SUVEN Life Sciences

- Partnering Drug Discovery & Development

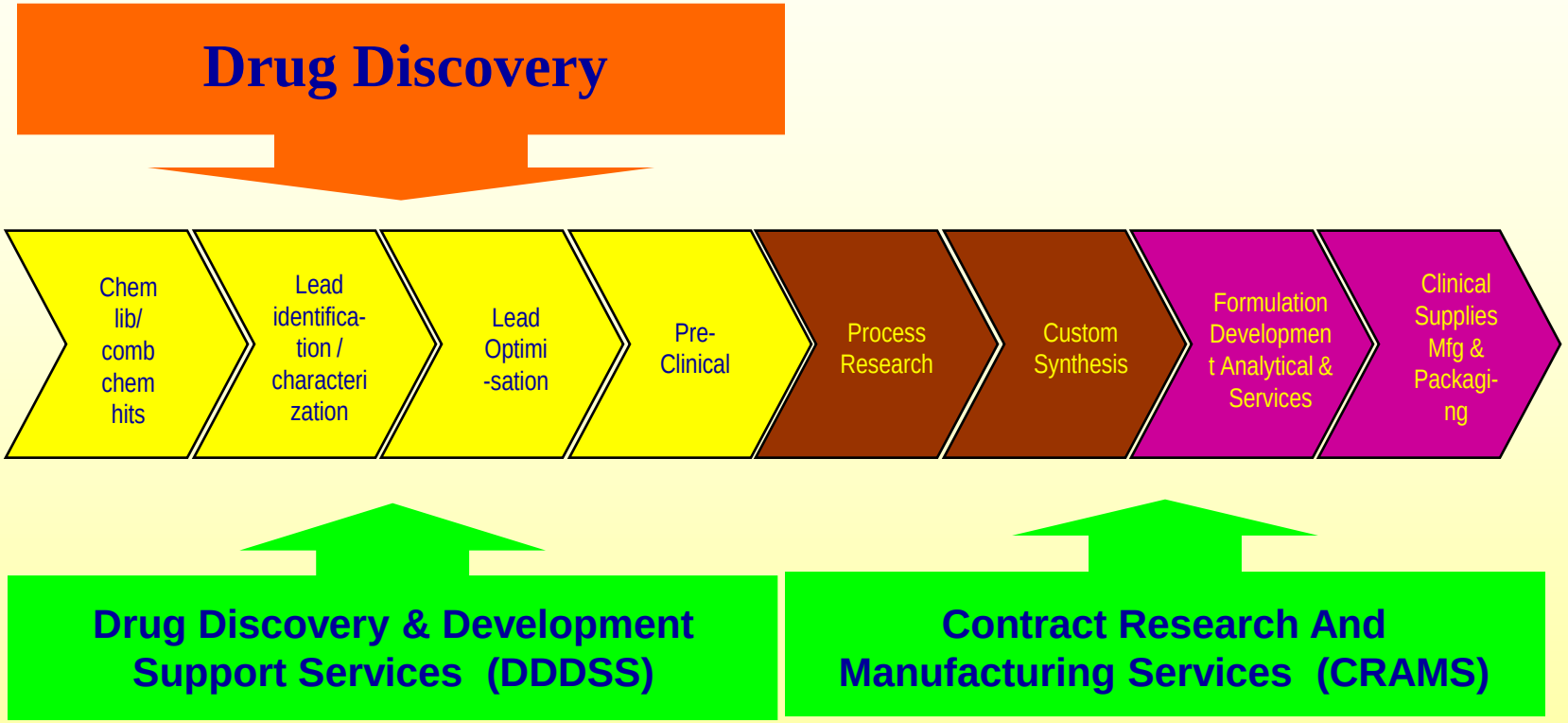
……and beyond!

Vision

To Emerge as a leading player by providing full spectrum services in drug discovery, development, manufacturing and support services under collaboration with leading global life science players

Graduated from Contract Research to Collaborative Research

Suven's Business Model



Collaborative Research Partner (CRP) …
Seamless transition

BUSINESS STRUCUTRE

- In operation since 1989 to 2004 as SUVEN PHARMACEUTICAL LTD.
- Profitable for the last decade
- Transformed to SUVEN LIFE SCIENCES LTD from 2003
- Strong asset base and financial fundamentals
- Pioneering efforts in C-R-A-M-S since 1994
- Pioneering initiatives in DDDSS in 2005
- Relationships with many Global Life Science majors
- IPO in 1995 - Listed on NSE and BSE
- More than 300 scientific professional

High growth potential

20 years of Pharmaceutical Relationship

- Profitable every year since founding in 1989
- Listed on NSE & BSE

DDDSS
- **Leader in CNS based internal discovery in India**
- **State of the art facility, models**
- **Multiple big pharma relationships**

CRAMS
- **Leader and innovator for many NCE based intermediates**
- **600+ projects**
- **380+ R&D professionals**

Relationship with more than 22 global pharmaceutical companies

FORMULATIONS
- **Pharmaceutical product development**
- **Product scale up and manufacturing services**
- **Pharmaceutical Analytical services**
- **Regulatory management services111**

STRATEGIC BUSINESS SEGMENTS

- API's & Intermediates Manufacturing
- Contract Research and Manufacturing
- Services (C-R-A-M-S)
- Formulation Development Centre (FDC)
- Drug Discovery and Development
- Support Services (DDDSS)
- Collaborative Research Partnerships (CRP)

Full spectrum services in Drug Discovery, Development and Manufacturing

Multi facility, Multi location

Corporate Office
Biopharma GLP

Suven USA
Business office

Jeedimetla
Suven R&D–Pilot Plant

Suryapet
Suven Intermediate Mfg. facility

Pashamylaram
Suven API & Formulation facility

FACILITIES

Banjara Hills, Hyderabad

- Corporate office
- Biopharmaceutical Research **(GLP)**

SUVEN USA New Jersey

- Business Development
- Project Management
- Intellectual Property Management

Jeedimetla, Hyderabad R&D Center & Pilot Plant

- Process Research
- Discovery R&D,Analytical R&D
- Killo lab,30L CM Reactors(32) 50L – 4000 L GL/SS

Suryapet. A.P Intermediate Manufacturing Facility

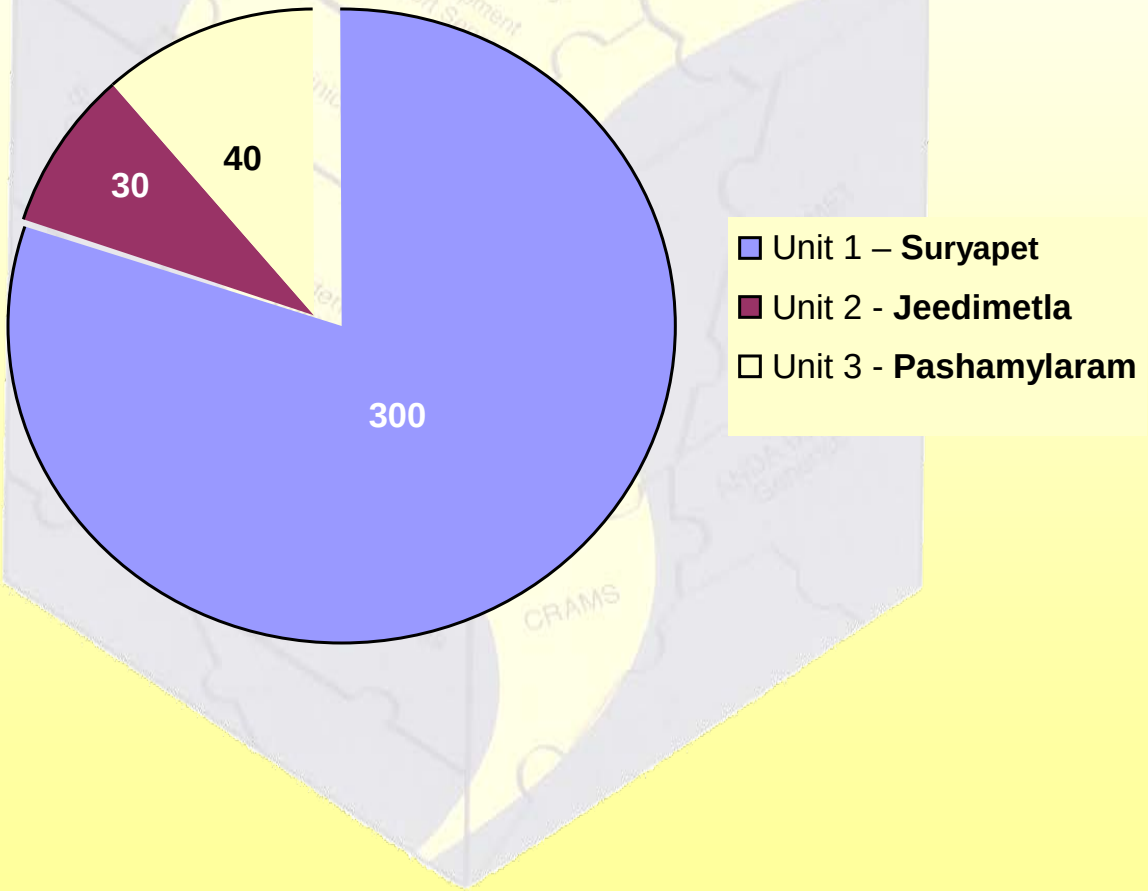
- 300 CM reactors(93)
- 500 L to 10 KL GL/SS
- GMP Intermediates

Pashamylaram, Hyd. API & Formulation Manufacturing

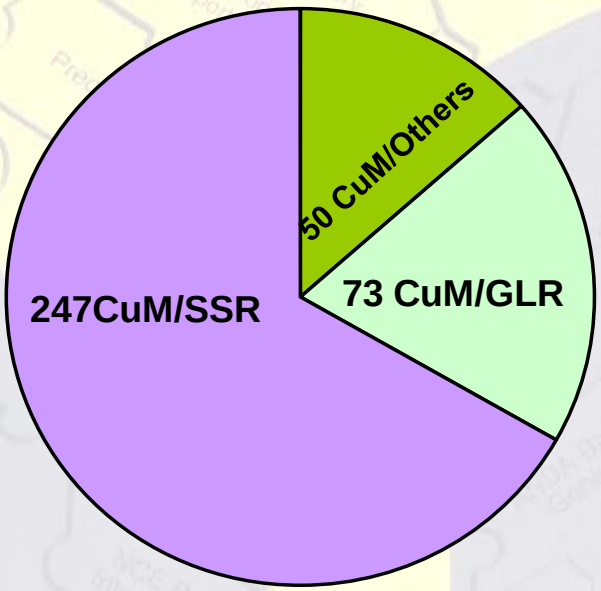
- 120 kL Reaction volume
- 50L – 6000 L GL/SS (45)
- API Manufacturing
- Formulation Manufacturing
- Formulation R&D

Any stage scalable at short time

Reactor Capacities (M^3) across Suven's facilities



Reactor Capacities (M^3) by MOC



HUMAN RESOURCES

Total Employees	**786**
– R&D	**382**
– Manufacturing & Services	**358**
– Administration / Sales	46

HUMAN RESOURCES

R&D	-	**382**
– Analytical Development	-	43
– Discovery	-	169
– Process R&D	-	105
– Formulation Development	-	65

HUMAN RESOURCES

Qualifications:

PhD's / MD	-	31
MS / M Phil / M Tech	-	410
BS / B Tech / Engg. Diploma	-	345
Total	**-**	**786**

Regulatory Information

(DMF/Product Dossier/Technical Information Submitted)

Regulatory Authority & Country	APIs		Intermediates		Drug Product/ Formulation	
	Suven	Customer Specific	Suven	Customer Specific	Suven	Customer Specific
FDA, USA.	12	4	2	0	1	0
EDQM	2	0	0	0	0	0
MHRA, UK	1	0	0	0	0	0
Netherlands	1	0	0	0	0	0
17 EU Countries	1	0	0	0	0	0
Registration at China	2	0	0	0	0	0
Registration at Korea	2	0	0	0	0	0
PMDA, Japan	2	0	2	0	0	0

MANAGEMENT SYSTEMS

- cGMP (current Good Manufacturing Practices)
- ISO 9001:2008 (Quality Management System)
- ISO 14001:2004 (Environmental Management System)
- OHSAS 18001:2007 (Occupational Health and Safety Assessment Series)

RESEARCH & DEVELOPMENT CAPABILITIES

R&D PROFESSIONAL

- Highly qualified and experienced scientific professional manpower.
- State of the art DST approved R&D facility
- Willing to accept challenging product development opportunities
- Fast technology transfer from laboratory to industrial scale
- New product / process development in collaboration with leading global pharmaceutical / fine chemical companies

RESEARCH & DEVELOPMENT CAPABILITIES

RESEARCH & DEVELOPMENT ACTIVITIES

- Synthetic organic Chemistry
- Building Blocks, Scaffolds and Intermediate compounds for generating analogues
- Custom Synthesis of lead compounds in grams and kilograms
- Intermediates in Multi-kilograms
- R & D for process optimization
- R & D for hazardous chemical Reaction
- Collaborative research
- R & D for clean technologies

RESEARCH & DEVELOPMENT CAPABILITIES

PRECLINICAL AND CLINICAL DEVELOPMENT SUPPORT

- Contract Research – Laboratory
- Custom Synthesis – laboratory
- Process Research- optimization of process
- Custom manufacturing- Pilot plant
- Scale-up of synthesis to provide quantities from grams to kilograms
- Synthesis of reference compounds, fully characterized to meet GLP requirement

RESEARCH & DEVELOPMENT CAPABILITIES

SCALE-UP/COMMERCIAL SUPPORT

- **Scale-up of established processes**
- **Process optimisation**
- **Identification of alternate viable synthetic methods**
- **Scale up synthesis of gram/ kilogram quantities of building blocks**
- **Manufacture of intermediates**

RESEARCH & DEVELOPMENT CAPABILITIES

MEDICINAL CHEMISTRY CAPABILITIES

- **Support for:**
- **Lead optimization**
- **Synthesis of reference compounds**
- **Starting materials**
- **Intermediates / Building blocks**
- **Preparation of compound**
- **libraries**

RESEARCH & DEVELOPMENT CAPABILITIES

PROJECT MANAGEMENT

- A Project Team is led by a Project Manager and a team of scientists to guarantees the quality and the timelines of each project.

- The Project Manager is the single point of contact with the Client. The entire communication process is through Secured E-mails, regular teleconferences, videoconferences and periodic Report.

- The Project manager will report the progress on a weekly basis, detailing the progress and future direction of the project.

- Finally a detailed project report will be provided upon the completion of the Project and all the materials and information deemed necessary will be transferred to the client based on the initial terms and conditions of the agreement.

RESEARCH & DEVELOPMENT CAPABILITIES

SECURITY / CONFIDENTIALITY

Intellectual Property

- **Suven Life sciences Limited will strictly adhere and implement the recently approved international patent law.**

- **To ensure the security and confidentiality of client data, we uses data only for the purpose intended. Access to client data is restricted to the Team leaders working on the respective project and observe strict standards of confidentiality.**

- **All Confidential Information and any other information in whatever form or medium supplied by the Client to us shall be delivered immediately upon demand at any time until the partnership remains in force or thereafter.**

- **All confidential information shall remain the property of the Client.**

RESEARCH & DEVELOPMENT CAPABILITIES

REACTION CAPABILITIES

- Alkylations
- Acylation
- Amidation
- Chiral alkylation
- Condensation
- Cyanation
- Cyclo-condensation
- Formylations
- Grignard reactions
- Halogenation Using bromine,
- chlorine, POCl3 etc.,
- Heck Arylation
- chiral Amines syntheis
- Asymmetric synthesis
- Carbohydrates
- Grignard reaction
- Horner-Emmons Wadsworth
- reaction
- Organoborane

RESEARCH & DEVELOPMENT CAPABILITIES

- Hydrogenation using pd/c, Pt/c, Rh/c and Rani-Ni
- Metallation – MeLi / n-BuLi / LDA/HMDS
- Mitsunobu Reaction
- Oxidation – Jones, swern, $KMnO_4$, $NaIO_4$, Nitric acid
- Reductions – Catalytic, Metal hydrides, High pressure, Metal catalysed, Birch reductions, Diborane, LAH, DIBAL-H, Catalytic, $NaCNBH_3$
- Suzuki Coupling
- Asymmetric synthesis
- Enzymatic resolution

RESEARCH & DEVELOPMENT CAPABILITIES

SUVEN Life Sciences

For Target molecule without chemistry information

❖**Chemistry route selection phase (1-2 weeks based on**

- **Retro-synthetic analysis**
- **Literature search**
- **Raw material availability**
- **Capabilities of chemistry and facilities**
- **Raw material cost**
- **Paper costing**

❖**Proof of concept phase**

- **pilot experiments (2-4 weeks)**
- **Molecule identification and characterization**

❖Optimization phase (2–3 weeks)

- Process optimization
- process variation
- critical parameters
- In–process control parameters
- specification settings
- safety evaluation.

Scale–up phase (4–6 weeks)

- Raw material procurement
- Facility identification
- Batch record writing
- Scale–up implementation
- Dispatch of products
- Campaign report writing

Note: This timeline is considering 4-6 steps synthetic process.The timeline may vary if the special raw material is required with respect to scale-up.

RESEARCH & DEVELOPMENT CAPABILITIES

SUVEN Life Sciences

For Target molecule with small scale process given

❖Raw material availability (one week)
- Capabilities of chemistry and facilities
- Raw material cost
- Paper costing

❖Optimization phase (2-4 weeks)
- Process optimization
- process variation
- critical parameters
- In-process control parameters
- specification settings
- safety evaluation.

❖Scale-up phase (4-6 weeks)
- Raw material procurement
- Facility identification
- Batch record writing
- Scale-up implementation
- Dispatch of products
- Campaign report writing

Note: This timeline is considering 4-6 steps synthetic process. The timeline may vary if the special raw material is required.

RESEARCH & DEVELOPMENT CAPABILITIES

SUVEN Life Sciences

CHIRAL TECNOLOGY PRODUCTS

SUFINAMIDE CHIRAL TECHNOLOGY VIZ.,	**t-Butylsufinamide (R &S)** **p-Toluenesulfinamide (R&S)** **P-Toluenemethane sulfoxide (R&S)** **2.4.6-trimethylphenylsulfinamide (R&S)**
PYRROLIDINE RELATED TECHNOLOGY	**3-Hydroxytetrahydrofuran (R&S)** **3-hydroxypyrrolidine (R&S)** **3-Aminopyrrolidine (R&S)** **3-Cyanopyrrolidine (R&S)** **3-Carboxypyrrolidine (R&S)** **3-Hydroxy-N-benzylpyrroline (R&D)** **3-Aminotetrahydrofuran (R&S)** **Pyrrolidine-3-carboxylic acid (R&S)**
SUGAR DERVATIVES	**4-Hydroxy-2-pyrrolidone (R&S)** **2-Hydroxy-1,4-diol (R&S)**

RESEARCH & DEVELOPMENT CAPABILITIES

SUVEN Life Sciences

PROJECT REPORTING

- Gantt Chart provided at start of project
- Weekly reports provided every week of specified days on status
- Teleconferences on periodic basis as per the customer.
- Project coordinator accessible round the clock
- Detailed report submitted within 3-5 weeks on completion of project covering
- Project summary
- Experimental details
- Synthetic Scheme, Raw Materials, Critical Issues, Stepwise Process
- Description, Modifications carried out to documented processes,
- Development history of process on parameters and conditions.
- process safety information.
- Suggestion for further improvement if any
- Literature References,
- Analytical methods and data

RESEARCH & DEVELOPMENT CAPABILITIES

ENVIRONMENT AND HEALTH AND SAFETY

Safety

- **PPE is a culture**
  - **Apron**
  - **safety glasses**
  - **Safety gloves**
  - **Face shield**
  - **Dust respirator**
  - **Splash Goggle**
  - **Vapor Respirator**
  -
- **Safety Manager**
- **Safety Audits**
- **HAZOP studies**

Health

- **Pre-employment medical clearance**
- **Periodic Health Check**

Environment

- **Waste segregation**
- **Waste minimization**
- **Compliance to local laws**

Coming together is a beginning
Keeping together is progress
Working together is success.

–HENRY FORD

THANK YOU