



September 12, 2022

Key Metrics

ORMP - NASDAQ	\$8.52
Pricing Date	September 12 2022
Price Target	\$30.00
52-Week Range	\$31.54 - \$3.59
Shares Outstanding (mm)	38.8
Market Capitalization (mm)	\$330.8
3-Mo Average Daily Volume	1,387,498
Institutional Ownership	24%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	\$4.47
Price/Book	1.9x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPSFY: August

	2021A	Prior 2022	Curr. 2022E	Prior 2023E	Curr. 2023E
1Q-nov	(0.23)	--	(0.27)A	(0.29)E	(0.28)E
2Q-feb	(0.17)	(0.28)E	(0.27)A	(0.29)E	(0.27)E
3Q-may	(0.17)	(0.28)E	(0.29)E	(0.29)E	(0.26)E
4Q-aug	(0.15)	(0.28)E	(0.29)E	(0.29)E	(0.25)E
FY	(0.78)	(1.12)E	(1.13)E	(1.15)E	(1.06)E
P/E					

Revenue (M)

	2021A	Prior 2022	Curr. 2022E	Prior 2023E	Curr. 2023E
1Q-nov	0.7	--	0.7A	--	0.7E
2Q-feb	0.7	--	0.7A	--	0.7E
3Q-may	0.7	--	0.7E	--	0.7E
4Q-aug	0.7	--	0.7E	--	0.7E
FY	2.7	--	2.7E	--	2.7E

Company Description:

Oramed Pharmaceuticals, Inc. is a clinical-stage biotechnology company that is developing orally formulated therapeutics, including an oral insulin and, through subsidiary Oravax Medical, an oral Covid-19 vaccine. The company was founded in 2006 and has offices in New York and Jerusalem.

Oramed Pharmaceuticals, Inc.

Rating: Buy

Clinical Updates, 2Q Recap; Discuss ORMD-0801

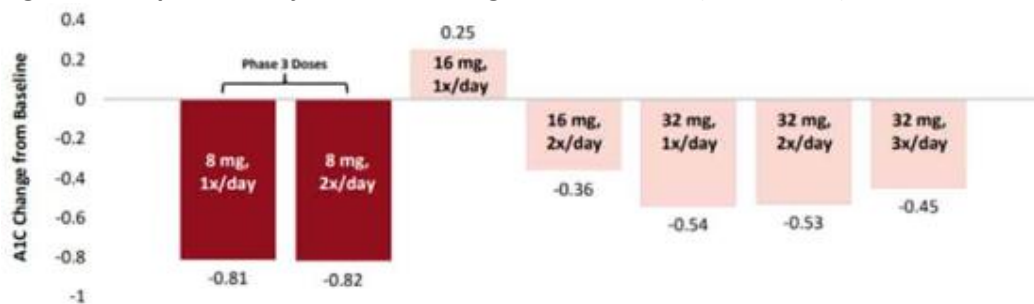
Outlook

Investment Highlights:

- Summary.** Oramed is developing a platform of orally administered large molecule therapeutics. The company is currently running two phase 3 studies of ORMD-0801 (oral insulin). In May, the company announced that it had completed enrollment of ORA-D-013-1, its first phase 3 study of ORMD-0801, in patients with type 2 diabetes (T2DM), with a total of 710 patients (vs a target of 675), and in July, 50% enrollment (vs planned n of 450) was announced in ORA-D-013-2, the second phase 3. We expect topline results in January 2023 for the first phase 3. Additionally, we anticipate phase 2 data on ORMD-0801 in NASH in 3Q22, and ORMD-0901 (oral GLP-1) bioavailability data in 4Q22.
- Recent updates.** Oramed shared its financial results for 2Q22 (on 8/10), with revenue of \$0.7mm in-line with expectations. Total OpEx was \$12.1mm vs \$5.1mm in 2Q21. As of 6/30, Oramed had ~\$134mm of cash, equivalents, securities, and deposits, and no debt. On 9/1, Oramed entered into a non-binding MOA with Medicox for 10-year commercialization exclusivity, pending regulatory approval, in Korea, including a \$2mm upfront payment.
- ORA-D-013-1 and -013-2.** The fully-enrolled phase 3 study is the first and larger of the two phase 3 studies. Enrolled patients are those with T2DM and inadequate glycemic (blood sugar) control on two or three oral glucose lowering agents. Dosing schemes include 8mg 1x/day at night and placebo 45-mins before breakfast, 8mg 2x/day at night and 45-mins before breakfast, and placebo 2x/day at night and 45-mins before breakfast. The primary endpoint is glycemic control (mean change from baseline in A1C) at 26-weeks. The second phase 3 study is studying 8mg of ORMD-0801 in patients with inadequate glycemic control who are on no medications or only metformin (1L T2DM treatment).
- Our view on ORMD-0801.** Oramed is attempting to be the first mover in bringing an oral insulin to the market. The phase 2 results included placebo-adjusted A1C lowering of ~0.8 in the two 8mg arms. We've previously noted the trial's non-linear dose response. The two phase 3 studies bifurcate the addressable patients into, basically, early vs later-stage T2DM, and we believe an oral insulin with even modest A1C lowering benefits could add value to the treatment landscape, given the convenience benefits of an oral therapeutic.
- Rating and target.** We rate shares of ORMP a BUY with a \$30 price target. We value shares with a discounted cash flow model incorporating a 15% discount rate and a forecast of mid-single-digit-% peak share of the insulin market in the U.S., along with a PoS adjustment. Option value is ascribed to the balance of the pipeline. Risks include: 1) clinical trial outcomes, 2) financial, 3) regulatory, 4) competition, 5) operational, 6) Covid-19, 7) macro, and others.

ORMD-0801 Phase 2b

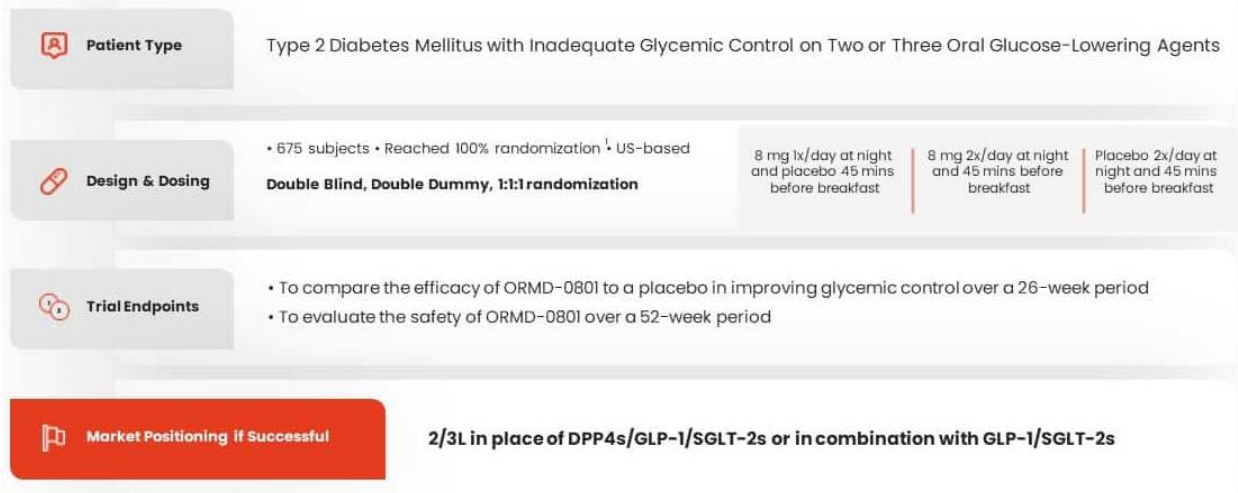
Fig. 1. Mean placebo-adjusted A1C change from baseline (at week 12)



Source: Oramed

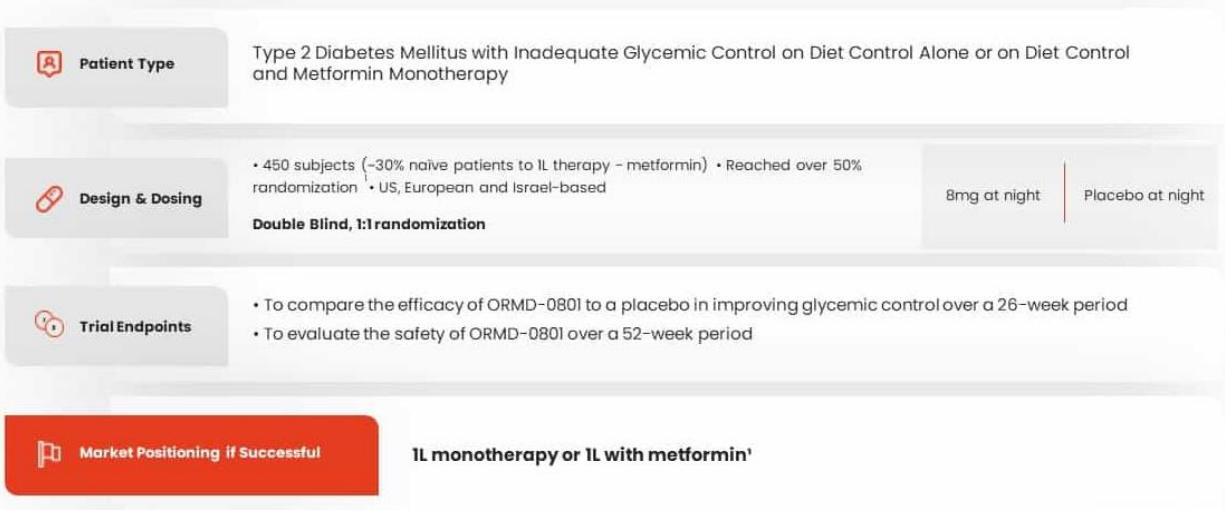
ORMD-0801 phase 3 trials

Fig. 2. ORA-D-013-1



Source: Oramed

Fig. 3. ORA-D-013-2



Source: Oramed

Valuation summary

Discounted cash flow - valuation summary

Interim years value	\$567,180,585
Terminal value	\$590,411,606
Total value	\$1,157,592,191

Oral insulin

Peak insulin market share	6.0%
Peak sales estimate	\$1,098,023,898
Discount rate	15%
Terminal growth rate	2%

Price target	\$30
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Source: Aegis Capital estimates

Income statement

	FY:19A	FY:20A	FY:21A	FY:22E				FY:23E					
	FY:19A	FY:20A	FY:21A	1QA	2QA	3QE	4QE	FY:22E	1QE	2QE	3QE	4QE	FY:23E
	8/31/2019	8/31/2020	8/31/2021	3/31/2022	6/30/2022	9/30/2022	12/31/2022	12/31/2022	3/31/2023	6/30/2023	9/30/2023	12/31/2023	12/31/2023
Revenues	2.7	2.7	2.7	0.7	0.7	0.7	0.7	2.7	0.7	0.7	0.7	0.7	2.7
<i>Growth</i>													
Cost of revenues	0.1												
Gross profit	2.6	2.7	2.7	0.7	0.7	0.7	0.7	2.7	0.7	0.7	0.7	0.7	2.7
<i>Gross margin</i>													
Research and development	13.5	10.2	21.0	5.8	9.2	9.3	9.4	33.6	9.5	9.6	9.6	9.7	38.4
Sales and marketing				0.6	0.4			1.0					
General and administrative	3.7	4.2	5.9	5.5	2.5	2.6	2.6	13.2	2.7	2.7	2.8	2.9	11.1
Operating gain (loss)	(14.6)	(11.8)	(24.2)	(11.3)	(11.4)	(11.2)	(11.3)	(45.2)	(11.5)	(11.6)	(11.8)	(11.9)	(46.8)
<i>Operating margin</i>													
Interest income	1.1	0.7	1.2	0.5	0.4			0.9					
Interest expense	0.5	0.4	0.0										
Income (loss) from changes in fair value of investments													
Income (loss) before tax	(14.1)	(11.5)	(23.0)	(10.7)	(11.1)	(11.2)	(11.3)	(44.3)	(11.5)	(11.6)	(11.8)	(11.9)	(46.8)
Tax	0.3												
Net income	(14.4)	(11.5)	(23.0)	(10.7)	(11.1)	(11.2)	(11.3)	(44.3)	(11.5)	(11.6)	(11.8)	(11.9)	(46.8)
Unrealized income on available for sale securities													
Total other OCI													
Total comprehensive gain (loss)													
NCI			0.8	0.3	0.5			0.8					
Net income			(23.0)	(10.4)	(10.5)			(21.0)					
Diluted gain (loss) per share	(0.82)	(0.56)	(0.78)	(0.27)	(0.27)	(0.29)	(0.29)	(1.13)	(0.28)	(0.27)	(0.26)	(0.25)	(1.06)
<i>Diluted weighted average shares outstanding</i>	<i>17.45</i>	<i>20.53</i>	<i>28.47</i>	<i>38.68</i>	<i>38.80</i>	<i>39.21</i>	<i>39.62</i>	<i>39.07</i>	<i>41.50</i>	<i>43.38</i>	<i>45.26</i>	<i>47.15</i>	<i>44.32</i>

Source: Aegis Capital estimates; company filings

Required Disclosures

Price Target

Our price target on ORMP is \$30

Valuation Methodology

We value ORMP using a discounted cash flow analysis.

Risk Factors

- **Development risk.** Drugs in clinical development may not advance due to inadequate safety, efficacy, or patient tolerance. The outcomes of clinical trials are risky and inherently unknowable ex ante. A negative clinical trial outcome could cause shares to decline in value.
- **Regulatory risk.** Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a drug candidate at all.
- **Dilution risk.** The firm may require substantial funding to complete the clinical development of its candidates and establish commercial infrastructure, and future capital raises could be dilutive to existing shareholders.
- **Competition risk.** We expect competition for the company's drugs from several public and private companies developing pharmaceuticals.
- **Reimbursement risk.** Sales of the firm's drugs could depend upon reimbursement from private, as well as public, reimbursement agencies.
- **Market risk.** Even if the company succeeds in clinical trials and gaining approval to market its drug, it could struggle or fail to gain market acceptance, especially given its differentiated profile versus existing therapeutic options.
- **Other risks.** There may be other risks, including COVID, other externalities, key man, or other risks. Our failure to state a risk specifically does not obviate its presence or potential impact on the value or price of shares in Oramed.

For important disclosures go to www.aegiscap.com.

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Investment Banking Services/Past 12 Mos.

Rating	Percent	Percent
BUY [BUY]	93.18	46.34
HOLD [HOLD]	6.82	16.67
SELL [SELL]	0.00	0.00

Meaning of Ratings

- A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
- B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
- C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

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