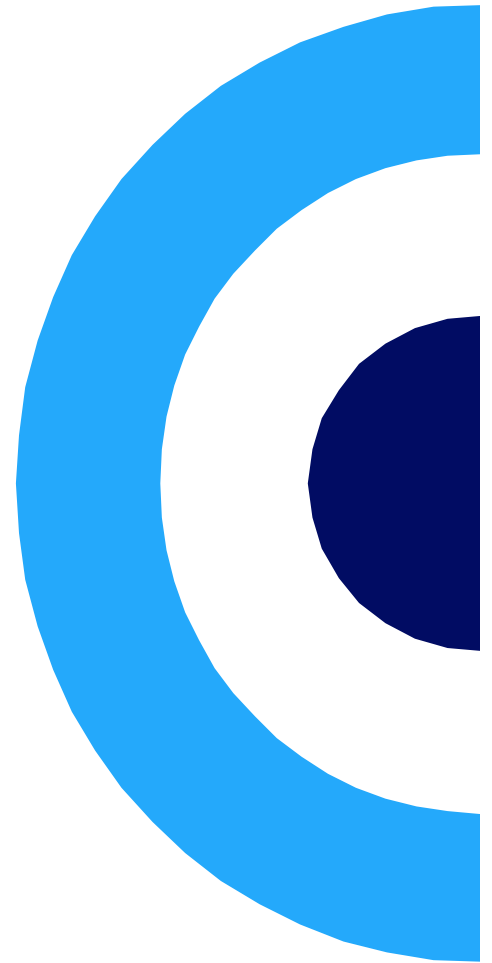


Windhover Therapeutic Partnership Conference: Diabetes and Metabolic Diseases

Nov 4, 2008

Healogix, Inc.
100 Witmer Road, Suite 260
Horsham, PA 19044
Office: 215.863.8160
Fax: 215.830.5051
Email: info@healogix.com
www.healogix.com

HEALOGIX



Type 2 Diabetes: Major Opportunity



⦿ **233,619**

(# Who Died in 2005 in the US from Diabetes and Related Causes)

⦿ **23.2 MM**

(# of People in the US with Type 2 Diabetes)

⦿ **\$178B**

(Annual Medical Expense in US Attributable to Type 2 Diabetes)

⦿ **\$12.5B**

(Annual Expenditures for Type 2 Diabetes Medications in 2007)

⦿ **32% and 17%**

(Estimated % of People in US and EU who are Overweight)

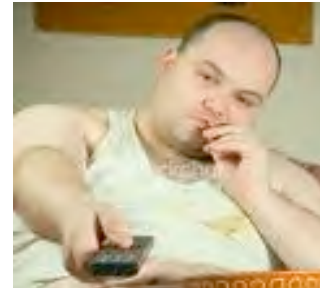
The Key Drivers of Type 2 Diabetes and Metabolic Diseases



- ⦿ **Aging Population**



- ⦿ **Sedentary Population**



- ⦿ **Increasingly Obese Population**



High unmet medical needs for diabetes and obesity



⦿ Obesity

- ⦿ Drug that works with a minimum of side effects and/or safety concerns so it can be used broadly

⦿ Type 1 diabetes:

- ⦿ Prevention
- ⦿ Disease altering therapies

⦿ Type 2 diabetes:

- ⦿ New therapies to slow or stop progression
- ⦿ Improve diagnosis rate

⦿ Improved compliance in treatment/control of both diseases

Obesity is an Area with Extreme Unmet Need

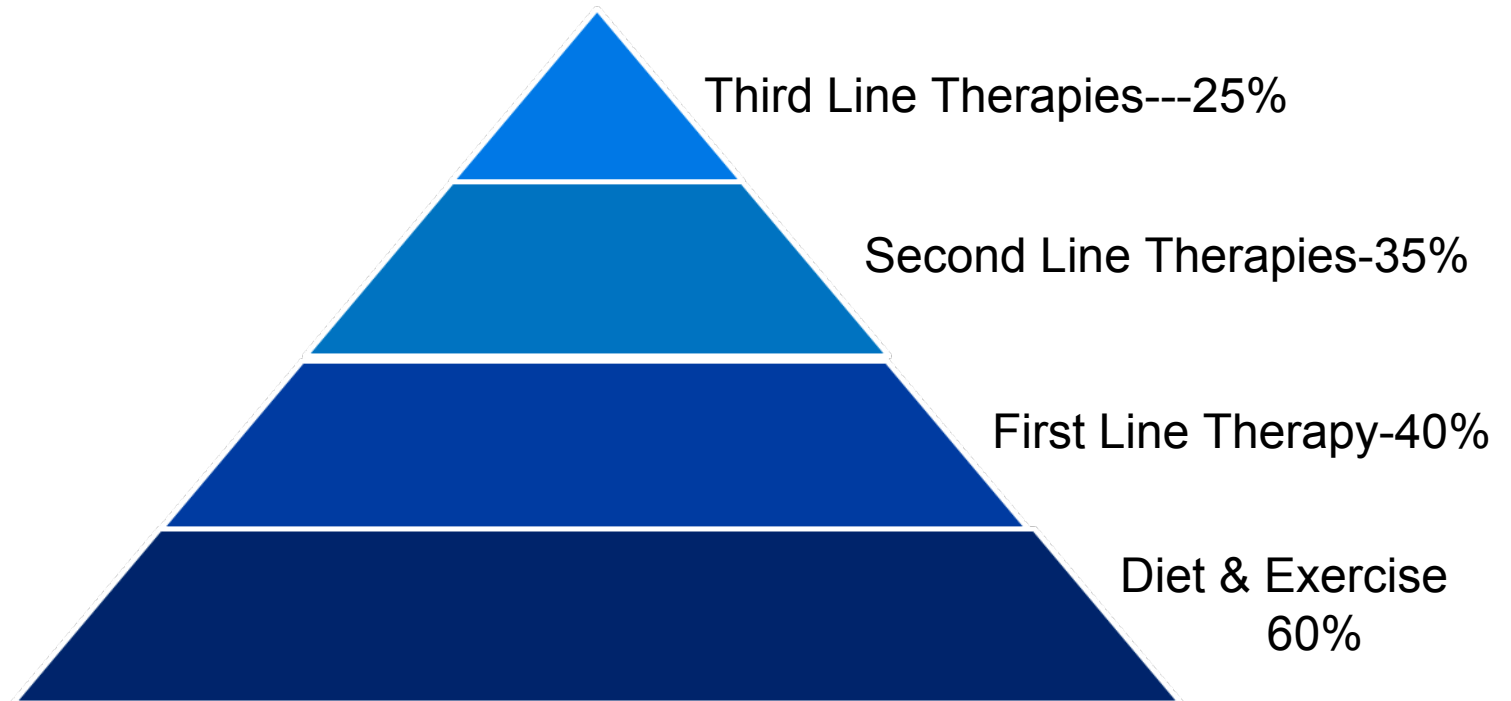


- ⦿ Failures Associated with Rimonabant have been a major setback for products in this area
- ⦿ GSK's Alli® has reinvigorated this category somewhat
- ⦿ The challenges are developing a product that clears the high safety hurdles
- ⦿ No doubt, there is huge financial promise for any company that succeeds

Type 2 Diabetes is Preventable and Controllable



- “Diabetes is a disease that can be kept in check in most cases by simply practicing prevention,” Dr. Sami Beg, Associate Medical Director of U.S. Preventive Medicine

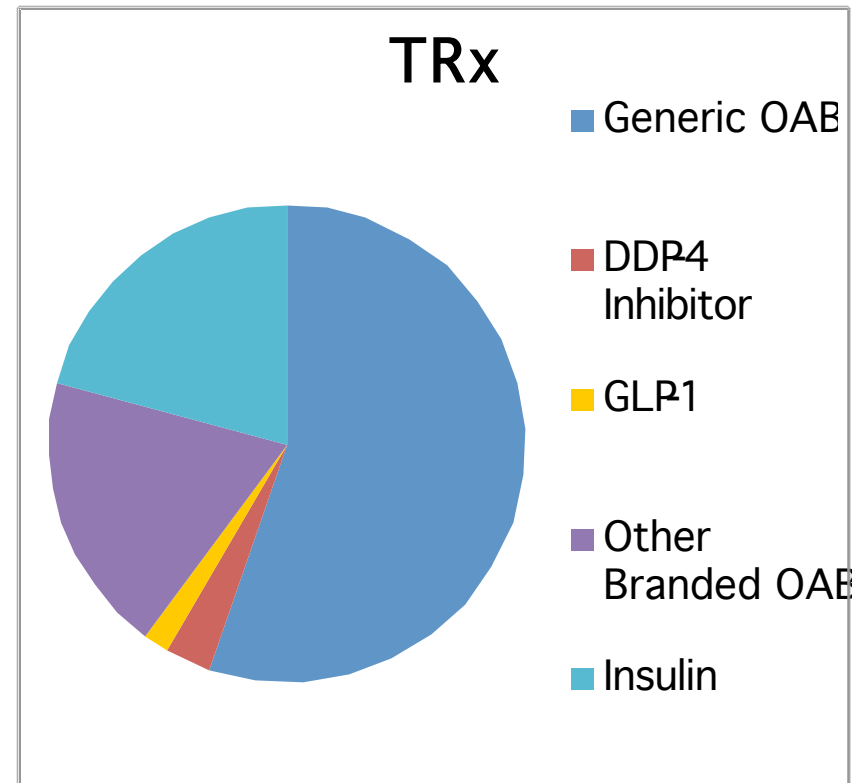


Type 2 Diabetes Market is Currently Dominated by Mature Products



- ◉ Metformin and Sulphonylurea are most commonly used Oral anti diabetes drug
- ◉ DDP-4, GLP-1 and TZD are used in later stage of treatment process, often in combination with older drugs or insulin.
- ◉ DDP-4 US sales quickly approached one \$billion after launched in 2007
- ◉ GLP-1's US sale passed \$500M after three years in the market

Profile of Drugs Being Used to Treat Type 2 Diabetes in



Source: Ver

The Good and Bad News of Type 2 Diabetes Drug Development



The Good News

- Seemingly insatiable current and future demand
- Both physicians and payers recognize the need to treat and control Type 2 Diabetes
- Add on therapy has been supported thus far by payers
- Drug companies can usually know if a drug is effective quite early in development



The Bad News

- High safety requirements
- Large trials are required
- Large trials are expensive
- Lots of future competition
- Order of entry and effective marketing will be critical
- Payers could easily implement treatment algorithms as well as within class step edits

Late stage diabetes products pipeline is crowded with products in DPP-4 ,GLP-1, TZD Classes



- ◉ Large Market Potential but Competitively Crowded
- ◉ Order of Entry, Product Differentiation, and Sales and Marketing Spend will Drive Success

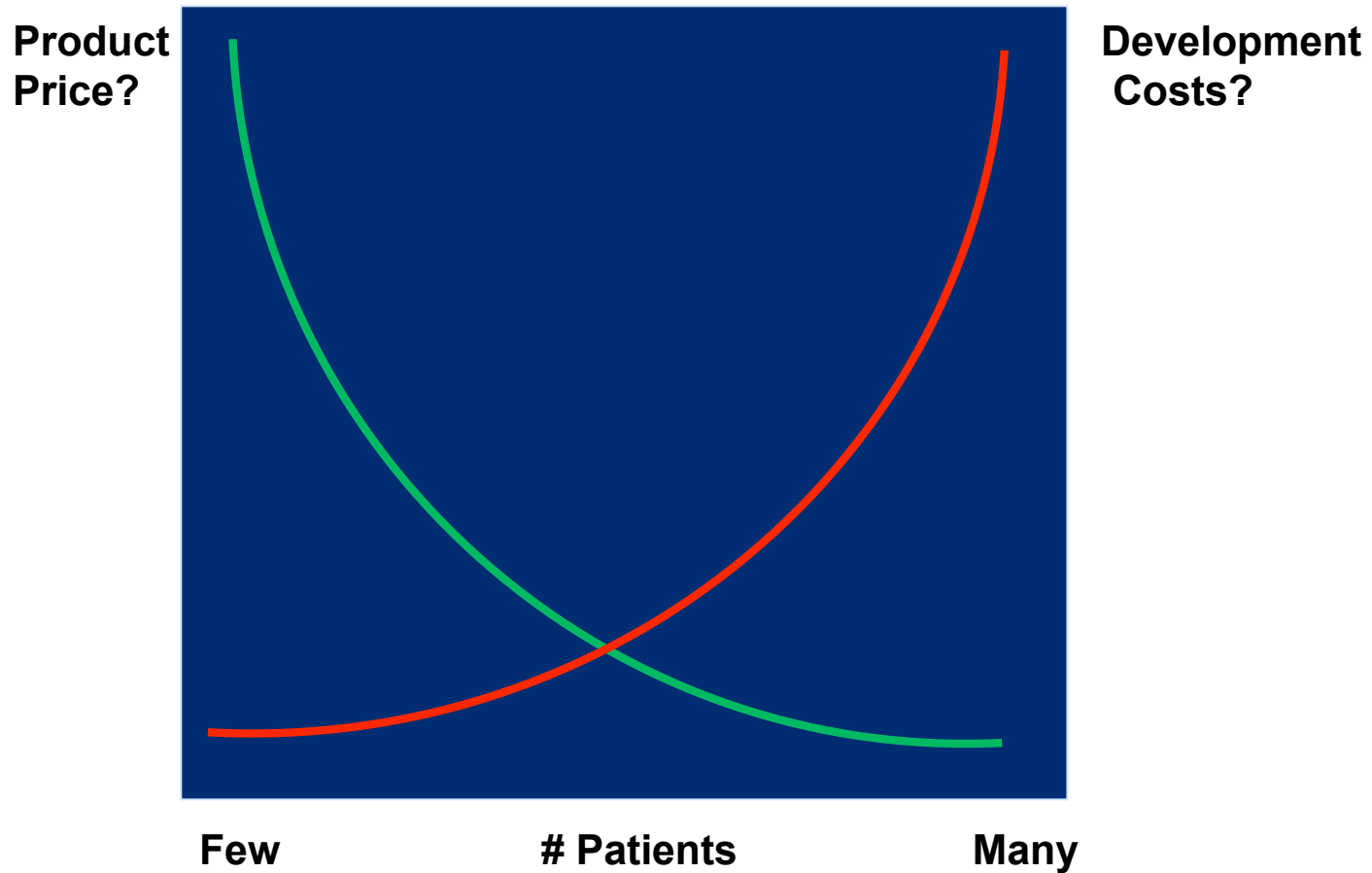
Near Term Type 2 Diabetes Pipeline

Company Name	Product / Molecule	Description
Takeda	Alogliptin / SYR- 322	DPP-4 inhibitor
Novartis	Galvus / vildagliptin	DPP-4 inhibitor
Bristol-Myers Squibb	Saxagliptin / BMS-477118	DPP-4 inhibitor
Boehringer Ingelheim	BI 1356 BS	DPP-4 inhibitor
Novo Nordisk	Liraglutide / NN2211	GLP-1 agonist
Elixir Pharmaceuticals	Glufast / mitiglinide	GLP-1 agonist
Sanofi-aventis	AVE0010	GLP-1 agonist
Daiichi Sankyo Inc	Rivoglitazone / CS-011	PPAR-gamma agonist
Dr Reddys Laboratories	Balaglitazone	PPAR-gamma agonist

Can the Promise of Future Success Offset the High Costs of Development?



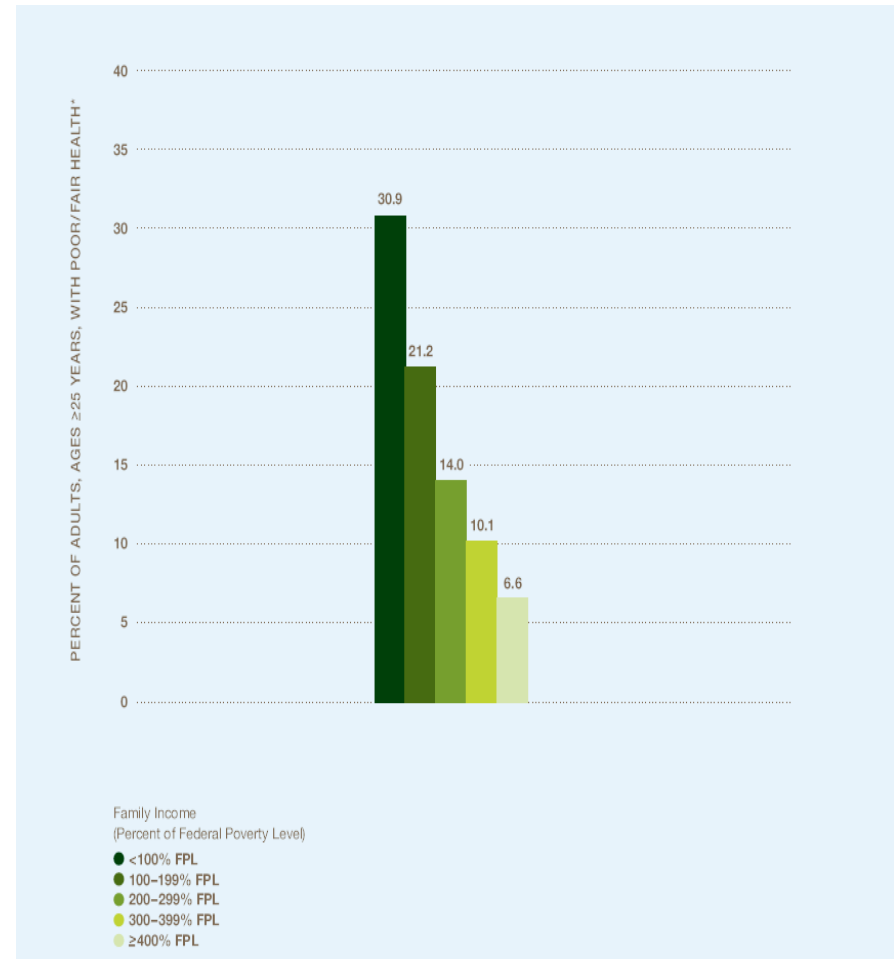
The Commercialization Framework



Who Is The “Average” Consumer and Why Does This Matter Relative to Future Deals?



- Mean household income of ~\$58,000 (median is ~\$48,000)
- High school graduate, maybe “some” college
- Current post-tax expenses equal 80% of pre-tax income (95% for median income)
- Minimal financial assets
- Reads at 6th-8th grade level
- Roughly 30%-50% chance of being “*health illiterate*,” “*health innumerate*” or both



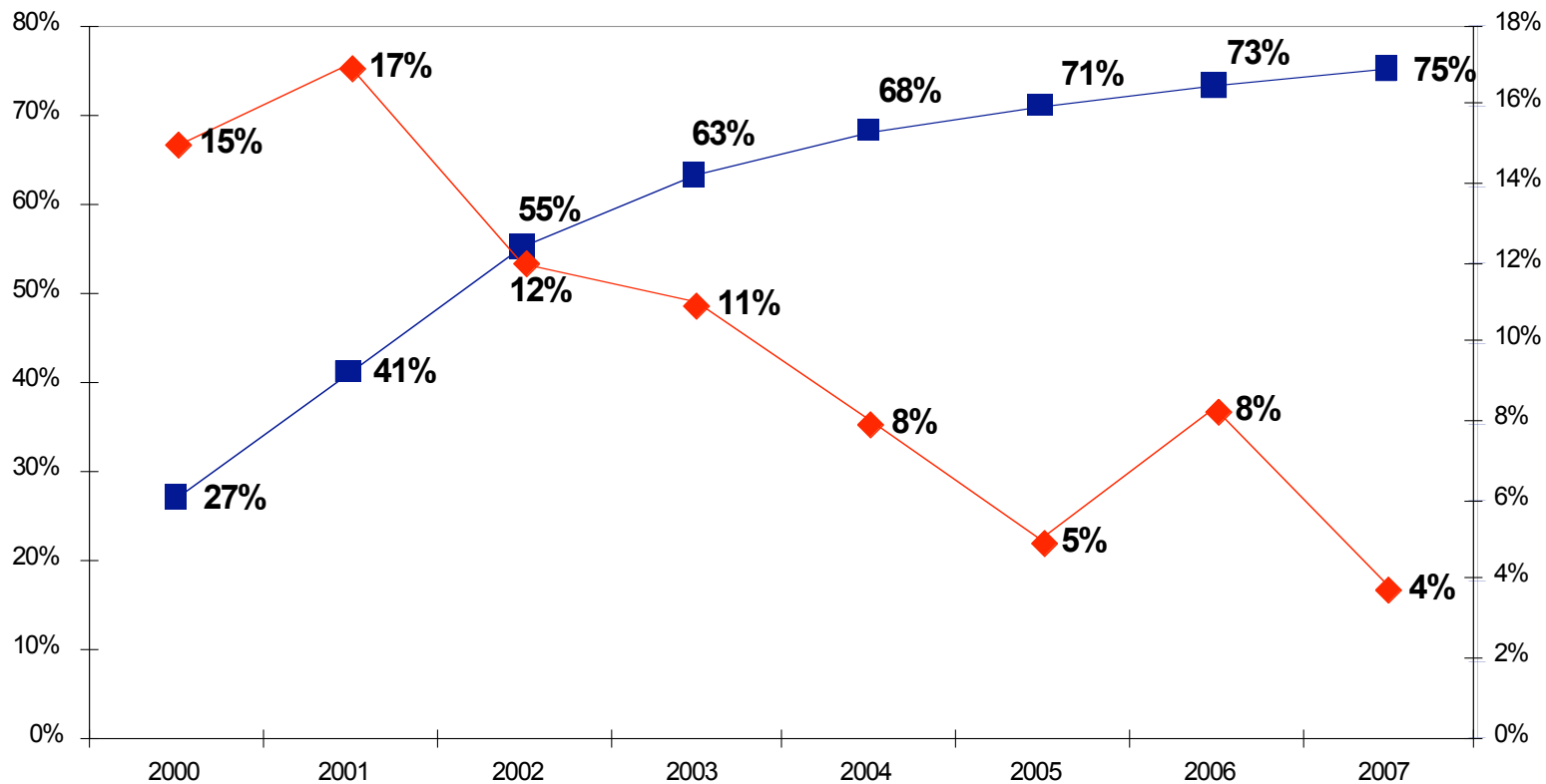
SOURCE: Robert Wood Johnson Foundation

Payers Have Successfully Countered Biopharma Promotion By Changing Consumer Cost Sharing (Three Tier Co-Pay And Effect On Rx Demand)



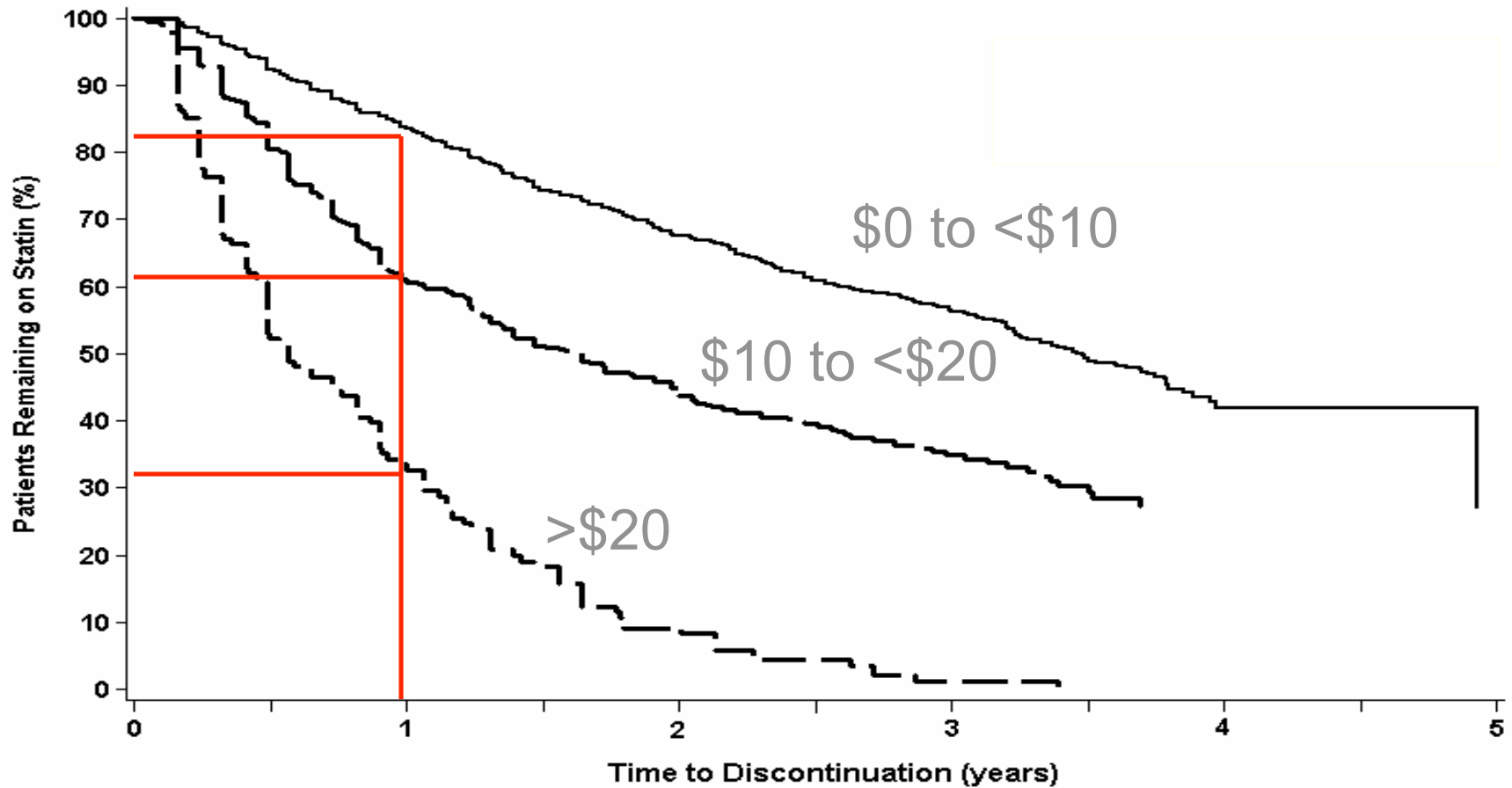
**% Covered Workers
W/3+ Tiered Formulary**

**% Change In
Rx Spending**



SOURCES: Kaiser Family Foundation & IMS Health

Even Small Co-Payment Differentials Matter



SOURCE: Ellis JJ. J Gen Intern Med 2004;19:639-646.

A balanced portfolio of known and new targets are key to building a sustainable franchise



Well Known target/pathway:

- Most diabetes late stage programs are focused on existing targets, or improvement of existing molecules, -- higher probability of getting to market
- Requires rigorous business case preparation
 - Growing competition
 - Tougher pricing and reimbursement environment
- As early as possible, drug development must include portfolio planning:
 - Product attributes/label
 - Pricing, and reimbursement analysis

New target/pathway

- Sustaining long term growth requires investment in new therapeutic targets/pathways
- The risk is higher, so is the potential return.
- To mitigate risk companies must leverage the most advance science and technology in clinical development: e.g. pharmacogenomics and biomarkers
- Acquiring later stage programs costs more than early stage programs but early stage programs are riskier. How to achieve balance?

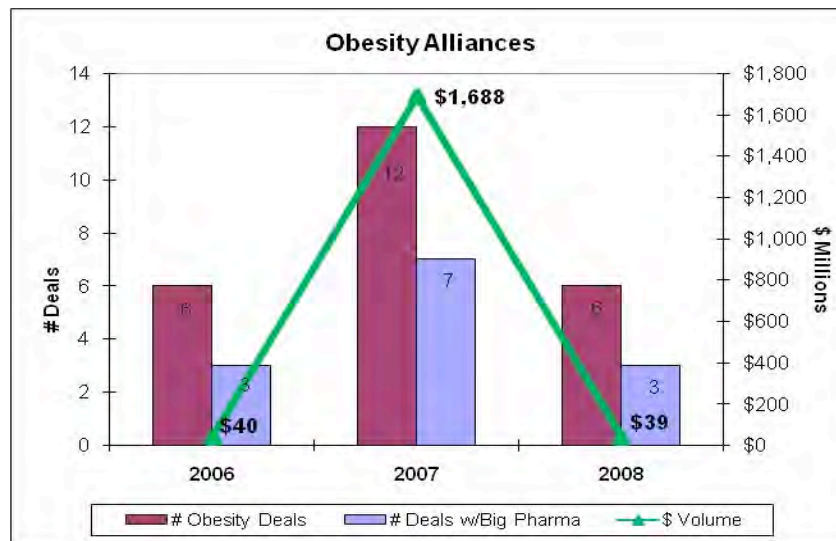
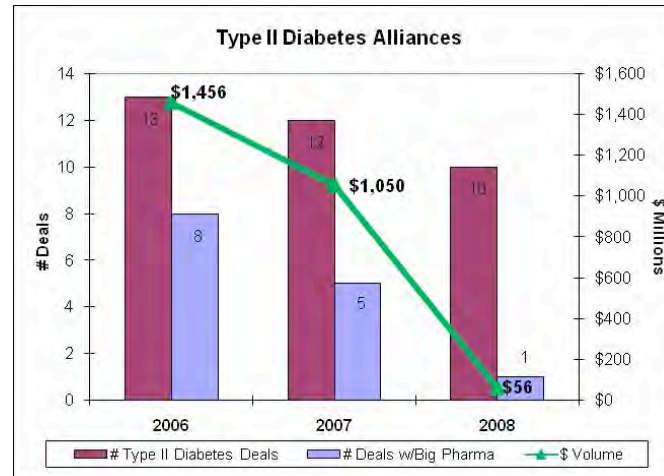
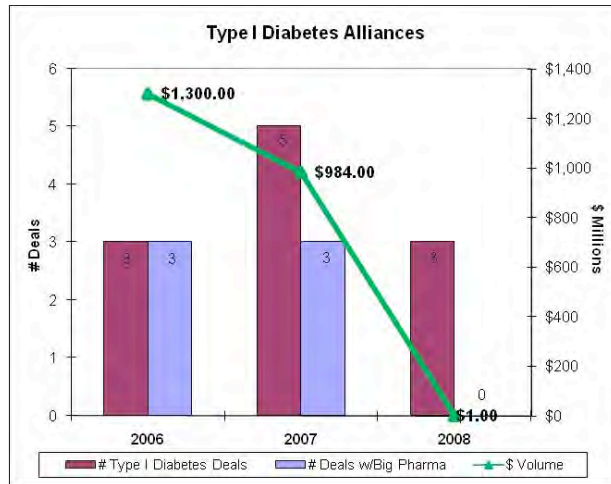
The Combination of Unmet Need, Population Size, and Price Potential Make Type 2 Diabetes a Fertile Partnership Opportunity



- ◉ Reduce cost of development to each partner
- ◉ Share development risk
- ◉ Better pivotal trial design
- ◉ Allow more effective marketing post-launch
- ◉ Resulting in higher revenues overall and to each respective partner

A Profile of Recent Deal Activity in Type 2 Diabetes

- Diabetes deals with Big Pharma have almost ceased in 2008
- Obesity deals with Big Pharma are still relatively active



Source: Windhover Deal Database

The Selection Process for Promising Licensing Candidates



- ⦿ Large market, large unmet need, with increasing opportunity
- ⦿ History of the molecule and drug
- ⦿ Strong science
- ⦿ Strong company
- ⦿ Diversity of indications
- ⦿ Potential for new opportunities beyond the initial indications
- ⦿ Multi-level partnering opportunities, i.e., biotech to biotech as well as pharma to biotech

A Profile of 2008 Most Promising Licensing Candidates



Company	Product	Phase of Development	Disease Target
Cure DM	CDM1101	Preclinical	Type 2 Diabetes
Vitreo Retinal Technologies Inc.	Injectable Product	Phase II	
Bayhill Therapeutics	BHT 3021	Phase I/II	Type 1 Diabetes
7TM Pharma A/S.	Obineptitide	Phase I/II	Obesity
Genaera Corp	Trodusquemine (MSI-1436)	Phase I	Obesity
Intercept Pharmaceuticals.	TGR5 agonist	Preclinical	Metabolic Disorder
Metabolex	MBX-2982	Phase I	Diabetes
Elixir Pharmaceuticals	EX 1350	Phase I	Obesity
Incyte Corp.	INCB13739	Phase I	Type 2 Diabetes

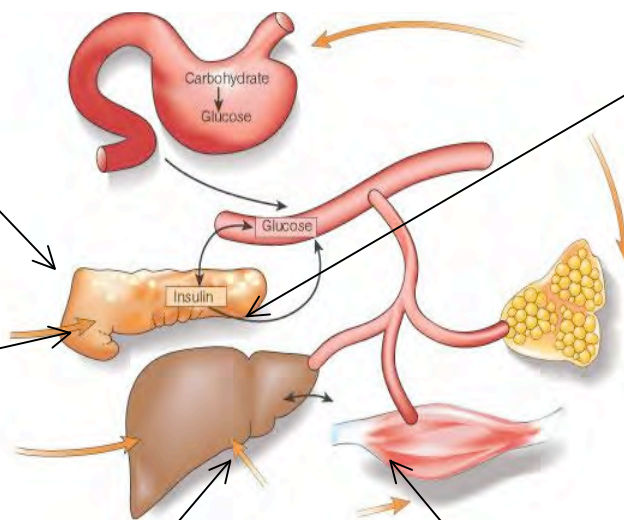
Diabetes Products



Project 1: CDM1101
CureDM

Project 3; BHT3021
Bayhill Therapeutics

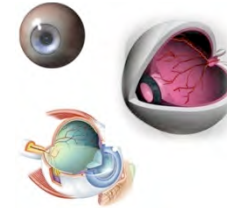
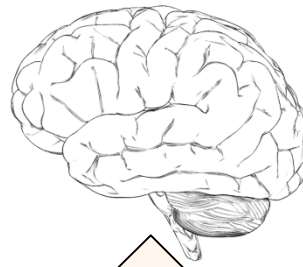
Project 6: TGR5 agonist
Intercept Pharmaceuticals



Project 7: MBX-2982
Metabolex

Project 9: INCB13739
Incyte Corp

Obesity and Diabetic Retinopathy Products

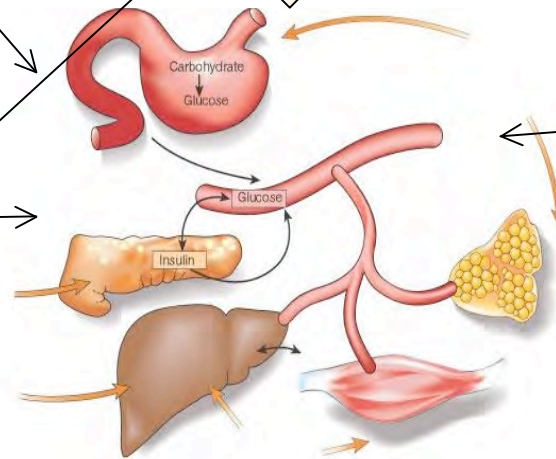


Project 4: Obinipitide,
7TM Pharma A/S

Project 2: Diabetic retinopathy,
Vitreo Retinal Technologies
Inc.

Project 5: Trodusquemine
Genaera Corp

Project 8: EX-1350
Elixir



CDM1101 for diabetes, CureDM Inc.



- ◉
- ◉ **CureDM is a biopharmaceutical company focusing on novel therapies that may prevent, ameliorate or reverse diabetes and allow for the discontinuation of insulin.**
- ◉ **CureDM has identified a proprietary human peptide called Human Prolslet Peptide (HIP) that stimulates development of new, functioning insulin producing islets from existing progenitor cells in the pancreas, without the use of gene therapy or transplant methods.**
- ◉ **Diabetic animals treated with HIP are insulin-free and normoglycemic after 30 days of treatment without apparent side effects. The company has created an optimized clinical candidate currently undergoing toxicity and safety studies required for an IND filing in 2009.**
- ◉ **HIP development represents a promising new approach which could potentially reverse type 2 diabetes and prevent disease manifestation in prediabetes.patients.**

Vitreosolve, Vitreo Retinal Technologies Inc.



- ◉ **Vitreoretinal Technologies, Inc. is a California Corporation, founded in July 1999 to discover, develop, and commercialize novel therapeutic and diagnostic systems for the treatment of serious ocular diseases.**
- ◉ **Vitreosolve treatment will greatly decrease the development of Diabetic Retinopathy.**
- ◉ **Extensive off shore human safety testing has confirmed that these products all appear to be safe with a broad therapeutic range and negligible toxicity profile over a one-year period.**
- ◉ **Preliminary human efficacy studies done off shore have also established the proof of principle for each of the above products with up to one year of follow up.**
- ◉ **To date, several hundred patients have been followed in off-shore Phase-II studies.**

BHT3021 for type 1 diabetes, Bayhill Therapeutics



- ◉ **Bayhill Therapeutics is a clinical-stage biopharmaceutical company leveraging its proprietary therapeutic BHT-DNA™ platform to develop a pipeline of novel and targeted treatment candidates for autoimmune diseases.**
- ◉ **BHT-3021 is a plasmid encoding proinsulin designed to tolerize the immune system to proinsulin, thereby turning off the self directed immune attack.**
- ◉ **This product candidate's potential to improve glucose control could reduce or eliminate insulin dependence and long-term complications of T1D, which would address a major unmet need and capitalize on a significant commercial market opportunity.**
- ◉ **Patient enrollment is currently underway in a Phase I/II placebo-controlled clinical trial of BHT-3021 to evaluate safety and pharmacodynamics, immune tolerance and pancreatic function in patients with T1D.**
- ◉ **Preliminary data from the trial have been positive and the announcement of top-line results is expected in the first half of 2009.**

Obinipitide for obesity, 7TM Pharma A/S



- ◉ 7TM Pharma is a biotech company focusing on discovery and development of new drugs targeting 7TM receptors. 7TM Pharma's primary therapeutic area is metabolic diseases.
- ◉ Obinipitide is a synthetic analogue of two natural human hormones, PYY3-36 and Pancreatic Polypeptide, which normally are released during a meal. These hormones are known to play a role in the regulation of food intake and appetite in man as satiety signals from the GI-tract.
- ◉ Obinipitide integrated the properties of both of these hormones into a single molecule.
- ◉ In pre-clinical studies in diet-induced obese animals the dual active Obinipitide has demonstrated clear superiority in respect of long term reduction in body weight as compared e.g. to the natural hormone PYY3-36, which targets the Y2 receptor only.
- ◉ A first-in-man Phase I/II clinical study demonstrated that the drug candidate is safe and well tolerated in man. Importantly, in obese human subjects once-a-day subcutaneous (s.c.) dosing of Obinipitide inhibited food intake at a statistically significant level up to 9 hours after dosing.

Trodusquemine (MSI-1436) for obesity, Genaera Corp.



- ◉ **Genaera Corporation is a biotech company focused on advancing the science and treatment of metabolic diseases.**
- ◉ **Trodusquemine, a first-in-class molecule, has significant market opportunities with the potential to redefine the treatment paradigm for obesity and type 2 diabetes.**
- ◉ **Trodusquemine is acting upon a scientifically validated target. Trodusquemine is a potent appetite suppressant that has been found to cause weight loss without metabolic rebound and normalize both fasting blood glucose, blood cholesterol and triglyceride levels in obese animals.**
- ◉ **MSI-1436 simultaneously enhances insulin sensitivity through inhibition of PTP-1B. This molecule is the only drug candidate which inhibits PTP-1B both centrally and peripherally.**
- ◉ **Trodusquemine treats type 2 diabetes, obesity and non-alcoholic steatohepatitis (NASH). It is in Phase I trial.**

TGR5 agonist for metabolic disorder, Intercept Pharmaceuticals.



- ◉ Intercept Pharmaceuticals, Inc. is a clinical stage biopharmaceutical company developing therapeutics for the treatment of chronic fibrotic and metabolic diseases.
- ◉ TGR5, a cell-surface receptor that responds to bile acids, is part of the G protein-coupled receptors (GPCRs). Bile acids have been shown to increase the metabolic rate in fat cells by binding to TGR5
- ◉ TGR5 is also involved with cytokine production and the role of bile acids in the immune system.
- ◉ The company's current drug development programs are focused on modulating bile acid receptors with an initial focus on amelioration of metabolic and hepatic function in chronic liver diseases.
- ◉ Intercept has a series of potent TGR-5 agonists which may have clinical potential in metabolic conditions such as diabetes or obesity and immune-related conditions.

MBX-2982 for diabetes, Metabolex Inc.



- **Metabolex discovers and develops novel therapeutics to treat type 2 diabetes and related metabolic disorders**
- **MBX-2982 belong to a new class of diabetes drug, agonist of the islet-specific G protein-coupled receptor (GPCR) GPR-119, a GPCR that is expressed in pancreatic islets and the gastrointestinal tract.**
- **Pre-clinical studies conducted show that GPR119 agonists can stimulate glucose-dependent insulin secretion and release of incretin hormones such as GLP-1, and thus may preserve beta cell health.**
- **This novel dual mechanism may provide a unique therapeutic benefit in the treatment of type 2 diabetes.**
- **Unlike exenatide, MBX-2982 can be delivered orally. In addition, MBX-2982 may provide additional benefit when used in combination with a DPP-4 inhibitor, or other oral therapies.**
- **MBX-2982 is in Phase 1 study.**

EX-1350 for obesity & diabetes, Elixir Pharmaceuticals



- ◉ Elixir is a pharmaceutical company focused on the discovery, development and commercialization of novel pharmaceuticals for the treatment of metabolic diseases such as diabetes and obesity. \
- ◉ Ghrelin has recently been highlighted as one of the most important modulators of metabolic function in mammals. Pharmacologically blocking the ghrelin receptor holds the potential to treat a broad range of metabolic diseases, including diabetes and obesity.
- ◉ EX-1350 is a small molecule antagonist compound that potently block the ghrelin receptor.
- ◉ Oral administration of these compounds in animal models of diet-induced obesity and early diabetes deliver similarly favorable metabolic effects to those seen in knockout models
- ◉ Elixir is currently completing selection of a clinical candidate and expects to file an IND application with the FDA in 2009, initiating a phase I clinical trial shortly thereafter.

INCB13739 for Type 2 Diabetes, Incyte Corp



- Incyte is a Wilmington, Delaware-based drug discovery and development company with a growing pipeline of novel small molecule drugs
- INCB13739 is a potent, selective oral compound which completely inhibits the production of intra-adipose and intra-hepatic cortisol by 11beta-HSD1, while maintaining normal systemic cortisol levels, which are essential for immune function and response to stress.
- 11beta-HSD1 is an enzyme that converts the biologically inactive steroid cortisone into the potent biologically active hormone cortisol, which is known to act as a functional antagonist of insulin action in multiple target tissues.
 - Liver: cortisol reduces insulin's ability to suppress glucose production.
 - Muscle: cortisol reduces insulin's ability to promote glucose uptake.
 - Adipose: cortisol blocks insulin's ability to suppress free fatty acid release.
- By reducing the insulin resistance caused by intracellular cortisol, an 11beta-HSD1 inhibitor may be useful as a treatment for type 2 diabetes and also in allied conditions such as dyslipidemia, cardiovascular disease, obesity and hypertension.

Conclusions



- ⦿ **All of the above companies have focused on new targets in the pathological process**
- ⦿ **All in the early stages of development.**
- ⦿ **Capital market turmoil: strong balance sheet = negotiation leverage, whether on the licensee OR licensor side:**
 - ⦿ **2 of preceding 9 are public companies with strong balance sheets, 1 public company has less than a year's cash.**
 - ⦿ **6 are private companies of which 2 withdrew IPO filings**
 - ⦿ **Later stage development funding depends on access to public market size capital OR partnership.**

- **How will partnering be affected by the recent turmoil in the financial markets?**



Windhover Therapeutic Partnership Conference: Diabetes and Metabolic Diseases

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Presented by Harris Kaplan, Jun Huangpu, PhD, MBA

HEALOGIX

(410) 215-9595

harris.kaplan@healogix.com

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