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**(NASDAQ: ORMP)**

Price	\$15.85
52 Week Range	(\$2.40 - \$23.57)
<b>Price Target</b>	<b>\$25.00</b>
Market Cap (mil)	\$308.33
Shares out (mil)	32.51
3-Mo Avg Vol	765,137
Cash per share	\$2.57
Total Debt (mil)	NA
Debt/Equity	NA

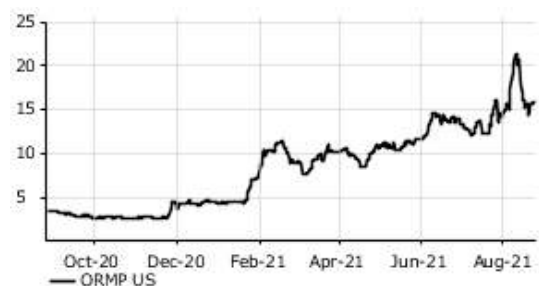
General: \* Cash per share is pro-forma

**EPS \$**

Yr Aug	2020A		2021E		2022E	
	Actual	Curr	Prev	Curr	Prev	Prev
Nov	(0.15)A	(0.22)A	–	(0.19)E	(0.17)E	
Feb	(0.21)A	(0.17)A	–	(0.20)E	(0.19)E	
May	(0.10)A	(0.17)A	(0.16)E	(0.20)E	(0.19)E	
Aug	(0.13)A	(0.19)E	(0.16)E	(0.21)E	(0.20)E	
YEAR	(0.56)A	(0.75)E	(0.70)E	(0.80)E	(0.75)E	

**Revenues (millions) \$**

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



**Oramed Pharmaceutical, Inc.**

**Buy**

**Volatility: 5**

**Estimate Change**

**Confirmatory second Phase 3 trial for oral insulin advancing on track - Maintain Buy \$25 PT**

ORMP reports that the second, confirmatory Phase 3 trial - ORA-D-13-02 in type 2 diabetes - has hit the 25% enrollment status, which we believe keeps the program on-track for potential mid-2023 top line data. ORMP's first Phase 3 trial - ORA-D-13-01 in type 2 diabetes - hit their 50% enrollment point in June 2021, and we continue to see that trial on-track for a late-2022/early 2023 top line data readout. See Figure 3 below for our clinical trial estimates. ORMD-0801 is a novel oral insulin capsule that could revolutionize the treatment paradigm for type 2 diabetes. 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. An effective oral insulin option like ORMD-0801 should rapidly gain significant acceptance in the T2DM population over injecting insulin, in our opinion. 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 joint venture with Premas Biotech (private) 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 are reiterating our Buy rating and our \$25 price target 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 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 should find broad usage for COVID-19, too.** While the US and many other countries had appeared to be getting control of the COVID-19 pandemic through immunizations & infections, the Delta variant breakthrough demonstrates the challenges still ahead of us. It also reinforces the need for continued development of new options for COVID-19 treatment. An effective orally available vaccine could be an absolute game-changer, in our opinion, as injection site reactions and needle-avoidance would be eliminated with an oral vaccine option.

**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	\$743,357	\$18.00
Oravax oral COVID vaccine	\$205,618	\$5.00
ORMD-0801 for NASH	\$43,175	\$1.00
Cash (end-'FY22E) & other	\$47,176	\$1.00
<b>SUM</b>	<b>\$1,039,326</b>	<b>\$25.00</b>
Fully diluted shares out '22E (000)		40,880

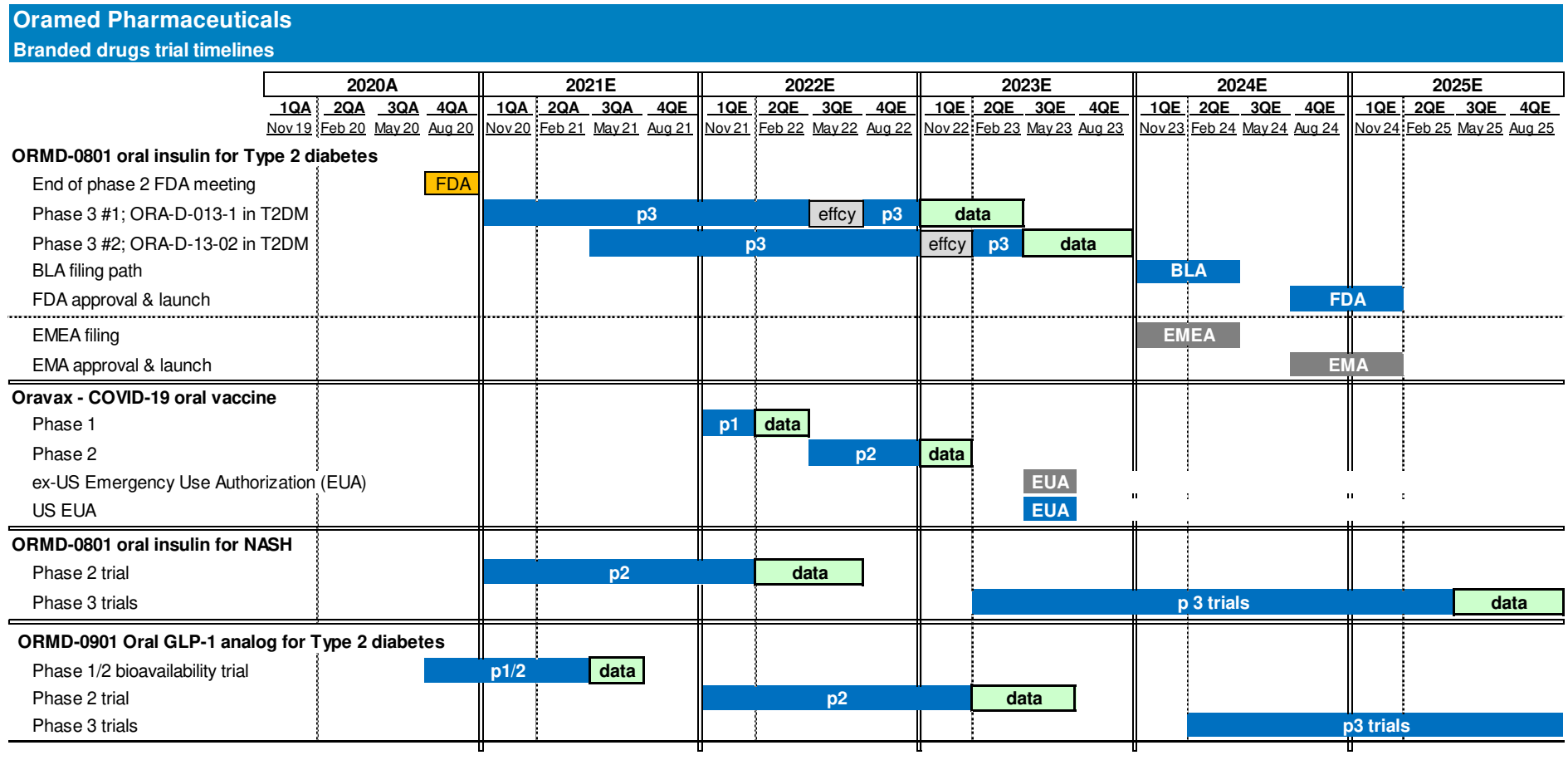
Source: AGP estimates

Figure 2. Variance analysis

Oramed Pharmaceuticals					
Variance analysis					
(000's)					
	3Q20A May 20	3Q21A May 21	3Q21E May 21	Variance	% Y/Y
Revenues	681	681	681	0	0%
<b>Total Revenue</b>	<b>\$681</b>	<b>\$681</b>	<b>\$681</b>	<b>\$0</b>	<b>0%</b>
R&D Expense	1,925	5,502	4,250	1,252	186%
SG&A Expense	1,030	1,297	1,500	(203)	26%
<b>Operating Income</b>	<b>(2,274)</b>	<b>(6,118)</b>	<b>(5,069)</b>	<b>(1,049)</b>	<b>169%</b>
Interest Inc, net	200	493	250	243	147%
Income Taxes	0	0	0	0	NM
Other income	(210)	418	(50)	468	-299%
<b>Net Income</b>	<b>(2,284)</b>	<b>(5,207)</b>	<b>(4,869)</b>	<b>(338)</b>	<b>128%</b>
Wgt'd Avg Shares (M)	23,215	29,930	31,004	(1,075)	29%
<b>EPS</b>	<b>(\$0.10)</b>	<b>(\$0.17)</b>	<b>(\$0.16)</b>	<b>(\$0.02)</b>	<b>77%</b>

Source: AGP estimates

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)	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	3QA 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	5,502	5,750	20,895
Selling, general & admin	1,081	1,391	1,030	730	4,232	727	1,664	1,297	1,500	5,188
Total operating expenses	3,103	4,711	2,955	3,698	14,467	6,501	5,533	6,799	7,250	26,083
<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>(6,118)</b>	<b>(6,569)</b>	<b>(23,382)</b>
Interest income, net	209	169	200	112	690	257	260	493	250	1,260
other inc / fin expense	(323)	180	(210)	(91)	(444)			418		418
<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>(5,207)</b>	<b>(6,319)</b>	<b>(21,704)</b>
<b>Earnings per share</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>(\$0.17)</b>	<b>(\$0.19)</b>	<b>(\$0.75)</b>
Weighted avg. shares (000)	17,472	17,818	23,215	23,622	20,532	25,746	27,004	29,930	33,130	28,952
Fully diluted shares (000)	21,839	22,659	28,409	29,325	25,558	31,024	32,406	35,235	39,880	34,636

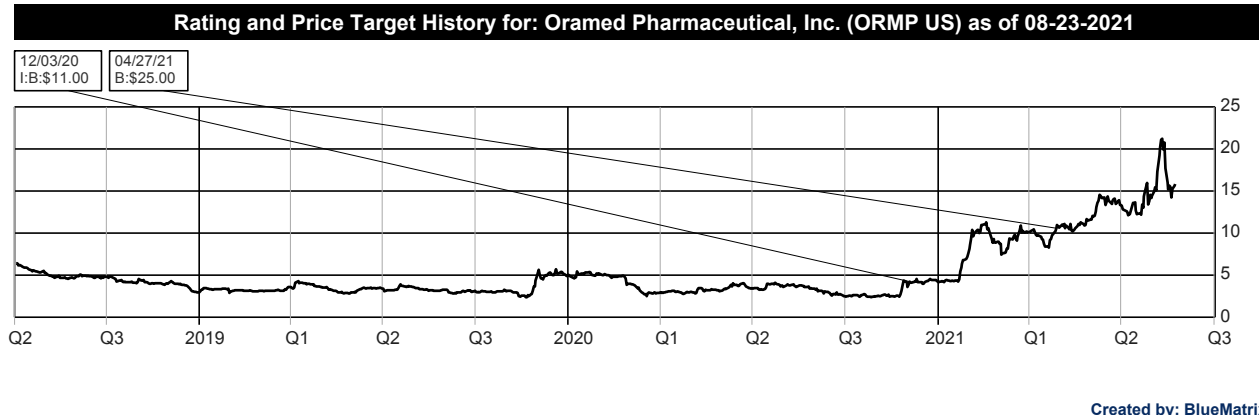
Source: Company reports; AGP estimates

Figure 5: Annual Income Statement

<b>Oramed Pharmaceuticals</b>					
<b>Annual income statement</b>					
(\$000 except per share)	<b>2020A</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>	<b>Comments</b>
	Aug 20	Aug 21	Aug 22	Aug 23	
<b>Revenues</b>					
Revenues	\$2,710	\$2,701	\$2,724	\$2,724	License agreement here
<b>Total revenues</b>	<b>\$2,710</b>	<b>\$2,701</b>	<b>\$2,724</b>	<b>\$2,724</b>	
<b>Expenses</b>					
COGS	0	0	0	0	
<b>Gross profits</b>	<b>2,710</b>	<b>2,701</b>	<b>2,724</b>	<b>2,724</b>	
Research & development	10,235	20,895	24,750	27,250	2 Phase 3 trials 2021-2023
Selling, general & admin	4,232	5,188	5,800	7,000	
Total operating expenses	14,467	26,083	30,550	34,250	
<b>Inc (loss) from ops</b>	<b>(11,757)</b>	<b>(23,382)</b>	<b>(27,826)</b>	<b>(31,526)</b>	
Interest income	690	1,260	400	400	
Income tax	0	0	0	0	
other inc / fin expense	(444)	418	0	0	
<b>Net income (loss)</b>	<b>(11,511)</b>	<b>(21,704)</b>	<b>(27,426)</b>	<b>(31,126)</b>	
<b>Earnings per share</b>	<b>(\$0.56)</b>	<b>(\$0.75)</b>	<b>(\$0.80)</b>	<b>(\$0.85)</b>	
Weighted avg. shares (000)	20,532	28,952	34,380	36,630	
Fully diluted shares (000)	25,558	34,636	40,880	36,630	
<b>Cash &amp; equivalents</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



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Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [BUY]	106	86.89	36	33.96
HOLD [NEUTRAL]	14	11.48	0	0
SELL [SELL]	0	0.00	0	0
NOT RATED [NR]	2	1.64	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.

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**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

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