The Future of Diabetes Control
Forward Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements about future activities related to the clinical development plans for the company's drug candidates, including the potential timing, design and outcomes of clinical trials; and the company's ability to develop and commercialize product candidates. Forward-looking statements represent our management's judgment regarding future events. All statements, other than statements of historical facts, including statements regarding our strategy, future operations, future clinical trial results, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The company's forward-looking statements are subject to a number of known and unknown risks and uncertainties that could cause actual results, performance or achievements to differ materially from those described or implied in the forward-looking statements, including, but not limited to, the success of our product candidates, particularly our proprietary formulations of injectable insulin that are designed to be absorbed more rapidly than the "rapid-acting" mealtime insulin analogs presently used to treat patients with Type 1 and Type 2 diabetes and our glucagon presentation that is intended to treat patients experiencing severe hypoglycemia; our ability to successfully complete a Phase 2 clinical trial of a proprietary insulin formulation in a timely manner, and the outcome of that trial; our ability to conduct pivotal clinical trials, other tests or analyses required by the U.S. Food and Drug Administration, or FDA, to secure approval to commercialize a proprietary formulation of injectable insulin or a stable glucagon presentation; the success of our formulation development work with insulin analog-based formulations of a proprietary injectable insulin and a stable glucagon presentation; our ability to secure approval from the FDA for our product candidates under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act; the progress, timing or success of our research, development and clinical programs, including any resulting data analyses; our ability to develop and commercialize a proprietary formulation of injectable insulin that may be associated with less injection site discomfort than Linjeta™ (formerly referred to as VIAject®), which is the subject of a complete response letter we received from the FDA; our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of any such collaborations into which we enter, or our ability to commercialize our product candidates ourselves; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; the degree of clinical utility of our product candidates; the ability of our major suppliers to produce our products in our final dosage form; our commercialization, marketing and manufacturing capabilities and strategies; our ability to accurately estimate anticipated operating losses, future revenues, capital requirements and our needs for additional financing; and other factors identified in our most recent report on Form 10-Q for the quarter ended March 31, 2013. The company disclaims any obligation to update any forward-looking statements as a result of events occurring after the date of this presentation.
## Company Overview – Diabetes Focus

### Strategy and Technology
- Optimize PK and stability of FDA-approved therapeutics
- Rapid development through 505(b)(2) regulatory process
- Focus on multi-billion dollar insulin and glucagon diabetes markets

### Pipeline

#### Ultra-Rapid-Acting Prandial Insulins
- RHI-based ⇒ BIOD-123 Phase 2 trial completed; top line data 3Q13
- Analog-based ⇒ Positive Phase 1 top line data reported
- Concentrated insulin ⇒ BIOD-531 Phase 1 trial 4Q13; top line data 1Q14

#### Glucagon
- Rescue product: Portable, easy to use, room temperature presentation ⇒ Pivotal trial 2H14; Projected NDA filing 2015
- Pump use liquid formulations under development

### Resources
- ~40 employees based in Danbury, CT
- $42.4 MM in cash and equivalents as of June 30, 2013
- 23.0 MM shares outstanding assuming conversion of preferred shares
Company Overview – Leadership

Management

Errol B. De Souza, Ph.D.
President and CEO

Alan S. Krasner, M.D.
Chief Medical Officer

Gerard J. Michel
Chief Financial Officer

Paul Bavier
General Counsel

Erik Steiner
VP Operations

Board of Directors

Ira W. Lieberman, Ph.D.
Chairman

Julia R. Brown

Errol B. De Souza, Ph.D.

Barry H. Ginsberg, M.D., Ph.D.

Daniel L. Lorber, M.D.

Brian J. G. Pereira, M.D.

Davey S. Scoon
Normal Insulin and Glucagon Physiologic Response is Required to Keep Glucose in the Normal Range

Normal Insulin and Glucagon Physiologic Response

- Plasma Insulin (µU/mL)
- Blood Glucose (mg/dL)

1st phase insulin response to a meal signals liver to suspend glucose production

**Rapid-acting analog insulin segment:** NovoLog®, Humalog®, and Apidra®

Basal insulin manages glucose produced by the liver between meals

**Long acting insulin segment:** Lantus® and Levemir®

Glucagon signals liver to produce glucose when glucose is low

Glucagon currently used in emergency only — under investigation for pump use

**NORMAL GLUCOSE RANGE**

- Blood Glucose (mg/dL)
- 0
- 20
- 40
- 60
- 80
- 100
- 120

Illustrative Normal Target

Meal

Meal

Meal

Time
Current and Potential Market and Pipeline

Based on IMS U.S. and Europe Ex Factory data and internal Biodel projections

**Ultra-Rapid-Acting Prandial Insulin**
- RHI based
- Prototype formulation showed better post prandial control

**Ultra-Rapid-Acting Conc. Insulin**
- RHI based
- Faster onset than currently marketed U-500 and mixes
- Basal coverage
- Proof of concept demonstrated in swine

**Proprietary Formulation Technology**

**Glucagon**
- Improved rescue formulations
- Orphan indications
- Bi-hormonal pump

*will compete in both concentrated and mix segments*
## Ultra-Rapid-Acting Prandial Insulin for the Treatment of Diabetes

<table>
<thead>
<tr>
<th>Market Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>~$8B in US and EU; projected to grow to ~$10B by 2020</td>
</tr>
<tr>
<td>Key Products: Humalog®, NovoLog®, and Apidra®</td>
</tr>
<tr>
<td>Existing players need to extend franchises with improved products due to near term patent expirations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unmet Medical Need</th>
</tr>
</thead>
<tbody>
<tr>
<td>PK profiles of RHI or rapid acting analogs do not match 1st phase insulin response since insulin hexamer is poorly absorbed</td>
</tr>
<tr>
<td>Mismatch in PK profiles results in glycemic swings after meals</td>
</tr>
<tr>
<td>Poor glycemic control in people with diabetes leads to morbidities (such as hypoglycemia, weight gain, blindness, kidney disease, nerve damage, amputation, etc.)</td>
</tr>
</tbody>
</table>
## Ultra-Rapid-Acting Prandial Insulin for the Treatment of Diabetes

<table>
<thead>
<tr>
<th>Biodel Solution</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Remove zinc via EDTA to destabilize insulin hexamer; citric acid masks surface charges, preventing re-aggregation</td>
<td></td>
</tr>
<tr>
<td>■ Mimic 1\textsuperscript{st} phase insulin response</td>
<td></td>
</tr>
<tr>
<td>■ Applicable to both RHI and rapid acting analogs</td>
<td></td>
</tr>
<tr>
<td>■ Intellectual Property Protection: EU $\Rightarrow$ 2025; US $\Rightarrow$ 2026</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>■ RHI-based BIOD-123</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Trial completed</td>
</tr>
<tr>
<td>■ 3Q13: Phase 2 top line data</td>
</tr>
<tr>
<td>■ 2014: Potential for initiation of pivotal studies</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>■ Analog-based BIOD-238 and BIOD-250</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ 1Q13: Phase 1 top line data reported</td>
</tr>
<tr>
<td>■ Working to replicate BIOD-250 PK and tolerability profiles utilizing lispro (Humalog® API), aspart (NovoLog® API), and achieving commercial stability</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>■ RHI-based concentrated insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ 2Q13: BIOD-531 candidate selected for Phase 1 development</td>
</tr>
<tr>
<td>■ Engineering batch completed</td>
</tr>
<tr>
<td>■ IND submitted to FDA</td>
</tr>
<tr>
<td>■ Two clinical supply batches scheduled for 3Q13</td>
</tr>
<tr>
<td>■ Initiate Phase 1 clinical trial in 4Q13</td>
</tr>
<tr>
<td>■ Top line data anticipated in 1Q14</td>
</tr>
</tbody>
</table>
Pharmacokinetic Profiles of Analog Insulins Do Not Match Profile in Healthy Individuals

First 15 to 30 minutes critical for glucose control

<table>
<thead>
<tr>
<th>PK Metrics</th>
<th>Normal Insulin Levels Following Meal(^1)</th>
<th>Regular Human Insulin SC Injection(^2)</th>
<th>Humalog(^\circledR) SC Injection(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early ½ (T_{max}) (minutes)</td>
<td>~15</td>
<td>37 ± 7.0</td>
<td>26 ± 3.2</td>
</tr>
<tr>
<td>(T_{max}) (minutes)</td>
<td>~30 — 40</td>
<td>120 ± 22</td>
<td>66 ± 10.8</td>
</tr>
</tbody>
</table>

- Increase dose to minimize postprandial hyperglycemia
  - OR
  - Decrease dose to minimize hypoglycemic events

**Glycemic Variability**
- Oxidative stress
- Diabetic vascular complications
- Quality of life

**Long Term Glucose Control**
- Blindness
- Kidney disease
- Nerve damage, amputation

**Hypoglycemia**
- Loss of consciousness
- Coma and death

**Weight gain**
- Increased morbidity and mortality
- Increased insulin resistance

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\(^1\) Journal of Nutrition. 1996, 126: 2807-2812
\(^2\) Diabetes. 1988, 37: 736-44
IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING. 2007, 54: 1740-1749
\(^2\) Diabetologia. 2008;51(9):1602-1606
Ultra-Rapid-Acting Insulins Which Replicate “Normal” Insulin Response May Represent a Step Change in Insulin Therapy

Ultra-Rapid-Acting Insulins May Address the Market’s Unmet Need

- Faster Onset
- Less Glycemic Variability
- Less Weight Gain

Market Value

Mimics Normal Pancreatic Response to Meal

- Faster Onset
- Less Glycemic Variability
- Less Weight Gain

Ultra-Rapid-Acting Insulin

2005

- Biodel initiated first-in-man studies with Linjeta™, or BIOD-090; the term “ultra-rapid-acting insulin” did not exist

2013

- Novo Nordisk: “NN1218” Phase 3 initiation late 2013
  - Halozyme
  - Sanofi-Aventis
  - Eli Lilly
Biodel’s Ultra Rapid Insulins’ Unique Mechanism Results in More Rapid Absorption Relative to Marketed Prandial Insulins

Biodel Technology: EDTA chelates zinc to destabilize insulin hexamer; citric acid masks insulin monomers’ surface charges, impeding re-aggregation and facilitating absorption

Analog insulins have modified the primary structure using genetic engineering to decrease the tendency to form hexamers.

United States
- Patent: US7279457
- Expiration: 2026

European Union
- Patent: EP1740154
- Expiration: 2025

- Broad composition of matter patents
- Multiple additional patents filed
- Protects various insulin formulations:
  - RHI-based
  - Analog-based
  - Subcutaneous delivery
  - Sub-lingual delivery
  - Non-hexameric insulin
  - Multiple combinations of excipients
- No external royalties
Summary of Biodel’s EDTA/Citrate Recombinant Human Insulin (RHI) and Analog Formulations

- BIOD-090 (VIAject™, Linjeta™) and BIOD-100 (Linjeta™) - RHI based
  - Multiple Phase 1, 2 and 3 studies
  - Superior PK/PD (versus RHI and Humalog®) trending towards better postprandial control, less weight gain and lower rates of hypoglycemia (Phase 3 studies vs. RHI)…
  - … but poor injection site tolerability

- BIOD-123 - RHI based
  - Phase 1 trial demonstrated superior PK (versus Humalog®) with excellent tolerability
  - Phase 2 trial with top line data anticipated in 3Q2013

- BIOD-250 – Lispro (Humalog®) based
  - Phase 1 trial demonstrated superior PK (versus Humalog®) with excellent tolerability
Aside from Tolerability, Trials with Previous BIOD-090 (Linjeta™) Formulation Showed Strong Trends Towards Superior Clinical Profile

- **Early**
  - $\frac{1}{2} T_{\text{max}} \text{ (min)}$
    - BIOD-100: 23.3 ± 1.0
    - Humalog®: 7.9 ± 0.5

- **T_{\text{max}} \text{ (min)}**
  - BIOD-100: 57.1 ± 3.4
    - Humalog®: 29.4 ± 4.6

- **Tolerability**
  - (VAS 0 – 100 mm)
    - BIOD-100: 5.3 ± 1.0
    - Humalog®: 17.3 ± 2.5

**BIOD-90 Clinical Profile**

- **Glycemic Variability**
  - Narrower glycemic excursions compared to Humalog® in standard meal challenge test
  - Reductions in markers of oxidative stress

- **Long Term Glucose Control**
  - HbA1c adequately controlled
  - Non-inferiority versus RHI (narrowly missed; study design and other issues identified)

- **Hypoglycemia**
  - Less hypoglycemia versus RHI

- **Weight gain**
  - Less weight gain versus RHI
BIOD-123 ("Linjeta™" with MgSO₄) Replicates Linjeta™ PK Profile in Type 1 Diabetes Patients …
...With Better Injection Site Tolerability

- Primary endpoint of injection site tolerability was measured on a 100 mm Visual Analog Scale (VAS); 0 = no discomfort; 100 = worst possible discomfort; 3 = usual injection.
- Data represents means ± standard error, *p < 0.05 vs. Humalog®

### Injection Site Discomfort Severity

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humalog® (n=12)</td>
<td>10</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>(83.3%)</td>
<td>(16.7%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BIOD-123 (n=11)</td>
<td>7</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>(63.6%)</td>
<td>(36.4%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Tolerability

<table>
<thead>
<tr>
<th></th>
<th>Humalog®</th>
<th>BIOD-123</th>
</tr>
</thead>
<tbody>
<tr>
<td>(VAS 0 – 100mm)</td>
<td>1.8 ± 1.1</td>
<td>3.6 ± 2.1</td>
</tr>
<tr>
<td>Absolute Severity Score (0=none, 1=mild)</td>
<td>0.17 ± 0.11</td>
<td>0.36 ± 0.15</td>
</tr>
<tr>
<td>Relative Severity Score</td>
<td>2.92 ± 0.08</td>
<td>2.91 ± 0.25</td>
</tr>
</tbody>
</table>

*Primary endpoint of injection site tolerability was measured on a 100 mm Visual Analog Scale (VAS); 0 = no discomfort; 100 = worst possible discomfort; 3 = usual injection.*
BIOD-123 Phase 2 Trial Design

Randomized 2 arm study, ~130 Type 1 diabetes patients, ~30 U.S. investigative centers

- **Primary Endpoint**
  - HbA1c control

- **Secondary Endpoints**
  - Postprandial glucose control
  - Glycemic variability
  - Hypoglycemic event rates
  - Weight changes

**Study duration**
- 18 weeks
  - 6 weeks active titration
  - 12 weeks stable dosing

**BIOD-123 vs. Humalog®**

- Basal insulin: Lantus®

**Milestones**
- 1Q13: Enrollment completed
- 3Q13: Top line data anticipated
Humalog®, NovoLog® and Apidra® Analogs Formulated with BIOD-100 Excipients Have an Ultra-Rapid-Acting Insulin Pharmacokinetic Profile in Diabetic Swine


Preclinical study: Pharmacokinetic profiles in diabetic swine
In Man, Lispro Based* BIOD-238 and BIOD-250 Demonstrated a More Rapid In and Out vs. Humalog®

* Biodel's proprietary excipients added to commercial Humalog® to create BIOD-238 and BIOD-250
### Improved PK Performance of BIOD-238 and BIOD-250 vs. Humalog® Supported By Multiple Measurements

<table>
<thead>
<tr>
<th>Variable</th>
<th>BIOD-238 N=10</th>
<th>BIOD-250 N=11</th>
<th>Humalog® N=10</th>
<th>P-value BIOD-238 vs. Humalog®</th>
<th>P-value BIOD-250 vs. Humalog®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Absorption</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early $\frac{1}{2} T_{\text{max}}$ (minutes)</td>
<td>$13.7 \pm 1.8$ (13.6)</td>
<td>$14.6 \pm 1.9$ (12.9)</td>
<td>$24.9 \pm 2.9$ (22.6)</td>
<td>$&lt;0.001$</td>
<td>$0.001$</td>
</tr>
<tr>
<td>$T_{\text{max}}$ (minutes)</td>
<td>$35.5 \pm 2.4$ (37.5)</td>
<td>$40.9 \pm 6.1$ (40.0)</td>
<td>$62.5 \pm 8.4$ (60.0)</td>
<td>$0.013$</td>
<td>$0.025$</td>
</tr>
<tr>
<td>AUC$_{\text{ins0-30 min}}$ (mU*min/L)</td>
<td>$1276 \pm 164$ (1104)</td>
<td>$1185 \pm 133$ (1260)</td>
<td>$596 \pm 126$ (652)</td>
<td>$&lt;0.001$</td>
<td>$0.002$</td>
</tr>
<tr>
<td><strong>Decline from peak concentration</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Late $\frac{1}{2} T_{\text{max}}$ (minutes)</td>
<td>$123.8 \pm 10.0$ (125.2)</td>
<td>$142.6 \pm 16.5$ (137.8)</td>
<td>$166.4 \pm 10.6$ (183.2)</td>
<td>$0.006$</td>
<td>$0.040$</td>
</tr>
</tbody>
</table>

*Data represent the Mean ± SEM; Median Values are presented in parentheses.*
…With BIOD-250 Demonstrating Improved Injection Site Tolerability

- Primary endpoint of injection site discomfort was measured on a Visual Analog Scale (VAS) from 0 (no discomfort) to 100 (worst possible discomfort) (mm).
- Data represent means ± standard error, *p < 0.05 vs. Humalog®

<table>
<thead>
<tr>
<th></th>
<th>BIOD-238</th>
<th>BIOD-250</th>
<th>Humalog®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolerability</td>
<td>24.2 ± 7.0</td>
<td>2.7 ± 1.6</td>
<td>8.2 ± 4.5</td>
</tr>
<tr>
<td>(VAS 0 – 100mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absolute Severity</td>
<td>1.1 ± 0.2</td>
<td>0.1 ± 0.1</td>
<td>0.5 ± 0.2</td>
</tr>
<tr>
<td>Score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative Severity</td>
<td>3.6 ± 0.3</td>
<td>2.9 ± 0.2</td>
<td>3.2 ± 0.1</td>
</tr>
<tr>
<td>Score</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injection Site Discomfort Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>BIOD-238 (n=10)</td>
</tr>
<tr>
<td>BIOD-250 (n=11)</td>
</tr>
<tr>
<td>Humalog® (n=10)</td>
</tr>
</tbody>
</table>
Conclusions & Next Steps

- BIOD-238 and BIOD-250 demonstrate significantly more “rapid in” and “rapid out” pharmacokinetic profiles relative to Humalog®
- Injection site tolerability of BIOD-250 is similar to that of Humalog®
- Magnesium sulfate has again been shown to effectively improve injection site tolerability
- Lower concentrations of EDTA appear to be associated with similar injection site tolerability as formulations with concentrations of EDTA similar to Linjeta™ prototype formulation

Current focus:

- Replicating pharmacokinetic and tolerability profiles of BIOD-250 in formulations utilizing lispro, the active pharmaceutical ingredient in Humalog®
- Achieving commercial stability
- Exploring development of aspart-based ultra-rapid-acting insulin formulations made from API
Concentrated Ultra-Rapid-Acting Insulin - BIOD 531 - Has a Rapid Onset, Basal Type Duration and Low Volume – It Can Target Two Market Segments

- Insulin resistant Type 2 diabetes patients using high volumes
  - ~$300MM market
  - Humulin® R U-500R currently only product on the US market
    - Generally used BID for both prandial and basal coverage
    - Poor post prandial control

- Mix Patients
  - ~$1.5B market
  - NovoLog® and Humalog® primary competitors
    - Generally used BID for both prandial and basal coverage
    - Surprisingly reduced “rapid action” versus prandial analogs – protamine seems to blunt rapid onset (in diabetic swine)
Concentrated Ultra-Rapid-Acting Insulin Program
BIOD-531 Selected as Lead Candidate

- BIOD-531
  - Concentrated U-400 formulation
  - RHI
  - Disodium EDTA
  - Citrate
  - Magnesium sulfate *(shown in multiple clinical studies to mitigate injection site pain associated with EDTA)*

- Preclinical results demonstrated
  - More rapid rate of absorption and onset of action than Humulin® R, U-500 and Humalog® premixes
  - Duration of action similar to Humulin® R, U-500 and Humalog® premixes

- BIOD-531
  - May provide superior meal-time glucose control relative to Humulin® R, U-500
  - Enable patients to improve prandial control using small injection volumes
BIOD-530 Vs. Humulin® R U-500R Dose 0.25 U/kg – PK and PD Profiles in Diabetic Swine

Mean Baseline subtracted glucose and insulin (+/-SEM)

**Lilly U-500R vs. BIOD-530**

- **C<sub>max</sub>**: 135.5±22.7 vs. 155.4±15.6
- **T<sub>max</sub>**: 94±17.1 vs. 41.7±12.2*
- **T<sub>50%early</sub>**: 26.9±5.0 vs. 11.4±2.4*
- **AUC**: 21610±3103 vs. 21535±4034

*<sup>p</sup>&lt;0.05

**Potentially superior performance for the insulin resistant patient**
BIOD-531 Vs. Humalog® 75/25
Dose 0.25 U/kg – PK and PD Profile in Diabetic Swine

![Graph showing glucose levels over time for BIOD-531 and Humalog® 75/25]

- **Potentially superior performance for the mix patient**

**Study 0.028**

<table>
<thead>
<tr>
<th></th>
<th>Humalog® 75/25 (n=10)</th>
<th>BIOD-531 (n=10)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cₘₐₓ</strong></td>
<td>55±5</td>
<td>131±21*</td>
<td>.009</td>
</tr>
<tr>
<td><strong>Tₘₐₓ</strong></td>
<td>86±19</td>
<td>79±18</td>
<td>.79</td>
</tr>
<tr>
<td><strong>T₅₀%early</strong></td>
<td>35±6</td>
<td>24.6±5</td>
<td>.29</td>
</tr>
<tr>
<td><strong>AUC</strong></td>
<td>9673±1167</td>
<td>20188±4192*</td>
<td>.02</td>
</tr>
</tbody>
</table>

*<p<0.05
Concentrated Ultra-Rapid-Acting Insulin Program Development Plans

- File an Investigational New Drug Application amendment with the FDA
- Initiate Phase 1 clinical trial
  - Euglycemic clamp methodology
  - Randomized, blinded, n=12
  - Four-way cross-over design
  - Compare BIOD-531 to Humulin® R, U-500 and to Humalog® 75/25 premix
    - Pharmacokinetic
    - Pharmacodynamic
    - Tolerance profiles

- Timelines
  - Engineering batch completed
  - IND submitted to FDA
  - Clinical supply batches scheduled for 3Q13
  - Initiate Phase 1 clinical trial in 4Q13
  - Top line data anticipated in 1Q14
Glucagon for the Treatment of Severe Hypoglycemia

<table>
<thead>
<tr>
<th>Market Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>$115 MM in US</td>
</tr>
<tr>
<td>Key Products: Glucagon Emergency Rescue Kit; GlucaGen® HypoKit™</td>
</tr>
<tr>
<td>Market is severely under-penetrated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unmet Need</th>
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</thead>
<tbody>
<tr>
<td>Marketed glucagon is unstable as a liquid and must be stored as a lyophilized cake requiring seven or more steps for administration</td>
</tr>
<tr>
<td>Requisite care giver training is a large barrier</td>
</tr>
<tr>
<td>Needlestick protection</td>
</tr>
<tr>
<td>Complexity limits ambulance use</td>
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</tbody>
</table>
Limitations of Current Glucagon Treatment of Severe Hypoglycemia

- Seven or more steps required for reconstitution and administration
- Difficult care giver training required
- Risk of dosing error
- Needle exposure
- Complexity results in underuse of glucagon as a rescue treatment
- Only 10% to 20% of high-risk patients currently have an unexpired glucagon kit
- More than 200,000 hospitalizations per year estimated due to severe hypoglycemia

Currently Available Kits and Instructions
Glucagon for the Treatment of Severe Hypoglycemia

<table>
<thead>
<tr>
<th>Biodel Solution</th>
<th>Room temperature presentation</th>
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<tbody>
<tr>
<td></td>
<td>Small, portable user-friendly device</td>
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<td>Requires little to no training</td>
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<td></td>
<td>Automatically reconstitutes lyophilized glucagon thereby reducing dosing errors</td>
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<td>User-controlled needle retraction upon full dose delivery virtually eliminates risk of needle stick injuries</td>
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<tr>
<th>Milestones</th>
<th>Secured long-term commercial supply of bulk glucagon in 3Q12</th>
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<tbody>
<tr>
<td></td>
<td>Announced novel presentation and formulation combinations 2Q13</td>
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<tr>
<td></td>
<td>Appoint contract manufacturing partner 2Q13</td>
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<td></td>
<td>Submit IND to FDA by 2Q14</td>
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<tr>
<td></td>
<td>Initiate pivotal clinical study during the 2H14</td>
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<td></td>
<td>Anticipate NDA filing in 2015</td>
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</table>
Biodel’s Room Temperature Intuitive Portable Glucagon Rescue Device Designed to Require Little to No Training

1. After back cover is removed, twist to reconstitute and unlock front cover.

2. Remove needle shield and push plunger to give dose.

3. After dose delivery, the needle is automatically retracted.
Candidate Formulation, BIOD-961, Has Comparable Stability to Lilly Glucagon Under Accelerated Conditions

**Lilly Commercial vs. Biodel BIOD-961**

**Glucagon Potency**

- Storage Conditions: 40°C

**High Molecular Weight Protein (HMWP)**

- Storage Conditions: 40°C
Eight Beagle dogs were injected subcutaneously with 0.5 mg of BIOD-961 or a commercially available glucagon reconstituted from a rescue kit (Lilly or Novo Nordisk) using a randomized three way cross-over design on three study days.
Glucagon Market – Sources of Potential Growth

- Type 1
  - Currently there is ~10% penetration in Type 1 population
  - Leading cause of sudden death in Type 1 patients
  - #1 cause of ER visits
  - Project 70% penetration

- Type 2
  - Less than 5% penetration in Type 2 patients
  - Project 30% of Type 2 patients new to insulin will receive product, and
  - 30% of all high-risk Type 2’s will receive product

- Emergency Responder
  - Lyophilized drugs have high risk of dosing error
  - Less than 50% of paramedic units carry glucagon due to State restrictions
  - Project 75% penetration with liquid formulation

- Current market appears heavily penetrated
  - Rapid share shift likely due to OSHA requirements

- Pricing
  - ER visits cost $5,000 or more per emergency event
  - 20% premium is easily supportable
Glucagon Rescue Indication Development Plan

- Secured long-term commercial supply agreement for bulk glucagon in 3Q12
- Formulation optimized and process development underway
- Received FDA feedback on proposed development plan
- 505(b)(2) pathway will reference existing safety and efficacy data
- Announced novel room temperature presentation 2Q13
  - 15-year supply agreement with Unilife Corporation
  - Customized proprietary dual-chamber device
  - Worldwide exclusivity for use with glucagon
- Secure contract manufacturing partner 3Q13
- Submit IND to FDA by 2Q14
- Initiate pivotal clinical study during the 2H14
- Anticipate NDA filing in 2015
News Flow & Projections

RHI Ultra-Rapid-Acting Insulin

Top Line Data Phase 1

Possibly Initiate Phase 3

Top Line Data Phase 2

Calendar Q 1Q13 2Q13 3Q13 4Q13 1H14 2H14 2015

Analog Ultra-Rapid-Acting Insulin

Concentrated Ultra-Rapid-Acting Insulin

Glucagon

Lead Candidate Selected

Initiate Phase 1

Submit IND 2Q14

Initiate Pivotal Clinical Trial

Submit NDA 2015

Acquire Proprietary Device

Engage Manufacturer

Submit IND 2Q14

Initiate Pivotal Clinical Trial

Submit NDA 2015