James Molloy
(617) 283-5521, jmolloy@allianceg.com
Sales & Trading 888-543-4448

Oramed Pharmaceutical, Inc.

Buy

Volatility: 5

Price Target Change

Estimate Change

(NASDAQ: ORMP)

Price	$6.58
52 Week Range	($3.59 - $29.24)
Price Target	**$35.00**
Market Cap (mil)	$350.22
Shares out (mil)	38.83
3-Mo Avg Vol	274,035
Cash per share	$4.15
Total Debt (mil)	NA
Debt/Equity	NA

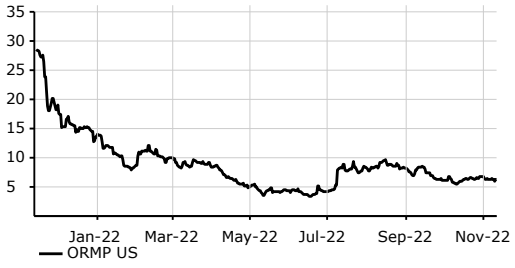
*General: * Switch to Dec FY in 1Q22*

EPS $

Yr Aug	2021A	2022E		2023E	
	Actual	Curr	Prev	Curr	Prev
Nov	(0.22)A	(0.31)A	–	(0.23)E	(0.21)E
Feb	(0.17)A	(0.27)A	(0.54)A	(0.24)E	(0.21)E
May	(0.17)A	(0.18)A	(0.20)E	(0.26)E	(0.22)E
Aug	(0.06)A	(0.19)E	(0.20)E	(0.27)E	(0.21)E
YEAR	(0.78)A	(0.95)E	(1.25)E	(1.00)E	(0.85)E

Revenues (millions) $

Yr Aug	2021A	2022E		2023E	
	Actual	Curr	Prev	Curr	Prev
Nov	1A	1A	–	1E	–
Feb	1A	1A	–	1E	–
May	1A	1A	–	1E	–
Aug	1A	1E	–	1E	–
YEAR	3A	3E	–	3E	–



ORMP-0801 approaching a significant inflection point with 1Q23 top line data

ORMP recently reported their 3Q22 results detailing the completion of some significant milestones, particularly the positive results gathered from their Phase 2 nonalcoholic fatty liver disease (NASH) clinical trial of their ORMD-0801 oral insulin product candidate. This trial (ORA-D-N020) demonstrated a clinically meaningful reduction of liver fat in treated patients from baseline at 12 weeks, with a positive safety profile, showcasing the potential this candidate has in targeting both diabetes and NASH. ORMP is currently conducting two Phase 3 clinical trials (ORA-D-013-1 and -2) of 8 mg ORMD-0801 to determine its efficacy in T2D patients. ORA-D-013-1 remains apace with expectations to have topline results announced in January 2023, in-line with expectations. ORA-D-013-1 continues enrolling patients with the last enrollment update provided this past July noting 50% enrollment completion on its targeted 450 patients.We anticipate this confirmatory trial could read out top-line data in mid-2023. While there are multiple options available to treat Type 2 Diabetes (T2DM), we believe that an effective oral insulin option like ORMD-0801 could rapidly gain significant acceptance in the T2DM population over injected options. We estimate that if approved ORMD-0801 could reach $850M in sales by 2030, the 6th year of launch. By comparison, Eli Lilly's (LLY, NR) injectable GLP-1 agonist Trulicity (dulaglutide) is projected to hit $4.9B in WW sales in 2020, the 6th year of launch. ORMP's oral COVID-19 vaccine program remains underway in an open label Phase 1 trial with the South African Health Products Regulatory Authority. Preliminary data was positive in early October, with the vaccine eliciting an immune response, providing protection against COVID-19, with the potential to also protect against prevalent and emerging COVID-19 strains. We are reiterating our Buy rating but lowering our price target to $35 from $40 previously. We have lowered our price target based on our expectation for a longer clinical trial for the oral COVID-19 vaccine. We now assume ORMP will be required to conduct a Phase 2 trial, rather than getting an Emergency Use Authorization (EUA) after the Phase 2 trials. We have also lowered our expectations for cash at the end of 2023, based on our current spending projections. Our price target is based on a sum-of-the-parts with ORMD-0801 for T2DM as the majority of the reason to own ORMP, valued at $25/share, Oravax oral vaccine for COVID-19 valued at $2/share, ORMD-0801 for NASH valued at $3/share, and the remaining programs (ORMP-0901, oral leptin) plus cash (end-FY23) at $5/share.

ORMD-0801's efficacy in reducing liver fat in NASH patients showcased in Phase 2 ORA-D-N02 trial. Positive topline results from the Phase 2 clinical trial of ORMD-0801 in Type 2 Diabetes patients with NASH were announced this past September. ORA-D-N02 is a double-blind, randomized, placebo-controlled, multi-center 12-week study in which 32 patients (30 who completed) were treated with either 8 mg ORMD-0801 dosed twice daily or placebo. Results detailed ORMD-0801 treatment to be effective in reducing liver fat, as noted through the percentage Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF), as well as steatosis and fibrosis measured through fibroscan, lipids, and HbA1c, all of which aid in determining the stage of a patient's liver disease. Through this, it may be gathered that ORMD-0801 possesses the potential to target both diabetes and NASH, a positive as a single agent may be applied to these two commonly co-occurring conditions in patients. No difference in adverse events for ORMD-0801 compared to placebo were also found, suggesting a positive safety profile for this candidate.

Phase 3 clinical trials progressing, topline data expected early 2023. The ORA-D-013-1 trial is the larger of the two Phase 3 trials and is designed to study 8 mg ORMD-0801 1x daily at night and placebo 45 minutes before breakfast, 8 mg ORMD-0801 2x daily, at night, and 45 minutes before breakfast, as well as placebo 2x daily, at night, and 45 minutes before breakfast in 710 patients with T2D who are also on 2-3 oral glucose-lowering agents to aid in managing their diagnosis. The primary endpoint includes determining the efficacy of ORMD-0901 vs placebo, as determined by HbA1c levels, and the secondary endpoint is to assess the change in fasting plasma

glucose from baseline at 26 weeks. With enrollment for this trial now complete, the company expects topline results to be announced in January 2023.

The ORA-D-013-2 clinical trial is also progressing as it is halfway through enrolling its planned 450 patients across 36 sites in the US and 25 sites in Europe and Israel. The study is set to study 8 mg ORMA-08-1 administered at night vs placebo with the primary and secondary endpoints mirroring those of the ORA-D-013-1 trial. Topline results for this trial are also expected in January 2023, with an aim to file a Biologics License Application (BLA) with the FDA in 2024.

ORMD-0801 could revolutionize treatment of T2DM. ORMD-0801 utilizes ORMP's Protein Oral Delivery (POD) technology, which is designed to protect orally delivered proteins through the stomach to be released in the lower intestine. We believe that an effective oral version of injectable insulin would grab significant market share, and could potentially replace injected insulin altogether.

Early data from oral vaccine trial suggest vaccine's potency in protecting against COVID-19. The Phase 1 clinical trial of ORMP's oral vaccine candidate is an open-label, first-in-human, proof-of-concept, dose escalation, dose-finding trial to determine the safety, tolerability, and immunogenicity of a low and high dose of this vaccine candidate in up to 24 patients. Results from the first cohort (n=12), which were administered the low dose oral COVID-19 vaccine, have been positive and established that the vaccine presented a significant immunoglobulin G (IgG) antibody response that was 2-6-fold over baseline, representing a potent immune response. This trial is also set to continue with an additional 12 patients to be treated with the high dose of the oral COVID-19 vaccine. We now anticipate this vaccine will likely require a Phase 3 trial, rather than ORMP seeking an EUA after Phase 2.

Reiterate Buy rating, lowering our price target to $35 from $40 previously. We have lowered our price target based on our expectation for a longer clinical trial for the oral COVID-19 vaccine. We now assume ORMP will be required to conduct a Phase 2 trial, rather than getting an Emergency Use Authorization after the Phase 2 trials. We have also lowered our expectations for cash at the end of 2023, based on our current spending projections. Our price target is based on a sum-of-the-parts with ORMD-0801 for T2DM valued at $25/share, Oravax oral vaccine for COVID-19 valued at $2/share, ORMD-0801 for NASH valued at $3/share, and the remaining programs (ORMP-0901, oral leptin) plus cash (end-FY23) at $5/share.

Valuation:

We value Oramed Pharmaceutical, Inc. at $35/share based on a sum-of-the-parts primarily due to our expectations for ORMP-0801 for Type 2 Diabetes (T2DM). We anticipate ORMP receives FDA/EMA approval for ORMP-0801 for T2DM in 1H25, with a launch also in 1H25Y25. We anticipate WW sales reaching $850M by FY30. We place a 4x multiple on WW sales, discounted back 7 years at 15% for our $25/share value. We value Oravax at $2/share based on expectations for approval and $200M in sales by 2030. We place a 4x multiple on sales discounted back 4 years at 35%. We anticipate ORMD launches ORMD-0801 for NASH in FY27 with US sales reaching $350M by FY30. We place a 4x multiple on US sales, discounted back 8 years at 40% for our $3/share value. We value the remaining technology at ORMP (ORMP-0901 oral GLP-1 analog, Oral leptin for weight loss) and cash (end FY23E) at $5/share for our $35/share valuation.

Risks to achievement of target price:

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

Raising additional capital may cause dilution. If the company requires additional funding through raises in equity offerings, or similar financial instruments shareholders' ownership interests will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect shareholders' rights.

Please see the company's SEC filings for a more comprehensive discussion of potential risks.

Company description:

Oramed is developing oral delivery solutions for drugs delivered via injection. The company focuses in the research and development of pharmaceutical solutions, including an oral insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules or pills for delivery of other polypeptides including COVID-19 vaccines. The company was founded by Nadav Kidron and Miriam Kidron on April 12, 2002 and is headquartered in New York, NY.

Figure 1: Sum-of-the-Parts Analysis

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
ORMD-0801 for T2D	$1,118,657	$25.00
Oravax oral COVID vaccine	$92,191	$2.00
ORMD-0801 for NASH	$142,771	$3.00
Cash (end-'FY23E)	$247,317	$5.00
SUM	$1,600,936	**$35.00**
FY23 fully diluted shares out		44,350

Source: Company presentation

Figure 2: Variance analysis

Oramed Pharmaceuticals
Variance analysis

(000's)	3Q21A May 21	3Q21A	3Q21E	Variance	% Y/Y
License revenues	$681	$682	$681	$1	$0
Total Revenue	**$681**	**$682**	**$681**	**$1**	**0%**
R&D Expense	5,502	5,347	7,000	(1,653)	-3%
SG&A Expense	1,297	3,524	1,500	2,024	172%
Operating Income	**(6,118)**	**(8,189)**	**(7,819)**	**(370)**	**34%**
Interest Inc, net	493	1,036	100	936	110%
Income Taxes	0	100		100	NM
Other income	418	193		193	-54%
Net Income	**(5,207)**	**(7,060)**	**(7,719)**	**659**	**36%**
Wgtd Avg Shares (000)	29,930	39,100	39,233	(133)	31%
EPS	**($0.17)**	**($0.18)**	**($0.20)**	**$0.02**	**4%**

Source: Company reports

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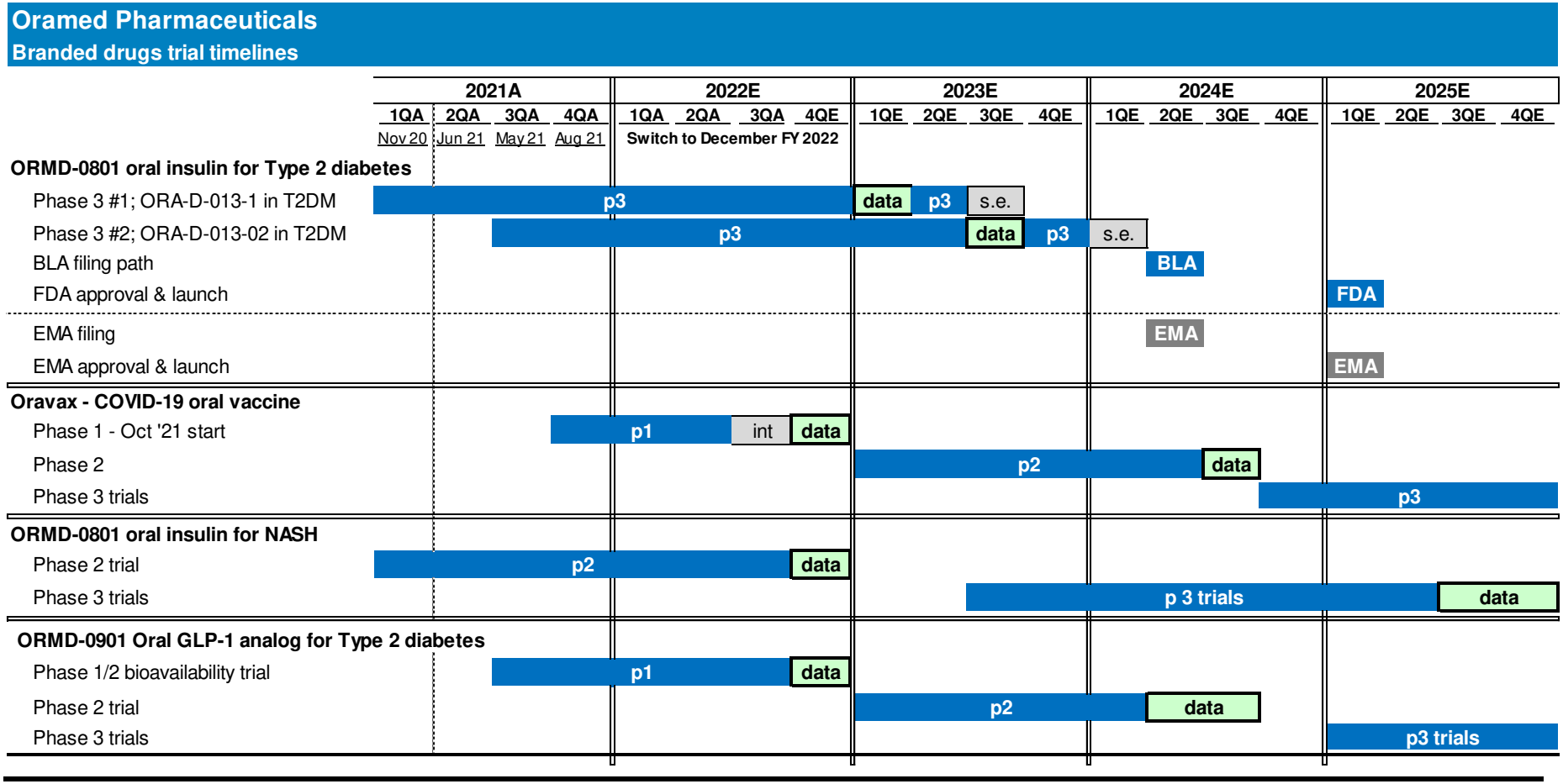
Figure 3: Potential clinical trial timelines



Source: Company reports; AGP estimates

Figure 4: Quarterly Income Statement

Oramed Pharmaceuticals
Quarterly income statement

($000 except per share)	2021A 1QA Nov 20	2021A 2QA Jun 21	2021A 3QA May 21	2021A 4QA Aug 21	2021A Year Aug 21	2022E 1QA	2022E 2QA	2022E 3QA	2022E 4QE	2022E Year
						Switch to December FY 1Q22				
ORMD-0801 sales										
License revenues	$674	$1,340	$681	$681	$3,376	$681	$674	$682	$681	$2,718
Total revenues	**$674**	**$1,340**	**$681**	**$8**	**$2,703**	**$904**	**$674**	**$682**	**$681**	**$2,941**
Expenses										
COGS					0					0
Gross profits	**674**	**1,340**	**681**	**8**	**2,703**	**904**	**674**	**682**	**681**	**2,941**
Research & development	5,774	9,366	5,502	347	20,989	9,037	9,179	5,347	6,500	30,063
Selling, general & admin	727	3,028	1,297	885	5,937	4,193	2,912	3,524	3,750	14,379
Total operating expenses	6,501	12,394	6,799	1,232	26,926	13,230	12,091	8,871	10,250	44,442
Income (loss) from ops	**(5,827)**	**(11,054)**	**(6,118)**	**(1,224)**	**(24,223)**	**(12,326)**	**(11,417)**	**(8,189)**	**(9,569)**	**(41,501)**
Interest income, net	257	1,082	493	(590)	1,242	71	350	1,036	2,175	3,632
other inc / fin expense		485	418	(152)	751	587	534	193	195	1,509
Net income (loss)	**(5,570)**	**(9,487)**	**(5,207)**	**(1,966)**	**(22,230)**	**(11,668)**	**(10,533)**	**(7,060)**	**(7,299)**	**(36,560)**
Earnings per share	**($0.22)**	**($0.32)**	**($0.17)**	**($0.06)**	**($0.78)**	**($0.31)**	**($0.27)**	**($0.18)**	**($0.19)**	**($0.95)**
Weighted avg. shares (000)	25,746	29,348	29,930	31,196	28,469	37,113	38,795	39,100	39,350	38,590
Fully diluted shares (000)	31,014	34,450	35,235	37,946	34,661	41,008	42,272	42,816	43,100	42,299

Source: FactSet; AGP estimates

Figure 5: Annual Income Statement

Oramed Pharmaceuticals
Annual income statement

($000 except per share)	2021A	2022E	2023E	2024E	2025E	Comments
	Aug 21	Switch to December FY 1Q22				
Revenues						
ORMD-0801 sales					$50,000	1H25 launch
License revenues	$3,376	$2,718	$2,724	$2,800	$2,800	License agreement here
Total revenues	**$2,703**	**$2,941**	**$2,724**	**$2,800**	**$52,800**	
Expenses						
COGS	0	0	0	0	11,900	
Gross profits	2,703	2,941	2,724	2,800	40,900	
Research & development	20,989	30,063	30,750	31,000	32,250	2 Phase 3 trials 2021-2023
Selling, general & admin	5,937	14,379	15,750	16,000	21,000	
Total operating expenses	26,926	44,442	46,500	47,000	53,250	
Inc (loss) from ops	**(24,223)**	**(41,501)**	**(43,776)**	**(44,200)**	**(12,350)**	
Interest income	1,242	3,632	3,325	1,625	1,200	
Income tax	0	200	0	0	0	
other inc / fin expense	751	1,509	0	0	0	
Net income (loss)	**(22,230)**	**(36,560)**	**(40,451)**	**(42,575)**	**(11,150)**	
Earnings per share	**($0.78)**	**($0.95)**	**($1.00)**	**($1.00)**	**($0.25)**	
Weighted avg. shares (000)	28,469	38,590	40,600	42,600	44,600	
Fully diluted shares (000)	34,661	42,299	44,350	46,350	48,350	
Cash & equivalents	**$175,249**	**$184,723**	**$147,317**	**$107,747**	**$100,362**	

Source: FactSet; AGP estimates

Important Research Disclosures

Created by: BlueMatrix

Distribution of Ratings/IB Services

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [BUY]	113	81.88	4	3.54
HOLD [NEUTRAL]	18	13.04	2	11.11
SELL [SELL]	1	0.72	0	0
NOT RATED [NR]	6	4.35	1	16.67
UNDER REVIEW [UR]	0	0.00	0	0

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Buy: Expected to materially outperform sector average over 12 months and indicates total return of at least 10% over the next 12 months.

Neutral: Returns expected to be in line with sector average over 12 months and indicates total return between negative 10% and 10% over the next 12 months.

Sell: Returns expected to be materially below sector average over 12 months and indicates total price decline of at least 10% over the next 12 months.

Not Rated: We have not established a rating on the stock.

Under Review: The rating will be updated soon pending information disclosed from a near-term news event.

Volatility Index

1 (Low): Little to no sharp movement in stock price in a 12 month period

2 (Low to medium): Modest changes in stock price in a 12 month period

3 (Medium): Average fluctuation in stock price in a 12 month period

4 (Medium to High): Higher than average changes in stock price in a 12 month period

5 (High): Extremely sharp movements in stock price in a 12 month period

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