

Sector:

Pharmaceuticals

Project Title:

Integrated Research and Development Center

Project Description

Indian Pharmaceutical companies are breaking out of their traditional reputation of being generic copycats by moving upstream in the value chain and increasing focus on new drug discovery. India's research and development (R&D) capabilities have now been recognized the world over. A new breed of service providers with specialized skills across different research verticals is emerging very fast. These players offer high-end, high quality, cost effective services across various research segments.

With outsourcing and offshoring becoming key buzz words, pharmaceutical firms across the globe are increasingly showing interest in these service providers and transferring large part of their discovery research to them.

To support this research driven industry segment, the Government of Madhya Pradesh (GOMP) proposes to establish an integrated R&D center in the State. The center would be an integrated facility offering specialty services in drug discovery (preclinical research). The center has been conceptualized as a geographic concentration of research laboratories, support center, animal facility, administrative offices and various other amenities of specific and generic use with capabilities across the entire discovery value chain. It would ameliorate technology bottlenecks by facilitating access to high end, comprehensive research functions at one place. This would expedite drug development by rapid screening and testing due to faster movement of potential leads across different research verticals.

The center would be established on 3 acres of land and would provide approximately 0.1 million sq. feet of lab space for various experimentation functions. Broadly the center would offer services in the following segments

- ✓ Research Biology
- ✓ Research Chemistry
- ✓ Pharmacology
- ✓ Pharmacokinetics and Pharmacodynamics
- ✓ ADME - Toxicology

The center would primarily cater to the needs of Multinational and Indian pharmaceutical companies, clinical research organizations (CRO's) and domestic generic companies contemplating to move upstream.

For the envisaged project the GOMP invites participation from private players, pharmaceutical companies and CRO's. Further, multiple players can set up different specialty function's as per their suitability and competence.

Project Rationale

With drug discovery getting more complex, expensive and time consuming, outsourcing specific research functions to specialized service providers helps save substantial time and cost an imparts competitive advantage to the research driven pharma companies.

Preclinical research market is growing at a substantial rate and presents immense opportunities for domestic research firms. The key growth drivers are increased outsourcing and offshoring by big pharma which has embraced it as key strategy to expedite new drug discovery, minimize risk and maximize returns.

Sensing high growth potential, large numbers of research players have evolved rapidly and offer specialized discovery services across specific segment such as analogue research, Chemoinformatics, ADME etc. An Integrated R&D center combines various research verticals at one place and hastens the discovery process by offering access to multiple experimentation and screening simultaneously at a single location. The center would provide high end instrumentation and research infrastructure and would aid domestic players to capture large pie of the lucrative preclinical research market.

Madhya Pradesh is increasingly preferred by the domestic and multinational corporate houses to establish their operational centers. The state offers unmatched advantages in terms of equidistance connectivity, low manpower and land costs, ample availability of skilled labour etc. The integrated R&D center would further consolidate its position among the upcoming knowledge hubs in the Country.

Proposed Facilities

The Center would have following specialized research laboratories:

Proteomics	Synthetic Chemistry
Functional Genomics	Analysis
Chemoinformatics	Pharmacology
Bioinformatics	Toxicology
Drug Designing	Bioanalysis

There will be a Central Instrumentation Lab with following key equipments:

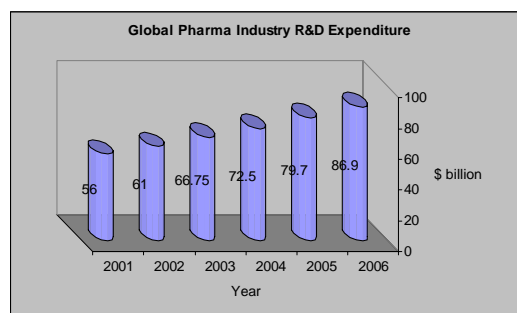
- FT - NMR
- GC – MS
- LCMS
- MALDI – TOF
- FT – IR
- Atomic Absorption Spectrometer
- HPLC etc.

Further the center would have following facilities

- ✓ Central Animal Facility.
- ✓ Intellectual Property Management cell
- ✓ IT Center
- ✓ Conference and Seminar Rooms
- ✓ Central Library
- ✓ Cafeteria

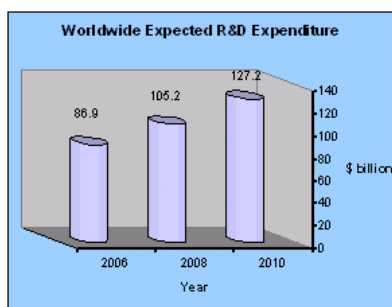
Market Potential and Demand Dynamics

Research and development (R&D) forms the lifeline of pharmaceutical industry. Despite stringent patent laws, the effective recovery period for any drug ranges from 10 – 8 years. Further, generic companies are increasingly making inroads into the lucrative blockbuster market riding on the



Source: Business Insight – Steve Birch

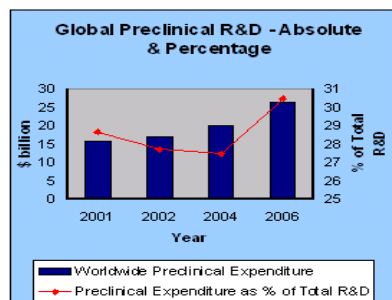
back of Para-IV challenge. This has forced big pharma to continuously launch new molecules in the market. A substantial rise in the R&D budget of companies has been noticed over the years towards this endeavor.



Source: Business Insight – Steve Birch

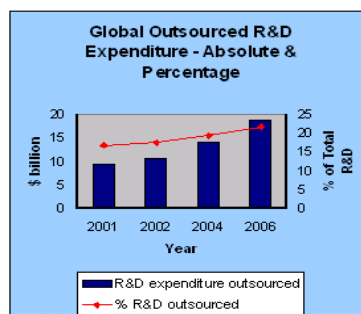
At present pharmaceutical companies across the globe spend somewhere between 10 to 15% of the revenues on research. The global R&D market in 2006 is estimated to be around USD 86.9 bn and forms the lifeblood of the industry. The global R&D spend is expected to break the USD 100 bn mark in 2008, growing at a CAGR of almost 10% from 2006 onwards, it is estimated to reach an astronomical USD 127.2 bn by 2010.

A substantial amount of total Research fund is spend on preclinical R&D i.e preparing the potential molecule from promising leads to therapeutic solutions ready for human testing. Global preclinical Pharma R&D expenditure for 2006 is estimated to be roughly USD 26.5 bn which is close to one third of the total R&D investment worldwide.



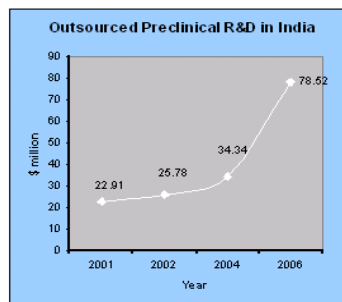
Source: Business Insight –Charles River Labs

As per estimates, over USD 50 bn would be spent on preclinical R&D alone in 2010 as drug at the preclinical stage decline over the years. With fewer new product launches worldwide from 2002 to 2005, the focus on preclinical research has heightened. Preclinical R&D investment is thus expected to at least maintain its CAGR of 8.11% as it did over 2001-2005. From the revenue perspective, the current global CRO market is estimated at USD 10 billion and growing at an annual rate of 14 to 16 percent.



Source: Business Insight – Steve Birch

A total of USD 18.8 billion out of the global R&D spend would be outsourced in 2006, representing 21.7% of total R&D expenditure. The collective level of onshore and offshore outsourcing will double by the year 2010. From USD 18.8 bn in 2006 to USD 36 bn, showcasing an increase in the percentage of outsourced R&D to 28.3%. Approximately 57 percent of the large pharmaceutical companies in US will outsource 20 percent or more of R&D operations in 2006.



Source: Business Insight –Charles River Labs

Historically India has maintained a share of 0.7% of the Preclinical Outsourcing market. With activity picking up rapidly, in 2006 the

market is pegged at \$78.5 million. Further, Indian preclinical outsourcing market has the potential to reach USD 407 million by 2010. This figure is based on the estimate that India's share in global offshoring shall be around 1-3%.

The envisaged integrated R&D center would help attract substantial amount of outsourced preclinical R&D to the Country and will further position India as a prominent research hub.

Why Madhya Pradesh?

- The State has a rapidly burgeoning base of pharmaceutical industry. Major players such as Ranbaxy, Lupin and IPCA already have a foot hold in the State and are on the road to expansion under the favorable industrial policies and initiatives by the State Government.
- Madhya Pradesh is envisaging a pharma cluster at Indore and has constituted a board for Biodiversity and life sciences under the chairmanship of the Chief Minister.
- Efforts are also being made to establish national level training centers through support of large industrial houses of MP. This would ensure that the State will never be short of professional expertise. This is an added advantage to the investors looking to invest in the in the State as there would be a wide availability of qualified and skilled professionals at a relative low manpower investment cost.
- MP has the right blend on freshers and laterals for the clinical trial and pharmaceutical industry. The institutes across the State are well equipped to provide trained manpower in each domain. There are 9 key pharmacy colleges in the state supported by 6 medical colleges and 43 management institutes (including one of the six Indian Institutes of Management at Indore). The laterals have experience of working in India's leading pharmaceutical companies such as Ranbaxy, Lupin, NPIL, etc.
- Every year ~300 Students pass-out from the State key pharmacy colleges which can provide adequate skilled manpower for the industry. some key pharmacy colleges are as follows:
 - ✓ B. R. Natha College of Pharmacy, Mandsaur
 - ✓ College of Pharmacy, Indore
 - ✓ Department of Pharmacy, Bhopal
 - ✓ Dr. Harisingh Gour Viswavidyalaya, Sagar
 - ✓ Institute of Pharmacy, Gwalior
 - ✓ R.K.D.F. Institute of Sciences & Technology, Mandideep
 - ✓ Shri G.S. Institute of Technology & Science, Indore
 - ✓ V.N.S. Institute of Pharmacy, Bhopal

Location Analysis

The integrated R&D center would be located in the envisaged Pharma cluster at Indore. Various factors which positioned Indore as a location of choice are:

- ✓ High quality of life
- ✓ Well developed infrastructure
- ✓ Ample availability of economic land
- ✓ Availability of skilled manpower
- ✓ Commercial capital of MP



Government Support

The State Government of Madhya Pradesh would be the key implementing and facilitating agency for the project. It will assist the private partner in identification of land and expedite clearances of various proposals across various administrative departments.

Proposed Investment

The total investment for the project is estimated to be around USD 15.5 mn or INR 70 crores.

Returns

The Internal Rate of Return from the project is estimated to be in the range of 13 – 15%.

Coordinating Agency

Madhya Pradesh State Industrial Development Corporation