Biocon

# Innovative Science
# Affordable Medicine

J.P. Morgan Health Conference January 10, 2011

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## SAFE HARBOR

Certain statements in this presentation 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, nor our directors, 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. Statements on Strategy or on Direction of policy should not be construed as events which require prior notification to Indian Regulatory Authorities. Such events will crystallize only once full regulatory steps have been taken in India.

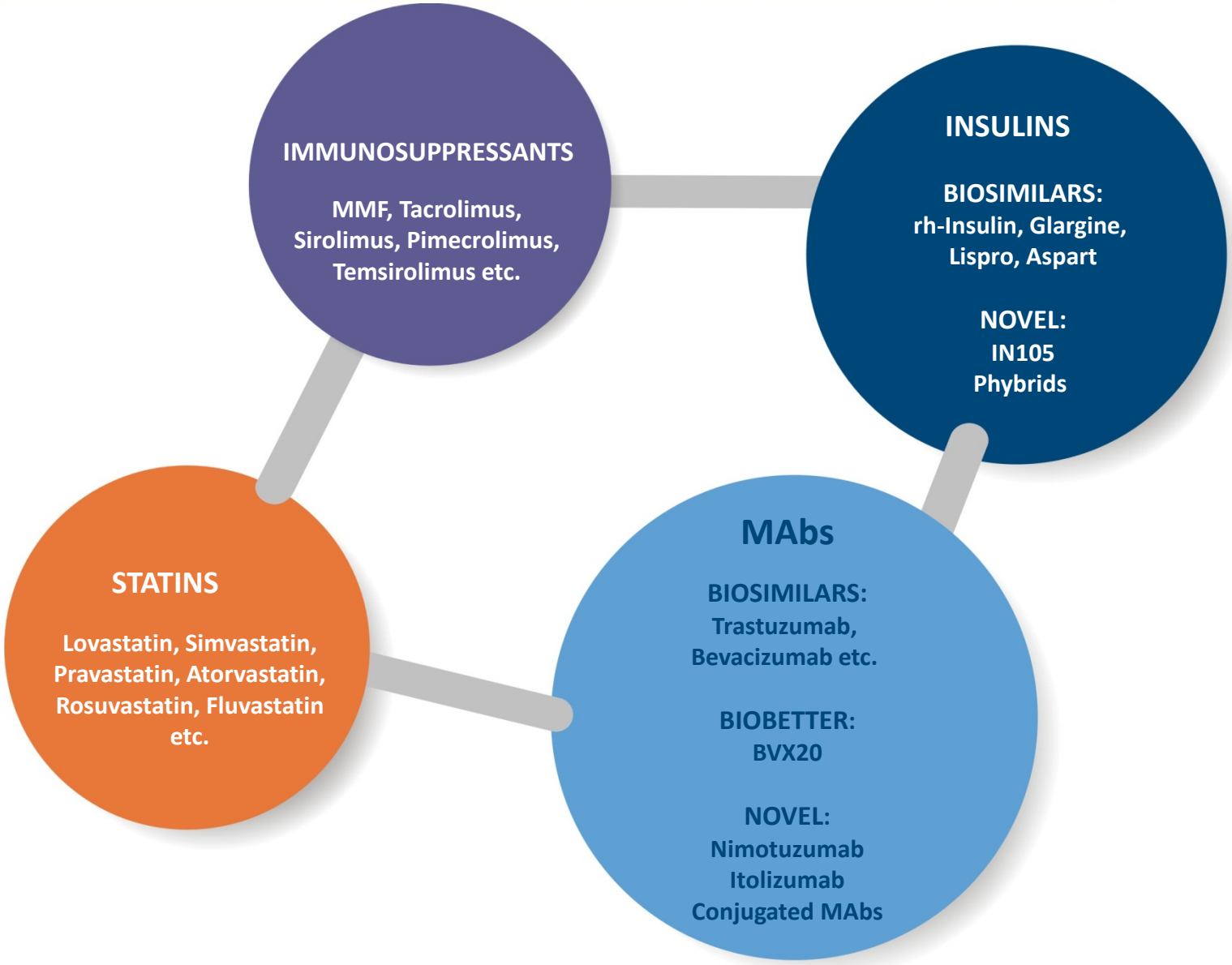
To be a global Biopharmaceutical enterprise committed to delivering affordable products and services for patients, partners and healthcare systems across the world.

Reduce therapy costs of chronic diseases with Generics & Biosimilars

Seek research and marketing partnerships that provide global access

Leverage India's cost & clinical base to deliver high value, licensable R&D assets

# PRODUCT PIPELINE - A PORTFOLIO APPROACH

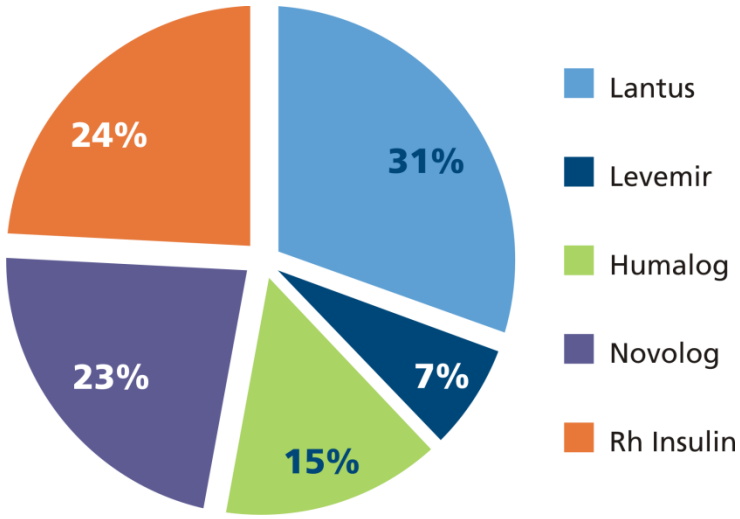


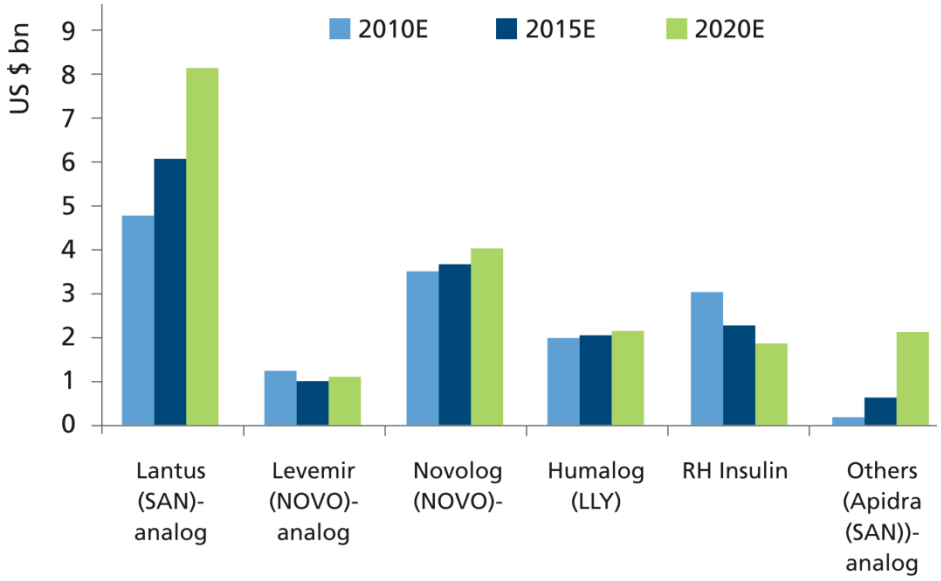
## RESEARCH & MARKETING: A PARTNERSHIP APPROACH

| DISEASE | PRODUCTS | CATEGORY | PARTNER |
|---|---|---|---|
| DIABETES | INSULIN + ANALOGS | BIOSIMILAR | PFIZER |
| DIABETES | PHYBRIDS | NOVEL | AMYLIN |
| ONCOLOGY & IMMUNE DISORDERS | MAbs | BIOSIMILAR | MYLAN |
| ONCOLOGY & IMMUNE DISORDERS | ITOLIZUMAB<br>BVX 20<br>Cancer Vaccines | NOVEL<br>NOVEL<br>NOVEL | CIM<br>VACCINEX<br>IATRICa |

# TOTAL INSULIN MARKET 2009

**Total 2009 Insulin Market USD ~13 bn** → **~ USD 20 bn in 2020**




**Growth forecast of ~6% per annum***

Sources: Industry reports

*Factoring the advent of Biosimilar Insulins

# BIOCON'S INSULIN BUSINESS

**Biocon's ranking in the Indian Market:**

**#20** in the OAD market

**#3** in the rh-Insulin market

**#2** in the Glargine market

**The 2007-2010 CAGR figures for unit sales of Insulin 40 IU:**

Market: **10.6%**

Biocon: **12.7%**

NN: **9.3%**

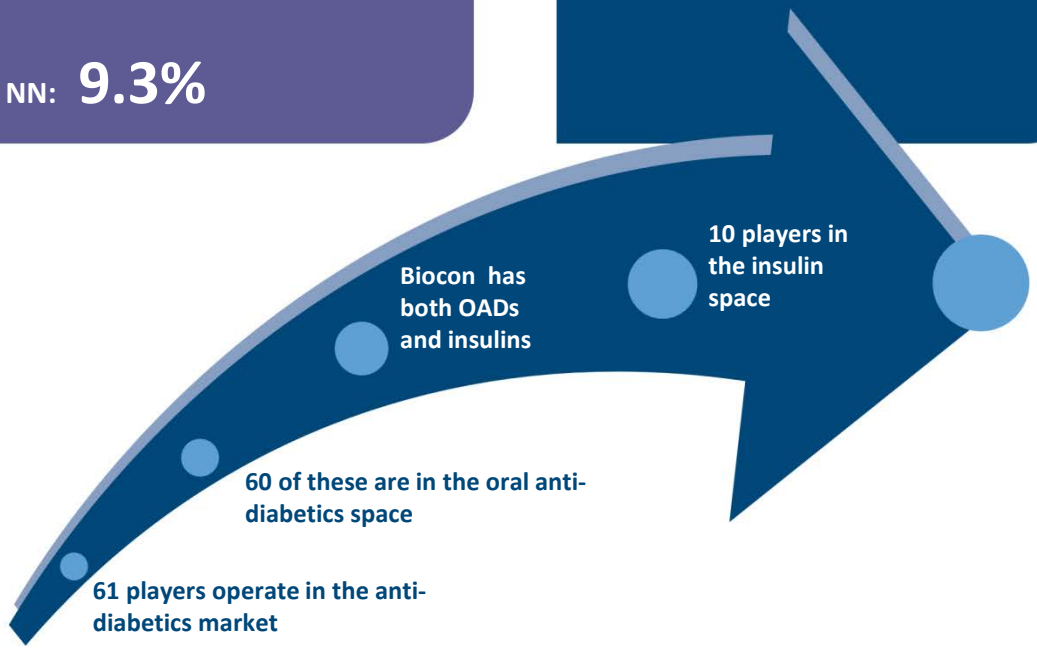
**Biocon's market share by volume:**

rh-Insulin: **10.8%**

Glargine: **13.2%**

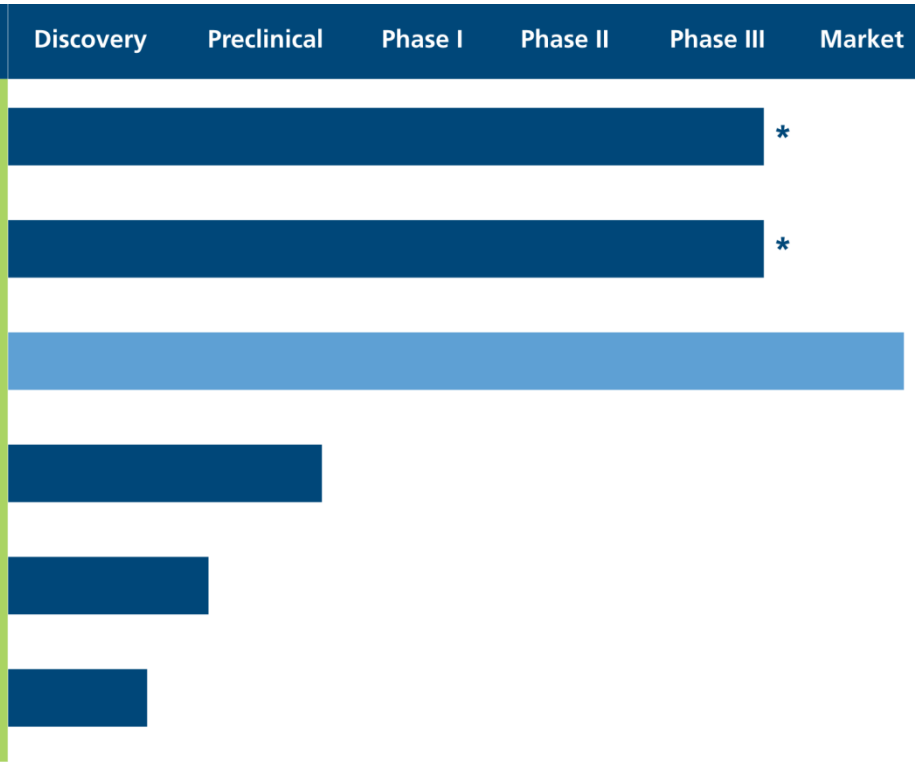
Source : IMS HEALTH – HAS+SSA DATA– SEPT-MAT 10

**Pens will be introduced in H2 2011**



## High Potential Novel Pipeline

| Product | Areas | Names |
|---|---|---|
| Novel Molecules | Diabetes | IN105 (Oral Insulin) |
| | Oncology / Auto immune | Itolizumab (Anti CD6 mAb) |
| | Oncology | Nimotuzumab (Anti EGFR mAb) |
| | Oncology | BVX 20 (Anti CD20 mAb |
| | Diabetes | Hybrid Peptide |
| | Oncology | Fusion mAbs (Tumour Vaccines) |




* Proof of Concept Phase III trials

## IN-105 : FIRST CUT DATA OF PHASE III PoC ~ 260 PTS STUDY

### Efficacy

- HbA1c drop upto 0.8% from baseline observed in drug arm
- Greater than expected placebo effect observed
- Significant drug effect in several subsets
- Statistically significant reduction in PPG throughout trial
- Frequent SMBG likely to have influenced placebo effect

### Safety

- Excellent overall safety profile
- No clinically relevant hypoglycemia observed
- Data indicates drug is not immunogenic
- Data indicates drug is weight neutral

### Studies

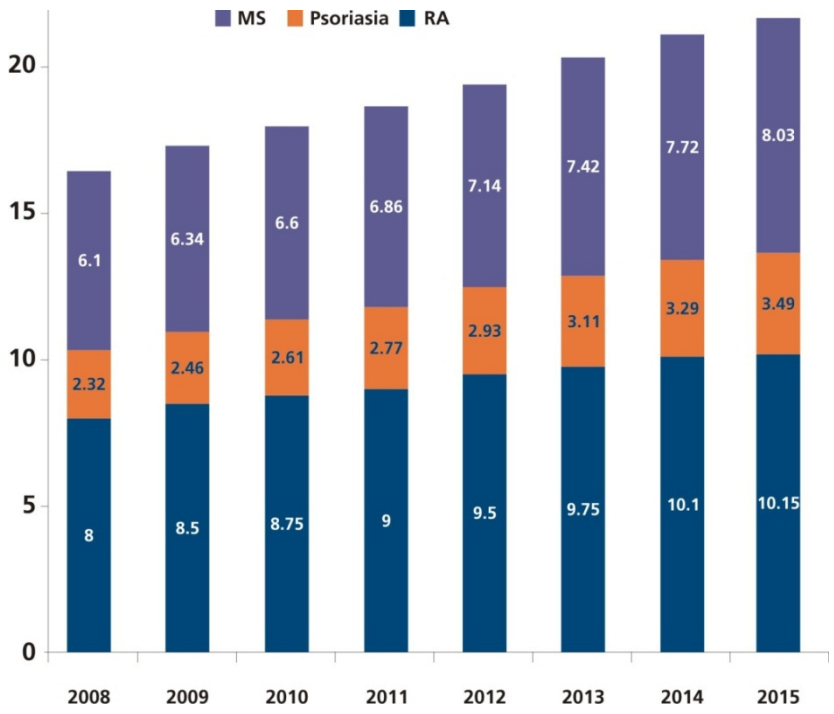
- Further studies under US IND on Type I Diabetes ongoing
- Further studies to be conducted post partnering

## *Itolizumab* : A PIPELINE WITHIN A PRODUCT

- *Itolizumab* is an immune-modulating Anti-CD6 antibody
- CD6 is Predominantly expressed by T cells & a B cell subset.

### Potential for CD6 targeting:

- Chronic Plaque Psoriasis (on-going)
- Rheumatoid Arthritis (on-going)
- Psoriatic arthritis
- Multiple sclerosis




**RA, MS & PSORIASIS MARKET TO EXCEED $20 BN BY 2015***

* Datamonitor

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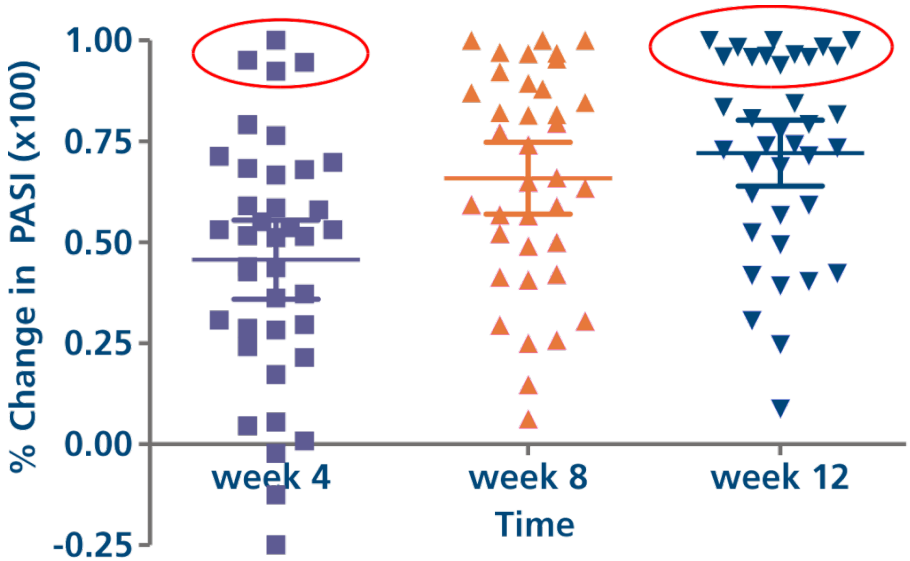
## Mean PASI improved by almost 50% at week 4 and 75% by week 12 in the overall study




| | At Week 8 N(%) | At Week 12 N(%) |
|---|---|---|
| PASI 50 | 27 (67.50 %) | 29 (72.50 %) |
| PASI 75 | 17 (42.50 %) | 18 (45.00 %) |
| PASI 90 | 8 (20.00 %) | 12 (30.00 %) |
| PASI 100 | 3 (7.50 %) | 3 (7.50 %) |

**PASI Improvement**

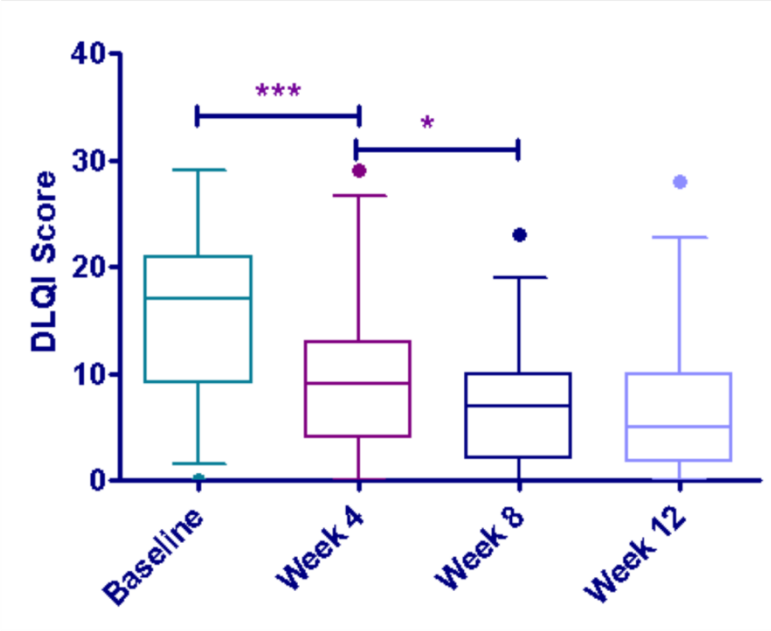
# *Itolizumab:* SIGNIFICANT CHANGE IN QoL OBSERVED

## SF36

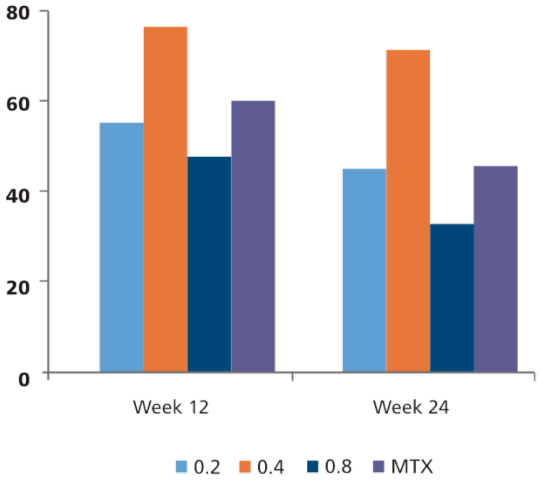
| | Mean Scores at Visits | | |
|---|---|---|---|
| SF-36 Parameters | Baseline | Week 12 | P-Value |
| PCS | 39.23 | 46.69 | 0.000 |
| Physical Function | 38.14 | 46.04 | <.0001 |
| Role Physical | 37.69 | 45.76 | 0.003 |
| Bodily Pain | 36.61 | 45.80 | 0.000 |
| General Health | 37.56 | 43.85 | 0.011 |
| MCS | 38.18 | 44.97 | 0.000 |
| Mental Health | 36.28 | 45.47 | <.0001 |
| Role Emotional | 34.99 | 41.84 | 0.028 |
| Social Function | 36.26 | 42.31 | 0.008 |
| Vitality | 47.10 | 53.56 | <.0001 |

Note: P-Value is generated using paired t test

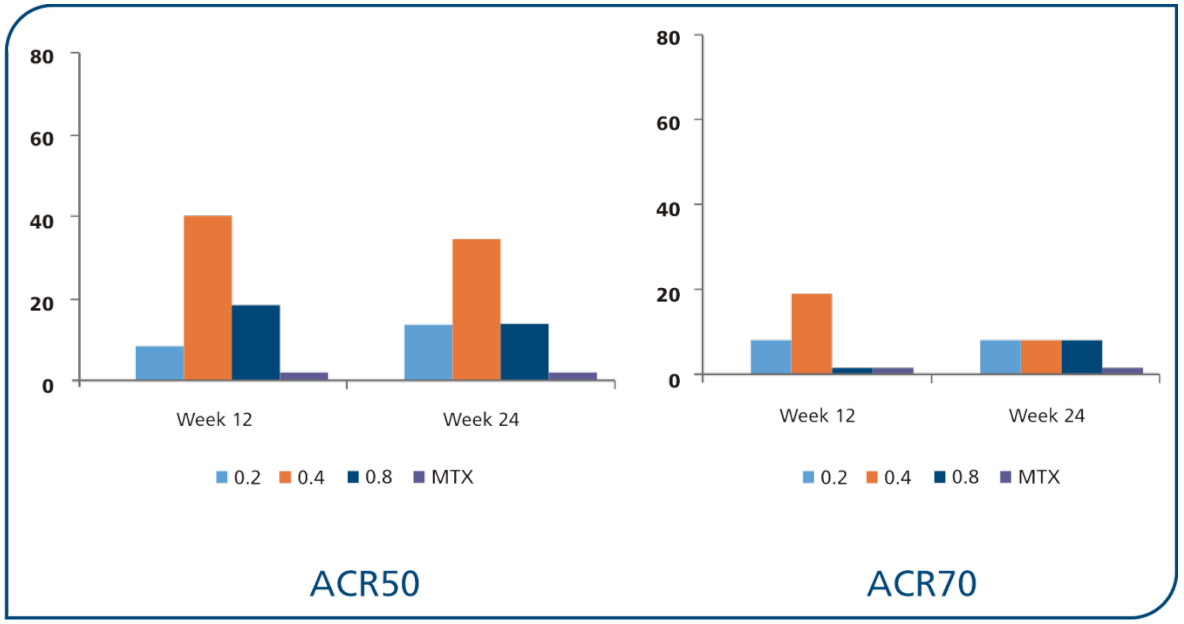
## DLQI



## 0.4mg/kg weekly dosing of *Itolizumab* induced ACR50 response in 37% of the patients - Full Analysis Set(FAS)




ACR20




ACR50 ACR70

## None of the patients in the MTX arm achieved an ACR50 or ACR70 response

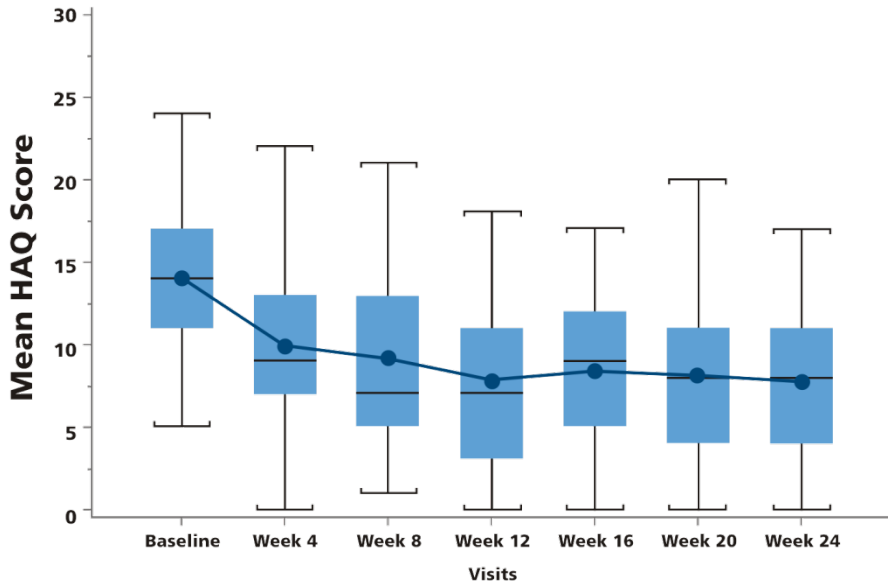
# *Itolizumab:* SIGNIFICANT IMPROVEMENT IN QoL & DISABILITY

## SF36

| | Mean Scores at Visits | | |
|---|---|---|---|
| SF-36 Parameters | Baseline | Week 12 | P-Value |
| PCS | 34.1 ± 6.7 | 39.9 ± 8.0 | 0.0001 |
| Physical Function | 31.8 ± 11.1 | 37.4 ± 11.3 | 0.0062 |
| Role Physical | 34.4 ± 8.7 | 38.9 ± 8.3 | 0.083 |
| Bodily Pain | 32.3 ± 8.7 | 40.6 ± 8.6 | <.0001 |
| General Health | 31.5 ± 9.0 | 38.6 ± 8.7 | 0.0002 |
| MCS | 34.6 ± 8.2 | 39.9 ± 7.8 | 0.0008 |
| Mental Health | 33.5 ± 10.5 | 39.7 ± 8.9 | 0.0011 |
| Role Emotional | 29.1 ± 11.6 | 36.0 ± 9.6 | 0.003 |
| Social Function | 33.1 ± 10.6 | 37.5 ± 9.4 | 0.0049 |
| Vitality | 42.0 ± 7.5 | 45.8 ± 8.0 | 0.0005 |

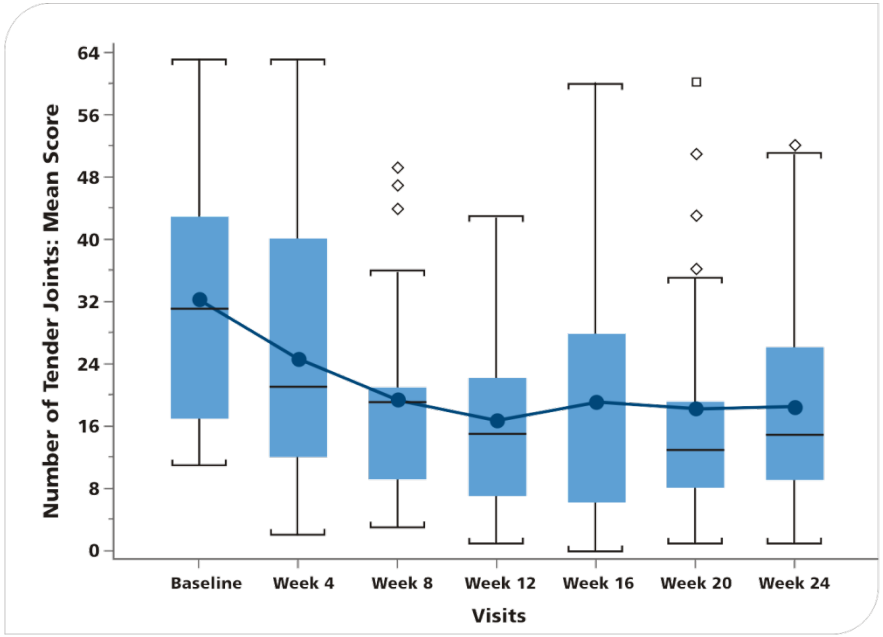
Note: P-Value is generated using paired t test

## HAQ (i)

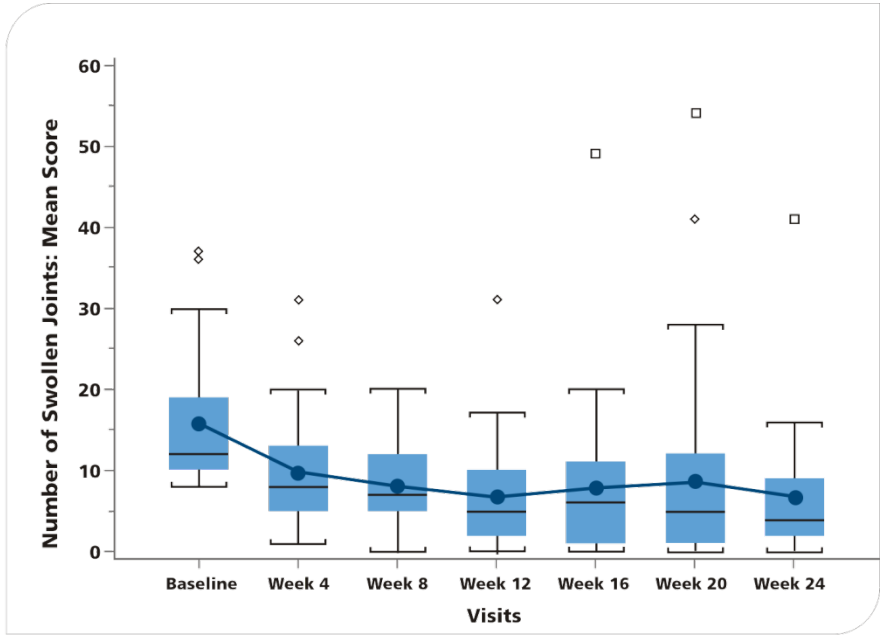


# *Itolizumab:* DECREASE IN TENDER AND SWOLLEN JOINT COUNTS

## TENDER JOINT COUNT




## SWOLLEN JOINT COUNT




**Significant improvement sustained over 24 weeks**

## *Itolizumab:* COMPARISON OF TRIALS – DMARD FAILURES

| Trial Metrics | Itolizumab | Abatacept | anti-TNFs | Tocilizumab |
|---|---|---|---|---|
| Previous lines of DMARD therapy | 1.35 | NR | 1.4-1.9 | 1.4 |
| Duration of disease | ~ 5 yrs | 8.5 yrs | 7-9 yrs | 7 yrs |
| Effective dose | 0.4mg/kg | ~ 10mg/kg | 80-200mg/wk | 8mg/kg |
| Median dose of Methotrexate | ~ 14.5 | 16.1 | ~ 15 | 14.5 |
| DAS28 - CRP baseline | ~ 6 | 6.4 | ~ 5.8 | 6.7 |
| ACR50 @ 12 w | ~ 37% | 32% | ~ 35% | ~ 30% |
| HAQ change from baseline @ 12 weeks | 0.84 | 0.45 | 0.4 | 0.55 |
| Percent of patients with at least 1 AE | 70% | 75% | 60-80% | 72% |
| Infusion reactions | ~ 15% | 9% | 12-37% | ~ 8% |
| Infections | 10.50% | 54% | 35% | ~ 35% |
| Serious infections | < 5% | 7.2 | ~ 5 | ~ 4 |

- Low infection rates is a key differentiator
- Low dose allows a lower therapy cost

# *Itolizumab:* CLINICAL PLAN 2011/2012

| | Year | 2011 | | | | 2012 | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Registration trials in 2011-12** | **Activity** | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| **Itolizumab Phase III Psoriasis** | Trial conduct | | | | | | | | |
| (Status: accrual complete) | Primary end point | | | | | | | | |
| N: 213 evaluable, 250 randomized | Analysis and report | | | | | | | | |
| Double blind | India Registration | | | Apply | | | | | |
| Randomized controlled trial | **USFDA pre-IND advice** | | | | | | | | |
| **Itolizumab Phase III RA** | India CTA filing and approval | | | | | | | | |
| (Status: CTA filed) | Trial conduct | | | | | | | | |
| N=332 evaluable, 360 randomized | Primary end point | | | | | | | | |
| Double blind | India Registration | | | | | | | Apply | |
| Randomized controlled trial | **USFDA IND** | | | | | | | | |

## BVX20 – AN ENHANCED ANTIBODY

| Functional Activity | Rituximab | BVX20 |
|---|---|---|
| Monoclonal antibody Isotype | Chimeric IgG1 | Humanized IgG1 |
| Epitope in CD20 antigen | Similar or overlapping epitope to Rituximab | |
| Complement dependent cytotoxicity (CDC) | Lower | Off rate CDC activity higher than Rituximab* |
| Antibody dependent cell mediated cytotoxicity (ADCC) | Similar to Rituximab | |

* Potentially indicative of lower dose and higher efficacy in CLL

## Phase I/II trial : BVX20 + Relapse/Refractory NHL

Weekly therapy for 4 weeks on ~ 50 pts

Primary endpoint: safety; F/u for 2 years

PK on first and last dose

Multi-centric study: First patient dosing: Q1 2011

US-IND : Q3 2011

# EMERGING MARKETS: HIGH GROWTH – HIGH RETURNS

## Biosimilar Insulins

- Current EM ~$1.5 billion
- 5 year CAGR 15%
- EM estimated to be a $5 billion Insulins market by 2020
- Emerging Markets account for 70% of world's Diabetic Population
- Lower regulatory barriers offer faster market entry

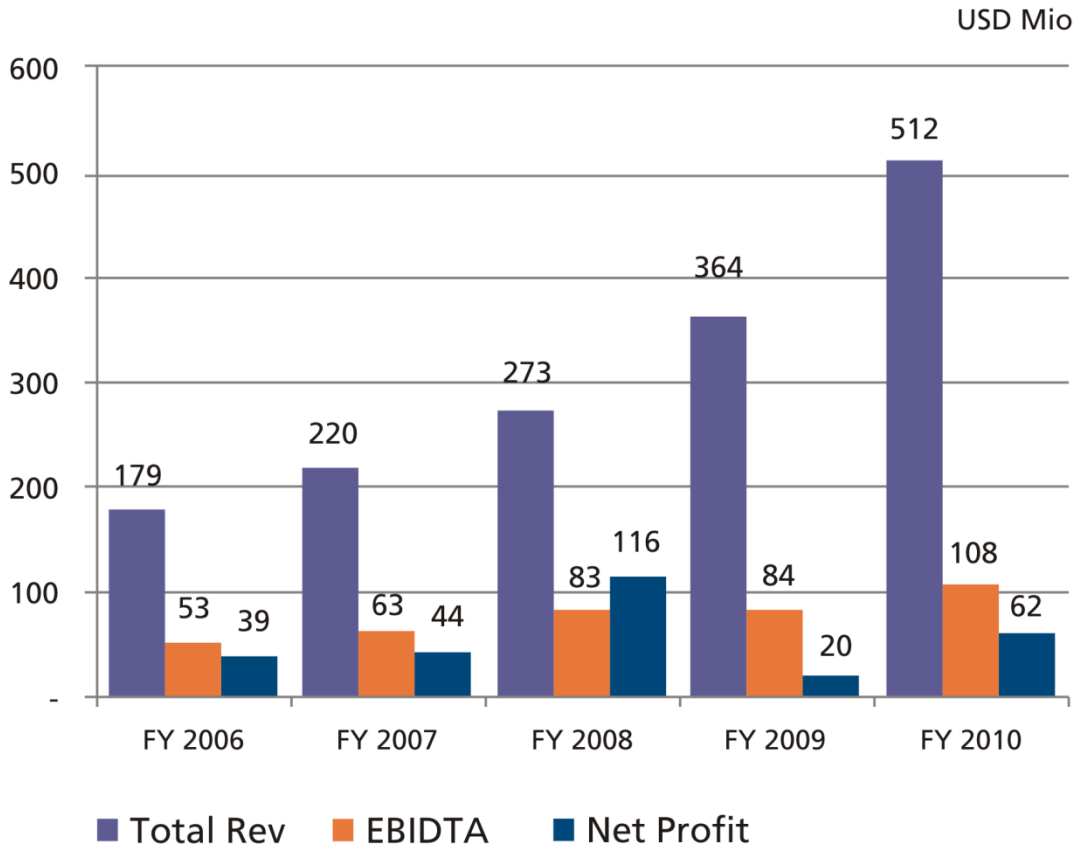
## Biosimilar mAbs

- Current market size estimated at $1.5 billion
- Estimated to be a $2.6 billion market by 2016

## Generics

- 50% of European prescriptions, 75% of US prescriptions
- Generics growth outlook robust over next 6 years ($185 bn patent cliff)
- 3-year CAGR (2007-10) at 11%. Global Pharma at 5.5% CAGR
- APAC accounts for 16% of $124 bn generics mkt with fastest growth

# TOPLINE 5 YEAR CAGR 24%




**5 year average**
**EBITDA Margin** **27%**

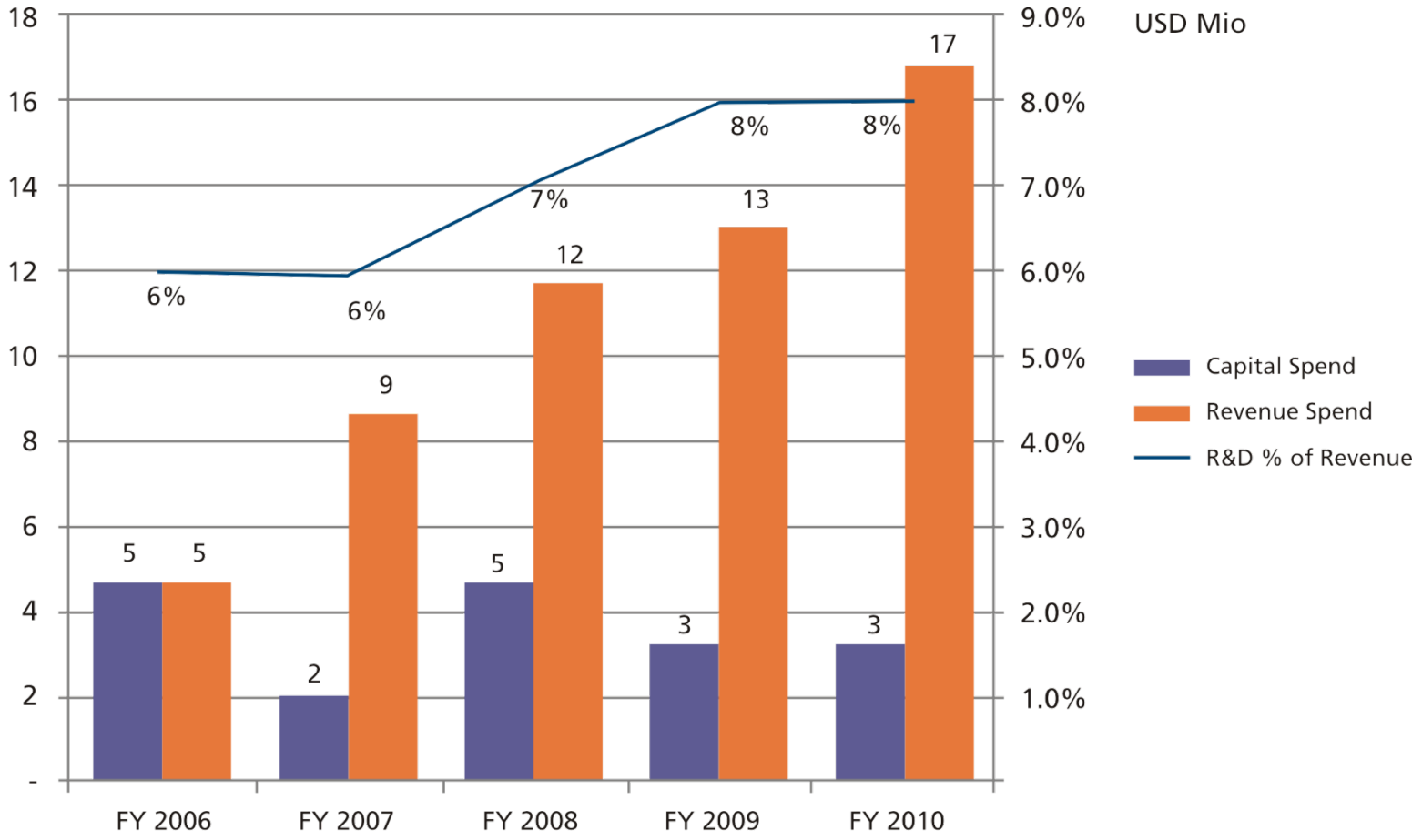
**5 year average**
**PAT Margin** **20%**

| | |
|---|---|
| Equity | $426 M |
| Net Debt | $ 4 M |

Balance sheet as of 30.09.2010

Fiscal year average exchange rates used

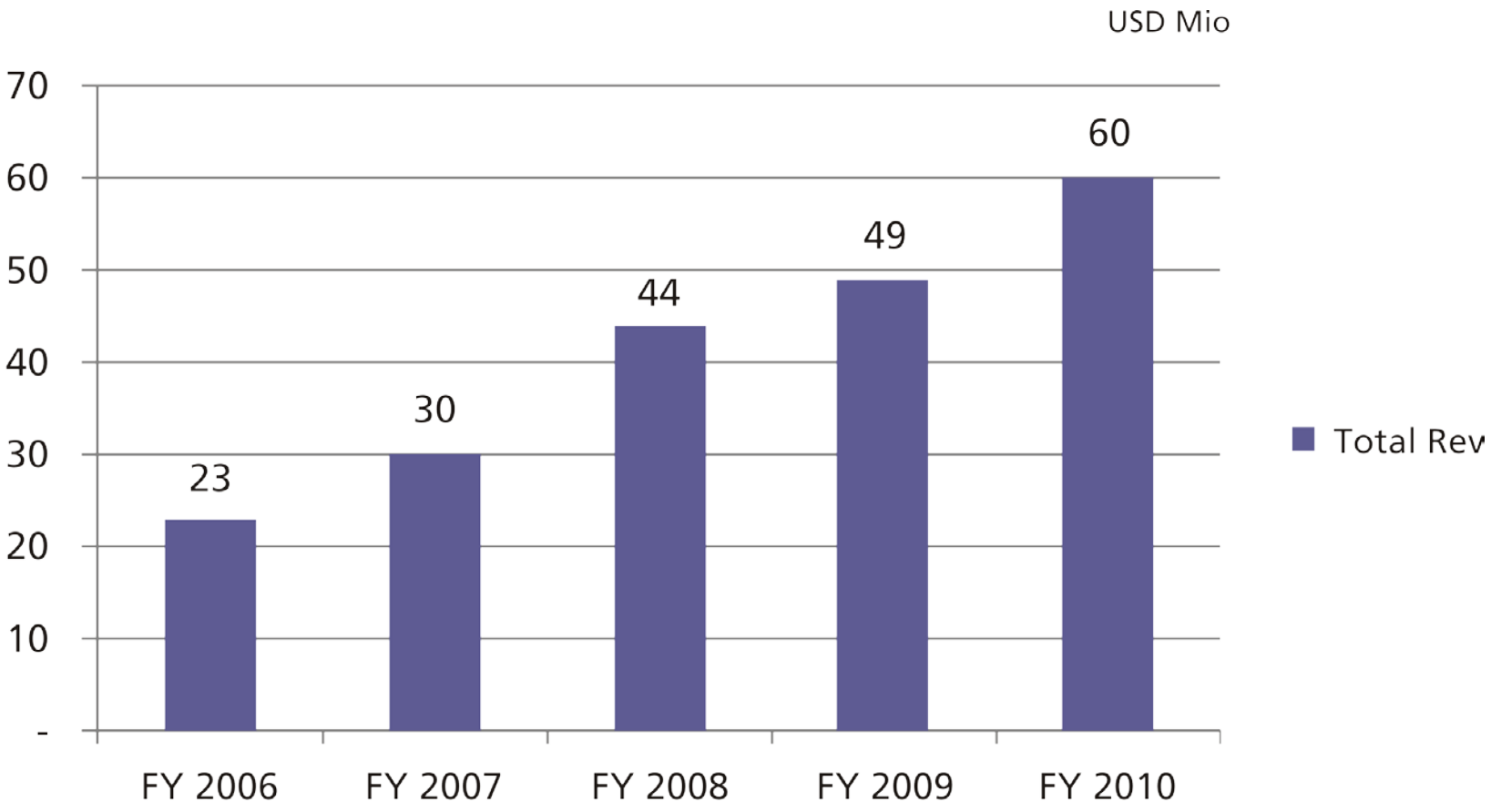
## SELF FINANCED R&D




**Biocon amongst Top 10 Pharma R&D spenders in India - Economic Times**

**Fiscal year average exchange rates used**

# Top line 5 year Revenue CAGR of 21%




Fiscal year average exchange rates used

# RESEARCH SERVICES: ALIGNING WITH GLOBAL TRENDS

## Dynamic and Favorable Macro Environment for Research Services

- Externalization a key driver as Pharma & Biotech R&D is reinventing itself
- Move from component to integrated programs
- Chemistry to Biologics
- FTE to Preferred Supplier to Strategic Development Partner
- Cost/time productivity arbitrage to innovation and value addition
- Expanding Biologics pipelines within Big Pharma far exceeding internal capacity

**BIOLOGICS: Constitute >25% of drug pipelines. In-licensing from small Biotechs accounts for 35% of Biologics in development.**

## Syngene / Clinigene well placed to address these opportunities

- Integrated Platform offering end-to-end solutions for NCE & NBE
- Increasing focus on long term strategic partnerships vs. transaction based model
- Development capabilities for biologics include scale-up & bioanalytics
- Flexible service models including FTE/FFS, Co-development and Risk Sharing
- Strong infrastructure in early clinical development and translational medicine
- Clinical experience in novel Biologics supported by Phase I unit

**BBRC: A new paradigm in externalized R&D pioneered by BMS at Syngene. A dedicated, integrated R&D hub pursuing pipeline development with 450 researchers.**

## SUMMARY: GROWTH DRIVERS 2011

- **EMERGING MARKETS**
- **BIOSIMILAR INSULINS: PFIZER**
- **BIOSIMILAR mAbs: EMERGING MARKETS**
- **LICENSING OF NOVEL PROGRAMS: IN105, *Itolizumab***
- **RESEARCH SERVICES: Syngene & Clinigene**
- **STATINS, IMMUNO-SUPPRESSANTS, PROSTS: APIs & ANDA Dossiers**

# Thank You