



AEGIS CAPITAL CORP

November 2, 2021

Key Metrics

ORMP - NASDAQ	\$25.32
Pricing Date	Nov 2 2021
Price Target	\$35.00
52-Week Range	\$25.68 - \$2.47
Shares Outstanding (mm)	32.5
Market Capitalization (mm)	\$822.9
3-Mo Average Daily Volume	806,904
Institutional Ownership	12%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	\$2.23
Price/Book	11.4x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS FY: August

	Prior 2020A	Curr. 2021E	Prior 2021E	Curr. 2022E	Prior 2022E
1Q-Nov	(0.15)	--	(0.23)A	(0.13)E	(0.15)E
2Q-Feb	(0.21)	--	(0.17)A	(0.12)E	(0.15)E
3Q-May	(0.10)	(0.14)E	(0.17)A	(0.12)E	(0.14)E
4Q-Aug	(0.13)	(0.13)E	(0.16)E	(0.12)E	(0.14)E
FY	(0.56)	(0.66)E	(0.74)E	(0.49)E	(0.59)E
P/E					

Revenue (M)

	Prior 2020A	Curr. 2021E	Prior 2021E	Curr. 2022E	Prior 2022E
1Q-Nov	0.7	--	0.7A	--	0.7E
2Q-Feb	0.7	--	0.7A	--	0.7E
3Q-May	0.7	--	0.7A	--	0.7E
4Q-Aug	0.7	--	0.7E	--	0.7E
FY	2.7	--	2.7E	--	2.7E

Company Description:

Oramed Pharmaceuticals, Inc. is an 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.

Company Update / Price Target Change / Estimates Change

Oramed Pharmaceuticals, Inc.

Rating: Buy

Oral Insulin And Oravax Medical Both Progressing;
Reiterate BUY, Raise PT

Investment Highlights:

- Summary.** Following significant progress across Oramed's numerous clinical-stage programs, especially ORMD-0801, oral insulin for indications including type 2 diabetes (T2DM) and nonalcoholic steatohepatitis (NASH), and with the Covid-19 vaccine program at subsidiary Oravax Medical, along with making a key commercially-focused hire, we're highlighting the company's progress and reconsidering the upside potential, which we feel is considerable. Shares of ORMP have fared well so far in 2021, +491% YTD, significantly outperforming the biotech industry overall, with, for instance, the S&P Biotech ETF (XBI; NR) down 8% YTD.

- Updates.** Oramed has made significant progress with ORMD-0801 for the treatment of T2DM, including announcing in August (8/24) near 65% enrollment in ORA-D-013-1 (the first and larger of the phase 3 trials; planned n=675) and 25% enrollment in ORA-D-013-2 (planned n=450). Given that we're now in October, we think it likely that enrollment has continued to advance meaningfully since then. We expect topline results in 2022 and believe a successful outcome and subsequent FDA approval would position Oramed advantageously as the first mover with an oral insulin product. As a reminder, Oramed embarked on its phase 3 program subsequent to readout of a successful phase 2 study, which we've previously discussed, including in our July 2020 [update](#). Additionally, in September (9/15), Oramed announced over 50% enrollment of its phase 2 study of ORMD-0801 in patients suffering from nonalcoholic steatohepatitis (NASH). Efficacy endpoints in the study will include change in liver fat content, fibrosis, and steatosis measured via MRI-PDFF after 12-weeks of treatment. In addition, Oramed has been making progress with Oravax Medical (discussed below), and - in what we consider a meaningful vote of confidence - the company announced the hiring of industry veteran Michael Rabinowitz as Chief Commercial Officer (effective 8/1). Mr. Rabinowitz formerly held multiple senior commercial and financial roles at Merck (MRK; NR) over the course of two decades.

- Oravax Medical.** As a reminder, Oravax medical is Oramed's majority-owned subsidiary representing a JV between Oramed and Premas Biotech. Oravax is developing an oral Covid-19 vaccine utilizing Premas' virus-like particle vaccine technology to target three SARS CoV-2 virus surface proteins, administered via Oramed's proprietary oral encapsulation technology. Oramed announced (10/29) that Oravax had received South African approval to initiate a phase 1 trial. In our view, an oral Covid vaccine could have significant value as a booster option particularly if and as Covid-19 proves to be an endemic indication. We think Oravax could make an interesting standalone company at some point ahead.

- Valuation and estimates.** We rate shares of ORMP a BUY and raise our price target to \$35 (from \$20). Our updated price target is predicated on a discounted cash flow valuation. Among other adjustments, we now treat Oravax Medical as tangible value in the model. At 5/31, cash and equivalents were \$57mm, while deposits and marketable securities in the aggregate were another ~\$20mm. Risks include: 1) clinical, 2) financial, 3) operational, 4) competition, 5) regulatory, and other.

Valuation

Discounted cash flow - valuation summary

Interim years value	\$891,435,889
Terminal value	\$198,287,063
Total value	\$1,145,377,019

Oral insulin

Peak insulin market share	2.05%
Peak sales estimate	\$265,189,359
Discount rate	12%
Terminal growth rate	2%

Oravax Medical

Peak Covid vaccine booster share	8%
Discount rate	20%
Terminal growth rate	2%
Oravax Medical (Oramed share)	\$55,654,067

Price target	\$35
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Source: Aegis Capital estimates

Income statement

	FY:19A		FY:20A		FY:21E				FY:22E			
	FY:19A 8/31/2019	FY:20A 8/31/2020	1Q A 11/30/2020	2Q A 2/28/2021	3Q A 5/31/2021	4QE 8/31/2021	FY:21E 8/31/2021	1QE 11/30/2021	2QE 2/28/2022	3QE 5/31/2022	4QE 8/31/2022	FY:22E 8/31/2022
Revenues	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	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	5.8	3.9	5.5	5.0	20.1	4.9	4.8	4.7	4.6	18.8
General and administrative	3.7	4.2	0.7	1.7	1.3	1.3	5.0	1.3	1.4	1.4	1.4	5.6
Operating gain (loss)	(14.6)	(11.8)	(5.8)	(4.9)	(6.1)	(5.6)	(22.4)	(5.5)	(5.5)	(5.4)	(5.3)	(21.7)
<i>Operating margin</i>												
Interest income	1.1	0.7	0.3	0.3	0.5	0.5	1.5	0.5	0.5	0.5	0.5	2.0
Interest expense	0.5	0.4										
Income (loss) from changes in fair value of investments												
Income (loss) before tax	(14.1)	(11.5)	(5.6)	(4.6)	(5.6)	(5.1)	(20.9)	(5.0)	(5.0)	(4.9)	(4.8)	(19.7)
Tax	0.3											
Net gain (loss)	(14.4)	(11.5)	(5.6)	(4.6)	(5.6)	(5.1)	(20.9)	(5.0)	(5.0)	(4.9)	(4.8)	(19.7)
Unrealized income on available for sale securities												
Total other OCI												
Total comprehensive gain (loss)												
Diluted gain (loss) per share	(0.82)	(0.56)	(0.23)	(0.17)	(0.17)	(0.16)	(0.74)	(0.15)	(0.15)	(0.14)	(0.14)	(0.59)
<i>Diluted weighted average shares outstanding</i>	17.45	20.53	23.75	27.00	29.93	32.51	28.30	32.93	33.34	33.75	34.16	33.54

Source: Aegis Capital estimates; company filings

Required Disclosures

Price Target

Our price target on ORMP is \$35

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.
- **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.
- **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.

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Investment Banking Services/Past 12 Mos.		
Rating	Percent	Percent
BUY [BUY]	93.94	40.86
HOLD [HOLD]	6.06	33.33
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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