

**James Molloy**  
 (617) 283-5521, [jmolloy@alliancecg.com](mailto:jmolloy@alliancecg.com)  
 Sales & Trading 888-543-4448

**(NASDAQ: ORMP)**

Price	\$9.78
52 Week Range	(\$2.40 - \$12.73)
<b>Price Target</b>	<b>\$25.00</b>
Market Cap (mil)	\$308.33
Shares out (mil)	32.26
3-Mo Avg Vol	858,958
Cash per share	\$2.77
Total Debt (mil)	NA
Debt/Equity	NA

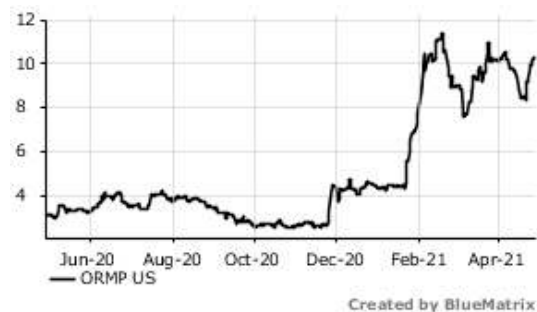
General: \* Cash per share is pro-forma

**EPS \$**

Yr Aug	2020A		2021E		2022E	
	Actual	Curr	Prev	Curr	Prev	
Nov	(0.15)A	(0.22)A	(0.13)E	(0.17)E		-
Feb	(0.21)A	(0.17)A	(0.16)E	(0.19)E		-
May	(0.10)A	(0.16)E	(0.17)E	(0.19)E		-
Aug	(0.13)A	(0.16)E	(0.19)E	(0.20)E	(0.19)E	
YEAR	(0.56)A	(0.70)E	(0.65)E	(0.75)E		-

**Revenues (millions) \$**

Yr Aug	2020A		2021E		2022E	
	Actual	Curr	Prev	Curr	Prev	
Nov	1A	1A	-	1E		-
Feb	1A	1A	-	1E		-
May	1A	1E	-	1E		-
Aug	1A	1E	-	1E		-
YEAR	3A	3E	-	3E		-



**Oramed Pharmaceutical, Inc.**

**Buy**

**Volatility: 5**

**Price Target Change**

**Estimate Change**

**ORMP Grand Rounds webinar highlights the Game-Changing Potential for Oral Insulin & Oral COVID-19 Vaccines - Maintain Buy, raise PT to \$25**

We recently held a fireside chat with management of ORMP to discuss the ongoing Phase 3 trials of ORMD-0801 oral insulin for diabetes, as well as the recently announced Oravax oral vaccine for COVID-19. We continue to see significant upside from current levels and we are reiterating our Buy rating and raising our price target to \$25 from \$11 previously. ORMP continues its rapid development of ORMD-0801, a novel oral insulin capsule that could revolutionize the treatment paradigm for type 2 diabetes. We anticipate that the company could soon announce hitting 50% enrollment in the first Phase 3 trial, and has initiated the second confirmatory Phase 3 trial already. We anticipate that the 6-month top line efficacy data from the 1st trial could be available as soon as 1H22, with the top line data from the 2nd trial ~6 months behind the 1st. We continue to believe that an effective oral insulin option like ORMD-0801 would rapidly gain significant acceptance in the T2DM population over injecting insulin. We estimate that - if approved - ORMD-0801 could reach \$850M in sales by 2030, the 6th year of launch. Additionally ORMP recently announced a joint venture with Premas Biotech (private) to develop Oravax, an oral vaccine for COVID-19 that could be a significant opportunity for ORMP as well. Oravax is starting Phase 1 trials in the current Q, and we anticipate safety results as soon as early next Q, with Phase 2 potentially starting 2H21. The Oravax vaccine is expected by ORMP to be thermally stable, obviating the need for complex cold-chain delivery & storage, which would be almost as significant as eliminating the painful needle stick (and injection site reactions) of current vaccine injections. We anticipate rapid development of Oravax - assuming all goes well in trials - with a greater demand ex-US in countries such as India, where the COVID-19 crisis continues to explode every day (potentially over 300,000 new cases/day as of most recent reports). We continue to like ORMP here and we are reiterating our Buy rating and raising our price target to \$25 from \$11 previously. Our price target is based on a sum-of-the-parts with ORMD-0801 for T2DM valued at \$18/share, Oravax oral vaccine for COVID-19 valued at \$5/share, ORMD-0801 for NASH valued at \$1/share, and the remaining programs (ORMP-0901, oral leptin) plus cash (end-'22) at \$1/share for our \$25 price target.

**ORMD-0801 for T2DM has already started second Phase 3 trial.** ORMP continues to see solid enrollment in their 1st Phase 3 trial, and we anticipate that they could soon announce hitting 50% enrollment in this trial in mid-21. The second Phase 3 trial is underway as well, and we estimate that this trial is ~6 months behind the 1st trial.

**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.

**Oravax oral vaccine could revolutionize treatment for COVID-19, too.** While the US and many other countries appear to be getting control of the COVID-19 pandemic through immunizations & infections, much of the world is still deep in the throes of this pernicious pandemic. Notably India has surpassed 350,000 new cases per day by official count, and Canada has seen an alarming second spike as well. An effective orally available vaccine could be an absolute game-changer, in our opinion. Injection site reactions and needle-avoidance would be eliminated with an oral vaccine option.

**An oral vaccine would likely find broad usage ex-US & in developing countries.** It's anticipated that the Oravax oral tablet would not have the expensive and resource intensive cold-chain requirements of the current injected vaccines. This would be a significant positive for distribution in much of the world where cold chains are not readily available. The US appears to be turning a corner with respect to COVID-19 so far - assuming no new vaccine resistant variants emerge - so we anticipate ex-US adoption

is likely first. That said, should COVID-19 vaccinations require annual boosters, as is feared may be the case, we believe that an oral version again would be vastly preferable to injections.

**Maintain Buy rating, \$25 price target.** Our price target is based on a sum-of-the-parts with ORMD-0801 for T2DM valued at \$18/share, Oravax oral vaccine for COVID-19 valued at \$5/share, ORMD-0801 for NASH valued at \$1/share, and the remaining programs (ORMP-0901, oral leptin) plus cash (end-'22) at \$1/share for our \$25 price target.

**Valuation:**

We value ORMP at \$25/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 2HFY24 (August FY), with a launch in 1HFY25 with WW sales reaching \$850M by FY30. We place a 4x multiple on WW sales, discounted back 8 years at 20% for our \$18/share value. We value Oravax at \$5/share based on expectations for approval and \$250M in sales by 2025, discounted back 3 years at 55%. We anticipate ORMD launches ORMD-0801 for NASH in FY27 with US sales reaching \$300M by FY30. We place a 4x multiple on US sales, discounted back 8 years at 50% for our \$1.00/share value. We value the remaining technology at ORMP (ORMP-0901 oral GLP-1 analog, Oral leptin for weight loss) and cash (end FY22E) at \$1.00/share for our \$25/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:**

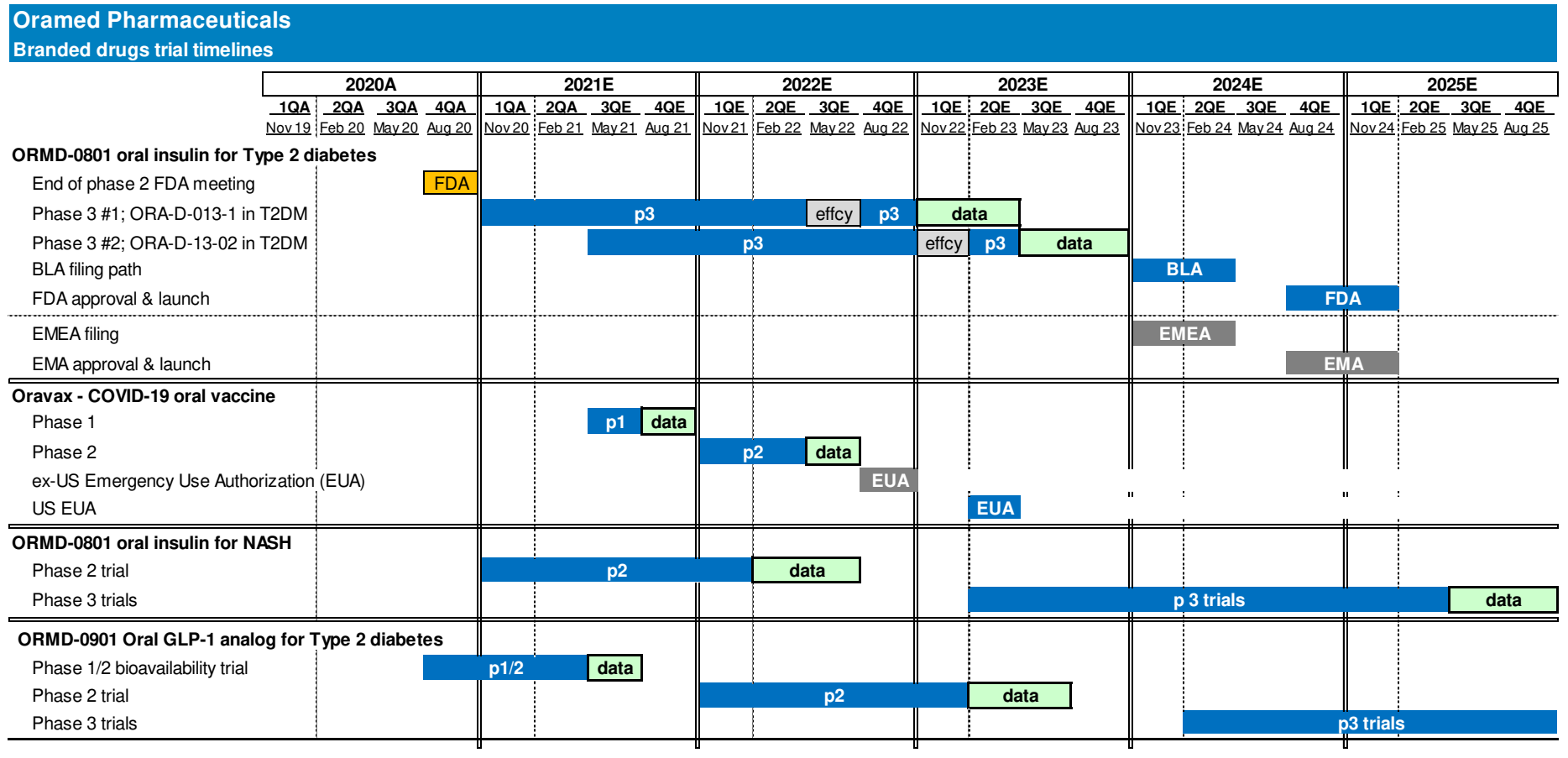
Oramed is developing oral delivery solutions for drugs delivered via injection. The company focuses in the research and development of pharmaceutical solutions, including an oral insulin capsule to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules or pills 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

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
ORMD-0801 for T2D	\$776,445	\$18.00
Oravax oral COVID vaccine	\$214,830	\$5.00
ORMD-0801 for NASH	\$46,822	\$1.00
Cash (end-'22E) & other	\$47,176	\$1.00
<b>SUM</b>	<b>\$1,085,273</b>	<b>\$25.00</b>
Fully diluted shares out '22E (000)		42,754

Source: AGP estimates

Figure 2: Potential clinical trial timelines



Source: Company reports; AGP estimates

Figure 3: Quarterly Income Statement

Oramed Pharmaceuticals										
Quarterly income statement										
(\$000 except per share)	2020A				2020A Year Aug 20	2021E				2021E Year Aug 21
	1QA Nov 19	2QA Feb 20	3QA May 20	4QA Aug 20		1QA Nov 20	2QA Feb 21	3QE May 21	4QE Aug 21	
Revenues	\$674	\$674	\$681	\$681	\$2,710	\$674	\$665	\$681	\$681	\$2,701
<b>Total revenues</b>	<b>\$674</b>	<b>\$674</b>	<b>\$681</b>	<b>\$681</b>	<b>\$2,710</b>	<b>\$674</b>	<b>\$665</b>	<b>\$681</b>	<b>\$681</b>	<b>\$2,701</b>
<b>Expenses</b>										
COGS										0
<b>Gross profits</b>	<b>674</b>	<b>674</b>	<b>681</b>	<b>681</b>	<b>2,710</b>	<b>674</b>	<b>665</b>	<b>681</b>	<b>681</b>	<b>2,701</b>
Research & development	2,022	3,320	1,925	2,968	10,235	5,774	3,869	4,250	4,750	18,643
Selling, general & admin	1,081	1,391	1,030	730	4,232	727	1,664	1,500	1,500	5,391
Total operating expenses	3,103	4,711	2,955	3,698	14,467	6,501	5,533	5,750	6,250	24,034
<b>Income (loss) from ops</b>	<b>(2,429)</b>	<b>(4,037)</b>	<b>(2,274)</b>	<b>(3,017)</b>	<b>(11,757)</b>	<b>(5,827)</b>	<b>(4,868)</b>	<b>(5,069)</b>	<b>(5,569)</b>	<b>(21,333)</b>
Interest income, net	209	169	200	112	690	257	260	250	250	1,017
Income taxes other inc / fin expense	(323)	180	(210)	(91)	(444)	0	0	(50)	(50)	(100)
<b>Net income (loss)</b>	<b>(2,543)</b>	<b>(3,688)</b>	<b>(2,284)</b>	<b>(2,996)</b>	<b>(11,511)</b>	<b>(5,570)</b>	<b>(4,608)</b>	<b>(4,869)</b>	<b>(5,369)</b>	<b>(20,416)</b>
<b>EPS as reported</b>	<b>(\$0.15)</b>	<b>(\$0.21)</b>	<b>(\$0.10)</b>	<b>(\$0.13)</b>	<b>(\$0.56)</b>	<b>(\$0.22)</b>	<b>(\$0.17)</b>	<b>(\$0.16)</b>	<b>(\$0.16)</b>	<b>(\$0.70)</b>
Weighted avg. shares (000)	17,472	17,818	23,215	23,622	20,532	25,746	27,004	31,004	33,504	29,315
Fully diluted shares (000)	21,839	22,659	28,409	29,325	25,558	31,024	32,406	37,754	40,254	35,360

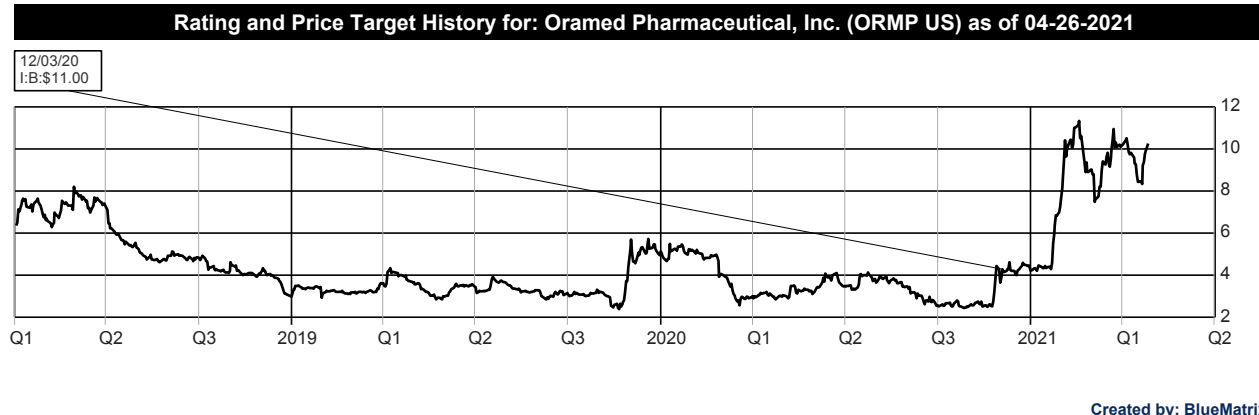
Source: Company reports; AGP estimates

Figure 4: Annual Income Statement

Oramed Pharmaceuticals						
Annual income statement						
(\$000 except per share)	2019A	2020A	2021E	2022E	2023E	Comments
	Aug 19	Aug 20	Aug 21	Aug 22	Aug 23	
<b>Revenues</b>						
Revenues	\$2,703	\$2,710	\$2,701	\$2,724	\$2,724	License agreement here
<b>Total revenues</b>	<b>\$2,703</b>	<b>\$2,710</b>	<b>\$2,701</b>	<b>\$2,724</b>	<b>\$2,724</b>	
<b>Expenses</b>						
COGS	90	0	0	0	0	
<b>Gross profits</b>	<b>2,613</b>	<b>2,710</b>	<b>2,701</b>	<b>2,724</b>	<b>2,724</b>	
Research & development	13,522	10,235	18,643	24,250	26,750	2 Phase 3 trials 2021-2023
Selling, general & admin	3,722	4,232	5,391	5,700	6,600	
Total operating expenses	17,244	14,467	24,034	29,950	33,350	
<b>Inc (loss) from ops</b>	<b>(14,631)</b>	<b>(11,757)</b>	<b>(21,333)</b>	<b>(27,226)</b>	<b>(30,626)</b>	
Interest income	1,061	690	1,017	400	400	
Income tax	(300)	0	0	0	0	
other inc / fin expense	(485)	(444)	(100)	(200)	(200)	
<b>Net income (loss)</b>	<b>(14,355)</b>	<b>(11,511)</b>	<b>(20,416)</b>	<b>(27,026)</b>	<b>(30,426)</b>	
<b>EPS as reported</b>	<b>(\$0.82)</b>	<b>(\$0.56)</b>	<b>(\$0.70)</b>	<b>(\$0.75)</b>	<b>(\$0.80)</b>	
Weighted avg. shares (000)	17,454	20,532	29,315	36,254	38,254	
Fully diluted shares (000)	21,878	25,558	35,360	42,754	38,254	
<b>Cash &amp; equivalents</b>	<b>\$33,577</b>	<b>\$30,383</b>	<b>\$29,176</b>	<b>\$45,555</b>	<b>\$43,828</b>	

Source: Company reports; AGP estimates

## Important Research Disclosures



### Distribution of Ratings/IB Services

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [BUY]	97	87.39	36	37.11
HOLD [NEUTRAL]	12	10.81	0	0
SELL [SELL]	0	0.00	0	0
NOT RATED [NR]	2	1.80	0	0
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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