AEGIS CAPITAL CORP

Pharmaceuticals
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Initiating Coverage

December 3, 2013

Key Metrics

ORMP - NASDAQ	$7.82
Pricing Date	Dec 2 2013
Price Target	$25.00
52-Week Range	$10.68 - $3.60
Shares Outstanding (mm)	7.9
Market Capitalization ($mm)	$61.8
3-Mo Average Daily Volume	32,434
Institutional Ownership	0%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	$0.58
Price/Book	13.5x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS ($) FY: August

	2012A	Prior 2013A	Curr. 2013A	Prior 2014E	Curr. 2014E
1Q-Nov	(0.08)	--	(0.14)	--	(0.18)E
2Q-Feb	(0.17)	--	(0.19)	--	(0.18)E
3Q-May	(0.09)	--	(0.19)	--	(0.18)E
4Q-Aug	(0.20)	--	(0.09)	--	(0.20)E
FY	(0.54)	--	(0.59)	--	(0.74)E
P/E	NM		NM		NM

Source: BigCharts.com

Company Description:
Oramed Pharmaceuticals, Inc. (http://www.oramed.com/) is an emerging firm in the diabetes sector based in Givat Ram, Israel.

Oramed Pharmaceuticals, Inc.

Rating: Buy

Optimizing Oral Diabetes Therapy

Investment Highlights:

- **Initiating Coverage.** We are initiating coverage of Oramed Pharmaceuticals, Inc., with a Buy rating and a 12-month price target of $25.00 per share. Oramed is an emerging biopharmaceuticals firm in the diabetes sector, and has developed two proprietary drug candidates, both of which are risk-mitigated from a mechanistic perspective, in our view. Oramed's lead candidate, ORMD-0801, is an orally-ingestible capsule formulation of human insulin. The second candidate, ORMD-0901, is an orally-bioavailable formulation of exenatide, currently sold under the trade name Byetta by AstraZeneca (AZN/NYSE, Not Rated) and Bristol-Myers Squibb (BMY/ NYSE, Not Rated). In our view, Oramed represents an attractively valued entity in the diabetes sector and possesses the added advantage of 505(b)(2) pathway eligibility for both of its lead drug candidates. The firm also has a proprietary technology platform for enhancing the oral bioavailability of peptide- and protein-based drugs.
- **Considerable Market Potential.** Since 1921, insulin has been a mainstay of diabetes therapy. This hormone represents the focal point of diabetes as a disease, since it is the fulcrum via which the human body controls glucose absorption and metabolism. Total sales of all insulin products are estimated to exceed $8bn annually. Oramed's second drug candidate is a member of the so-called glucagon-like peptide 1 (GLP-1) agonist therapeutic sub-class. Byetta and its longer-acting cousin, Bydureon, are the most well-known members of this class. In 2012, Byetta and Bydureon together generated over $500mm in total sales. The total sales of all GLP-1 agonist drugs is estimated to be approaching $2bn annually.
- **Significant Value Drivers Ahead.** In the near-term, we expect Oramed to release data from a Phase 2a trial of ORMD-0801 in type 2 diabetic patients. This trial should pave the way for a Phase 2b trial in this patient population. Positive Phase 2b data could set the scene for a transformative licensing transaction or an acquisition of Oramed by an established diabetes market participant such as AstraZeneca, Novartis (NVS/NYSE, Not Rated), Novo Nordisk (NVO/NYSE, Not Rated), or Sanofi S.A. (SNY/NYSE, Not Rated).
- **Attractive Valuation.** Oramed trades at a ~$60mm enterprise value. In our view, with positive Phase 2a data in hand and a Phase 2b trial under way, Oramed could trade at an enterprise value of approximately $300mm in 12 months' time. The firm has a highly differentiated technology platform and is pursuing risk-mitigated drug development in a cost-effective manner. To date, since inception in 2006, Oramed has accumulated a total deficit of only ~$40mm, showing how cost-consciously it conducts operations.

The Disclosure section may be found on pages 53 - 55 of this report.

Investment Thesis

Oramed Pharmaceuticals, Inc. is an emerging biotechnology firm developing novel therapeutic approaches for diabetes. The firm's lead candidate, ORMD-0801, is an orally-ingestible capsule-based formulation of insulin – a naturally-occurring hormone that lies at the root of the pathology in diabetes. A peptide hormone, insulin is produced primarily in the pancreas and plays a central role in the regulation of carbohydrate and lipid metabolism. Insulin signaling governs the absorption of glucose from the bloodstream by cells in the liver, skeletal muscles and adipose tissue of the body. There are two principal forms of diabetes mellitus – type 1 diabetes, which involves a failure by the body to produce insulin due principally to autoimmune destruction of the beta cells in the pancreas; and type 2 diabetes, which involves resistance to insulin by various cells in the body of the patient. The net result is effectively the same – inefficient glucose control and an inability to perform metabolic processes properly. Although insulin can be produced recombinantly and administered via injection to patients who are insulin-deficient, the repeated injections are problematic and can cause issues with compliance. Accordingly, therefore, many companies have attempted to develop orally-bioavailable forms of insulin. However, thus far none have been particularly successful. In our view, the Oramed solution could permit the introduction of the first truly effective orally-bioavailable insulin preparation. The approach is relatively low-risk from a clinical development perspective, in our view, because insulin's effectiveness and mechanism of action in diabetes patients is well-known and extensively characterized. Thus, the clinical program for ORMD-0801 should yield positive data, since Oramed's oral formulation has shown favorable pharmacokinetics. The firm is also developing an orally-bioavailable glucagon-like peptide 1 (GLP-1) receptor agonist, designated ORMD-0901. GLP-1 agonists are among the world's fastest-growing prescription diabetes drugs. Like insulin preparations, the GLP-1 agonist drugs currently on the market are principally administered via injection. Accordingly, we believe that Oramed could have a similar value proposition in this market. The firm's proprietary oral formulations are covered by U.S.-issued patents that initially expire in 2026 – 2029 without term extensions.

We are initiating coverage on ORMP with a Buy rating and a 12-month price target of $25.00 per share, implying a total firm value of ~$315mm, assuming ~12mm shares outstanding (fully-diluted) at end-2014. An investment in ORMP may involve above-average risk and volatility, since the firm is still an emerging entity.

Investment Positives

Risk-Mitigated Drug Profile. Insulin, in our view, is a tried-and-tested diabetes therapy. The hormone has been administered as a drug – whether in naturally-occurring, purified form or as a recombinantly-produced agent – for several decades. In our view, Oramed could move ORMD-0801 through proof-of-concept Phase 2 development within the next 12 – 15 months and subsequently ink a significant transformative commercialization partnership with an established company in the diabetes domain.

Multiple Near-Term Value Drivers. Oramed is slated to report data from a Phase 2a trial of ORMD-0801 in the coming days; the firm could also move ORMD-0801 into a larger Phase 2 trial and advance ORMD-0901 as a single agent as well as ORMD-0801 and ORMD-0901 as a combination therapy into earlier-stage trials in 2014.

Significant Valuation Discrepancy. We would draw investors' attention to the fact that Oramed shares currently trade at an enterprise value of roughly $60 million, far below the $1.8 billion valuation for MannKind Corporation – which has only an inhalable version of insulin. While Oramed is admittedly significantly earlier-stage, we believe that over time its valuation could approach that of MannKind, especially if clinical development data continue to demonstrate positive efficacy and safety.

Investment Risks

Financial Outlook and History of Unprofitable Operations. Oramed Pharmaceuticals has incurred operating losses since its inception and, in our view, may not achieve sustainable profitability for several years. Although the firm has been able to obtain capital in order to fund its operations, it is not known whether the company will be able to continue this practice, or be able to obtain other types of financing to meet operating needs. While the company recently managed to successfully raise $4.6 million through a registered direct public offering to support the advancement of its lead pipeline drug candidate in the U.S., which in our view provides an operational window for at least the next six to nine months, we believe that any additional broadening of the clinical-stage pipeline could require additional capital. Given these factors, shares of Oramed Pharmaceuticals may constitute above-average risk and volatility, in our opinion.

FDA Unpredictability. Drug development is a multi-year process that requires human clinical trials prior to market entry. The agency may require more clinical data from Oramed Pharmaceuticals prior to granting approval for any of its regulatory applications, necessitating further trials. Review times at the FDA may prove longer than expected. Also, the agency could elect not to accept Oramed's – or its partner's – regulatory filings petitioning for approval of ORMD-0801 and ORMD-0901. If clinical data and/or other supporting evidence are not accepted or considered insufficient grounds for approval, marketing authorization for Oramed's lead products could be delayed or might not occur at all, preventing the firm from realizing the commercial potential of these agents.

Partnership Risk. Oramed has embarked upon a development path that involves focusing on clinical advancement of its lead drug candidates in diabetes, while eschewing an emphasis on building commercial infrastructure and becoming a fully-integrated company. The firm aims to optimize the commercialization of its lead program by either partnering this agent with an established firm in the healthcare sector – preferably one with an established presence in diabetes – or by attracting acquisition interest from such a company. This introduces several elements of risk from a partnering / trade sale perspective – the possibility that the company's partnership deals may not involve terms that are lucrative enough to justify the investment that Oramed has made in the development of its lead drug candidates; the possibility that Oramed's partners do not invest sufficiently in the commercialization of Oramed's products; and the risk that the firm's partners may not be the best-positioned competitively to ensure maximal penetration of Oramed's drugs into their target markets. Furthermore, should Oramed fail to attract a partner at all, the firm would have to raise substantial additional capital to fund the establishment of a sales force. Such infrastructure may not be capable of supporting the successful launch of ORMD-0801 or ORMD-0901.

Insufficient Diversification Risk. While we view Oramed as a risk-mitigated investment opportunity because of the fact that both insulin and GLP-1 receptor agonists have been approved and prescribed for diabetes over many years, we note that the firm does not have a clinical pipeline beyond ORMD-0801 and ORMD-0901 and is heavily concentrated within the diabetes space, which is a highly competitive area replete with a large number of entrenched competitors. Accordingly, therefore, if the firm's lead drugs fail to demonstrate statistically significant efficacy and acceptable safety and tolerability in proof-of-concept trials, Oramed may find itself without strategic options.

Competitive Landscape. Oramed is aiming to compete with other companies within the drug industry, many of which have more capital, more extensive research and development capabilities, and greater human resources. Some of these competitors include AstraZeneca, Bristol-Myers Squibb, Eli Lilly & Co., GlaxoSmithKline, Novo Nordisk and Sanofi S.A. These companies all have drugs already on the market for

various forms of diabetes and many of their franchises are well-entrenched. In addition, these competitors may develop new or enhanced products or processes that may be more effective, less expensive, safer or more readily available than any products or processes that Oramed may be capable of developing. Finally, there are several generic versions of injectable insulin already on the market, with more potentially being launched in the coming years, which may make it difficult for Oramed and / or its partners to establish a niche for ORMD-0801.

Geopolitical Risk. Oramed's operations are presently located in the State of Israel, which has since its establishment in 1948 been subject to significant hostility from its predominantly Arab neighbors. Various geopolitical factors, including – but not limited to – civil unrest, terrorist actions, military aggression by the armed forces of Israel's neighbors, and / or the deployment of nuclear weapons by regimes hostile to the State of Israel could all have a material impact on Oramed's operational integrity and the firm's ability to execute on its strategic plan.

Intellectual Property Risk. The company relies on patents and trade secrets to protect its products from competition. A court might not uphold Oramed's intellectual property rights, or it could find that Oramed infringed upon another party's property rights. In addition, generics firms could potentially find loopholes in Oramed's intellectual property estate, which may enable them to launch generic versions of ORMD-0801 and/or ORMD-0901, in addition to other drugs that Oramed could develop in the future, prior to the expiration of patent protection.

Reimbursement Risk. Following the institution of broad-based healthcare reform policy, reimbursement agencies have grown more wary of systematically reimbursing for drugs that are either unnecessary or provide marginal benefit at excessive cost. If Medicare spending growth continues to outpace GDP growth, and the government's ability to fund healthcare becomes impaired, changes could be made to reimbursement policy that would negatively affect Oramed, despite what we believe to be the compelling value proposition inherent in both ORMD-0801 and ORMD-0901.

Additional Risks. Oramed ended its most recently-reported quarter (4Q FY2013) with about $7.5 million in cash and equivalents. While the firm is not projected to burn a significant amount of cash near-term, the current cash balance is only likely to sustain operations through the next two or three quarters. Other sources of cash could include: licensing fees from partnerships, warrant and option exercises, or the issuance of more shares. If ORMD-0801 fails to demonstrate efficacy and safety in proof-of-concept development, Oramed may not be able to raise cash at all.

Industry Risks. Emerging biotechnology and pharmaceuticals stocks are inherently volatile and increasingly subject to development and regulatory risk. Meeting or missing commercialization milestones may result in a significant change in the perception of the company and the stock price. We do not anticipate volatility subsiding in the near term.

For additional risk considerations, please refer to the company's SEC filings.

Valuation

Comparables Analysis: Given that Oramed Pharmaceuticals is currently unprofitable and considering our belief that sustainable profitability is unlikely near-term, we use a discounted cash flow-based approach to value the shares. Based on a comparables analysis, it appears the stock is worth $25.00 per share, utilizing our estimate of a ~$300 million risk-adjusted net present value (rNPV) for ORMD-0801 and ORMD-0901 in diabetes. This assumes that the shares trade in-line with the comps' present average enterprise value of ~$290 million and that the firm has ~12 million shares outstanding (fully-diluted) and roughly $15 million in cash as of the end of fiscal 2014.

Table 1: Comparable Company Analysis
(Millions, Except Per-Share Data)

Development	Therapeutic Area	Company	Ticker	Rating	Closing price 12/2/2013	Shares (MM)	Market cap ($MM)	Cash ($MM)	Debt ($MM)	Enterprise value ($MM)
Preclinical	Oncology	Agios Pharmaceuticals	AGIO	Not Rated	$17.28	31	539	195	0	344
Phase 2	CNS / Neuropsychiatry	Alcobra Ltd.	ADHD	Buy	$17.05	11	190	47	0	143
Phase 1	Metabolic Disorders	Biodel	BIOD	Not Rated	$2.22	19	42	42	0	0
Phase 2	Various	BioLineRx	BLRX	Buy	$2.63	24	62	19	0	43
Phase 1	Various	Compugen Ltd.	CGEN	Not Rated	$10.27	39	402	48	0	354
Marketed	Metabolic Disorders	Furiex Pharmaceuticals	FURX	Not Rated	$44.39	10	460	35	57	483
Phase 1	Fibrotic Disorders	Galectin Therapeutics	GALT	Buy	$7.94	18	145	10	0	136
Phase 2	Infectious Diseases	Idenix Pharmaceuticals	IDIX	Not Rated	$5.40	134	724	149	0	575
Phase 2	Oncology	Infinity Pharmaceuticals	INFI	Not Rated	$14.44	48	694	250	0	444
Phase 2	Stem Cells	Neostem	NBS	Buy	$6.32	26	164	55	4	113
Phase 2	Oncology	OncoMed Pharmaceuticals	OMED	Not Rated	$14.00	28	391	129	0	262
Phase 3	Metabolic Disorders	Orexigen Therapeutics	OREX	Not Rated	$6.18	101	626	83	0	544
		Average					**355**			**289**
								Discrepancy		
Current valuation	**Metabolic Disorders**	**Oramed Pharmaceuticals**	**ORMP**	**Buy**	**$7.82**	**8**	**62**	**4**	**0**	**58**
			Derived 12-month comparable value							**Projected**
Target valuation (12-month)	**Metabolic Disorders**	**Oramed Pharmaceuticals**	**ORMP**	**Buy**	**$25.00**	**12**	**307**	**15**	**0**	**289**

Source: First Call and Aegis Capital Corp. estimates

Free Cash Flow: We estimate that Oramed Pharmaceuticals is likely to be free cash flow negative for the foreseeable future. We define free cash flow as operating cash flow minus capital expenditures and dividend payments. We utilize a discounted cash flow analysis supporting a risk-adjusted Net Present Value (rNPV) framework to derive our $25.00 price target. This approach is described further in the next section of the report.

Our detailed analysis is split into five main components – our discounted cash flow model based on the rNPV for ORMD-0801 (presented overleaf); our assessment of the market for this agent and the associated sales model for the drug; the risk-adjusted value of ORMD-0901; and the near-term financial outlook for the firm. Our historical income statement and financial projections are presented at the back of this report.

Risk-Adjusted Net Present Value Analysis

We have projected the total firm value for Oramed based on a sum-of-the-parts valuation of the firm's two lead candidates in diabetes, calculated using a risk-adjusted Net Present Value (NPV) approach; the rNPV of the firm's technology platform focusing on the formulation of peptide drugs for oral administration; and the projected cash position as of end-2014. Peak annual global sales for the firm's lead candidate, ORMD-0801, are projected to be ~$2.1 billion in aggregate. Those of ORMD-0901 are projected to be $2.8 billion. These yield a total risk-adjusted NPV of $300 million (see Table 2 below), factoring in a 35% tax rate, 8% – 12.5% royalty from a partner and a 20% discount rate. We are not ascribing any value to Oramed's spun-out foray into osteoporosis, Entera Bio.

Table 2: Composite Risk-Adjusted Net Present Value Analysis

ORMD-0801 - Global	
Total diabetes patients[1]	60MM
Patients seeking treatment[2]	12.5MM
Peak market share[3]	8%
Treatment revenue/prescription/course of therapy[4]	$1,500
Peak sales[5]	$2.1B
Launch[6]	2021
Peak sales year	2026
Protection expires[7]	2030
Discount rate	20%
Probability of success[8]	60%
Risk-adjusted NPV[9]	$175MM
NPV per share	$14.00
Estimated Net Cash Position ($MM; end-2014)	$15MM
Additional Value Drivers (ORMD-0901, combination regimen)	100MM
Total enterprise value	$300MM
Shares Outstanding (MM; end-2014)	12MM
Present value-derived price target	$25.00

Notes on assumptions:

[1] Type 2 diabetes mellitus patients - worldwide (only includes U.S. and European Union)
(Source: National Institute of Health, American Diabetes Association)

[2] Patients with type 2 diabetes seeking therapy
(Source: Aegis Capital Corp. estimates)

[3] Peak market share - blended; factoring in competition from injected insulins, other oral insulins, incretin mimetics and other drugs

[4] Revenue/year/prescription - estimated to be higher than injected intermediate insulin (wholesale acquisition cost)

[5] Peak sales - treatment revenue/year x treated patients x peak market share

[6] Launch in 2021 (US) / 2022 (EU)

[7] Patent expiry starting in 2026 - 2030; Hatch-Waxman extensions may provide up to an additional five years of protection

[8] Probability of success - ORMD-0801 is in Phase 2 testing (oral insulin formulation, known to be an effective diabetes therapeutic)

[9] Cash flow fully taxed at 35% following launch; upfront payments and milestones cancel out operating loss carry-forwards

Source: Company reports; Aegis Capital Corp. estimates

If successful in proof-of-concept testing, we believe that Oramed could be acquired by a larger firm either prior to ORMD-0801 entry into pivotal testing or shortly thereafter. Several precedent transactions in the diabetes space could be comps to what Oramed could command in a takeout if ORMD-0801 succeeds in Phase 2 trials, and could prove conservative if both ORMD-0801 and ORMD-0901 are successful. These transactions include the $7 billion acquisition of Amylin in June 2012 by AstraZeneca and Bristol-Myers Squibb, and the licensing of ZP2929, an oxyntomodulin derivative, from Zealand Pharma A/S by Boehringer Ingelheim for up to €376 million in milestones plus royalties (including €41 million during the first two years of the collaboration agreement).

The diabetes market is highly competitive. Several well-established pharmaceutical firms – e.g., AstraZeneca / Bristol-Myers Squibb, Novo Nordisk, and Sanofi S.A. – have large diabetes franchises. Various injectable insulins are available. Some of these are long-acting, which may make them resistant to competition from an orally-bioavailable but shorter-acting drug. Insulin is available worldwide under different trade names.

Company Overview

Oramed Pharmaceuticals was originally founded in 2006, based on a proprietary technology platform derived from the work of Dr. Miriam Kidron, the company's chief scientist. In 2007, the company conducted several clinical studies of an orally-ingestible insulin capsule formulation, in order to assess both the safety/tolerability and absorption properties of what eventually became known as ORMD-0801. Based on the pharmacokinetic and pharmacologic outcomes of these trials, the firm decided to advance ORMD-0801 in clinical development. Subsequently, the company also developed an orally-ingestible capsule formulation of exenatide, a well-characterized glucagon-like peptide 1 (GLP-1) receptor agonist, designated as ORMD-0901. This candidate has also been advanced into clinical testing and is being developed both as a single agent as well as a combination therapy with ORMD-0801. The firm's pipeline is shown below.

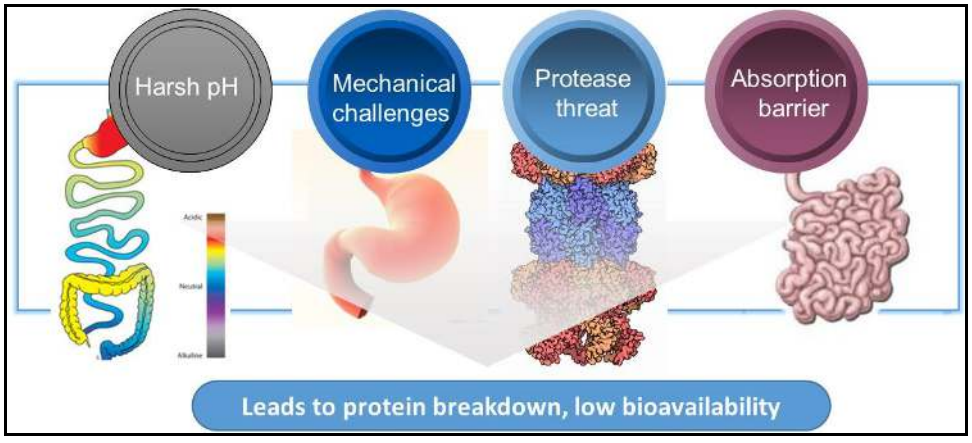
Figure 1: Oramed Pharmaceuticals Development Pipeline

Therapy	Indication	Preclinical	Phase 1	Phase 2 (ex-US)	Phase 2 (FDA)	Timeline
ORMD – 0801 Oral Insulin	T2DM					Q3, '13: Phase 2a intiated Q2, '14: Phase 2b multi-center study projected initiation
	T1DM					Q3 '13: Initiated ex-US single-center trial patient recruitment Q2, '14: Phase 2 (ex-US) multi-center trial projected initiation
ORMD-0901 Oral Exenatide	T2DM					Q1 '13: Phase 1 / 2 (ex-US) study initiated Q3 '13: Pre-IND package submitted to FDA
Combination Therapy	T2DM					Q1, '13: First-in-human PoC trial initiated

Source: Oramed Pharmaceuticals, Inc.

The firm has been working in parallel on both ORMD-0801 and ORMD-0901 for the past several years. The figure below shows how proteins are typically broken down in the gastrointestinal tract, preventing them from being efficiently delivered in oral form. The Oramed platform is designed to protect proteins from these degradation pathways, thereby enabling therapeutics such as insulin and exenatide to be formulated in capsules for oral delivery. While oral delivery of biologic agents such as insulin has long been under investigation, historically results have been poor. In our view, Oramed could become a leader in the development and commercialization of an oral insulin product.

Figure 2: Gastrointestinal Tract Protein Degradation Mechanisms



Source: Oramed Pharmaceuticals, Inc.

ORMD-0801 (oral insulin capsules) – Development History

In November 2007, the company successfully completed animal studies in preparation for the Phase 1b clinical trial of ORMD-0801. In January 2008, Oramed commenced non-FDA-sanctioned Phase 1b clinical trials with its oral insulin capsule, in healthy human volunteers with the intent of dose optimization. In March 2008, the firm successfully completed these Phase 1b clinical trials. Subsequently, during the following month, Oramed commenced a non-FDA-sanctioned Phase 2a study to evaluate the safety and efficacy of its oral insulin capsule in Type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem, Israel. In August 2008, the firm announced positive results from this trial. In July 2008, Oramed was given the green light by the Institutional Review Board Committee of Hadassah Medical Center to conduct a non-FDA-sanctioned Phase 2a study to evaluate the safety and efficacy of the oral insulin capsule on Type 1 diabetic volunteers. In September 2008, Oramed formally initiated this trial. In July 2009, the firm reported positive results from this study, indicating that ORMD-0801 could be deployed effectively as a therapy for both Type 1 as well as Type 2 forms of diabetes.

In April 2009, Oramed began a consulting service agreement with ADRES Advanced Regulatory Services Ltd. (ADRES), which was amended in February 2012, pursuant to which ADRES would provide services for the purpose of filing an Investigational New Drug (IND) application with the FDA to conduct a Phase 2 proof-of-concept study with ORMD-0801 according to agency requirements. The approval process and – if approved – registration for commercial use as an oral drug is expected to take several years. Oramed began a non-FDA-sanctioned Phase 2b study in South Africa in May 2009 to evaluate the safety, tolerability and efficacy of the oral insulin capsule on Type 2 diabetic volunteers. In May 2010, the firm reported that the capsule was found to be well-tolerated and exhibited a positive safety profile. No cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

In September 2010, the firm reported positive results from an exploratory clinical trial testing the effectiveness of its oral insulin capsule in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This completed exploratory study was a proof of concept study for defining a novel indication for ORMD-0801. We believe the encouraging results justify further development of the ORMD-0801 capsule in uncontrolled diabetes.

In February 2010, Oramed contracted with Vetgenerics Research G. Ziv Ltd., a clinical research organization, to conduct a toxicology trial on the firm's oral insulin capsules. In March 2011, the company reported the successful completion of the resulting comprehensive toxicity study for ORMD-0801. This study was completed under conditions prescribed by the FDA's Good Laboratory Practices (GLP) regulations.

Oramed inked a Master Services Agreement with Medpace, Inc. in September 2012 to retain Medpace as the contract research organization (CRO) for Oramed's upcoming Phase 2 clinical trial for ORMD-0801. This trial, the first proof-of-concept study to be conducted under FDA sanction for ORMD-0801, was originally expected to start in early 2013 in the U.S., and was expected to be completed in December 2013.

In March 2013, however, due to a request from the FDA, work on beginning this Phase 2 study was temporarily halted. Effectively, Oramed filed its Investigational New Drug (IND) application with the FDA on ORMD-0801 in December 2012, with the aim of securing permission to begin the Phase 2 clinical trial of ORMD-0801 in order to evaluate the safety, tolerability and efficacy of the candidate on patients with Type 2 diabetes. However, the FDA requested that a Phase 2a sub study be completed before

Oramed could be allowed to proceed with the originally-envisaged Phase 2b trial. The Phase 2a sub study, which is an in-patient study with 30 individuals that began in July 2013, is expected to be completed in late 2013. Currently, therefore, contingent upon favorable data from the Phase 2a sub study, Oramed now expects to begin the Phase 2b clinical trial in the third quarter of calendar 2014.

ORMD-0801 is manufactured by Encap Drug Delivery. In May 2010, Oramed inked an agreement with SAFC Pharma (SAFC) in order to develop a process to produce one of Oramed's oral capsule ingredients and in June 2011, Oramed issued a purchase order to SAFC for producing the ingredient. In July 2010, Oramed established a Manufacturing and Supply Agreement (MSA) with Sanofi-Aventis Deutschland GmbH (Sanofi-Aventis, now known as Sanofi S.A.) According to the MSA, Sanofi is supplying Oramed with specified quantities of recombinant human insulin to be formulated with Oramed's proprietary encapsulation technology and used for clinical trials in the U.S.

ORMD-0901 (oral exenatide capsules) – Development History

In September 2008, Oramed initiated the preclinical testing of ORMD-0901, an orally-bioavailable formulation of a known analog of GLP-1, a gastrointestinal hormone. The pre-clinical trials include animal studies which suggest that the GLP-1 analog (exenatide, derived from the exendin-4 molecule derived from the saliva of the Gila monster – a form of poisonous lizard), when combined with Oramed's absorption promoters, is absorbed through the gastrointestinal tract and retains its biological activity.

Glucagon-like peptide-1 (GLP-1) is an incretin hormone - a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. The incretin concept was hypothesized when it was noted that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. In addition to stimulating insulin release, GLP-1 was found to suppress glucagon (a hormone involved in regulation of glucose) release from the pancreas, slow gastric emptying to reduce the rate of absorption of nutrients into the blood stream, and increase satiety. Other important beneficial attributes of GLP-1 are its effects of increasing the number of beta cells (cells that manufacture and release insulin) in the pancreas and, possibly, protection of the heart.

In September 2009, Oramed received approval from its Institutional Review Board to commence human clinical trials of ORMD-0901, its oral GLP-1 analog, after successful preclinical results were reported. The trials are being conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem. The first study monitored the responses of healthy males to a single dose delivered 60 minutes before a glucose load and was completed in December 2009. ORMD-0901 was well tolerated by all subjects and demonstrated physiological activity, as extrapolated from ensuing subject insulin levels when compared to those observed after treatment with placebo.

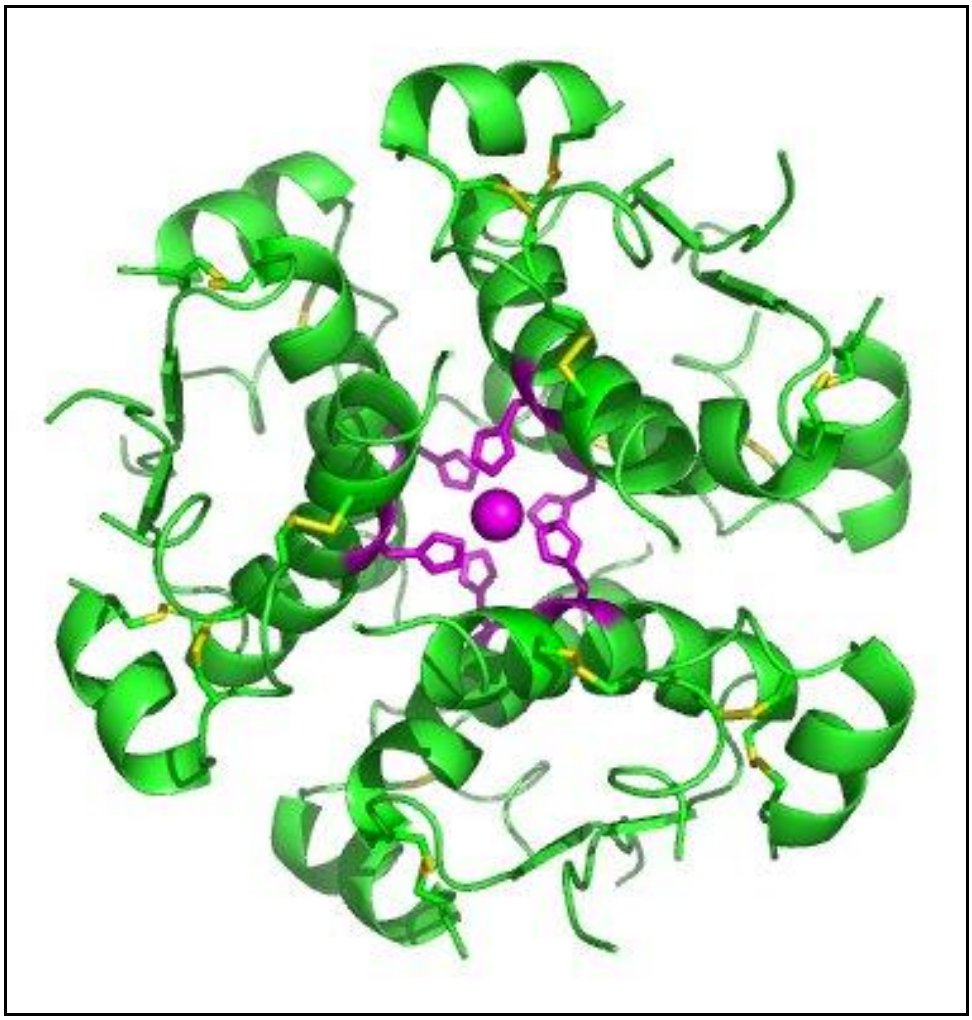
In June 2012, Oramed presented an abstract that described the impact of the firm's oral insulin capsule formulation, ORMD-0801, when delivered in combination with its oral exenatide capsule formulation, ORMD-0901. The work that was presented assessed the safety and effectiveness of a combination of oral insulin and oral exenatide treatments delivered to pigs prior to food intake. The drug combination resulted in significantly improved blood glucose regulation vs. administration of each drug separately.

In January 2013, Oramed began a clinical trial for its oral exenatide capsule on healthy volunteers and type 2 diabetic patients. In February 2013, the firm commenced an initial human clinical trial in Type 2 diabetic patients with its oral insulin capsule delivered in combination with its oral exenatide capsule.

Oramed Oral Formulation Platform Overview

Oramed's lead drug candidate is a proprietary, orally-ingestible capsule formulation of insulin. The structure of insulin (herein depicted as a hexamer, with the pink structures representing the histidine residues involved in binding zinc) is depicted below.

Figure 3: Insulin Structure



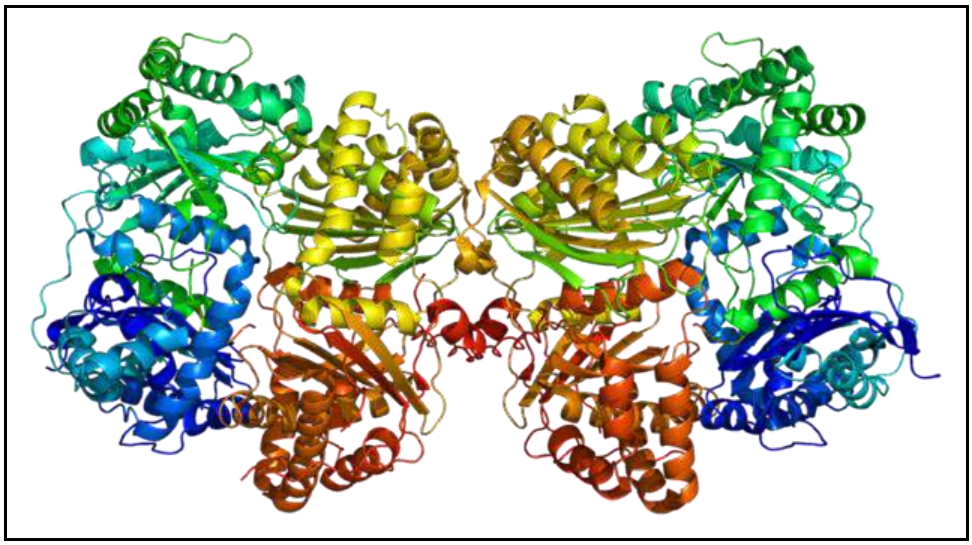
Source: Brookhaven Protein Data Bank

Insulin is susceptible to protease degradation in the gastrointestinal tract, preventing its native form from being rendered orally-bioavailable for human therapeutic use. Several proteases attack the insulin molecule, but the most well-known insulin-specific protease is known alternatively as insulysin or insulinase, but chiefly as Insulin Degrading Enzyme (IDE), a large zinc-binding protease of the M16A metalloprotease sub-family. This enzyme is known to cleave multiple short polypeptides of varying lengths.

IDE was first identified by its ability to degrade the B chain of the hormone insulin. This activity was observed over 50 years ago, though the enzyme specifically responsible for B chain cleavage was identified more recently. This discovery revealed considerable amino acid sequence similarity between IDE and the previously characterized bacterial protease pitrilysin, suggesting a common proteolytic mechanism. IDE knockout mice exhibit a diabetic phenotype, an emergent condition that arises as a response to

hyperinsulinemia in the tissues. In addition, inhibitors of IDE administered in preclinical models have been shown to reduce the degradation of insulin that is given simultaneously via injection, demonstrating the central role that IDE plays in the catabolism of insulin.

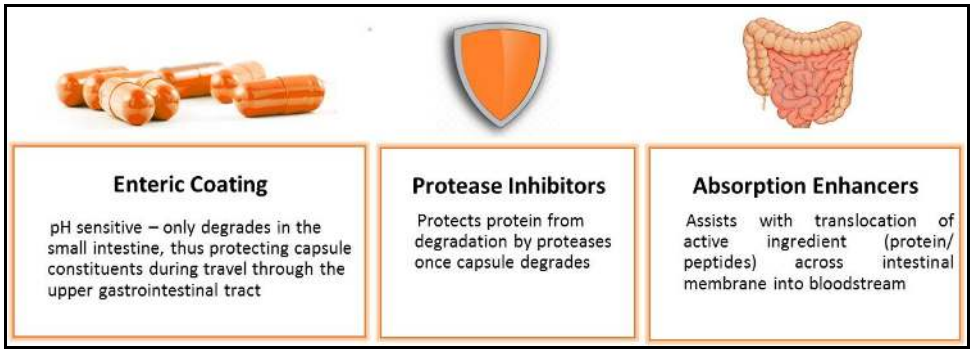
Figure 4: IDE Molecular Structure



Source: Brookhaven Protein Data Bank

As shown below, Oramed has developed a multifaceted approach to the protection of the insulin molecule, which involves a proprietary capsule formulation that utilizes enteric coating to maintain the peptide in a pH-stabilized microenvironment; protease inhibitors to shield the drug from degradation by IDE and other proteases; and absorption enhancers that permit the drug to penetrate the intestinal mucosa and enter the bloodstream.

Figure 5: Receptor Pathway Regulation



Source: Oramed Pharmaceuticals, Inc.

The Oramed platform possesses several advantages – there is no modification of the actual active pharmaceutical ingredient, thereby bypassing the requirement for extensive animal toxicology studies; the substances used in the orally-ingestible formulations are all off-the-shelf and cost-effectively obtainable; and the approach is versatile and adaptable to different dosing regimens and dosage levels, as well as the types of proteins that can be utilized. We note that, thus far, Oramed itself has focused on two peptide drugs that have applicability in diabetes – namely, insulin (a 51-amino acid peptide hormone) and exenatide (derived from exendin-4, a 37-amino acid peptide). However, the company has also demonstrated the validity of its technology platform in the creation of an orally-bioavailable version of parathyroid hormone (PTH) for the treatment of osteoporosis, which is being developed by a spin-off from Oramed called Entera Bio.

Diabetes Mellitus Overview

Diabetes mellitus refers to a group of metabolic diseases in which a person has high blood sugar, either because the pancreas does not produce enough insulin, or because cells do not respond to the insulin produced endogenously (insulin resistance). This high blood sugar produces the classical symptoms of polyuria (frequent urination), polydipsia (increased thirst), and polyphagia (increased hunger). There are three main types of diabetes mellitus (DM).

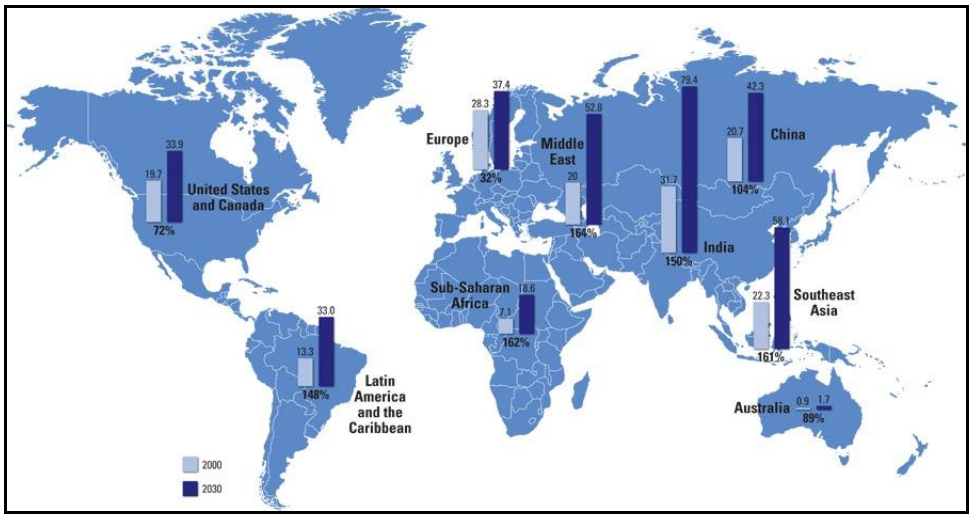
- Type 1 DM (T1DM) results from failure to produce insulin, and currently requires the sufferer to inject insulin or wear an insulin pump. This form was previously known as "insulin-dependent diabetes mellitus" (IDDM) or "juvenile diabetes".
- Type 2 DM (T2DM) involves insulin resistance, in which cells fail to use insulin properly, sometimes with absolute insulin deficiency. This was previously known as non-insulin-dependent diabetes mellitus (NIDDM) or "adult-onset diabetes".
- The third main form, gestational diabetes, occurs when pregnant women without prior diabetes history develop high blood glucose. It may precede T2DM.

Other forms of diabetes mellitus include congenital diabetes, which is due to genetic defects of insulin secretion, cystic fibrosis-related diabetes, steroid diabetes, which is induced by high doses of glucocorticoids, and several forms of monogenic diabetes.

Epidemiology

As shown below, the global incidence of diabetes is on the rise, particularly with respect to Type 2 diabetes. Various lifestyle factors are typically considered to be the cause of this global "epidemic", with a reliance on a high-carbohydrate, high-fat diet the main culprit. As developing countries become more exposed to diets rich in refined foods – particularly refined sugar – the incidence of diabetes in those regions tends to rise.

Figure 6: Global Diabetes Prevalence (2000 – 2030E)



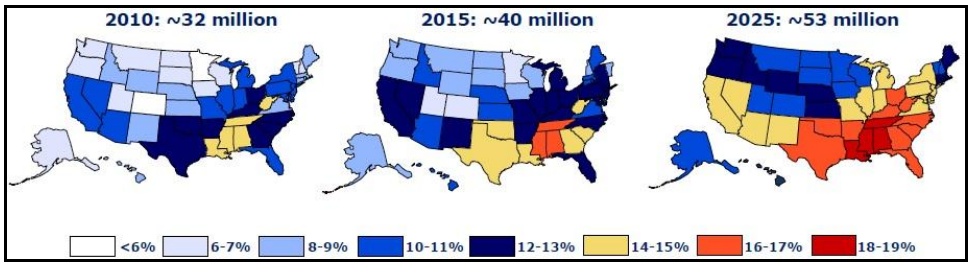
Source: New England Journal of Medicine

While the emergence of type 1 diabetes appears to require an environmental trigger and is known to have a genetic component, the development of type 2 diabetes is due primarily to lifestyle factors and genetics. A number of lifestyle factors are known to be important to the development of type 2 diabetes, including obesity – defined by a body mass index (BMI) >30 – lack of physical activity, poor diet, stress, and urbanization. Excess body

fat is associated with 30% of cases in those of Chinese and Japanese descent, 60% – 80% of cases in those of European and African descent, and 100% of Pima Indians and Pacific Islanders. Those who are not obese often have a high waist–hip ratio.

Dietary factors also influence the risk of developing type 2 diabetic disease. Consumption of sugar-sweetened drinks in excess is associated with increased risk. The type of fats in the diet is also important, with saturated fats and trans fatty acids increasing the risk and polyunsaturated and monounsaturated fat decreasing the risk. Eating large amounts of white rice appears to also play a role in increasing risk. A lack of exercise is believed to cause roughly 7% of cases. As shown below, the prevalence of diabetes across the U.S. is rapidly increasing, and was projected to increase by roughly 40% between 2010 and 2025. Most of the cases are projected to occur in the so-called "Stroke Belt" – parts of the southeastern and southwestern U.S., including states such as Alabama, Kentucky, Louisiana, Mississippi, Missouri, and Texas, which are associated with high-fat diets, lower standard-of-living conditions, and sedentary habits.

Figure 7: U.S. Diabetes Prevalence (2010 – 2025E)



Source: American Diabetes Association (ADA)

Symptomatology

As mentioned above, there are three cardinal symptoms of diabetes – polyuria (frequent urination), polydipsia (increased thirst), and polyphagia (increased hunger). Individuals with hyperglycemia can gain weight rapidly, and diabetics may lose weight dramatically upon first exposure to exogenous insulin. Diabetes is a case of metabolic dysfunction. Acute symptoms include diabetic ketoacidosis and non-ketotic hyperosmolar coma. Serious long-term complications include cardiovascular disease, chronic renal failure, and diabetic retinopathy (retinal damage). Diabetics can develop serious consequences of poor vascular health, including painful diabetic neuropathy (PDN) and diabetic foot ulcers, which in some cases can be so severe as to necessitate amputation of extremities.

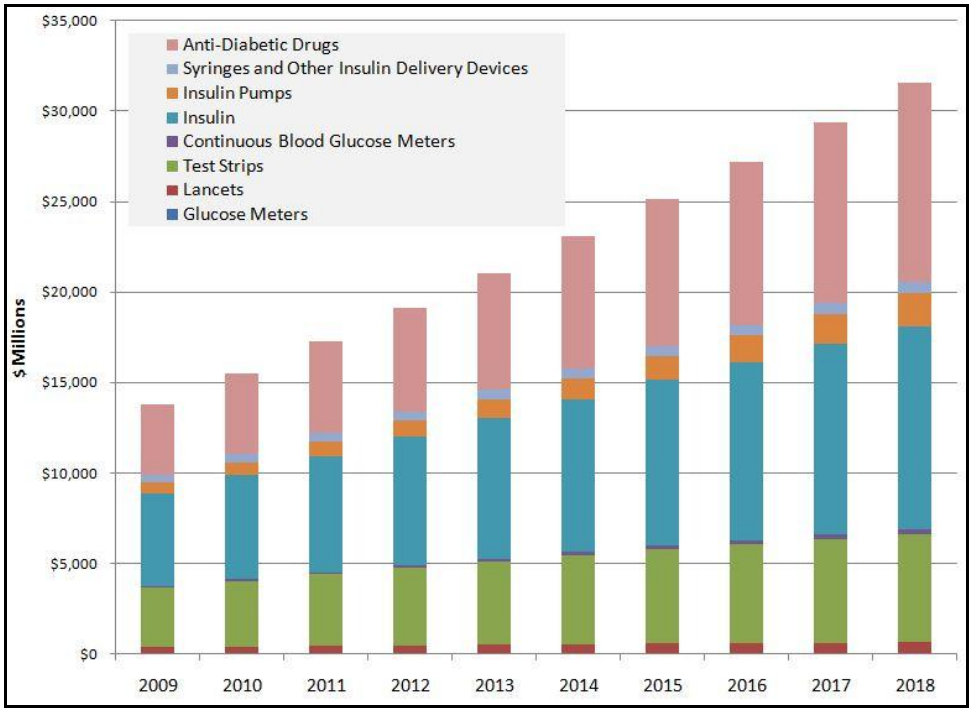
Insulin is the principal hormone that regulates uptake of glucose from the blood into most cells (primarily muscle and fat, but not the CNS). Therefore, insulin deficiency or insulin receptor insensitivity plays a central role in all forms of diabetes. Humans are capable of digesting some carbohydrates; starch and disaccharides like sucrose are converted within a few hours to simpler forms – mainly monosaccharide glucose, the principal carbohydrate energy source for the body. The rest are passed on for processing by gut flora largely in the colon. Insulin is released into the blood by beta cells (β-cells), found in the islets of Langerhans in the pancreas, in response to rising levels of blood glucose.

Type 1 diabetes mellitus is characterized by loss of the insulin-producing beta cells, leading to insulin deficiency. The beta cells are typically lost due to an autoimmune attack by T cells. T1DM causes ~10% of diabetes cases in North America and Europe. Sensitivity and responsiveness to insulin are usually normal, especially in the early stages. While this form of the disease can affect adults or children, it was originally termed juvenile diabetes because the majority of cases were pediatric.

The most common form of diabetes, T2DM is characterized by insulin resistance, which may be combined with reduced insulin secretion. Defective responsiveness of body tissues to insulin is believed to involve the insulin receptor. However, the specific defects are not known. In the early stages of type 2 diabetes, the predominant abnormality is reduced insulin sensitivity. At this stage, hyperglycemia can be reversed by improving insulin sensitivity or reduce glucose production by the liver.

Diabetes diagnosis and therapy constitutes a massive market, slated to exceed $30 billion annually within the next five years (see bar chart below). As the onset of diabetes increases worldwide, these estimates may indeed prove conservative.

Figure 8: Overall Worldwide Diabetes Market (2009 – 2018E)



Source: Datamonitor

Diagnosis

Diabetes mellitus is characterized by recurrent or persistent hyperglycemia, and is diagnosed by demonstrating any one of the following:

- Fasting plasma glucose level ≥7.0mmol/l (126mg/dl)
- Plasma glucose ≥11. mmol/l (200mg/dL) two hours after a 75g oral glucose load as in a glucose tolerance test
- Symptoms of hyperglycemia and casual plasma glucose ≥11.1 mmol/l (200mg/dl)
- Glycated hemoglobin (also known as HbA_{1C}) ≥6.5%.

A positive result, in the absence of unequivocal hyperglycemia, should be confirmed by a repeat of any of the above methods on a different day. It is preferable to measure a fasting glucose level because of the ease of measurement and the considerable time commitment of formal glucose tolerance testing, which takes two hours to complete and offers no prognostic advantage over the fasting test. According to the current definition, two fasting glucose measurements above 126 mg/dl (7.0 mmol/l) is considered diagnostic for diabetes mellitus. People with fasting glucose levels from 110 to 125mg/dl (6.1 – 6.9 mmol/l) are considered to have impaired fasting glucose. Patients with plasma glucose at

or above 140mg/dL (7.8mmol/L), but not over 200mg/dL (11.1mmol/L), two hours after a 75g oral glucose load, are classified with impaired glucose tolerance. The table below provides a summary of diabetes diagnostic criteria, which principally focus on levels of fasting blood glucose – the principal measure of glucose metabolism efficiency.

Table 3: Diabetes Diagnostic Criteria

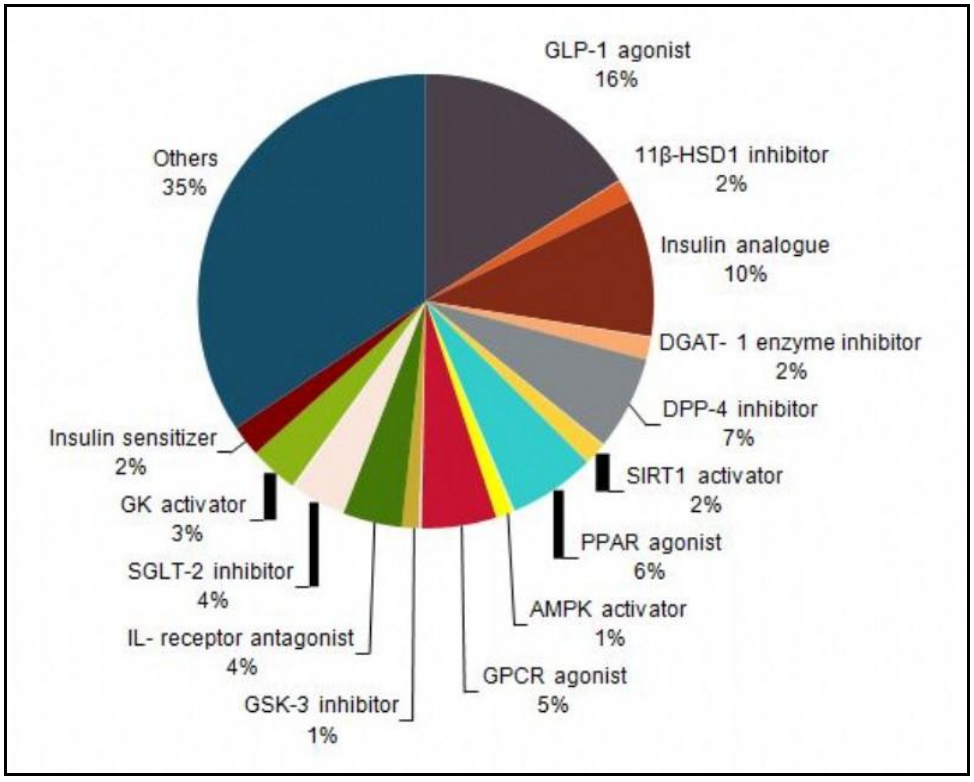
Condition	2 hour glucose	Fasting glucose	HbA_{1c}
	mmol/l(mg/dl)	mmol/l(mg/dl)	%
Normal	<7.8 (<140)	<6.1 (<110)	<6.0
Impaired fasting glycaemia	<7.8 (<140)	≥ 6.1(≥110) & <7.0(<126)	6.0–6.4
Impaired glucose tolerance	≥7.8 (≥140)	<7.0 (<126)	6.0–6.4
Diabetes mellitus	≥11.1 (≥200)	≥7.0 (≥126)	≥6.5

Source: American Diabetes Association (2010)

Therapy

Diabetes drugs either aim to replace insulin or reduce insulin resistance. Today, nearly a century after its introduction in 1921, injectable insulin supplementation remains the mainstay of diabetes therapy. Afrezza, an inhalable formulation, is currently under review by the FDA in the U.S. Several firms, including Oramed, are developing oral formulations of insulin. Other diabetes drugs include insulin sensitizers such as the biguanides (e.g. metformin), the thiazolidinediones (TZDs), and the incretin mimetics, including the GLP-1 agonists, the DPP-IV inhibitors, and the SGLT2 inhibitors.

Figure 9: Diabetes Drug Segmentation

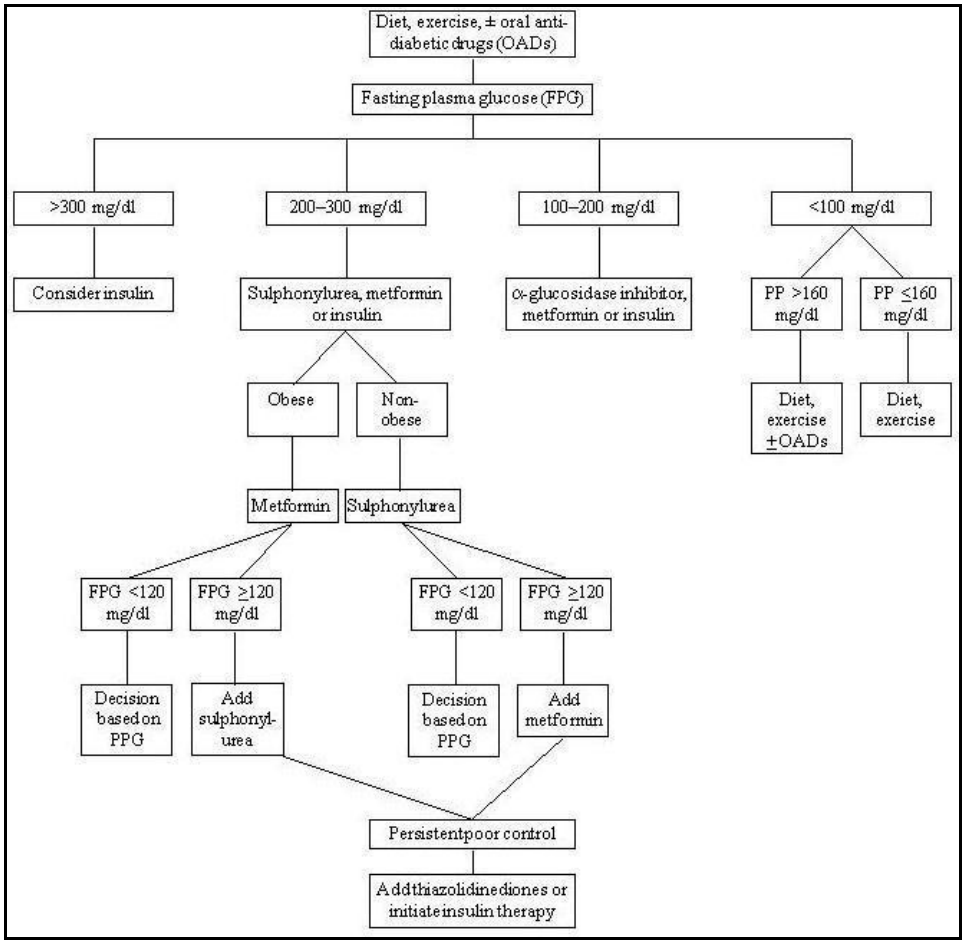


Source: Datamonitor

Marketed Diabetes Drugs

The flow chart below shows the diabetes treatment continuum. Generally, early-stage diabetes is managed primarily using dietary management, insulin therapy, and supplementation with sulphonylurea, biguanides (e.g. metformin) and α-glucosidase inhibitors. If glucose control remains poor, other drugs may be added to the regimen.

Figure 10: Diabetes Treatment Decision Tree



Source: American Diabetes Association

Recently, a range of other therapeutic drug classes has been developed in order to augment the armamentarium. These agents typically fall into two categories – incretin mimetics, aimed at mimicking the hormones that are typically produced naturally by the body to stimulate the release of insulin following a meal; and cardiovascular risk reduction agents – principally, peroxisome proliferator-activated receptor agonists such as the thiazolidinediones, which modulate PPARα and / or γ receptors.

Incretin Mimetics

This class of drugs represents the newest agents that have been developed primarily to address Type 2 diabetes. Incretin mimetics are designed to decrease the body's resistance to insulin and thereby permit a return to normalized glucose control. They fall into three principal categories – the glucagon-like peptide 1 (GLP-1) receptor agonists; the dipeptidyl peptidase IV (DPP IV) inhibitors, and the sodium-dependent glucose transporter 2 (SGLT2) inhibitors.

Glucagon-like peptide 1 (GLP-1) receptor agonists

The GLP-1 receptor agonists are peptidomimetic drugs that have been rationally designed to act as analogs of GLP-1 itself. They are aimed mainly at restoring insulin sensitivity.

Byetta® / Bydureon® (exenatide) – AstraZeneca / Bristol-Myers Squibb

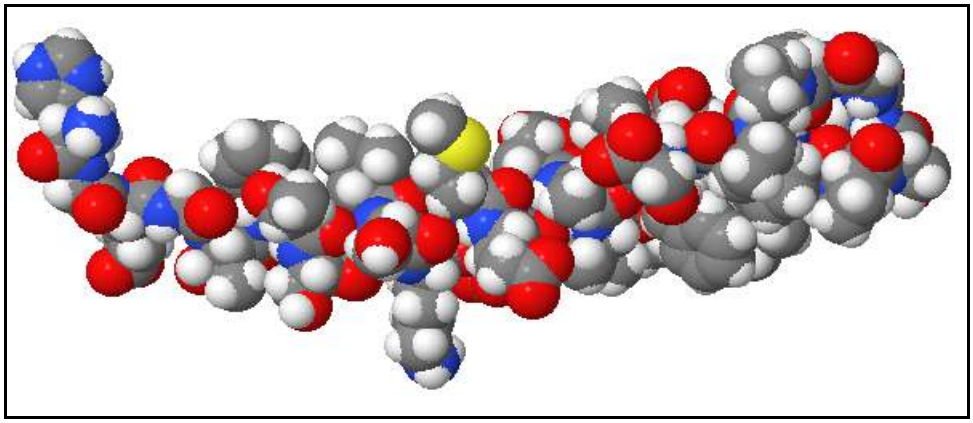
The first of the GLP-1 analogs to be approved to treat diabetes, Byetta was developed by Amylin Pharmaceuticals following the 1992 work of Dr. John Eng at the VA Medical Center (Bronx, NY). Dr. Eng first isolated the hormone exendin-4 from the saliva of the Gila monster, a poisonous lizard found in desert locations across the southwestern U.S.

Figure 11: Gila Monster (*Heloderma suspectum*)

Source: Wikipedia

It was observed that exendin-4 could mimic many of the actions of GLP-1 in humans. Amylin therefore elected to develop it as a drug.

Figure 12: Byetta (exenatide) Chemical Structure



Source: ADIS R&D Insight

As depicted in the space-filling chemical structure on the previous page, exenatide is a 39-amino-acid peptide. The molecule functions as an insulin secretagogue, with gluco-regulatory effects. Exenatide was approved by the FDA on April 28, 2005 for patients whose diabetes was not well-controlled on other oral medication. The medication is injected subcutaneously twice-daily, typically abdominally, using a filled pen-like device.

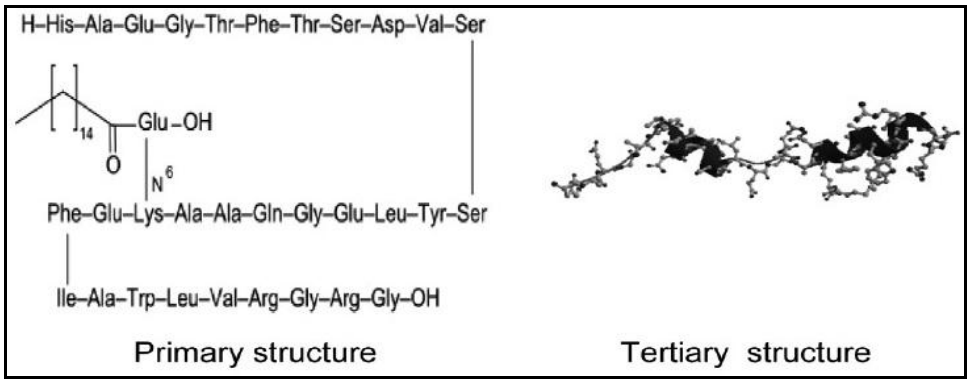
The incretin hormones GLP-1 and glucose-dependent insulinotropic peptide (GIP) are produced by the L and K endocrine cells of the intestine following ingestion of food. GLP-1 and GIP stimulate insulin secretion from the beta cells of the islets of Langerhans in the pancreas. Only GLP-1 causes insulin secretion in the diabetic state; however, GLP-1 itself is ineffective as a clinical treatment for diabetes as it has a very short half-life *in vivo*. Exenatide bears 50% amino acid homology to GLP-1 and has a longer *in vivo* half-life. Commercially, the drug is produced by direct chemical synthesis. Historically, exendin-4 is naturally secreted in the saliva and concentrated in the tail of the Gila monster. Given this history, exenatide is sometimes referred to as "lizard spit". Exendin-4 shares extensive homology and function with mammalian GLP-1, but is resistant to degradation by DPP-IV – which breaks down GLP-1 in mammals – allowing a longer pharmacological half-life. Subsequent clinical testing led to the discovery of the also-desirable glucagon and the appetite-suppressant (anorectic) effects of the drug.

Exenatide raises insulin levels quickly (within ten minutes of dosage), with insulin levels falling over the next couple of hours. A dose taken after meals has a much smaller effect on blood sugar than one taken beforehand. The effects on blood sugar diminish after six to eight hours. Byetta is available at 5µg and 10µg dosage levels. Treatment begins with the 5µg dosage, which is increased in the absence of side effects. Amylin subsequently developed a longer-acting version of exenatide (Bydureon), approved in January 2012 after lengthy delays. This product provides sustained delivery of exenatide, enabling once-weekly dosing – a significant advantage when the drug is administered via injection to patients who may already be required to take other injections. Bydureon uses patented biodegradable microspheres – an Alkermes patented technology – to deliver exenatide in a sustained-release manner. The microspheres are composed of polylactide coglycolide acid polymer. Amylin was acquired by Bristol-Myers Squibb for $7 billion in June 2012, in a deal that also involved Bristol's expansion of an existing partnership with AstraZeneca, which paid Bristol $3.4 billion for access to the Amylin diabetes portfolio.

Victoza® (liraglutide) – Novo Nordisk

Liraglutide is a long-acting GLP-1 agonist developed by Novo Nordisk for the treatment of type 2 diabetes. The product was approved by the European Medicines Agency (EMA) on July 3, 2009, and by the FDA on January 25, 2010.

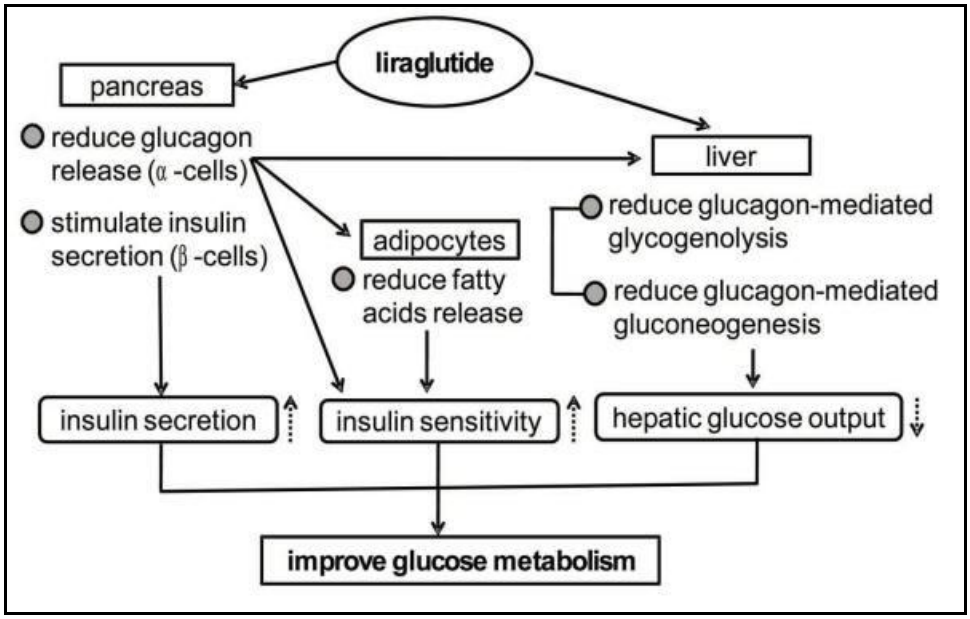
Figure 13: Victoza (liraglutide) Chemical Structure



Source: ADIS R&D Insight

Liraglutide is an acylated human glucagon-like peptide-1 (GLP-1) agonist, with a 97% amino acid sequence identity to endogenous human GLP-1(7-37). GLP-1(7-37) represents less than 20% of total circulating endogenous GLP-1. Like GLP-1(7-37), liraglutide activates the GLP-1 receptor, a membrane-bound cell-surface receptor coupled to adenylyl cyclase by the stimulatory G-protein, G_s, in pancreatic beta cells. Liraglutide increases intracellular cyclic AMP (cAMP), leading to insulin release in the presence of elevated glucose concentrations. This insulin secretion subsides as blood glucose concentrations decrease and approach euglycemia.

Figure 14: Victoza (liraglutide) Mechanism of Action



Source: Novo Nordisk

In addition, liraglutide decreases glucagon secretion in a glucose-dependent manner. The mechanism of blood glucose lowering also involves a delay in gastric emptying. GLP-1(7-37) has a half-life of 1.5–2 minutes due to degradation by the ubiquitous endogenous enzymes, DPP-IV and neutral endopeptidases (NEP). Unlike native GLP-1, liraglutide is stable against metabolic degradation by both peptidases and has a plasma half-life of 13 hours after subcutaneous administration. The pharmacokinetic profile of liraglutide, which permits once-daily dosing, is a result of self-association that delays absorption, plasma protein binding and stability against metabolic degradation by DPP-IV and NEP.

Syncria® (albiglutide)

Syncria® (U.S.) / Eperzan® (Europe), which carries the generic name albiglutide, is a dipeptidyl peptidase-4-resistant glucagon-like peptide-1 (GLP-1) dimer fused to human albumin. Albiglutide has a half-life of four to seven days, which is considerably longer than the two most widely-used GLP-1 analogs currently on the market, exenatide (Byetta) and liraglutide (Victoza). However, it is likely to be viewed as slightly inferior to the pharmacokinetic profile of Bydureon. GlaxoSmithKline, which obtained the rights to this drug through its relationship with and acquisition of Human Genome Sciences, filed for approval of albiglutide in the U.S. in January 2013 and in Europe in March 2013. The FDA's PDUFA date for albiglutide is April 15, 2014.

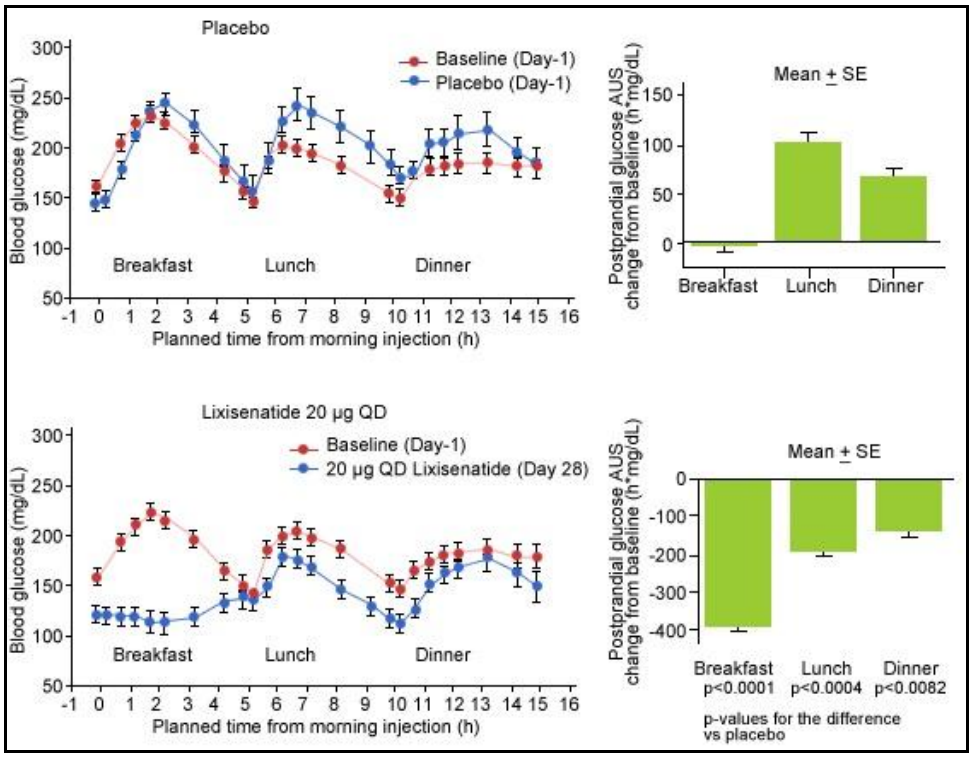
GlaxoSmithKline presented data from five Phase 3 trials of albiglutide in June 2013. The primary efficacy endpoint for these studies was the change from baseline in HbA1c compared to placebo and/or active comparators assessed after one or two years of

treatment. Secondary endpoints included fasting plasma glucose (FPG) and weight. These studies were specifically designed to assess durability of albiglutide effect on HbA1c and other continuous variables when used in various combination therapies, at different stages of the disease, and in various degrees of renal impairment. Albiglutide achieved the primary efficacy endpoint in these five studies, although a hierarchical analysis of non-inferiority to pioglitazone was not met in one of them.

Lyxumia™ (lixisenatide) – Sanofi S.A. / Zealand Pharma A/S

Another once-daily GLP-1 agonist, lixisenatide was developed by Zealand Pharma A/S and subsequently partnered with Sanofi S.A., which obtained regulatory approval for the drug in Europe in February 2013. It is currently marketed in various European countries under the trade name Lyxumia.

Figure 15: Lixisenatide Glucose Control Data



Source: Zealand Pharma A/S

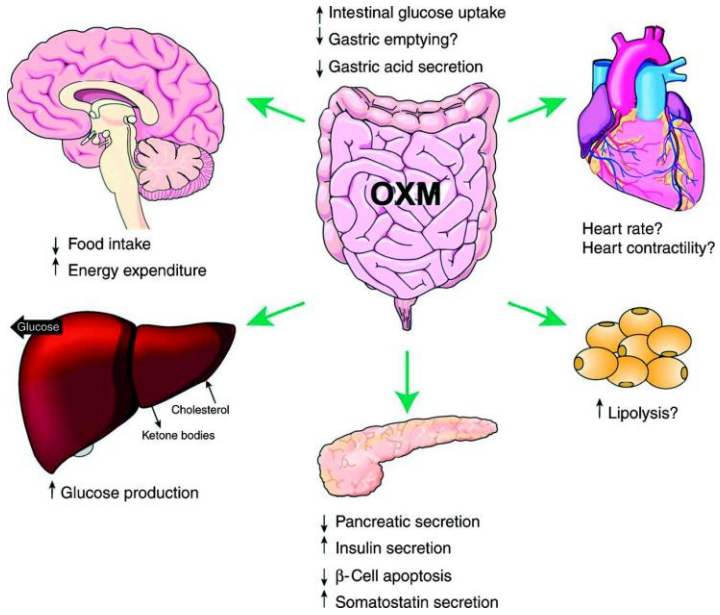
While lixisenatide was originally filed for approval in the U.S. and had been assigned a PDUFA date in December 2013, Sanofi elected to withdraw the regulatory submission in September 2013 after it became apparent that the FDA wanted to see long-term safety data from a large Phase 3 trial evaluating lixisenatide with respect to coronary event risk.

The Elixa trial is comparing lixisenatide against placebo in about 6,000 type 2 diabetics who had recently experienced an acute coronary event such as a heart attack. The goal is to see whether the drug affects cardiovascular outcomes for patients. Sanofi is also slated to begin a Phase 3 trial of lixisenatide in combination with Sanofi's long-acting insulin injection product, Lantus, in the first half of 2014. Lantus loses patent protection in 2015 and the successful development of lixisenatide plus Lantus as a combination product could potentially enable Sanofi to extend the lifespan of its long-acting insulin franchise. We note that this strategy is very similar to the concept that Oramed is exploring with the combination of ORMD-0801 with ORMD-0901.

Oxyntomodulin Derivatives

Beyond the traditional GLP-1 receptor agonists, several newer agents in the incretin mimetic sub-class are currently being developed. Some of these agents are dual agonists of the GLP-1 and the glucagon receptor (e.g. oxyntomodulin and derivatives). The most well-known of these is ZP2929, which was also developed by Zealand Pharma and partnered with Boehringer Ingelheim.

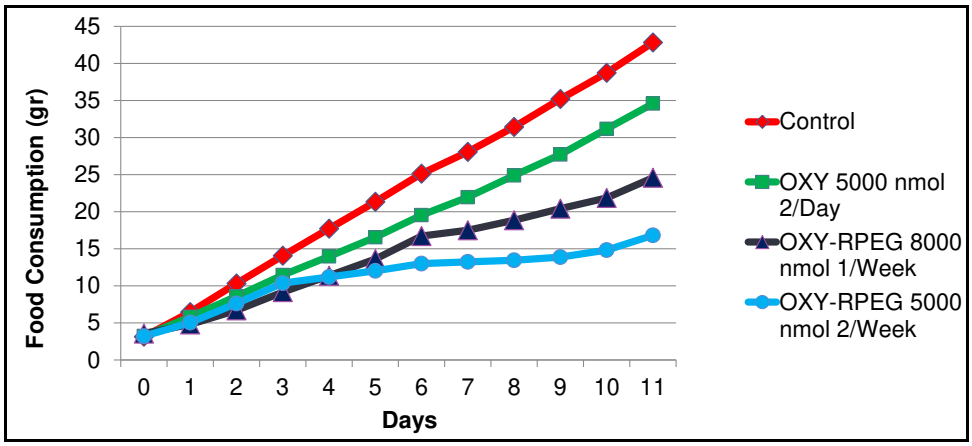
Figure 16: Oxyntomodulin Mechanism of Action



Source: Journal of Endocrinology (2010)

Another drug, MOD-6030, was developed using a proprietary technology platform for reversibly PEGylating centrally-acting peptides that was invented at the Weizmann Institute of Science in Israel. This drug, which is effectively a long-acting version of oxyntomodulin that preclinically demonstrated potential for semi-monthly dosing, was originally created by PROLOR Biotech, an emerging Israeli biotechnology firm that was acquired in an all-stock transaction by OPKO Health, a specialty pharmaceuticals and diagnostics firm founded by Dr. Phillip Frost. The data shown below that the drug functions as a potent anorectic with better efficacy than native oxyntomodulin.

Figure 17: Oxyntomodulin-RPEG Preclinical Weight Loss Data

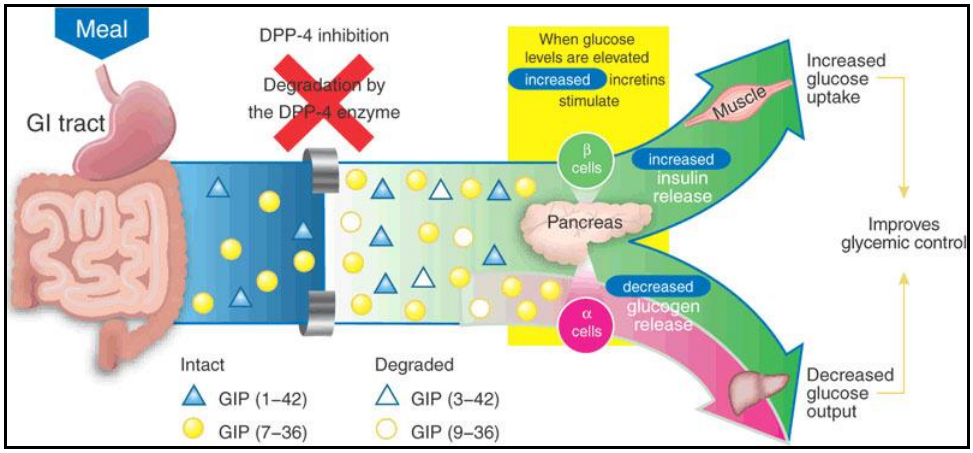


Source: PROLOR Biotech, Inc.

Dipeptidyl peptidase IV (DPP-IV) inhibitors

Also called gliptins, the DPP-IV) inhibitors were developed with the aim of providing diabetics with an orally-bioavailable way to achieve more reliable glucose control. These drugs are typically administered to type 2 diabetics already taking insulin. Glucagon increases blood glucose levels, and DPP-IV inhibitors reduce glucagon and blood glucose levels. DPP-IV inhibitors increase levels of the incretins – chiefly, glucagon-like peptide 1 (GLP-1) and gastric inhibitor polypeptide (GIP) – which inhibit glucagon release. This, in turn, increases insulin secretion, decreases gastric emptying, and decreases blood glucose levels. The figure below illustrates the mechanism of action of these drugs.

Figure 18: DPP-IV Drug Mechanism of Action



Source: Molecular Biology of the Cell (2005)

The DPP-IV inhibitors selectively block DPP-IV, which is an antigenic enzyme expressed on the surface of most cell types and is associated with immune regulation, signal transduction and apoptosis. It is an intrinsic membrane glycoprotein and a serine exopeptidase that cleaves X-proline dipeptides from the N-terminus of polypeptides. The first inhibitors were characterized in the late 1980s and 1990s. Each inhibitor was important to establish an early structure activity relationship (SAR) for subsequent investigation. The inhibitors are typically classified as either non-covalent or covalent binders. DPP-4 is a dipeptidase that selectively binds substrates that contain proline at the P1-position; thus, many DPP-4 inhibitors have five-membered heterocyclic rings that mimic proline, e.g. pyrrolidine, cyanopyrrolidine, thiazolidine and cyanothiazolidine. These compounds commonly form covalent bonds to the catalytic residue Ser630.

In 1994, researchers from Zeria Pharmaceuticals unveiled cyanopyrrolidines with a nitrile function group that was assumed to form an imidate with the catalytic serine. Concurrently other DPP-4 inhibitors without a nitrile group were characterized, but these contained other serine-interacting motifs, e.g. boronic acids, phosphonates or diacyl hydroxylamines. These compounds were not as potent because of the similarity of DPP-4 and prolyl oligopeptidase (PEP) and also suffered from chemical instability. In 1995, Ferring Pharmaceuticals published on two cyanopyrrolidine compounds, which had excellent potency and improved chemical stability.

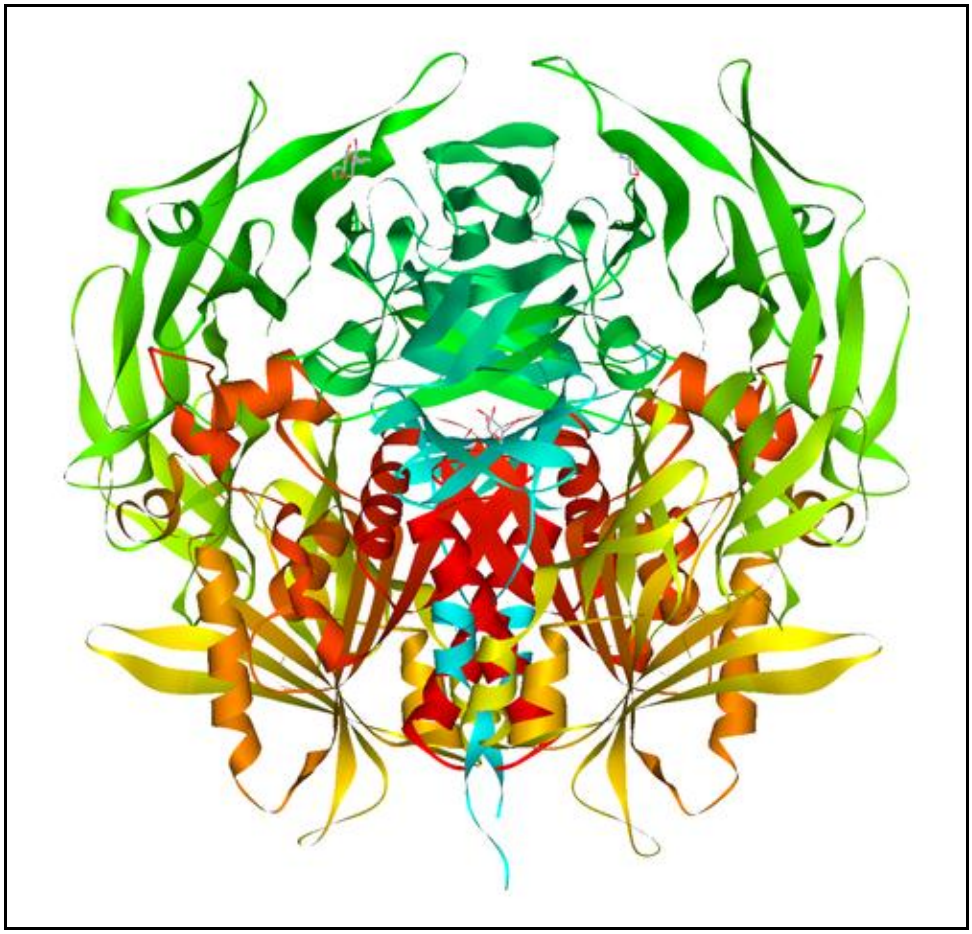
In 1995, Edwin Villhauer at Novartis started to explore N-substituted glycinyl-cyanopyrrolidines based on the fact that DPP-4 identifies N-methylglycine as a N-terminal amino acid. This group of new cyanopyrrolidines became the basis for a popular field of research in subsequent years. Some trials with dual inhibitors of DPP-4 and vasopeptidase were performed, since vasopeptidase inhibition is believed to enhance the anti-hyperglycemic effect of DPP-4 inhibition by stimulating insulin secretion.

Many structurally diverse DPP-4 inhibitors have been discovered. This is not surprising, considering the properties of the binding site:

1) A deep lipophilic pocket combined with several exposed aromatic side chains for achieving high affinity small molecule binding.
2) A significant solvent access that makes it possible to tune the physicochemical properties of the inhibitors that leads to better pharmacokinetic behavior.

The DPP-IV enzyme is a 766-amino acid transmembrane glycoprotein in the prolyloligopeptidase family with three components; a cytoplasmic tail, a transmembrane region and an extracellular head, which is divided into a catalytic domain and an eight-bladed β-propeller domain. The structure of the enzyme is depicted in the figure below.

Figure 19: DPP-IV Molecular Structure



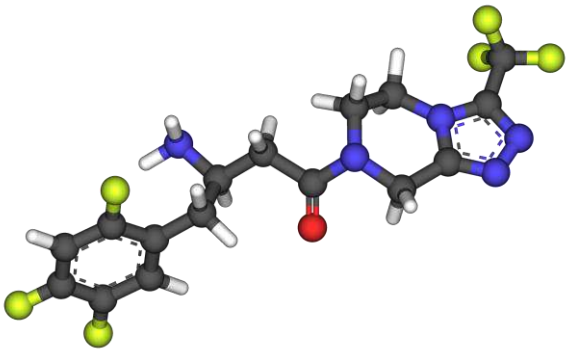
Source: Brookhaven Protein Data Bank

The first DPP-IV inhibitor drugs for type 2 diabetes were approved several years ago, with the initial product across the regulatory finish line being Merck & Co.'s sitagliptin. This agent was originally approved in October 2006. Merck and Novartis both had drug candidates under review at the FDA simultaneously, with the Novartis drug, vildagliptin, eventually being denied approval in the U.S. due to the fact that it was observed to cause skin rash in cynomolgus monkeys. Vildagliptin was eventually approved in various ex-U.S. markets, but has never been launched in the U.S. In our view, the FDA's decision was irrational and has remained controversial; it permitted Merck to enjoy a virtual monopoly of the DPP-IV inhibitor sector for several years, until AstraZeneca and Bristol-Myers Squibb finally obtained approval for Onglyza (saxagliptin) in July 2009.

Januvia™ (sitagliptin) – Merck & Co.

The DPP-IV inhibitors have proven to be extremely successful drugs from a commercial perspective, particularly the first of these agents to be launched, sitagliptin. Developed by Merck & Co., sitagliptin – originally identified as MK-0431 and currently known via its trade name Januvia™ – became the fastest-ramping launch in Merck's history. It has also been developed as an accompaniment to other oral anti-hyperglycemic agents, particularly thiazolidinediones (TZDs) and metformin – one of these combination products is called Janumet™. The structure of sitagliptin is shown in the figure below.

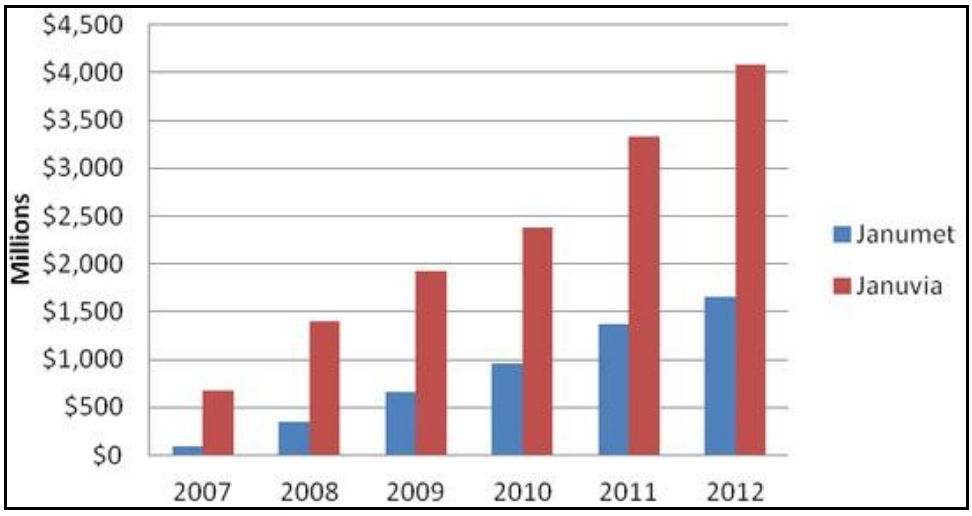
Figure 20: Januvia (sitagliptin) Chemical Structure



Source: ADIS R&D Insight

The figure below shows the growth in the sales of both Januvia and Janumet – sometimes referred to as "Merck's dynamic diabetes duo." These are undoubtedly highly successful drugs – currently estimated to generate roughly $6 billion a year in sales for Merck – and have been heavily instrumental in changing the face of type 2 diabetes therapy. One of the main advantages for these drugs is the ability to achieve adequate glucose control in patients who are unresponsive or only partially responsive to biguanides and / or sulfonylureas, with the added benefit of lack of association with hypoglycemia or weight gain, which is frequently an issue with sulfonylurea drug therapy.

Figure 21: Januvia® / Janumet® Historical Sales Data



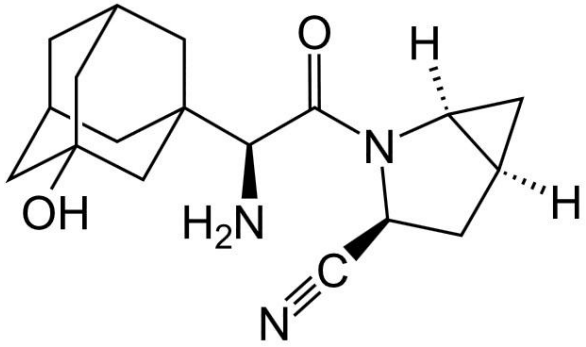
Source: ADIS R&D Insight

Januvia is comparatively less potent than the other gliptins, requiring dosing at 100mg/day. It must be dose-adjusted for those with impaired renal function to 25mg/day.

Onglyza™ (saxagliptin) – AstraZeneca / Bristol-Myers Squibb

Approved in July 2009, saxagliptin is currently deployed at a 5mg once-daily dosage. Its absorption is unaffected by food. Saxagliptin is metabolized mainly by cytochrome P450 (CYP) 3A4 to a major active monohydroxylated metabolite, 5-hydroxy saxagliptin, which is half as potent as saxagliptin. Approximately 75% of the total dose of saxagliptin is renally excreted (comprising 24% saxagliptin, 36% 5-hydroxy saxagliptin and minor metabolites of saxagliptin), while 22% of a saxagliptin dose was eliminated in the feces, mainly as metabolites. The drug is generally not dose-adjusted for patients with mild renal impairment, although it is usually given at half the normal dose to those with moderate-to-severe renal impairment or end-stage renal disease.

Figure 22: Onglyza (saxagliptin) Chemical Structure

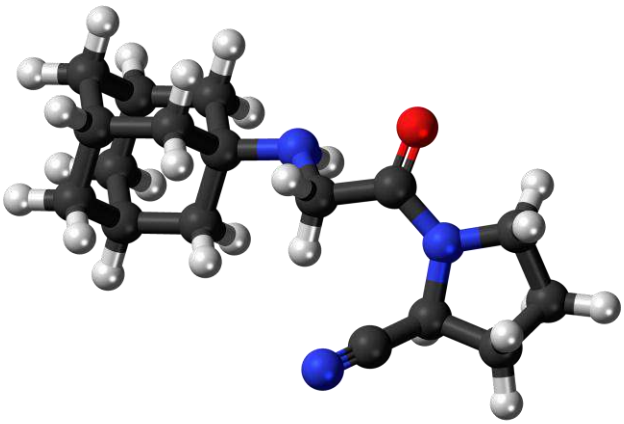


Source: ADIS R&D Insight

Galvus (vildagliptin) – Novartis AG

While it has never been approved in the U.S., Galvus was initially approved in Europe in October 2007. Widely considered an under-appreciated drug, vildagliptin has achieved significant commercial success outside the U.S., with 2012 net sales of $910 million. Substantial traction has been achieved by Novartis with this agent in emerging markets. The typical dose is 50mg twice-daily. Its absorption is unaffected by food. Vildagliptin is extensively metabolized by the liver and has >90% bioavailability following a single oral dose. No dosage adjustment is required for liver disease although a 30% higher amount of inactive metabolites is retained in patients with severe liver disease. No dose adjustment is required for mild renal insufficiency; however, for patients with moderate-to-severe renal impairment, half the recommended dose is suggested.

Figure 23: Galvus (vildagliptin) Chemical Structure

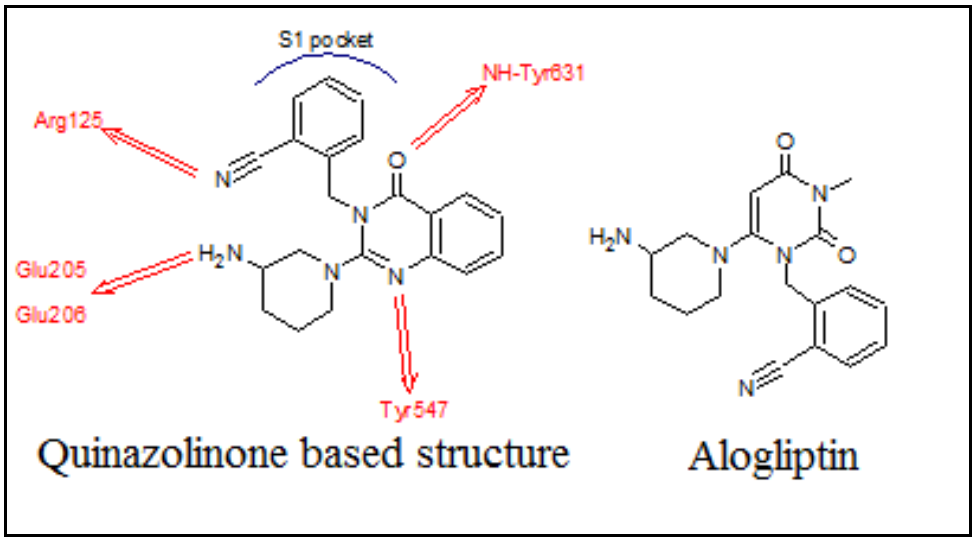


Source: ADIS R&D Insight

Nesina (alogliptin) – Takeda Pharmaceutical Co. Ltd. / Furiex Pharmaceuticals

Originally developed by Syrrx, acquired by Takeda in 2005, alogliptin had a rough path to market in both the U.S. and Europe. The drug was filed with the FDA in December 2007 but failed to gain approval; subsequently, a pair of New Drug Applications (NDAs) were filed for both alogliptin as a single agent as well as in combination with pioglitazone. Both of these were rejected in 2012. Takeda, however, persisted and eventually obtained approval for alogliptin as a single agent (Nesina), in a combination formulation with metformin (Kazano), and in combination with pioglitazone as Oseni.

Figure 24: Nesina (alogliptin) Chemical Structure

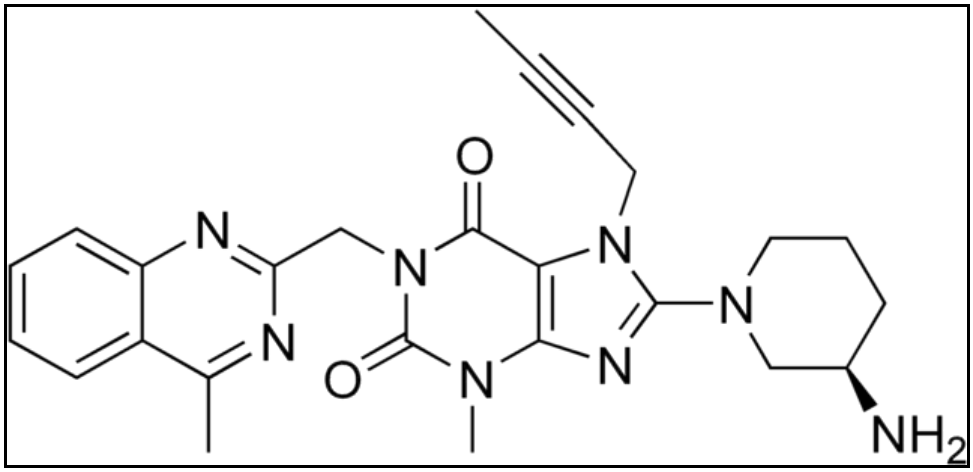


Source: ADIS R&D Insight

Tradjenta (linagliptin) – Boehringer Ingelheim / Eli Lilly & Co.

Initially developed in Boehringer Ingelheim's labs as BI-1356, linagliptin was approved in the U.S. in May 2011. Dosed at 5mg once-daily, it is comparatively more potent than the earlier-generation agents sitagliptin and vildagliptin. Only 5% is eliminated renally; thus, it appears safer than other gliptins in patients with kidney function impairment. Intriguingly, it has also shown preclinical activity in wound healing.

Figure 25: Tradjenta (linagliptin) Chemical Structure

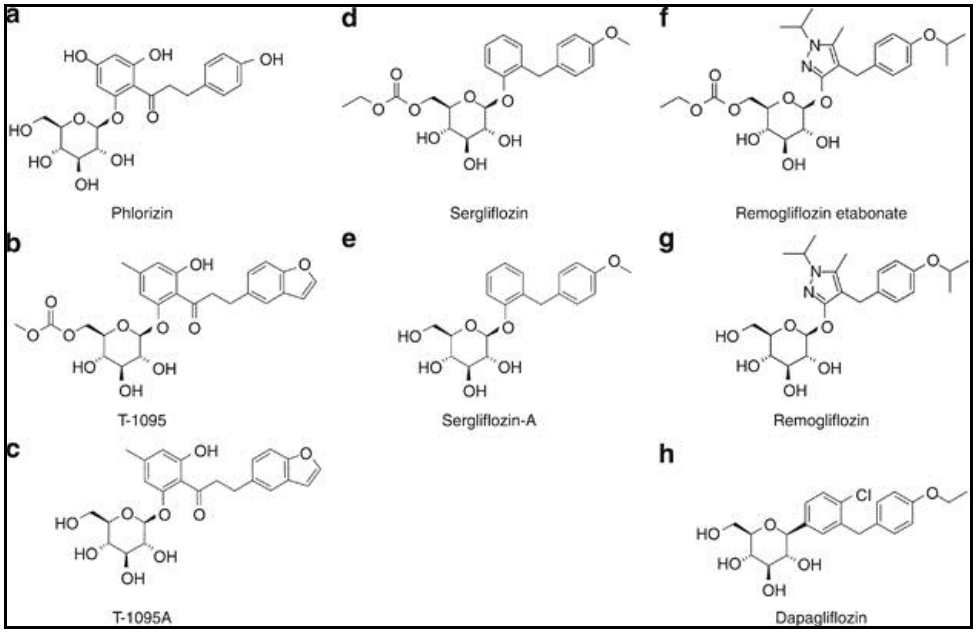


Source: ADIS R&D Insight

Sodium / glucose co-transporter 2 (SGLT2) inhibitors

The newest therapeutic sub-class of anti-diabetic drugs, the SGLT2 inhibitors all block the activity of SGLT2, a member of the glucose transport protein family that serves as the major co-transporter involved in glucose reabsorption in the kidney. The idea is that blockade of this protein would stimulate glucose excretion through the urine.

Figure 26: Chemical Structures of SGLT2 Inhibitors



Source: ADIS R&D Insight

Forxiga (dapagliflozin) is approved in Europe and Australia but was rejected by the FDA due to safety concerns. Dapagliflozin was one of two drugs, along with saxagliptin, that were originally discovered in Bristol's laboratories to which AstraZeneca obtained partial rights. AstraZeneca and Bristol inked their global diabetes collaboration agreement in January 2007. This deal involved an upfront payment of $100 million by AstraZeneca to Bristol-Myers Squibb. From 2007 through 2009, the majority of development costs were to be funded by AstraZeneca. Any additional development costs will be shared equally. Bristol-Myers Squibb was also slated to receive additional payments of up to $650 million based on development and regulatory milestones. In addition, potential sales milestones of up to $300 million per product were also possible. The firms were to share profits and losses along with commercialization expenses equally on a global basis, excluding Japan. Bristol manufactures both products and books all sales.

In addition to Forxiga, Janssen Pharmaceuticals (a division of Johnson & Johnson) has an SGLT2 inhibitor called canagliflozin (trade name Invokana), which won FDA approval in March 2013. This drug was originally developed by Mitsubishi Tanabe Pharma. However, an elevated risk of stroke has been observed in clinical trials.

Other agents in the SGLT2 inhibitor class include ipragliflozin (ASP1941), developed by the Japanese firm Astellas; empagliflozin (BI-10773), developed by Boehringer Ingelheim; tofogliflozin from Chugai Pharma, being developed in collaboration with Kowa and Sanofi S.A.; and remogliflozin etabonate, developed by GlaxoSmithKline. Ipragliflozin, empagliflozin and tofogliflozin are in Phase 3 development, while remogliflozin is in Phase 2b testing currently. We anticipate that, in the next 2 – 3 years, most of these candidates are likely to obtain regulatory approval in multiple territories.

Older-Generation Agents

Other type 2 diabetes drugs include the biguanides (e.g., metformin), the sulfonylurea derivatives (e.g. chlorpropamide, glipizide, tolazamide) and the thiazolidinediones (TZDs, also known as glitazones, e.g. piloglitazone, rosiglitazone, and troglitazone).

Biguanides

These drugs were first characterized as components of *Galega officinalis* (French lilac) extracts, which were used in diabetes therapy for centuries. Introduced in the 1950s, the biguanide agent metformin is the only anti-diabetic drug that has been consistently shown to prevent the cardiovascular complications of diabetes. Metformin is still widely deployed, typically as the front-line therapy of choice for endocrinologists.

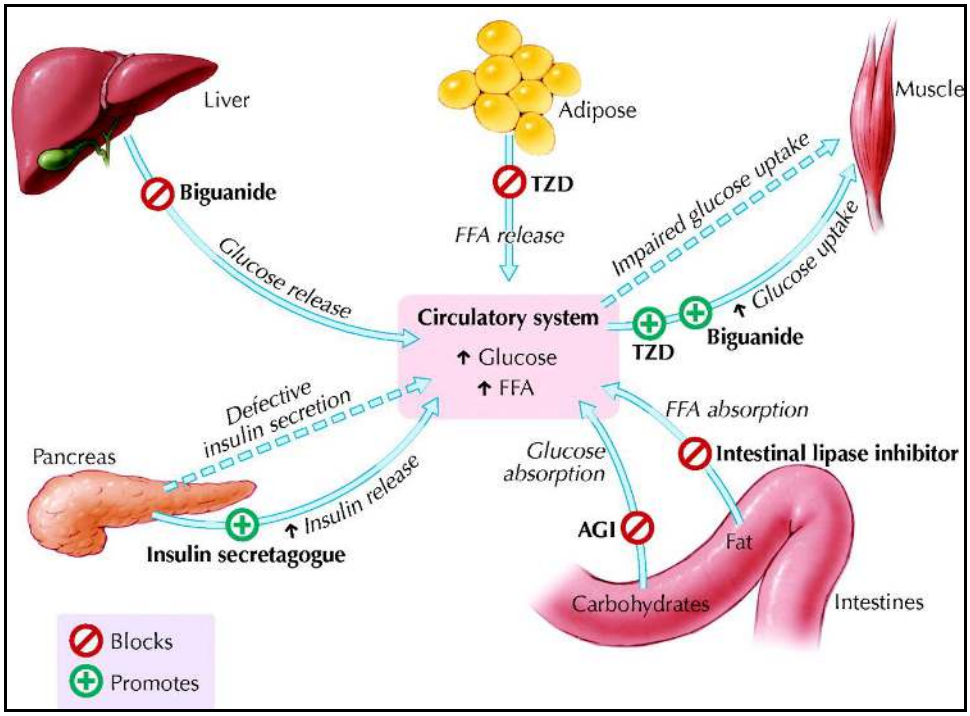
Sulfonylurea derivatives

Sulfonylureas bind to an ATP-dependent potassium ion (K^+) channel on the cell membranes of beta cells. This inhibits a tonic, hyperpolarizing efflux of potassium, thus causing the electric potential over the membrane to become more positive. This depolarization opens voltage-gated Ca^{2+} channels. The rise in intracellular calcium leads to increased fusion of insulin granulae with the cell membrane, and thus increased insulin secretion. There is also evidence that sulfonylureas sensitize β-cells to glucose, limit hepatic glucose production, and decrease lipolysis and hepatic insulin clearance.

Thiazolidinediones (TZDs)

These drugs act by activating peroxisome proliferator-activated receptors (PPARs). TZDs can reduce insulin resistance, modify adipocyte differentiation, inhibit angiogenesis, suppress leptin (stimulating appetite) and enhance adiponectin production.

Figure 27: Diabetes Drug Mechanisms of Action



Source: American Diabetes Association (ADA)

Anti-Diabetic Insulin Formulations

The table below summarizes the currently-marketed insulin formulations that have achieved regulatory approval. These are principally recombinantly produced.

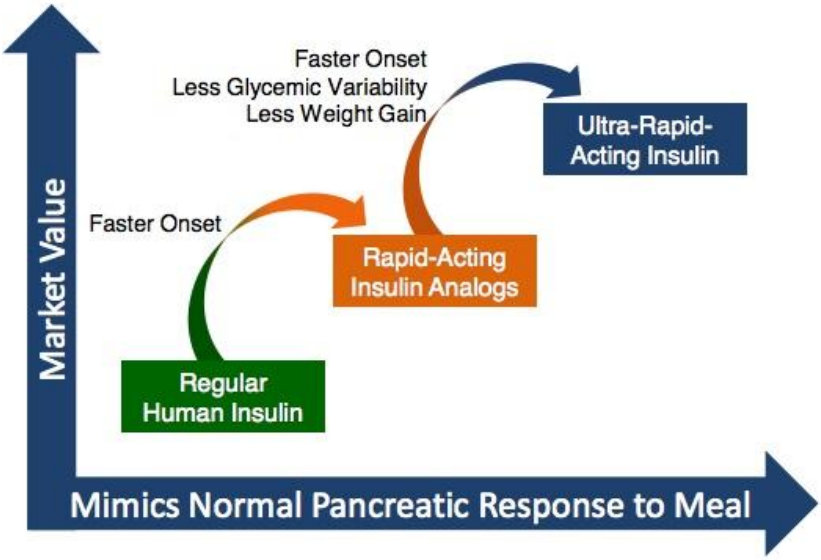
Table 4: Marketed Insulin Formulations

Brand Names	Onset	Peak	Duration	Role in Blood Sugar Management
Rapid-Acting				
Humalog	15-30 min.	30-90 min	3-5 hours	Covers insulin needs for meals eaten at the same time as the injection. This type of insulin is used with longer-acting insulin.
Novolog	10-20 min.	40-50 min.	3-5 hours	
Apidra	20-30 min.	30-90 min.	1-2.5 hours	
Short-Acting				
Regular (R) humulin	30 min-1 hour	2-5 hours	5-8 hours	Covers insulin needs for meals eaten within 30-60 minutes
Velosulin (for use in the insulin pump)	30 min-1 hour	2-3 hours	2-3 hours	
Intermediate-Acting				
NPH - Novolin (N)	1-2.5 hours	3-10 hours	18-24 hours	Covers insulin needs for about half the day or overnight. Often combined with rapid- or short-acting insulin.
Long-Acting				
Ultralente (U)	30 min-3 hours	10-20 hours	20-36 hours	Covers insulin needs for about one full day. This type of insulin is often combined with rapid- or short-acting insulin.
Lantus	1-1½ hour	No peak time	20-24 hours	
Levemir or detemir	1-2 hours	6-8 hours	Up to 24 hours	
Pre-Mixed				
Novolin 70/30	30 min.	2-12 hours	Up to 24 hours	These products are generally taken twice a day before mealtime.
Novolog 70/30	10-20 min.	1-4 hours	Up to 24 hours	
Humulin 50/50	30 min.	2-5 hours	18-24 hours	
Humalog mix 75/25	15 min.	0.5-2.5 hours	16-20 hours	

Source: Company reports; Wolters Kluwer competitive intelligence database

The insulin market is becoming more and more segmented, with companies having focused on developing either longer-acting insulin formulations that reduce injection frequency or faster-acting versions (see below).

Figure 28: Ultra-Rapid Insulin Advantages



Source: Biodel, Inc.

Table 5: Experimental Insulin Preparations – Competitive Landscape

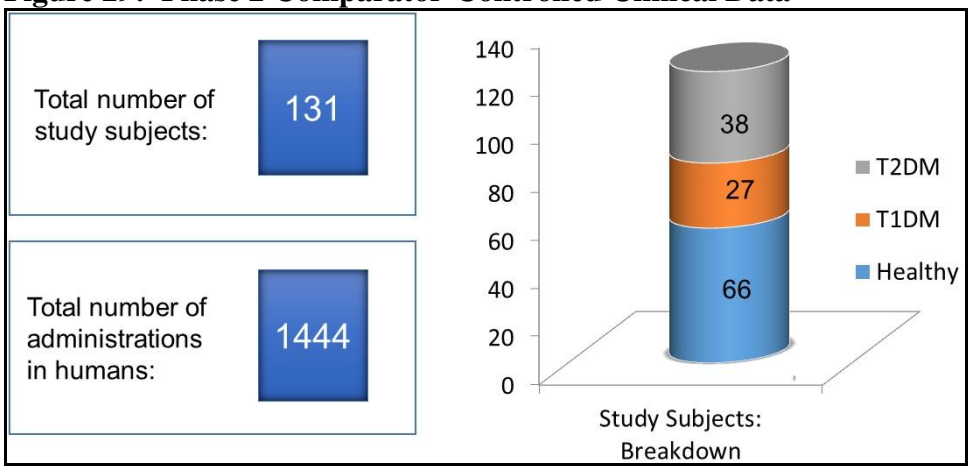
Trade Name	Generic Name	Sponsor	Route of Administration	Mechanism of Action	Clinical Stage
NN1953	OI338GT	Novo Nordisk & Merrion Pharmaceuticals	oral	long-acting basal insulin analogue (includes adsorption enhacers)	Phase 1
NN1954	OI362GT	Novo Nordisk & Merrion Pharmaceuticals	oral	long-acting basal insulin analogue (includes adsorption enhacers)	Phase 1
NN1956	OI287GT	Novo Nordisk & Merrion Pharmaceuticals	oral	long-acting basal insulin analogue (includes adsorption enhacers)	Phase 1
BIOD-123	Oral Insulin	Biodel	oral	mimics first-phase insulin-release, reducing hepatic glucose production: maintains normal glucose levels	Phase 1
IN-105	Oral Insulin	Biocon & Bristol-Meyers Squibb	oral	orally delivered and targeted towards liver, absorbed in GI tract.	Phase 2
Capsulin	Capsulin	Diabetology	oral	protection of insulin from enzymatic digestion and facilitation of absorption across intestinal mucosa	Phase 2
Afrezza	Technospere Insulin	Mannkind Corporation	inhalation	ultra-rapid acting insulin powder	Phase 3
Oral-lyn	Oral Recosulin	Generex & Shreya Life Sciences	buccal spray	basal insulin spray that reduces hemoglobin A1c (HbA1c)	Phase 3

Source: Company Reports; EvaluatePharma; ADIS R&D Insight; ClinicalTrials.gov (http://www.clinicaltrials.gov/)

ORMD-0801 Experimental Data

An overview of the proof-of-concept clinical data generated thus far with ORMD-0801 indicates, in our view, that the drug has encouraging activity in diabetic patients. We note that Oramed is developing this drug primarily to suppress elevated fasting blood glucose (FBG) levels, which are considered a significant issue in type 2 diabetics. The condition of elevated FBG levels typically arises as a result of excessive nocturnal glucose production from the liver. Roughly 70% of individuals with impaired FBG control develop type 2 diabetes. Approximately 80% of type 2 diabetics exhibit abnormal FBG levels and fail to achieve adequate glycemic control with older-generation anti-diabetic drugs such as metformin or TZDs. Even drugs currently used to control FBG levels have significant adverse events, leading to a substantial unmet need for drugs that control FBG levels in a more natural, physiologically-appropriate manner. The figure below depicts the number of patients who have been given ORMD-0801 to date in completed trials, and the total number of administrations of the drug that have occurred.

Figure 29: Phase 2 Comparator-Controlled Clinical Data



Source: Oramed Pharmaceuticals, Inc.

The above figure demonstrates that a significant number of exposures to ORMD-0801 have already occurred, and that the drug has thus far exhibited a solid safety profile. We note that ORMD-0801 is eligible for submission via the 505(b)(2) pathway, which means that an abbreviated path to market can be envisaged that would allow Oramed and its potential collaborators to utilize existing safety and efficacy data generated with injectable insulin preparations in order to file an NDA in the U.S.

Oramed's methodology of dosing oral insulin has not only a dosing convenience rationale but also a physiological one. Since the blood glucose – insulin secretion system forms a closed loop in order to minimize systemic exposure to insulin above specific levels and maintain homeostasis – with peripheral insulin being responsible for glucose uptake in fat and muscle – it has been hypothesized that the most natural way to provide glucose control would be to optimize insulin delivery through the portal vein instead of attempting to deliver it systemically via intravenous or subcutaneous injection. First-pass hepatic metabolism extracts roughly 80% of secreted insulin.

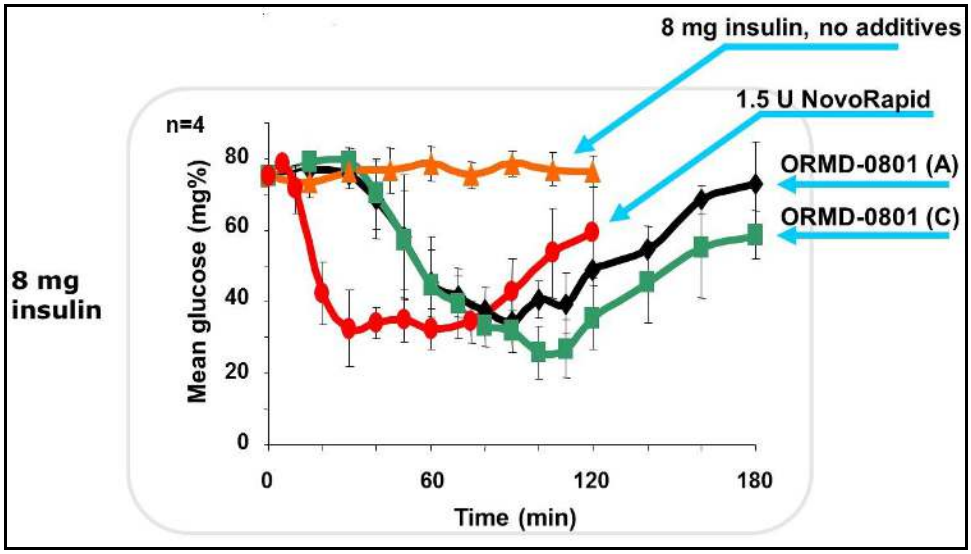
The system of dosing insulin orally in a protease-protected formulation is optimized to provide a more physiological presentation of insulin, thus enabling reduction of insulin resistance and stimulating endogenous insulin secretion. Oramed developed its capsule formulation specifically for this purpose. In our view, this is one of the most rational approaches to diabetes therapy that we have come across.

Oramed's initial preclinical data with ORMD-0801 were promising. The drug was assessed in animal toxicology trials, with 28-day data showing no safety signals in Sprague-Dawley rats at doses three times above levels being deployed in human subjects.

Preclinical Efficacy Data

Proof-of-concept efficacy studies were performed in both beagle dogs as well as pigs. The figure below illustrates the data obtained with ORMD-0801 benchmarked against native insulin and NovoRapid in dogs.

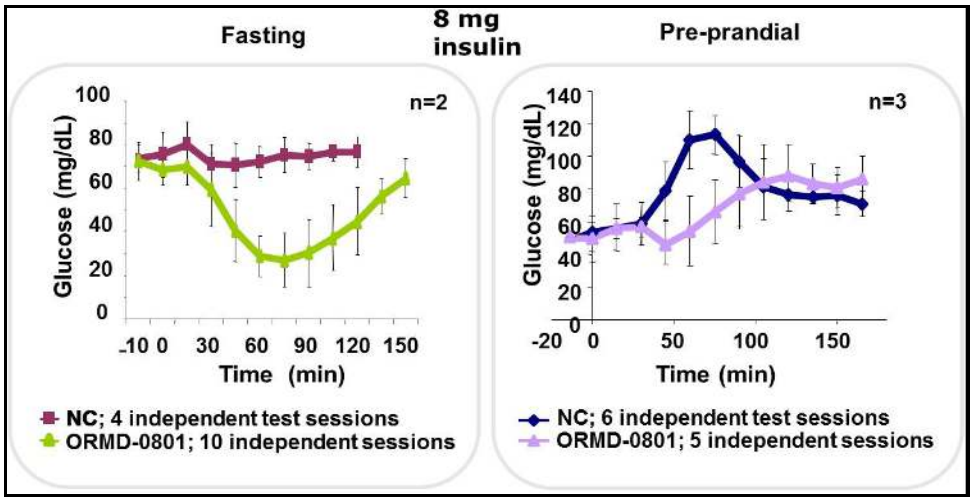
Figure 30: Preclinical Canine Efficacy Data



Source: Oramed Pharmaceuticals, Inc.

As shown above, a 60% – 75% drop in blood glucose levels was observed in in healthy, non-diabetic cannulated beagle dogs within 30 – 100 minutes of administration of therapy. No hypoglycemia or adverse events were seen in these animals over the course of three years of testing, which we find extremely encouraging. The figure below shows similar data in pigs, wherein, similarly, no hypoglycemia or adverse events were seen.

Figure 31: Porcine Preclinical Efficacy Data



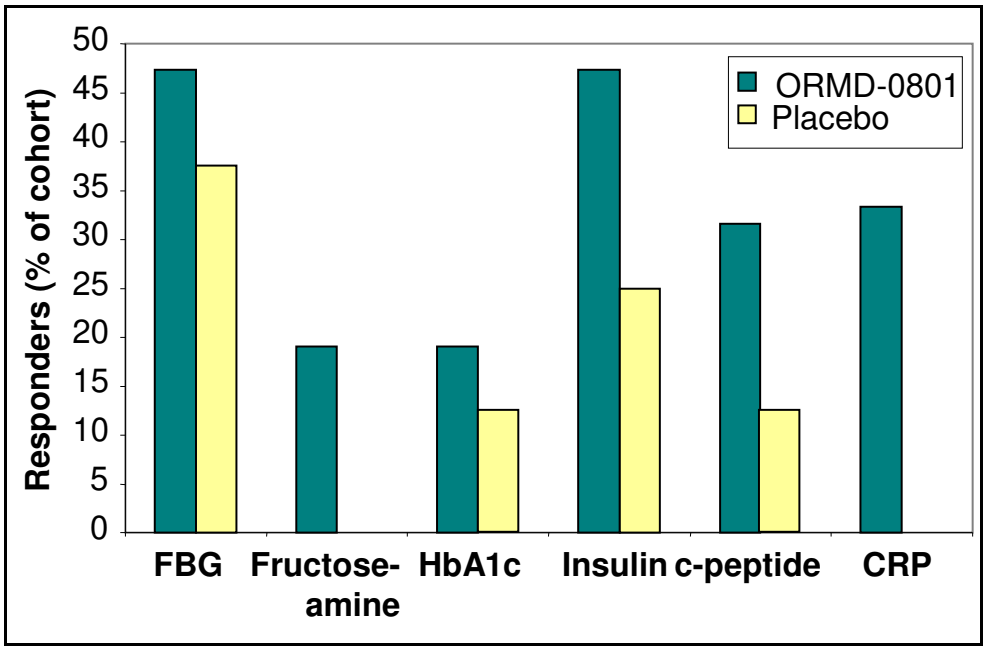
Source: Oramed Pharmaceuticals, Inc.

Type 2 Diabetes Phase 2 Proof-of-Concept Data

The firm's first proof-of-concept trial, conducted in Israel without FDA sanction, was a six-week study that enrolled 29 type 2 diabetics. Unusually for such a small study, it had a placebo-controlled, randomized, double-blinded design. In this trial, 21 patients received orally-ingestible insulin capsules at bedtime, while nine received placebo.

Safety data from this trial, which was concluded in August 2008, proved that the first extended exposure to ORMD-0801 was safe and well-tolerated. No serious adverse events were reported and no cumulative effects were observed. Although two hypoglycemic events were recorded, both were mild in severity. The efficacy results demonstrated that ORMD-0801 reduced markers of both hyperglycemia and inflammation. The percentages of patients showing clinically-relevant reductions n C-reactive peptide (CRP), fasting blood glucose, and HbA1c levels were all higher in the treatment cohort vs. placebo. We note that, as shown below, the difference in fasting blood glucose seen in this trial was not massive; however, the small size of the study and the limited duration made it unlikely that a significant difference would be seen.

Figure 32: Phase 2a Proof-of-Concept Efficacy Data



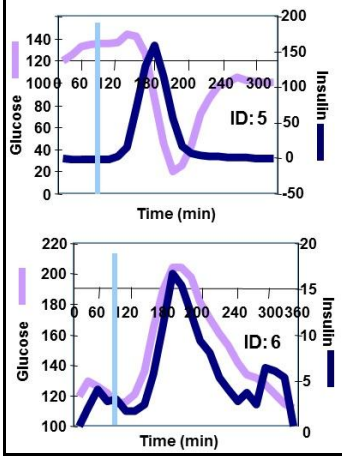
Source: Oramed Pharmaceuticals, Inc.

Oramed is currently conducting a Phase 2a trial in the U.S. under an FDA-sanctioned IND. This study was stipulated to be necessary by the agency ahead of advancing ORMD-0801 into a formal Phase 2b trial with the aim of demonstrating statistically significant impact of the drug on fasting blood glucose and other relevant parameters. The Phase 2a trial is a 30-subject study being conducted on an in-patient basis. Although it is randomized and double-blinded, patients are only being subjected to one week of treatment. The trial is, therefore, neither powered for efficacy signal detection nor designed with a sufficiently long treatment period to enable monitoring of treatment effect. The primary endpoint is safety and tolerability. We expect Oramed to announce data from this trial in the coming days; if positive, we anticipate that this should permit the firm to move ORMD-0801 into a Phase 2b multi-site trial in the U.S., which would likely enroll >100 individuals and assess the drug for a minimum of 24 weeks with the primary endpoint being reduction in FBG. Other endpoints would likely include reductions in CRP, HbA1c and various other inflammatory and glycemic markers.

Type 1 Diabetes Phase 2 Proof-of-Concept Data

In addition to the Phase 2a trial in type 2 diabetics, Oramed also conducted an exploratory study in Israel evaluating ORMD-0801 in type 1 diabetes. ORMD-0801 effectively prevented the expected rise in fasting blood glucose (FBG) concentrations among type 1 diabetics, demonstrating its utility in both type 1 and type 2 diabetics.

Figure 33: Type 1 Diabetes Phase 2a Proof-of-Concept Efficacy Data

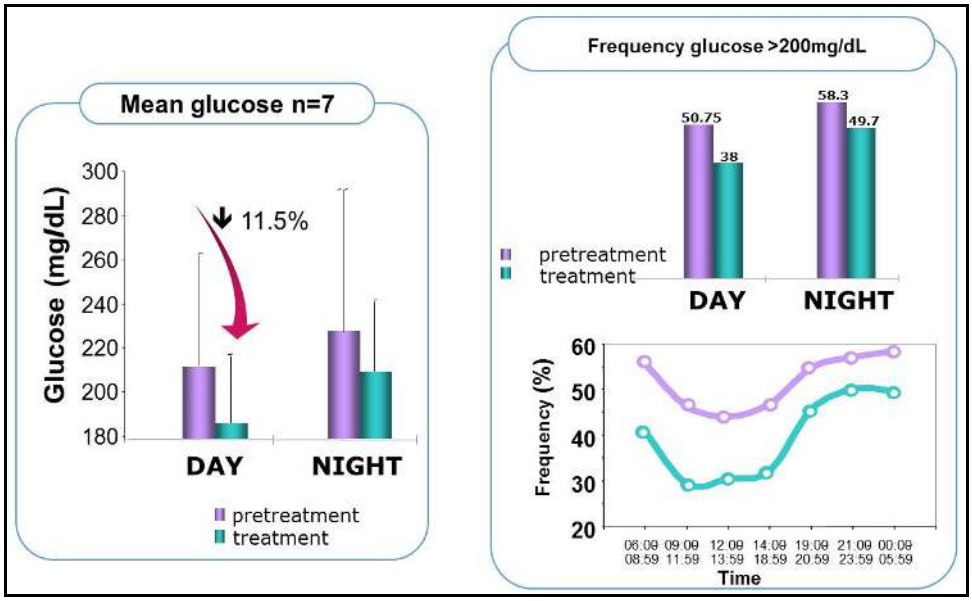


Subject #	Rate of glucose change (mg/dL*hr^{-1})
2	43.7
3	-0.7
4	-15.5
5	10.9
6	-6.1
7	-28.7
8	-18.4
9	5.5

Source: Oramed Pharmaceuticals, Inc.

While this trial was very tiny and did not involve a placebo arm, it did show the effectiveness of the drug at reducing FBG. In this trial, seven patients were administered ORMD-0801 at a dose of one capsule (8mg insulin) given thrice-daily. As shown below, the mean glucose level declined by 11.5% during the day. The frequency with which FBG levels rose above 200mg/dL was also reduced following treatment with ORMD-0801. Taken together, these data appear to indicate that ORMD-0801 could be capable of controlling FBG levels in type 1 diabetics as well as type 2 sufferers.

Figure 34: Type 1 Diabetes Phase 2a Results – Glucose Control Data

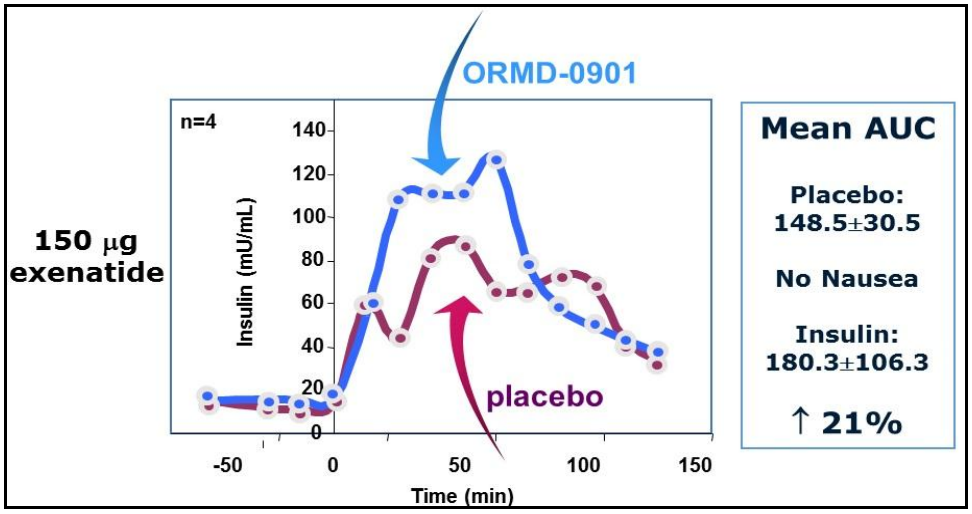


Source: Oramed Pharmaceuticals, Inc.

ORMD-0901 Experimental Data

We are herein presenting an overview of Oramed's data on its oral exenatide candidate, ORMD-0901. Thus far, to our knowledge, no other firm has comparable data to Oramed in the oral GLP-1 space. The first mover advantage confers significant commercial value, as has been illustrated with sitagliptin. Oramed's oral exenatide project, designated ORMD-0901, is currently in Phase 1b / 2a development. The preclinical data with ORMD-0901 were filed with the FDA in the third quarter of calendar 2013, with the aim of opening a formal IND that would permit trials to be conducted at U.S. clinical sites. We expect Oramed to begin clinical testing of ORMD-0901 in the U.S. in the second half of 2014. The figure below depicts exploratory, placebo-controlled clinical data generated in four healthy volunteers with ORMD-0901 in a pre-prandial setting.

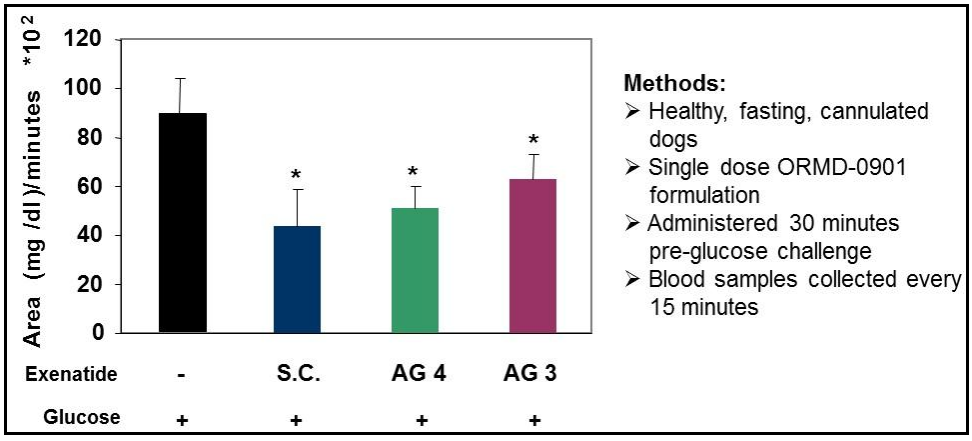
Figure 35: Type 1 Diabetes Phase 2a Proof-of-Concept Efficacy Data



Source: Oramed Pharmaceuticals, Inc.

In healthy, fasting, cannulated beagle dogs, orally-ingestible formulations of exenatide using the Oramed proprietary technology platform demonstrated the ability to blunt so-called "glucose excursions" following glucose challenge. Subcutaneous exenatide delivery amounted to a 51% reduction in mean glucose $AUC_{0\text{-}150}$, while the oral formulations AG4 and AG3 prompted 43% and 29% reductions, respectively (p=0.068, demonstrating a treatment-related trend for the sample size).

Figure 36: Type 1 Diabetes Phase 2a Proof-of-Concept Efficacy Data

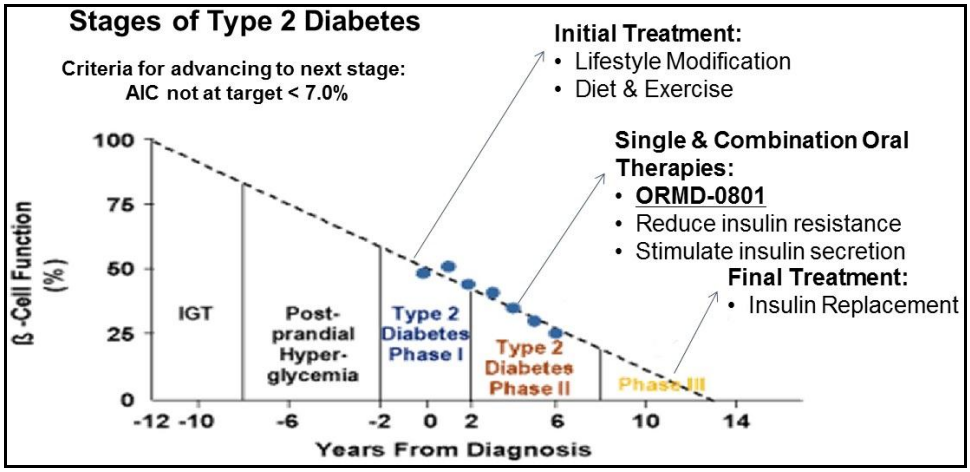


Source: Oramed Pharmaceuticals, Inc.

Diabetes Market Overview

We have assessed the opportunity for ORMD-0801 (an orally-ingestible capsule formulation of insulin) only in type 2 diabetes. It is important to note that Oramed is not attempting to replace injectable forms of insulin. Instead, the firm is trying to position ORMD-0801 as an earlier treatment option for patients with type 2 diabetes who have not yet had to resort to chronic insulin therapy. The goal would be to decrease insulin resistance as shown below, along with stimulating endogenous insulin secretion and attenuating some of the harm associated with hyperglycemic conditions that may build up overnight in type 2 diabetics. This is the rationale behind the evening administration time for ORMD-0801. We note that the convenient oral route of administration should be an important advantage for the drug in this context, and that our market assumptions do not factor in any usage in type 1 diabetes or as end-stage chronic insulin replacement.

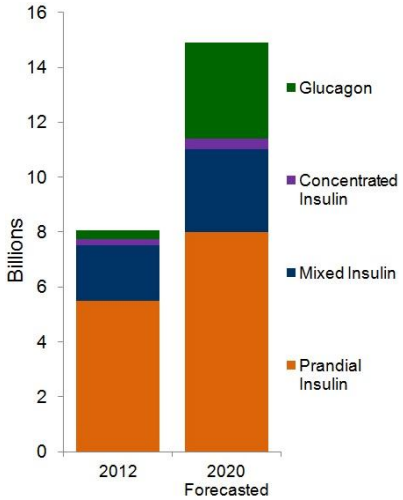
Figure 37: ORMD-0801 Treatment Continuum Positioning



Source: Oramed Pharmaceuticals, Inc.; Decision Resources

The figure below shows the insulin drug market. As can be seen from the bar chart, this segment of the overall diabetes drug sector is expected to expand from roughly $8 billion in 2012 to over $15 billion in 2020 – a growth rate significantly in excess of the roughly 7% compound annual growth rate (CAGR) of the diabetes drug market overall.

Figure 38: Insulin Market Growth

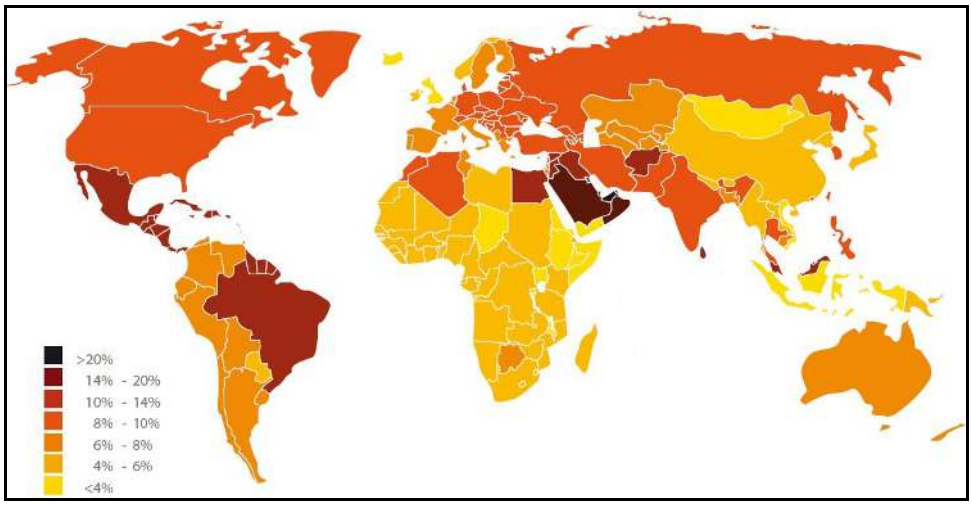


Source: Decision Resources

ORMD-0801 Market Model

We have modeled sales of ORMD-0801 in the target market – type 2 diabetes – within the context of the U.S. and Europe only. In these territories, we have assumed roughly 8.5% prevalence of disease within the U.S. population and roughly 7% prevalence in Europe. This yields a patient population of approximately 12.5 million individuals, which is expected to rise to over 16 million people over the course of the next decade as the prevalence of type 2 diabetes continues to increase. The figure below shows that global prevalence of diabetes is likely to rise significantly over the next 10 – 12 years.

Figure 39: Diabetes Estimated Global Prevalence (2025)



Source: World Health Organization (WHO)

In our view, Oramed could price its therapy at a level significantly above that of currently-deployed injectable insulin formulations, primarily because of the convenience of administration associated with an orally-ingestible capsule. We expect that Oramed or its potential future commercialization partner could price ORMD-0801 at roughly $1,600 per patient annually in the U.S. and at $1,200 per patient annually in Europe.

Since Oramed is a small, development-stage biotechnology company, we have assumed that ORMD-0801 would likely be out-licensed to a larger, more established firm – most likely a global participant in the diabetes market with an existing sales and marketing franchise in this domain. We believe that Oramed could elect to license out the global rights to ORMD-0801 following the completion of proof-of-concept Phase 2 development in the U.S. In our view, such a transaction would involve the payment of an upfront licensing fee, additional sums for attainment of development-stage as well as commercial milestones, and royalties on net sales of ORMD-0801.

We have assumed that the net royalty rate to Oramed on sales of ORMD-0801 would be in the 9% – 12.5% range, factoring in Oramed's own obligations to its other licensing partners. Our valuation does not currently involve any accounting for upfront or milestone fees, which is likely to be conservative. We have utilized a 35% effective tax rate and a discount rate of 20%, and we assume that ORMD-0801 could be launched in the U.S. in 2021 and in Europe in 2022. While we have projected that Oramed's potential future partner is only likely to achieve approximately 10% market share at peak in the 2026 time frame and roughly 5.5% market share in Europe, these assumptions still yield a $2.1 billion peak sales number. In our view, considering the total net sales of insulin products currently at roughly $8 billion and given the projected growth in the overall diabetes market, these assumptions do not seem particularly aggressive.

Table 6: Oral Insulin (ORMD-0801) Estimated Global Sales – Type 2 Diabetes Market Size Model

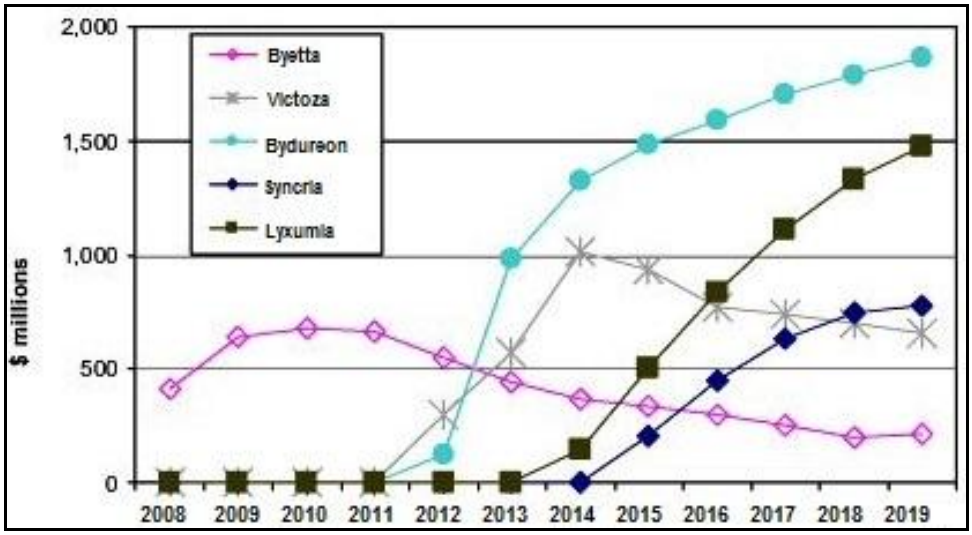
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
US Population	315,000,000	318,937,500	322,924,219	326,960,771	331,047,781	335,185,878	339,375,702	343,617,898	347,913,122	352,262,036	356,665,311	361,123,628	365,637,673	370,208,144	374,835,746	379,521,193	384,265,208	389,068,523
Patients with type 2 diabetes mellitus	26,145,000	27,109,688	28,094,407	28,772,548	29,132,205	29,496,357	30,204,437	30,925,611	31,312,181	31,703,583	32,456,543	32,862,250	33,638,666	34,059,149	34,859,724	35,674,992	36,505,195	36,961,510
Prevalence	*8.3%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*10%*	*10%*
Patients seeking treatment	6,536,250	6,777,422	7,023,602	7,193,137	7,283,051	7,374,089	7,551,109	7,731,403	7,828,045	7,925,896	8,114,136	8,215,563	8,409,666	8,514,787	8,714,931	8,918,748	9,126,299	9,240,377
% seeking treatment	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
ORMD-0801 Penetration Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	2.1%	3.9%	5.7%	8.2%	9.5%	7.8%	5.6%	3.2%	1.9%
Patients on ORMD-0801									23,484	166,444	316,451	468,287	689,593	808,905	679,765	499,450	292,042	175,567
Average annual cost per patient ($)									1,600	1,648	1,697	1,748	1,801	1,855	1,910	1,968	2,027	2,088
U.S. ORMD-0801 sales ($ MM)									**38**	**274**	**537**	**819**	**1,242**	**1,500**	**1,299**	**983**	**592**	**367**
European Population	400,000,000	405,000,000	410,062,500	415,188,281	420,378,135	425,632,861	430,953,272	436,340,188	441,794,440	447,316,871	452,908,332	458,569,686	464,301,807	470,105,580	475,981,899	481,931,673	487,955,819	494,055,267
Patients with type 2 diabetes mellitus	28,000,000	29,160,000	30,344,625	31,139,121	31,528,360	31,922,465	32,321,495	33,598,194	34,018,172	34,890,716	36,232,667	37,144,145	37,608,446	38,548,658	40,458,461	41,446,124	42,452,156	43,476,863
Prevalence	*7%*	*7%*	*7%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*9%*	*9%*	*9%*	*9%*
Patients seeking treatment	5,600,000	5,832,000	6,068,925	6,227,824	6,305,672	6,384,493	6,464,299	6,719,639	6,803,634	6,978,143	7,246,533	7,428,829	7,521,689	7,709,732	8,091,692	8,289,225	8,490,431	8,695,373
% seeking treatment	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
ORMD-0801 Penetration Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.5%	1.8%	3.1%	4.5%	5.6%	5.2%	4.6%	2.5%	1.2%
Patients on ORMD-0801										34,891	130,438	230,294	338,476	431,745	420,768	381,304	212,261	104,344
Average annual cost per patient ($)										1,200	1,236	1,273	1,311	1,351	1,391	1,433	1,476	1,520
European ORMD-0801 sales ($ MM)										**42**	**161**	**293**	**444**	**583**	**585**	**546**	**313**	**159**
Total ORMD-0801 sales ($ MM)									**38**	**316**	**698**	**1,112**	**1,686**	**2,084**	**1,884**	**1,529**	**905**	**525**
Royalty rate to Oramed Pharmaceuticals									**9.0%**	**10.0%**	**11.0%**	**12.0%**	**12.0%**	**12.5%**	**12.5%**	**12.5%**	**12.5%**	**12.5%**
Total ORMD-0801 royalty-based revenue ($ MM)									**3**	**32**	**77**	**133**	**202**	**260**	**236**	**191**	**113**	**66**

Source: Company Reports and Aegis Capital Corp. estimates

ORMD-0901 Market Model

We have modeled sales of ORMD-0901 in the target market – type 2 diabetes – within the context of the U.S. and Europe only. In our view, the oral exenatide product opportunity is potentially even more compelling than that of the oral insulin, since exenatide is still a highly-priced premium product and is also considered to have extremely high efficiency in achieving insulin sensitization among the currently-marketed anti-hyperglycemic drugs. The figure below shows how GLP-1 agonist product sales have evolved since these drugs were originally introduced.

Figure 40: GLP-1 Agonist Projected Sales (2008 – 2019E)



Source: Wolters Kluwer Healthcare Analytics; IMS Health; Datamonitor

We expect that Oramed or its potential commercial partner could price ORMD-0801 at $8,000 per patient annually in the U.S. and at $6,000 per patient annually in Europe. This is comparable, in our view, to the pricing of other GLP-1 agonists. Similar to the case of ORMD-0801, we have assumed that ORMD-0901 would likely be out-licensed to a larger, more established firm – most likely a global participant in the diabetes market with an existing sales and marketing franchise in this domain. We believe that Oramed could elect to license out the global rights to ORMD-0901 following the completion of proof-of-concept Phase 2 development in the U.S. In our view, such a transaction would involve payment of an upfront licensing fee, other sums for attainment of development-stage as well as commercial milestones, and royalties on net sales of ORMD-0901.

In our model, the net royalty rate to Oramed on sales of ORMD-0901 is projected to be in the 7% – 10% range, factoring in obligations to other licensing partners. Our valuation does not account for any putative upfront or milestone fees. We utilize a 35% effective tax rate and a discount rate of 20%, and we assume that ORMD-0901 could be launched in the U.S. in 2019 and in Europe in 2020. While we have projected that Oramed's potential future partner is only likely to achieve 2.5% market share at peak in the 2026 time frame and roughly 2% market share in Europe, these assumptions still yield a $2.8 billion peak sales number. Although total net sales of GLP-1 agonists were less than $2 billion in 2012, given the projected growth in their market penetration rates, we do not consider these assumptions aggressive. Victoza, a once-daily injection, is slated to exceed $1 billion in sales in 2013, less than four years post-approval. Bydureon is also projected to exceed $1 billion in U.S. annual sales, and it is an injectable as well (albeit once-weekly). Near-term competitive threats could emerge in the forms of Syncria, Lyxumia, ZP2929, MOD-6030 and other GLP-1 agonists not currently on the market.

Table 7: Oral Exenatide (ORMD-0901) Estimated Global Sales – Type 2 Diabetes Market Size Model

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
US Population	315,000,000	318,937,500	322,924,219	326,960,771	331,047,781	335,185,878	339,375,702	343,617,898	347,913,122	352,262,036	356,665,311	361,123,628	365,637,673	370,208,144	374,835,746	379,521,193	384,265,208	389,068,523
Patients with type 2 diabetes mellitus	26,145,000	27,109,688	28,094,407	28,772,548	29,132,205	29,496,357	30,204,437	30,925,611	31,312,181	31,703,583	32,456,543	32,862,250	33,638,666	34,059,149	34,859,724	35,674,992	36,505,195	36,961,510
Prevalence	*8.3%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*9%*	*10%*	*10%*
Patients seeking treatment	6,536,250	6,777,422	7,023,602	7,193,137	7,283,051	7,374,089	7,551,109	7,731,403	7,828,045	7,925,896	8,114,136	8,215,563	8,409,666	8,514,787	8,714,931	8,918,748	9,126,299	9,240,377
% seeking treatment	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
ORMD-0901 Penetration Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%	0.7%	1.1%	1.4%	1.7%	2.2%	2.5%	2.1%	1.7%	1.4%	1.1%	0.7%
Patients on ORMD-0901							15,102	54,120	86,108	110,963	137,940	180,742	210,242	178,811	148,154	124,862	100,389	64,683
Average annual cost per patient ($)							8,000	8,240	8,487	8,742	9,004	9,274	9,552	9,839	10,134	10,438	10,751	11,074
U.S. ORMD-0901 sales ($ MM)							**121**	**446**	**731**	**970**	**1,242**	**1,676**	**2,008**	**1,759**	**1,501**	**1,303**	**1,079**	**716**
European Population	400,000,000	405,000,000	410,062,500	415,188,281	420,378,135	425,632,861	430,953,272	436,340,188	441,794,440	447,316,871	452,908,332	458,569,686	464,301,807	470,105,580	475,981,899	481,931,673	487,955,819	494,055,267
Patients with type 2 diabetes mellitus	28,000,000	29,160,000	30,344,625	31,139,121	31,528,360	31,922,465	32,321,495	33,598,194	34,018,172	34,890,716	36,232,667	37,144,145	37,608,446	38,548,658	40,458,461	41,446,124	42,452,156	43,476,863
Prevalence	*7%*	*7%*	*7%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*8%*	*9%*	*9%*	*9%*	*9%*
Patients seeking treatment	5,600,000	5,832,000	6,068,925	6,227,824	6,305,672	6,384,493	6,464,299	6,719,639	6,803,634	6,978,143	7,246,533	7,428,829	7,521,689	7,709,732	8,091,692	8,289,225	8,490,431	8,695,373
% seeking treatment	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
ORMD-0901 Penetration Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	0.8%	1.1%	1.2%	1.4%	1.6%	1.8%	1.5%	1.3%	0.9%	0.5%
Patients on ORMD-0901								20,159	54,429	76,760	86,958	104,004	120,347	138,775	121,375	107,760	76,414	43,477
Average annual cost per patient ($)								6,000	6,180	6,365	6,556	6,753	6,956	7,164	7,379	7,601	7,829	8,063
European ORMD-0901 sales ($ MM)								**121**	**336**	**489**	**570**	**702**	**837**	**994**	**896**	**819**	**598**	**351**
Total ORMD-0901 sales ($ MM)							**121**	**567**	**1,067**	**1,459**	**1,812**	**2,379**	**2,845**	**2,754**	**2,397**	**2,122**	**1,678**	**1,067**
Royalty rate to Oramed Pharmaceuticals							**7.0%**	**7.5%**	**8.0%**	**8.5%**	**9.0%**	**9.5%**	**10.0%**	**10.0%**	**10.0%**	**10.0%**	**10.0%**	**10.0%**
Total ORMD-0901 royalty-based revenue ($ MM)									**85**	**124**	**163**	**226**	**285**	**275**	**240**	**212**	**168**	**107**

Source: Company Reports and Aegis Capital Corp. estimates

Intellectual Property

The Oramed intellectual property (IP) portfolio is shown below. Some of the firm's most valuable IP is still pending; in particular, a patent application that the firm filed on the usage of a combination regimen composed of both ORMD-0801 and ORMD-0901.

Table 8: Oramed Pharmaceuticals Patent Portfolio

Patent / Application Number	Title	Filing/Grant Date	Expiry Date*	Country	Description
PCT/IL2009/000223	Methods and compositions for oral administration of proteins	26/Feb/09		PCT	Directed to combination of 2 protease inhibitors
2009230718	Methods and compositions for oral administration of proteins	15/Oct/10	26-Feb-29	Australia	Notice of Allowance received
PI 0907077-0	Methods and compositions for oral administration of proteins	25/Sep/10	26-Mar-28	Brazil	Requested examination; Awaiting first office action.
2719272	Methods and compositions for oral administration of proteins	22/Sep/10	26-Feb-29	Canada	Request for examination due 26.2.14.
200980118673.4	Methods and compositions for oral administration of proteins	22/Nov/10	26-Feb-29	China	Awaiting Certificate of Patent.
9725603.6	Methods and compositions for oral administration of proteins	12/Oct/10	26-Feb-29	EU	Awaiting European Search Report/Examination Report
3996/KOLNP/2010	Methods and compositions for oral administration of proteins	25/Oct/10	26-Feb-29	India	Requested examination; Awaiting first office action
208165	Methods and compositions for oral administration of proteins	15/Sep/10	26-Feb-29	Israel	Responded to first Official Action; awaiting further Official Action or allowance
2011-501337	Methods and compositions for oral administration of proteins	24/Sep/10	26-Feb-29	Japan	Notice of Allowance received
588603	Methods and compositions for oral administration of proteins	9/Jul/12	26-Feb-29	New Zealand	Granted
2010/07522	Methods and compositions for oral administration of proteins	27/Dec/12	26-Feb-29	South Africa	Granted
2010141292	Methods and compositions for oral administration of proteins	26/Oct/10	26-Feb-29	Russia	Granted
12/934,754	Methods and compositions for oral administration of proteins	27/Sep/10	26-Feb-29	USA	Responded to first Official Action; awaiting further Official Action or allowance
PCT/IL2006/001019	Methods and compositions for oral administration of proteins	31/Aug/06		PCT	
2006288703	Methods and compositions for oral administration of proteins	5/Jan/12	8/31/2026	Australia	Granted
2,621,577	Methods and compositions for oral administration of proteins	31/Aug/06	8/31/2026	Canada	Pending
200680041231.0	Methods and compositions for oral administration of proteins	4/May/08	8/31/2026	China	Pending
6780455.9	Methods and compositions for oral administration of proteins	6/Mar/08	8/31/2026	EU	Pending
8113931.7	Methods and compositions for oral administration of proteins	24/Dec/08	8/31/2026	Hong Kong	Pending EP grant
1140/CHENP/2008	Methods and compositions for oral administration of proteins	6/Mar/08	8/31/2026	India	Pending
189956	Methods and compositions for oral administration of proteins	1/May/12	8/31/2026	Israel	Granted
5222727	Methods and compositions for oral administration of proteins	15/Mar/13	8/31/2026	Japan	Granted
PCT/IL2009/000461	Methods and compositions for oral administration of exenatide	3/May/09		PCT	
2009245294	Methods and compositions for oral administration of exenatide	19/Nov/10	5/3/2029	Australia	Pending
PI 0908292-1	Methods and compositions for oral administration of exenatide	5/Nov/10	5/5/2028	Brazil	Pending
2,723,434	Methods and compositions for oral administration of exenatide	3/Nov/10	5/3/2029	Canada	Pending
200980116254.7	Methods and compositions for oral administration of exenatide	5/Nov/10	5/3/2029	China	Pending; undergoing reexamination
9742563.1	Methods and compositions for oral administration of exenatide	2/Dec/10	5/3/2029	EU	Pending
11109635.9	Methods and compositions for oral administration of exenatide	12/Sep/11	5/3/2029	Hong Kong	Pending
4599/KOLNP/2010	Methods and compositions for oral administration of exenatide	2/Dec/10	5/3/2029	India	Pending
208967	Methods and compositions for oral administration of exenatide	27/Oct/10	5/3/2029	Israel	Pending
2011-508050	Methods and compositions for oral administration of exenatide	4/Nov/10	5/3/2029	Japan	Pending
589390	Methods and compositions for oral administration of exenatide	5/Mar/12	5/3/2029	New Zealand	Granted
2010/08090	Methods and compositions for oral administration of exenatide	29/Aug/12	5/3/2029	South Africa	Granted
2010146372	Methods and compositions for oral administration of exenatide	12/Nov/10	5/3/2029	Russia	Pending
13/855,346	Methods and compositions for oral administration of exenatide	2/Apr/13	5/3/2029	USA	Pending (Divisional)
PCT/IL2013/050091	Protease inhibitor-containing compositions and methods for producing and using them	31/Jan/13	31-Jan-33	PCT	Oramed-style compositions comprising improved SBTI
PCT/IL2013/050007	Methods and compositions for treating diabetes	3/Jan/13	3-Jan-33	PCT	Oramed-type combinations of insulin and exenatide
61/763,996	Methods and compositions for treating non-alcoholic fatty liver disease (NAFLD), hepatic steatosis, and sequellae thereof	13/Feb/13	to be determined	US provisional	Utility/PCT applications due 3-Jan-2014

Source: Company reports

Financial Review and Outlook

Revenue: We do not forecast any revenue from either product sales or research activities in either 2013 or 2014. Management does not provide guidance.

Gross Margins: As a development-stage company, there are historically no costs of goods sold. We project that the gross margins on both ORMD-0801 and ORMD-0901 are likely to exceed 90% upon launch, which should enable healthy cash flow generation.

Operating Expenses: For fiscal 2014, we estimate roughly $6.5 million in operating expenses. We estimate R&D of only $3.8 million in fiscal 2014, as the company advances its lead drug candidates, ORMD-0801 and ORRMD-0901, through proof-of-concept development in the U.S. However, the R&D expense should rise in fiscal 2015 to $5.4 million, as larger trials for ORMD-0801 and ORMD-0901 begin enrollment.

Taxes: We assume a roughly 40% corporate tax rate after all net operating loss carry-forwards are exhausted. However, in our view the firm should not have significant tax liabilities prior to 2020. At the end of fiscal 2013, Oramed Pharmaceuticals had ~$5.6 million in U.S. federal net operating loss carry-forwards, expiring in the years 2025 through 2032. We would expect that the firm could have as much as $60 million – $70 million in net operating losses by the time ORMD-0801 receives approval in the U.S. for the treatment of diabetes. Accordingly, it is relatively unlikely – at least in the initial revenue-generating years – that the firm would have a substantial effective tax rate.

Share Count: The outstanding fully-diluted share count stands at roughly 10.3 million. The fully-diluted shares account for the conversion of 2.3 million shares in the form of options and warrants. Given the company's cash position, strategic goals, and capital structure, a share repurchase program is unlikely, in our view.

EPS: We forecast EPS of ($0.74) and ($0.92) for fiscal 2014 and 2015, respectively. Currently, we cannot estimate when the company is likely to achieve cash flow break-even or attain sustainable profitability. However, if the firm's lead drug candidate, ORMD-0801, demonstrates positive safety data and additional indications of efficacy in the recently-completed Phase 2a trial, we anticipate that Oramed should be able to obtain a partnership or option-based licensing agreement on this compound. Upfront and other licensing fees could offset the firm's cash burn on a temporary basis.

Balance Sheet: The firm held roughly $7.5 million in cash at the end of the third quarter of 2013, following the completion of a registered direct follow-on offering in July 2013. We anticipate that the firm may need to raise additional capital near-term with which to fund operations through the second half of 2014 and beyond. Following the receipt of data from its pilot study, we believe that Oramed Pharmaceuticals may elect to raise additional capital in order to have as many strategic options available as possible (including being able to launch the drug in the U.S. independently using either a contract or in-house specialty sales force).

Cash Flow: We estimate that the firm will consume roughly $6.5 million in operating cash flows during fiscal 2014 and a further $9.3 million during fiscal 2015. We think additional funding may be required within the next six to nine months to support envisaged operational activities, including the completion of additional clinical trials with both ORMD-0801 as well as ORMD-0901.

Guidance: The firm does not provide financial guidance.

Financing History / Capital Structure

Over the course of its history since inception, Oramed Pharmaceuticals has raised roughly $40 million to support its operating activities. In our view, the firm has demonstrated an extremely capital-efficient operating history. Many other companies in the pharmaceuticals arena expend hundreds of millions of dollars in drug development in order to advance a single drug candidate into pivotal clinical trials.

Table 9: Financing History

		Net Proceeds	Shares	Price	Notes
Private Company					
	Common Stock	$ -			
	Common Stock	$ -			
	Convertible Preferred	$ -			
	Convertible Preferred	$ -			
Public Company					
	IPO	$ -			
	Secondary	$ 4,238,008	658,144	$ 7.00	July 2013 register direct
		$ 4,442,149	1,137,336	$ 4.44	2012 PIPE. Net of finders fee. Warrant coverage of 50% (five-year warrants at $6.00)
		$ 628,630	199,172	$ 3.16	DNA share swap - Oct 2012
		$ 3,694,212	984,209	$ 3.84	2010-11 PIPE. Net of finders fee. Warrant coverage of 35% (five-year warrants at $6.00)
		$ 5,029,800	722,434	$ 7.20	July 2008 PIPE. Warrant coverage of 50% (three-year warrants at $10.80)
		$ 2,580,000	430,121	$ 6.00	July 2007 PIPE. Warrant coverage of 100% (three-year warrants at $9.00)
	Total	$ 20,612,799	4,131,416	$ 5.29	
Total Amount		$ 41,225,598	658,144		

Source: Oramed Pharmaceuticals Inc.

From inception through the end of fiscal year 2013 (calendar end-August 2013), the firm incurred losses in an aggregate amount of $22.1 million. The firm has anticipated that it would require approximately $5.7 million to finance its operations through the end of fiscal 2014 (calendar end-August 2014).

Table 10: Capital Structure

	Number of Shares	Exercise Price	Expiration Date	Total Cash
Cash, cash equivalents and marketable securities				$7,518,955
Common Stock	7,947,872			
Warrants	848,824	$0.48	4/13/2023	$407,436
Options	1,511,522	$0.36	7/2/2018	$544,148
Fully Diluted Shares	**10,308,218**			**$8,470,538**

Source: Oramed Pharmaceuticals, Inc.

Between August and November 2012, Oramed completed a private placement pursuant to which the firm sold an aggregate of 1,137,336 "units" at a purchase price of $4.44 per unit for total consideration of roughly $5 million. Each unit consisted of one share of the firm's common stock and a five-year warrant to purchase 0.50 of a share of the firm's common stock at an exercise price of $6.00 per share.

Subsequently, in July 2013, the company sold 658,144 shares of common stock, at a price of $7.00 per share, to various investors in a registered direct offering. This yielded aggregate net proceeds of approximately $4.2 million. In July and August 2013, the firm issued a total of 33,709 shares of its common stock, valued at $244,457, in the aggregate, to certain service providers. In our view, Oramed may raise more capital near-term in order to extend the operational window beyond the runway available with existing funds.

Management Team

The firm's management comprises individuals with substantial track records in the biotechnology industry. The two co-founders are still members of the executive team.

Nadav Kidron, Esq.
President & Chief Executive Officer
The founder of Oramed, Nadav Kidron has served as CEO since the firm's inception in 2006. He is an Advisory Board Member for The Trendlines Group, a group that invests in and develops innovation-based businesses; a director of Entera Bio, a joint venture formed by Oramed and DNA Biomedical Solutions; and an international lecturer on Israel's entrepreneurial culture and its roots as a source of innovative ideas. He holds a Bachelor of Law Degree and an International Masters in Business Administration, both from Bar-Ilan University in Israel. Mr. Kidron is a fellow of the Merage Business Executive Leadership Program and a member of the Israeli Bar Association.

Miriam Kidron, Ph.D.
Chief Scientific Officer
Since co-founding Oramed in 2006 with her son Nadav, Dr. Miriam Kidron has served as the firm's chief scientist. She originally earned her Ph.D. in biochemistry from the Hebrew University of Jerusalem. For nearly 20 years, Dr. Kidron has been a senior researcher in the Diabetes Unit at Hadassah-Hebrew University Medical Center in Jerusalem, Israel, earning the Bern Schlanger Award for her work on diabetes research. She was formerly a visiting professor at the Medical School at the University of Toronto and is a member of the American, European and Israeli Diabetes Associations.

Yifat Zommer, CPA, M.B.A.
Chief Financial Officer
Ms. Zommer joined the company in 2009. She previously served as CFO for Witech Communications Ltd and CTWARE Ltd. Prior to that she was an audit manager in PriceWaterhouseCoopers Israel, where she served for five years. Ms. Zommer holds a Bachelor of Accounting and Econimics degree from the Hebrew University and a Master's degree in Business Administration (MBA) from Tel-Aviv University. She is a certified public accountant in Israel.

Ehud Arbit, M.D.
Director, R&D
Dr. Arbit joined the company in mid-2008, having previously served as the vice president of Medical Research at Emisphere Technologies. Previously, Dr. Arbit held various academic positions as Professor at Cornell University Medical College, and was also a member of the Memorial Sloan-Kettering Cancer Center (MSKCC) in New York City, where he served as a division director. Dr. Arbit has numerous publications in peer reviewed journals and had served on the editorial boards of several medical journals.

Josh Hexter
Chief Operating Officer / Vice-President, Business Development
Josh Hexter joined Oramed in the spring of 2013. He brings to Oramed more than 15 years of biotech industry experience in various operational and business development roles. He was most recently Executive Director of Corporate In-Licensing at BioLineRx Ltd. Previously, he worked in private equity and venture capital, where he served as CEO of a VC-backed startup, Biosensor Systems Design, where he was instrumental in shaping the company's strategic focus and in forging business development agreements with Fortune 100 companies. Mr. Hexter earned a bachelor's degree from the University of Wisconsin and a master's degree in management from Boston University.

Board of Directors

The firm's Board of Directors includes several senior-level individuals with substantial expertise in the biotech industry. In our view, the board possesses the strategic and industrial expertise necessary to help successfully guide the direction of the firm.

Nadav Kidron, Esq.
Chairman of the Board
See management biographies above.

Miriam Kidron, Ph.D.
Non-Independent Director
See management biographies above.

Michael Berelowitz, M.D.
Independent Director / Head, Scientific Advisory Board
Dr. Berelowitz has been involved in the biomedical sciences for over 40 years across clinical medical practice, basic and clinical research, and teaching. Over the course of his career, he has authored and co-authored more than 100 peer-reviewed journal articles and book chapters in the areas of pituitary growth hormone regulation, diabetes and metabolic disorders. After completing his medical and specialty training at the University of Cape Town Medical School, Dr. Berelowitz held academic faculty positions at the University of Chicago – Michael Reese Hospital and the University of Cincinnati College of Medicine, and then served as Professor of Medicine, Pharmacology and Biophysics at SUNY Stony Brook School of Medicine for over a decade, where he led the Division of Endocrinology and Metabolism. In 1996, Dr. Berelowitz joined Pfizer, Inc. and over the course of the next 15 years was assigned positions of increasing responsibility leading the diabetes unit, cardiovascular group, global medical organization and finally serving as Senior VP and Head of Clinical Development and Medical Affairs in the Specialty Care Business Unit, in which role he worked from 2009 - 2011. Dr. Berelowitz has chaired the Task Force on Research of the New York State Council on Diabetes and has served on the Board of Directors of the American Diabetes Association and the Clinical Initiatives Committee of the Endocrine Society. He has also served on several editorial boards of peer-reviewed publications in his area of expertise, including *The Journal of Clinical Endocrinology and Metabolism*, *Endocrinology*, *Reviews in Endocrine and Metabolic Disorders* and *Clinical Diabetes*. Dr. Berelowitz currently serves as a biopharmaceuticals consultant, and is a member of several Boards of Directors or scientific advisory boards, including the Endocrine Fellows Foundation, Metacure, Ltd. and Haptocure, Ltd., in addition to his appointment on Oramed's board.

Harold Jacob, M.D.
Independent Director
Dr. Jacob joined the Oramed Board in August 2008, having previously served on the company's scientific advisory board. He practiced clinical gastroenterology in New York and served as Chief of Gastroenterology at St. Johns Episcopal Hospital and South Nassau Communities Hospital, and was a Clinical Assistant Professor of Medicine at the State University of New York (SUNY). Dr. Jacob founded and served as Editor-in-Chief of *Endoscopy Review* and has authored numerous publications in the field of gastroenterology. Currently, he is president of Medical Instrument Development Inc., a company which provides a range of support and consulting services as well as patenting its own proprietary medical device. He has advised a spectrum of companies and served as a consultant and then as the Director of Medical Affairs at Given Imaging Ltd., which is the company that developed the first swallowable wireless pill camera for inspection of the intestine. He has licensed patents to a number of companies including Kimberly Clark Ballard. Currently, he is CEO of NanoVibronix, a medical device company using surface acoustics to prevent catheter-acquired infection as well as for other uses.

Gerald Ostrov
Independent Director
Mr. Ostrov began his career with Johnson & Johnson's Health Care Division in 1976. In 1982, he left Johnson & Johnson to become Vice President of Marketing for Ciba-Geigy's Consumer Pharmaceuticals division. Ciba-Geigy merged with Sandoz to form Novartis in 1996. Mr. Ostrov was named President of Ciba Consumer Pharmaceuticals in 1985 and served in that capacity until rejoining Johnson & Johnson in 1991 as President of the corporation's Personal Products Company. In 1993, he was promoted to Company Group Chairman and added Northern Europe Consumer & Personal Care products to his responsibilities. In 1995, he became responsible for all Consumer and Personal Care businesses in North America. He assumed Vision Care global responsibilities on October 1, 1998 and retired in 2006 as Company Group Chairman responsible for Johnson & Johnson's Worldwide Vision Care businesses. Mr. Ostrov came out of retirement to serve as Chairman and CEO of Bausch & Lomb from January 2008 to March 2010. He stabilized and restructured this business following its privatization by a syndicate of private equity investors led by Warburg Pincus. His focus was on creating an innovative pipeline to build long-term value, improving the firm's organizational structure and recruiting qualified leadership, and reducing costs while improving quality. Mr. Ostrov increased operating profit and cash flow even while operating in the dire economic conditions of 2008 and 2009, and served as a consultant to Bausch & Lomb after he departed his operational role at the firm in order to ensure continuity for the company. Bausch & Lomb was subsequently acquired by Valeant Pharmaceuticals International in 2013 for $8.7 billion. Mr. Ostrov consults and lectures regarding new technologies in the consumer products and consumer medical device fields. He serves on the Board of Orasure, a NASDAQ-listed firm that recently received FDA approval for the first over-the-counter human immunodeficiency virus (HIV) diagnostic product, currently available through various retailers. He is also a founder, shareholder, and board member of Adlens Beacon, a privately-held company currently focusing on the introduction of the first self-adjustable reading glasses product to optical retailers. He also serves in a leadership role at various philanthropic organizations.

Leonard Sank
Independent Director
Mr. Sank has been an Oramed director since 2007. He is an entrepreneur and businessman, based in South Africa, who has over 20 years of experience in important leadership roles in developing businesses. He currently serves on the board of directors of several other companies in a variety of sectors.

Scientific Advisory Board

The Scientific Advisory Board contains various luminaries in the scientific and clinical domains of the biotechnology and pharmaceuticals sectors. This group also includes individuals with substantial expertise in diabetes and metabolic disorders.

Michael Berelowitz, M.D.
Independent Director / Head, Scientific Advisory Board
See Board of Directors biographies above.

John Amatruda, M.D.
Professor Amatruda was formerly the Senior Vice President and Franchise Head, Diabetes and Obesity at Merck Research Laboratories. He is board-certified in internal medicine, endocrinology and metabolism and has been involved with several novel candidate compounds, INDs, translational studies, development programs and four NDAs. Prof. Amatruda comes to Oramed with over 15 years of experience in academic medicine and 17 years of experience in industry. He has an extensive track record as a principal investigator for basic and clinical research projects funded by the National Institutes of Health (NIH), as well as in teaching, clinical practice, and management. At Bayer, he created and managed a metabolism drug discovery group for 10 years where he was responsible for the strategy of multiple drug candidates while he also developed external collaborations and was on the senior leadership team of the firm's international drug discovery platform. At Merck, he led drug development groups focusing on the treatment of diabetes, obesity, atherosclerosis and cardiovascular disease. Under his supervision, these groups filed four worldwide regulatory submissions applying for the approval of novel drugs. Prof. Amatruda also has experience with Advisory Committee meetings, agency interactions, labeling and launches. As the franchise head at Merck, he was also responsible for discovery research. He has often published in peer-reviewed journals and also has served as a reviewer for several journals including *Diabetes Care* and the *Journal of Clinical and Experimental Medicine*. Prof. Amatruda received his B.A. from Yale University and his M.D. from the Medical College of Wisconsin, and completed his internship and residency in internal medicine and fellowship in endocrinology and metabolism at The Johns Hopkins Hospital.

Nir Barzilai, M.D.
Born in Israel, Dr. Barzilai was the chief medic of the Israeli army before enrolling in the Israel Institute of Technology Medical School, where he received his medical degree. As a medical student, he provided medical assistance in various developing countries and conducted biomedical research at Baylor College of Medicine, the NIH, and The Royal Free Hospital in London, U.K. His residency was in Medicine and Geriatrics at Hadassah Hospital (Hebrew University) and at Yale University, followed by training in Endocrinology and Molecular Biology at Cornell University Medical College and at The Albert Einstein College of Medicine. Dr. Barzilai has published over 200 peer-reviewed papers, reviews and chapters in textbooks. He is the founding Director of the Institute for Aging Research at the Albert Einstein College of Medicine Glenn Center for the Biology of Human Aging and the NIH-funded Nathan Shock Center for Excellence in Biology of Aging. He is a Chaired Professor of Medicine and Genetics and a member of the Diabetes Research Center, the Divisions of Endocrinology and Geriatrics. Dr. Barzilai was a recipient of numerous prestigious awards, is an advisor to the NIH on several projects and initiatives, and is a member of the NIA-Biology study section. He serves on several advisory boards for different pharmaceutical companies and start-ups, is a member of various editorial boards and serves as a reviewer for numerous other journals.

Ele Ferrannini, M.D., Ph.D.
Prof. Ferrannini has published over 500 papers and 50 book chapters, and is amongst the most frequently-cited scientists in his field. He has had extensive training in nuclear medicine and internal medicine, specializing in diabetes studies. Prof. Ferrannini additionally completed – *cum laude* – a sub-specialty in diabetes and metabolic diseases from the University of Torino in Italy. He has worked at various institutions including the Department of Internal Medicine, University of Pisa School of Medicine; the CNR (National Research Council) Institute of Clinical Physiology, Pisa, Italy; the Department of Clinical Physiology at the Karolinska Institute in Stockholm, Sweden; and the Diabetes Division of the Department of Medicine at the University of Texas Health Science Center in San Antonio, TX. He was previously the President of the European Association for the Study of Diabetes (EASD), the European equivalent of the American Diabetes Association (ADA), and was awarded the 2011 Claude Bernard Prize and Lecture during the 47th Annual EASD Meeting in Lisbon, Portugal.

Avram Hershko, M.D., Ph.D.
Professor Hershko joined the Oramed Scientific Advisory Board in July 2008. He gained his M.D. in 1965 and Ph.D. in 1969 from the Hebrew University – Hadassah Medical School in Jerusalem, and served as a physician in the Israel Defense Forces (1965-67). After a post-doctoral fellowship with Gordon Tomkins at the University of San Francisco (1969-72), he joined the faculty of the Haifa Technion, becoming professor in 1980. He is now Distinguished Professor in the Unit of Biochemistry in the B. Rappaport Faculty of Medicine of the Technion. His research interests concern the mechanisms by which cellular proteins undergo degradation. Dr. Hershko and his colleagues showed that cellular proteins are degraded by a highly selective proteolytic system. This system tags proteins for destruction by linkage a protein called ubiquitin, which had previously been identified in many tissues, as the name suggests, but whose function was previously unknown. Subsequent work in Hershko's and many other laboratories has shown that the ubiquitin system has a vital role in controlling a wide range of cellular processes, such as the regulation of cell division, signal transduction and DNA repair. Abnormalities in the ubiquitin system result in diseases such as certain types of cancer. For his work in the characterization of the cellular pathways governing protein degradation, Dr. Hershko was awarded the Nobel Prize in Chemistry for 2004 in conjunction with his former doctoral student, Aaron Ciechanover, and their colleague, Irwin Rose. His many honors include the Israel Prize for Biochemistry (1994), the Gardner Award (1999), the Lasker Prize for Basic Medical Research (2000), the Wolf Prize for Medicine (2001) and the Louisa Gross Horwitz Award (2001). Dr. Hershko is a member of the Israel Academy of Sciences (2000) and a Foreign Associate of the U.S. Academy of Sciences (2003).

Derek LeRoith, M.D., Ph.D.
Professor LeRoith has been a member of Oramed's scientific advisory board since 2006 and is currently the Director of Research of the Division of Endocrinology, Diabetes and Bone Diseases at the Mount Sinai School of Medicine in New York, NY. He has worked at the NIH since 1979 in the fields of endocrinology and diabetes and rose to be head of the Diabetes Branch at the NIH in Bethesda, MD, a position he held until 2005. In 2010, he also became the Director of the Diabetes and Metabolism Clinical Research Center of Excellence, Clinical Research Institute at the Rambam – Health Care Campus in Israel. His main interests have focused on roles of insulin and insulin-like growth factors (IGFs) in normal and disease states. In these areas, he has published over 500 peer-reviewed articles and reviews in high-profile journals. He is also the senior editor of a textbook on diabetes, and has edited books on the IGFs. Dr. LeRoith has made major contributions to the understanding of the basic pathophysiology of Type 2 diabetes as well as the role of the IGFs in various disorders – especially cancer – and is considered a world expert on these topics. He is the editor of a number of diabetes- and growth factor-related journals, has been on the advisory boards of a number of firms, and co-chairs two national committees that deal with the education of endocrinologists and primary care physicians.

Public Companies Mentioned in this Report:

Agios Pharmaceuticals (AGIO/NASDAQ)

Alcobra Ltd. (ADHD/NASDAQ – Buy)

AstraZeneca (AZN/NYSE)

Biodel (BIOD/NASDAQ)

BioLineRx (BLRX/NASDAQ – Buy)

Compugen (CGEN/NASDAQ)

Eli Lilly & Co. (LLY/NYSE)

Furiex Pharmaceuticals (FURX/NASDAQ)

Galectin Therapeutics (GALT/NASDAQ – Buy)

GlaxoSmithKline (GSK/NYSE)

Idenix Pharmaceuticals (IDIX/NASDAQ)

Infinity Pharmaceuticals (INFI/NASDAQ)

Johnson & Johnson (JNJ/NYSE)

Lexicon Pharmaceuticals (LXRX/NASDAQ)

Neostem (NBS/NASDAQ – Buy)

OncoMed Pharmaceuticals (OMED/NASDAQ)

Orexigen Therapeutics (OREX/NASDAQ)

Pfizer (PFE/NYSE)

Sanofi S.A. (SNY/NYSE)

Table 11: Oramed Pharmaceuticals, Inc. (ORMD) – Historical Income Statements, Financial Projections

FY end August 31
$ in thousands, except per share data

		2013A					2014E					
	2012A	1QA	2QA	3QA	4QA	2013A	1QE	2QE	3QE	4QE	2014E	2015E
Revenue												
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-
Service revenue	-	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-	-
Expenses												
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-	-
Research & development	1,681	393	749	836	295	2,272	800	900	1,000	1,100	3,800	5,400
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-	-
General and administrative	1,203	339	511	499	683	2,032	700	750	800	850	3,100	4,200
Total expenses	2,884	732	1,260	1,335	978	4,304	1,500	1,650	1,800	1,950	6,900	9,600
Gain (loss) from operations	(2,884)	(732)	(1,260)	(1,335)	(978)	(4,304)	(1,500)	(1,650)	(1,800)	(1,950)	(6,900)	(9,600)
Other income/expense												
Financial income	13	72	67	85	(43)	180	90	75	60	30	255	-
Financial expense	(199)	(299)	(33)	(6)	25	(313)	(25)	(25)	(25)	(25)	(100)	(120)
Realized loss on marketable securities	(184)	-	6	(39)	164	131	-	-	-	-	-	-
Reclassification adjustment	-	-	(51)	(18)	(21)	(90)	-	-	-	-	-	-
Unrealized gain on available-for-sale securities	-	-	54	(55)	264	263	-	-	-	-	-	-
Total investment income and other	(370)	(227)	43	(34)	389	170	65	50	35	5	155	(120)
Loss before provision for income taxes	(3,254)	(959)	(1,217)	(1,369)	(589)	(4,133)	(1,435)	(1,600)	(1,765)	(1,945)	(6,745)	(9,720)
Deferred income tax benefit	90	-	-	-	205	205	-	-	-	-	-	-
Net loss/income	(3,164)	(959)	(1,217)	(1,369)	(383)	(3,928)	(1,435)	(1,600)	(1,765)	(1,945)	(6,745)	(9,720)
Net loss per share (basic)	(0.54)	(0.14)	(0.17)	(0.19)	(0.09)	(0.59)	(0.18)	(0.18)	(0.18)	(0.20)	(0.74)	(0.92)
Net loss per share (diluted)	(0.54)	(0.14)	(0.17)	(0.19)	(0.09)	(0.59)	(0.18)	(0.18)	(0.18)	(0.20)	(0.74)	(0.92)
Weighted average number of shares outstanding (basic)	5,884	6,826	7,213	7,223	7,924	7,209	7,973	8,898	9,823	9,873	9,142	10,560
Weighted average number of shares outstanding (diluted)	5,884	6,826	7,213	7,223	7,924	7,209	7,973	8,898	9,823	9,873	9,142	10,560

Source: Company Reports and Aegis Capital Corp. estimates

Table 12: Oramed Pharmaceuticals, Inc. (ORMD) – Historical Balance Sheet, Financial Projections

FY end August 31
$ in thousands, except per share data

		2013A					2014E					
	8/31/12A	11/30	2/28	5/30	8/31	8/31/13A	11/30	2/28	5/31	8/31	8/31/14E	8/31/15E
Assets												
Current assets:												
Cash and cash equivalents	4,431	5,531	2,040	1,105	2,272	2,272	6,284	19,531	17,966	16,221	16,221	28,426
Short-term deposits	454	-	2,317	2,324	5,247	5,247	-	-	-	-	-	-
Marketable securities	200	1,065	987	803	956	956	956	956	956	956	956	956
Restricted cash	16	16	16	16	16	16	16	16	16	16	16	16
Accounts receivable	88	76	440	334	-	-	-	-	-	-	-	-
Prepaid expenses	2	19	36	62	90	90	90	90	90	90	90	90
Related parties	0	2	3	1	5	5	5	5	5	5	5	5
Grants receivable	85	100	100	179	58	58	58	58	58	58	58	58
Total current assets	5,276	6,808	5,939	4,824	8,644	8,644	7,409	20,657	19,092	17,347	17,347	29,552
Property and equipment	5	2	2	6	6	6	6	6	6	6	6	6
Amounts funded in respect of employee retirement rights	5	5	7	7	6	6	6	6	6	6	6	6
Other assets	9	9	9	9	5	5	5	5	5	5	5	5
Total Assets	5,295	6,825	5,957	4,846	8,660	8,660	7,425	20,673	19,108	17,363	17,363	29,568
Liabilities and shareholder equity												
Current liabilities												
Accounts payable and accrued expenses	597	287	422	399	451	451	451	451	451	451	451	451
Related parties	-	-	-	-	-	-	-	-	-	-	-	-
Other current liabilities	47	47	47	47	47	47	47	47	47	47	47	47
Total current liabilities	644	335	469	446	498	498	498	498	498	498	498	498
Deferred revenue	-	-	-	-	-	-	-	-	-	-	-	-
Other long-term liabilities	637	-	-	-	-	-	-	-	-	-	-	-
Employee rights upon retirement	7	12	12	13	8	8	8	8	8	8	8	8
Long-term deferred tax liability	228	228	228	228	23	23	23	23	23	23	23	23
Total Liabilities	1,517	575	709	687	529	529	529	529	529	529	529	529
Shareholder's equity												
Common stock	80	87	87	87	95	95	95	97	97	97	97	99
Additional paid-in capital	21,590	24,778	24,993	25,273	29,856	29,856	29,856	44,501	44,501	44,501	44,501	65,425
Accumulated other comprehensive income	-	236	245	132	303	303	303	303	303	303	303	303
Deficit accumulated	(17,892)	(18,851)	(20,076)	(21,333)	(22,124)	(22,124)	(23,359)	(24,759)	(26,324)	(28,069)	(28,069)	(36,789)
Total shareholder's equity	3,778	6,250	5,248	4,159	8,131	8,131	6,896	20,143	18,578	16,833	16,833	29,038
Total liability and shareholder's equity	5,295	6,825	5,957	4,846	8,660	8,660	7,425	20,673	19,108	17,363	17,363	29,568

Source: Company Reports and Aegis Capital Corp. estimates

Table 13: Oramed Pharmaceuticals, Inc. (ORMD) – Historical Statement of Cash Flows, Financial Projections

FY end August 31
$ in thousands, except per share data

		2013A					2014E					
	2012A	1QA	2QA	3QA	4QA	2013A	1QE	2QE	3QE	4QE	2014E	2015E
Cash flows from operating activities												
Net loss	(3,344)	(959)	(1,226)	(1,256)	(791)	(4,232)	(1,435)	(1,600)	(1,765)	(1,945)	(6,745)	(9,720)
Adjustments for:												
Depreciation and amortization	15	2	1	1	2	5	-	-	-	-	-	-
Amortization of debt discount	-	-	-	-	-	-	-	-	-	-	-	-
Exchange differences	62	19	6	(14)	8	19	-	-	-	-	-	-
Stock based compensation	271	218	223	186	92	719	200	200	200	200	800	1,000
Common stock issued for services	108	-	-	94	151	244	-	-	-	-	-	-
Gain on sale of investment	-	-	(28)	(41)	18	(51)	-	-	-	-	-	-
Impairment of investments	184	-	-	-	-	-	-	-	-	-	-	-
Impairment of available for sale securities	-	-	-	-	-	-	-	-	-	-	-	-
Imputed interest	-	-	-	-	-	-	-	-	-	-	-	-
Exchange of warrants	-	297	-	-	-	297	-	-	-	-	-	-
Changes in fair value of warrant liabilities	143	(45)	-	-	-	(45)	-	-	-	-	-	-
Change in operating assets & liabilities		-	-	-	-	-	-	-	-	-	-	-
Prepaid expenses and other current assets	(31)	(21)	(383)	3	397	(3)	-	-	-	-	-	-
Restricted cash	-	-	-	-	-	-	-	-	-	-	-	-
Accounts payable and accrued expenses	203	(310)	135	(23)	52	(146)	-	-	-	-	-	-
Liability for employee rights upon retirement	(2)	5	(1)	1	(5)	1	-	-	-	-	-	-
Provision for uncertain tax position	90	-	-	-	(205)	(205)	-	-	-	-	-	-
Total change in operating assets & liabilities	260	(326)	(249)	(19)	240	(353)	-	-	-	-	-	-
Cash flows from operating activities	**(2,302)**	**(793)**	**(1,273)**	**(1,050)**	**(280)**	**(3,395)**	**(1,235)**	**(1,400)**	**(1,565)**	**(1,745)**	**(5,945)**	**(8,720)**
Cash flows from investing activities												
Purchase of property and equipment	(2)	-	-	(5)	(2)	(6)	-	-	-	-	-	-
Purchase of short term deposits	(475)	-	(1,863)	-	(3,984)	(5,847)	-	-	-	-	-	-
Proceeds from sale of short term deposits	1,800	454	(454)	-	1,054	1,054	5,247	-	-	-	5,247	-
Proceeds from sale of investment and marketable securities	450	-	114	113	-	227	-	-	-	-	-	-
Funds in respect of employee rights upon retirement	(4)	(0)	(1)	(2)	1	(2)	-	-	-	-	-	-
Other	-	-	-	-	5	5	-	-	-	-	-	-
Cash flows from investing activities	**1,769**	**454**	**(2,204)**	**106**	**(2,926)**	**(4,570)**	**5,247**	**-**	**-**	**-**	**5,247**	**-**
Cash flows from financing activities												
Proceeds from sales of common stocks and warrants - net of iss	3,489	1,458	(8)	-	4,264	5,715	-	14,648	-	-	14,648	20,925
Proceeds from exercise of warrants and options	-	-	-	-	110	110	-	-	-	-	-	-
Proceeds from convertible notes	-	-	-	-	-	-	-	-	-	-	-	-
Proceeds from short term note payable	-	-	-	-	-	-	-	-	-	-	-	-
Cash flows from financing activities	**3,489**	**1,458**	**(8)**	**-**	**4,374**	**5,824**	**-**	**14,648**	**-**	**-**	**14,648**	**20,925**
Net increase/ decrease in cash and cash equivalents	**2,956**	**1,120**	**(3,485)**	**(943)**	**1,168**	**(2,140)**	**4,012**	**13,248**	**(1,565)**	**(1,745)**	**13,949**	**12,205**
Effect of exchange rate	(39)	(20)	(7)	8	(0)	(18)	-	-	-	-	-	-
Cash and cash equivalents, beginning of period	1,513	4,431	5,531	2,040	1,105	4,431	2,272	6,284	19,531	17,966	2,272	16,221
Cash and cash equivalents, end of period	4,431	5,531	2,040	1,105	2,272	2,272	6,284	19,531	17,966	16,221	16,221	28,426

Source: Company Reports and Aegis Capital Corp. estimates

Required Disclosures

Price Target

Our 12-month price target is $25.00 per share.

Valuation Methodology

We utilize a discounted cash flow-based risk-adjusted Net Present Value (rNPV) approach to value the shares. Using this methodology, we derive a total firm value of $315 million, which translates into a price objective of $25.00 per share, assuming $15 million in cash and approximately 12 million shares outstanding (fully-diluted) as of the end of fiscal 2014.

Risk Factors

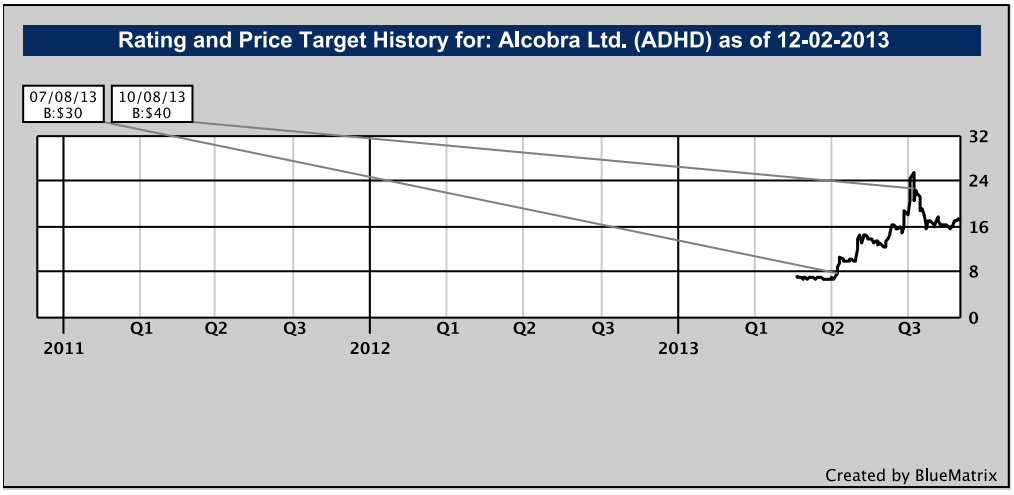
Issues that could prevent the achievement of our price objective include, but are not limited to, clinical, regulatory, competitive, reimbursement and financial risks. Drugs in clinical development may not advance due to inadequate safety, efficacy, or tolerability. Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a drug candidate at all. The firm may require substantial funding to complete the clinical development of its candidates and establish commercial infrastructure, which could be dilutive to current shareholders. We expect competition for the company's drugs from several public and private companies developing pharmaceuticals. Sales of the firm's drugs could depend upon reimbursement from private, as well as public, reimbursement agencies.

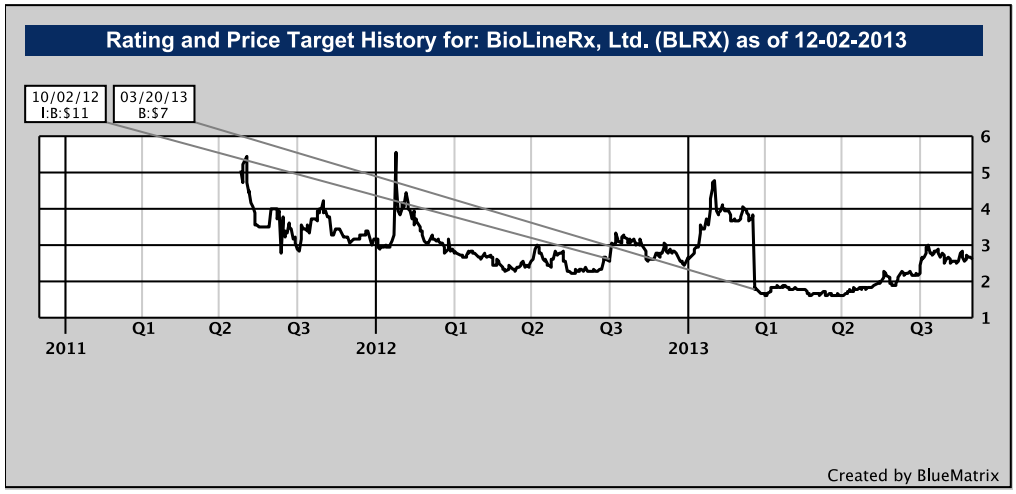
For important disclosures go to www.aegiscap.com.

Research analyst compensation is dependent, in part, upon investment banking revenues received by Aegis Capital Corp.

Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.

Aegis Capital Corp. has performed investment banking services for and received fees from Oramed Pharmaceuticals, Inc., Alcobra Ltd. and Galectin Therapeutics, Inc. within the past 12 months.




Rating and Price Target History for: BioLineRx, Ltd. (BLRX) as of 12-02-2013
10/02/12
I:B:$11
03/20/13
B:$7
6
5
4
3
2
1
Q1
Q2
Q3
Q1
Q2
Q3
Q1
Q2
Q3
2011
2012
2013
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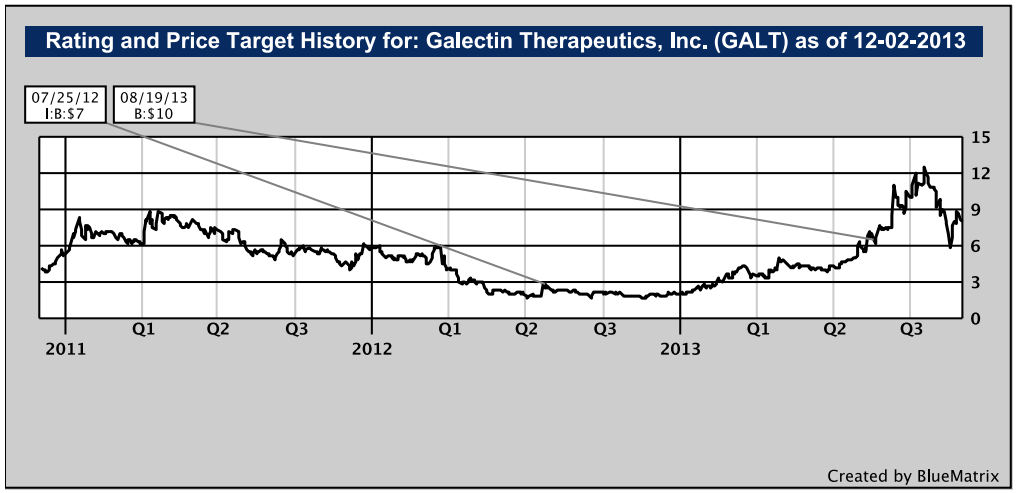
Rating and Price Target History for: Galectin Therapeutics, Inc. (GALT) as of 12-02-2013
07/25/12
I:B:$7
08/19/13
B:$10
15
12
9
6
3
0
Q1
Q2
Q3
Q1
Q2
Q3
Q1
Q2
Q3
2011
2012
2013
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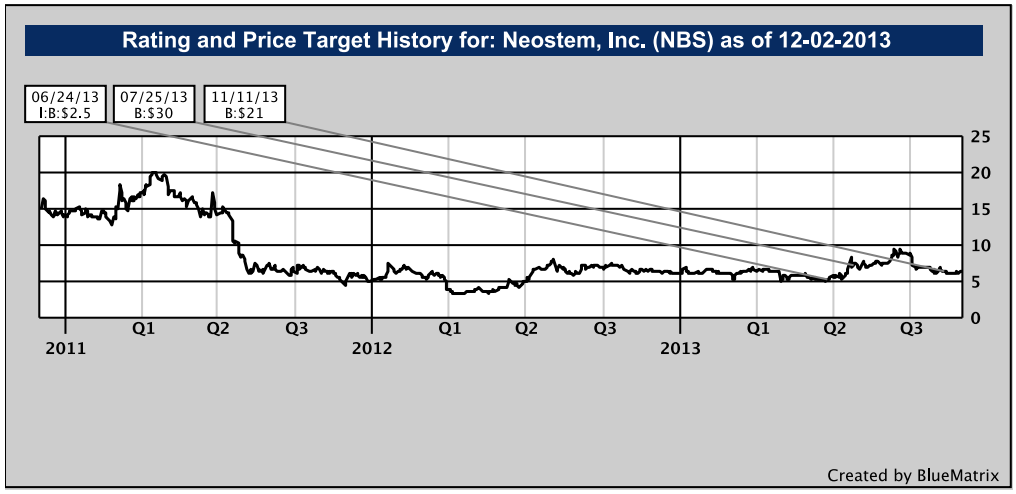

Rating	Percent	Investment Banking Services/Past 12 Mos. Percent
BUY [BUY]	82.05	28.12
HOLD [HOLD]	17.95	14.29
SELL [SELL]	0.00	0.00

Meaning of Ratings

A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

The information contained herein is based upon sources believed to be reliable but is not guaranteed by us and is not considered to be all inclusive. It is not to be construed as an offer or the solicitation of an offer to sell or buy the securities mentioned herein. Aegis Capital Corp., its affiliates, shareholders, officers, staff, and/or members of their families, may have a position in the securities mentioned herein, and, before or after your receipt of this report, may make or recommend purchases and/or sales for their own accounts or for the accounts of other customers of the Firm from time to time in the open market or otherwise. Opinions expressed are our present opinions only and are subject to change without notice. Aegis Capital is under no obligation to provide updates to the opinions or information provided herein. Additional information is available upon request.

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