

# Oramed Pharmaceuticals Biotechnology

US Equity Research  
23 August 2021

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Rating  
**BUY**  
unchanged

Price Target  
**US\$30.00**  
unchanged

ORMP-NASDAQ

Price  
**US\$15.85**

**Market Data**

52-Week Range (US\$) :	2.40 - 23.57
Market Cap (US\$M) :	515.3
Shares Out., Basic (M) :	32.5
Enterprise Value (US\$M) :	447
Cash (US\$M) :	69.6

FYE Aug	2020A	2021E	2022E
Revenue (US\$M)	2.7	3.7	2.5
EPS GAAP (US\$)	(0.56)	(0.90)	(1.52)

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	-	-	-	-

## Strong clinical progress made for oral insulin in T2D and NASH

### Investment Recommendation

We had the pleasure of hosting Oramed at our 41st Annual Growth Conference. Chief Commercial Officer Michael Rabinowitz joined our discussion and presented the latest corporate update. Mr. Rabinowitz presented data from the clinical programs conducted by the company to date, and emphasized the flagship product, oral insulin, ORMD-0801, designed and developed using the company's proprietary POD (Protein Oral Delivery) technology. In our opinion, the company's lead product, ORMD-0801 has the potential to become the first commercialized orally delivered insulin in the U.S. Oramed also plans on initiating a clinical trial for its oral COVID-19 vaccine in 2H21. We believe shares are currently undervalued and do not represent the company's long-term growth potential. We reiterate our BUY rating for ORMP shares and maintain our target price at \$30.

Figure 1: Revenue build of ORMD-0801 for T2D in the U.S.

	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E
Oramed Pharmaceuticals, Inc. (ORMP)													
T2D Revenue Build													
Type 2 Diabetics (T2D) - U.S.													
U.S. population (MM)	337.6	340.0	342.4	344.9	347.3	349.8	352.3	354.8	357.3	359.8	362.4	364.9	367.5
T2D prevalence rate	10.1%	10.2%	10.3%	10.4%	10.5%	10.6%	10.7%	10.8%	10.9%	11.0%	11.1%	11.2%	11.3%
T2D diagnosis rate	58,086,942	54,913,285	55,865,951	56,840,378	57,844,578	58,874,542	59,929,387	61,012,106	62,122,700	63,261,166	64,427,395	65,621,287	66,842,844
Diagnosed T2D patients, U.S.	26,849,716	27,581,155	28,332,521	29,104,256	30,275,662	31,100,432	31,967,670	32,817,989	33,133,416	33,063,278	32,018,473	30,999,688	30,476,963
Percentage of T2D patients taking injectable insulin	16%	16%	16%	16%	16%	16%	16%	16%	16%	16%	16%	16%	16%
T2D patients that use injectable insulin	4,305,954	4,413,385	4,528,203	4,646,679	4,844,106	4,976,069	5,111,627	5,250,878	5,461,347	5,610,134	5,767,956	5,919,960	6,156,298
ORMD-0801 market penetration	0.1%	0.2%	0.6%	1.5%	3.3%	7.6%	11.6%	11.6%	13.0%	15.0%	15.0%	15.0%	15.0%
Patients adopting ORMD-0801	4,296	8,826	27,199	69,850	159,855	348,325	460,046	577,597	709,975	841,515	864,443	887,993	823,445
WAC per patient per year	\$1,144.4	\$3,269.7	\$3,347.8	\$3,168.8	\$3,577.9	\$3,680.0	\$3,790.4	\$3,901.7	\$4,021.3	\$4,141.9	\$4,266.2	\$4,394.2	\$4,526.0
Gross to net rate	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%
Net realized price per patient per year	\$740.8	\$2,125.2	\$2,176.2	\$2,058.9	\$2,325.9	\$2,397.5	\$2,468.1	\$2,538.5	\$2,608.1	\$2,677.6	\$2,746.1	\$2,813.6	\$2,880.1
U.S. Product Sales - ORMD-0801 for T2D (\$MM)	\$11.6	\$24.5	\$77.9	\$206.0	\$485.5	\$1,089.6	\$1,482.2	\$1,616.8	\$2,426.8	\$2,962.7	\$3,134.7	\$3,316.7	\$3,552.6

Source: Company reports, Canaccord Genuity estimates.

### Estimated 2024 launch of ORMD-0801 for T2D

We believe Oramed has the potential to launch ORMD-0801 as early as 2H24. Our projections assume the initiation of two pivotal Phase III trials which are both now enrolling. As of June 8, 2021, the first Phase III has achieved 50% randomization. We expect top-line data from the Phase III trials in early 2023 followed by a BLA filing. The second Phase III trial was initiated in March 2021.

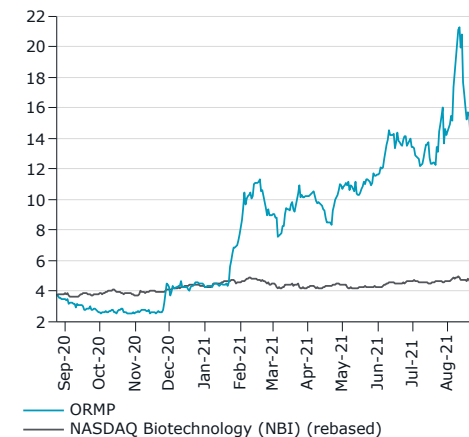
We assume a market launch of ORMD-0801 for T2D in 2H24 targeting patients both on current anti-diabetic drug regimens as well as those using diet for glycemic control. Our peak sales estimate for the T2D indication in the U.S. is ~\$3.6B in 2036 with a peak market penetration of 15% in the U.S. Our revenue build does not include the T1D, NASH, and oral COVID-19 vaccine programs as they are in relatively earlier clinical development stages.

### Investment highlights

- ORMD-0801 has the potential to be a game-changer in the treatment of T2D as an oral insulin
- Oravax is preparing to initiate clinical trials for its oral COVID-19 vaccine in 2H21
- ORMD-0801 is in Phase IIa for the treatment of NASH
- Oramed is in a strong financial position with \$70M cash on hand

### ORMD-0801 has the potential to be a game-changer in treatment of T2D

ORMD-0801 is the first oral insulin program to successfully reach Phase III clinical development. Oramed looks to position ORMD-0801 as an early-stage treatment option for pre-type 2 diabetics. By targeting patients before they need to be on other oral or injectable agents, ORMD-0801 offers the potential to stave off other therapies for a longer period.



Source: FactSet

Priced as of close of business 23 August 2021

Oramed is the only company conducting two Phase III oral insulin studies under an FDA protocol. While the first Phase III trial will assess ORMD-0801's effect in patients who are already on two or three glucose-lowering medications, the second study focuses more on patients who are on diet control alone and metformin monotherapy.

Prior positive results from a Phase IIb study demonstrated a strong glycemic lowering effect of ORMD-0801. The 8mg once daily treatment group showed a 0.95 reduction of HbA1c, compared with 0.14 reduction in the placebo group. A stronger A1c reduction of 1.4 was observed in patients who had a higher baseline level of HbA1c (>9%). The Phase IIb study exhibited a promising safety profile with no increase in adverse events, hypoglycemic events, or weight gain.

If approved, ORMD-0801 will gain 12-year marketing exclusivity in the U.S.

#### **Oravax is prepared for the initiation of the oral vaccine trial**

In March 2021, Oramed announced the joint venture Oravax Medical, which focuses on developing novel oral COVID-19 vaccines. Oravax is based on Oramed's POD technology and Premas Biotech's novel vaccine technology. The oral COVID-19 vaccine will be a VLP (virus-like particles) vaccine targeting three proteins of the SARS-CoV-2 virus: the Spike protein, the membrane protein, and the envelope protein. This triple-antigen vaccine is expected to be effective against variants of the virus.

Mr. Rabinowitz stated that Oravax is ready to initiate a clinical study for the oral vaccine in Israel once approved by the Israeli Ministry of Health. GMP manufacturing for the oral vaccine is underway. The VLP vaccine is being tested in preclinical studies against COVID-19 variants including the Delta variant.

#### **Multiple collaboration for various programs and open to partnerships**

Besides the partnership with Premas on the oral vaccine, Oramed also has another collaboration to develop and commercialize ORMD-0801 in Greater China with Hefei Tianhui Incubator of Technologies Co., Ltd. ("HTIT"). Oramed has received, to date, \$33M in milestone payments from HTIT. Another \$17M payment is expected over the next two to three years. This collaboration started in 2015 and HTIT gets the exclusive right to ORMD-0801 in Greater China. The approval of the IND application was approved by the NMPA in March 2019, and a Phase III study is currently ongoing in China.

When asked about whether the company has plans to form partnerships for its NASH program, Mr. Rabinowitz stated that Oramed is open to all types of partnerships once more data become available from the two ongoing Phase II studies. With many very established players in the insulin market, Mr. Rabinowitz believes that ORMD-0801 has a clear advantage in being orally delivered. The company is looking at multiple scenarios in terms of building the commercial capabilities to prepare for potential product launch and is also open to ex-U.S. partnership and license opportunities.

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### Investment Recommendation

Date and time of first dissemination: August 23, 2021, 23:01 ET

Date and time of production: August 23, 2021, 23:01 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 08/23/21)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	636	66.32%	44.81%
Hold	160	16.68%	26.25%
Sell	9	0.94%	33.33%
Speculative Buy	145	15.12%	61.38%
	959*	100.0%	

\*Total includes stocks that are Under Review

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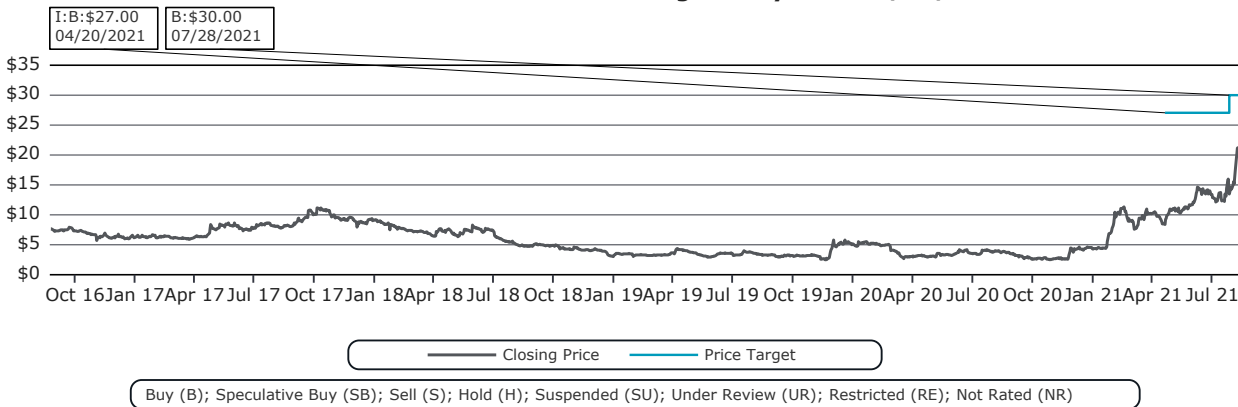
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