

# Oramed Pharmaceuticals Inc. (ORMP – \$4.00\*)

Healthcare: Specialty Pharmaceuticals Neutral; \$5.00 PT; \$69.6M Market Cap

Company Update Thursday, December 13, 2018

# Revenue/EPS for 4Q18 In Line/Beats; Slight Push Out to Pipeline Time line; Maintaining Neutral, \$5 PT; Upcoming Data Could be Impactful to Trading

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ST	OCK DA	TA	
Market Cap (mil) 52-Week Range 3-Month ADTV Shares Outstanding Float (%) Short Interest Beta Enterprise Val. (mil Fiscal Year-End	\$3.9	\$69.6 1 – \$9.48 25,161 17.4 69.5 303,496 1.16 \$22.8 August	
	NINGS D	ATA	
EPS (Pro Forma)	2017A	2018A	2019E
1Q 2Q 3Q 4Q FY P/E	\$(0.20) \$(0.24) \$(0.15) \$(0.20) \$(0.79) NM	\$(0.18) \$(0.20) \$(0.30) \$(0.18) \$(0.86) NM	\$(0.20) \$(0.23) \$(0.25) \$(0.27) \$(0.95) NM
FINA	ANCIAL D	ATA	
FY Rev. (mil)	2017A \$2.5		2019 \$3.
BALAN	ICE SHEE	T DATA	
Cash & Equivalents Current Assets Total Assets Total Liabilities Accounts Payable Total Debt Shareholders' Equi' S in millions.			4Q18 \$46.8 \$31.0 \$47.4 \$16.3 \$2.1 \$0.0 \$31.1

#### **Summary and Recommendation**

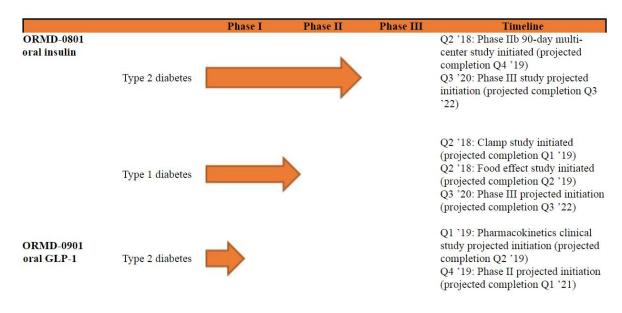
Oramed Pharmaceuticals (ORMP) filed its 10-K for FY18 (FYE: August) on Wednesday, 11/28. The company does not host a conference call. ORMP's top-line/EPS came in at \$0.6M/(\$0.18), compared to our/consensus estimates of \$0.6M/(\$0.29) and \$0.6M/(\$0.28), respectively. Revenues were tied to milestone payments received through ORMP's out-license agreement with Hefei Tianhui Incubator of Technologies (HTIT), amortized through June 2023. ORMP's EPS beat was primarily due to lower R&D expense than our estimates called for. Meanwhile, ORMP remains well capitalized to meet its near-term objectives and exited 4Q18 with \$46.8M in cash/ investments, no debt, and a current ratio of 6.8:1.0. We continue to believe ORMP's pipeline offers an intriguing opportunity if data from studies come in favorably, potentially positioning it to introduce "game-changing" offerings to diabetes patients. Nevertheless, we believe concerns we addressed in our last update note remain relevant today. We believe the key factor that will move us off the sidelines will be related to HbA1c reductions the company is able to obtain from current studies. HbA1c reductions that are more favorable than 0.5% without an increase in adverse events would meaningfully increase our conviction in ORMP's platform and would likely dramatically change the company's position in the market and represent a substantial trading event as it would uniquely position the company's offering to treat patients with insulin earlier in the treatment paradigm. As a result, we are maintaining our Neutral rating and \$5 PT.

#### **Key Points**

• Update on time line for lead candidates. ORMP updated the timing of its pipeline which resulted in most studies being pushed out slightly. Changes from our last update include: (1) ORMP's 90-day Phase IIb dosing study with 285 type 2 diabetes (T2D) patients which commenced during C2Q18 and is focused on assessing safety and the effect of ORMD-0801 (oral insulin) on HbA1c levels, the primary registrational endpoint for the FDA, is now projected to be completed by C4Q19 versus C2Q19 previously; (2) the company's Phase III study for ORMD-0801 in T2D is has now been pushed out to C3Q20 from C1Q20, but is still projected to be completed by C3Q22; (3) the company's Clamp study for ORMD-0801 for type 1 diabetes (T1D) which commenced during C2Q18, is now currently projected to be completed during C1Q19 versus C4Q18; (4) ORMP's U.S. food effect study for ORMD-0801 for T1D, which began enrolling patients during C2Q18, is now projected to be completed during C2Q19 versus C1Q19; (5) the company's Phase III study for ORMD-0801 in T1D has been pushed out to C3Q20 from C1Q20, but is still projected to be completed by C3Q22; and (6) ORMP is now expected to commence its PK study for T2D with ORMD-0901 (oral GLP-1) in C1Q19 which was pushed out from C3Q18 and its projected completion is expected in C2Q19, one quarter later than previously projected; (7) finally, ORMP now anticipates its Phase II study for ORMD-0901 will now be initiated and completed in C4Q19 and C1Q21, respectively, versus C1H19 and C4Q20 previously. Exhibit 1 provides clarification on the expected timing of ORMP's primary candidates.

- Other points of interest. Last month, ORMP announced it successfully randomized over 50% of the patients in its 285 patient, 90-day Phase IIb dosing study for ORMD-0801 in T2D. We believe the rate of enrollment aligns with management's expectation to complete the study by the end of next calendar year. We believe data, particularly related to HbA1c reduction levels, will be a critical data point to monitor, likely be a significant trading event for ORMP, and also be the data point potential strategic partners will focus on when deciding a commercialization partnership. ORMP previously noted that 29 day data from a previous study showed ORMD-0801 achieved a statistically significant change in HbA1c of -0.01%. As ORMD-0801 is expected to compete with oral anti-diabetic (OAD) medications, we believe the study will need to show an average reduction of at least 0.5% for the study to be deemed successful, and position the candidate as viable alternative to OADs in the market. However, there is limited data that can be utilized as a comparative and a provide a theoretical crosswalk between 29 day and 90 day studies, which makes handicapping ORMD-0801's success in improving its HbA1c level metrics challenging. Meanwhile, the company announced various leadership changes last month as Joshua Hexter resigned as the company's COO. The company subsequently hired Dr. Mark Hasleton, PhD, to serve as its VP Business Development. Dr. Hasleton has had significant industry experience and previously held senior positions at Bristol Myers Squibb and Teva Pharmaceutical.
- Revised estimates. Due to ORMP's 4Q18 results, we are modifying our FY19 estimates and are taking our top-line/EPS/adj. EBITDA from 6.5M/(1.24)/(20.7M) to 3.7M/(0.95)/(14.9M). We are still hesitant to expand our model's time horizon passed 2019 as we believe it is prudent to see upcoming data from pending studies before we feel comfortable assigning risk-adjusted estimates.
- Maintaining Neutral and \$5 PT. Our PT is based on a 13x (from 7x) EV/sales multiple to our FY19 revenue estimate of \$3.7M. Admittedly, we view our valuation as more of a place holder, as we believe shares will likely remain range bound until compelling efficacy data or a strategic partnership are established, and companies at this stage in ORMP's development trade on risk-adjusted estimates based on commercial potential in the out years.

**Exhibit 1: ORMP Candidates' Time Line** 



Source: Company reports

#### **Valuation**

We establish our \$5.00 price target by assigning a 13x EV/sales multiple to our FY19 revenue estimate of \$3.7M.

#### **Risks**

Regulatory risk. There is a risk that the company will be unable to receive regulatory approvals or will experience delays in receiving approval. Additionally, the company must obtain several foreign regulatory approvals to be able to sell products internationally.

Clinical risk. The development of clinical drug candidates is inherently risky and may never lead to marketable products. ORMP's lead drug candidate, ORMD-0801, is in clinical development and depends on third-party suppliers for raw materials. As the company does not control these parties, it is not able to guarantee that the clinical operations will be performed in a timely and adequate manner.

Brutal competition. There are many larger companies that focus on ORMP's markets. These companies could develop new, more effective offerings that could decrease the company's ability to obtain market share or establish strategic partnerships.

Financial risk. ORMP is currently developing several clinical candidates and may need additional capital in the future to continue research and development programs and for the commercialization of its products.

Liquidity risk. The company has a relatively small float and a relatively small market cap. Investors could potentially be at risk of finding a liquid market to buy or sell shares.

Manufacturing risk. ORMP may be unable to manufacture or contract with third parties for the manufacture of insulin-based applications and/or other orally digestible drugs.

Positive outcomes. Any positive clinical data, strategic partnerships, or other forms of data could result in the share price increasing from current levels.

Risk to our price target. Our estimates and/or valuation analysis may prove to be too conservative, in which case ORMP would likely exceed our price target.

## Oramed Pharmaceuticals Inc. (ORMP)

FYE: August

Income Statement (\$000s except per share data)	2016A	2017A	1Q18A	2Q18A	3Q18A	4Q18A	2018A	1Q19E	2Q19E	3Q19E	4Q19E	2019E
income diatement (40003 except per share data)	Aug	Aug	Nov	Feb	May	Aug	Aug	Nov	Feb	May	Aug	Aug
Revenues	641	2,456	611	604	617	617	2,449	617	1.038	1.038	1.038	3,731
Revenues	041	2,430	011	004	017	017	2,443	017	1,000	1,000	1,000	3,731
Cost of revenues	490	187	0	0	(86)	0	(86)	0	280	0	0	280
Gross Profit	151	2,269	61 <u>1</u>	604	703	617	2,535	617	758	1,038	1,038	3.451
Gross Margin	23.6%	92.4%	100.0%	100.0%	113.9%	100.0%	103.5%	100.0%	73.0%	100.0%	100.0%	92.5%
Orosa wangin	20.070	32.470	100.070	100.070	110.070	100.070	100.070	100.070	70.070	100.070	100.070	32.070
Operating expense												
Research and development	7,709	10,281	2,327	2,724	4,194	2,734	11,979	3,200	3,700	4,400	4,800	16,100
General and administrative	2,452	2,759	1,016	991	1,043	1,033	4,083	1,100	1,200	1,300	1,200	4,800
Total operating expense	10,161	13,040	3,343	3,715	5,237	3,767	16,062	4,300	4,900	5,700	6,000	20,900
Total expense	10,651	13,227	3,343	3,715	5,151	3,767	15,976	4,300	5,180	5,700	6,000	21,180
Operating income	(10,010)	(10,771)	(2,732)	(3,111)	(4,534)	(3,150)	(13,527)	(3,683)	(4,142)	(4,662)	(4,962)	(17,449)
	(10,010)	(10,771)	(2,732)	(0,111)	(4,554)	(3,130)	(10,021)	(3,003)	(4,142)	(4,002)	(4,302)	(17,443)
Other income (expense)												
Financial income (expense)	381	691	201	195	180	224	800	234	221	240	216	910
Total other income (expense)	381	691	201	195	180	224	800	234	221	240	216	910
Total Street meeting (oxportion)	331	331	-01				330	204		0	0	3.0
Earnings before income tax	(9,629)	(10,080)	(2,531)	(2,916)	(4,354)	(2,926)	(12,727)	(3,449)	(3,921)	(4,422)	(4,746)	(16,538)
Income tax (recovery) expense	1,335	400	0	0	0	(2,020)	(12,727)	0,110)	0,021)	0	(1,7 10)	(10,000)
Net income (loss)	(10,964)	(10,480)	(2,531)	(2,916)	(4,354)	(2,926)	(12,727)	(3,449)	(3,921)	(4,422 <u>)</u>	(4,746)	(16,538)
Net moone (1033)	(10,504)	(10,400)	(2,551)	(2,310)	(4,554)	(2,320)	(12,727)	(3,443)	(5,521)	(4,422)	(4,140)	(10,550)
Net income (loss)	(10,964)	(10,480)	(2,531)	(2,916)	(4,354)	(2,926)	(12,727)	(3,449)	(3,921)	(4,422)	(4,746)	(16,538)
Unrealized gain (loss) on available for sale securities	(452)	295	326	(414)	(115)	504	301	0,110)	0	0	(1,7 10)	(10,000)
Comprehensive income (loss)	(11,416)	(10,185)	(2,205)	(3,330)	(4,469)	(2,422)	(12,426)	(3,449)	(3,921)	(4,422 <u>)</u>	(4,746)	(16,538)
Comprehensive meanic (1033)	(11,410)	(10,100)	(2,200)	(0,000)	(4,400)	(2,722)	(12,420)	(3,443)	(5,521)	(4,422)	(4,140)	(10,550)
Diluted EPS	(0.87)	(0.79)	(0.18)	(0.20)	(0.30)	(0.18)	(0.86)	(0.20)	(0.23)	(0.25)	(0.27)	(0.95)
Diluted share count	12,624	13,309	14,239	14,446	14,519	16,325	14,882	17,360	17,390	17,420	17,450	17,405
Tax rate	-14%	-4%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	, 0	.,0	0,0	0,0	0,70	0,0	0,0	0,0	0,0	0,70	070	0,70
Adjusted EBITDA												
Operating income	(10,010)	(10,771)	(2,732)	(3,111)	(4,534)	(3,150)	(13,527)	(3,683)	(4,142)	(4,662)	(4,962)	(17,449)
Depreciation and amortization	4	5	1	2	1	2	6	2	<u>2</u>	2	2	` ´ 8
EBITDA	(10,006)	(10,766)	(2,731)	(3,109)	(4,533)	(3,148)	(13,521)	(3,681)	(4,140)	(4,660)	(4,960)	(17,441)
Stock based compensation	735	1,647	548	351	363	384	1,646	550	600	650	750	2,550
Adjusted EBITDA	(9,271)	(9,119)	(2,183)	(2,758)	(4,170)	(2,764)	(11,875)	(3,131)	(3,540)	(4,010)	(4,210)	(14,891)
FCF	4,646	(5,838)	(2,728)	(3,479)	(3,805)	(4,650)	(14,662)	(2,515)	3,642	(4,809)	(4,534)	(8,216)
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Selected Financial Information												
Price	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
Market cap	50,497	53,237	56,957	57,783	58,076	65,301	59,529	69,440	69,560	69,680	69,800	69,620
Cash & investments	42,589	38,505	41,350	37,997	34,418	46,790	46,790	44,275	47,917	43,108	38,574	38,574
Debt, short and long-term	0	0	0	0.,007	0 ., 0	0	0	0	0	0	0	0
Enterprise value	7,908	14,732	15,607	19,786	23,658	18,511	12,739	25,165	21,643	26,572	31,226	31,046
Revenue LTM	641	2,456	2.457	2,450	2,450	2,449	2,449	2,455	2,889	3,310	3,731	3,731
Adjusted EBITDA LTM	(9,271)	(9,119)	(9,080)	(8,825)	(11,009)	(11,875)	(11,875)	(12,823)	(13,605)	(13,445)	(14,891)	(14,891)
EV/Sales	12.3	6.0	6.4	8.1	9.7	7.6	5.2	10.3	7.5	8.0	8.4	8.3
EV/BITDA	(0.9)	(1.6)	(1.7)	(2.2)	(2.1)	(1.6)	(1.1)	(2.0)	(1.6)	(2.0)	(2.1)	(2.1)
	(0.0)	(1.5)	( )	()	(1)	(1.0)	()	(2.0)	(1.5)	(2.5)	(1)	(2.1)
Y-O-Y revenue growth	nmf	283%	0%	-1%	0%	0%	0%	1%	72%	68%	68%	52%

\*Source: Company filings & B. Riley FBR, Inc. estimates



## **Oramed Pharmaceuticals Inc. (ORMP)**

FYE: August

Common Size (as percentage of net revenues):	2016A	2017A	1Q18A	2Q18A	3Q18A	4Q18A	2018A	1Q19E	2Q19E	3Q19E	4Q19E	2019E
	Aug	Aug	Nov	Feb	May	Aug	Aug	Nov	Feb	May	Aug	Aug
Revenues	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Cost of revenues	76%	8%	<u>0%</u>	0%	-14%	0%	-4%	0%	27%	0%	0%	8%
Gross Profit	24%	<u>8%</u> <b>92%</b>	100%	100%	114%	0 <u>%</u> 100%	104%	100%	73%	100%	0 <u>%</u> 100%	<u>8%</u> <b>92%</b>
Operating expense												
Research and development	1203%	419%	381%	451%	680%	443%	489%	519%	356%	424%	462%	432%
General and administrative	383%	112%	<u>166%</u>	<u>164%</u>	169%	167%	167%	<u>178%</u>	<u>116%</u>	<u>125%</u>	116%	129%
Total operating expense	<u>1585%</u>	<b>531%</b>	<u>547%</u>	<u>615%</u>	<u>849%</u>	611%	656%	<u>697%</u>	<u>472%</u>	<u>549%</u>	<u>578%</u>	<u>560%</u>
Total expense	<u>1662%</u>	<u>539%</u>	<u>547%</u>	<u>615%</u>	<u>835%</u>	611%	652%	<u>697%</u>	<u>499%</u>	<u>549%</u>	578%	568%
Operating income	-1562%	-439%	-447%	-515%	-735%	-511%	-552%	-597%	-399%	-449%	-478%	-468%
Other income (expense)												
Financial income (expense)	<u>59%</u>	<u>28%</u>	33%	<u>32%</u>	<u>29%</u>	36%	33%	<u>38%</u>	<u>21%</u>	<u>23%</u>	21%	24%
Total other income (expense)	59%	28%	33%	32%	29%	36%	33%	38%	21%	23%	21%	24%
Earnings before income tax	-1502%	-410%	-414%	-483%	-706%	-474%	-520%	-559%	-378%	-426%	-457%	-443%
Income tax (recovery) expense	208%	<u>16%</u>	<u>0%</u>	<u>0%</u>	0%	0%	0%	<u>0%</u>	0%	<u>0%</u>	0%	0%
Net income (loss)	-1710%	-427%	-414%	-483%	-706%	-474%	-520%	-559%	-378%	-426%	-457%	-443%
Net income (loss)	-1710%	-427%	-414%	-483%	-706%	-474%	-520%	-559%	-378%	-426%	-457%	-443%
Unrealized gain (loss) on available for sale securities	<u>-71%</u>	12%	<u>53%</u>	<u>-69%</u>	<u>-19%</u>	82%	12%	<u>0%</u>	<u>0%</u>	<u>0%</u>	0%	0%
Comprehensive income (loss)	-1781%	-415%	-361%	-551%	-724%	-393%	-507%	-559%	-378%	-426%	-457%	-443%
Adjusted EBITDA												
Operating income	-1562%	-439%	-447%	-515%	-735%	-511%	-552%	-597%	-399%	-449%	-478%	-468%
Depreciation and amortization	<u>1%</u> -1561%	0%	<u>0%</u>	0%	<u>0%</u>	0%	0%	<u>0%</u>	0%	<u>0%</u>	0%	0%
EBITDA		-438%	-447%	-515%	-735%	-510%	-552%	-597%	-399%	-449%	-478%	-467%
Stock based compensation	115%	67%	90%	<u>58%</u>	<u>59%</u>	62%	67%	<u>89%</u>	<u>58%</u>	<u>63%</u>	72%	68%
Adjusted EBITDA	-1446%	-371%	-357%	-457%	-676%	-448%	-485%	-507%	-341%	-386%	-406%	-399%

<sup>\*</sup>Source: Company filings & B. Riley FBR, Inc. estimates

# Oramed Pharmaceuticals Inc. (ORMP)

FYE: August

Balance Sheet (\$000s except per share data)	2016A	2017A	1Q18A	2Q18A	3Q18A	4Q18A	2018A	1Q19E	2Q19E	3Q19E	4Q19E	2019E
	Aug	Aug	Nov	Feb	May	Aug	Aug	Nov	Feb	May	Aug	Aug
Assets												
Cash & cash equivalents	3,907	3,969	1,258	3,295	3,673	4,996	4,996	2,481	6,123	22,189	17,655	17,655
Total cash	3,907	3,969	1,258	3,295	3,673	4,996	4,996	2,481	6,123	22,189	17,655	17,655
Short-term deposits	24,254	13,293	14,992	14,379	15,990	20,875	20,875	20,875	20,875	0	0	0
Marketable securities	2,855	2,860	2,722	3,229	3,710	4,592	4,592	4,592	4,592	4,592	4,592	4,592
Restricted cash	16	16	0	0	0	0	0	0	0	0	0	0
Prepaid expenses and other current assets	198	<u>159</u>	<u>163</u>	224	209	574	<u>574</u>	<u>574</u>	<u>574</u>	<u>574</u>	574	574
Total current assets	31,230	20,297	19,135	21,127	23,582	31,037	31,037	28,522	32,164	27,355	22,821	22,821
Long-term deposits and investment	11,043	16,232	17,780	13,788	8,752	13,542	13,542	13,542	13,542	13,542	13,542	13,542
Marketable securities	530	2,151	4,598	3,306	2,293	2,785	2,785	2,785	2,785	2,785	2,785	2,785
Amounts funded in respect of employee rights upon retirement	11	14	14	15	15	16	16	16	16	16	16	16
Property and equipment	<u>16</u>	<u>18</u>	<u>17</u>	<u>18</u>	<u>17</u>	<u>17</u>	<u>17</u>	<u>16</u>	<u>15</u>	<u>14</u>	13	<u>13</u>
Total assets	42,830	38,712	41,544	38,254	34,659	47,397	47,397	44,881	48,522	43,712	39,177	39,177
<u>Liabilities</u>												
Accounts payable and accrued expenses	1,411	2,716	2,599	2,156	3,143	2,058	2,058	3,058	3,058	3,058	3,558	3,558
Deferred revenue	2,162	2,449	2,449	2,449	2,449	2,449	2,449	2,449	4,152	4,152	4,152	4,152
Payable to related parties	<u>48</u>	0	<u>76</u>	<u>113</u>	<u>45</u>	46	<u>46</u>	<u>46</u>	<u>46</u>	<u>46</u>	46	<u>46</u>
Total current liabilities	3,621	5,165	5,124	4,718	5,637	4,553	4,553	5,553	7,256	7,256	7,756	7,756
Deferred revenues	12,604	13,837	13,226	12,622	12,005	11,388	11,388	10,771	16,030	14,992	13,954	13,954
Employee rights upon retirement	14	18	19	19	19	20	20	20	20	20	20	20
Provision for uncertain tax position	11	11	11	11	11	11	11	11	11	11	11	11
Other liabilities	390	443	423	404	330	313	313	<u>313</u>	<u>313</u>	<u>313</u>	313	313
Total liabilities	16,640	19,474	18,803	17,774	18,002	16,285	16,285	16,668	23,630	22,592	22,054	22,054
Common stock	157	163	170	171	172	207	207	207	207	207	207	207
Additional paid-in capital	71,943	75,170	80,871	81,939	82,584	99,426	99,426	99,976	100,576	101,226	101,976	101,976
Accumulated other comprehensive income (loss)	106	401	727	313	198	702	702	702	702	702	702	702
Retained earnings (accumulated deficit)	(46,016) <b>26,190</b>	(56,496)	(59,027)	(61,943)	(66,297)	(69,223)	(69,223)	(72,672)	(76,593)	(81,015)	(85,761)	(85,761)
Total shareholders' equity		19,238	22,741	20,480	16,657	31,112	31,112	28,213	24,892	21,120	17,124	17,124
Total liabilities and shareholders' equity  *Source: Company filings & B. Pilay ERP. Inc. estimates	42,830	38,712	41,544	38,254	34,659	47,397	47,397	44,881	48,522	43,712	39,177	39,177

\*Source: Company filings & B. Riley FBR, Inc. estimates

\*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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