



# Laxai Pharma Ltd.

(OTC: LAXAF)

## Investor Presentation

[www.laxai.com](http://www.laxai.com)

New Jersey, USA



## DISCLAIMER

*This presentation contains forward-looking statements. Some forward-looking statements may be identified by words like "expects", "anticipates", "plans", "intends", "indicates" or similar expressions. The statements are not a guarantee of future performance and are inherently subject to risks and uncertainties. The Company's actual results could differ materially from those currently anticipated due to a number of factors, including, but not limited to, successful integration of structural changes, including restructuring plans, acquisitions, technical or manufacturing or distribution issues, the competitive environment for the Company's products, the degree of market penetration of the Company's products, and other factors*



## Agenda

- LAXAI
  - ✓ Overview
  - ✓ Mission and Values
  - ✓ Strategic Business Units
    - Discovery Research
    - Clinical Research Services
  - ✓ Differentiators
  - ✓ Management Team
- Market Trends
- Financial Highlights
- Goals and Strategies



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## LAXAI: Overview

### Organization

- US based CRO operating since 2004
- India operations commenced in 2007
- Minority Owned Business – MBE Certified
- 150+ employees in US and India
- ISO 9001:2000 certified
- Provides Contract research services to global pharmaceutical and biotech industry

### Management

- Leadership team with successful track record in the CRO industry
- Strong scientific and professional management
- Renowned Scientific Advisory Board
- Headquartered in South Plainfield, New Jersey

### Services

- Discovery
  - ✓ Medicinal Chemistry
  - ✓ Biology
  - ✓ Integrated Collaborative Research
  - ✓ Process R&D and Analytical
- Development
  - ✓ Clinical Research
- Strategic Partnership with Temple University for Discovery Services



## Mission and Values

### Mission

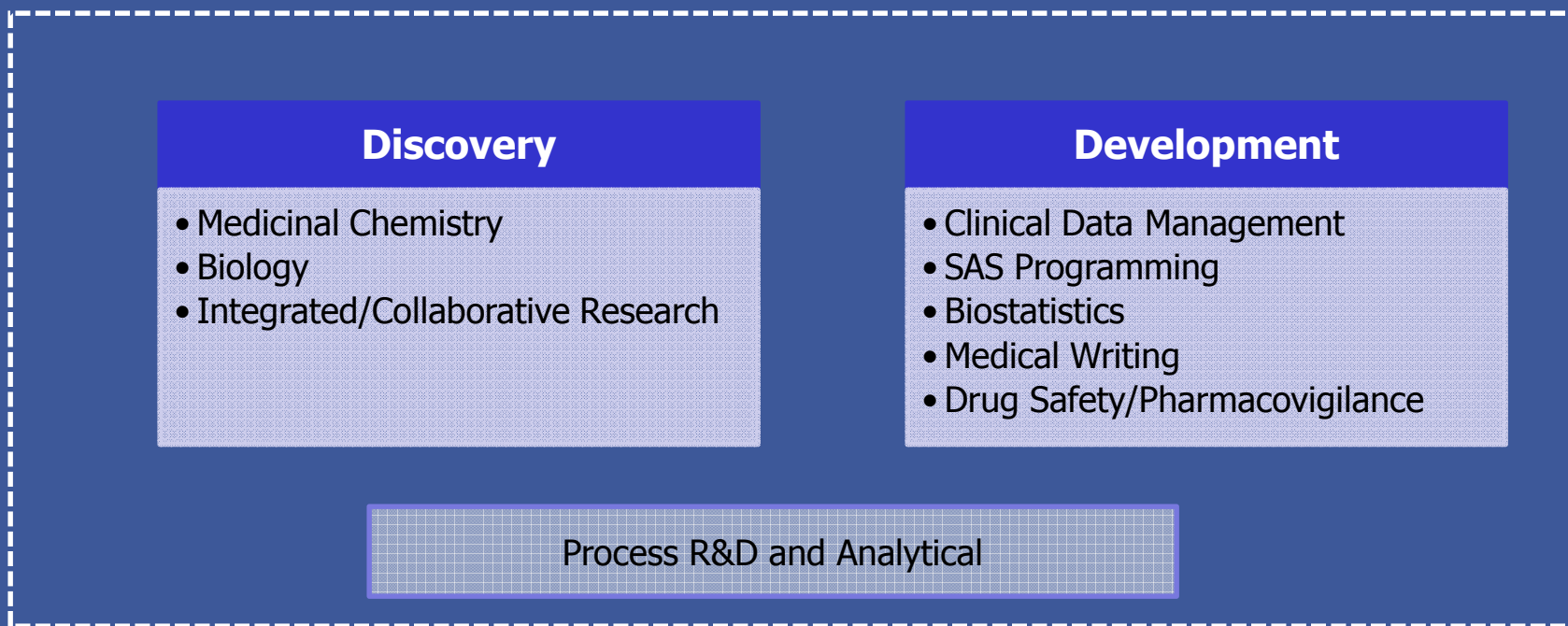
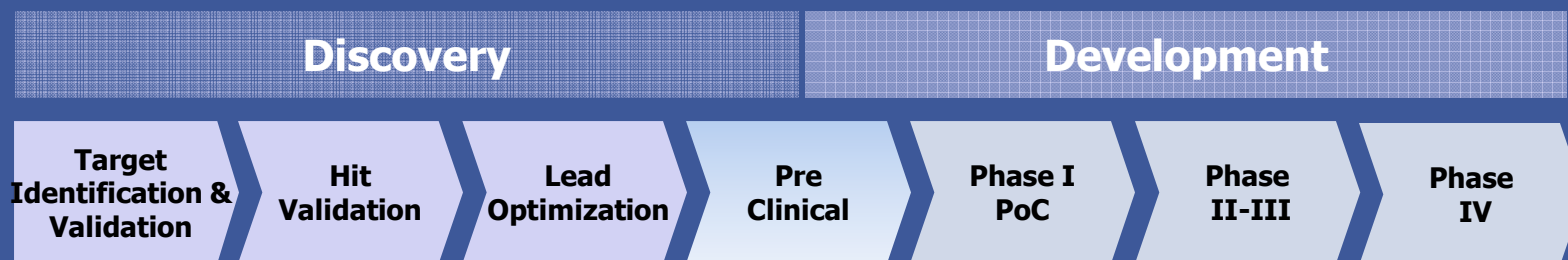
- Deliver outstanding value to our biopharmaceutical clients and stakeholders

### Values

- **Quality:** Committed to excellence in Science & Delivery
- **Integrity:** Demonstrate integrity and maintain high ethical and legal standards
- **Team Work:** Working together seamlessly to achieve company goals
- **Culture:** Built on the key values of mutual respect, transparency, pro-activeness, professionalism and commitment



## Business Portfolio





## Discovery Research Services

- Medicinal Chemistry
  - ✓ Synthesis of Building Blocks, Scaffolds, Intermediates, Analogs, Focused Libraries, Reference, Standard and Impurity
- Biology
  - ✓ In vitro and In vivo Pharmacology, ADME
- Integrated Research/Collaborative Research
  - ✓ Hit to Lead, Lead Optimization
- Process Development & Analytical
  - ✓ Route scouting, Parameter Optimization, Lab validation, Process Scale Up
  - ✓ Analytical method development and validation, stability profile, physicochemical property determination



## Facilities and Infrastructure – Discovery Research Services

12,000 sq ft Laboratory space



- NMR (400 MHz)
- LC/MS
- HPLC (UV, PDA and ELSD)
- UV / FTIR
- Microwave Synthesizer
- Parallel Synthesizers
- Combiflash
- Prep HPLC
- Rota Vapors
- Hydrogenators
- GC



## Clinical Research Services

### ▪ Clinical Data Management

- ✓ Full spectrum of services
  - From CRF Design until database lock
  - Final datasets generation
  - Paper, Electronic Data Capture and Hybrid

### ▪ SAS Programming

- ✓ Analysis Datasets generation
- ✓ Tables, Listing and Figure generation using SAS
- ✓ CDISC mapping services – SDTM and ADAM

### ▪ Biostatistics

- ✓ Study design and Protocol development
- ✓ Power/Sample size calculation
- ✓ Statistical Analysis
- ✓ Integrated Summaries

### ▪ Medical Writing

- ✓ Clinical Study Report
- ✓ IND/NDA
- ✓ CRF Design
- ✓ Statistical Analysis Plan
- ✓ Informed Consent
- ✓ Investigator Brochure
- ✓ Literature/Journal & Presentations
- ✓ Package Inserts & Labeling

### ▪ Drug Safety/Pharmacovigilance

- ✓ Data collection/AE/SAE logging
- ✓ Medical coding
- ✓ Adverse Events/SAE Evaluation
- ✓ Narratives preparation
- ✓ Regulatory reporting

**Training:** Good Clinical Practices, FDA regulations, Standards, Processes and Validation, Data Analytics , CDM Systems, EDC Implementation, CDISC standards, Biostatistics and SAS Programming, SAS Accredited Training

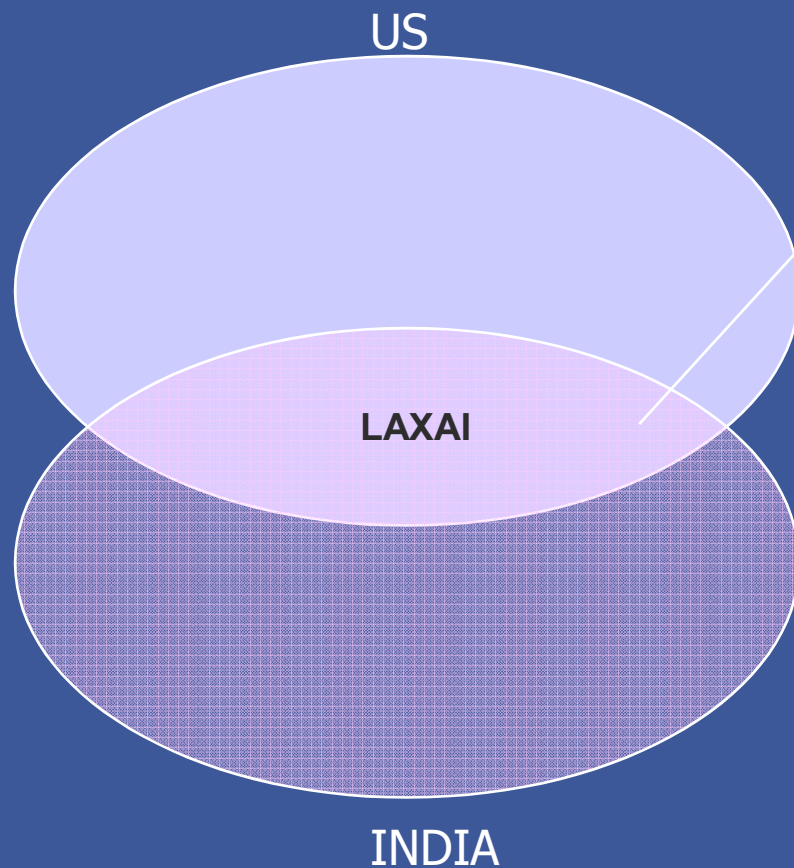


## Facilities & Infrastructure – Clinical Research Services

- 15,000 sq ft Clinical Research Solution Center
- Technology Infrastructure including work stations, servers, etc.
- Validated Clinical Data Management Systems to support Sponsors Clinical research (Oracle Clinical, Medidata RAVE, MedDRA, WHO-Drug)
- Entire suite of SAS Clinical Solutions for Biostatistics analysis & CDISC compliance
- Redundant Network/Business Continuity Plan & Disaster Recovery
- Archive room



## LAXAI Differentiators



### Unique Positioning

#### Compared with Indian CROs

- ✓ US based Project Management
- ✓ Option of 100% US delivery team
- ✓ Solution centers in US
- ✓ In-house staffing solution for scalability

#### Compared with US CROs

- ✓ Cost effective (Savings > 25%) with no compromise on quality
- ✓ Blended Onsite/ Offsite / Offshore business models
- ✓ In-house staffing solution for scalability
- ✓ Training services in US



## Management Team

**Ram Ajjarapu**, Executive Chairman

**Naren Mallakunta**, Chief Executive Officer (Interim)

**Vamsi Maddipatla**, Executive Director

**Dr. Shailesh Dave**, Senior Vice President – Operations

**Dr. Narinder Mohal**, Senior Vice President - Head of Chemistry Services



## Magid Abou-Gharbia , PhD – Scientific Advisor

- Associate Dean and Professor of Medicinal Chemistry at the School of Pharmacy of Temple University
- Prior to this, for twenty six years, he was the Senior Vice President of Chemical and Screening Sciences at Wyeth Pharmaceuticals
- Responsible for bringing 5 drugs into the market including: (1) Effexor®, a first-in-class serotonin-norepinephrine reuptake inhibitor (SNRI) antidepressant; (2) Mylotarg®, an antibody-targeted anti-cancer agent; (3) Tygacil®, a broad-spectrum antibiotic; (4) Pristiq®, a second generation SNRI for treatment of depression; and (5) Torisel®, a cell cycle inhibitor for treatment of renal cell carcinoma
- Inventor on 99 US-issued US patents and over 350 patents worldwide
- Alfred Burger Award in Medicinal Chemistry (2008), American Institute of Chemists (AIC) Chemistry Pioneer Award (2007), Researcher of the Year (2006) from Health Care Institute of NJ (HINJ); Trailblazer Award (2006) from Science Spectrum; The Procter Medal (2003)
- Named in list of most Prolific Inventor of the Decade by US Patent & Trade Mark (1998)
- Induction into the New Jersey Inventors Hall of Fame (2004)
- Top 10 scientists of New Jersey by the New Jersey Business Magazine



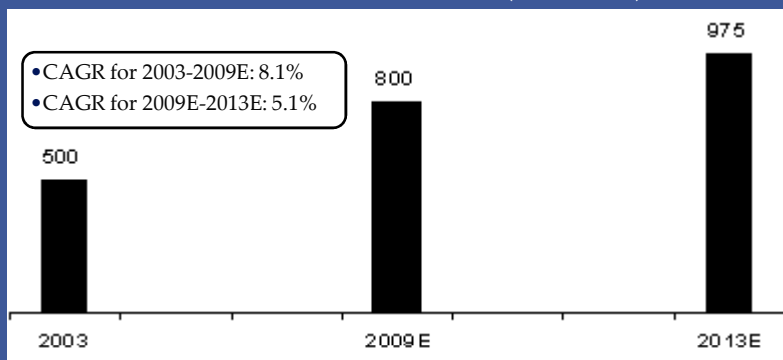
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## Global Pharma Industry driven by increasing R&D

Global Pharma Market (in USD bn)



- New drugs in development have increased at a CAGR of 4.8 % over the last ten years between 1999-2009
- There has been a corresponding increase in R&D expenditure from USD 75bn in 2003 to USD 110bn at present (with USD 36bn on Research and USD 74bn on Development)

- Demographic shift towards an older population with greater incidence of lifestyle diseases driving growth
- Emerging Markets expected to contribute more than half of global Pharma market growth by 2013 (CAGR of 14% in 2009-2013)

New Drugs under Development



Cost of bringing one new drug to the market has increased 7x to USD 880 mn from USD125 mn in the 1980s  
On an average, each NDA requires 70 clinical trials and 4,200 patients at present against 30 clinical trials and 1,300 patients in early 1980s



# Outsourcing becoming imperative for Global Pharma players

## Increasing Genericismation

- USD 50bn and € 2bn worth patented drugs going off-patent in US and Europe by 2010, respectively
- Several blockbuster drugs facing patent challenges by large generic companies

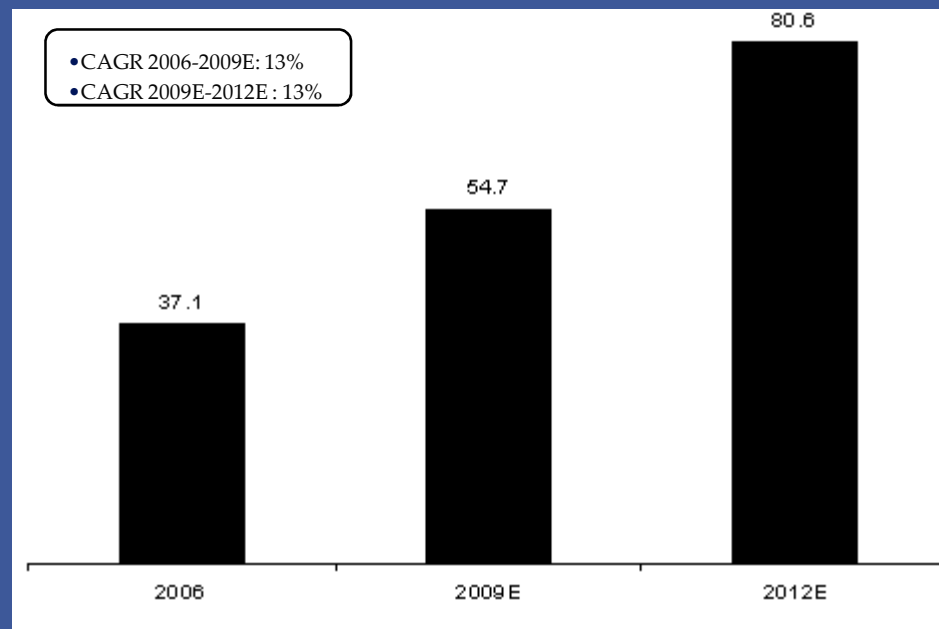
## Declining R&D productivity

- Rate of New Drug Approvals (including molecules) by UD-FDA has declined in last few years (19 in 2006 vs. 38 in 2000)
- Reduction in number of blockbuster drugs at the cost of increased R&D expenditure leading way to outsourcing

## Increasing Cost Pressures

- Drug development costs have risen from USD 802 bn in 2001 to USD 1318 in 2006 led by increasing regulatory pressures, longer and larger clinical sample studies
- Only 2 out of 10 drugs ever generate revenues exceeding R&D costs

Global Contract Research and Manufacturing Services (CRAMS) Market (in USD bn)



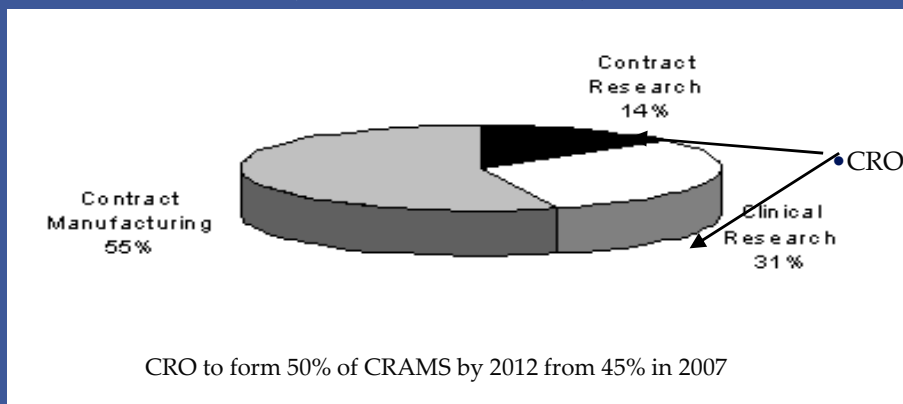
Leading to emergence of Global CRAMS market resulting in lower costs and reduced time to market for Pharma companies

• Source: PhRMA profile 2008, US FDA



# Global CRO market – a USD 40bn opportunity by 2012

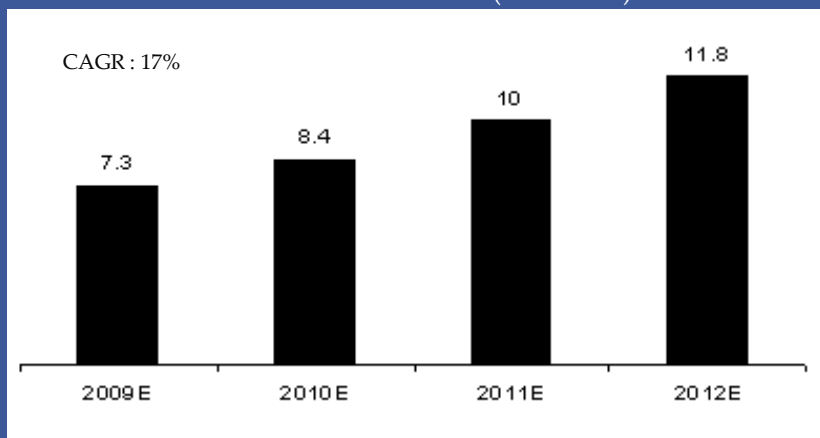
Segment-wise Global CRAMS Market in 2007  
(Market size USD 41.7bn)



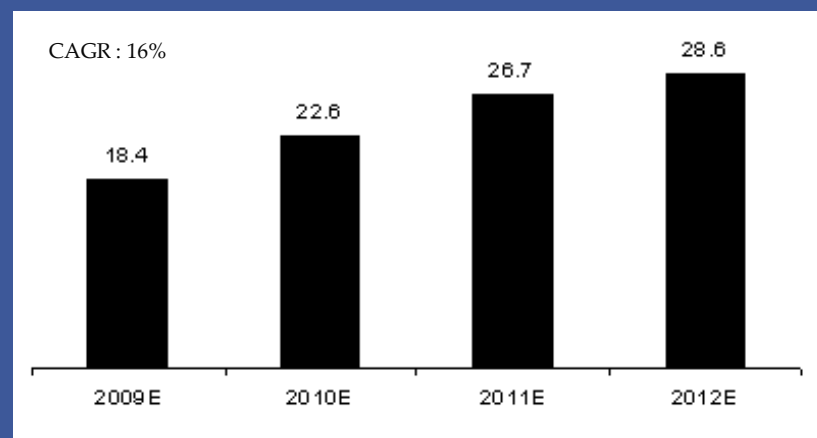
## Contract Research:

- Chemistry Services: Building Blocks, Compound Synthesis, Libraries, Process Research
- Biology Services: Protein Expression, Structural Analysis, Target Validation, Assay Development, Screening, Analogue Creation
- Clinical Research:
  - Phase I-IV, BA/BE, Clinical Data Management & Biostats
  - Others: Clinical Studies Management, Medical Writing, Regulatory Services
- Contract Manufacturing:
  - API & Intermediaries
  - Formulations, Dosage forms (solid, liquid, injectibles)

Contract Research Market (in USD bn)



Clinical Research Market (in USD bn)



Source: Frost & Sullivan



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## Financial Highlights

- Capitalization
  - 60.1 million shares outstanding
  - 5.8 million shares underlying options and warrants
- Cash balance of \$175,000 (as of 3/31/10)
- Cash flow positive
- Pro forma revenues in 2009 - \$6.35 m



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## Short Term Goals for 2010

- Complete two or more additional acquisitions in US and India
- Transition to higher value Discovery Services by offering collaborative research services
- Add Clinical Trials and Clinical Pharmacology into the portfolio of services
- Raise additional capital efficiently if needed for acquisitions
- Core focus on increasing cash flow
- Add additional high profile board members



## Goals & Strategies

### Goals for FY12

- Revenues : US\$ 30 Million
- EBITDA : 20-28%
- Be an integrated services company across the drug discovery and development pipeline

### Strategies

- **DISCOVERY:** Transition to higher value Discovery Services by offering collaborative research services by partnering Big Pharma and Biotech
- **DEVELOPMENT:** Add Clinical Trials and Clinical Pharmacology into the portfolio of services
- **INFRASTRUCTURE:** Invest in labs in the US and expansion in India
- **BUSINESS DEVELOPMENT:** Extensive investment in Business Development
- **DELIVERY:** Strengthen operational efficiency and execution