Important disclosures can be found on pages 16 - 20 of this report.

Oramed Pharmaceuticals Inc. (ORMP – $6.82*)

Coverage Initiated

Jerusalem, Israel
November 18, 2015

Outperform
Price Target: $15.00

STOCK DATA	
52-Week Range	$9.84 – $3.71
3-Month ADTV	61,650
Market Cap (mil)	$79.1
Shrs Outstanding (mil)	11.6
Float (%)	85.8
Fiscal Year-End	August

EARNINGS DATA			
EPS	2014A	2015E	2016E
1Q	($0.14)	($0.19)A	—
2Q	($0.12)	($0.15)A	—
3Q	($0.18)	($0.15)A	—
4Q	($0.18)	($0.16)	—
FY	($0.62)	($0.65)	($0.63)

BALANCE SHEET DATA	
	3Q15
Cash & Equivalents	$17.1
Current Assets	$17.3
Total Assets	$22.1
Total Liabilities	$0.8
Total Stockholder Equity	$21.3
Total Debt	$0.0

$ in millions.

Christopher S. James, M.D.
646.885.5470 . cjames@fbr.com

Justin A. Kim
646.885.5426 . justinkim@fbr.com

Potential Blockbuster Insulin Drug; Awaiting Data from Phase IIb Study; Initiating at Outperform

Summary and Recommendation

We are initiating coverage of Oramed Pharmaceuticals Inc. (ORMP) with an Outperform rating and a 12-month price target of $15 per share. Oramed is developing novel orally administered capsules for the delivery of polypeptides, including oral insulin and oral exenatide. The company has two clinical candidates: ORMD-0801, an oral insulin in Phase IIb development, and ORMD-0901, an oral GLP-1 analog in Phase I development. After completing small Phase IIa studies in patients with type 1 and type 2 diabetes (T1D and T2D), Oramed initiated a 180-patient Phase IIb T2D study in June 2015 with ORMD-0801. As of September 9, 98 patients were enrolled, and we expect data from this 28-day study in mid 2016. We believe that the data with both ORMD-0801 and ORMD-0901 are encouraging and provide a rationale for advanced development. We also believe that additional diabetes data in mid 2016, if positive, could potentially move the stock toward our price target.

Key Points

- **Awaiting upcoming Phase IIb data with ORMD-0801.** Oramed completed a Phase IIa study in 30 patients with T2D. During the seven-day study period, patients were treated with either 460 IU or 690 IU insulin. Overall, ORMD-0801 led to a consistent short-lived rise in plasma insulin levels, which positively affected fasting blood glucose (FBG) concentrations. However, a manufacturing fault that limited the efficacy of the 690 IU dose made a dose-dependent signal unclear. Despite several limitations, including its size, short duration, manufacturing issue, and low bioavailability, we believe additional clinical data could significantly increase investor confidence in the success of ORMD-0801. We anticipate data in mid 2016.
- **Partnership likely after Phase IIb data.** Given the capital requirements of a Phase III study in diabetes, we think Oramed will need to partner ORMD-0801. We view a collaboration as likely after the Phase IIb study is completed. The allowance of Oramed's patent for oral administration in the U.S. increases the probability of securing a major U.S. partner, in our view. That said, we believe several additional studies may be needed to assess efficacy and risks of ORMP-0801 for T2D with common co-administered drugs and in common clinical-use scenarios, based on general FDA guidance.
- **ORMD-0901 shows biologic activity in a small clinical trial.** ORMD-0901 is an oral exenatide GLP-1 analog-based preparation designed with Oramed's oral formulation technology. Oramed completed non-FDA approved clinical trials of ORMP-0901 in healthy volunteers at a medical center in Jerusalem. The first-in-human study demonstrated retained biological activity after oral administration of ORMD-0901 followed by an oral glucose load. While these data are encouraging, we point out that only six subjects were analyzed for safety, with just four subjects considered for the efficacy evaluations. We expect the start of a Phase Ib study with ORMD-0901 in 2016.
- **Valuation.** We base our $15 price target on a probability-weighted DCF and sum-of-the-parts (SOTP) valuation, which we derive by forecasting sales and resulting cash flows for each clinical program.

The Debate™

Debatable Point	Our Thoughts	Time Frame	Impact
Will ORMD-0801 show positive safety and efficacy in the current Phase IIb study?	We have reviewed the previous Phase IIa study results to handicap the potential success of ORMD-0801 in the current Phase IIb study. Overall, ORMD-0801 showed a consistent and short-acting rise in plasma insulin, which positively decreased plasma glucose levels with the 8 mg capsule (16 mg dose). We note that these results can only be described as trends, as the study was not powered to show statistical significance. In the 24 mg dose, there was a manufacturing fault associated with the 16 mg capsule, which makes us uncertain regarding the existence of a dose-related effect. That being said, we think there is a significant market opportunity for oral insulin if the Phase IIb outcome is positive and view the risk-reward profile as favorable.	6 to 12 Months	
Will Oramed successfully partner ORMD-0801 to support late-stage clinical trials, approval, and commercialization?	If ORMD-0801 is shown to be both safe and effective, Oramed plans to ultimately seek a strategic partner or partners with extensive drug development experience and marketing capabilities. Given the likely size and scope (approximately 3,000 patients over 24 weeks) of a Phase III program in T1D and T2D, we would expect Oramed to attempt to partner ORMD-0801 after the Phase II studies are complete. The strategic partner(s) would be responsible for global clinical trials, post-marketing studies, and label expansion, which are outside of Oramed's core developmental capabilities. We expect to see a partnership or partnerships following Phase IIb data, which we think should read out in the mid-2016 time frame.	6 to 18 Months	
Will Oramed's oral GLP-1 candidate (ORMD-0901) prove to be safe and effective in T2D patients?	ORMD-0901 is an oral exenatide GLP-1 analog-based preparation designed with Oramed's oral formulation technology. Oramed completed non-FDA approved clinical trials of ORMD-0901 in healthy volunteers at a medical center in Jerusalem. The first-in-human study demonstrated retained biological activity on insulin excursions after oral administration of ORMD-0901 followed by an oral glucose load. While these data are encouraging and provide a rationale for advanced development, only six subjects were analyzed for safety, and only four subjects were considered for the efficacy evaluations due to adverse events reported upon glucose load.	2 Years+	

Investment Thesis

Given its focus on developing orally administered peptides that are currently available as injectables, we view Oramed as owning platform technology with a strong patent estate. As of FY14, Oramed has 24 patents allowing for oral delivery of proteins and exenatide, with 28 patents pending. The lead product is currently in a 180-patient Phase IIb study for T2D. We believe the data for both ORMD-0801 and ORMD-0901 are compelling and would be buyers of the stock at these levels.

Valuation

Our $15 price target is based on probability-weighted DCF and sum-of-the-parts (SOTP) analyses of the commercial opportunities available to the company. Our model incorporates a 13.5% discount rate and a 3% growth rate, which is in line with development-stage companies.

Catalysts/Milestones

- 2016: initiate Phase Ib ex-U.S. study with ORMD-0901 oral GLP-1.
- Mid 2016: data from 180-patient Phase IIb study with ORMD-0801 oral insulin.

Initiating with an Outperform Rating and $15 Price Target

Oramed Pharmaceuticals Inc. is developing a proprietary platform technology focused on creating orally administered polypeptides. The company has two oral candidates in development in the diabetes space: ORMD-0801, an insulin analog for T1D and T2D, and ORMD-0901, an exenatide analog for T2D. ORMD-0801 is currently in a Phase IIb study in T2D patients with an expected data readout in mid 2016. Oramed also plans to initiate a Phase II multisite study with ORMD-0901 under a U.S. IND in 2016. We think the overall U.S. diabetes market is an attractive, albeit crowded, market with projected sales of more than $24 billion in 2015. We think there is potential for ORMD-0801 to be a blockbuster oral therapy in the diabetes therapeutic market, despite a confounding result in the Phase IIa study.

Valuation Methodology

We are initiating coverage of Oramed with a $15 price target, which implies roughly 120% upside potential to current share price levels. Our $15 price target is based on probability-weighted DCF and sum-of-the-parts (SOTP) analyses of the commercial opportunities available to the company. Our model incorporates a 13.5% discount rate, which is in line with development-stage companies. We ascribe a 20% probability of success (PoS) to ORMD-0801 in T1D and T2D, as we are keen on seeing the results of the Phase IIb trial without the use of the 16 mg capsule. Our SOTP analysis shows that 74% of the total value of ORMP can be ascribed to ORMD-0801 T2D, given its large market size relative to T1D and ORMD-0901 GLP-1 for T2D patients. We ascribe a 10% PoS to ORMD-0901, which completed a Phase I study in healthy volunteers.

ORMP Sum-of-the-Parts Analysis ($ in Millions)

	EV		PoS		EV		Per Diluted Share	
ORMD-0801 - T2D	655.0	*	20.0%	=	131.0	74%	11.05	74%
ORMD-0801 - T1D	116.9	*	20.0%	=	23.4	13%	1.97	13%
ORMD-0901 GLP-1 - T2D	238.3	*	10.0%	=	23.8	13%	2.01	13%
Total Firm Value	1,010.1	*	17.6%	=	178.2	100%	15.03	100%
Total Equity Value					**178.2**	100%	**15.03**	100%
Fully Diluted Shares							11.9	

Source: FBR Research

ORMP DCF Analysis ($ in Millions)

Present Value of FCF	1,010.1
Blended PoS	0.18
Present Value of Equity	178.2
Diluted Shares Outstanding	11.9
Equity Value per Share	**$ 15.03**
Upside/(Downside) Potential	**120.4%**
Terminal Value Summary	
Perpetual Growth Rate	2.0%
Terminal Free Cash Flow	438.6
Terminal Value	3,822.0
Present Value of FCF	1,010.1
Present Value of TV	565.1
Terminal Value % of EV	**55.9%**

Source: FBR Research

Will ORMD-0801 Show Positive Safety and Efficacy in the Current Phase IIb Study?

We have reviewed the previous Phase IIa study results to handicap the potential success of ORMD-0801 in the current Phase IIb study. The overall ORMD-0801 results demonstrated a consistent and short-acting rise in plasma insulin, which positively decreased plasma glucose levels with the 8 mg capsule (460 IU). That said, these results can only be described as trends, as the study was not powered to show statistical significance, and a manufacturing fault may have contributed to the limited efficacy for the 16 mg capsule (690 IU). Data with the (8 mg + 16 mg) dose were excluded in previous analyses but are consistent with trends if considered solely as an 8 mg dose. Since the existence of a dose-related effect is not entirely clear to us at this time, we are cautiously optimistic and see potential for a positive Phase IIb study outcome.

An Orally Bioavailable Insulin Remains an Elusive Unmet Need

In 2014, 21 million individuals were diagnosed with diabetes mellitus in the U.S. across all age groups. It is estimated that approximately 95% of individuals with diabetes worldwide have type 2 diabetes mellitus (T2D). There are 12 classes (insulin inclusive) of drugs approved and marketed for the treatment of patients with T2D in the U.S. Most approved and marketed insulin therapies are administered only subcutaneously (SC), often as multiple injections per day or through subcutaneous infusion with insulin pump delivery. An orally bioavailable insulin-formulated drug could ensure better patient compliance and counteract the risk of hypoglycemia and weight gain associated with the subcutaneous delivery of insulin by mimicking the physiological route of naturally secreted insulin. Furthermore, Oramed's bedtime insulin administration could also offset the abnormal fasting blood glucose (FBG) levels, an indication of diabetes and an obstacle to glycemic management in T2D patients.

ORMD-0801 Data in T2D

ORMD-0801 is Oramed's oral insulin for the treatment of diabetes, which is designed to effectively deliver insulin to the system while withstanding the harsh chemical environment of the gastrointestinal tract. A Phase IIa sub-study was conducted prior to starting a larger multicentered Phase II trial to address the FDA's noted concerns of mitigating potential risks of hypoglycemia.

A randomized, double-blinded, placebo-controlled Phase IIa study was carried out to evaluate the pharmacokinetics and pharmacodynamics of bedtime administration of ORMD-0801 oral insulin in 30 adult T2D patients inadequately controlled with diet and exercise and/or metformin. After a five-day placebo run, the patients were fitted with a blinded continuous glucose monitor (CGM). The study was followed by a single placebo dose on day 1 and a subsequent seven-day ORMD-0801 (460 IU, 690 IU, and placebo) treatment in an in-patient setting. The plasma insulin and c-peptide levels were measured for five hours post dosing. No hypoglycemic events or ORMD-0801 related adverse events were reported in the study.

Phase IIa Results Pivot Focus to Phase IIb Study

Overall, the patients treated with ORMD-0801 reported higher mean plasma insulin levels throughout the 180-minute day 8 post-dosing period in comparison to baseline. Moreover, in the first hour post-dosing, the plasma insulin exposure was 20.53 µIU*hr/mL greater in ORMD-0801 patients compared to placebo and demonstrated a concentration time course similar to that of the plasma c-peptide. The fasting CGM data reported a mean –30.24 mg/dL difference in the last two days of active treatment in comparison to placebo.

That being said, the 690 IU dose (8 mg + 16 mg) data showed confounding results, namely a smaller difference in CGM between the treatment and placebo arm than the 430 IU (8 mg + 8 mg) dose. We note that these results may have been due to manufacturing faults limiting the efficacy of the 16 mg capsule.

Phase IIa Results (CGM)

Fasting CGM Glucose (mg/DL)	Placebo (n = 10)	ORMD-0801 8 mg + 8 mg (16 mg dose, n = 10)	Difference (ORMD-0801 - placebo)	ORMD-0801 8 mg + 16 mg (24 mg dose, n=8)	Difference (ORMD-0801 - placebo)
Last 2 days of data	156.26 (58.62)	126.02 (27.26)	-30.24	136.12 (43.17)	-20.14
All 7 days	154.37 (57.99)	129.27 (27.43)	-25.1	144.83 (39.28)	-9.54
Nighttime mean (SD) CGM Glucose (mg/DL)	**Placebo (n = 10)**	**ORMD-0801 8 mg + 8 mg (16 mg dose, n = 10)**	**Difference (ORMD-0801 - placebo)**	**ORMD-0801 8 mg + 16 mg (24 mg dose, n=8)**	**Difference (ORMD-0801 - placebo)**
Last 2 days of data	167.95 (64.17)	135.64 (39.40)	-32.31	150.24 (49.26)	-17.71
All 7 days	165.85 (60.76)	139.73 (38.86)	-26.12	149.38 (38.25)	-16.47
Daytime mean (SD) Fasting CGM Glucose (mg/DL)	**Placebo (n = 10)**	**ORMD-0801 8 mg + 8 mg (16 mg dose, n = 10)**	**Difference (ORMD-0801 - placebo)**	**ORMD-0801 8 mg + 16 mg (24 mg dose, n=8)**	**Difference (ORMD-0801 - placebo)**
Last 2 days of data	176.06 (63.70)	153.23 (40.16)	-22.83	158.58 (40.67)	-17.48
All 7 days	175.99 (61.12)	152.55 (36.99)	-23.44	163.05 (30.28)	-12.94

Source: Company reports

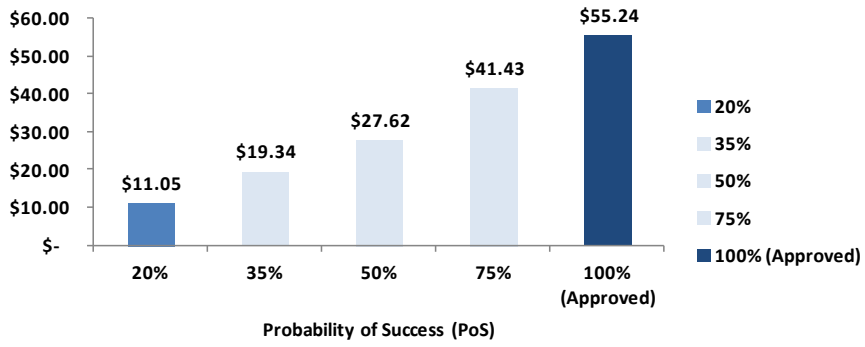
Phase IIb Study for ORMD-0801 in T2D: Potential Inflection Point

A randomized, double-blinded, multicenter Phase IIb study is currently enrolling patients to evaluate the effect of ORMD-0801 in approximately 180 patients at more than 30 U.S. sites. The study will evaluate the safety and pharmacodynamic effects of ORMD-0801 on mean nighttime glucose. As of September 9, 2015, more than 50% of patients had been randomized in the Phase IIb study. We believe enrollment could be completed in early 2016, with an anticipated data readout in the middle of 2016 (May/June).

ORMD-0801 in T2D Sensitivity Analysis

We assign a 20% PoS to ORMD-0801 in T2D, worth $11.05 per share. At 100% success or developmental approval, we estimate that ORMD-0801 could be worth $55.24 per share in T2D. Every 10% increase in probability of success is worth an incremental $5.52 per share, according to our model. We note that diabetes is a very competitive therapeutic area with many commercialized therapies in the market.

ORMD-0801 in T2D Probability of Success Analysis ($ per Share)



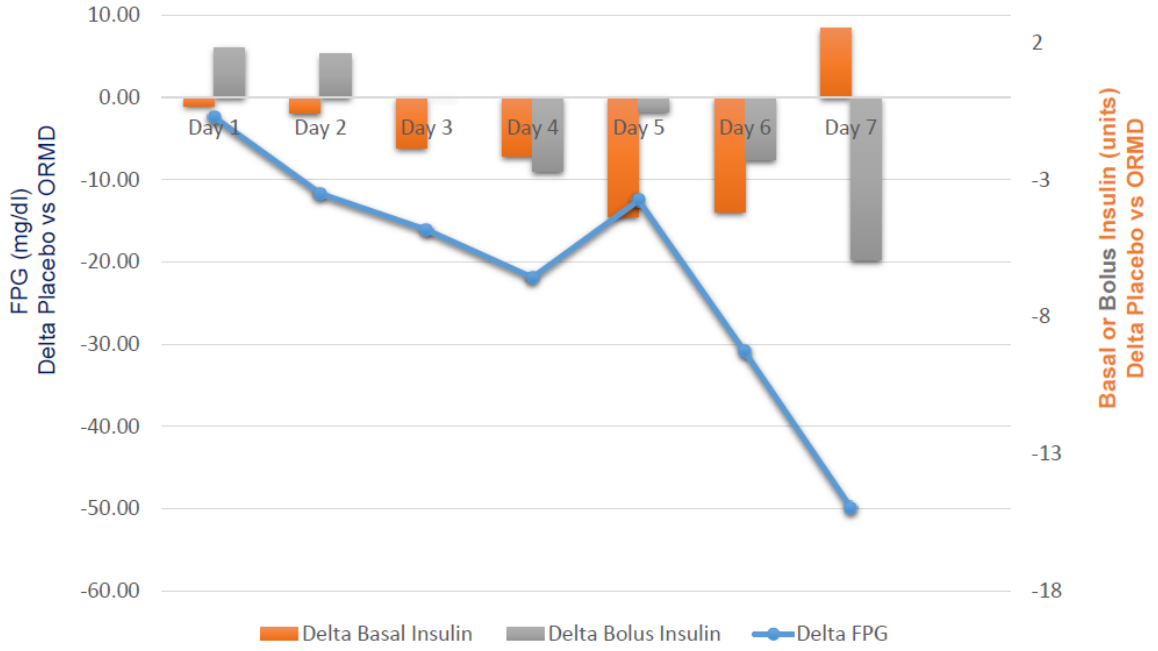
Source: FBR Research

ORMD-0801 May Have a Role in T1D

A randomized, double-blinded, placebo-controlled Phase IIa study was conducted to evaluate the impact of preprandial ORMD-0801 in 25 T1D patients over a seven-day period. Patients were administered ORMD-0801 capsules or placebo three times a day, 45 minutes prior to meals.

Overall, patients demonstrated decreased levels of post-prandial glucose when compared to placebo. As shown below, fasting plasma glucose (FPG) levels were consistently under baseline, peaking at –60.2 mg/dl on day 7, compared with –10.2 mg/dl in the placebo cohort. A direct correlation was observed between reduced FPG levels and reduced rapid-acting insulin requirements, with a mean difference of –5.9 mIU/ml insulin intake between active and placebo cohorts on day 7. An equal number of hypoglycemic events were reported in both the cohorts on the last day of treatment, requiring clinical intervention.

FPG in Type 1 Diabetes (T1D) Patients

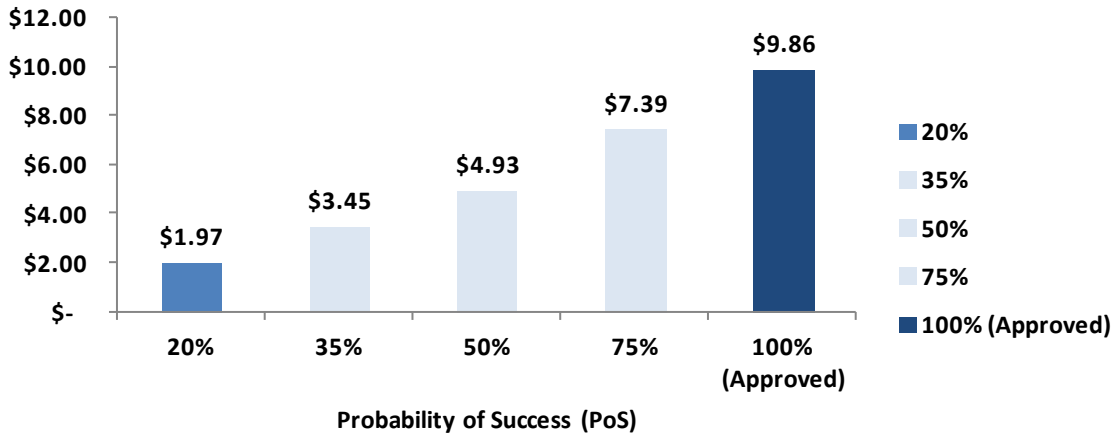


Source: Company reports

ORMD-0801 in T1D Sensitivity Analysis

We assign a 20% PoS to ORMD-0801 in T1D, worth $1.97 per share. At 100% success or developmental approval, we estimate that ORMD-0801 could be worth $9.86 per share in T1D. Every 10% increase in probability of success is worth an incremental $0.99 per share, according to our model. We note that T1D patients account for approximately 5% of patients with diabetes in the U.S.

ORMD-0801 in T1D Probability of Success Analysis ($ per Share)



Source: FBR Research

Will Oramed Successfully Partner ORMD-0801 to Support Late-Stage Clinical Trials, Approval, and Commercialization?

Given the typically large size of a pivotal trial for treatment in T1D and T2D, Oramed plans to seek a strategic partner before entering late-stage clinical development. As an example, Sanofi's (SNY – Not Rated) long-acting insulin analog, Toujeo, was approved off four registrational studies with 3,020 patients with either T1D (n=546) and T2D (n=2,474) over a 26-week period. We think a strategic partner will not only support the necessary investment for a pivotal stage trial but also lend expertise toward gaining regulatory approval and commercialization of ORMD-0801.

We think the potential for a partnership, as well as the attractiveness of such an agreement, will be largely influenced by the outcome of the Phase IIb study in T2D. We note that the MannKind Corporation (MNKD – Not Rated) entered an agreement with Sanofi following approval of its inhalable insulin therapy Afrezza. Under the terms of the Sanofi/MannKind agreement, MannKind received an up-front payment of $150 million and could receive potential milestone payments of up to $775 million. Finally, Sanofi is leading the commercial efforts for Afrezza, whose profits will be split 65%/35% Sanofi/MannKind. We note that this agreement was finalized following FDA approval of Afrezza. On very positive Phase IIb data, we think that there could be a number of potential strategic partnerships for Oramed, and below we provide a list of large pharmaceutical corporations active in the diabetes space.

Major Players in the Diabetes Space*

Company	Market Cap ($M)	Approved Therapies
Novo-Nordisk	107,454.36	IDegLira, Levemir, NovoLog, Prandin, Ryzodeg, Tresiba, Victoza
Sanofi	111,820.44	Afrezza, Amaryl, Apidra, Lantus, Lyxumia, Toujeo
Merck & Co.	149,366.16	Janumet, Januvia, Marizev
Eli Lilly	88,147.77	Basaglar, Bydureon, Byetta, Glyxambi, Humalog, Humulin, Jardiance, Jentadueto, Synjardy, Tradjenta, Trulicity
AstraZeneca	79,091.11	Bydureon, Byetta, Farxiga, Kombiglyze, Onglyza, Symlin, Xigduo
Novartis	208,381.11	Eucreas, Fortamet, Galvus, Starlix
Boehringer Ingelheim	Private	Basaglar, Glyxambi, Jardiance, Jentadueto, Synjardy, Tradjenta

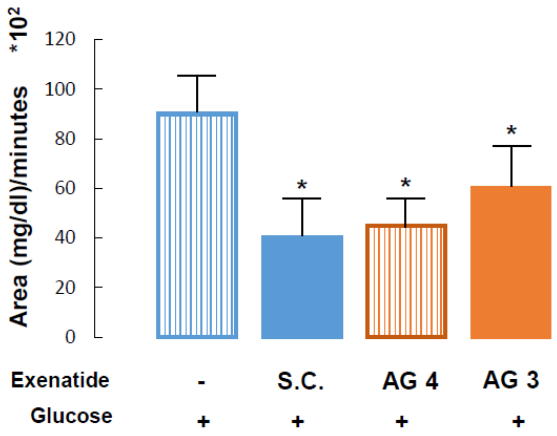
*As of November 16, 2015.

Source: Company reports and FactSet

Will Oramed's Oral GLP-1 Candidate (ORMD-0901) Prove to Be Safe and Efficacious in T2D Patients?

ORMD-0901 is an oral exenatide GLP-1 analog-based preparation using Oramed's proprietary oral formulation technology. The preclinical studies were completed in 2009, according to the company. The results showed a reduction of glucose excursion in dogs. Subcutaneous delivery of exenatide led to a 51% reduction in mean glucose $AUC_{0\text{-}150}$, compared with formulations of ORMD-0901 that led to a 43% and 29% reduction. We describe these as trends since the data were not statistically significant due to the small sample size (*p = 0.068).

Treatment-Related Trends of Glucose Lowering in Dogs



Source: Company reports

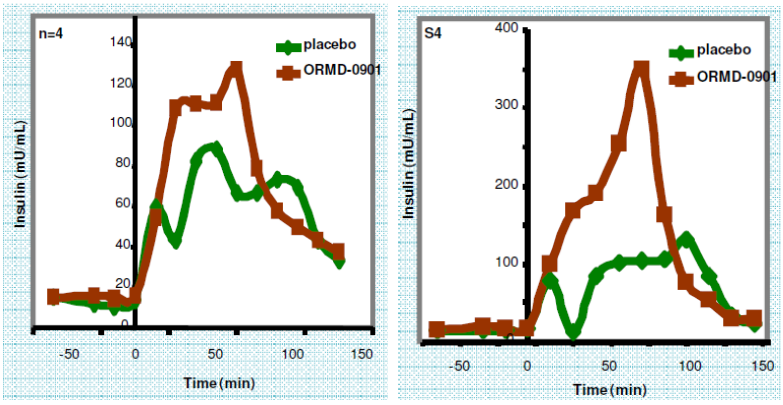
Phase I Study Design in Healthy Volunteers

Oramed conducted a first-in-human, single-blind, two-period study of ORMD-0901 in healthy subjects. Six healthy male volunteers were administered a placebo (visit one) or 150 µg oral exenatide (visit two). The participants were challenged with a 75 g oral glucose load 60 minutes after oral administration (time: zero) and monitored for 150 minutes. Blood samples were drawn every 15 minutes throughout the monitoring session to assess the changes in plasma insulin levels. Importantly, the data of six subjects were considered for the safety assessment, but only four subjects were considered for the efficacy evaluation due to adverse events reported upon glucose load at visit one (placebo).

Results of Phase I Study Support Proof-of-Principle

Overall, we think the data suggest bioactivity and an induced insulin release following oral exenatide absorption. As seen below, insulin levels peaked in both placebo and exenatide-treated subjects within 60 to 70 minutes after a glucose load. The mean peak insulin concentration in exenatide-treated subjects was 21% higher than in the placebo group. Insulin levels returned to baseline within 150 minutes in both sessions. The mean $AUC_{0\text{-}150}$ was 17.6% higher in the exenatide group versus placebo. We view these data as providing proof-of-principle for ORMD-0901's retained biological functionality with the harsh environment of the human gut. Furthermore, we believe the results, albeit in a limited number of patients, provide a rationale for further development. ORMD-0901 was well tolerated by all six subjects, and no serious adverse events (SAEs) were observed. Additionally, there was no nausea reported in this study, which is the most frequently reported adverse reaction for injectable exenatide.

Insulin Responses following ORMD-0901 Administration

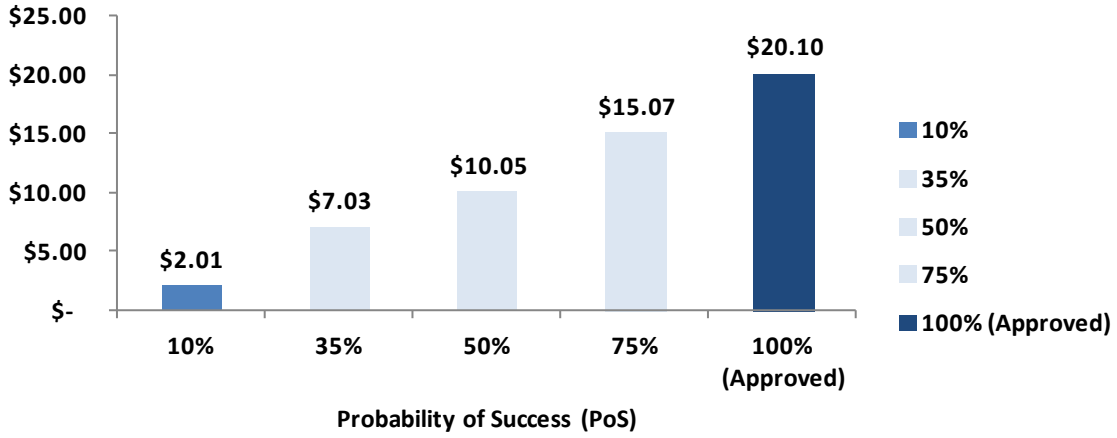


Source: Company reports

ORMD-0901 in T2D Sensitivity Analysis

We assign a 10% PoS to ORMD-0901 in T2D, worth $2.01 per share. At 100% success or developmental approval, we estimate that ORMD-0901 could be worth $20.10 per share in T2D. Every 10% increase in probability of success is worth an incremental $2.01 per share, according to our model. We note that the addressable market for exenatide is a significantly smaller subset of the market for insulin in T2D.

ORMD-0901 in T2D Probability of Success Analysis ($ per Share)



Source: FBR Research

Financial Profile

F3Q15 Earnings Review

On July 1, 2015, Oramed reported EPS of ($0.15) for the third quarter ending May 31, 2015. R&D spending for the quarter decreased to $0.915 million from $1.136 million in F2Q15. G&A spend increased to $0.719 million from $0.538 million in F2Q15. The company reported a cash and equivalents balance of $17.15 million, and we estimate that it will end the fiscal year with approximately $16.8 million. We believe these resources should give the company a cash runway into early FY17.

Letter of Intent with Sinopharm/Hefei

On July 7, 2015, Oramed announced that it had signed a non-binding Letter of Intent (LOI) for an investment and license agreement in China with Sinopharm Capital Management and Hefei Life Science & Technology Park Investments and Development Co. (Sinopharm/Hefei). The potential deal gives Oramed $50 million in stock purchase funds and milestones payments in exchange for a roughly 10% stake in Oramed Pharmaceuticals and the rights for oral insulin in China. In addition, Oramed would receive 10% in royalties on sales in China associated with the oral insulin. In exchange for exclusively negotiating with Sinopharm/Hefei for 60 days (amended later to December 22, 2015), Oramed received $500,000 as a no-shop fee.

If the deal is agreed upon, Sinopharm/Hefei will purchase 1.2 million shares of common stock at a price of $10.39 per share from Oramed and deliver an up-front payment of approximately $11 million. An additional $26.5 million would be paid out following the completion of milestones. We believe this deal with a large healthcare player could further validate the oral delivery platform and Oramed's commitment to the diabetes space.

Management[1]

Nadav Kidron, Esq., chief executive officer, president, and director. Mr. Kidron currently serves as CEO and director of Oramed, which he co-founded in 2006. He is on the board of directors of Entera Bio, a joint venture formed by Oramed and DNA Biomedical Solutions. He received a bachelor's degree in law and an International Masters of Business Administration from Bar-Ilan University in Israel. He is a fellow of the Merage Business Executive Leadership Program and a member of the Israeli Bar Association.

Miriam Kidron, Ph.D., chief scientific officer and director. Dr. Kidron currently serves as chief scientific officer and director of Oramed Pharmaceuticals, which she co-founded in 2006. Dr. Kidron is a pharmacologist and biochemist; she received her Ph.D. in biochemistry from the Hebrew University of Jerusalem. Dr. Kidron has been a senior researcher in the diabetes unit at Hadassah-Hebrew University Medical Center in Jerusalem, Israel, for 20 years and earned the Bern Schlanger Award for her work on diabetes research. Earlier on, she was a visiting professor at the medical school at the University of Toronto and is a member of the American, European, and Israeli Diabetes Associations.

Yifat Zommer, CPA, chief financial officer. Ms. Zommer serves as chief financial officer of Oramed Pharmaceuticals, which she joined in 2009. Previously she served as chief financial officer for Witech Communications Ltd. and CTWARE Ltd. Before that, she was an audit manager at Kesselman & Kesselman, a member of PwC, where she worked for five years. Ms. Zommer received a bachelor's degree in accounting and economics from The Hebrew University, a masters of business administration from Tel-Aviv University, and a master's degree in law (LL.M.) from Bar-Ilan University. She is a certified public accountant in Israel.

[1] *Source: Company reports*

Risks

Clinical risk. The development of clinical drug candidates is inherently risky and may never lead to marketable products. Oramed's lead drug candidate, ORMD-0801, is at an early stage of 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.

Competitive risk. Several companies are developing candidates or marketing products for the same treatment indications for which Oramed is developing product candidates. These candidates or products may negatively affect future pricing power or market opportunities for Oramed's developmental candidates.

Financial risk. Oramed 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 with a market capitalization under $100 million on common shares outstanding. Investors could potentially be at risk of finding a liquid market to buy or sell shares.

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.

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

Company Profile

Oramed Pharmaceuticals Inc. develops a proprietary platform technology focused on creating orally administered oral polypeptides. The company has two oral candidates in development in the diabetes space: ORMD-0801, an insulin analog for type 1 diabetes (T1D) and type 2 diabetes (T2D), and ORMD-0901, an exenatide analog for type 2 diabetes (T2D). ORMD-0801 is currently in a Phase IIb study in T2D patients, which is expected to read out in 2016. In F3Q16, Oramed plans to initiate a Phase II multi-site study with ORMD-0901 under a U.S. IND.

Income Statement—Oramed Pharmaceuticals Inc. (ORMP)

$ in Millions

	2011A	2012A	2013A	2014A	1Q15A	2Q15A	3Q15A	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Royalties														
ORMD 0801- T2D	-	-	-	-	-	-	-	-	-	-	-	-	-	5.3
ORMD 0801- T1D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ORMD-0901 -T2D	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Product Royalties	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**5.3**
Gross Profit	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**5.3**
Operating Expenses:														
Research and Development	(1.2)	(1.7)	(2.3)	(3.3)	(1.3)	(1.1)	(0.9)	(1.0)	(4.3)	(4.5)	(5.7)	(6.4)	(7.2)	(7.9)
Selling, General and Administrative	(1.3)	(1.2)	(2.0)	(2.6)	(0.6)	(0.5)	(0.7)	(0.8)	(2.7)	(3.0)	(3.4)	(3.9)	(4.6)	(5.1)
Total Operating Expenses	(2.4)	(2.9)	(4.3)	(5.9)	(1.9)	(1.7)	(1.6)	(1.8)	(7.0)	(7.5)	(9.2)	(10.4)	(11.8)	(13.0)
Growth		18%	49%	37%	15%	-12%	-2%	11%	19%	7%	22%	13%	14%	10%
% of Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	244%
Operating Profit/(Loss) (EBIT)	(2.4)	(2.9)	(4.3)	(5.9)	(1.9)	(1.7)	(1.6)	(1.8)	(7.0)	(7.5)	(9.2)	(10.4)	(11.8)	(7.7)
Growth		18%	49%	37%	15%	-12%	-2%	11%	19%	7%	22%	13%	14%	-35%
Financial income	0.0	0.0	0.2	0.2	0.0	0.0	0.1	0.1	0.2	0.0	0.1	0.5	0.4	0.4
Financial expenses	(0.0)	(0.2)	(0.3)	(0.0)	(0.0)	(0.0)	-	(0.0)	(0.0)	-	(0.3)	(0.9)	(1.6)	(2.2)
Other Income (Expense), Net	0.8	(0.2)	-	-	-	-	-	-	-	-	-	-	-	-
Net Profit/(Loss) - Pretax	(1.6)	(3.3)	(4.4)	(5.7)	(1.9)	(1.6)	(1.6)	(1.8)	(6.9)	(7.5)	(9.4)	(10.8)	(13.0)	(9.4)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
(Taxes)/Tax Benefits	0.0	(0.1)	0.2	(0.0)	-	-	-	-	-	-	-	-	-	-
Net Income (After Taxes)	(1.6)	(3.3)	(4.2)	(5.7)	(1.9)	(1.6)	(1.6)	(1.8)	(6.9)	(7.5)	(9.4)	(10.8)	(13.0)	(9.4)
Growth		114%	27%	35%	16%	-14%	-3%	12%	21%	9%	25%	15%	20%	-28%
Basic Net Profit/ (Loss) per Common Share	**(0.02)**	**(0.57)**	**(0.59)**	**(0.62)**	**(0.19)**	**(0.15)**	**(0.15)**	**(0.16)**	**(0.65)**	**(0.63)**	**(0.68)**	**(0.60)**	**(0.73)**	**(0.53)**
Weighted Average Shares Outstanding	65.0	5.9	7.2	9.2	10.1	10.8	10.8	10.8	10.7	11.9	13.9	17.9	17.9	17.9
Growth		-91%	23%	28%	10%	7%	0%	0.0%	15%	11%	17%	29%	0%	0%
Diluted Net Profit/ (Loss) per Common Share	**(0.02)**	**(0.57)**	**(0.59)**	**(0.62)**	**(0.19)**	**(0.15)**	**(0.15)**	**(0.16)**	**(0.65)**	**(0.63)**	**(0.68)**	**(0.60)**	**(0.73)**	**(0.53)**
Fully Diluted Average Shares	65.0	5.9	7.2	9.2	10.1	10.8	10.8	10.8	10.7	11.9	13.9	17.9	17.9	17.9
Growth		-91%	23%	28%	10%	7%	0%	0.0%	15%	11%	17%	29%	0%	0%

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Christopher S. James, M.D. 646.885.5470 . cjames@fbr.com

Source: Company reports and FBR Research

Balance Sheet—Oramed Pharmaceuticals Inc. (ORMP)

$ in Millions

	2011A	2012A	2013A	2014A	1Q15A	2Q15A	3Q15A	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Current assets:														
Cash and cash equivalents	1.5	4.4	2.3	1.8	6.7	1.1	3.8	2.2	2.2	7.1	36.4	78.2	88.4	101.1
Short-term deposits	1.8	0.5	5.2	18.5	17.0	16.4	12.5	12.6	12.6	12.7	12.8	13.0	13.4	14.0
Marketable securities	0.4	0.2	1.0	1.0	0.7	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.9
Restricted cash	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Accounts receivable - other	0.5	0.1	-	-	-	-	-	-	-	-	-	-	-	0.4
Prepaid expenses and other current assets	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Related parties	-	0.0	0.0	0.3	-	-	-	-	-	-	-	-	-	-
Grants receivable from the Office of the Chief Scientist	0.0	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total current assets	4.3	5.3	8.6	21.8	24.5	18.3	17.3	15.7	15.7	20.7	50.2	92.1	102.7	116.7
Investment in a joint venture	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Long-term deposits and investment	0.0	0.0	0.0	0.0	0.0	4.7	4.8	4.8	4.8	4.8	4.8	4.8	4.8	4.8
Amounts funded for employee rights upon retirement	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Property and equipment, net	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.5	1.0	2.9
Total assets	4.3	5.3	8.7	21.8	24.6	23.0	22.1	20.6	20.6	25.6	55.2	97.4	108.5	124.4
Liabilities and stockholders' equity														
Current liabilities:														
Accounts payable and accrued expenses	0.4	0.6	0.5	0.9	0.8	0.6	0.7	0.9	0.9	0.9	0.9	0.9	-	0.3
Related parties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Account payable with former shareholder	0.0	-	-	-	-	-	-	-	-	-	-	-	-	-
Total current liabilities	0.4	0.6	0.5	1.0	0.8	0.6	0.8	1.0	1.0	1.0	1.0	1.0	0.0	0.3
Warrants	-	0.6	-	-	-	-	-	-	-	-	-	-	-	-
Long-term debt	-	-	-	-	-	-	-	-	-	-	25.0	50.0	75.0	100.0
Employee rights upon retirement	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Provision for uncertain tax position	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total liabilities	0.6	1.5	0.5	1.0	0.9	0.6	0.8	1.0	1.0	1.0	26.0	51.0	75.1	100.4
Common stock	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Additional paid-in capital	18.2	21.6	29.9	48.0	53.2	53.5	54.0	54.0	54.0	66.4	80.4	108.4	108.4	108.4
Accumulated other comprehensive income	-	-	0.3	0.5	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Accumulated Loss	(14.5)	(17.9)	(22.1)	(27.8)	(29.7)	(31.4)	(32.9)	(34.7)	(34.7)	(42.2)	(51.5)	(62.3)	(75.3)	(84.7)
Total stockholders' (deficit) equity	3.7	3.8	8.1	20.8	23.7	22.3	21.3	19.6	19.6	24.6	29.2	46.4	33.4	24.0
Total liabilities and stockholders' equity	4.3	5.3	8.7	21.8	24.6	23.0	22.1	20.6	20.6	25.6	55.2	97.4	108.5	124.4

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Christopher S. James, M.D. 646.885.5470 . cjames@fbr.com

Source: Company reports and FBR Research

Discounted Cash Flow (DCF) Analysis—Oramed Pharmaceuticals Inc. (ORMP)

$ in Millions

	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	TVE
EBIT	**(5.9)**	**(7.0)**	**(7.5)**	**(9.2)**	**(10.4)**	**(11.8)**	**(7.7)**	**5.3**	**57.1**	**128.0**	**233.1**	**349.7**	**408.4**	**456.6**	**511.6**	**574.3**	**646.1**	
Effective Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	
Tax Expense	-	-	-	-	-	-	-	-	-	(38.40)	(69.93)	(104.90)	(122.51)	(136.97)	(153.47)	(172.30)	(193.82)	
NOPAT	**(5.9)**	**(7.0)**	**(7.5)**	**(9.2)**	**(10.4)**	**(11.8)**	**(7.7)**	**5.3**	**57.1**	**89.6**	**163.2**	**244.8**	**285.9**	**319.6**	**358.1**	**402.0**	**452.3**	
Add: Depreciation & Amortization	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.4	1.5	1.9	2.7	4.2	6.5	8.8	11.3	13.8	16.4	
Less: Change in Working Capital	0.2	0.3	(0.1)	(0.1)	(0.1)	(1.4)	(0.9)	(1.1)	(2.2)	(2.9)	(3.9)	(4.4)	(2.7)	(2.4)	(2.7)	(3.0)	(3.3)	
Less: Capital Expenditures	(0.0)	(0.0)	(0.0)	(0.2)	(0.3)	(0.5)	(2.1)	(7.8)	(3.6)	(7.3)	(12.9)	(19.2)	(22.4)	(25.0)	(28.0)	(31.4)	(35.3)	
Unlevered Free Cash Flow	(5.8)	(6.7)	(7.6)	(9.5)	(10.8)	(13.6)	(10.5)	(3.2)	52.8	81.3	149.1	225.4	267.2	301.0	338.7	381.4	430.0	
Terminal Value																		438.6
Total Free Cash Flows	(5.8)	(6.7)	(7.6)	(9.5)	(10.8)	(13.6)	(10.5)	(3.2)	52.8	81.3	149.1	225.4	267.2	301.0	338.7	381.4	430.0	438.6
Discount Period	0.9	0.1	1.1	2.1	3.1	4.1	5.1	6.1	7.1	8.1	9.1	10.1	11.1	12.1	13.1	14.1	15.1	15.1
Discount Factor	0.9	1.0	0.9	0.8	0.7	0.6	0.5	0.5	0.4	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.1	0.1
Discounted Free Cash Flows	**(5.1)**	**(6.6)**	**(6.6)**	**(7.3)**	**(7.3)**	**(8.1)**	**(5.5)**	**(1.5)**	**21.5**	**29.1**	**47.1**	**62.7**	**65.5**	**65.0**	**64.5**	**64.0**	**63.6**	**64.9**

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Christopher S. James, M.D. 646.885.5470 . cjames@fbr.com

Source: Company reports and FBR Research

Sum-of-the-Parts (SOTP) Analysis—Oramed Pharmaceuticals Inc. (ORMP)

$ in Millions

	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	TVE
ORMD-0801 - T2D																		
Royalty Revenue						-	5	12	57	83	174	225	261	303	352	409	475	
Gross Income	-	-	-	-	-	-	5	12	57	83	174	225	261	303	352	409	475	
R&D Share	(2.9)	(4)	(4)	(5)	(5)	(5)	(5)	(6)	(6)	(7)	(10)	(13)	(16)	(18)	(21)	(25)	(29)	
G&A Share	(2.4)	(2)	(3)	(3)	(4)	(4)	(4)	(5)	(5)	(6)	(7)	(7)	(8)	(9)	(10)	(10)	(12)	
Operating Income	(5.3)	(6.3)	(6.7)	(8.1)	(8.7)	(9.3)	(4.6)	1.8	46.2	70.7	157.2	204.2	237.7	276.6	321.8	374.2	435.2	
Less: Tax	-	-	-	-	-	-	-	-	-	(21)	(47)	(61)	(71)	(83)	(97)	(112)	(131)	
NOPAT	(5.3)	(6)	(7)	(8)	(9)	(9)	(5)	2	46	49	110	143	166	194	225	262	305	
Plus: Share of Noncash	0.1	0	(0)	(0)	(0)	(1)	(2)	(3)	(3)	(5)	(10)	(11)	(11)	(11)	(12)	(13)	(15)	
Unlevered FCF	(5.2)	(6)	(7)	(8)	(9)	(11)	(6)	(1)	43	45	101	132	156	182	213	249	290	2,574
Discount Factor	-	1.0	0.9	0.8	0.7	0.6	0.5	0.5	0.4	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.1	0.1
Discounted FCF	-	(6)	(6)	(6)	(6)	(6)	(3)	(0)	17	16	32	37	38	39	41	42	43	381

ORMD-0801 - T2D	655

ORMD-0801 - T1D																		
Royalty Revenue	-	-	-	-	-	-	-	3	5	22	29	54	63	65	68	71	74	
Gross Income	-	-	-	-	-	-	-	3	5	22	29	54	63	65	68	71	74	
R&D Share	(0.2)	(0)	(0)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(2)	(3)	(4)	(4)	(4)	(4)	(4)	
G&A Share	(0.1)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	
Operating Income	(0.3)	(0.4)	(0.4)	(0.6)	(0.8)	(1.2)	(1.5)	1.0	3.6	20.4	26.6	50.4	58.4	60.8	63.3	65.9	68.6	
Less: Tax	-	-	-	-	-	-	-	-	-	(6)	(8)	(15)	(18)	(18)	(19)	(20)	(21)	
NOPAT	(0.3)	(0)	(0)	(1)	(1)	(1)	(2)	1	4	14	19	35	41	43	44	46	48	
Plus: Share of Noncash	0.0	0	(0)	(0)	(0)	(0)	(1)	(2)	(0)	(1)	(2)	(3)	(3)	(2)	(2)	(2)	(2)	
Unlevered FCF	(0.3)	(0)	(0)	(1)	(1)	(1)	(2)	(1)	3	13	17	32	38	40	42	44	46	406
Discount Period		0.1	1.1	2.1	3.1	4.1	5.1	6.1	7.1	8.1	9.1	10.1	11.1	12.1	13.1	14.1	15.1	
Discount Factor		1.0	0.9	0.8	0.7	0.6	0.5	0.5	0.4	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.1	0.1
Discounted FCF	-	(0)	(0)	(0)	(1)	(1)	(1)	(0)	1	5	5	9	9	9	8	7	7	60

ORMD-0801 - T1D	117

ORMD-0901 GLP-1 - T2D																		
Royalty Revenue							-	5	10	41	55	105	124	131	139	148	157	
Gross Income	-	-	-	-	-	-	-	5	10	41	55	105	124	131	139	148	157	
R&D Share	(0.2)	(0)	(0)	(0)	(1)	(1)	(1)	(1)	(2)	(3)	(4)	(8)	(10)	(11)	(11)	(12)	(13)	
G&A Share	(0.1)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(2)	(2)	(2)	(2)	
Operating Income	(0.3)	(0.4)	(0.4)	(0.5)	(0.9)	(1.3)	(1.5)	2.6	7.3	37.0	49.3	95.1	112.3	119.2	126.5	134.1	142.3	
Less: Tax	-	-	-	-	-	-	-	-	-	(11)	(15)	(29)	(34)	(36)	(38)	(40)	(43)	
NOPAT	(0.3)	(0)	(0)	(1)	(1)	(1)	(2)	3	7	26	34	67	79	83	89	94	100	
Plus: Share of Noncash	0.0	0.0	(0.0)	(0.0)	(0.0)	(0.2)	(0.6)	(4.1)	(0.5)	(2.4)	(3.0)	(5.3)	(5.1)	(4.9)	(4.8)	(4.8)	(4.9)	
Unlevered FCF	(0.3)	(0)	(0)	(1)	(1)	(1)	(2)	(2)	7	23	32	61	73	79	84	89	95	842
Discount Factor	-	1.0	0.9	0.8	0.7	0.6	0.5	0.5	0.4	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.1	0.1
Discounted FCF	-	(0)	(0)	(0)	(1)	(1)	(1)	(1)	3	8	10	17	18	17	16	15	14	124

ORMD-0901 GLP-1 - T2D	238

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Christopher S. James, M.D. 646.885.5470 . cjames@fbr.com

Source: Company reports and FBR Research

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

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Buying Calls or Puts--Investors may lose the entire premium paid.

Selling Covered Calls--Selling calls on long stock position. Risk is that the stock will be called away at strike, limiting investor profit to strike plus premium received.

Selling Uncovered Calls--Unlimited risk that investors may experience losses much greater than premium received.

Selling Uncovered Puts--Significant risk that investors will experience losses much greater than premium income received.

Buying Vertical Spreads (Calls--long call and short call with higher strike; Puts--long put and short put with lower strike) Same expiration month for both options. Investors may lose the entire premium paid.

Buying Calendar Spreads (different expiration months with short expiration earlier than long). Investors may lose the entire premium paid.

Selling Call or Put Vertical Spreads (Calls--short call and long call with higher strike; Puts--short put and long put with a lower strike, same expiration month for both options.) Investors risk the loss of the difference between the strike prices, reduced by the premium received.

Buying Straddle--Buying a put and a call with the same underlying strike and expiration. Investors risk loss of the entire premium paid.

Selling Straddle--Sale of call and put with the same underlying strike and expiration.) Unlimited risk that investors will experience losses much greater than the premium income received.

Buying Strangle--Long call and long put, both out of the money, with the same expiration and underlying security. Investors may lose the entire premium paid.

Selling Strangle--Short call and put, both out of the money, with the same expiration and underlying security. Unlimited risk of loss in excess premium collected.

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Rating	FBR Research Distribution [1]	FBR Banking Services in the past 12 months[1]
BUY [Outperform]	59.19%	32.20%
HOLD [Market Perform]	37.44%	9.58%
SELL [Underperform]	3.36%	6.67%

(1) As of midnight on the business day immediately prior to the date of this publication.

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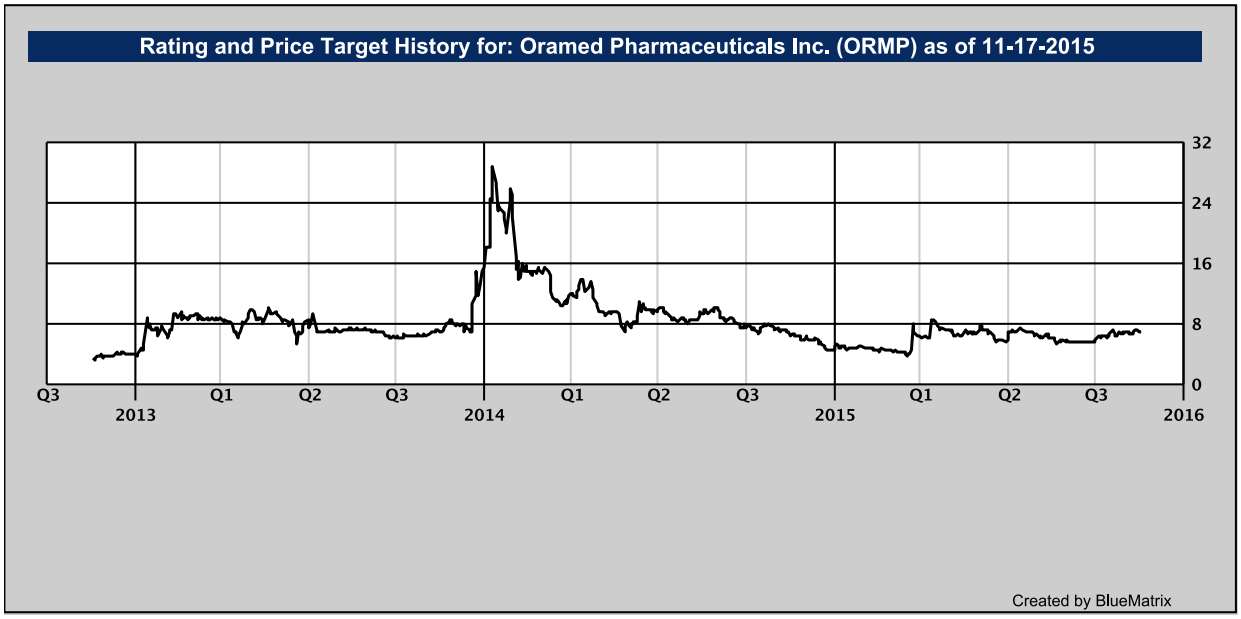
Rating and Price Target History for: Oramed Pharmaceuticals Inc. (ORMP) as of 11-17-2015
32
24
16
8
0
Q3
Q1
Q2
Q3
Q1
Q2
Q3
Q1
Q2
Q3
2013
2014
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