

Ref: Syn/CS/SE/IP/2023-24/Apr/12

#### **Syngene International Limited**

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CIN: L85110KA1993PLC014937

www.syngeneintl.com

April 26, 2023

То,	То,
The Manager,	The Manager,
BSE Limited	National Stock Exchange of India Limited
Corporate Relationship Department	Corporate Communication Department
Dalal Street, Mumbai – 400 001	Bandra (EAST), Mumbai – 400 051
Scrip Code: 539268	Scrip Symbol: SYNGENE

Dear Sir/Madam,

# <u>Sub: Investor Presentation under Regulation 30 of SEBI (Listing Obligations and Disclosure</u> Requirements) Regulations, 2015.

With reference to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, please find enclosed the Investor Presentation for the quarter and year ended March 31, 2023. The Company will use this presentation for any meeting scheduled with analysts or institutional investors up to June 30, 2023.

The above-mentioned Investor Presentation will also be available on website of the Company www.syngeneintl.com.

This is for your information and records.

Thanking You,
Yours faithfully,
For **SYNGENE INTERNATIONAL LIMITED** 

Priyadarshini Mahapatra

Company Secretary and Compliance Officer

**Enclosed:** Investor Presentation.



# **Investor Presentation**

**April 2023** 



# Safe harbour



Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements.

Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, business outlook of our clientele and their research and development efforts, our ability to successfully implement our strategy, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currencies, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition, changes in political conditions in India and changes in the foreign exchange control regulations in India.

Neither the company, nor its directors and any of the affiliates have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition.



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**Operating Highlights** 



# Q4 FY23 performance

#### **Operating Highlights**

- Strong growth in the fourth quarter, added to a positive performance over the course of the year
- The growth of Discovery Services and Dedicated Centers remained steady. The
  research facility in Hyderabad, which is a vital part of our Discovery Services,
  continued to expand and now houses approximately 900 scientists.
- Growth in Development Services was driven predominantly by further orders from existing clients, which reflects the high service levels and sustained ontime delivery
- Manufacturing Services continued to support the long-term partnership with Zoetis, following the successful regulatory inspections by the US, European and UK regulatory authorities.

#### **Q4 Financial Highlights**

Total Revenue Rs.10,172 Mn

Reported EBITDA Rs. 3,369 Mn

Profit After Tax Rs. 1,787 Mn

EBITDA **Margin at 33.1%**PAT **Margin at 17.6%** 



# **Full Year FY23 performance**

#### **Operating Highlights**

- Delivered full-year results ahead of our upgraded guidance
- FY23 delivered the highest absolute year-on-year increase in revenue and EBITDA in the last 5 years
- All four divisions of the Company delivered sustained growth through the year.
- The biologics manufacturing partnership with Zoetis signed in the first quarter, is expected to be worth US\$ 500 Mn over 10 years, subject to regulatory approvals and market demand
- Our partnership with BMS marked 25 years of collaboration in March 2023. It is BMS' biggest R&D facility outside the US
- Commissioned a state-of-the-art sterile fill-finish facility and a kilo lab for polymers and specialty materials
- Dedicated PROTACs (proteolysis-targeting chimeras) facility for clients involved in researching treatments for cancer and other therapy areas was opened at Hyderabad
- In addition to successful regulatory audits of its biologics facilities, Syngene successfully nearly eighty audits from regulators and clients in the past year endorsing the quality standards

#### **FY23 Financial Highlights**

Total Revenue Rs.32,638 Mn

Reported EBITDA Rs. 10,053 Mn

Profit After Tax Rs. 4,644 Mn

EBITDA Margin at 30.8% PAT Margin at 14.2%



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Syngene – Putting Science to Work



# Partner in innovation: #Puttingsciencetowork

# Who we are and what we do We aim to be a world class partner delivering innovative scientific solutions for clients



We offer integrated solutions across research, development and manufacturing



Sector expertise include pharmaceuticals, biotech, nutrition, animal health, consumer goods and specialty chemicals



Our team includes more than ~5,000 scientists out of total ~6,000+ headcount, operating across 3 state-ofthe-art campuses located in India's leading life science hubs: Bangalore, Mangalore and Hyderabad



Established track record in discovery research and development for small and large molecules. Emerging presence in commercial manufacturing

# **Key facts and figures**

400+

active clients

**15** 

collaborations with top 20 pharmaceutical companies

400+

patents held with clients

**World class** infrastructure

of 2 Mn+ sq. ft. qualified to meet international standards

Rs. 45,587 Mn (US\$563Mn\*)

Gross Block of Investments ^ Rs. 32,638 Mn (US\$403Mn\*) FY23 Revenue

Rs. 4,644 Mn (US\$57Mn\*) FY23 PAT before exceptional item

**~6,000+** headcount including ~5,000+ talented scientists



# International accreditations



- USFDA,OHSAS 18001
- GLP, cGMP, AAALAC & CPCSEA Certified facilities
- CAP accreditation, ISO/IEC 27001:2013 accreditation
- EMA and PMDA approved, AAALAC accredited facility
- The safety assessment laboratories and large molecule bioanalytical lab are ISO IEC 17025:2017 certified by the National Accreditation Board for Testing and Calibration Laboratories (NABL)



# Our experience spans multiple industry segments and partnerships with global leaders across the world















# Our journey so far

#### **Globalization and strategic collaboration**

- Expanded into formulations development
- Contract with Endo Pharmaceuticals to develop novel anti cancer biological therapeutic molecules
- Extension of collaboration with BMS;
- Merger of Clinigene
- Crossed annual turnover of Rs. 5 Billion

# 2010 -2014

2001 -2009

#### **Expansion**

- Expanded service offerings to include chemical development, safety assessment, biologics development
- · Collaboration with BMS to set up BBRC, Syngene's first dedicated R&D Center

# 2019 -2023

#### **Continued investments and** growth

- Expanded collaboration with BMS, Amgen and Zoetis
- Expansion of IDD platform
- Laboratory capacity expansion in Bangalore, Hyderabad
- Expansion in Mangalore for commercial API manufacturing
- Capacity and capability addition in Biologics manufacturing
- Entered in long-term partnership with Zoetis for Biologics commercial-scale manufacturing
- Commissioned sterile fill-finish facility in Bangalore



# Collaboration with

Amgen to set up a dedicated R&D center

2015 -

2018

IPO and further

collaborations

IPO and listing



**Foundation** 

Operations started

Expansion of R&D Lab

Granted 100% EOU status

by the Government of India



# Our broad capabilities, spanning the value chain, facilitates integration and captures additional benefits for clients

#### **Research business**



**Discovery Services** 

Flexible Platform with capability across multiple modalities including small molecule, large molecule, peptides, oligonucleotides, antibody drug conjugates, PROTACs

**SynVent -** our proprietary platform for Integrated Drug Discovery

**SARchitect**- our proprietary platform for data visualization and analysis, including features specifically designed to foster collaboration between scientific experts across geographies

#### **Dedicated R&D Centers**



**Ring-fenced** infrastructure for exclusive operations for an individual client

**Dedicated,** multi-disciplinary team of scientists

Access to entire Syngene ecosystem for specialist research and development operations

## **Development and Manufacturing business**

#### **Development Services**



Pre-clinical to clinical trials

Drug substance and drug product development

Associated services to demonstrate the safety, tolerability and efficacy of the selected drug candidate

cGMP-compliant manufacturing of clinical supplies, and registration batches for small molecules

#### **Manufacturing Services**



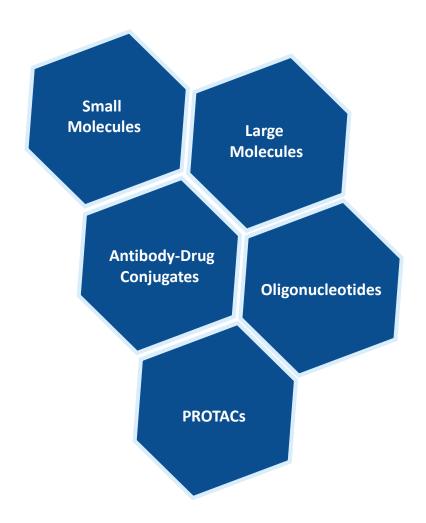
Manufacturing of small and large molecules for commercial supplies

cGMP-compliant facilities

State-of-the art API manufacturing and Biologics manufacturing facilities



# A 'one-stop-shop' for discovery research, development and manufacturing services (small and large molecules)



Discovery	Discovery Development		Discovery Deve			Manufacturi
Chemistry		Drug Substance Development				
		Clinical Su Drug Product Development		Clinical Supplies		
Biology	Int	Integrated Drug Substance – Drug Product		НРАРІ		
Safo	ety Asses	ssment		Specialty Molecules		
		HPU* (Phase 1)		, ,		
Integrated Drug Disco	very	Bio Analytical Lab (Large Molecules)	С	ommercial Supplies		
Therapeutic Anti Discovery & Engine		Stability & Analytical Services				
Cell Line Develop		Bioprocess Development, I Clinical Manufacturing (M				
		Clinical Manufacturing (N cs: Bioinformatics, get dossiers, systems	1icrot	oial & Mammalian)		

\* Human Pharmacology Unit



## Flexible collaboration models



#### **Dedicated R&D centers**

- Dedicated scientific and support teams work exclusively on the client's projects
- Clients are provided with customized and ringfenced infrastructure
- Long-term strategic alliances that last usually five years or more



#### Full time equivalent (FTE)

- Pre-defined numbers of scientific personnel from pre-determined disciplines work fulltime on client projects
- Deliverables and team composition evolve as the project advances
- Agreements are typically renewed annually



#### Fee for service

- Client contracts for agreed services within a defined scope
- Flexible, 'on demand' personnel and research infrastructure deployed to achieve the project objectives
- Engagements may be short-term or longterm



#### **Productivity-based model**

 Resources and services are directly linked to productivity generated by our team



#### **Risk-reward**

- Relationship spans a portfolio of milestonedriven research projects
- Client benefits from reduced upfront payments in exchange for significant successbased milestone payments against preagreed criteria



# Delivery-based contract for CDMO business

 Per kg or per batch model with built-in milestones progressing towards achievement of outcome and delivery of drug substance, drug product

... we are open to any single or combination of above



# Our state-of-the-art infrastructure

#### **Bangalore campus**

90 acres housing most of Syngene's capabilities











Mangalore campus Commissioned March 2020 Capacity: 70KL

Reactor size: 2-12KL



**Bangalore campus** 

Manufacturing plant scale: Mammalian-~100-2000L Microbial - ~200-500L



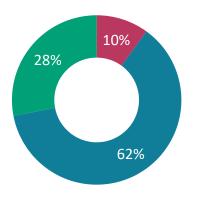


# **Experienced workforce: building capabilities and careers**

~6,000+
total headcount

# 5000+ scientists delivering high quality solutions – create a competitive edge

■ PhDs ■ Master's Degree ■ Others



#### Inspiring technical excellence and providing opportunities to grow

Nurturing young talent and enhancing science skills

- Syngene Training Academy offers new graduate recruits a six-month extended induction to help them understand the Company's vision and values while acquiring the skills to be an industrial scientist
- Science Certification Program is open to all employees to enhance their capabilities keep their skills up to date and provide opportunities for continuous learning

# Developing leaders and managers

- Emerging Leaders Development Program is designed to help strong managers transition from managerial to leadership roles
- Manager Development Program is designed for first- and second-line managers to develop basic management skills and performance management to help them manage their teams and ensure that they are making a positive contribution to the organizational goals

Promoting workplace diversity

- The Company has strong equal opportunity policies to protect against all forms of discrimination and provide a workplace where all employees can deliver their best work
- Support provided to parents of young families. 27% of employees are female and 14% of management positions are held by females



# Operational robustness driving strategy execution

# Continuous improvement embedded in operations driven by certified operational leaders

Six Sigma Black Belt certified staff in each service line and support function Green belt certified staff across operations All employees white belt certified

# Quality management system: digitized and audit-ready

80 customer and regulator audits in the last financial year

8 successful USFDA audits in the last 4 years

#### **Client-focused commercial organization**

Leaders based in the US, Europe, UK and Asia Close to client locations



# Focused execution through strong Project Management

Structured program management for executing client projects enabled by SynPro platform and SynPro Academy ensuring delivery of client projects

#### Digital as a differentiator

Al capability in all research teams

IoT for maintenance and infrastructure reliability

Data Management, IT infrastructure and security systems to strengthen our proposition as a strategic partner to clients

#### Strategic Sourcing that makes a difference

Strategic supplier management to avoid supply chain disruption Supply distributed across the world to ensure business continuity



3

**Syngene strengths** 



# **Syngene strengths**

#### A global scale CRO/CDMO

- Integrated Drug Discovery, Development and Manufacturing service provider
- Small and large molecules, ADCs, oligonucleotides
- Listed on Indian Stock Exchanges (NSE and BSE)

## **Solutions through innovation**

- IP fully assigned to clients
- Track record of data management and security
- Over 400+ patent filings by clients recognizing Syngene scientists



#### **Quality matters**

- Fully digitized quality organization
- Strong compliance track record with global regulators
- US FDA, EMA and PMDA approved, GLP certified, AAALAC accredited facilities
- 80 client and regulator audits in the last financial year











#### Science in our DNA

- Located in 3 top India life science hubs: Bangalore, Mangalore and Hyderabad
- ~5000+ qualified scientists including ~500 PhDs (~6,000+ total headcount)
- Resilient supply chain management
- 2 Mn+ sq. ft. world-class R&D and manufacturing infrastructure

#### Blue chip client list

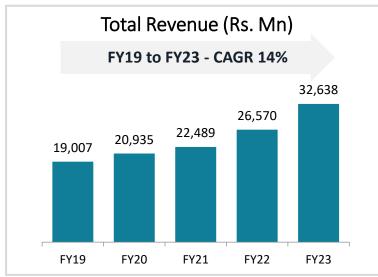
- + 400+ active clients
- Partnering with large / mid-size / emerging biopharma and other industries
- Clients concentrated in US, Europe & Japan
- Track record of working with diverse industry sectors

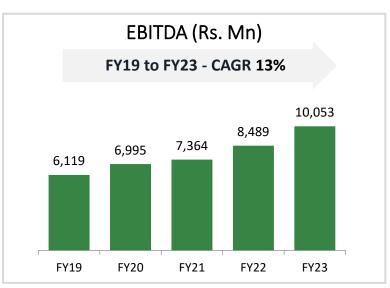
#### Making a difference

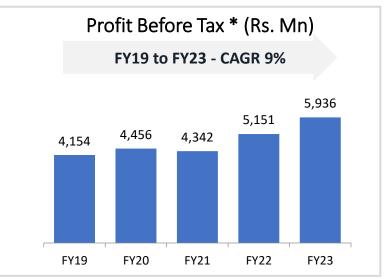
- Partnerships have delivered numerous clinical candidates
- Delivery history for integrated CMC programs up to clinical trials and beyond

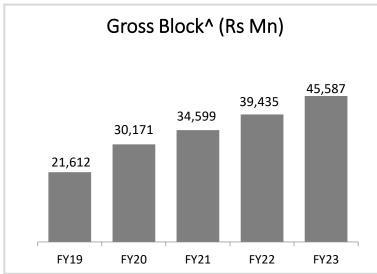


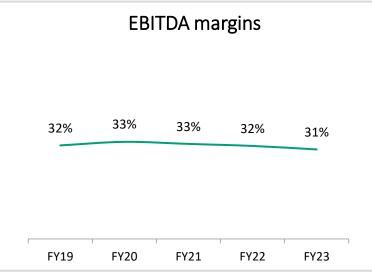
# Strong track record of growth and profitability

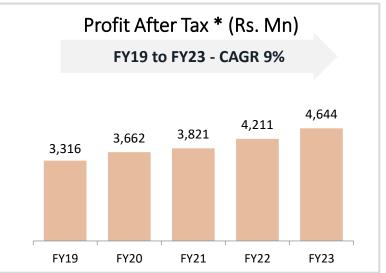












# Levers for future growth

#### Expand/extend existing clients

- Service integration
- Flexible business models including dedicated centers

#### **Engage New Clients**

 Tailored service offerings, high quality infrastructure and access to qualified personnel

Offtake in commercial manufacturing in both biologics and small molecule API

#### **Integrated Drug Discovery**

 Proprietary model leveraging breadth of capabilities to deliver end-to-end project requirements



**Capacity** 

FTE services, manufacturing, formulation, biologics, stability

Forward Capability

Client

engagement

#### Capability additions

- New capabilities across multiple domains including adjacent sectors
- Stability, analytical and bio-analytical services, viral testing, clinical scale injectable fill finish
- New platforms: antibody drug conjugates, CAR-T, PROTACs



# **Committed to safety and sustainability**

#### Safety is our first priority

- Accredited with ISO 45001:2018 for Occupational Health and Safety (OH&S) measures
- Risk assessments are an integral part of our operation: a proactive approach in incident prevention
- Kavach, our flagship safety program, has delivered improvement in safety metrics and drives focus on industrial safety for all employees
- 13.7 million manhours without Lost Time Incident (LTI) on rolling 12-month basis for FY22

#### **Committed to environmental protection**

- Accredited with ISO 14001:2015 for our Environment Management System
- 20% reduction in freshwater usage; 152KL rainwater harvested
- 92% of the total waste generated is recycled in an environment-friendly manner for FY22
- 3R's operations constantly monitored to identify opportunities to reduce, reuse, and recycle waste
- 59,700 tCO2 emissions avoided in FY22 through efficiency measures
- 74 Mn KWH of electricity usage from green energy sources up 18% from FY21
- 86% of total energy consumption from green energy sources in FY22
- Member of the United Nations Global Compact

Refer to the <u>CSR link</u> on our website to know about our corporate social responsibility pursuits on healthcare, education, environment, rural development Refer to the <u>ESG Report</u> on our website to know more



# Industry recognition for our scientific capability and best practices



- Bio-Excellence Award 2018: At Bengaluru Tech Summit, Bengaluru
- Best Bioprocessing Excellence Award 2018 -At 5<sup>th</sup> Biologics Manufacturing Asia, Singapore
- Healthcare Company of the Year 2018: At the 7<sup>th</sup> Annual VC Circle Awards 2018, Mumbai
- HR Excellence Award 2018 'For Best Talent
  Management Strategy': World HRD Congress,
  Mumbai

2018

- CMO Leadership Award Winner 2020 under Categories: Capabilities, Compatibility, Expertise and Service
- Bioprocessing Excellence Awards 2020 in the category 'Bioprocessing Excellence in South Asia—Viral Clearance and Safety Testing'
- Great Place to Work Certified™ Company
- (ASSOCHAM) CSR & NGO Awards 2020 for our contribution to COVID-19 relief work in Karnataka.

2020

- **CMO Leadership Awards 2022** Received 6 awards for all categories, including Capabilities, Compatibility, Expertise, Quality, Reliability and Service
- CMO Leadership Award Champion 2022 Additional Recognition received in CMO Leadership Awards 2022 for top performance in all categories
- 'Most Preferred Workplaces of 2022' by Team Marksmen
   Daily in association with India Today Recognized for its
   holistic reorientation of the business landscape in the
   context of the pandemic, and for creating a collaborative
   and empowering culture for its employees.

2022

 Ranked as one of the 25 fastest growing companies in India by Outlook Business

2019

 CMO Leadership Awards 2019 - Presented by Life Science Leader Magazine

- FICCI CSR Award for Environmental Sustainability -At the 17th Edition of the awards in New Delhi
- Safe Workplace Champion Award At the 8th Manufacturing Supply Chain Summit and Awards
- Best Leadership Development Program for Middle Management Award - At the 6th Global Training and Development Leadership Awards
- India Pharma Award 2019 For "Excellence in Contract Research and Manufacturing Services" at CPhI & P-MEC India Expo.
- Utthama Suraksha Puraskar 2019 (Pharma and Chemical Manufacturing Category) by National Safety Council of India (NSCI). Leadership Awards

**Dream Companies to Work Award** at the 29<sup>th</sup> Edition of the World HRD Congress Awards.

2021

- Asian Leadership Award for Excellence in Branding and Marketing in the Contract Research Development and Manufacturing category
- CRISIL awards Syngene Top score among Indian Pharma: for Environment Safety Governance (ESG)
- Syngene ranked #69 in Fortune India magazine's list of 'Top 100 Indian wealth creators 2021'
- India Pharma Awards 2021 for Operational Excellence:
   Manufacturing organized by Informa Markets, India
- Best Governed Company in the Listed Segment: Medium Category at the 21st National Awards for Excellence in Corporate Governance by The Institute of Company Secretaries of India (ICSI)
- Most Innovative New Learning Programme at the L&D Vision & Innovation Award organized by Transformance Forums
- Mahatma Award 2021 Under Health & Wellbeing Category
- **Best Corporate Foundation Award** at the World CSR Congress

# Robust risk management framework

Syngene has a risk management framework to identify, monitor, report and manage risk Every risk owner monitors and manages risks relevant to their area of responsibility

• Identify and mitigate risk in respective business areas

**Risk Owner** 

#### **Executive Committee (EC)**

- Sign-off on Enterprise Risk Framework annually
- Review and approve the key updates to enterprise risks and deep-dive into few risk areas every quarter

• Sign-off on Enterprise Risk Framework annually

- Ensure that appropriate measures are in place to mitigate the risks
- Review updates to enterprise risks and deep dive into few risk areas every quarter

**Board Risk Committee** 

#### **Board of Directors(BOD)**

- Provide strategic direction on mitigation of risks
- Ensure principal risks are properly managed

Risk identification

Risk assessment

Risk analysis and rating

Risk mitigation

Monitoring and reporting

Refer Annual report for complete risk profile and risk mitigation strategy



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**Financials** 



# **Q4FY23** financial highlights

Particulars	Q4 FY23	Q4 FY22	YoY change	Q3 FY23	QoQ change
Revenue from operations	9,944	7,581	31%	7,859	27%
Other income	228	147	56%	172	32%
Reported revenue	10,172	7,728	32%	8,031	27%
Material costs	2,938	2,149	37%	2,061	43%
Staff costs	2,528	1,797	41%	2,192	15%
Other direct costs	273	238	15%	264	3%
Other expenses	1,022	985	4%	876	17%
Foreign exchange (gain)/loss, net	42	-91	-146%	156	-73%
EBITDA	3,369	2,650	27%	2,482	36%
EBITDA Margin	33.1%	34.3%		30.9%	
Depreciation and Finance Cost	1,060	859	23%	1,083	-2%
РВТ	2,309	1,791	29%	1,399	65%
Tax	522	313	67%	302	73%
PAT	1,787	1,478	21%	1,097	63%
PAT Margin	17.6%	19.1%		13.7%	



# **FY23** financial highlights

Particulars	FY23	FY22	YoY Change
Revenue from operations	31,929	26,042	23%
Other income	710	528	34%
Reported revenue	32,639	26,570	23%
Material costs	8,602	7,490	15%
Staff costs	8,876	7,408	20%
Other direct costs	1,109	872	27%
Other expenses	3,580	2,859	25%
Foreign exchange (gain)/loss, net	418	-548	-176%
EBITDA	10,054	8,489	18%
EBITDA Margin	30.8%	32.0%	
Depreciation and Finance Cost	4,118	3,338	23%
РВТ	5,936	5,151	15%
Tax	1,292	940	37%
PAT before exceptional item	4,644	4,211	10%
PAT Margin	14.2%	15.8%	
PAT after exceptional item	4,644	3,958	17%
PAT Margin after exceptional item	14.2%	14.9%	

## **Balance Sheet Highlights**

#### As on 31st March 2023

Shareholders' funds	36,180
Net Fixed assets	28,437
Other net assets (1)	(1,818)
Net cash/(debt) <sup>(2)</sup>	9,561
Total Use of Funds	36,180

(1) Other Assets calculated as (Inventories + Trade Receivables + Unbilled Revenues + Advance Tax + FX premium less (Trade payables + Others current liabilities) at the end of the year (2) Net cash / (Net debt) calculated as the Cash & cash equivalents (Cash and bank balances + Current investments + Fixed deposits) less Total debt (Short-term borrowings + Long-term borrowings) at the end of the year



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**Shareholding and Share Information** 



# **Syngene and Biocon Group**

# Syngene

Syngene is an operationally independent publicly listed subsidiary of Biocon Limited, established in 1993 as India's first Contract Research Organization. Company has 25+ years of experience in novel molecule discovery, development and manufacturing services



**Biocon Limited**, founded in 1978, is an innovation-led global biopharmaceuticals company and has majority holding in key operating entities including Syngene

**Syngene** 

#### **Integrated services:**

- Discovery research
- Development
- Manufacturing small/large molecules

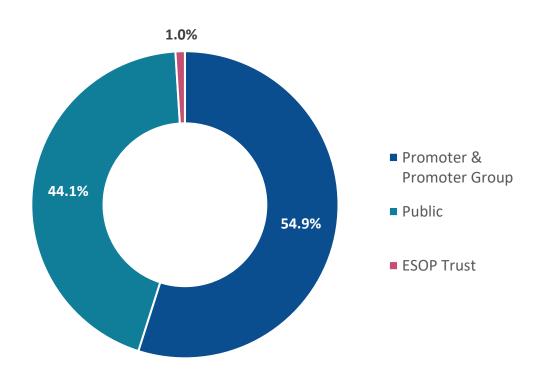


- Product Based
- Biosimilars
- Formulations and Compounds
- Alternative Therapeutic Drugs



# **Shareholding and Share Information**

# **Syngene's Shareholding Pattern\***



## **Syngene's Share Information\***

NSE Ticker	SYNGENE
BSE Ticker	539268
Market Cap (Rs. Mn)	2,38,653
% free-float	44%
Free-float market cap (Rs. Mn)	1,05,290
Share Outstanding (Mn)	401

## For more details

#### Visit our website www.syngeneintl.com



https://twitter.com/SyngeneIntl



https://www.linkedin.com/company/syngene-international-limited



https://www.facebook.com/syngeneintl/



https://www.youtube.com/channel/UCIC4WSA1k5YAC531gMLkbIQ

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Appendix



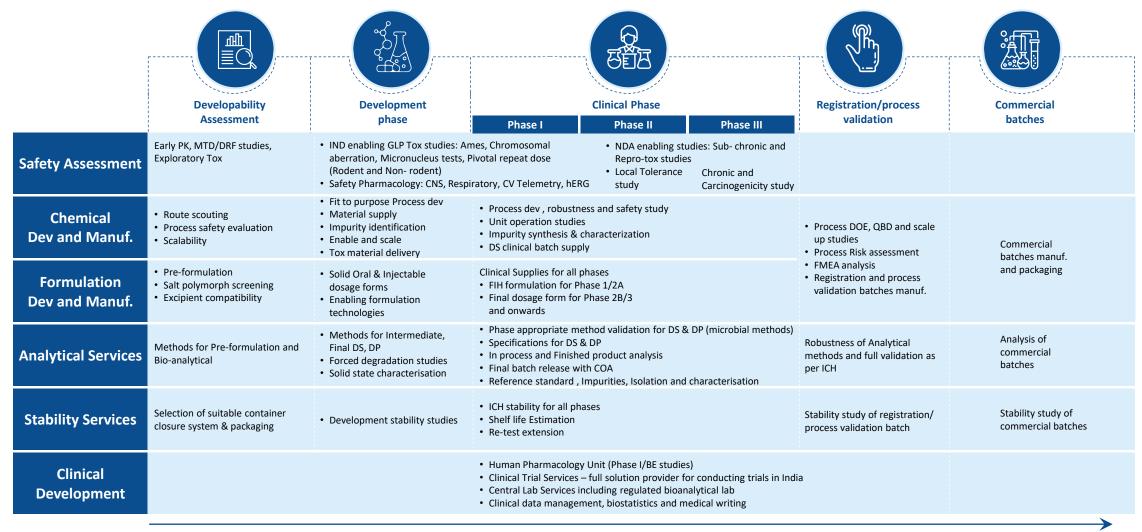
# **Discovery Services**

	Target Identification and Validation	Hit Identification	Hit to Lead	Lead Optimization	IND Enabling	IND / Ph1 DE
Biology Translation	1. The 2. Med	In vitro assays: 1. Biochemical 2. Orthogonal 3. HTS Formats  Cheses:  Trapeutic chanistic get Engagement	In vitro assays: 1. Cellular Mechanistic 2. Cellular Functional 3. Relevant Off-Target(s) In vitro ADME assays: 1. Protein Binding 2. Metabolism 3. CYP Inhib/Induct Research Operating Plan: 1. Assay Priority 2. Key Studies 3. Critical Path	In vivo assays/studies: 1. PK (R/NR) 2. PD, PK/PD 3. Efficacy  Hypothesis: 1. Patient Selection	Later Translational:  1. PK/PD/Efficacy 2. Refinement of patient selection hypothesis 3. Biomarkers  Human Dose Projection 1. h-PK Projection 2. PK/PD/Efficacy data 3. Safety/Tox data	Ph1-HV or Patient (as appropriate): 1. Exposure 2. PD
Chemistry Development Formulation Clinical Development	HTS/DEL/Fragments/Virtual Screening 1. Library Design/Synthesis/ Maintenance 2. Hit validation, Resynthesis 3. Series Qualification, Prioritization		Optimization: 1. Biochem/Cell Potency 2. Selectivity 3. Phys/Chem Properties 4. In Vitro/Vivo Tool Cmpds	Optimization: 1. Tgt Optimal h-Profile 2. Candidate Selection 3. Backup Strategy	Drug Substance (DS, aka API)  1. Route Scouting (define specs)  2. Scale Up  3. Manufacture/Stability	Drug Product (DP) 1. Pre-Formulation Studies 2. Ph1 Suitable Formulation 3. Prototype/Stability 4. Manufacture/Stability 5. IND, BA/BE, DDI and Phase clinical trials 6. GCP Bioanalysis
Safety Assessment		In vitro Safety: 1. hERG 2. Ion Channels	Tox-Suitable Formulation (maximize exposure)	DRF Tox (R/NR) Bioanalysis GLP Tox (R/NR) GLP Bioanalysis	MTD or RP2D (as appropriate)	

Iterative Data Analysis and Interpretation, Models, Hypothesis Generation



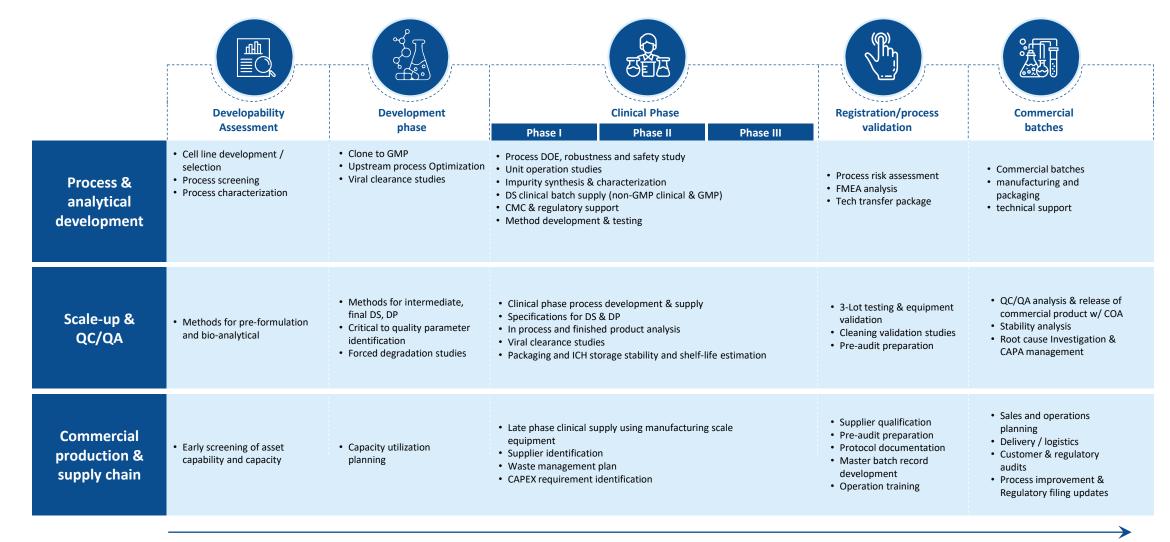
# **Development Services and Manufacturing Services**







# **Biologics Development and Manufacturing services**





# Thank you

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