, and 76% of the physicians who participated in the survey responded that they "definitely would" or "probably would" prescribe ORMD-0801 for T2D patients.

Upcoming anticipated clinical catalysts for Oramed

- Six-month top-line efficacy data read-out from the larger ORMD-0801 Phase III study (ORA-D-013-1) anticipated in 2H22.
- Completion of patient enrollment of the second ORMD-0801 Phase III T2D study, ORA-D-013-2, is expected in 2022.
- Top-line data read-out from Phase II study of ORMD-0801 in NASH is expected in 2H22. The study is fully enrolled.

Oramed changes fiscal year to calendar fiscal

On March 30, the company filed a form 10-QT with the SEC for the transition period from September 1, 2021, to December 31, 2021, and provided updated financial results covering the last four months of 2021 ended December 31, 2021. The company recorded a net loss of $12.3M, or ($0.31) per share, for the four-month period. The prior EPS for 4Q21 ended November 30, 2021, was ($0.22). Cash and cash equivalents as of December 31, 2021, were $146.3M.

For the four-month period, R&D expenses were $9.0M, compared to $6.4M for a three-month period ended on November 30, 2021. The R&D expenses were $5.8M for the same three-month period in 2020. G&A expenses for the four-month period ended December 31, 2021, were $3.3M compared to $1.7M and $0.7M for the three month-period ended November 30, 2021, and November 30, 2020, respectively.

Model adjustments

We reiterate our BUY rating for shares of ORMP and maintain our $30 12-month price target. We updated our model with the company's latest financial results, including the three-month period results and four-month period results before and after the transition of the company's fiscal year schedule. We increased our projected probability of success for T2D program from 40% to 45%. We also estimated a $75M capital raise in 3Q22 assuming positive results from the Phase III T2D study and Phase II NASH study.

Figure: Oramed Pharmaceuticals, Inc. (ORMP) - income statement ($MM) - Transition period from September 1, 2021 to December 31, 2021

	2019	2020	2021				2021	FY transition		2022E					2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
	Aug-19	Aug-20	Nov-20	Feb-21	May-21	Aug-21	Aug-21	Nov-21 3 months	Dec-21 4 months	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	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	2.7	0.7	0.7	0.7	0.7	2.7	0.7	0.9	0.7	0.7	0.7	0.7	2.7	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
Total Revenue	**2.7**	**2.7**	**0.7**	**0.7**	**0.7**	**0.7**	**2.7**	**0.7**	**0.9**	**0.7**	**0.7**	**0.7**	**0.7**	**2.7**	**2.7**	**11.6**	**24.5**	**77.9**	**206.0**	**485.5**	**1089.6**	**1482.2**	**1916.8**	**2426.8**	**2962.7**	**3134.7**	**3316.7**	**3552.6**
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	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	2.7	0.7	0.7	0.7	0.7	2.7	0.7	0.9	0.7	0.7	0.7	0.7	2.7	2.7	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	10.2	5.8	3.9	5.5	5.8	21.0	6.4	9.0	10.0	13.0	14.0	13.0	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	4.2	0.7	1.7	1.3	2.2	5.9	1.7	3.3	1.7	1.7	1.3	0.3	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	0.6	0.9	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	14.5	6.5	5.5	6.8	8.1	26.9	8.7	13.2	11.7	14.7	15.3	13.3	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)**	**(11.8)**	**(5.8)**	**(4.9)**	**(6.1)**	**(7.4)**	**(24.2)**	**(8.1)**	**(12.3)**	**(11.0)**	**(14.0)**	**(14.6)**	**(12.6)**	**(52.3)**	**(58.8)**	**(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	0.7	(0.3)	0.3	0.5	0.8	1.2	(0.1)	(0.2)	0.2	0.2	0.4	0.0	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	(0.4)	0.0	0.0	0.0	(0.0)	(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
Loss (gain) fair value of investments	0.0	0.0	0.0	0.0	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
Net loss attributable to non-controlling interests	0.0	0.0	0.0	0.0	0.4	(1.2)	(0.8)	0.0	0.6	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)	(5.6)	(4.6)	(5.2)	(6.9)	(22.2)	(7.9)	(11.7)	(10.8)	(13.8)	(14.2)	(12.6)	(51.5)	(58.0)	(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	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%*	*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*
Net Income (Loss)	**(14.4)**	**(11.5)**	**(5.6)**	**(4.6)**	**(5.2)**	**(6.9)**	**(22.2)**	**(7.9)**	**(11.7)**	**(10.8)**	**(13.8)**	**(14.2)**	**(12.6)**	**(51.5)**	**(58.0)**	**(75.5)**	**(74.8)**	**(35.2)**	**56.0**	**238.9**	**637.1**	**895.0**	**1180.5**	**1516.0**	**1868.6**	**1979.7**	**2097.2**	**2250.4**
EPS - basic	**($0.82)**	**($0.56)**	**($0.23)**	**($0.17)**	**($0.17)**	**($0.24)**	**($0.78)**	**($0.22)**	**($0.31)**	**($0.27)**	**($0.35)**	**($0.33)**	**($0.25)**	**($1.13)**	**($0.99)**	**($1.19)**	**($1.14)**	**($0.54)**	**$0.86**	**$3.65**	**9.7**	**13.7**	**18.1**	**23.2**	**28.6**	**30.3**	**32.1**	**34.4**
EPS - diluted	**($0.82)**	**($0.56)**	**($0.23)**	**($0.17)**	**($0.17)**	**($0.24)**	**($0.78)**	**($0.22)**	**($0.31)**	**($0.27)**	**($0.35)**	**($0.33)**	**($0.25)**	**($1.13)**	**($0.99)**	**($1.19)**	**($1.14)**	**($0.54)**	**$0.86**	**$3.65**	**9.7**	**13.7**	**18.1**	**23.2**	**28.6**	**30.3**	**32.1**	**34.4**
Weighted average basic shares	17.5	20.5	23.7	27.0	29.9	28.5	28.5	36.7	37.1	39.7	39.6	42.6	49.8	45.5	58.6	63.5	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4
Weighted average diluted shares	17.5	20.5	23.7	27.0	29.9	28.5	28.5	36.7	37.1	39.7	39.6	42.6	49.8	45.5	58.6	63.5	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4	65.4

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: April 07, 2022, 23:11 ET

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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 04/08/22)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	647	68.61%	41.11%
Hold	134	14.21%	23.13%
Sell	10	1.06%	20.00%
Speculative Buy	147	15.59%	52.38%
	943*	100.0%	

*Total includes stocks that are Under Review

Canaccord Genuity Ratings System

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

HOLD: The stock is expected to generate risk-adjusted returns of 0-10% during the next 12 months.

SELL: The stock is expected to generate negative risk-adjusted returns during the next 12 months.

NOT RATED: Canaccord Genuity does not provide research coverage of the relevant issuer.

"Risk-adjusted return" refers to the expected return in relation to the amount of risk associated with the designated investment or the relevant issuer.

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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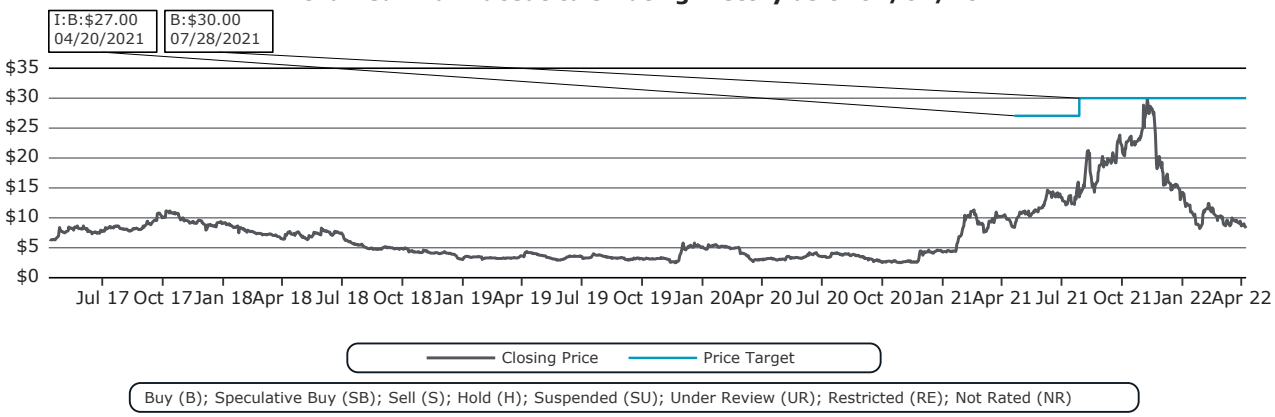
Oramed Pharmaceuticals Rating History as of 04/07/2022



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