

Initiating Coverage

January 7, 2014

TICKER	NASDAQ: ORMP
RATING	BUY
PRICE TARGET	\$27.00
Price (January 06, 2013)	\$18.15

Oramed Pharmaceuticals

Improving the Gold Standard in Diabetes; Initiate at Buy and \$27 PT

Market Data and Valuation Multiples

Market Cap (M):	\$172.9
Shares out (M):	9.5
Float (M):	7.2
Daily Vol, 3 Mo Avg (M):	0.3
52-Week Range:	\$19.29-\$3.72
Cash & Cash Eq (M):	\$18.0
Debt (M):	\$0.0

Cash & Cash Eq is an estimate, and includes \$15.8M in gross proceeds raised in a December 2013 equity financing.

Financial Metrics

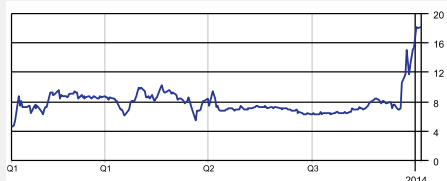
Short Interest (M):	0.1
Instit. Holdings (%):	28.4%
Cash Burn (M):	\$5.7
Short Interest (% of Float):	1.7%

Cash Burn represents OpEx spend expected in FY2014.

EPS	1Q	2Q	3Q	4Q	FY
2012	-0.10A	-0.17A	-0.09A	-0.19A	-0.57A
2013	-0.16A	-0.17A	-0.17A	-0.17A	-0.59A
2014	-0.16E	-0.19E	-0.16E	-0.13E	-0.64E

Note: Historical quarterly EPS figures may not add up, due to a 1:12 reverse stock split that took place in 2013.

1-Year Price History



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We initiate coverage with a Buy rating and \$27 one-year PT (~50% upside). ORMP is using proprietary formulation technology to develop ORMD-0801 and ORMD-0901, oral versions of insulin (long the gold standard) and exenatide (marketed as Byetta and the longer acting Bydureon), respectively—both well-established injected diabetes therapies. ORMP's lead asset is '801 (oral insulin), for which P2a data are expected this month. If positive (which we assume), this will not only pave the way for a larger P2b trial later this year, but it could also serve as a near-term catalyst, driving the stock toward our PT. As we see '801 as a >\$1B opportunity should the P2b data (expected in 1H15) turn out positive, we believe a significant partnership deal with a global diabetes player could follow.

- Platform technology addresses a large market opportunity.** ORMP uses its proprietary Protein Oral Delivery (POD) technology to develop oral treatments for diabetes, which is growing in epidemic-like proportions (there are an estimated 366M diabetics worldwide, costing ~\$548B in '13). ORMP is currently focused on advancing two POD-enabled candidates, '801 and '901, which we believe both possess significant commercial potential. A combination '801-'901 program is also in the pipeline.
- We model peak sales >\$1B for '801 and '901.** We built detailed market models for '801 and '901, projecting US launches in 2019 and 2020, respectively. '801 is being developed as a novel night-time therapy to control fasting glucose (i.e., not a replacement for injected insulin, a \$15B market), so its use will likely require some patient/physician education. That said, we model '28 US/EU sales of \$1.6B. Upside (not in our model) rests in use in a prediabetic population (there are ~79M in the US alone). Meanwhile, the '901 strategy is more straightforward: an oral option to the injected GLP-1's, which are a \$2B + market. We model \$1.2B in '28 US/EU sales. To achieve these sales figures, ORMP will need to attract partners.
- Big recent stock gains; upcoming data offers another catalyst.** ORMP shares are up 150% in just the past weeks, following PK data release for '801 in Type I diabetics. Yes, the move has been sharp, but given a lack of Street following (one other covering analyst, few institutional holders), we believe awareness in ORMP is still in its infancy and view the move as justifiable given a still modest ~\$150M EV. Next up is P2a data for '801, which could come next week. We see low risk; thus we're not expecting to witness a big bounce similar to that seen after last month's '801 PK data.
- Waiting for US IP.** ORMP has been issued multiple ex-US patents, but we are still awaiting US-issued IP. A look at the US patent prosecution history informs us that this has been an ongoing process; thus, ultimate issue of US IP will be a key step in increasing our confidence in the ORMP story.
- Valuation/risks.** Our PT is based on an '801 and '901-driven DCF taken out to 2028, using a 25% discount rate and a 0% terminal growth rate. Risks include: negative clinical trial data for either '801 or '901, failure to obtain strong US IP, any regulatory delays/setbacks, and dilutive financings.

IMPORTANT DISCLOSURES AND CERTIFICATIONS.

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EXECUTIVE SUMMARY

We initiate coverage on Oramed Pharmaceuticals (ORMP) with a BUY rating and \$27 price target. ORMP is a drug formulation company developing orally delivered therapies for Type I and Type II diabetes. We view ORMP as both a near-term and long-term play, with upcoming Phase IIa data expected for lead candidate ORMD-0801 shortly, representing a potential near-term catalyst for the shares. Further behind, ORMP is also developing ORMD-0901, an oral GLP-1 analogue for treating Type II diabetes (currently in Phase Ib/IIa), as well as a combination ORMD-0801 and ORMD-0901 product. Our key investment takeaways are:

- 1. ORMP is focused on diabetes, a very large commercial market.** Diabetes has reached pandemic proportions: according to the International Diabetes Foundation (IDF), there were an estimated 366M diabetics in 2011, projected to reach 552M in 2030. Although global sales of existing diabetes drugs are over \$35B, there are still numerous issues with regard to: 1) compliance (injections are inconvenient); 2) sustainable glycemic control; and 3) safety. We see '801, an oral insulin, as an add-on therapy for Type I and Type II diabetics to reduce hypoglycemic episodes, and also as a potential preventative measure in pre-diabetics. As for '901, we see it as an alternative and potential replacement for the GLP-1 analogues (>\$2B in sales in 2012), which are available only as injectables. Both the insulin and GLP-1 markets are well-established, proven commercial markets.
- 2. We believe ORMP's assets have \$1B+ potential.** '801 is an oral insulin-based product. Injected insulin has been used to treat diabetes since the 1920s and is well established as the gold standard for treatment of both T1DM and T2DM. We estimate the global insulin market at ~\$15B. '901 is an oral formulation of an already approved drug, Byetta, a GLP-1 analogue. In assessing '801 and '901's market potential, we have built market models for each. Based on our assumptions, we model both assets as >\$1B opportunities.
- 3. Potential for lower cost of development and accelerated regulatory timelines.** '801 and '901 are both modified versions of previously approved products; thus, ORMP is pursuing both candidates as 505(b)(2) new drug application (NDA) strategies. The 505(b)(2) pathway can be viewed favorably, as it offers the potential of FDA approval in a quicker and less costly fashion. ORMP has already received positive feedback from the FDA that '901 can be pursued using a 505(b)(2) strategy; while the company is still awaiting word on '801, we currently do not foresee any obstacles.
- 4. There is a near-term catalyst that could generate additional interest and shareholder value.** This month (potentially next week), we expect ORMP to report Phase IIa safety, pharmacokinetic (PK) and pharmacodynamic (PD) data for lead candidate '801 in Type II diabetics. Given the data seen in previous trials and that efficacy is not being assessed at this stage, we are bullish on the prospects of positive data. The Phase IIa data represents a de-risking event and a key gating step before initiation of a larger Phase IIb trial (expected later this year). Thus we believe the stock could move higher (toward our PT) upon announcement of positive data.
- 5. Potentially lucrative partnerships await.** Given the size of the global diabetes market and assuming positive Phase IIb efficacy and safety data, we believe that both '801 and '901 possess high potential as licensing/partnership opportunities for ORMP. Indeed, we've seen two precedent deals: Biocon licensing its oral insulin to Bristol-Myers Squibb (BMY, NR) in 2012 (*even after failed Phase III data*), and Merriam Pharmaceuticals (private) licensing its Phase I oral insulin to diabetes giant Novo Nordisk (NVO, NR). We model partnership deals for both '801 and '901 in excess of \$300M each in milestone payments, with ORMP also receiving royalties up to 20%.

VALUATION

Exhibit 1: DCF Valuation

(In millions of US\$)	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Revenue	\$0.0	\$0.0	\$27.0	\$30.0	\$6.0	\$27.0	\$53.0	\$92.9	\$90.6	\$212.9	\$184.5	\$356.0	\$504.1	\$388.4	\$600.6	\$566.2
Gross Profit	0.0	0.0	27.0	30.0	6.0	27.0	53.0	92.9	90.6	212.9	184.5	356.0	504.1	388.4	600.6	566.2
Operating Income/Loss	(4.3)	(5.7)	19.0	18.7	(6.4)	13.5	45.8	85.4	82.8	204.6	175.8	346.9	494.5	378.3	590.1	555.1
Tax %	0%	0%	0%	20%	0%	20%	27%	27%	27%	27%	27%	27%	27%	27%	27%	27%
NOPAT	(4.3)	(5.7)	19.0	14.9	(6.4)	10.8	33.7	62.7	60.8	150.4	129.2	255.0	363.5	278.1	433.7	408.0
Plus: D&A	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	0.0	0.0
Less: Capex	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)	(0.0)	(0.0)
Less: Change in working capital	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.6)	(0.6)	(0.6)	(0.7)	(0.7)
Unlevered FCF to ORMP	(\$4.7)	(\$6.1)	\$18.6	\$14.6	(\$6.8)	\$10.4	\$33.2	\$62.3	\$60.3	\$149.8	\$128.7	\$254.4	\$362.9	\$277.4	\$433.0	\$407.3

	FCFF
Discount Rate	25.0%
Terminal Growth Rate	0.0%
Terminal Value	\$1,629
Implied FCF Multiple	4.0x
NPV of 2014-2030 Cash Flows	\$176
Plus: NPV of Terminal Value	72
Enterprise Value	248
Plus: Excess Cash/CE	12
Firm Value	259
Less: MV of Debt	0
Less: MV of Preferred Stock	0
Public Equity Value	\$259
# Of Shares Outstanding	9.7

DCF Value per Share **\$26.70** We round to \$27

Current Price	\$18.15
Potential Appreciation	47%

General guidelines on discount rate assumptions:

- 10% - product approved/marketed, have partner
- 12.5% - NDA/BLA filed, have partner
- 15% - NDA/BLA filed, have positive P3 data
- 20% / 25% - in P3, have positive P2b data
- 25% / 30% - in P2b, have positive P2a data
- 30% / 35% - in P2a, have positive P1 data
- 40% - in P1, solid preclinical data
- 50% - preclinical development

Sensitivity Table

	LT Growth Rate				
Discount Rate	-2.0%	-1.0%	0.0%	1.0%	2.0%
17.5%	\$58	\$60	\$61	\$63	\$65
20.0%	\$44	\$44	\$45	\$46	\$48
22.5%	\$33	\$34	\$34	\$35	\$36
25.0%	\$26	\$26	\$27	\$27	\$28
27.5%	\$21	\$21	\$21	\$21	\$22
30.0%	\$17	\$17	\$17	\$17	\$17
32.5%	\$14	\$14	\$14	\$14	\$14

Source: MLV & Co.

Given the early-stage nature of ORMP, we believe a discounted cash flow (DCF) analysis is the most appropriate methodology to value the stock. Our DCF valuation is shown above, and our full financial model can be found in the back of this report. Briefly, our key model assumptions are:

- ORMD-0801 and ORMD-0901 being launched with a partner in 2019 and 2020, respectively, in the US, with EU commercial launches occurring a year after;
- No revenue contribution from ORMD-0801 and ORMD-0901 in non-US/non-EU territories (upside to our model);
- No revenue contribution from ORMD-0801 in the pre-diabetic population (upside to our model).
- No revenue contribution from the combined ORMD-0801/ORMD-0901 formulation;
- Patent protection and no generic entry throughout our forecast period (out to 2028);
- ORMD-0801 achieving US/EU sales of \$1B by 2025, ORMD-0901 achieving US/EU sales of \$1B by 2027;
- A 25% discount rate for our DCF, appropriate, we believe, given our view that companies in Phase IIb (where we assume ORMP will be in one year) deserve a 25-30% discount rate. We are at the low end of the 25-30% range given the lower risk 505(b)(2) NDA filing strategy; and
- A 0% terminal growth rate for our DCF given our view that as oral pills (i.e., small molecules vs. biological agents), there is a greater risk that generic versions of both ORMD-0801 and ORMD-0901 could come to the market.

(Note that our total revenue forecasts for ORMP are derived from ORMD-0801- and ORMD-0901-related revenue coming to the company in the form of royalties and milestone payments; they *do not* represent our end-user sales estimates.)

Taken together, our analysis results in \$26.70 per share, which we round to \$27 for our price target (PT). At ORMP's closing price of \$18.15 on January 6, 2014, this implies upside of 47% over the next 12 months. This warrants a BUY rating.

Scenario Analysis

As seen in Exhibit 1, above, we have provided a sensitivity table that allows investors to evaluate ORMP under various discount and terminal growth rate assumptions, which ultimately helps define potential upside and downside. Below, we spell out where we think the stock could go as ORMP's story plays out:

- **Potential upside**

- **\$34** – We see upside to our PT on positive Phase IIb data for ORMD-0801 (expected in 2015). In that scenario, lowering the discount rate to 22.5% from 25% seems reasonable given the de-risking nature of positive Phase IIb data.
- **\$45** – We see further upside should ORMP, following positive Phase IIb data, secure a large pharmaceutical partnership deal for ORMD-0801. This could warrant us lowering the discount rate from 22.5% to 20%, as we'd be more confident in commercial success.

- **Potential downside**

- **\$11** – Should Phase IIa fail, we could envision removing all ORMD-0801-related revenue from our model, leaving ORMD-0901-related revenue. If we were to increase the discount rate to 35% from the current 25% (to reflect ORMD-0901's stage of development), we could see ORMP as a \$11 stock (~40% downside from current levels).
- **<\$2** – The worst-case scenario for ORMP is if both programs fail in clinical trials. Should this occur, we believe the stock could easily approach cash per-share levels (typical of highly distressed companies). Current cash per share is \$1.89 (*pro forma* for a recent financing), while estimated cash per share at the end of 2014 is \$1.19.

Valuation Case Studies: Amylin Pharmaceuticals and MannKind Corporation (MNKD, BUY)

ORMP currently has a \$173M market cap (MC) and an enterprise value (EV) of ~\$150M. As a comparison, we've looked at the historical MCs and EVs for Amylin Pharmaceuticals (developer of approved products Byetta and Bydureon, was acquired by BMY) and MannKind (MNKD, Buy, developer of Afrezza, an inhaled insulin now pending US approval), two diabetes-focused biotechs. In December 2001, when Byetta was in Phase II, Amylin had a ~\$600M MC and a \$650M EV. Meanwhile, MNKD went public in August 2004, with Afrezza already in Phase III. As of September 2004, MKND had a ~\$500M MC and a \$450M EV. While Amylin and MNKD were not truly equivalent companies then, relative to where ORMP is now (from data and FDA approval perspectives), we believe comparing these three companies is a still fair exercise. Based on our assumptions that ORMP will continue to make progress and show positive Phase II (and ultimately Phase III) data, we believe ORMP shares can approach similar valuations.

INVESTMENT RISKS

Clinical risk. At present, ORMD-0801 and ORMD-0901 are in the very early stages of clinical development. Given the lack of diversification in ORMP's portfolio, failure to meet primary endpoints in the ongoing Phase II trials can be detrimental to the share price. Also, many small- and medium-sized pharmaceutical companies have attempted to deliver insulin orally with a limited degree of success in later clinical stages. We currently do not possess enough data to determine whether ORMP will have a different fate.

Competitive risk. ORMP's success is dependent on its ability to maintain a competitive advantage in the crowded but thriving diabetes market. Although oral insulin capsules may gain popularity due to their anticipated efficacy, safety, and/or tolerability, they still need to compete head-to-head with insulin injections, pumps, and inhalers. In addition, there are other small biotechnology companies focused on developing oral insulin drugs that have partnered up with pharmaceutical companies, as well as larger pharmaceutical companies with their own internal programs. If ORMP's products cannot show superior clinical results or do not reach the market first, their commercial potential may be negatively affected.

Regulatory risk. We believe ORMD-0801 can be pursued via the 505(b)(2) regulatory pathway, a drug development program with a faster time to market. However, the company has yet to receive official guidance from the FDA that it can (whereas it does have such guidance for ORMD-0901). There are also some unique challenges facing this pathway: 1) it often requires substantial additional innovative work, and 2) unlike traditional New Drug Application (NDA), wherein the sponsor owns all the data necessary for approval, filing of a 505(b)(2) application may be delayed due to reference drug patent or exclusivity protection. Lastly, there is always the risk that the FDA may choose not to accept the data generated by ORMP for its candidates as supportive of approvals, as well as the risk that the regulatory process could get delayed.

Intellectual property risk. In our view, ORMP's patents are critical in determining its product's commercial longevity and potential success. Currently, ORMP maintains a moderate patent estate in the ex-US around ORMD-0801, ORMD-0901, and its Protein Oral Delivery platform. Various patents are still pending in the US, and we have no way of knowing whether they will be issued. In addition, should certain key patents be found invalid or expire, this could prevent the drugs from reaching their peak commercial potential. Failure to receive US IP would negatively impact ORMP's ability to partner.

Partnering risk. ORMP's long-term strategy is to seek a strategic commercial partner(s) with extensive experience in the development, commercialization, and marketing of insulin applications. Obtaining such partnership is crucial, as it would substantially support late-stage clinical trials and commercialization. In the event ORMP is not able to enter into a collaborative agreement on commercially reasonable terms, or at all, the company may be unable to advance its pipeline. This would materially impact our forecasts.

Financing risk. Given significant resources needed to advance the pipeline, ORMP has financed its operations through several private placements of common stock. With a recent equity financing of \$15.8M, we do not expect much risk in the short run. However, if ORMP fails to secure a licensing deal, it is very likely that additional financings will be needed. This could prove to be dilutive to existing shareholders, and in the event of any financing overhang it could also potentially limit stock price appreciation.

COMPANY PROFILE

Founded in 2006, ORMP is an Israel-based pharmaceutical company that aims to improve the treatment of diabetes through the oral delivery of insulin and exenatide. The company's proprietary Protein Oral Delivery (POD) platform allows the active ingredients to travel from the gastrointestinal tract via the portal vein to the bloodstream. The platform also has the potential to orally deliver medications and vaccines that can only be injected today. ORMP's short-term business strategy is to conduct further R&D on its current drug portfolio, but in the long run, the company plans to seek a strategic commercial partner(s) to develop, commercialize, and market its candidates.

Exhibit 2: ORMP Pipeline

Drug	Active Ingredient(s)	Indications	Clinical Status	Partner
ORMD-0801	Insulin	Type I Diabetes Type II Diabetes	Phase IIa	N/A
ORMD-0901	Exendine	Type II Diabetes	Phase Ib/IIa	N/A
ORMD-0801 with ORMD-0901	Insulin and Exendine	Type II Diabetes	First-in-human: proof of concept trial initiated	N/A

Source: Company reports

DIABETES – AN OVERVIEW

Diabetes is a chronic condition characterized by hyperglycemia, or elevated blood glucose levels. If left untreated, diabetes may lead to complications such as cardiovascular disease, chronic renal failure, retinopathy, and amputations. Diabetes experts have long regarded low or absent insulin secretion by pancreatic β cells and/or insulin signaling as hallmarks of disease. Beyond that, a catabolic hormone, glucagon, which is secreted by pancreatic α cells, also plays a role in disrupting the metabolic balance.

Before taking a deep-dive into the disease itself, we first need to understand the basics of glucose regulation. As plasma glucose level rises above 4.4 to 5.6 mmol/L after a meal, it is taken up into β cells to trigger insulin release into the hepatic portal vein. Subsequently, insulin stimulates glucose uptake in liver and muscle cells. In the postprandial state, hepatic portal insulin sequesters >30% of the glucose load and suppressing glucose production by 65-80%. The rest of the excessive glucose is then stored as fat or glycogen in adipocyte and muscle cells. Plasma glucose and insulin excursions occur in parallel and are tightly

linked throughout the day, thereby ensuring adequate glucose regulation.

During fasting, glucose level falls, and soon stimulates glucagon release from α cells. The hormone acts primarily on the liver to increase glucose production. In the mean time, the pancreas maintains a basal level of insulin to inhibit unnecessary glycogenolysis, ketogenesis and gluconeogenesis, ultimately achieving euglycemia. Here we need to note that basal insulin accounts for 40-50% of a person's daily insulin output. It is this interplay between insulin (basal and stimulated) and glucagon that maintains glucose level within a narrow range. For diabetic patients, such balance is perturbed.

Although many types of diabetes exist, for the purpose of this report, we will focus on the two major forms: Type I and Type II.

Type I

Type I diabetes mellitus (T1DM), also known as insulin-dependent diabetes, is an autoimmune disease where the immune system attacks and destroys pancreatic β cells. Hence little or no insulin is produced to facilitate the uptake of glucose. Clinically, T1DM is marked by fluctuations in glycemic readings and poor glycemic control.

At present, the cause for the autoimmune response has yet to be elucidated, but it may involve genetic, environmental and viral factors. The onset of T1DM occurs most often in childhood and during early adult years. Without adequate treatment, T1DM can lead to diabetic ketoacidosis, which is a fat metabolic process that releases ketones (a toxic acid) into plasma. The most morbid complication of ketoacidosis is cerebral edema, or swelling of the brain tissue.

Type II

In contrast to T1DM, type II diabetes (T2DM) is a progressive disease characterized by impaired β cell function and insulin sensitivity (or insulin resistance). The body first responds to resistance by secreting more insulin; over time, the β cell fails to keep up with the hormonal demand, often resulting in chronic hyperglycemia. In both fasting and fed states, the suppression of hepatic glucose output is ineffective, resulting in chronic hyperglycemia over time.

T2DM is multi-causal, commonly associated with obesity, dyslipidemia, hypertension, inflammation and endothelial dysfunctions. Again, the exact mechanism underlying its

development has not been completely unveiled, but both genetics and environmental factors play definite roles.

In terms of the numbers, T1DM accounts for 5-10% of diagnosed diabetics, while T2DM accounts for the remaining 90-95%.

A Pandemic

Despite advances in therapies for diabetes, treatment regimens and educational programs, diabetes remains a major cause of morbidity and mortality worldwide. To put it into perspective, 4.8M people died from diabetes (or its complications) in 2012, and the World Health Organization (WHO) projects that deaths will increase by two-thirds between 2008 and 2030.

In the US alone, the American Diabetes Association (ADA) estimates that there are currently ~25.8M people living with diabetes. Keep in mind that this number does not include the 79M additional Americans who are considered to be pre-diabetic. With obesity on the rise, these figures are expected to significantly grow in the next decade. The statistics are sobering on a global scale as well: according to the International Diabetic Federation (IDF), there were approximately 366M diabetics in 2011 worldwide, a figure that could rise to 552M in 2030. The largest increase in incidence is in T2DM, and is expected to continue increasing in every country, with the highest numbers expected in China, India, and the US. The cost of the disease is also staggering; the ADA reports that the US spent \$176B on medical treatments alone in 2012 (direct pharmaceutical care ~ \$15B), and the IDF puts the cost at \$548B for 2013. With as many as 175M undiagnosed cases worldwide, diabetes will continue to add a financial burden on society.

Many diabetes drugs have become blockbusters

Overall, Diabetes Drugs Have Been Big Commercial Successes

Commercially speaking, the current global market for drugs treating diabetes is one of the largest (if not already *the* largest). It is believed that antidiabetic medicines generated as much as \$35.6B in sales in 2012—a figure projected to grow to \$55.3B in 2017 (represents a CAGR of 9%).

Not surprisingly, many currently available diabetes drugs generate global sales in excess of \$1B (i.e., are “blockbusters”). These include:

- **Lantus**, an injected basal insulin;
- **Novolog** and **Humalog**, both injected fast-acting insulin analogs;

- **Victoza**, an injected GLP-1 agonist;
- **Januvia**, an oral DPP-IV inhibitor; and
- **Actos**, an oral thiazolidinedione/TZD.

Within this total diabetes pharmaceutical market, insulin products alone represent some \$15B in annual sales.

Exhibit 3 : Classes and Examples of Branded Drugs for Diabetes

Class	Tradename	Generic name	Company	Delivery	Approved	'12 WW Sales (M)
Thiazolidinediones	Actos	pioglitazone	Takeda	Oral	1999	\$3,048
	Avandia	rosiglitazone	GlaxoSmithKline	Oral	1999	\$9
DPP-IV inhibitors	Januvia	sitagliptin	Merck	Oral	2006	\$4,086
	Onglyza	saxagliptin	BMS/AstraZeneca	Oral	2009	\$709
	Tradjenta	linagliptin	Eli Lilly/BI	Oral	2011	\$190
DPP-IV combinations	Janumet	sitagliptin, metformin	Merck	Oral	2007	\$1,659
GLP-1 analogs	Byetta	exenatide	BMS/AstraZeneca	Injected	2005	\$573
	Bydureon	exenatide XR	BMS/AstraZeneca	Injected	2012	\$113
	Victoza	liraglutide	Novo Nordisk	Injected	2010	\$1,680
Insulins	Lantus	insulin glargine	Sanofi-Aventis	Injected	2000	\$6,457
	Humalog	insulin lispro	Eli Lilly	Injected	1996	\$2,395
	Humulin	human insulin (rDNA)	Eli Lilly	Injected	1982	\$1,239

Source: Company reports, MLV & Co.

INSULIN – A BRIEF HISTORY

Since its introduction in the 1920s, insulin therapy revolutionized the treatment and natural history of both T1DM and T2DM. Following its first clinical use, major improvements have been achieved in insulin purification, production, formulation, regimens and delivery systems. Up until the 1980s, animal insulin extracted from bovine or porcine pancreas was the only commercially available formulations. These agents were impure, often leading to immunological reactions. As the millennium approaches, genetic engineering had become advanced enough to allow scientists to make human insulin in large scale and easily manipulate its molecular structure. The first insulin analog was then created in 2000, to replace animal insulin.

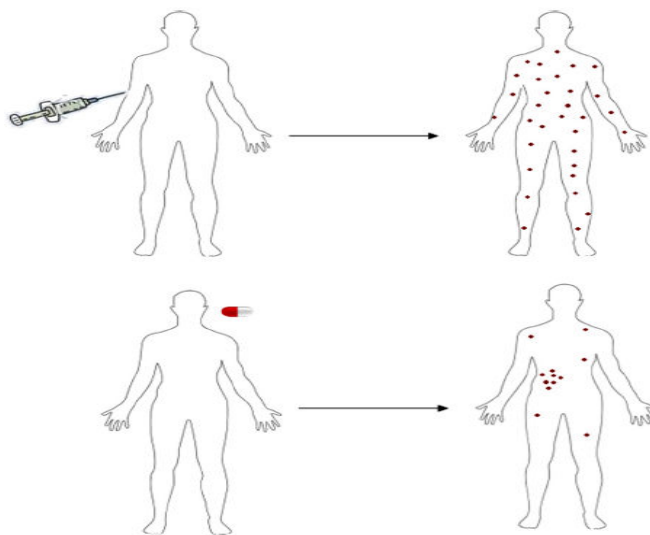
THE ORAL INSULIN MARKET

Why is Oral Insulin Better?

At first, the emphasis of oral insulin was on improving compliance, but as the current understanding of diabetes evolves, additional emphasis has been placed on the physiological importance of the hepatic route. The current mode of insulin therapy is by subcutaneous injection. Not only is this a non-

physiological way, but it also poses many side effects, such as allergy, resistance, edema, and lipodystrophy (degenerative adipose tissue). With injection, as well as via other routes, namely pulmonary, nasal, or buccal, insulin reaches the systemic circulation first, so only about 20% of insulin actually hits the liver. If insulin can be successfully absorbed in the intestines, it can be transferred directly to the liver such that its effect on hepatic glucose production would be similar to that induced by endogenous insulin—hence more “physiological.”

Exhibit 4: Difference Between the Distribution of Insulin Following Subcutaneous Injection and Oral Administration



Source: Rekha MR and Sharma CP, "Oral delivery of therapeutic protein/peptide for diabetes – future perspectives." *International Journal of Pharmaceutics* (2013): 48-62.

Another limitation of insulin is instability. Being a biologic, insulin vials are often labeled with “unopened at room temperature between 10-30 days” and “opened at room temperature or refrigerated between 10-30 days.” This is an important issue for patients residing in warm climates and remote areas, which happen to be developing countries where logistics and living conditions affect the maintenance of insulin half-life. An oral drug that is non-inferior to standard insulin will be more cost-effective and dominate those markets.

Why is it so difficult?

In order for oral insulin to be absorbed into the bloodstream, it has to travel through the stomach, small intestine, and colon intact. More important, the drug needs to be biologically

available when it reaches its destination. The problem of low bioavailability faced by oral delivery is caused by:

1. Stomach acids that denature proteins/peptides;
2. Proteolytic enzymes in the stomach and intestines that degrade proteins;
3. Mucin lining in the stomach acts as a physical barrier for drug absorption; and
4. There is impermeability of macromolecules across the intestinal wall.

Finally, the absorption of insulin to the systemic circulation can only be done two ways: transcellular and paracellular. The paracellular route occupies <1% of the total intestinal epithelium surface area, but it is the most preferred mode of transport of hydrophilic drugs such as insulin.

Oral Insulin Failures

There have been several attempts to develop an oral insulin product over the past decades, but none have succeeded thus far. Below, we describe two such efforts that highlight some of the prior difficulties that have been seen:

1. Emisphere (EMIS, NR)

In the early 2000s, EMIS designed low-molecular weight chemical entities that interact non-covalently and weakly with proteins. The platform created an insulin carrier that increased the hormone's lipophilicity and absorbability. From 2001-2004, Emisphere performed a number of Phase I/IIa clinical/experimental studies evaluating the time-action profile of the formulation. In a randomized, controlled, double-blind, parallel group pilot study in 13 T2DM patients, blood glucose levels of the patients treated with oral insulin were significantly lower after an oral glucose tolerance test compared to baseline, but not when compared to the control group.

In 2006, a more extensive study was performed. In this 90-day double-blind Phase II trial, 145 T2DM patients were randomized in four groups and treated with three different insulin doses or placebo. No significant differences in metabolic control between groups were observed despite being on the highest dose (1000U of oral insulin per day).

In our view, the failure of Emisphere's product was no surprise. The formulation had a relative biopotency of

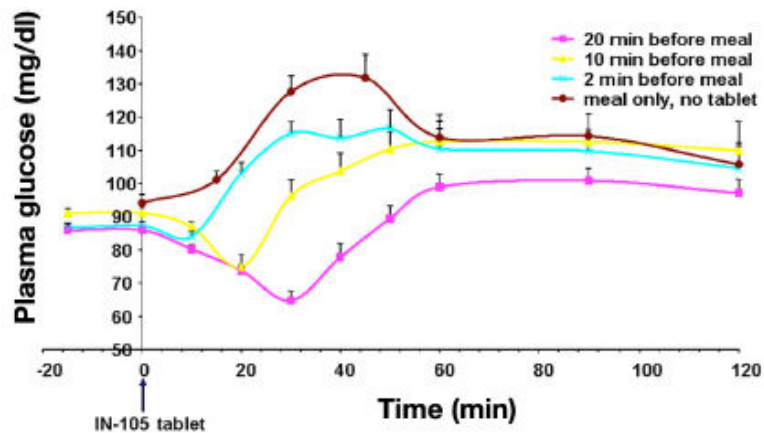
only 20% in the first 60 minutes after administration when taking into account glucose infusion rates (defined as the amount of glucose required to maintain satisfactory blood glucose levels). We would not have expected any significant improvement over injectable insulin, since this percentage is equivalent to the amount of insulin reaching the liver via subcutaneous delivery. When clinicians conducted studies using longer time intervals (0-6hr), the relative biopotency was even lower—a mere 3%.

2. Biocon (BIOCON.NSE, NR)

Biocon is an India-based pharmaceutical company that commercializes a human insulin product called Insugen in international markets. It has been developing an oral insulin formulation, IN-105, that is a human insulin molecule conjugated on position B29 within polyethylene glycol via an acyl chain. Pharmacokinetic and pharmacodynamics in healthy subjects have shown that IN-105 is absorbed rapidly and produces a corresponding drop in glucose.

In January 2011, Biocon announced that IN-105 failed to meet the primary objective of lowering HbA_{1c} by 0.7% compared with a placebo in a double-blind Phase III trial. The molecule did, however, meet parameters concerning safety and efficacy, and further assessment is currently ongoing. According to Biocon, failure to achieve primary endpoint might have been the result of patients on the placebo modifying their behavior during the study. A smaller prior study in 14 healthy subjects had shown that timing of a meal hampered the absorption of the oral insulin from the gut.

Exhibit 5: Plasma Glucose Levels and IN-105 at Different Time Intervals



Source: Heinemann L and Jacques Y, "Oral insulin and buccal insulin: a critical reappraisal." *Journal of Diabetes Science and Technology* (2009): 568-583.

Despite this Phase III failure, Biocon was nonetheless still able to attract a partnership with BMY. Exact terms of the collaboration have not been disclosed; however, following the data release of an ongoing Phase II trial, BMY may choose to assume full responsibility for IN-105, including all development and commercialization activities outside of India.

ORMD-0801

ORMD-0801 is ORMP's oral insulin dosage form based on the company's proprietary Protein Oral Delivery (POD) platform technology. POD combines unmodified human recombinant insulin with adjuvants designed to protect insulin from enzymatic degradation in the digestive system and to optimize absorption through the epithelial lining of the gut.

The adjuvant, or protective coating, has three components:

1. **A pH-sensitive enteric coating** – this degrades in the small intestine, thus protecting capsule constituents during travel through the upper gastrointestinal tract;
2. **Protease inhibitors** – these protect insulin from degradation by proteases once the capsule dissolves in the small intestine; and
3. **Absorption enhancers** – assists with translocation of insulin across intestinal membrane into the bloodstream.

Since the active ingredient ORMD-0801 contains insulin, it may be eligible for the 505(b)(2) regulatory pathway. It is important to note that ORMD-0801 is not intended to replace insulin therapies. The drug is being developed for early stages of T2DM, when it can still slow disease advancement by providing additional insulin to the body and allowing the pancreas to respite. More specifically, ORMD-0801 would act as a second-line therapy following metformin and focus exclusively on nighttime dosing (taken once a day) for patients with elevated fasting blood glucose (FBG) levels, prior to receiving insulin injections.

It has been well established that administration of insulin at earlier stages of T2DM can hamper disease progression. However, many patients are hesitant to participate in the regime because of inconvenience and absence of severe symptoms.

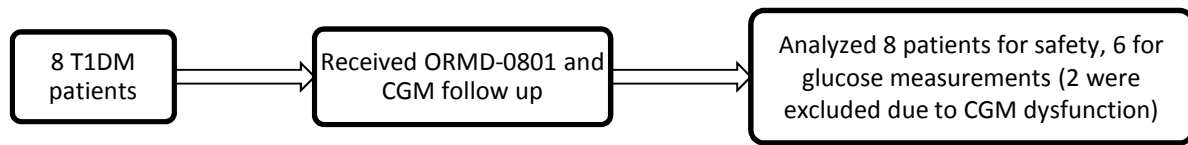
ORMP also proposes to introduce ORMD-0801 as a complementary agent to insulin injection in treating T1DM. The aim is to replace the bolus insulin dose (taken three times daily pre-prandial), potentially reducing multiple daily injections and the frequency of blood glucose fluctuations.

All currently available insulin formulations have a peaked-action profile; if the preparation were given at dinner time, the patient would experience excess insulin at midnight and low insulin (hence glucose production) at dawn. Therefore, if T2DM patients take ORMD-0801 nightly in the early course of the disease (β -cell can still function), it may help to control daytime glucose control, prevent β -cell fatigue and delay the progression to potential eventual intensive treatments.

Clinical Development – Phase I

In 2008, an uncontrolled Phase I study was conducted in eight T1DM patients to assess ORMD-0801's tolerability and the impact of the oral insulin in combination with standard insulin therapy. Patients were monitored over a 15-day period; baseline blood glucose behavior was determined over the initial 5-day pretreatment screening period. In the ensuing 10-day treatment phase, patients were asked to eat and continue diabetes treatment regimens as usual and to self-administer ORMD-0801 three times daily, 45minutes prior to meals.

Exhibit 6: Phase I Trial Design

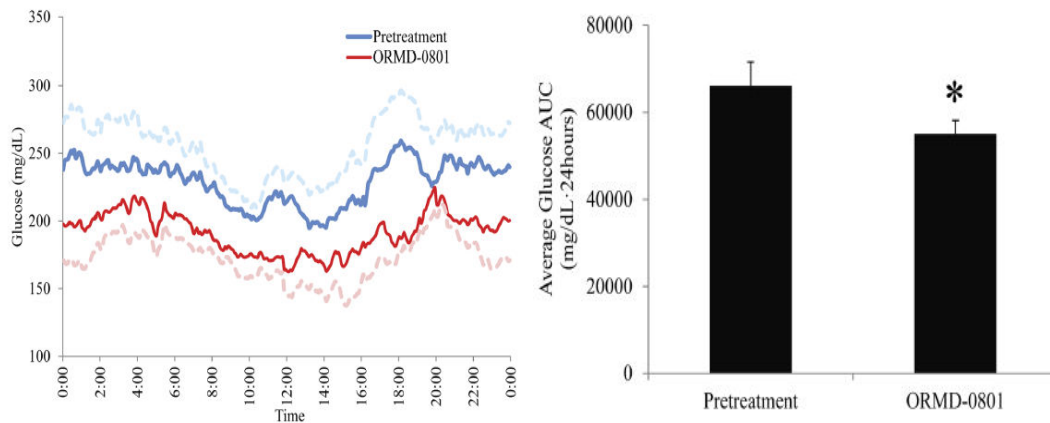


Note: CGM= continuous glucose monitoring device

Source: Eldor R, Arbit E and Kidron M. "Glucose-reducing effect of ORMD-0801 oral insulin preparation in patients with uncontrolled type 1 diabetes: a pilot study." *PLOS One* (2013): 1-4

All patients were compliant with the study protocol. No adverse events or hypoglycemic attacks were reported. Biochemical analyses revealed that blood glucose recordings were more frequently below 70 mg/dL during ORMD-0801 treatment, with an average $0.45\% \pm 0.2$ of readings in the pretreatment phase, versus $1.99\% \pm 0.88$ of readings while on the pill ($p=0.069$). In parallel, the frequency of glucose readings >200 mg/dL was 24.4% lower upon ORMD-0801 treatment ($p=0.023$). Pharmacodynamics data obtained six of the eight patients are depicted in the following exhibit.

Exhibit 7: (L) Mean Blood Glucose Levels of Six Patients; (R) Average Glucose Area Under the Curve



Source: Eldor R, Arbit E and Kidron M. "Glucose-reducing effect of ORMD-0801 oral insulin preparation in patients with uncontrolled type 1 diabetes: a pilot study." *PLOS One* (2013): 1-4

Briefly, the greatest reduction of mean blood glucose levels (21.1%) occurred between 5-7pm. ORMD-0801 was associated with a mean 16.6% decrease in glucose area under the curve (AUG) (66055 ± 5547 mg/dL/24 hours before treatment versus 55060 ± 3068 mg/dL/24 hours during treatment, $p=0.023$).

Due to the small sample size, it is impossible to predict whether this tendency is of clinical relevance. Nonetheless, we believe the significant reduction in glycemia was worthy of further investigation in a larger and longer clinical trial. If what was observed could be translated to reductions in both HbA_{1c} and diabetes-related complications, this would be regarded as clinically meaningful.

Clinical Development – Phase IIa (not FDA-sanctioned)

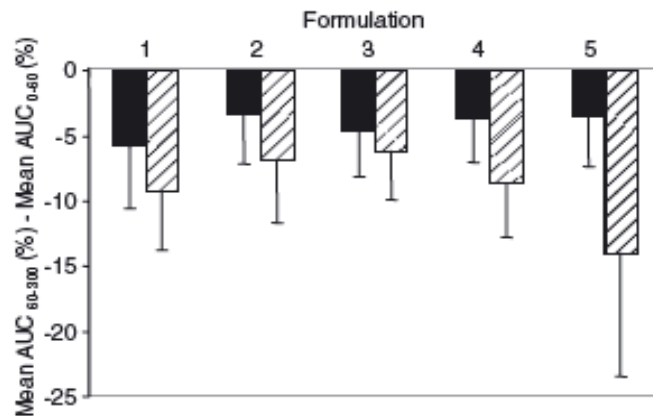
This open-label study provided pharmacodynamic information for five ORMD-0801 formulations and selected the best one to use in future studies. Eight health volunteers participated in five independent visits, where each was separated by a 72-96-hour washout period. After an overnight fast (for each visit), subjects were administered one of the five ORMD-0801 formulations. Parameters measured included safety, and C_{max} (max concentration) and T_{max} (time to reach C_{max}) for insulin and C_{min}, T_{min} and AUC for glucose and c-peptide (a byproduct of insulin production).

Exhibit 8: Composition of Oral Insulin Formulation

Visit	Carrier (mg)	Adjuvant A (mg)	Adjuvant B (mg)	Capsule Size (ml)
1	150	125	24	1
2	100	100	24	1
3	100	100	24	0.5
4	150	75	24	1
5	150	75	24	0.5

Source: Eldor R, Arbit E and Kidron M. "Open-label study to assess the safety and pharmacodynamics of five oral insulin formulations in healthy subjects." *Diabetes, Obesity and Metabolism* (2010): 219-223

In comparisons between formulations, ORMD-0801 induced significant reductions in c-peptide levels and plasma glucose concentrations between baselines and response periods ranging from 27-90% and 11 to 35% respectively. In comparison between time periods within each formulation, visits 4 and 5 induced the most prominent reductions. All five formulations were well tolerated, but formulation of visit 5 outperformed the others by inducing significant declines in c-peptide levels, and was consequently chosen as the lead formulation to be further advanced in future clinical studies.

Exhibit 9: Response vs. Baseline Glucose and C-peptide Levels

Note: black bar= glucose, striped bar= c-peptide

Source: Eldor R, Arbit E and Kidron M. "Open-label study to assess the safety and pharmacodynamics of five oral insulin formulations in healthy subjects." *Diabetes, Obesity and Metabolism* (2010): 219-223

Clinical Development – Phase IIa (not FDA-sanctioned)

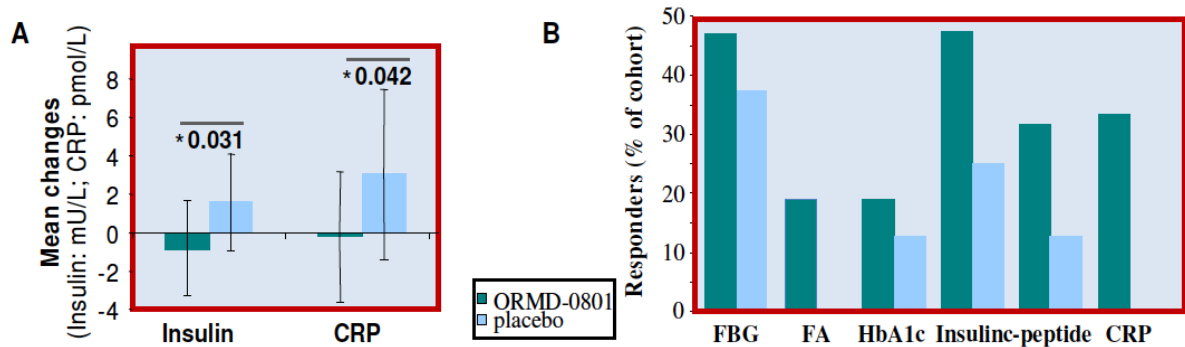
In another Phase IIa study, eight T1DM male subjects who regularly receive no-peak insulin were treated with two capsules of ORMD-0801 (8mg insulin each) during fasting. A standard 400 kcal meal was served at 10, 45 or 90 minutes thereafter. Unlike Biocon's IN-105, which is sensitive to meal schedules, ORMD-0801 caused significant increases in insulin levels in 61% of the treatment sessions, irrespective of the timing of food intake. In all cases, insulin levels returned to baseline within 45-300 minutes of peak recordings, demonstrating full clearance from the bloodstream. Glucose Cmax was reached at an approximate 100-minute lag from start of the meal, which in 17 out of 23 cases returned to basal levels before the end of monitoring session. No serious adverse events were recorded throughout the study. Thus, this study demonstrated some promise in the control of postprandial hyperglycemia in T1DM patients.

Clinical Development – Phase IIb (not FDA-sanctioned)

In 2009, ORMP initiated a Phase IIb study in South Africa to evaluate the safety, tolerability and efficacy of ORMD-0801 over a treatment period of six weeks in T2DM patients on diet alone, or diet and monotherapy with metformin. 21 patients were on oral insulin and eight patients were on placebo, all taken at bedtime. Efficacy evaluations showed that mean decreases in insulin and CRP (C-reactive protein) levels were drastically decreased following the six-week, once daily ORMD-0801 treatment, when compared to the placebo group. The percentage of subjects

demonstrating in insulin, c-peptide, FBG and HbA_{1c} was also consistently higher in the treatment cohort.

Exhibit 10: A) Plasma Marker Responses B) Percentage Responders



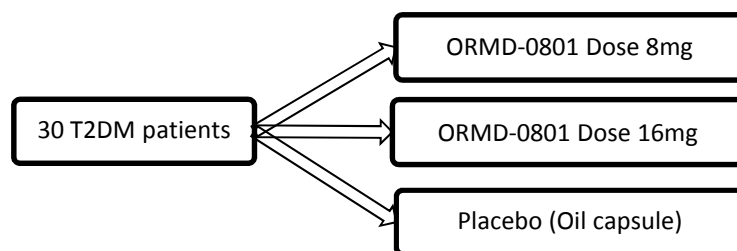
Source: Company presentation

The regimen proved to be safe and well tolerated, with the results allaying concerns that bedtime oral insulin might cause hypoglycemia. We are aware of the small sample size and the placebo effect that is well documented in literature; however, this was the first analysis of longer-term exposure to ORMD-0801.

Clinical Development – Phase IIa

We are currently awaiting results from a recently completed Phase IIa trial. Importantly, this would be the first trial conducted under an FDA-approved IND. This is a randomized, double-blind, placebo-controlled, inpatient study preceded by a five-day single-blind outpatient placebo run-in period. The trial aims to assess the safety, pharmacokinetics and pharmacodynamics of multiple bedtime doses of ORMD-0801 in T2DM patients who are inadequately controlled with diet and exercise or diet, exercise and metformin over the course of seven days.

Exhibit 11: Phase IIa Clinical Trial Design



Source: clinicaltrials.gov

Given that the main objectives of this study are demonstrating safety, PK and PD data – and not efficacy – we believe the data are very likely to be positive. We view this study as a gating step before the conduct of a more rigorous Phase IIb trial, which we would expect to begin sometime later this year, perhaps as early as 2Q14. Given the larger size and scope of that trial, we would expect a top-line readout of the Phase IIb data in 1H15.

Competition

In our view, the competitive environment for ORMD-0801 is quite heated; the good news is that its nearest rivals are still in early stages of development and none of them aim at night-time insulin administration for early-stage T2DM patients.

At this point, securing a deal with a bigger pharmaceutical company is of paramount importance, as it would help ORMP ultimately commercialize the product (ORMP is too small of a company to do this on its own). The key obviously is to demonstrate a clean safety profile and favorable morning plasma glucose and insulin levels. With solid data in hand, we'd be optimistic about potential partnerships.

Exhibit 12: Oral Insulin Competitive Landscape

Drug	Company	Mechanism of Action	Status	Partner(s)
IN-195	Biocon	Insulin conjugated with polyethylene glycol	Phase III (failed to reach primary endpoint)	Bristol-Myers Squibb
Capsulin	Diabetology	Dry powder with insulin, stabilizer and solubilizer	Phase II	N/A
Oshadi Insulin	Oshadi Drug Administration	Insulin is non-covalently associated mixture of pharmacologically inert silica nanoparticles having a hydrophobic surface, a polysaccharide, and insulin suspended in an oil	Phase II	N/A
NN1953 NN1954 NN1956	Merrion Pharmaceuticals	Insulin with patented absorption enhancers that activate micelle formation, facilitating transport of drug and substantially increasing absorption	Phase II	Novo Nordisk
Oradel Insulin	Apollo Life Sciences	Entraps insulin within nanolattices to protect them in the stomach and it uses targeting agents to promote the absorption of the active molecules from the intestine	Phase I	N/A
TrabiOral Insulin	Transgene	Patented targeted nano-encapsulation technology for increased drug loading and amplifying uptake mechanism	Preclinical	N/A
Oral-lyn	Generex Biotechnology	The RapidMist device is designed to propel insulin into the oral cavity as a fast-moving, fine-particle aqueous spray. The mixed micelles containing the insulin molecules transverse the superficial layers of oropharyngeal mucosa and, with the aid of absorption enhancers, insulin is rapidly absorbed into the blood stream	Phase III	Shreya Life Sciences, Benta SAL
Oral Insulin	Emisphere	Eligen drug delivery technology in combination with its proprietary insulins	Phase II	Novo Nordisk

Source: MLV & Co.

Here we need to note that Generex's Oral-lyn is not an oral insulin in the traditional sense. The insulin is delivered directly into the mouth via a metered dose spray (RapidMist device), but it is not absorbed through the portal system, so it still should be considered as a systemic insulin. That said, Oral-lyn has already been approved in Canada, Ecuador, India, Lebanon and Algeria.

ORMD-0901

ORMP's second asset, ORMD-0901, is an oral formulation of exenatide, which is already approved and marketed as a twice-daily injection under the trade name Byetta and as a twice-weekly injectable formulation known as Bydureon. Like ORMD-0801, it also employs ORMP's POD platform technology. Similar to ORMD-0801, the coating protects exenatide from enzymatic

breakdown and facilitates its absorption into the systemic circulation. With proposed advantages of higher compliance, non-invasive, administration, and diminished nausea, ORMD-0901 is being positioned as an alternative or even replacement to currently available injected GLP-1 analogues. (Beyond Byetta and Bydureon, another marketed GLP-1 is Novo Nordisk's [NVO, NR] Victoza, which is nearly a \$2B product).

ORMP has completed a Phase I study for ORMD-0901, and a Phase Ib/IIa trial (but not under an FDA IND) was initiated earlier this year. If positive, this would pave the way for a larger Phase IIb trial for ORMD-0901, and currently, we'd expect top-line data in 1H16.

Glucagon-like Peptide 1 (GLP-1) and Exenatide

GLP-1 is an incretin hormone – a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas and suppresses glucagon secretion. The advantage of incretin-based therapy over insulin stimulating drugs such as sulfonylurea agents is that insulin secretion is in a glucose-dependent manner. By feedback mechanism, insulinotropic effect of GLP-1 is lost at a plasma glucose concentration of less than 4.3 mmol/L. Exogenous administration of GLP-1 has been shown to lower blood glucose, slow gastric emptying and reduce food intake in T2DM patients. Other important beneficial attributes of GLP-1 are its effects of increasing the number of β cells in the pancreas and, possibly, protection of the heart.

Without pharmacological interference, GLP-1 has limited therapeutic value because it is rapidly degraded in vivo by the enzyme dipeptidyl peptidase-4 (DPP-4), giving it a plasma half-life of <2min. The two strategies used to overcome the barrier of degradation are DPP-4 inhibition and DPP-4-resistant GLP-1 receptor agonists. Agents developed using the first method are all in oral formulations while those using the second method are all in injectable formulations. Although DPP-4 inhibitors are superior in the delivery aspect, GLP-1 receptor agonists actually offer better efficacy.

Exenatide, a GLP-1 analogue, is derived from a naturally occurring peptide exendin-4, which was first isolated from the salivary secretions of the lizard *Heloderma suspectum*. It is injected twice daily as to provide adequate daily replacement of GLP-1. Exenatide is also one of the two available anti-diabetic drugs associate with weight loss, which is of utmost importance for T2DM patients.

Competition

Fueled by rising incidence of diabetes, the T2DM market is expected to reach \$45B in 2020 from \$23.4B in 2010. According to market research firm Decision Resources, GLP-1 receptor agonists and DPP-4 inhibitors will experience the biggest boost in market share in T2DM, with a combined market share that will increase from 20% in 2010 to 47% in 2020 in the US, France, Germany, Italy, Spain, the UK and Japan. There are only three approved GLP-1 analogues, and they are all limited by the delivery method. As can be deduced from the following exhibit, both needle size and dosing frequency are inversely proportional to product sales. Non-compliance is approximately 30% for T2DM patients and is a major issue for long-term disease management.

Exhibit 13: Approved GLP-1R Agonists

Drug	Company	Needle Size	Dosing	2012 WW Sales
Byetta	BMS/AstraZeneca	32 gauge, 4mm	Twice daily	\$573M
Bydureon	BMS/AstraZeneca	23 gauge, 8mm	Once weekly	\$113M
Victoza	Novo Nordisk	32 gauge, 4mm	Once daily	\$1.68B

Source: MLV & Co.

Being relatively new agents and less convenient than DPP-4 inhibitors, we believe that better GLP-1 analogue formulations can become a growth driver for the T2DM space. There are about 34 GLP-1 pipeline candidates designed to surpass commercially available products. Fortunately for ORMP, beside ORMD-0901, only a few other clinical stage agents are administered orally.

Exhibit 14: Oral GLP-1R Agonists in Development

Drug	Company	Mechanism of Action	Status	Partner
NN9924	Merrion Pharmaceuticals	GLP-1 with patented absorption enhancers that activate micelle formation, facilitating transport of drug and substantially increasing absorption	Phase I	Novo Nordisk
Oral GLP-1	Emisphere	GLP-1 with a SNAC carrier to transport it to the small intestine through weak and non-covalent interactions	Phase I	Novo Nordisk
Oral, non-peptide GLP-1 receptor agonists	Poxel	N/A	Preclinical/Lead optimization phase	N/A
TTP054	TransTech	Discovered using its proprietary drug discovery platform TTP Translational Technology; the drug stimulates the body's ability to regulate glucose levels via binding to a newly identified and patented pocket on the receptor.	Phase II	N/A

Source: MLV & Co.

Preclinical Data – Animal Models

Healthy, fasting, enterically cannulated pigs and beagle canines were administered a single dose of ORMD-0901 30 minutes before oral glucose challenge. Overall, the drug was well tolerated. Formulations RG3 and AG2 led to reduced glucose excursion in pigs, where AUC values were up to 43% lower than in control sessions. Individual animal responses demonstrated up to 100% lower glucose Cmax values, relative to baseline, after 5g/kg glucose loads, when pretreated with various GLP-1 analog formulations.

Exhibit 15: Composition of Oral GLP-1 Analogue Formulations

Formulation	Carrier (mg)	Adjuvant (mg)	Exenatide (µg)	Dosage Volume (ml)	Animal
AG2	150	125	50	0.8	Porcine
AG3	150	125	75	0.8	Canine
AG4	150	125	100	0.8	Canine + Porcine
AG6	150	125	150	0.8	Porcine
EG3	150	75	75	0.8	Porcine
RG3	100	75	75	0.8	Porcine

Source: Eldor R, Kidron et al. "Novel glucagon-like peptide-1 analog delivered orally reduces postprandial glucose excursions in porcine and canine models." *Journal of Diabetic Science and Technology* (2010): 1516-1523

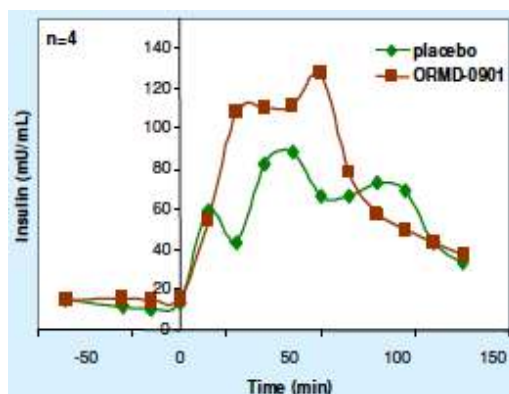
All canines demonstrated higher AUC values than in their ORMD-0901-treated sessions. Subcutaneous exenatide delivery resulted in a 51% decrease in mean glucose AUC, while formulations AG4 and AG3 prompted 43% and 29% reductions, respectively. Of the 20 ORMD-0901 treatment sessions, 18 experienced lower glucose Cmax values in comparison to their counterpart non-treated glucose test days.

Clinical Development – Phase Ia

In 2010, ORMP completed a single-blind, two-period study focusing on the induced insulinogenic responses to ORMD-0901. Six fasting, healthy, male volunteers were administered a placebo or ORMD-0901 (150 µg of exenatide), on visits 1 and 2, respectively. Subjects were challenged with a 75 g oral glucose load 60 minutes after capsule administration (time: 0) and monitored for 150 min.

The drug was well tolerated by all patients. Insulin levels peaked in both placebo and ORMD-0901 treated subjects within 60-76min of glucose load. However, the mean peak insulin concentration was 28% higher in the ORMD-0901 session than its placebo counterpart. Mean insulin AUC was also 17.6% higher after ORMD-0901 treatment. Some may inquire about the large standard deviation observed in the ORMD-0901 session and lack of statistical significance; given the small sample size, we are not too concerned over the data at this point. In all, we believe these results reflect induced insulin release following exenatide absorption and bioactivity.

Exhibit 16: Efficacy Results



Insulin		
	Mean AUC ₀₋₁₅₀	Std
Placebo	14.547	30.512
ORMD-0901	180.344	106.825
p-value	0.523	

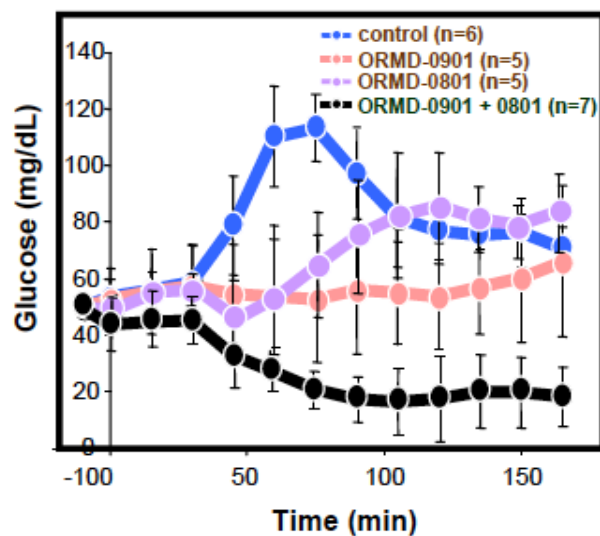
Source: Company presentation

ORMD-0801 AND ORMD-0901 COMBINATION

ORMP is also developing a third pipeline candidate, a combination therapy for managing T2DM. It consists of lower doses of both ORMD-0801 and ORMD-0901, potentially addressing the multiple metabolic targets of T2DM pathogenesis and curbing comorbidities.

In the preclinical setting, fasting pigs were treated with ORMD-0801 and/or ORMD-0901 capsules 30 minutes prior to caloric intake. Blood glucose concentrations were monitored over the ensuing four hours. Pigs pre-prandially treated with ORMD-0901, experienced static blood glucose concentrations throughout the 150 minutes following caloric intake ($p=0.002$). Similarly, ORMD-0801 curbed glucose excursions observed non-treated animals ($p=0.086$). More excitingly, a sharp, synergistic effect was imparted by simultaneous delivery of both agents, as expressed by blood glucose reduction reductions to >50% of mean baseline values, and to concentrations 5.2-fold lower than mean peak values at 75 minutes after feeding ($p<0.0001$).

Exhibit 17: Blood Glucose Profiles Following ORMD-0901 and ORMD-0801 Administration to Pigs



Source: Company presentation

In our view, these favorable results call for further testing to determine whether the combination therapy's ability to tightly regulate postprandial blood glucose can be replicated in human subjects. That said, we believe ORMD-0801 and ORMD-0901 are

higher priority projects, and given ORMP's current resources, we're not expecting any significant progress to be made in this combination program in the near-term.

ORMD-0801 AND ORMD-0901 MARKET MODELS

The main drivers of our valuation for ORMP are ORMD-0801 and ORMD-0901; in order to derive our revenue forecasts, we've developed market models (using a top-down approach) for both, which we describe in the following section. It is important to note that currently, we have chosen not to specifically forecast sales of ORMD-0801 and ORMD-0901 in territories outside of the US and the European Union (EU). Instead, we have elected to leave sales in potentially significant commercial markets—such as Latin America, Asia, Russia, the Middle East and Africa—as upside to our model.

Population

For the US market, at baseline for 2013, we start with numbers provided by the ADA: 1) 25.8M Americans living with diabetes by the end of the year; 2) 18.8M are currently diagnosed (translates to 72.8%); 3) 85% of T1DM, or 0.8M patients are treated with insulin; 4) 40% of T2DM, or 7.1M patients are in the early stages; and 5) 10% of T2DM, or 1.7M patients are treated by GLP-1R agonists. We then apply a 1% annual growth rate on the total number of US diabetics—a rate that could ultimately prove to be conservative given increasing diabetes and obesity (a key risk factor for diabetes) in the US. As we project out from 2014 to 2028 (the end of our forecast period), we then slightly up both the % of diabetics diagnosed (from 72.8% to 74.3%) and the % of patients that are treated with insulin and GLP-1 analogues.

Prevalence

With respect to prevalence, it is widely accepted that Type I diabetics represent 5-10% of total diabetics; the rest are Type II diabetics. In our model, we make no changes to the prevalence of Type I vs. Type II patients throughout our forecast period, so we have chosen to keep a 10% and 90% split for Type I and Type II diabetics throughout.

Penetration

ORMD-0801: In T1DM patients, we begin with a 0.5% penetration rate in 2019 (~8k patients) and steadily grow that out to 3% (~55k patients) in 2028, a low number given our view that main use will be in T2DM. In early stage T2DM patients, our penetration rate is

built on the number of patients who drop out of a metformin-based therapy. We assume that 90% of T2DM patients have metformin as first-line treatment and 30% of them fail to respond. Then, we begin with a 1.2% penetration rate in 2019 (~23.6k patients) and grow that out to 10% penetration (~218k patients) in 2028. We believe that given the convenience of oral dosing for an insulin product, 10% is a very reasonable estimate for the portion of the insulin market that can be captured.

ORMD-0901: In T2DM patients being treated with GLP-analogue injections, we start with a 0.5% penetration rate in 2020 (~13k patients) and grow that out to 4.2% in 2028 (~177k patients).

Pricing

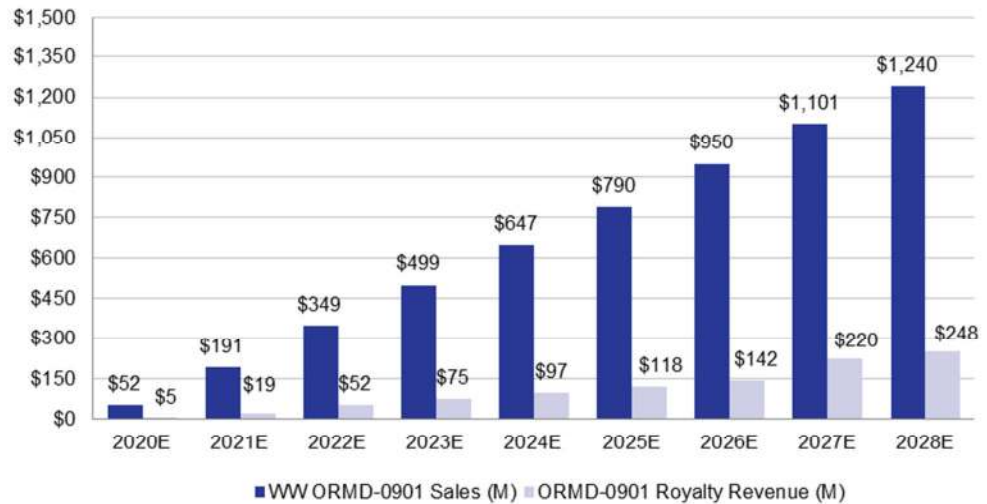
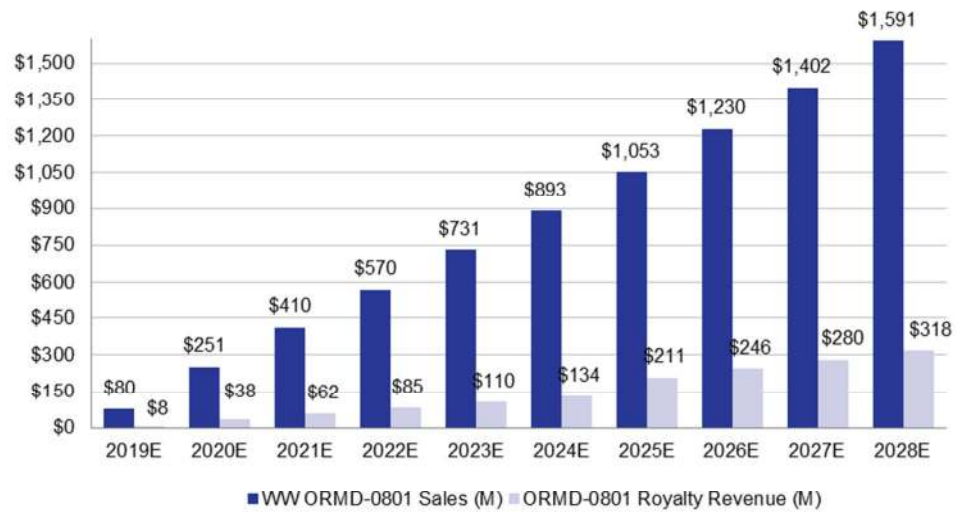
We have assumed annual cost of therapy for ORMD-0801 to be \$2,500 for both T1DM and T2DM in 2019. This is on par with current insulin products; we believe that the low COGS for a pill formulation can also give ORMP a good margin. For ORMD-0901, we have priced it at \$4,000 a year. We think this is quite reasonable since Bydureon, Victoza and Byetta all cost in the \$3,500-\$4,500/year range. For ORMD-0901, we assume a 5% annual price increase for two years after launch, then down to 1% increase for the rest of our forecast period. For ORMD-0801 we assume a 5% annual price increase.

Revenue Potential

Based on the inputs above, our first-year US ORMD-0801 and ORMD-0901 sales are \$79.7M and \$52.0M respectively—coming from just the US. We see US ORMD-0801 sales reaching \$1.1B and ORMD-0901 reaching \$826.9M in 2028. As for the European opportunity, for the sake of simplicity, we assume adoption will be half of that of the US. By assuming an approval in 2020 for ORMD-0801 and 2021 for ORMD-0901, we model their first year EU sales to be \$83.7M and \$63.8M respectively. By 2028, EU ORMD-0801 sales will reach \$530.2M and ORMD-0901 sales will reach \$413.4M.

In determining revenue coming to ORMP, we assume a partnership model, modeling tiered double-digit royalties to the company. Based on this, ORMP will receive \$8M in 2019, rising up to \$566.2M in 2028. We refer you to the section “Our Financial Model and Projections” found later in this report for further details of our partnership assumptions.

Exhibit 18: Product Sales and Royalty Revenues



Source: MLV & Co.

Exhibit 19: ORMD-0801 Revenue Model

Year	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	
US Diabetics	25,800,000	26,058,000	26,318,580	26,581,766	26,847,583	27,116,059	27,387,220	27,661,092	27,937,703	28,217,080	28,499,251	28,784,243	29,072,086	29,362,807	29,656,435	29,952,999	
Annual growth rate	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%	1.0%	1.0%	1.0%	
Total US diabetics	26,058,000	26,318,580	26,581,766	26,847,583	27,116,059	27,387,220	27,661,092	27,937,703	28,217,080	28,499,251	28,784,243	29,072,086	29,362,807	29,656,435	29,952,999	30,252,529	
% Diagnosed	72.8%	72.9%	73.0%	73.1%	73.2%	73.3%	73.4%	73.5%	73.6%	73.7%	73.8%	73.9%	74.0%	74.1%	74.2%	74.3%	
Total US diagnosed diabetics	18,800,000	19,186,245	19,404,689	19,625,584	19,848,955	20,074,832	20,303,242	20,534,212	20,767,771	21,003,948	21,242,772	21,484,271	21,728,477	21,975,418	22,225,125	22,477,629	
US Type I patients																	
Type I prevalence	5.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	
Total Type I patients	940,000	1,918,624	1,940,469	1,962,558	1,984,896	2,007,483	2,030,324	2,053,421	2,076,777	2,100,395	2,124,277	2,148,427	2,172,848	2,197,542	2,222,513	2,247,763	
% US patients on insulin	80.0%	80.1%	80.2%	80.3%	80.4%	80.5%	80.6%	80.7%	80.8%	80.9%	81.0%	81.1%	81.2%	81.3%	81.4%	81.5%	
Total patients on insulin	752,000	1,536,818	1,556,256	1,575,934	1,595,856	1,616,024	1,636,441	1,657,111	1,678,036	1,699,219	1,720,664	1,742,374	1,764,352	1,786,601	1,809,125	1,831,927	
% treated with ORMD-0801							0.5%	1.2%	1.7%	2.2%	2.6%	2.8%	2.9%	3.0%	3.0%	3.0%	
Type I patients on ORMD 0801							8,182	19,885	28,527	37,383	44,737	48,786	51,166	53,598	54,274	54,958	
Annual cost of therapy							\$2,500	\$2,625	\$2,756	\$2,894	\$3,039	\$3,191	\$3,350	\$3,518	\$3,694	\$3,878	
Type I revenue (MM)							\$20.5	\$52.2	\$78.6	\$108.2	\$135.9	\$155.7	\$171.4	\$188.5	\$200.5	\$213.1	
Growth								155%	51%	38%	26%	15%	10%	10%	6%	6%	
US Type II patients																	
Prevalence	95%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	
Total US Type II patients	17,860,000	17,267,620	17,464,220	17,663,025	17,864,060	18,067,349	18,272,917	18,480,791	18,690,994	18,903,553	19,118,494	19,335,844	19,555,629	19,777,876	20,002,613	20,229,866	
% in the early stages	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	
Total early stage patients	7,144,000	6,907,048	6,985,688	7,065,210	7,145,624	7,226,940	7,309,167	7,392,316	7,476,398	7,561,421	7,647,398	7,734,338	7,822,252	7,911,151	8,001,045	8,091,946	
% treated with Metformin	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	
Total patients on Metformin	6,429,600	6,216,343	6,287,119	6,358,689	6,431,062	6,504,246	6,578,250	6,653,085	6,728,758	6,805,279	6,882,658	6,960,904	7,040,027	7,120,035	7,200,941	7,282,752	
% patient fails	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	
Addressable patient population	1,928,880	1,864,903	1,886,136	1,907,607	1,929,318	1,951,274	1,973,475	1,995,925	2,018,627	2,041,584	2,064,797	2,088,271	2,112,008	2,136,011	2,160,282	2,184,826	
% treated with ORMD-0801							1.2%	2.2%	3.5%	4.6%	5.6%	6.6%	7.5%	8.4%	9.2%	10.0%	
Type II patients on ORMD-0801							23,682	43,910	70,652	93,913	115,629	137,826	158,401	179,425	198,746	218,483	
Annual cost of therapy							\$2,500	\$2,625	\$2,756	\$2,894	\$3,039	\$3,191	\$3,350	\$3,518	\$3,694	\$3,878	
Type II revenue (MM)							\$59.2	\$115.3	\$194.7	\$271.8	\$351.4	\$439.8	\$530.7	\$631.2	\$734.1	\$847.3	
Growth								95%	69%	40%	29%	25%	21%	19%	16%	15%	
ORMD-0801 US revenue (MM)							\$79.7	\$167.5	\$273.4	\$380.0	\$487.3	\$595.4	\$702.1	\$819.7	\$934.6	\$1,060.5	
Growth rate								110.2%	63.2%	39.0%	28.2%	22.2%	17.9%	16.8%	14.0%	13.5%	
ORMD-0801 EU revenue (MM)								\$83.7	\$136.7	\$190.0	\$243.7	\$297.7	\$351.0	\$409.9	\$467.3	\$530.2	
Growth rate									63.2%	39.0%	28.2%	22.2%	17.9%	16.8%	14.0%	13.5%	
Total US/EU ORMD-0801 revenue (MM)							\$79.7	\$251.2	\$410.0	\$570.0	\$731.0	\$893.1	\$1,053.1	\$1,229.6	\$1,401.8	\$1,590.7	
Growth rate									215.3%	63.2%	39.0%	28.2%	22.2%	17.9%	16.8%	14.0%	13.5%
ORMD-0801-RELATED ROYALTIES AND MILESTONES																	
WW end user sales							\$79.7	\$251.2	\$410.0	\$570.0	\$731.0	\$893.1	\$1,053.1	\$1,229.6	\$1,401.8	\$1,590.7	
Royalty rate applied							10%	15%	15%	15%	15%	15%	20%	20%	20%	20%	
Total WW sales-based royalties							\$8.0	\$37.7	\$61.5	\$85.5	\$109.6	\$134.0	\$210.6	\$245.9	\$280.4	\$318.1	
Growth rate									373%	63%	39%	28%	22%	17%	14%	13%	
Milestone payments			25.0			20.0	25.0	25.0	25.0	50.0		75.0	100.0				
Total WW ORMD 0801-Related Rev to ORMP			\$25.0	\$0.0	\$0.0	\$20.0	\$33.0	\$62.7	\$61.5	\$135.5	\$109.6	\$209.0	\$310.6	\$245.9	\$280.4	\$318.1	
Growth rate									-2%	120%	-19%	91%	49%	-21%	14%	13%	

Source: MLV & Co.

Exhibit 20: ORMD-0901 Revenue Model

Year	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
US Diabetics	25,800,000	26,058,000	26,318,580	26,581,766	26,847,583	27,116,059	27,387,220	27,661,092	27,937,703	28,217,080	28,499,251	28,784,243	29,072,086	29,362,807	29,656,435	29,952,999
Annual growth rate	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%	1.0%	1.0%	1.0%
Total US diabetics	26,058,000	26,318,580	26,581,766	26,847,583	27,116,059	27,387,220	27,661,092	27,937,703	28,217,080	28,499,251	28,784,243	29,072,086	29,362,807	29,656,435	29,952,999	30,252,529
% Diagnosed	72.8%	72.9%	73.0%	73.1%	73.2%	73.3%	73.4%	73.5%	73.6%	73.7%	73.8%	73.9%	74.0%	74.1%	74.2%	74.3%
Total US diagnosed diabetics	18,970,224	19,186,245	19,404,689	19,625,584	19,848,955	20,074,832	20,303,242	20,534,212	20,767,771	21,003,948	21,242,772	21,484,271	21,728,477	21,975,418	22,225,125	22,477,629
US Type II patients																
Prevalence	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
Total US Type II patients	17,073,202	17,267,620	17,464,220	17,663,025	17,864,060	18,067,349	18,272,917	18,480,791	18,690,994	18,903,553	19,118,494	19,335,844	19,555,629	19,777,876	20,002,613	20,229,866
% patients on GLP-1 analogues	10.0%	10.5%	11.0%	11.6%	12.2%	12.8%	13.4%	14.1%	14.8%	15.5%	16.3%	17.1%	18.0%	18.9%	19.8%	20.8%
Patients treated with GLP-1 analogues	1,707,320	1,813,100	1,925,430	2,044,716	2,171,388	2,305,902	2,448,746	2,600,433	2,761,511	2,932,562	3,114,201	3,307,086	3,511,910	3,729,414	3,960,381	4,205,644
% treated with ORMD-0901								0.5%	1.1%	1.8%	2.4%	2.9%	3.3%	3.7%	4.0%	4.2%
Total patients on ORMD-0901								13,002	30,377	52,786	74,741	95,905	115,893	137,988	158,415	176,637
Annual cost of therapy								\$4,000	\$4,200	\$4,410	\$4,454	\$4,499	\$4,544	\$4,589	\$4,635	\$4,681
ORMD-0901 US revenue (MM)								\$52.0	\$127.6	\$232.8	\$332.9	\$431.4	\$526.6	\$633.2	\$734.2	\$826.9
Growth rate									145.3%	82.5%	43.0%	29.6%	22.0%	20.3%	16.0%	12.6%
ORMD-0901 EU revenue (MM)									\$63.8	\$116.4	\$166.5	\$215.7	\$263.3	\$316.6	\$367.1	\$413.4
Growth rate										82.5%	43.0%	29.6%	22.0%	20.3%	16.0%	12.6%
Total US/EU ORMD-0901 revenue (MM)								\$52.0	\$191.4	\$349.2	\$499.4	\$647.2	\$789.9	\$949.9	\$1,101.4	\$1,240.3
Growth rate									268.0%	82.5%	43.0%	29.6%	22.0%	20.3%	16.0%	12.6%
ORMD-0901-RELATED ROYALTIES AND MILESTONES																
WW end user sales								\$52.0	\$191.4	\$349.2	\$499.4	\$647.2	\$789.9	\$949.9	\$1,101.4	\$1,240.3
Royalty rate applied								10%	10%	15%	15%	15%	15%	20%	20%	20%
Total WW sales-based royalties								\$5.2	\$19.1	\$52.4	\$74.9	\$97.1	\$118.5	\$142.5	\$220.3	\$248.1
Growth rate									268%	174%	43%	30%	22%	20%	55%	13%
Milestone payments				25.0			20.0	25.0	10.0	25.0		50.0	75.0		100.0	
Total WW ORMD 0901-Related Rev to ORMP				\$25.0	\$0.0	\$0.0	\$20.0	\$30.2	\$29.1	\$77.4	\$74.9	\$147.1	\$193.5	\$142.5	\$320.3	\$248.1
Growth rate									-4%	166%	-3%	96%	32%	-26%	125%	-23%

Source: MLV & Co.

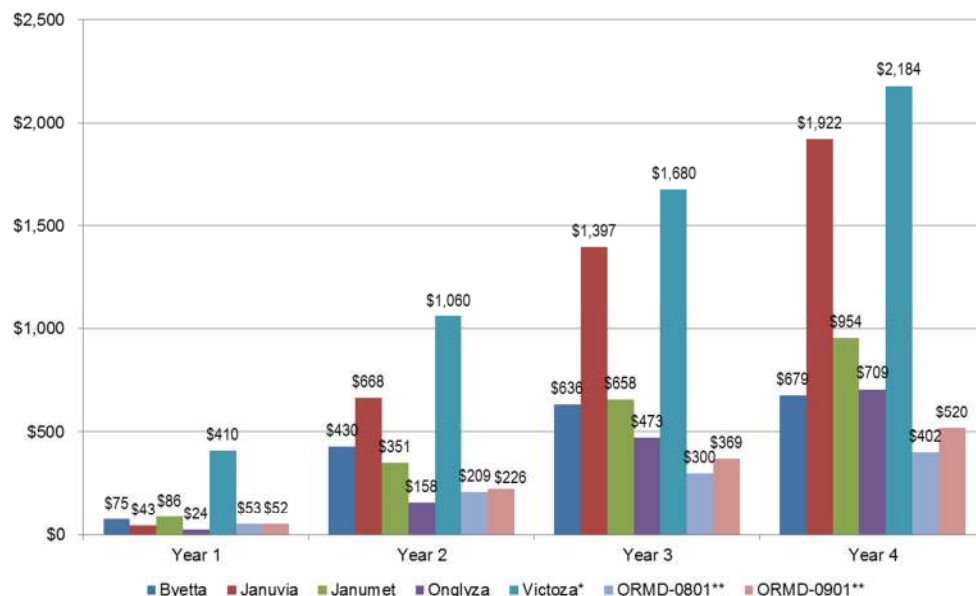
Many diabetes drugs have become blockbusters

Overall, Diabetes Drugs Have Been Big Commercial Successes

Within the diabetes pharmaceutical market, insulin products alone represent some \$20B in 2012 sales. Thus, overall, we see a significant market opportunity for ORMD-0801 and ORMD-0901. In the exhibits below, we have looked at the first four years of commercial sales for some of the more recent successfully launched drugs for diabetes and plotted that against our first four years of revenue projections for ORMD-0801 and ORMD-0901. In particular, we have chosen to look at:

- **Byetta**, a twice-daily injected GLP-1 analog that represented the very first GLP-1 product to the market;
- **Januvia**, a once-daily oral DPP-IV inhibitor that was the first DPP-IV inhibitor to come to market;
- **Janumet**, the first product combining the oral DPP-IV inhibitor Januvia with oral metformin;
- **Onglyza**, another once-daily DPP-IV inhibitor that was the second of its kind to reach the market; and
- **Victoza**, a once-weekly injected GLP-1 analog, that while the second GLP-1 overall, it was the first long-acting GLP-1 to hit the market.

Exhibit 21: Diabetes Drug Launches: Year 1 Through Year 4 Revenue (\$M)



Note: * MLV projection for Year 4 for Victoza (+30% Y/Y growth); ** MLV estimates

Source: MLV & Co.

As can be seen in the exhibit above, when compared to Byetta, Januvia, Janumet, Onglyza, and Victoza, our Year 4 revenues projection for ORMD-0801 and ORMD-0901 are lower than others. And further, as shown in the exhibit below, when we take a look at the 4-year compounded annual growth rate (CAGR) for each diabetes drug, our ORMD-0801 and ORMD-0901 projections lead to CAGRs at the lower end of the range.

Exhibit 22: Diabetes Drug Launches: Comparison of 4-Year CAGRs

Drug	Year 1 (\$M)	Year 2 (\$M)	Year 3 (\$M)	Year 4 (\$M)	4-year CAGR
Byetta	75	430	636	679	108%
Januvia	43	668	1397	1922	255%
Janumet	86	351	658	954	123%
Onglyza	24	158	473	709	209%
Victoza*	410	1060	1680	2184	75%
ORMD-0801**	80	251	410	570	93%
ORMD-0901**	52	191	349	499	113%

Note: * MLV projection for Year 4 for Victoza (+30% Y/Y growth); ** MLV estimates

Source: MLV & Co.

Thus, we do not believe our total end-user sales projection of >\$1B for both ORMD-0801 and ORMD-0901 is that unrealistic or overly optimistic.

INTELLECTUAL PROPERTY

ORMP has multiple issued patents in international territories, including very recently issued new intellectual property (IP) in Israel and Australia. However, we view the lack of granted patents in the US, the main commercial focus, as a potential risk. Based on a cursory review of the status of the key pending patents, we expect US patents to be issued but the scope of the claims granted is not yet known. Communications between the USPTO and the company within the next few quarters will provide clarity as to the scope of the claims granted.

US Patent Portfolio – Contains Pending Applications but No Issued Patents

Currently, ORMP has several pending non-provisional US patent applications (Exhibit 22). These applications cover both ORMD-0801 and ORMD-0901. The claims in the applications are directed

towards compositions of matter and methods of use of the assets.

Of the pending patent applications, the two germane US applications are Appln. Nos. 11/513,343 and 12/934,754 (hereinafter, '343 and '754, respectively). These applications contain broad claims that encompass the composition of matter of oral insulin (ORMD-0801) and oral exenatide (ORMD-0901), and the use of these compositions for the treatment of diabetes.

Status of '343 and '754

On 9/11/2013, Appln. No. '343 received a non-final rejection based on 35 USC 112(a) and 103(a). The 112(a) rejection was based on lack of support in the specification for a newly added claim limitation that excludes water and any other liquids from the composition. The 103(a) rejection was based on a combination of references regarding combining fish oil, insulin, protease inhibitors, absorption enhancers, and other elements into an oral composition for the treatment of diabetes. A response is statutorily required to be filed by 3/11/2014.

On 10/31/2013, Appln. No. '754 received a final rejection of all claims based on 35 USC 102(e). The examiner cited a previously filed US application by Miriam Kidron, PhD. Because Dr. Kidron is the named inventor on both applications, an affidavit under 37 CFR 1.132 may possibly be used to overcome the rejection. A response is statutorily required to be filed by 4/30/2014.

Next Steps with the USPTO

Although we view these rejections as a hurdle to the issuance of a patent containing the breadth of the claims in entirety, we anticipate issued patents based on narrower claims that may still cover the key elements of ORMD-0801 and ORMD-0901. We expect the company to participate in interviews with USPTO examiners within the next few months. Pending the outcome of these discussions, the company plans on pursuing the best strategy that maximizes the scope of the claims while still resulting in granted patents.

Clarity expected by 2Q14

We expect to have more clarity regarding these key applications by 2Q14. By this time, the company will have completed interviews with the examiners as well as filed responses to the rejections set forth by the USPTO. Publication of these materials should be available by 2Q14. We plan on revisiting our view of the US Patent Portfolio at that time.

Exhibit 23: Summary of US Patent Portfolio – Comprised of Pending US Applications

Appln No.	Title	Status	Expiry*	Relevant Asset
11/513,343	Methods and Compositions for Oral Administration of Proteins	On 9/11/2013, a Non-Final Rejection of all claims issued based on, <i>inter alia</i> , 112(a) and 103(a) rejections. 6-mo. response required by 3/11/2014.	2026	ORMD-0801 ORMD-0901
12/934,754	Methods and Compositions for Oral Administration of Proteins	On 10/31/13, a Final Rejection of all claims issued based on, <i>inter alia</i> , 102(e) (Kidron ref. (US 20070087957, Sept. 6, 2005)). 6-mo. response required by 4/30/14.	2028	ORMD-0801 ORMD-0901
13/855,346	Methods and Compositions for Oral Administration of Exenatide	Waiting for first office action (Appln filed 4/2/2013)	2028	ORMD-0901
PCT/IL2013/050007	Methods and Compositions for Treating Diabetes	Pending; On 1/3/13, PCT Appln filed claiming priority to US provisional appln. 61/631,339	2032	ORMD-0801 ORMD-0901
PCT/IL2013/050091	Protease inhibitor-containing compositions and compositions comprising same	Pending; On 1/31/13, PCT Appln filed claiming priority to two US provisional applns. 61/632,868 and 61/634,753	2032	ORMD-0801 ORMD-0901

Note: US Patents have not yet issued. Applications are pending and may or may not be issued. In the event, a patent is issued, an expiry date is estimated based on priority filing dates. These expiries do not include patent term adjustments and Hatch-Waxman extensions. As a result, expirations may occur more than 20 years from the estimated expiries.

Source: MLV & Co., USPTO.gov and company reports

International Patent Portfolio – Contains Pending Applications and Issued Patents

ORMP has over 30 International pending applications and granted patents. The company continues to receive issued patents. During fiscal year 2013 (ending 8/31/13), the company received at least 3 patents in addition to the 5 previously issued patents. We anticipate more granted International patents within the next few years. Exhibit 23 includes a summary of the company's 5 primary worldwide patents and applications.

Exhibit 24: Summary of Worldwide Patent Estate – Comprised of Issued Patents and Pending Applications

Title	Status	Expiry*	Relevant Asset
Methods and Compositions for Oral Administration of Proteins	Pending in US (Appln '343) and other countries; Approved in Australia, Canada, Europe, Israel, and Japan	2026	ORMD-0801 ORMD-0901
Methods and Compositions for Oral Administration of Proteins	Pending in US (Appln '754) and other countries; Approved in Australia, China, Israel, New Zealand, Russia, and South Africa	2028	ORMD-0801 ORMD-0901
Methods and Compositions for Oral Administration of Exenatide	Pending in US (Appln '346) and other countries; Approved in Israel, New Zealand, and South Africa	2028	ORMD-0901
Methods and Compositions for Treating Diabetes	Pending as PCT Appln for Potential filing in US and other countries	2032	ORMD-0801 ORMD-0901
Protease inhibitor-containing compositions and compositions comprising same	Pending as PCT Appln for Potential filing in US and other countries	2032	ORMD-0801 ORMD-0901

Note: Not all patents have issued. Many applications are still pending and may or may not be issued. In addition, estimated expiry dates are based on priority filing dates and do not include patent term adjustments or any other types of extensions. As a result, expirations may occur more than 20 years from the estimated expiries.

Source: MLV & Co., USPTO.gov and company reports

UPCOMING CATALYSTS

Exhibit 25: Upcoming Milestones/Catalysts

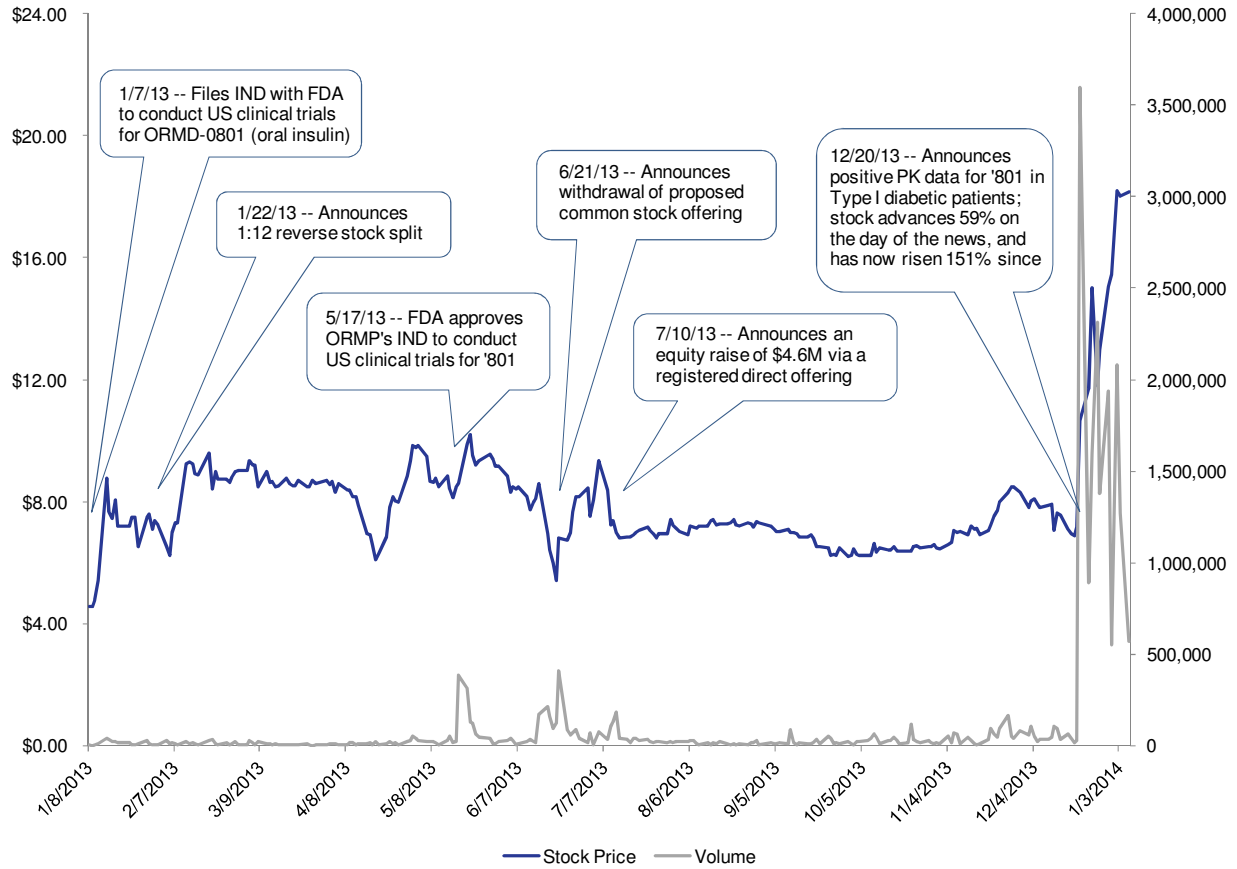
Date	Type	Program	Event
1Q14	Clinical	ORMD-0801	Announce Phase IIa data
2Q14	Clinical	ORMD-0801	Initiate Phase IIb study
2Q14	Clinical	ORMD-0901	Initiate pre-clinical and clinical trial in preparation for IND
2014	Regulatory	ORMD-0801 ORMD-0901	Potential issuance of US IP
4Q14/1H15	Regulatory	ORMD-0901	IND filing
1H15	Clinical	ORMD-0801	Announce Phase IIb data
1H15	Clinical	ORMD-0901	Initiate Phase II study
2H15	Corporate	ORMD-0801	Announce potential partnership and receive upfront payment
2H15	Clinical	ORMD-0801	Initiate Phase III study
1H16	Clinical	ORMD-0901	Announce Phase II data
1H16/2H16	Corporate	ORMD-0901	Announce potential partnership and receive upfront payment
4Q16	Clinical	ORMD-0901	Initiate Phase III study
2018	Regulatory	ORMD-0801	US regulatory filing
2019	Regulatory	ORMD-0801	EU regulatory filing
2019	Regulatory	ORMD-0801	Potential US approval and commercial launch
2019	Regulatory	ORMD-0901	US regulatory filing
2020	Regulatory	ORMD-0801	Potential EU approval and commercial launch
2020	Regulatory	ORMD-0901	Potential US approval and commercial launch
2020	Regulatory	ORMD-0901	EU regulatory filing
2021	Regulatory	ORMD-0901	Potential EU approval and commercial launch

Source: Company presentation, MLV & Co.

As seen from above, we believe ORMP has several major potential catalysts over the next 12 months that, if positive, could drive meaningful price appreciation for the stock. As a reminder, the most critical events are the release of top-line Phase IIa and Phase IIb data for ORMD-0801.

HISTORICAL STOCK CHART

Exhibit 26: One-Year Annotated Stock Chart



Source: Thomson ONE

CURRENT OWNERSHIP**Exhibit 27: Ownership**

Holder	Shares Owned	% of Shares Out	Latest Change	Holding as of
Regals Management	1,325,093	13.91	0	7/10/2013
Kidron Nadav	864,312	9.07	0	2/11/2013
Sabby Management LLC	790,000	8.29	0	12/26/2013
Bronfeld Zeev	475,226	4.99	0	12/13/2012
Sank Leonard	460,014	4.83	12,748	2/7/2013
DNA Biomedical Solutions	199,172	2.09	0	12/13/2012
Platinum Management NY LLC	26,573	0.28	26,573	9/30/2013
March Gestion de Fondos SA	11,429	0.12	11,429	9/30/2013
Finemark National Bank & Trust	3,473	0.04	0	9/30/2013
Tower Research Capital	2,333	0.02	1,233	9/30/2013
Wells Fargo & Company	1,334	0.01	(24)	9/30/2013
Technical Financial Services	600	0.01	600	7/31/2013
UBS AG	570	0.01	153	9/30/2013
Haberer Registered Investment Advisors	334	0.00	0	9/30/2013
Royal Bank of Canada	200	0.00	0	9/30/2013

Source: Bloomberg (as of 1/3/14)

MANAGEMENT PROFILE**Exhibit 28: Leadership**

Name	Position	Year Joined	Age
Management Team			
Nadav Kidron	President, CEO, Director	2006	39
Miriam Kidron	Chief Medical and Technology Officer, Director	2006	73
Leonard Sank	Director	2007	48
Harold Jacob	Director	2008	60
Michael Berelowitz	Director, Chairman of the Scientific Advisory Board	2010	69
Gerald Ostrov	Director	2012	63
Yifat Zommer	CFO, Treasurer, Secretary	2009	39
Joshua Hexter	COO, VP Business Development	2013	43
Scientific Advisory Board			
Avram Hershko	Member	2008	75
Derek LeRoith	Member	2007	68
Ele Ferrannini	Member	2007	N/A
Nir Barzilai	Member	2007	N/A
John Amatruda	Member	2010	69

Source: Company reports

The key individuals at ORMP, in our view, are:

- **Dr. Miriam Kidron** founded ORMP in 2006 and has served as the company's chief scientist since then. She is a pharmacologist and a biochemist with a Ph.D. in biochemistry. For close to 20 years, Dr. Kidron has been a senior research in the Diabetes Unit at Hadassah-Hebrew University Medical Center in Jerusalem, Israel, earning the Bern Schlanger Award for her work on diabetes research. During 2003 and 2004, she served as a consultant to Emisphere Technologies Inc.
- **Nadav Kidron** founded ORMP in 2006 and has served as the company's CEO since then. He is an Advisory Board Member for the Trendline Group, a group that invests and develops innovation-based businesses. He is also a Director of Entera Bio, a joint venture formed by Oramed and DNA Biomedical Solutions. In 2009, Mr. Kidron was a fellow at the Merage Foundation for U.S.-Israel Trade Programs for executives in the life sciences field. From 2003 to 2006, he was the managing director of the Institute of Advanced Jewish Studies at Bar Ilan University. Mr. Kidron holds an LL.B. and an International MBA from Bar Ilan University, Israel, and is a member of the Israel Bar Association.
- **Prof. Avram Hershko** earned his MD degree and Ph.D. degree from the Hebrew University-Hadassah Medical School of Jerusalem. He is the Distinguished Professor in the Unit of Biochemistry in the B. Rappaport Faculty of Medicine of the Technion. Prof. Hershko's main research interests concern the mechanisms by which cellular proteins are degraded, with a particular focus on ubiquitin. Prof. Hershko was awarded the Nobel Prize in Chemistry (2004) jointly with his former PhD student Aaron Ciechanover and their colleague Irwin Rose. His many honors include the Israel Prize for Biochemistry (1994), the Gairdner Award (1999), the Lasker Prize for Basic Medical Research (2000), the Wolf Prize for Medicine (2001) and the Louisa Gross Horwitz Award (2001).

OUR FINANCIAL MODEL AND PROJECTIONS

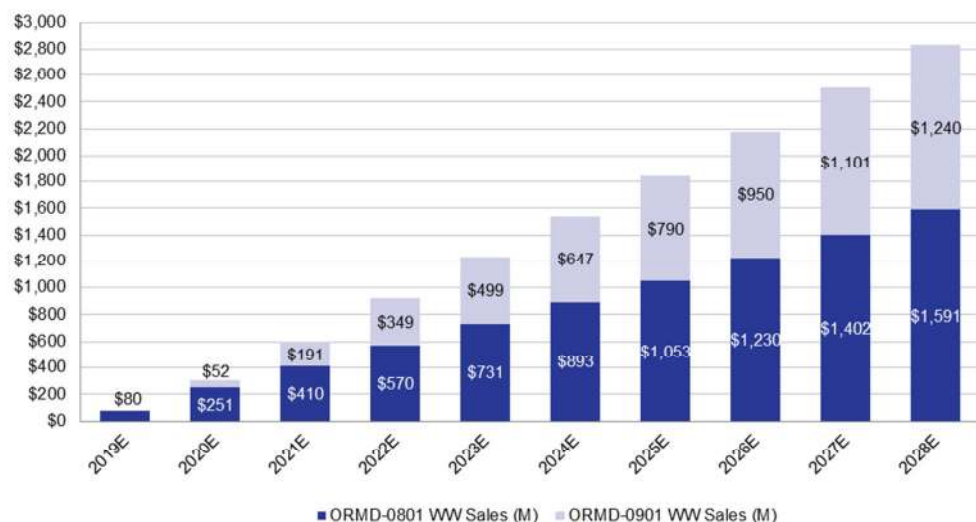
Revenue

As a development stage biotechnology company, ORMP yet to achieve profitability. Our model suggests, however, that the company will become profitable during its fiscal 2015, based on the receipt of a one-time milestone payment. Broadly speaking, we've modeled ORMP revenue coming in the form of:

1. R&D revenue – reimbursement from a partner for clinical trial costs;
2. Sales-based royalties on end-user sales of ORMD-0801 by a potential partner;
3. Sales-based royalties on end-user sales of ORMD-0901 by a potential partner;
4. Milestone payments (or amortized portions of milestone payments) related to developmental and regulatory advancements of ORMD-0801 and ORMD-0901; and
5. Sales-based milestone payments for the achievement of hitting certain cumulative end-user sales thresholds (i.e. \$250M, \$500M, \$750M, \$1B).

We project revenue for ORMP to begin in fiscal 2015 (again, based on receipt of a milestone payment). We expect ORMD-0801 and ORMD-0901 to get approved and launched in the US in 2019 and 2020 respectively (and then launched in the EU one year later). See below for our end-user sales projections.

Exhibit 29: ORMD-0801 and ORMD-0901 End-User Sales Projections



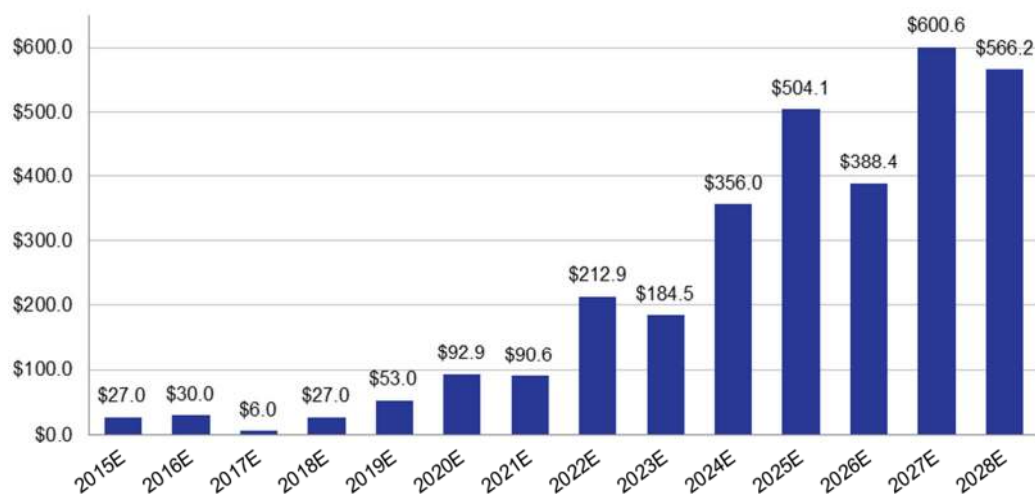
Source: MLV & Co.

It's important to note that we model partnership deals for both ORMD-0801 and -0901. Thus, we do not model ORMP recording end user sales. Instead, our ORMP revenue forecasts incorporate the following assumptions as it comes to partnership deals:

1. Receipt of upfront \$20M milestone payments for ORMD-0801 and ORMD-0901 (one for each);
2. Tiered royalties beginning at 10% on sales from \$0-\$249M, escalating to 15% on sales from \$250M-\$999M, and then 20% on sales greater than \$1B;
3. Receipt of developmental and regulatory milestones: \$5M for first patient in in Phase III and \$10M for last patient in Phase III; \$10M for US filing, \$5M for EU filing, \$20M for US approval, \$10M for EU approval; and
4. Receipt of sales milestones: we model \$25M upon the achievement of \$250M in total end-user sales; \$50M upon achieving \$500M in end-user sales; \$75M upon achieving \$750M in end-user sales; \$100 upon achieving \$1,000M in end-user sales.

Again, it is important to note that our current partnership assumptions take into account only cumulative sales in the US and the EU. Should ORMP be successful in partnering in other territories and regions (e.g., Latin America, Russia, Asia, Africa, and the Middle East), this would represent upside to our model.

Exhibit 30: ORMP Revenue Projections



Source: MLV & Co.

COGS/Gross Margin

ORMD-0801 and ORMD-0901 are small molecules, and thus we assume these candidates, if approved, will carry typical pharmaceutical-like margins (90-95%). However, we currently do not model COGS for ORMP in our financial model. The reason is that we assume partnership deals for both programs, and thus, expect any potential partner(s) to assume manufacturing.

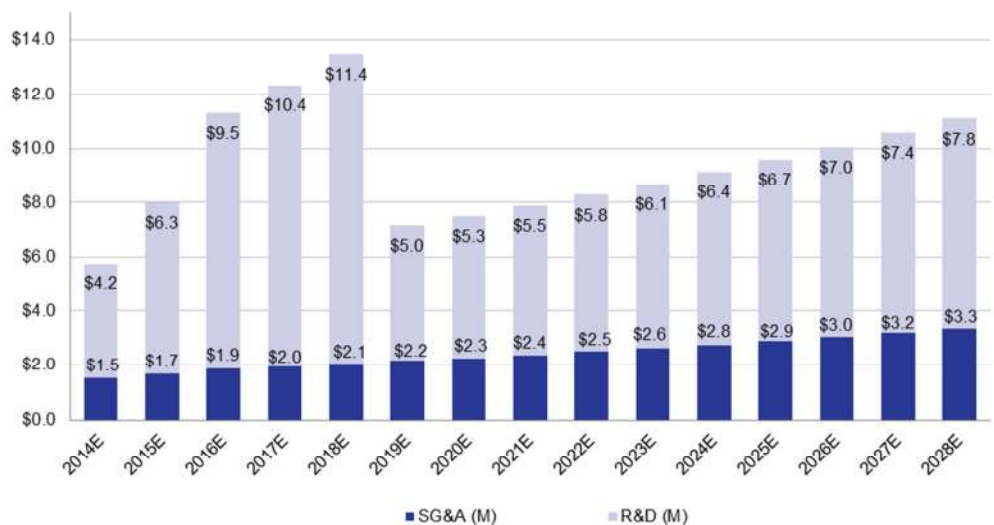
R&D

R&D is the primary driver of ORMP's corporate spending. In 2013, R&D was \$2.3M. For the next 12 months, we model R&D at \$4.2M given increased spend on ORMD-0801. As clinical testing for ORMD-0801 advances, we have modeled a \$3M spend on clinical costs, and a similar number for ORMD-0901's Phase II, and thus we see costs increasing through 2018. However, beginning in 2015, we assume partnerships for ORMD-0801 and ORMD-0901, and that partners will reimburse for direct Phase III trial costs.

SG&A

With regard to SG&A, we have modeled SG&A to be \$1.5M for 2014. After that, we assume a mid single-digit increase, given the expectation that the potential partner(s) would be responsible for product launch and commercialization.

Exhibit 31: OpEx Projections



Source: MLV & Co.

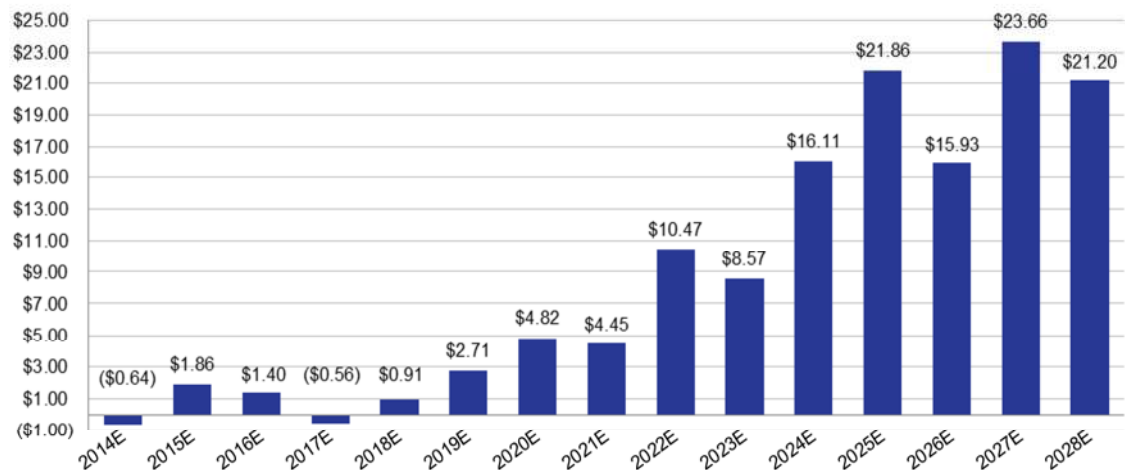
Tax

Given the lack of revenue, we believe ORMP now has approximately \$4M in accumulated net operating loss carry-forwards (“NOL”) as of the end of August 31, 2013 that can be used as an offset to future income. We project an additional \$5.7M of NOLs from 2014. Given existing NOLs, we model tax first being paid in 2016. We note that the current Israeli corporate tax rate is 26.5% (so Israel is not as tax-advantaged a country as one might think).

EPS

Currently, ORMP is not a profitable company. ORMP has a fiscal calendar year that ends in August, and it just reported FY13 EPS of (\$0.59). We currently project FY14 EPS of (\$0.64). However, given our expectation of a partnership deal for ORMD-0801 in 2015 and one for ORMD-0901 in 2016, we assume upfront milestone payments that will cause ORMP to be profitable in both years. Should these milestones fail to materialize, then it is likely that ORMP will be unprofitable. See the below exhibit on how we expect EPS to develop over the 2014-2028 time horizon.

Exhibit 32: EPS Projections



Source: MLV & Co.

Balance Sheet

As of August 31, 2013, ORMP had \$2.3M in cash and cash equivalents. It also has a cash burn rate of about \$1M per quarter. On December 27, 2013, the company raised \$15.8M (gross proceeds) in a registered direct offering. Based on our

current projections, we believe this should be sufficient to cover the company operating expenses over the next several years.

Potential Future Financings

Based on our current financial model, ORMP's limited OpEx, and the company's recent financing completed last month (gross proceeds of \$15.8M), we do not expect the company to necessarily require additional financing in the near term. Again, further out, we assume partnerships for both ORMD-0801 and ORMD-0901 that include upfront milestone payments. Should these partnerships fail to materialize, would expect ORMP to need to raise capital to fund future operations.

APPENDIX A: TREATMENTS AND LIMITATIONS

The treatment paradigms for T1DM and T2DM are quite different. Nevertheless, achieving euglycemia is the aim for both indications. A key test used in assessing how well diabetes is being controlled is the glycated hemoglobin test (HbA_{1c}).

Exhibit 33: Glucose Control Levels

	Normal	Target
HbA _{1c}	<6.0%/42 mmol/mol	<7%/53 mmol/mol
Fasting/pre-meal capillary plasma glucose	100 mg/dL	115 mg/dL
Post meal capillary plasma glucose	140 mg/dL	160 mg/dL

Source: International Disease Foundation

1. Type I diabetes

These patients require lifelong insulin replacement therapies, which consist of one or two daily insulin injections, one daily blood glucose test and visits to healthcare professionals every three months. Various forms of insulin are available: rapid-acting, short-acting, intermediate-acting, long-acting, premixed and premixed analogues. The aim of combining different insulin products is to replicate endogenous stimulate and basal release of the hormone, such that excursions in postprandial blood glucose are minimal and hepatic glucose production is properly regulated. Therefore, insulin replacement regimens consist of two components: the basal insulin administration provides a steady amount of background insulin throughout the day, while the

bolus administration provides a boost of insulin after a meal.

Exhibit 34: Available Insulin Preparation and Their Pharmacokinetic Parameters

Insulin	Trade Name	Manufacturer	Onset (h)	Peak (h)	Duration (h)	2012 WW sales
Rapid-acting						
Lispro	Humalog	Eli Lilly	0.2-0.5	0.5-2	3-4	\$2.4B
Aspart	Novolog	Novo Nordisk	0.2-0.5	0.5-2	3-4	\$2.8B
Glulisine	Apidra	Sanofi-Aventis	0.2-0.5	0.5-2	3-4	\$295.7M
Short-acting						
Regular	Humulin R Novolin ge Toronto	Eli Lilly Novo Nordisk	0.5-1	2-4	6-8	N/A
Intermediate-acting						
Isophane Insulin (NPH)	Humulin N Novolin N	Eli Lilly Novo Nordisk	1.5-4	4-10	Up to 20	N/A
Long-acting						
Glargine	Lantus	Sanofi-Aventis	1-3	None	Up to 24	\$6.4B
Detemir	Levemir	Novo Nordisk	1-3	None	Up to 24	\$1.8B
Premixed Human (NPH/Regular)						
70%/30%	Humulin 70/30 Novolin 70/30	Eli Lilly Novo Nordisk	0.5-1	3-12	Up to 24	N/A
50%/50%	Humulin 50/50 Novolin 50/50	Eli Lilly Novo Nordisk	0.5-1	2-12	Up to 24	N/A
Premixed Analogues						
NPL/Lispro: 75%/25%	Humalog Mix 75/25	Eli Lilly	0.2-0.5	1-4	24	N/A
NPL/Lispro: 50%/50%	Humalog Mix 50/50	Eli Lilly	0.2-0.5	1-4	24	N/A
IAP/Aspart: 70%/30%	Novolog Mix 30	Novo Nordisk	0.2-0.5	1-4	24	N/A

Note: IAP = insulin aspart protamine; NPH= neutral protamine Hagedorn; NPL= neutral protamine lispro

Source: Company reports, Biomedtracker, Borgono C and Zinman B, "Insulins: past, present and future." *Endocrinology Metabolism Clinics of North America* (2012): 1-24

From crude animal insulin extracts to novel human analogues, the medical community has witnessed tremendous progress in insulin therapy over the last 90 years. Albeit life-saving, all insulin is still only available in the injected (subcutaneous) formulation. The inherent inconvenience of the delivery method is an important contributor to non-compliance in insulin therapy. The Diabetes Attitudes, Wishes and Needs (DAWN) study found that 33% of insulin users dreaded their injection, and 22% had to mentally prepare themselves for the procedure. Such anxiety symptoms translate into less self-monitoring, fewer insulin injections and poorer glycemic control.

Based on data gathered thus far, the most pressing goal then, would be to develop less invasive means of

delivery. The following is a summary of novel systems that are either already available or are in development.

Exhibit 35: Insulin Delivery Methods

Type	Mechanism	Advantages	Disadvantages
Insulin Pen	Injection of pre-loaded insulin	Portable, convenient, accurate dosing	More expensive than syringes, wasted insulin, limited by insulin types, not available as a premix,
Insulin Pump	Programmed insulin release via battery-powered pump	Automatic insulin delivery	Tubing issues, requires frequent monitoring, skin irritation at infusion site, blockage in the device
Insulin Patch Pump	Similar to insulin pump, no tubing, uses a wireless controller	Small, convenient, tubeless	Adhesive intolerance, poor adherence
Insulin Jet Injector	High-pressured air	No needle	Very expensive, can be more painful than needles, hard to control, causes trauma at the injection site

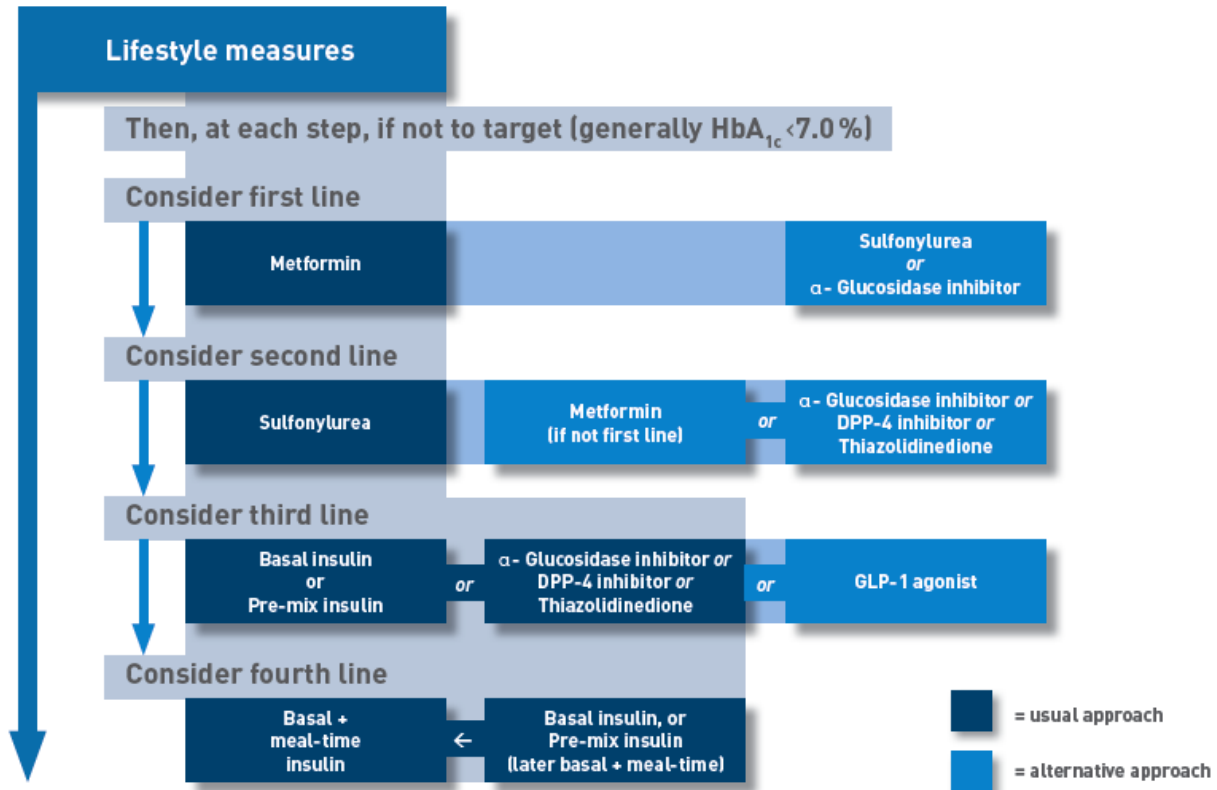
Source: Anhalt H and Bohannon N, "Insulin patch pumps: their development and future in closed-loop systems." *Diabetes Technology & Therapeutics* (2010): S51-S58, MLV & Co.

Unfortunately, the majority of the newer devices still uses needles and is much more expensive than traditional syringes. Although no studies have been conducted, we believe that these interventions still fail to address injection anxiety, a major cause of non-adherence.

2. Type II diabetes

The treatment of T2DM is multifactorial. Its heterogeneity and progressive nature can make disease management a cumbersome task. Ideally, blood glucose should be maintained at near-normal levels: pre-prandial levels of 90-130 mg/dL and HbA_{1c} of less than 7%. However, aggressive glucose lowering may not be the best strategy for all patients. The following exhibit depicts the treatment algorithm designed by the International Disease Foundation (IDF).

Exhibit 36: IDF Treatment Algorithm for Type II Diabetes



Source: International Disease Foundation

Of all the T2DM patients, 80-90% are obese. Since a small/mild increase in in body mass index (BMI) can increase the risk of T2DM by as much as three-fold, physicians almost always prescribe exercise and diet change as interventions for improving adipose tissue function. While some patients can manage T2DM with weight reduction and exercise alone, many still require medications to control their plasma glucose level. The main classes (and their brands) of drugs include:

Exhibit 37: Drugs for Type II Diabetes

Class	Trade Name	Generic Name	Mechanism	% HbA1c Reduction	Advantages	Disadvantages
Biguanides	Glucophage Glucophage ER	metformin metformin ER	Activates AMP-kinase, ↓ hepatic glucose production	1-2	Low cost, no hypoglycemia, improved lipid profile, ↓ CVD risk	GI intolerance, lactic acidosis (rare)
Sulfonylureas	Glucotrol Amaryl Orinase	glipizide glimepiride tolbutamide	Closes β cell potassium channels to ↑ insulin secretion	1-1.5	Low cost, ↓ microvascular risk	Hypoglycemia, weight gain, low durability
Meglitinides	Starlix Prandin	nateglinide repaglinide	Closes β cell potassium channels to ↑ insulin secretion	0.5-1	Short duration of action, less postprandial glucose excursions, dosing flexibility	Hypoglycemia, weight gain, low durability, frequent dosing schedule
Thiazolidinediones	Actos Avandia	pioglitazone rosiglitazone	Activation of PPAR-γ, ↑ insulin sensitivity	0.5-1.4	No hypoglycemia, durability, improved lipid profile	Edema, heart failure, weight gain, bone fractures, bladder cancer
α-Glucosidase Inhibitors	Precose Glyset	acarbose miglitol	Inhibits intestinal α- glucosidase, ↓ carbohydrate uptake	0.5-0.9	↓ Postprandial hyperglycemia	Flatulence and diarrhea, frequent dosing schedule
DPP-4 Inhibitors	Januvia Onglyza Tradjenta Nesina	sitagliptin saxagliptin linagliptin alogliptin	Inhibits DPP-4, ↑ GLP-1	0.5-0.8	No hypoglycemia, well tolerated	Urticaria/angio-edema
DPP-4 Combinations	Janumet Janumet XR Kombiglyze XR Jentadueto Kazano Oseni	sitagliptin, metformin sitagliptin, metformin XR saxagliptin, metformin XR linagliptin, metformin alogliptin, metformin alogliptin, pioglitazone	Activates AMP-kinase, inhibits DPP-4	0.4-1.1	No hypoglycemia	Kazano: upper respiratory tract infection, dizziness, diarrhea, back pain high blood pressure, Boxed Warning for lactic acidosis Oseni: upper respiratory tract infection, back pain, Boxed Warning for heart failure
GLP-1 Receptor Agonists	Byetta Bydureon Victoza	exenatide exenatide XR liraglutide	Activates GLP-1 receptor	0.5-1.5	Hypoglycemia rare, weight loss	GI side effects, injectable, requires training
Amylin Mimetics	Symlin	pramlintide	Activates amylin receptor, ↓ glucagon secretion, ↓ gastric emptying	0.5-1	↓ Postprandial hyperglycemia, weight loss	GI side effects, hypoglycemia, injectable, frequent dosing schedule

Source: Morsink L, Smits M and Diamant M, "Advances in pharmacologic therapies for type 2 diabetes." *Current Atherosclerosis Reports* (2013): 1-14.

Despite a broad range of effective blood glucose-lowering therapies, 25-50% of T2DM patients are not reaching recommended glycemic targets. Conventional T2D therapies are effective at lowering blood glucose, but they do not impact upon the progressive decline of β cell function, so glycemic control continues to deteriorate unless treatment is intensified. Unfortunately, intensifications are associated with weight gain and risk of hypoglycemia, thus necessitating the ongoing quest for novel treatment modalities.

APPENDIX B: FINANCIAL EXHIBITS

Exhibit 38: Annual P&L

Year ended August 31 (In millions of US\$)	FY 2011	FY 2012	FY 2013	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E	FY 2028E
REVENUES																		
R&D revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$2.0	\$5.0	\$6.0	\$7.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Royalty revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	8.0	42.9	80.6	137.9	184.5	231.0	329.1	388.4	500.6	566.2
WW milestone payments	0.0	0.0	0.0	0.0	25.0	25.0	0.0	20.0	45.0	50.0	10.0	75.0	0.0	125.0	175.0	0.0	100.0	0.0
1) ORMD 0801 Royalty Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	8.0	37.7	61.5	85.5	109.6	134.0	210.6	245.9	280.4	318.1
Note: US end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	79.7	167.5	273.4	380.0	487.3	595.4	702.1	819.7	934.6	1,060.5
Note: EU end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	83.7	136.7	190.0	243.7	297.7	351.0	409.9	467.3	530.2
Note: US/EU end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	79.7	251.2	410.0	570.0	731.0	893.1	1,053.1	1,229.6	1,401.8	1,590.7
Note: WW milestone payments	0.0	0.0	0.0	0.0	25.0	0.0	0.0	20.0	25.0	0.0	50.0	0.0	75.0	100.0	0.0	0.0	0.0	0.0
2) ORMD 0901-Related Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	\$0.0	0.0	5.2	19.1	52.4	74.9	97.1	118.5	142.5	220.3	248.1
Note: US end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	52.0	127.6	232.8	332.9	431.4	526.6	633.2	734.2	826.9
Note: EU end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	63.8	116.4	166.5	215.7	263.3	316.6	367.1	413.4
Note: US/EU end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	52.0	191.4	349.2	499.4	647.2	789.9	949.9	1,101.4	1,240.3
Note: WW milestone payments	0.0	0.0	0.0	0.0	0.0	25.0	0.0	0.0	20.0	25.0	10.0	25.0	0.0	50.0	75.0	0.0	100.0	0.0
Total Revenue	0.0	0.0	0.0	0.0	27.0	30.0	6.0	27.0	53.0	92.9	90.6	212.9	184.5	356.0	504.1	388.4	600.6	566.2
COGS	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	0.0	0.0	0.0	0.0
Gross Profit	0.0	0.0	0.0	0.0	27.0	30.0	6.0	27.0	53.0	92.9	90.6	212.9	184.5	356.0	504.1	388.4	600.6	566.2
Gross Margin %	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
R&D	1.2	1.7	2.3	4.2	6.3	9.5	10.4	11.4	5.0	5.3	5.5	5.8	6.1	6.4	6.7	7.0	7.4	7.8
% of Revenue	NM	NM	NM	NM	23.3%	31.5%	173.3%	42.4%	9.4%	5.7%	6.1%	2.7%	3.3%	1.8%	1.3%	1.8%	1.2%	1.4%
SG&A	1.3	1.2	2.0	1.5	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.8	2.9	3.0	3.2	3.3
% of Revenue	NM	NM	NM	NM	6.3%	6.2%	32.6%	7.6%	4.1%	2.4%	2.6%	1.2%	1.4%	0.8%	0.6%	0.8%	0.5%	0.6%
Total OpEx	2.4	2.9	4.3	5.7	8.0	11.3	12.4	13.5	7.2	7.5	7.9	8.3	8.7	9.1	9.6	10.1	10.6	11.1
Oper. Income (Loss)	(2.44)	(2.9)	(4.3)	(5.7)	19.0	18.7	(6.4)	13.5	45.8	85.4	82.8	204.6	175.8	346.9	494.5	378.3	590.1	555.1
Financial Expense	(0.02)	(0.2)	(0.4)	0.0	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)
Pre-tax income (Loss)	(1.59)	(3.2)	(4.4)	(5.7)	19.0	18.7	(6.4)	13.5	45.8	85.4	82.8	204.6	175.8	346.9	494.5	378.3	590.1	555.1
Taxes paid benefit (expense)	<u>(0.02)</u>	<u>(0.1)</u>	<u>0.2</u>	<u>0.0</u>	<u>0.0</u>	<u>3.7</u>	<u>0.0</u>	<u>2.7</u>	<u>12.1</u>	<u>22.6</u>	<u>21.9</u>	<u>54.2</u>	<u>46.6</u>	<u>91.9</u>	<u>131.0</u>	<u>100.3</u>	<u>156.4</u>	<u>147.1</u>
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	20.0%	0.0%	20.0%	26.5%	26.5%	26.5%	26.5%	26.5%	26.5%	26.5%	26.5%	26.5%	26.5%
Net Income (Loss)	(1.56)	(3.3)	(4.2)	(5.7)	19.0	14.9	(6.4)	10.8	33.7	62.7	60.8	150.4	129.2	255.0	363.5	278.1	433.7	408.0
Diluted EPS	(\$0.02)	(\$0.57)	(\$0.59)	(\$0.64)	\$1.86	\$1.40	(\$0.56)	\$0.91	\$2.71	\$4.82	\$4.45	\$10.47	\$8.57	\$16.11	\$21.86	\$15.93	\$23.66	\$21.20
Basic Shares Out	65.0	5.9	7.2	9.0	10.2	10.7	11.3	11.8	12.4	13.0	13.7	14.4	15.1	15.8	16.6	17.5	18.3	19.2
Diluted Shares Out	65.0	5.9	7.2	9.0	10.2	10.7	11.3	11.8	12.4	13.0	13.7	14.4	15.1	15.8	16.6	17.5	18.3	19.2

Source: MLV & Co.

Exhibit 39: Quarterly P&L

Year ended August 31 (In millions of US\$)	FY 2011	1Q Nov-11	2Q Feb-12	3Q May-12	4Q Aug-12	FY 2012	1Q Nov-12	2Q Feb-13	3Q May-13	4Q Aug-13	FY 2013	1Q Nov-13E	2Q Feb-14E	3Q May-14E	4Q Aug-14E	FY 2014E	FY 2015E
REVENUES																	
R&D revenue	\$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	\$0.0	\$0.0	\$2.0
Royalty revenue	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	0.0	0.0	0.0
WW milestone payments	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	0.0	0.0	25.0
1) ORMD 0801 Royalty Revenue	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	0.0	0.0	0.0
Note: US end user sales	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	0.0	0.0	0.0
Note: EU end user sales	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	0.0	0.0	0.0
Note: US/EU end user sales	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	0.0	0.0	0.0
Note: WW milestone payments	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	0.0	0.0	25.0
2) ORMD 0901-Related Revenue	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	0.0	0.0	0.0
Note: US end user sales	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	0.0	0.0	0.0
Note: EU end user sales	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	0.0	0.0	0.0
Note: US/EU end user sales	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	0.0	0.0	0.0
Note: WW milestone payments	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	0.0	0.0	0.0
Total Revenue	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	0.0	0.0	27.0
COGS	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	0.0	0.0	0.0
Gross Profit	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	0.0	0.0	27.0
Gross Margin %	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
R&D	1.2	0.2	0.7	0.2	0.5	1.7	0.4	0.7	0.8	0.3	2.3	0.8	1.4	1.1	0.9	4.2	6.3
% of Revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	23.3%
SG&A	1.3	0.3	0.2	0.3	0.4	1.2	0.3	0.5	0.5	0.68	2.0	0.37	0.37	0.40	0.40	1.5	1.7
% of Revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	6.3%
Total OpEx	2.4	0.5	0.9	0.5	0.9	2.9	0.7	1.3	1.3	1.0	4.3	1.2	1.8	1.5	1.3	5.7	8.0
Oper. Income (Loss)	(2.44)	(0.47)	(0.94)	(0.5)	(0.9)	(2.9)	(0.73)	(1.3)	(1.3)	(1.0)	(4.3)	(1.2)	(1.8)	(1.5)	(1.3)	(5.7)	19.0
Financial Expense	(0.02)	(0.02)	(0.01)	(0.01)	(0.2)	(0.2)	(0.3)	(0.03)	(0.01)	(0.0)	(0.4)	0.0	0.0	0.0	0.0	0.0	(1.0)
Pre-tax income (Loss)	(1.59)	(0.48)	(0.99)	(0.55)	(1.2)	(3.2)	(0.96)	(1.23)	(1.26)	(1.0)	(4.4)	(1.2)	(1.8)	(1.5)	(1.3)	(5.7)	19.0
Taxes paid benefit (expense)	(0.02)	0.0	0.0	0.0	(0.1)	(0.1)	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0
Tax rate	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%	0.0%	0.0%	0.0%
Net Income (Loss)	(1.56)	(0.48)	(0.99)	(0.55)	(1.13)	(3.3)	(1.0)	(1.2)	(1.3)	(1.2)	(4.2)	(1.2)	(1.8)	(1.5)	(1.3)	(5.7)	19.0
Diluted EPS	(\$0.02)	(\$0.10)	(\$0.17)	(\$0.09)	(\$0.19)	(\$0.57)	(\$0.16)	(\$0.17)	(\$0.17)	(\$0.17)	(\$0.59)	(\$0.16)	(\$0.19)	(\$0.16)	(\$0.13)	(\$0.64)	\$1.86
Basic Shares Out	65.0	4.8	5.8	5.9	5.9	5.9	5.8	7.2	7.2	7.2	7.2	7.3	9.5	9.6	9.7	9.0	10.2
Diluted Shares Out	65.0	4.8	5.8	5.9	5.9	5.9	5.8	7.2	7.2	7.2	7.2	7.3	9.5	9.6	9.7	9.0	10.2

Source: MLV & Co.

Exhibit 40: Revenue Statement

Year ended August 31 (In millions of US\$)	FY 2011	FY 2012E	FY 2013E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E	FY 2028E
R&D revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$2.0	\$5.0	\$6.0	\$7.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Royalty revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	8.0	42.9	80.6	137.9	184.5	231.0	329.1	388.4	500.6	566.2
WW milestone payments	0.0	0.0	0.0	0.0	25.0	25.0	0.0	20.0	45.0	50.0	10.0	75.0	0.0	125.0	175.0	0.0	100.0	0.0
1) ORMD 0801 Royalty Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	8.0	37.7	61.5	85.5	109.6	134.0	210.6	245.9	280.4	318.1
Note: US end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	79.7	167.5	273.4	380.0	487.3	595.4	702.1	819.7	934.6	1,060.5
Note: EU end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	83.7	136.7	190.0	243.7	297.7	351.0	409.9	467.3	530.2
Note: US/EU end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	79.7	251.2	410.0	570.0	731.0	893.1	1,053.1	1,229.6	1,401.8	1,590.7
Note: WW milestone payments	0.0	0.0	0.0	0.0	25.0	0.0	0.0	20.0	25.0	25.0	0.0	50.0	0.0	75.0	100.0	0.0	0.0	0.0
2) ORMD 0901 Royalty Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.2	19.1	52.4	74.9	97.1	118.5	142.5	220.3	248.1
Note: US end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	52.0	127.6	232.8	332.9	431.4	526.6	633.2	734.2	826.9
Note: EU end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	63.8	116.4	166.5	215.7	263.3	316.6	367.1	413.4
Note: US/EU end user sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	52.0	191.4	349.2	499.4	647.2	789.9	949.9	1,101.4	1,240.3
Note: WW milestone payments	0.0	0.0	0.0	0.0	0.0	25.0	0.0	0.0	20.0	25.0	10.0	25.0	0.0	50.0	75.0	0.0	100.0	0.0
Total Revenue	\$0.0	\$0.0	\$0.0	\$0.0	\$27.0	\$30.0	\$6.0	\$27.0	\$53.0	\$92.9	\$90.6	\$212.9	\$184.5	\$356.0	\$504.1	\$388.4	\$600.6	\$566.2

Source: MLV & Co.

Exhibit 41: Balance Sheet

Year ended August 31 (In millions of US\$)	FY Aug-09	FY Aug-11	FY Aug-12	FY Aug-13	FY Aug-14E	FY Aug-15E	FY Aug-16E	FY Aug-17E	FY Aug-18E	FY Aug-19E	FY Aug-20E	FY Aug-21E	FY Aug-22E	FY Aug-23E	FY Aug-24E	FY Aug-25E	FY Aug-26E	FY Aug-27E	FY Aug-28E
ASSETS																			
Current Assets																			
Cash & Cash equivalents	\$1.7	\$1.5	\$4.4	\$2.3	\$11.5	\$30.6	\$45.8	\$39.6	\$50.6	\$84.6	\$147.6	\$208.7	\$359.5	\$489.2	\$744.6	\$1,108.6	\$1,387.3	\$1,821.7	\$2,230.5
Short-term investments	1.0	1.8	0.5	5.2	1.5	1.5	1.6	1.6	1.7	1.7	1.8	1.8	1.9	2.0	2.0	2.1	2.1	2.2	2.3
Marketable securities	0.0	0.4	0.2	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.3	1.3	1.3
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	0.0	0.0	0.0	0.0	0.0
Accounts receivable	0.0	0.5	0.1	0.0	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.7	0.8	0.8
Prepaid expenses	0.0	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	0.1	0.1	0.2	0.2
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	0.0	0.0	0.0	0.0	0.0
Grants	0.4	0.0	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Total Current Assets	3.2	4.3	5.3	\$8.6	14.7	33.9	49.2	43.1	54.2	88.3	151.4	212.7	363.5	493.3	748.9	1,113.1	1,391.9	1,826.4	2,235.3
Long-term deposits	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	0.0	0.0	0.0	0.0	0.0
Amounts funded in respect of employee rights	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	0.0	0.0	0.0	0.0	0.0
PPE	0.1	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	0.0	0.0	0.0	0.0
TOTAL ASSETS	\$3.3	\$4.3	\$5.3	\$8.7	\$14.7	\$34.0	\$49.2	\$43.1	\$54.3	\$88.3	\$151.4	\$212.7	\$363.6	\$493.4	\$749.0	\$1,113.1	\$1,391.9	\$1,826.4	\$2,235.4
LIAB. & STOCKHOLDERS EQUITY																			
Current Liabilities																			
Accounts payable and accrued expenses	0.3	0.4	0.6	0.5	0.5	0.5	0.5	0.5	0.5	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.7
Related parties	0.0	0.0	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	0.1	0.1	0.1
Accounts payable with former shareholder	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	0.0	0.0	0.0	0.0	0.0
Total current liabilities	0.4	0.4	0.6	\$0.5	0.6	0.6	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8
Long-term Liabilities																			
Warrants	0.0	0.0	0.6	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	0.0	0.0
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	0.0	0.0	0.0	0.0	0.0
Provision for certain tax assets	0.1	0.1	0.2	0.0	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.6	0.6
Total long-term liabilities	0.1	0.2	0.9	0.0	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.6	0.6	0.6
TOTAL LIABILITIES	\$0.5	\$0.6	\$1.5	\$0.5	\$0.9	\$0.9	\$1.0	\$1.0	\$1.0	\$1.0	\$1.1	\$1.1	\$1.1	\$1.2	\$1.2	\$1.2	\$1.3	\$1.3	\$1.4
Stockholders' Equity																			
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	0.1	0.1	0.1	0.1	0.1
Other accumulated comprehensive income	0.0	0.0	0.0	0.3	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	0.1
APIC	12.7	18.2	21.6	29.9	41.7	41.9	42.1	42.4	42.7	43.0	43.4	43.8	44.3	44.8	45.4	46.0	46.7	47.5	48.4
(Accum. deficit)/RE	(10.0)	(14.5)	(17.9)	(22.1)	(27.9)	(8.9)	6.1	(0.3)	10.5	44.2	107.0	167.8	318.2	447.4	702.4	1,065.9	1,343.9	1,777.6	2,185.6
Total stockholders' equity	\$2.7	\$3.7	\$3.8	\$8.1	\$13.8	\$33.0	\$48.2	\$42.1	\$53.2	\$87.2	\$150.3	\$211.6	\$362.4	\$492.2	\$747.7	\$1,111.8	\$1,390.6	\$1,825.1	\$2,234.0
TOTAL LIABILITIES AND EQUITY	\$3.3	\$4.3	\$5.3	\$8.7	\$14.7	\$34.0	\$49.2	\$43.1	\$54.3	\$88.3	\$151.4	\$212.7	\$363.6	\$493.4	\$749.0	\$1,113.1	\$1,391.9	\$1,826.4	\$2,235.4

Source: MLV & Co.

Exhibit 42: Cash Flow Statement

Year ended August 31 (In millions of US\$)	FY Aug-11	FY Aug-12	FY Aug-13	1Q Nov-13E	2Q Feb-14E	3Q May-14E	FY Aug-14E	FY Aug-15E	FY Aug-16E	FY Aug-17E	FY Aug-18E	FY Aug-19E	FY Aug-20E	FY Aug-21E	FY Aug-22E	FY Aug-23E	FY Aug-24E	FY Aug-25E	FY Aug-26E	FY Aug-27E	FY Aug-28E	
CASH FLOW FROM OPERATING ACTIVITIES																						
Net income (loss)	(\$1.6)	(\$3.3)	(\$4.2)	(\$1.2)	(\$2.9)	(\$4.4)	(\$5.7)	\$19.0	\$14.9	(\$6.4)	\$10.8	\$33.7	\$62.7	\$60.8	\$150.4	\$129.2	\$255.0	\$363.5	\$278.1	\$433.7	\$408.0	
Depreciation and amortization	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Exchange differences	(0.0)	0.1	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	0.0	0.0	0.0	0.0	0.0	
Stock-based compensation	0.5	0.3	0.7	0.2	0.4	0.6	0.7	0.8	0.8	0.8	0.9	0.9	1.0	1.0	1.1	1.1	1.2	1.2	1.3	1.4	1.4	
Common stock issued for services	0.2	0.1	0.2	0.0	0.0	0.1	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.6	0.6	0.7	0.8	0.8	0.9	1.0	
Gain on sale of investment	(1.0)	0.0	(0.1)	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)	(0.1)	(0.1)	(0.1)	(0.1)	
Impairment of available for sale securities	0.2	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Imputed interest	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Exchange of warrants	0.0	0.0	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.6	0.6	
Change in fair value of warrants	0.0	0.1	(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)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	
<i>Changes in operating assets and liabilities</i>																						
Prepaid expenses and other current assets	(0.0)	(0.0)	(0.0)	(0.0)	(0.4)	(0.4)	(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)	(0.0)	
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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Accounts payable and accrued expenses	(0.0)	0.2	(0.1)	(0.3)	(0.2)	(0.2)	(0.1)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.3)	(0.3)	(0.3)	(0.3)	
Liability for employee rights upon termination	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Provision for uncertain tax position	(0.0)	0.1	(0.2)	0.0	0.0	0.0	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.4)	(0.4)	(0.4)	(0.4)	
Change in Working Capital	(0.1)	0.3	(0.4)	(0.3)	(0.6)	(0.6)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.5)	(0.5)	(0.5)	(0.5)	(0.6)	(0.6)	(0.6)	(0.6)	(0.7)	(0.7)	
Net Cash from Operations	(1.7)	(2.3)	(3.4)	(1.0)	(2.8)	(4.1)	(4.9)	19.9	15.9	(5.3)	11.9	34.9	64.0	62.2	151.8	130.8	256.7	365.3	280.0	435.8	410.2	
CASH FLOW FROM INVESTING ACTIVITIES																						
Purchase of PPE	(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)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	
Purchase of short-term deposits	(1.7)	(0.5)	(5.8)	0.0	(1.0)	(1.5)	(2.0)	(2.1)	(2.2)	(2.3)	(2.4)	(2.6)	(2.7)	(2.8)	(3.0)	(3.1)	(3.3)	(3.4)	(3.6)	(3.8)	(4.0)	
Proceeds from the sale of short-term deposits	0.0	1.8	1.1	0.5	0.1	0.2	1.1	1.1	1.2	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	2.0	2.1	
Proceeds from the sale of investments	0.0	0.5	0.2	0.0	0.0	0.0	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.4	
Funds in respect of employee rights upon termination	(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)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	
Lease deposits	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Net Cash from Investing	(1.7)	1.8	(4.6)	0.5	(0.9)	(1.3)	(0.7)	(0.8)	(0.8)	(0.8)	(0.9)	(0.9)	(1.0)	(1.0)	(1.1)	(1.1)	(1.2)	(1.2)	(1.3)	(1.4)	(1.4)	
CASH FLOW FROM FINANCING ACTIVITIES																						
Proceeds from sale of common stock, net	3.7	3.5	5.7	0.0	14.9	14.9	14.9	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	
Shares issued					1.6																	
Stock price					10.0																	
Proceeds from sale of warrants, net			0.1																			
Net Cash from Financing	3.7	3.5	5.8	0.0	14.9	14.9	14.9	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	
Net Increase in Cash	0.3	3.0	(2.1)	(0.5)	11.1	9.5	9.3	19.2	15.1	(6.1)	11.1	33.9	63.1	61.2	150.8	129.7	255.5	364.0	278.7	434.4	408.8	
Effect of exchange rates	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)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	
Net cash, End of Period	0.3	2.9	(2.2)	(0.6)	11.1	9.4	9.2	19.1	15.1	(6.2)	11.0	33.9	63.0	61.2	150.7	129.7	255.5	364.0	278.7	434.4	408.8	
Net Cash/Equivalents/Sec's, End of Period	1.5	4.4	2.3	1.7	13.4	11.7	11.5	30.6	45.8	39.6	50.6	84.6	147.6	208.7	359.5	489.2	744.6	1,108.6	1,387.3	1,821.7	2,230.5	

Source: MLV & Co.

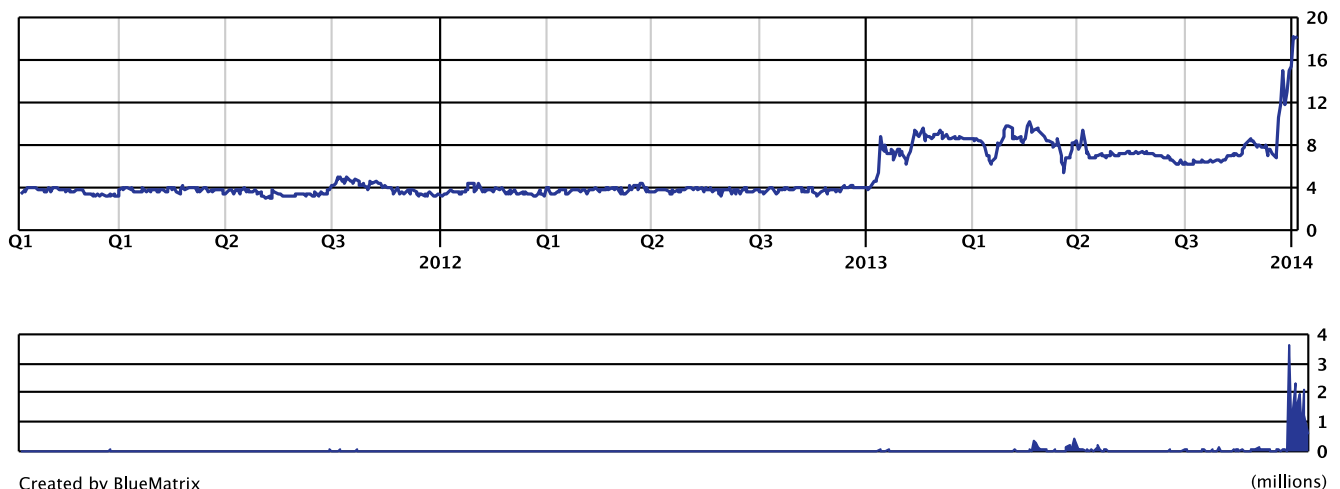
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