

# BIOPHORE

*Research. Innovation. Collaboration*

## ABOUT US

### What We Do

#### Overview



R&D driven company  
Focus on creating superior value proposition  
Providing end to end solutions

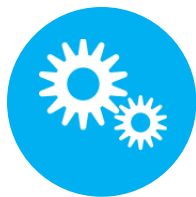


#### Specialists

Development for Regulated markets and PIV challenges  
Core capabilities in complex products, polymorph development and Injectables  
Consistently in Top 10 DMF filers for last 4 years

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#### Manufacturing



Four world class facilities  
USFDA approved API facilities  
Wide range of therapeutic areas  
US & EU approved solid oral manufacturing facility

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#### Products and Pipeline



Over 110 DMFs filed  
40+ projects in development  
More than 190 patents filed

## ABOUT US

# Inception and Growth



### Milestones

R&D center setup in 2007  
First API Manufacturing facility started in 2010  
Second API Manufacturing facility started in 2014  
Third API Manufacturing facility commissioned in 2018  
Acquired OSD facility in 2017



### Growth

First USDMF filed in 2010  
20 USDMFs by 2014  
42 USDMFs by 2016  
75 USDMFs by Oct '19



### Customers

Currently catering to over 300 customers  
Several in top 20 pharma companies as clients



### Awards

3rd highest USDMFs filer globally in '15 & '18  
Recognized as one of the fastest growing pharma companies by Silicon Review®  
Recognized as India's Small Giants by MSME Forum Govt of India

## ABOUT US

### Vision and Mission

#### Vision

Our aim is to place Biophore in the midst of most reliable knowledge based firms in the pharmaceutical sector in the immediate near-future through customer-focused approach

#### Mission

To be the most trusted R & D company in the complex and niche pharmaceutical molecule segments and achieve superior customer satisfaction through continuous innovation; and providing an inclusive work culture that helps our employees excel and grow

# OUR PRESENCE

## Global

**7 Locations**  
Across USA & India



**300 R&D Staff**

In synthesis, analytical, formulation,  
IP and regulatory



**1000 People**  
In manufacturing and  
Research



**Zenara Pharma**

Dedicated world-class solid orals  
manufacturing facility



**Over 40 Projects**  
In development stage at any  
point of time



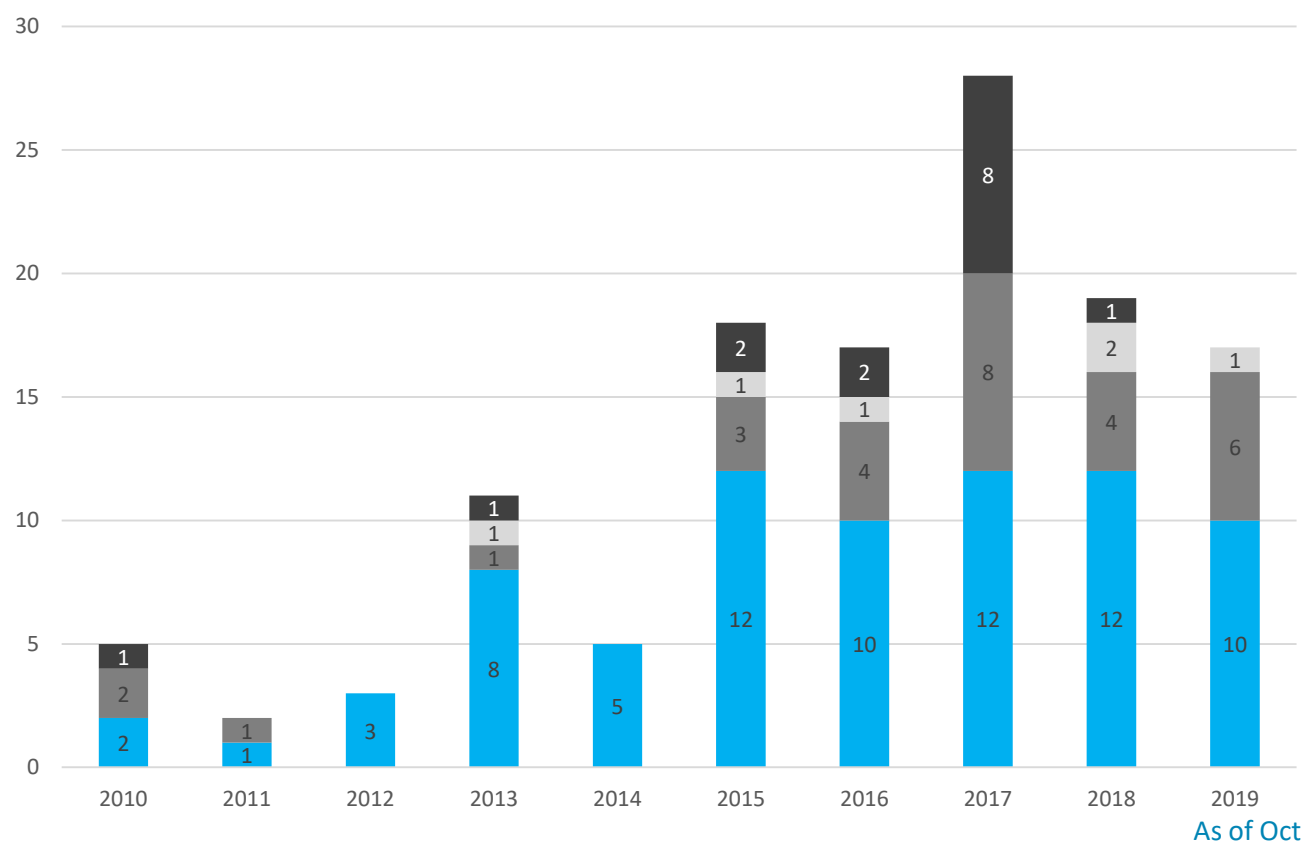
**US NJ Office**

For front end marketing and  
Regulatory submissions in USA



# DMFs

## Filing Growth



- USDMFs
- EUDMFs/CEP
- Canada DMFs
- Other DMFs

3<sup>rd</sup> highest US DMFs filer globally in 2015 & 2018

## DMFs

### Among the Top API players for US market

- US DMF filings from 2013-2019
- Ranked 7<sup>th</sup> in the list of most US DMF filers (Active)

Company	Number of Active US DMFs
MSN Laboratories	135
Sun	86
Aurobindo	86
Lupin	79
Teva	75
Mylan	70
Biophore	63
McLeods	62
Dr Reddy's Laboratories	55
Glenmark	55

# OUR MANAGEMENT

## Directors



**Dr. Jagadeesh Rangisetty**

CEO and Managing Director  
Biophore



**Dr. Manik Reddy**

Chief Scientific Officer  
Biophore



- M. Pharm. - BITS, Pilani
- Ph.D. - BITS, Pilani
- Post-Doc - VCU, Virginia, US



- Over 27 years of research experience
- More than 100 patents and publications



- Director of lab at VCU
- Was Vice-President and co-founder of Navinta LLC, New Jersey



- B. Pharm. - BITS, Pilani
- Ph.D. - VCU, Virginia, USA
- Post-Doc - VCU, Virginia and UGA, Georgia



- Over 18 years of research experience
- More than 100 patents and publications



- Worked at Navinta LLC, New Jersey
- Worked at Hospira, Colorado



## OUR TEAM

### Key People



**K. Ramesh**

COO

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More than 30 years experience in the industry. Was head of Supply Chain at DRL and was CEO of Vijayasri Organics previously



**Dr. Bhaskar Reddy**

AVP – R&D

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Ph.D in organic chemistry with post-doc experience from US. Has about 15 years of research experience.



**K. Kalyan**

VP – ARD and Compliance

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Is a post graduate in analytical chemistry. Has about 20 years experience in Pharma and was previously with Actavis and Cipla.

## OUR FACILITIES

### Corporate Office

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Located in Jubilee Hills, Hyderabad  
Functions of finance, IT and Business development operate from here

### Central R&D Center

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State of the Art R&D center of about 80,000 Sft at Pashamylaram, Hyderabad

### Vizag API Sites

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3 facilities located in Vizag Pharma city, equipped with capabilities to handle multiple categories, including niche APIs with best in class compliance

### Zenara Pharma

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Specializes in solid oral formulation manufacturing in Hyderabad

# OUR FACILITIES

## Zenara Pharmaceuticals

### Location and details



Located in Cherlapalli, Hyderabad  
Specialized in solid orals  
Acquired in 2017

### Regulatory Status



US & EU approved facility  
Also inspected by the  
ZAZIBONA, DCA

### Capabilities and Setup



Multi product manufacturing  
capability  
800 million units/annum capacity  
Specialized in Capsules, Tablets,  
gums and lozenges

### Formulations



Capsules, Tablets (IR, ER, Bilayer)  
Taste masking technologies  
Medicated chewing gums  
Pioneers in Nicotine gums

# OUR FACILITIES

## Sionc Pharmaceuticals

### Location and details



Located in Pharmacity  
Vizag  
100% EOU unit  
Operational since 2010

### Regulatory Status



USFDA inspected in 2013, 2016, 2019  
EU approved in 2015 and 2018  
CDSCO Written confirmation from  
2014

### Capabilities and Setup



7 clean rooms in facility  
Setup for both very small volume and  
medium volume products  
Also has **Oncology** manufacturing  
suite

### DMFs



Over 60 DMFs filed from the facility  
About 50 products manufactured in  
the facility  
Commercial supplies to US and EU

## OUR FACILITIES

### Azico-Biophore Pharma

#### Location and details



Located in Pharmacity  
Vizag  
Operational since 2014

#### Regulatory Status



USFDA inspected in 2015, 2018 &  
2019  
EU inspection in 2015 for  
Microbiology lab

#### Capabilities and Setup



7 clean rooms in facility  
**Lyophilization** and dialyzer capability  
**Peptide** manufacturing facility  
Dedicated **hormonal** products  
manufacturing facility

#### DMFs



30 DMFs filed from the facility  
About 40 products manufactured  
in the facility

# Our Products



## Oncology

### Orals and Injectables

	Status
Bendamustine	DMF
Bortezomib	DMF
Carfilzomib	DMF
Chlorambucil	DMF, CEP
Clofarabine	DMF, CEP
Decitabine	DMF
Melphalan (FB & HCl)	DMF, CEP
Plerixafor	DMF
Temozolomide	DMF, CEP

	Status
Tipiracil	DMF
Nilutamide	DMF, CEP
Palbociclib	DMF
Belinostat	DMF
Nelarabine	Developed
Ribociclib Succinate	Developed
Rucaparib Camsylate	Developed
Abemaciclib	U/D

## Contrast Agents

### MRI and Radio-contrast

	Status
Diatrizoate Meglumine	DMF
Diatrizoate Sodium	DMF
DOTA	DMF, CEP
DTPA (Pentetic Acid)	DMF
Gadobutrol	DMF
Regadenoson*	DMF
Sincalide	DMF Ready

	Status
Cyclen (FB & HCl)	DMF Ready
Ethiodized Oil	Developed
BOPTA	Developed
Gadoteridol	Developed
Iohexol	Developed
Iopamidol	Developed
Iopromide	Developed

### Dyes For Human Use

	Status
Isosulfan Blue	DMF
Indocyanine Green	Developed

\*Supportive product in Radiology



## Complex Characterization

### Iron Products

	Status
Ferric Citrate	DMF
Sucroferric Oxyhydroxide	DMF
Iron Sucrose	DMF Ready

### Peptides and Excipients

	Status
Icatibant	DMF
Sincalide	DMF Ready
Cetrorelix	DMF Ready
SBECD	DMF Ready

	Status
Vasopressin	Developed
Pasireotide	Developed
Etelcalcetide	U/D
Angiotensin II Acetate	U/D

## Other Niche Products

### Orphan Drugs

	Status
Trientine	DMF, CEP
Eliglustat	DMF
Nitisinone	DMF
Dichlorphenamide	Developed
Glycerol Phenylbutyrate	Developed
Edaravone	Developed
Sapropterin	Developed

### Topicals

	Status
Crisaborole	DMF
Tavaborole	DMF
Permethrin	DMF, CEP
Tretinoin	DMF, CEP
Docosanol	DMF
Isotretinoin	DMF

### Hormonal

	Status
Levothyroxine Sodium	DMF, CEP
Liothyronine Sodium	DMF, CEP



*Thank you*