

# GROWTH THROUGH EFFICIENCY

Corporate Presentation- 2019





# CORPORATE OVERVIEW

# Solara - at a glance

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Solara Active Pharma Sciences offers **Contract Research and Manufacturing and Development** Services across the entire value chain of a new chemical entity which covers from **Discovery to Commercial Phase**.

5

Manufacturing  
Sites

22

Successful  
USFDA Audits

+2500

Employees

2

R&D Centers

30

Years in the  
Industry

# Your RITE Partner for CRAMS

*Doing what is 'RITE' for the customers*

## RESPECT

R

We at Solara **respect** our **Employees**, **Customers** and **Partners**. Here we ensure that our client's expectations are consistently met

## INTEGRITY

I

Our business stands on the pillar of **integrity, honesty** and **fairness**. Everything we do here stands the test of public scrutiny

## TRANSPARENCY

T

Regularly engage with **investors, suppliers, customers**, and stakeholders by providing regular financial and business updates.

## EFFICIENCY

E

Working towards achieving a **high level** of **efficiency** in all process and systems and fulfilling the promises made to stakeholders.

# Solara's leadership team

*Leadership with several years of experience in the pharmaceutical industry*



**Jitesh Devendra** ,  
*Managing Director*

Jitesh has more than 20 years' experience and has led the North America API business as well as managed the Formulations P&L business of erstwhile Shasun Pharmaceuticals Limited, which got merged with Strides Shasun Limited. Jitesh has been responsible for P&L business for North America and Europe Finished Dosage Form and overall responsible for API business P&L.



**Bharat. R. Sessa**  
*CEO*

Bharath has over two decades of experience in the Pharmaceutical Industry. His expertise spans across the pharmaceutical, healthcare, consumer lifestyle and material sciences industry. He has held CXO level positions in companies like Philips, DSM Sinochem Pharmaceuticals, Royal DSM NV. Before deciding to pursue an opportunity with Solara, Bharath was the Managing Director at Nalco Water, India.



**Hariharan S. (Hari)**  
*CFO*

Hariharan is a Cost Accountant with rich and varied experience of more than 30 years in field of Corporate Finance, Accounts and Strategic planning. He played a vital role in the merger process of Shasun Pharmaceuticals Ltd. with Strides Shasun Limited.



**Sreenivasa Reddy B. (Sreeni)**  
*COO*

Sreeni has over 24 years of experience in Pharmaceutical Manufacturing, Technology Transfer, Project Management in setting up facilities, Quality Assurance, Plant operations and Sales & Marketing.



**Sundara Moorthy V. (Sundar)**  
*SVP- Quality Management & Regulatory Affairs*

Sundara Moorthy has done his Post Graduation in Organic Chemistry. He has rich and diversified experience of 23 years in the Quality Management, Regulatory Affairs and Compliance functions.



**Swaminathan Srinivasan (Swami)**  
*Head – Research & Development*

25+ years of experience in generic pharmaceutical industry with vast exposure in active pharmaceutical ingredient as well the Dosage forms with deep understanding of the industry dynamics. He was associated with Jubilant Life Sciences, Alembic, Dr. Reddy Laboratories, Orchid & Ranbaxy.





**Services &  
Capabilities**

# Wide gamut services across the development chain



## Chemistry

- Hit to Lead
- Lead Optimization



## Pre-clinical

- Synthesis & Purification
- Ref. Std. & Impurities



## Phase 1 to Phase 3

- Process Optimization
- cGMP Production



## Commercial

- Process Validation
- Capacities
- Cost Advantage

**Contract Development**

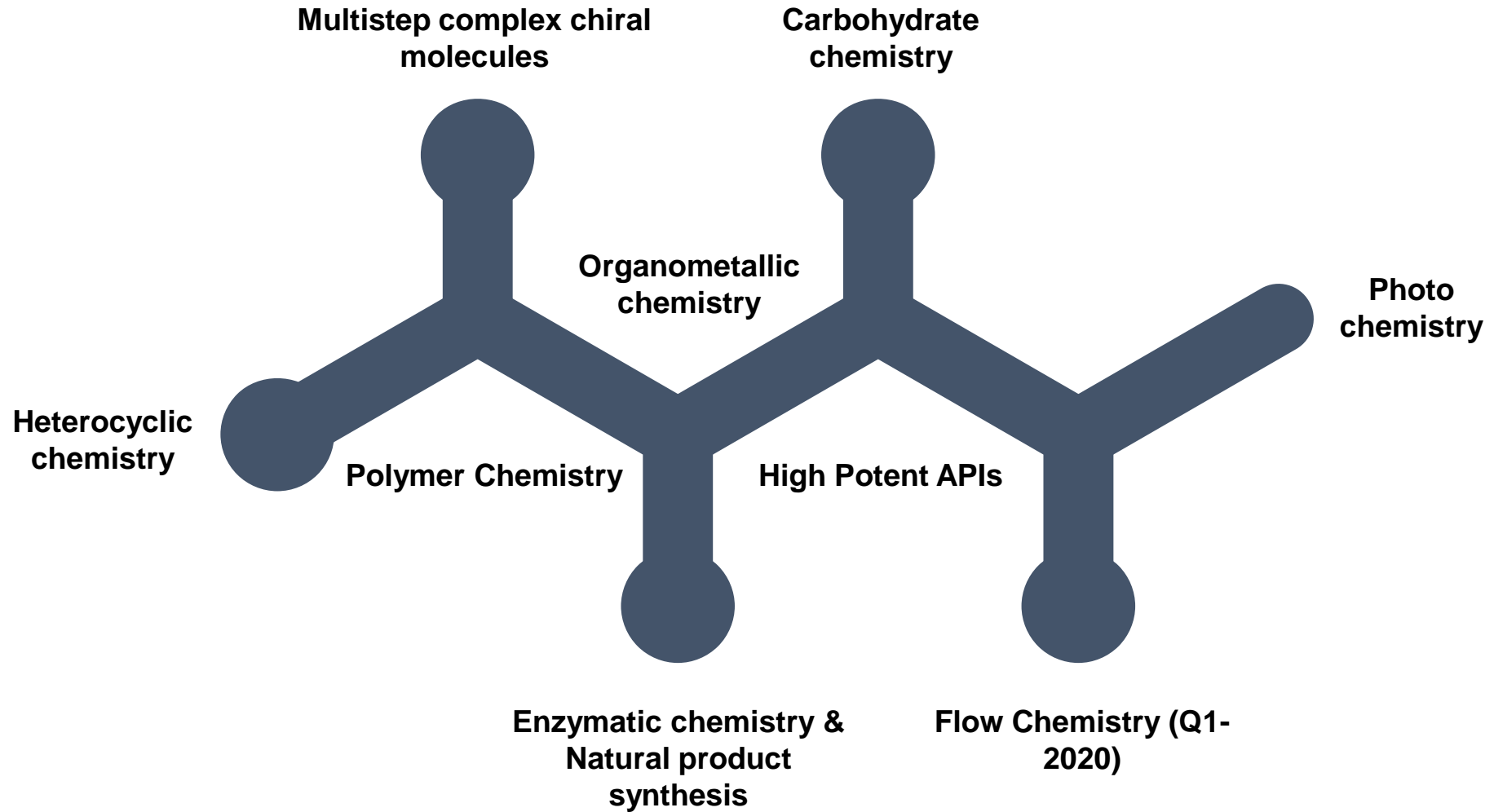
**Contract Manufacturing**

**Analytical services**

**FTE model programs**

**Regulatory support**

# R&D Capabilities in Synthetic Development





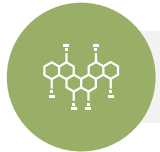
# Chemical Process Design, Development and Optimization



**Route Scouting**



**Tech Transfer Services**



**Chemical Process Engineering**



**Salt and Polymorph Screening**



**Process Development and Optimization**



**Identification & Characterization of Impurities**



**Chemical Process Safety**



**GMP Manufacturing**

# Process Analytical Research and Development

*US FDA audited and approved analytical laboratory facility with 21CFR Part 11 compliance systems*



**Method development**



**Method validation & transfer**



**Polymorph screening**



**Force degradation studies**



**Impurity isolation and characterization**



**Stability studies**



**Elemental impurities profiling**



**Genotoxic assessment**

# Offering 100% assurance on EHS & Safety

## Zero Liquid Discharge System

- Low TDS treatment followed by Biological treatment system cum RO Plant.
- High TDS treatment followed by Pre Chemical treatment cum MEE & RO Plant.
- Agitator Thin Film Drier followed by MEE Plant to separate solids.
- Recovered water used in gardening and utility for plant
- Solids disposed to government authorized landfills

## Biological Treatment Plant

- Biological Treatment Plant – LTDS & HTDS



## MEE

- Multiple Effect Evaporation System (MEE Plant)



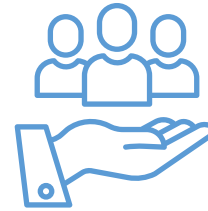
# Robust framework for IP protection



**Mandatory CDA for all employees to ensure confidentiality**



**Well established data systems for protection of information at all levels**



**All programs driven by customer need and there are no internal programs**



**IP assigned to client at the beginning of relationship**

# Our R&D Team



## **Swaminathan - Senior Vice President - R&D**

*Having Pharma industry experience more than 27 years  
Handled leadership and strategic roles in various organizations*



## **Ananda Ganesh - Head Project Management**

*Having 14 years of experience in Project management, Key account management and Client handling*



## **Sridharan - Head Process Engineering**

*26+ years of experience in scale-up, technology transfer & process engineering. Handled independent role in manufacturing*



## **Dr Uttam Ray - Head Process Development**

*Having industrial and academic experience more than 30 years in Process Research & Development and Life cycle management*



## **Dr Bheemashankar Kulkarni - Head Synthetic Development**

*More than 25 years of experience in medicinal chemistry and Custom synthesis*



## **Dr Srinivasan - Head Analytical Services**

*25+ years of experience, subject matter expert in Analytical & quality functions*



## **Venkatesh Prabhu – Head Analytical development**

*Having vast experience around 20 years in analytical chemistry, method development and optimization*



## **Dr Chandramouli - Group Leader Synthetic Development**

*More than 15+ years in custom synthesis and process research*



## **Dr Sanjay - Group Leader Process Development**

*Having experience more than 15+ years in Process Research, medicinal chemistry & drug discovery*

# Advanced Analytical capabilities

**01** ICP-MS

**02** LCMS-MS / LCMS

**03** GCMS-MS / GCMS

**04** Powder X-Ray Diffraction

**05** Solid state & Liquid state NMR

**06** Ion Chromatography

**07** Particle size analyzer

**08** Differential scanning Calorimetry

**09** Thermo Gravimetric analyzer

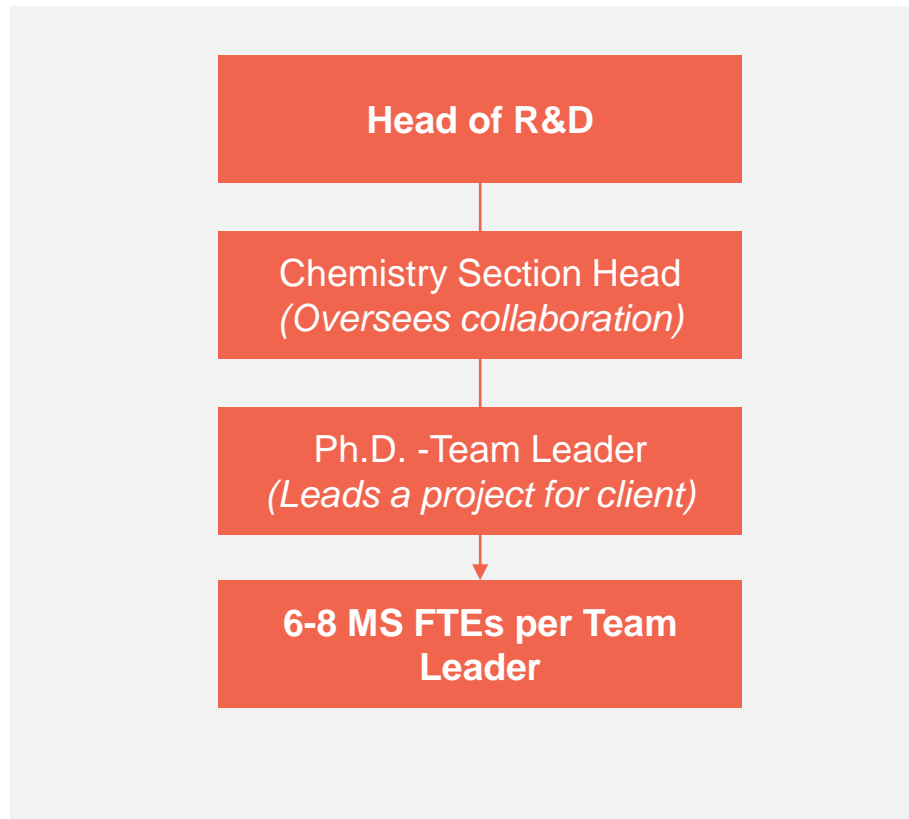




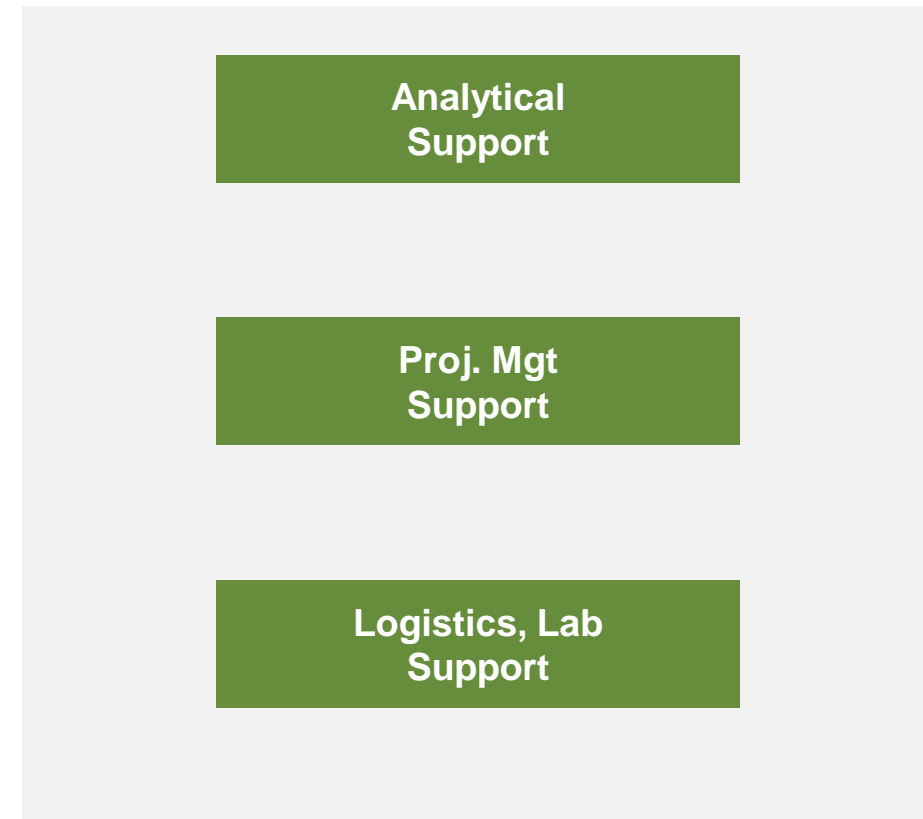
# Typical model for CRAMS engagement



## Core Project team



## Project Support





# OUR CAPABILITIES

# Dedicated research and development capabilities

*Two India based R&D Centre for best in class product development*



*Our R&D Centre in Chennai*

## ✓ Technical Expertise

Strong technical leadership to develop high-quality services that create strategic value for our partners and customers

## ✓ Development

R&D capability to develop over an entire cycle with new and better technologies at competitive cost

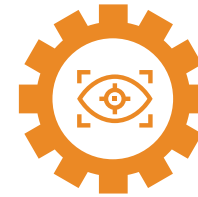
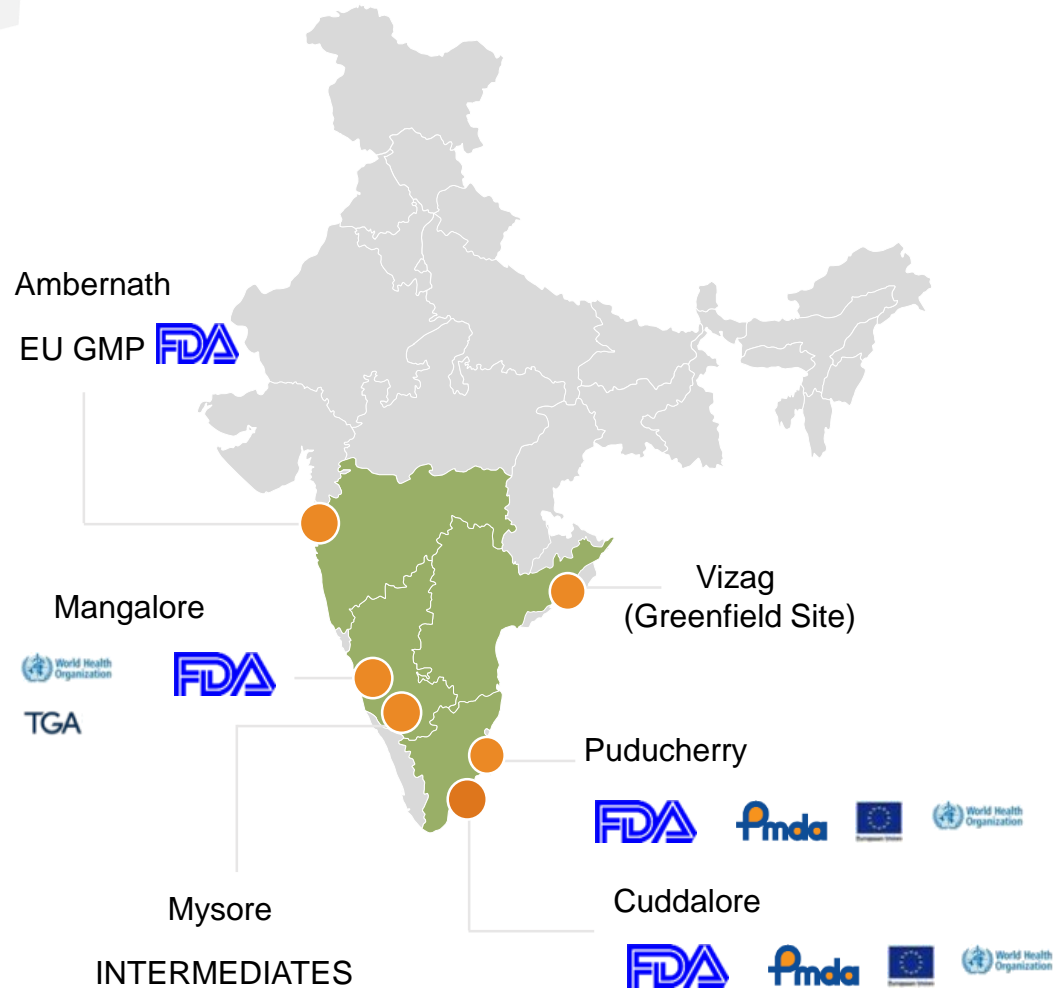


*Our R&D Centre in Bangalore*

## ✓ Regulatory Filings

Strong IP assessment capabilities and strong global regulatory expertise

# Five India based manufacturing sites with all approvals



## Core focus

- Mirrored facilities for developing products
- Deploy systems that are highly automated and stringent, specifically in the labor intensive areas.
- Focus on technology and production processes that represent a clear advantage against the industry standard



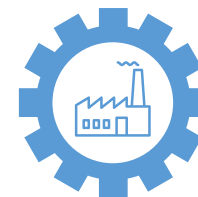
## Capabilities

- 1600 KL capacity with capabilities in high vacuum distillation, hydrogenation, halogenation, Grignard reaction, polymer chemistry amongst others



## Key Approvals

- Globally compliant API facilities with all regulatory approvals and adherence to the highest quality standards



## Manufacturing Strategy

- Capacity creation after assurance of demand and location based diversification for minimizing concentration risk



# Facilities

## Pondicherry Facility



- The buildings for the manufacturing of Intermediates and isolation of final drug substance are separate.
- Packing sections are controlled and meets ISO Class - 8 requirements.
- Reactors are in the range of 1200 L to 12,500 L of size with MOC of SS, MSGL, GL
- Highly flexible pilot plant with a broad range of equipment

## Multipurpose Cuddalore Facility



- FDA inspected cGMP multi purpose API and intermediate facility
- Broad range of reactor sizes with flexible containment and LEV facilities. The facility has reactors varying in size from 250 L to 12500 L
- Different material of construction SS, GL, SS-GL, MS-GL, Hastelloy
- Temperature ranges from  $-90^{\circ}\text{C}$  to  $+145^{\circ}\text{C}$
- Segregated hydrogenation facility with multiple gas scrubbing systems

# Facilities

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## Multipurpose Mangalore Facility

- Multi purpose cGMP API and intermediate facility inspected by DCD, USFDA, WHO, EDQM, MFDS, TGA, AEMPS, ISO-14001
- 6 Full fledged cleanrooms meeting ISO class-8 slandered can hand six products simultaneously
- Broad range of stainless steel and Mild steel glass lined reactors of size from 250 L to 6300L
- Self contained “Pilot facility” having SS, GL and all glass reactors of size 20 Lit to 250Lt
- Pressure reaction facility, Operating temperature ranges from  $-20^{\circ}\text{C}$  to  $+130^{\circ}\text{C}$










## Multipurpose Ambernath Facility







- FDA inspected cGMP multi purpose API and intermediate facility
- The facility has reactors varying in size from 250 L to 8000 L
- Different material of construction SS, GL, SS-GL, MS-GL
- Temperature ranges from  $-20^{\circ}\text{C}$  to  $+130^{\circ}\text{C}$
- Segregated hydrogenation facility with multiple gas scrubbing systems



# Regulatory Approvals – Inspection Track Record

Regulatory Agency	Latest Inspections at			
	Puducherry	Cuddalore	Mangalore	Ambernath
 <b>United States</b>	May-2017	Jul-2019	Jul-2018	Jan-2019
 <b>Europe</b>	Nov-2014	Jan-2017	Sept-2017	Oct-2017
 <b>Geneva</b>	-	Oct-2016	Feb-2018	-
 <b>India</b>	Jul-2018	Jan-2018	Aug-2018	Dec-2017
 <b>TGA,</b>	-	May-1998	Feb-2013	-
 <b>United Kingdom</b>	Jan-2017	Jan-2017	-	-
 <b>Japan</b>	Nov-2007	Mar-2017	-	-

# Regulatory Approvals – Inspection Track Record

Regulatory Agency	Latest Inspections at			
	Puducherry	Cuddalore	Mangalore	Ambarnath
 <b>MFDS, South Korea</b> <small>Ministry of Food and Drug Safety</small>	Feb 2017	Nov 2012	Jul 2018	---
 <b>Mexico</b> <small>Comisión Federal para la Protección contra Riesgos Sanitarios</small>	Sep 2015	Sep 2015	---	---
 <b>Slovenia</b>	Feb 2015	---	---	---
 <b>Denmark</b> <small>DANISH MEDICINES AGENCY</small>	Oct 2008	Oct 2008	---	---
 <b>AEMPS, Spain</b> <small>agencia española de medicamentos y productos sanitarios</small>	---	---	Sep 2017	---
 <b>Ireland</b> <small>Health Products Regulatory Authority</small>	Nov 2014	---	---	---

\*As Mysore is an intermediate site, no regulatory inspection has been conducted so far. Site has a valid GMP certificate issued by the Drug Control Department, Government of Karnataka



# EXPANSION PLANS





Upcoming State of Art manufacturing plant at Vizag, India



# Status of the project



## Investments

- Phase I Investment of ₹2,500m over a period of two years
- Funded through 30% equity and 70% term loan with capacity commitments from the long term customers



## Focus

- Cater to future growth of Solara
- Serves as an alternate site for our Key APIs and de-risk strategy
- Planned for all regulatory approvals including USFDA, EUGMP, PMDA amongst others



## Capability

- Dedicated and Multi Purpose blocks for Large Volume and Mid-Small Volume API
- Validation supply for new products
- Showcase facility for CRAMS business



## Project status

- Phase-I construction planned to be completed in Q2 FY 20
- Installation of equipment by Q3 FY 20
- Validation is scheduled in Q4 FY 20

# Other planned initiatives

Vizag green field multi purpose facility will be up and running in Q2 of 2020

Solara is looking to acquire kilo lab facilities in USA and Europe

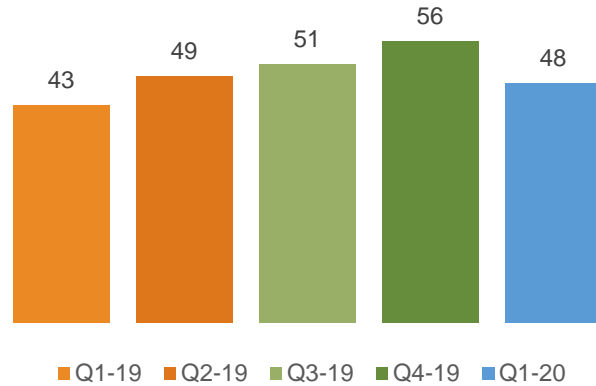
Willing to provide dedicated facilities for our esteemed customers based on their future requirement

Solara is looking to add its expertise in Flow Chemistry and High Potent Capabilities

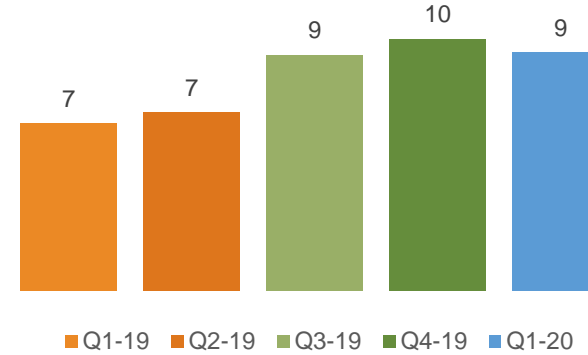


# Significant growth and profitability over 5 quarters

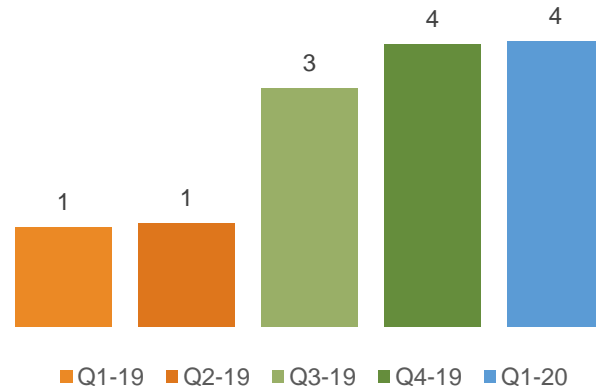
## REVENUE (\$ million)



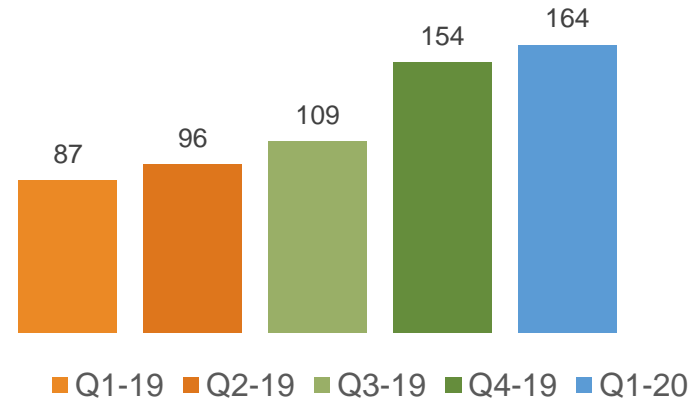
## EBITDA (\$ million)



## NET PROFITS (\$ million)



## MARKET CAP (\$ million)



- ➔ Well capitalized to fund future growth initiatives.
- ➔ Solara Active Pharma Sciences got listed at \$3.3 per share in 2018 and today share price is \$6.34
- ➔ Including for cash reserves and committed equity infusion from the promoters and our lead investor – TPG Growth, Solara has a surplus of ₹5 billion (\$68 million)
- ➔ Growth in Reported EBITDA margins over last 5 quarters
- ➔ Steady progress through the proactive cost improvement programs
- ➔ Fast expanding portfolio of new products and new customers to access new markets for existing products
- ➔ Strong leverage situation supporting better EBITDA to EPS conversion



**Collaboration  
With you**

# What Solara Can offer to you?



## Chemistry Services

- Hit to lead and Lead Optimization
- Synthetic Chemistry FTS's
- Route Scouting
- Feasibility studies
- Process optimization
- Scale-up batches [Gram to kg level]
- Impurities synthesis & Isolation
- Solubility & Particle engineering



## Analytical Services

- Method Development
- Method verification / validation
- Method transfer
- Characterization
- Qualification of Impurity standards
- Genotoxic studies
- Elemental impurities assessment
- Polymorph screening



## Manufacturing Services

- GMP synthesis and manufacturing
- Solara has 4 USFDA audited sites
- Having various size of equipment's and down streams with all MOCs
- Globally accepted compliance in supplying GMP material for phase-1 and above
- Solara will be able to dedicate a manufacturing block for your development programs
- Ensuring Delivery in FULL ON TIME

# Thank you

## REGISTERED OFFICE

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