



# Corporate Presentation

Financial Results H1 FY 2006

# Disclaimer

Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither our company, our directors, any member of the syndicate nor any of their respective affiliates have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition.

## Performance Highlights : H1 – FY 06

Revenues **Rs. 375 crs**      PAT **Rs.82 crs**

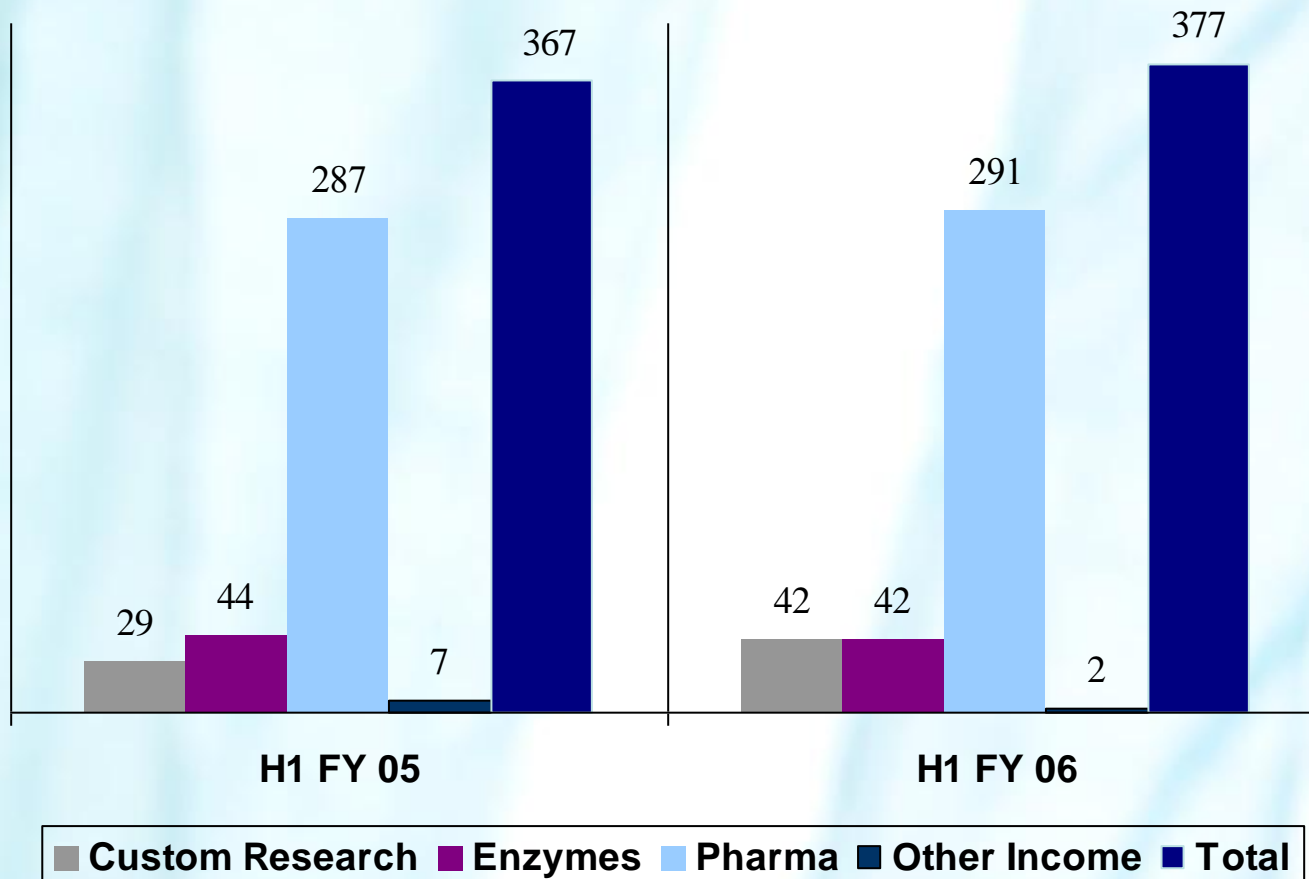
- Consolidated revenues grew by 4% over H1 – FY 05.
- Operating profits fell by 8% over H1 – FY 05.
- Profit after Tax showed a 22% decline over H1 – FY 05
- PAT margins maintained at a healthy 22%.
- Operating results were largely affected by challenging pricing conditions in the European Statins market.

# Performance Highlights : H1 – FY 06

Revenues **Rs. 375 crs** PAT **Rs.82 crs**

- Research Services, Enzymes, Insulin and other Bio-pharmaceutical products performed strongly.
- Good progress maintained on Biocon's discovery led Diabetes and Oncology research programs.
- The SEZ application for Biocon Park approved.

# Revenue Break Up



## P & L : H1 - 05 vs H1 - 06

<b>Particulars</b>	<b>H1- 05</b>	<b>% on Revenues</b>	<b>H1- 06</b>	<b>% on Revenues</b>
<b>Revenues</b>	<b>367</b>		<b>377</b>	
<b>EBIDTA</b>	<b>122</b>	<b>33%</b>	<b>112</b>	<b>32%</b>
<b>PBT</b>	<b>113</b>	<b>30%</b>	<b>98</b>	<b>26%</b>
<b>Tax</b>	<b>8</b>	<b>2%</b>	<b>16</b>	<b>4%</b>
<b>PAT</b>	<b>105</b>	<b>29%</b>	<b>82</b>	<b>22%</b>

## P&L : Q1- 06 & Q2 - 06

<b>Particulars</b>	<b>Q1 -06</b>	<b>% on Revenues</b>	<b>Q 2 - 06</b>	<b>% on Revenues</b>
<b>Revenues</b>	176		202	
<b>EBIDTA</b>	52	30%	60	30%
<b>PBT</b>	45	26%	53	26%
<b>Tax</b>	7	4%	9	5%
<b>PAT</b>	39	22%	44	22%

# Outlook

- **Discovery-led research programs in Diabetes and Oncology making good progress.**
- **Pre-clinical studies for Oral Insulin (IN105) is in progress.**
- **IN105 data presented for the first time at EASD.**
- **IND for IN105 is expected to be submitted by the end of this fiscal.**
- **Phase IIB clinical trials for EGFR antibody, *Biomab-EGF* is on track for completion by the end of this fiscal.**
- **Confident to deliver attractive operating margins for the full year.**



# Biologic Effectiveness of an Insulin Analogue Developed for Oral Insulin Delivery



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## Abstract

**Background and aims:** Oral insulin delivery is a highly desirable option for the treatment of diabetes. However, the development of a viable oral insulin formulation is a complex task. To meet these challenges, a novel oral insulin formulation, INS-105, was developed. The aim of this study was to evaluate the biologic effectiveness of INS-105 compared to Humulin, a standard insulin formulation, in a canine model. **Methods:** The biologic effectiveness of INS-105 and Humulin was evaluated in a canine model. The study was conducted in two periods. In Period 1, the biologic effectiveness of INS-105 was compared to Humulin. In Period 2, the biologic effectiveness of INS-105 was compared to Humulin. **Results:** The biologic effectiveness of INS-105 was found to be similar to Humulin. **Conclusion:** INS-105 is a viable oral insulin formulation.

## Introduction

Oral delivery of insulin could facilitate and potentially improve the treatment of diabetes, but it is associated with a number of challenges including bioavailability and reproducibility. To overcome those problems, new insulin analogues are being produced. Insulin 105 (INS-105) developed by Nobex Corporation, in collaboration with Biocon, is such a molecule.

## Aims

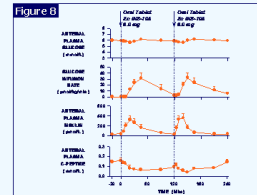
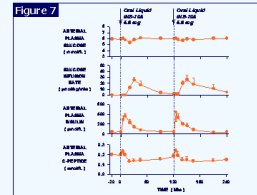
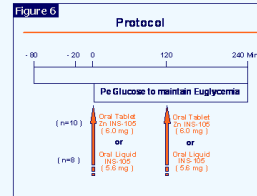
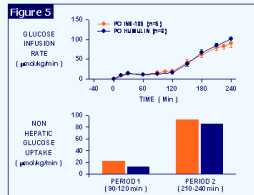
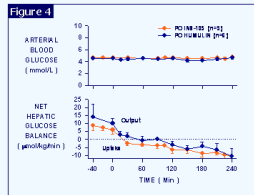
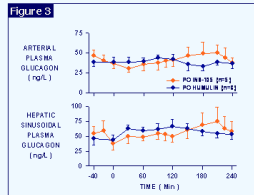
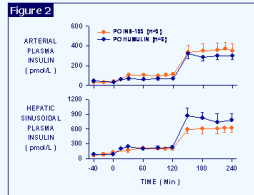
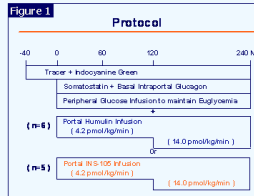
The goals of the present studies were to compare the bioactivity of INS-105 to that of Humulin when given intravenously and to assess the pharmacokinetics of orally delivered INS-105.

## Methods

- Mongrel dogs of either sex weighing ~ 22 kg
- Surgery ~ 16 days prior to study:
  - \* Sampling catheters were placed in the femoral artery, hepatic portal and left common hepatic veins as required
  - \* Infusion catheters were placed in the jejunal and splenic veins as required
  - \* Ultrasonic flow probes were placed on the hepatic artery and portal vein as required
- Dogs met the following criteria before the study:
  - \* Hematocrit > 36%, leukocyte count < 18,000/mm<sup>3</sup>, good appetite and normal stools
- 18 hr fast prior to portal insulin infusion studies
- 42 hr fast prior to oral insulin administration studies

## Calculations

- **Hepatic load in (HL<sub>in</sub>) = (A × AF) + (P × PF)**
  - \* A and P refer to arterial and portal vein glucose concentrations, respectively
  - \* AF and PF refer to hepatic artery and portal vein blood flow
- **Hepatic load out (HL<sub>out</sub>) = H × HF**
  - \* H is the hepatic vein glucose
  - \* HF is total hepatic blood flow
- **Net hepatic balance = HL<sub>out</sub> - HL<sub>in</sub>**
- **Hepatic sinusoidal hormone concentrations = HL<sub>in</sub> / HF**
- **Non-hepatic glucose uptake = glucose infusion rate - net hepatic glucose uptake**
- Data are mean ± SEM
- Statistics: ANOVA (SPSS)



## Summary & Conclusion Figures 1-5

The clearance and biologic activity of INS-105 are indistinguishable from those of Humulin. We thus conclude that INS-105 is a good candidate for oral insulin delivery.

## Summary & Conclusion Figures 6-8

Liquid INS-105 was rapidly (C-Max 10 min) and reproducibly absorbed following gavage administration. Its biologic activity was evident for 2 hours.

Zn INS-105, when delivered in pill form, was rapidly absorbed (C-Max 20 min). Its biologic activity was also evident for 2 hours. The AUC for plasma insulin was similar with the pill as with the liquid formulation.

In conclusion, insulin can be reproducibly delivered orally in a pill form such that physiologic levels of insulin result with a biologic effect lasting ~ 2 hours.

Thank You