Management Discussion and Analysis

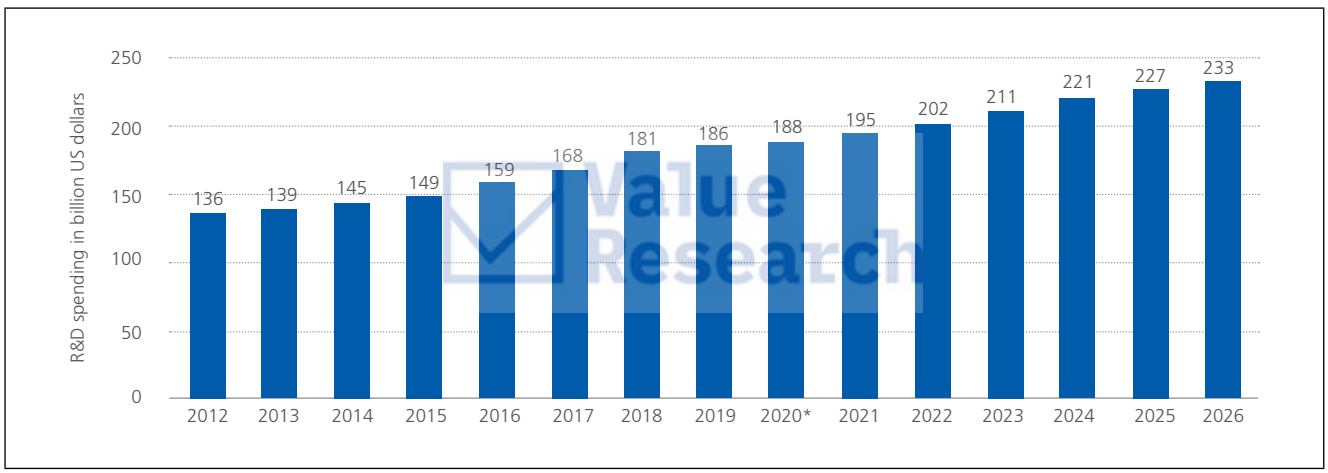
Research & Development

Recognizing the importance of research and development (R&D) in driving pharmaceutical innovation and competitiveness, governments and industries globally continue to make robust R&D investments in pharmaceuticals. To put this into context, global R&D expenditures have increased more than three-fold since 2000 - from USD USD 676 Bn to USD USD 2.0 Tn in 2018.[1]

The pharmaceutical and biotechnology industry, propelled by the imperative to bring breakthrough drugs in the market, is among the leading R&D spenders as a percentage of revenue.[2] In 2020, estimated R&D spend by the pharmaceutical industry stood at USD 188 bn, and by 2026, R&D spend by the pharmaceutical industry is estimated to reach over USD 230 bn. Around 17,700 prescription drugs were in the 2020 R&D pipeline, a number that has been growing year-on-year.[3]

Beyond the life sciences sector, companies in the segments of specialty chemicals, agrochemicals, animal nutrition, personal care and nutrition are also investing in R&D to keep their innovation pipelines flowing.

Global pharmaceutical R&D spending



While R&D spending is increasing, innovator companies continue to be challenged by the declining rate of investments in R&D. In the pharmaceutical industry, a considerable proportion of drug candidates fail during the regulatory process. This increases the average cost to develop and secure marketing approval for a new drug. The declining returns are encouraging many drug developers to outsource large parts of their R&D activities, along with leveraging new technologies, to make drug discovery and development cost-efficient and faster.

The economic downturn following the coronavirus (COVID-19) outbreak has strained financial resources for countries and corporations. At the same time, the pandemic is a powerful reminder that health-related R&D investments are critical for humanity. Besides the challenge of global economic volatility and an uncertain operating environment, the pharmaceutical and biopharmaceutical industry has also had to contend with suspended trials for drugs other than those for COVID-19, delayed product launches, a decline in in-person visits for healthcare professionals (HCP) and salesforce-HCP interactions, and delays in drug commercialization. Despite these hurdles, analysis from the Global Innovation Index (GII) 2020 Report suggests that R&D spending by the pharmaceutical and biotechnology sector will experience resilient growth in the post-pandemic world.[4]

[1] *https://fas.org/sgp/crs/misc/R44283.pdf*
[2] *https://www.statista.com/statistics/270233/percentage-of-global-rundd-spending-by-industry/*
[3] *https://www.statista.com/statistics/309471/randd-spending-share-of-top-pharmaceutical-companies/*
[4] *https://www.strategy-business.com/article/How-COVID-19-will-affect-investment-in-global-innovation?gko=276ed*

Contract Research Services Market

Contract Research Organizations (CROs) provide research services on a contractual basis to R&D-focused companies across multiple sectors such as pharmaceutical, biotechnology, nutraceuticals, animal health, medical devices, and speciality chemicals. CROs also provide support to academic institutes and government research organizations. In 2019, the pharmaceutical and biopharmaceutical companies segment accounted for the largest share of the global CRO services market.[5]

In the biopharmaceutical industry, activities that are typically outsourced span from basic research to late-stage development, encompassing genetic engineering, target validation, assay development, hit exploration and lead optimisation, safety and efficacy tests in animal models, and clinical trials involving humans. The biopharmaceutical sector's growing dependence on CROs can be inferred from the fact that the latter were involved in 50% of drug development work in 2018, up from 18% in 2006.[6] There is ample scope for growing the CRO services market as industry experts believe that 70-75% of R&D spend by the global pharmaceutical industry can potentially be outsourced.[7]

The global CRO services market is projected to reach USD73.77 bn by 2025 from USD 47.77 bn in 2020, at a CAGR of 9.1% over the five years.[8] Growing R&D expenditure, increased outsourcing of R&D activities and the increased number of clinical trials are the major factors propelling the market growth. The CRO market for early phase development services which includes chemistry, manufacturing and control (CMC) services, and preclinical services is also poised to register a robust growth rate as pharmaceutical firms outsource to counter the complexity of the drug development processes and meet stringent regulatory requirements. Among therapeutic areas, oncology accounts for the largest share of the global CRO services market and this segment is expected to maintain a strong growth as increasing incidence of cancer drives demand for development of new drugs.

Growth Drivers

Over the years, R&D outsourcing has gradually transitioned from being largely a cost arbitrage strategy to one of enhancing R&D productivity and speed-to-market and strategic choices being made by innovator companies to focus on their core competencies. The interplay of several factors, as explained below, positions the CRO industry to grow steadily in the coming years.

Expertise to manage complexities: With their extensive scientific expertise and regulatory knowledge, CROs help client companies to efficiently navigate the complexities of the drug development process. CROs are also increasingly adopting and integrating advanced technologies, such as high-throughput screening, bioinformatics and cheminformatics, to accelerate the discovery and development of a compound and improve R&D efficiency. According to research by Frost & Sullivan, the development duration for a new drug can be reduced by one-quarter to one-third with the help of CROs.

Partnering innovation in newer areas: The emergence of novel biological targets and therapeutic modalities offers promising opportunities for breakthrough drugs. The rising demand for personalised medicines also calls for innovation. However, biopharmaceutical companies, especially start-ups, do not always have the necessary expertise in-house to make the most of these developments. Entering into strategic collaborations with specialised CROs and leveraging their broad spectrum of services increases the possibility for client companies to discover and develop advanced therapies.

Driving flexibility in costs: Under the outsourced model, the client's need to invest in in-house facilities, equipment, technology and manpower has significantly reduced. This enables them to convert their traditional fixed costs into variable costs, thereby minimising their investment risk. Small and mid-sized firms also find externalization of R&D attractive as they can access high-quality services without committing to longer-term investments.

Pharmaceutical Contract Manufacturing Services Market

Partnering with a contract manufacturing organization (CMO) is a strategic choice by many pharmaceutical companies – from big players to smaller speciality entities. The capital-intensive nature of the business and complexity of the manufacturing requirements are among the primary reasons driving pharmaceutical companies to outsource commercial manufacturing. Additional factors providing a solid foundation for the growth of the CMO services market include growing demand for generic medicines and biologics or large molecules.

5 https://www.marketsandmarkets.com/Market-Reports/contract-research-organization-service-market-167410116.html#:~:text=%5B272%20Pages%20Report%5D%20The%20global,9.1%25%20during%20the%20forecast%20period

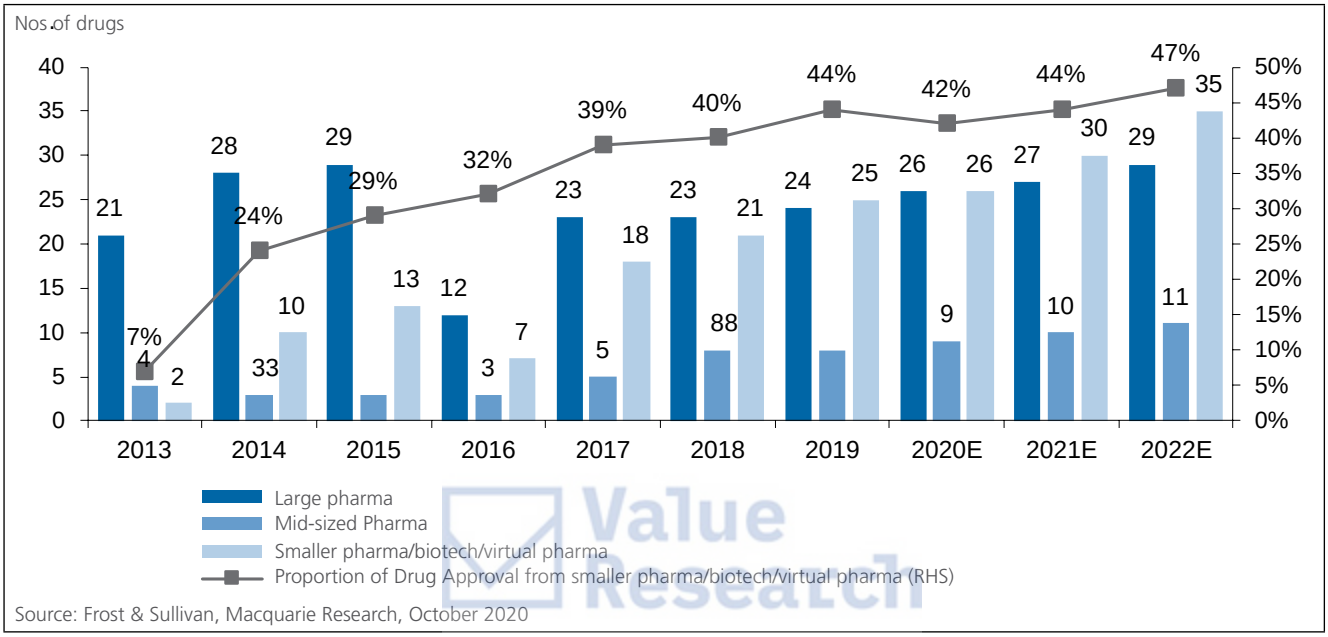
6 The Prize – India Pharma CRAMS/API: Stronger for longer, Macquarie Research

7 The Prize – India Pharma CRAMS/API: Stronger for longer, Macquarie Research

8 https://www.marketsandmarkets.com/Market-Reports/contract-research-organization-service-market-167410116.html#:~:text=%5B272%20Pages%20Report%5D%20The%20global,9.1%25%20during%20the%20forecast%20period.

The manufacture of biologics entails a far higher degree of expenditure and technical capabilities in comparison to small molecules. While a small molecule manufacturing facility calls for an investment of USD 30-100 million, the cost of building of a large biotechnological facility can be USD 200-500 million.[9] The influx of small and virtual biotech players who lack the expertise or the infrastructure to manufacture their products in-house is also augmenting the global pharmaceutical CMO market. As stated in a recent report from Frost &Sullivan, over 40% of innovative molecules are being developed by emerging biotech companies without later-stage manufacturing capabilities.[10]

Contribution by small pharma/biotech to new drug development globally



Source: Frost & Sullivan, Macquarie Research, October 2020

The combination of these factors contributes to a CAGR of 6.4% over the period 2020-2025, resulting in global pharmaceutical CMO market valued at USD 162.1 bn by 2025 from USD 109.67 bn in 2019.[11]

An important trend being witnessed in the CMO market for biologics is that innovators prefer to enter into a strategic alliance with a one-stop-shop service provider who has been involved in the discovery and development process because it helps to make the transition into commercial manufacturing more efficient and faster.

Company Overview

Established in 1993, Syngene International Limited (henceforth referred to as 'Syngene' or 'the Company') is an integrated research, development and manufacturing organization providing scientific services. Syngene's end-to-end services span a wide spectrum of modalities including small and large molecules, antibody-drug conjugates (ADCs), and oligonucleotides. The scientific services are largely accessed by the global pharmaceutical, biotechnology industry, nutrition, animal health, consumer goods, and speciality chemicals are among the other sectors being served by the Company. During the past year, the Company worked with more than 400 clients from multiple industry sectors.

Syngene's greatest strength is its highly qualified research team comprising over 4,000 scientists. Its state-of-the-art facilities, encompassing 1.9 Mn. sq. ft. is spread across three locations in India – Bangalore, Hyderabad and Mangalore. These facilities regularly clear regulatory inspections by the world's leading regulators including the USFDA, EMA and PMDA. Sustained investments in world-class technology and systems underpin the Company's ability to meet global compliance and quality standards, accelerate R&D activities, and respond with agility to evolving client needs.

[9] *Global Biologics Drug Discovery Market Analysis and Forecast, (2017-2025), BIS Research*

[10] *The Prize – India Pharma CRAMS/API: Stronger for longer, Macquarie Research*

[11] *https://www.reportlinker.com/p05778451/Pharmaceutical-Contract-Manufacturing-CMO-Market-Growth-Trends-and-Forecast.html?utm_source=GNW*

Throughout its 25-year-long journey, Syngene has maintained an excellent track record of data integrity, data security and client's intellectual property (IP) rights protection. As an end-to-end solutions provider, the Company has built deep trust-based relationships with its clients which drives longevity and sustained project engagement.

Business Divisions

Syngene has four business divisions: Dedicated R&D Centres; Discovery Services; Development Services; and Manufacturing Services.

Business Division	Dedicated R&D Centres	Discovery Services	Development Services	Manufacturing Services
Particulars	Dedicated R&D facilities for strategic clients providing exclusive access to research teams, infrastructure, and project management to support the client's R&D requirements.	Engaged in early-stage research from target identification to delivery of drug candidates for further development. Capabilities includes Chemistry, Biology, Safety Assessment, and Research Informatics for small molecules; recombinant DNA engineering, cell line development, Next Generation Sequencing, and protein sciences for large molecules.	Engaged in activities from pre-clinical to clinical trials, including drug substance and drug product development, and 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.	Engaged in the manufacturing of small and large molecules for commercial supplies through cGMP compliant facilities, a state-of-theart API manufacturing campus and a biologics manufacturing facility.

Collaboration Models

Syngene operates a range of collaboration models: from long-term relationships in the dedicated R&D centres to Full-Time Equivalent (FTE) contract, Fee-for-Service (FFS) contract and Risk-Reward sharing arrangements. Clients can select any one or a combination of the above models to deliver their R&D programs.

In the dedicated centre model,clients are provided with customized and ringfenced infrastructure. Dedicated scientific and support teams work exclusively on the client's project. These are Long-term strategic alliances that last usually five years or more. In the FTE model, a defined number of scientific personnel from pre-determined disciplines are identified to work full-time on client projects. These agreements are typically renewed annually. The scope of services and deliverables evolves as the project advances. Under the FFS model, client collaboration is done to deliver agreed services within a defined scope. Flexible, on demand personnel and research infrastructure are deployed to achieve the project objectives. The engagements may be short or long-term. In the risk-reward sharing model,across a portfolio of stage gate-driven research projects,the clients are benefitted from reduced upfront payments in exchange for significant success-based milestone payments against preagreed criteria. While client collaboration in Discovery Services are usually FTE-based, engagements in the Development and Manufacturing Services divisions are primarily based on the FFS model.

Operational Performance

DEDICATED R&D CENTRES

Syngene operates Dedicated R&D Centers for four clients: Bristol-Myers Squibb (BMS), Baxter Inc., Amgen Inc., and Herbalife. These collaborations have been in place for between five to fifteen years and represent the Company's ability to build longstanding relationships with its clients.

During the year, the dedicated R&D Centers witnessed healthy performance, primarily driven by business growth in the BMS and Baxter accounts. For both these Dedicated Centers, the scope of engagement as well as scientific team strength were expanded, and new infrastructure facilities were established. The Company also crossed a significant milestone with the extension of the collaboration with BMS until 2030 and expanding the scientists working by 40%.

The Company, in close collaboration with the clients, continued to invest in enhancing scientific expertise and operational performance to realize the shared goal of delivering cutting edge science and development of drugs across multiple disease areas and in the most efficient manner, to help serve millions of patients across the globe. For all the Dedicated Centers, R&D projects continued to be run as per expectations, including those that involved generation of crucial data for regulatory filing within strict target timelines, despite the COVID-19 pandemic. This was delivered as a result of meticulous planning by the teams, while keeping the health and safety of the scientists and enabling staff as the topmost priority.

The Company continued to engage with the Dedicated Center clients to discuss new technology, capability/capacity enhancements and ways to further expand the scope of partnership in research, development and manufacturing in the coming years.

DISCOVERY SERVICES

The Discovery Services division continues to be a core driver of revenue growth. Despite a temporary suspension of activities in the first quarter due to the COVID-19 pandemic, a robust performance was achieved for the full year by returning to near-normal operations promptly once sufficient protective measures were in place to ensure employee safety. Most of the planned objectives in terms of project deliverables, project timelines, new partnerships, team expansion, and capability enhancements were also achieved.

The Company entered into new FTE collaborations while expanding the team strength and scope of activity for several existing FTE contracts. Many FFS contracts were converted into FTE engagements, reflecting the Company's success in building strategic relations with its clients. The Company's integrated drug discovery approach facilitated the successful transition of projects into the Development Services Division. During the year, existing and new clients have been inspired by the pandemic to more aggressively diversify their global operations as part of their risk mitigation strategy, and Syngene's Discovery Services division has benefited from this trend.

The key collaborations for the year include an agreement signed with Deerfield Discovery and Development Corporation (3DC). As part of this five-year collaboration, Syngene will provide end-to-end discovery and preclinical development solutions, spanning multiple therapeutic areas and modalities. As part of this collaboration, 3DC has awarded Syngene four antibody integrated drug discovery (IDD) projects in the oncology and autoimmune segments to be executed during FY 2021-22.

For the past three years, the Company has conducted several research projects for C4 Therapeutics, seeking to discover innovative treatments for cancer and neurodegenerative conditions. Two new programs were added to this collaboration during the year.

Key scientific accomplishments include the successful delivery of two drug candidates for clinical development. Another project delivered a library of 600 compounds with a success rate of >95%.

One of Discovery Services' differentiators is the ability to provide most of the research capabilities of a major pharmaceutical company. Strengthening this position, developing the integrated drug discovery platform remained a core focus area to drive research programmes end-to-end through one service provider. Aligned with this objective, the Company launched SynVent, a platform for fully integrated therapeutic discovery and development across large and small molecules. SynVent IDD services are designed to provide the most effective and efficient means to conduct target validation, translational interrogation, therapeutic discovery, and preclinical development for clients.

Proteolysis-targeting chimeric molecules (PROTACs) represents an emerging technology for the discovery of novel targeted therapeutics. During the past year, the Company enhanced its expertise as an end-to-end service provider. The Experimental Polar Surface Area (EPSA) assay, which uses a critical fluid chromatography (SFC) technique, was initiated to improve design effectiveness with respect to membrane permeability for PROTAC targets in a high-throughput environment. The Company also built is expertise in the synthesis and purification of multigram quantities of PROTACs.

The Research Informatics unit was restructured into a solution-oriented business that is both client-centric and an enabler of data science adoption. This ability to integrate computational methods and data science into operations benefits both Syngene and client scientists and leaders in faster, better informed decision making, which will accelerate programs on the track from the earliest stages of discovery and candidate selection to preclinical evaluation, as well as during clinical trials.

The Company continues to enter into strategic alliances with other research institutions and companies to enhance the breadth and depth of integrated solutions available to clients.

The Phase I unit of the newly established research facility at Genome Valley, Hyderabad is operating close to full capacity. Genome Valley is India's first purpose-built cluster for life sciences R&D activities, thereby providing an enabling environment to drive scientific innovation and seamless delivery. Phase II construction was completed during the year while Phase III work is currently underway to support business expansion. At the Bangalore site, the analytical laboratory was expanded and equipped with new infrastructure.

Several other technical and digital capabilities were also added across the different disciplines of Discovery Services. These capability enhancements will further pave the way for greater integration among the various functions, to foster innovation at increased speed and lower costs.

DEVELOPMENT SERVICES

The Development Services Division reported a steady performance for the year. New clients were added across the various scientific disciplines while existing clients established broader relationships by accessing more services. Post the temporary suspension of operations following the COVID-19 disruption, business continuity in critical development services and clinical supplies manufacturing was quickly restored by realigning operations and implementing comprehensive safety-related measures.

The scientific highlights for the year include critical contribution in the development and progress of a drug to clinical trials for biopharmaceutical client Albireo Pharma. The drug will help to treat a particular genetic liver disease primarily in children. Syngene was involved in several campaigns of the drug substance - starting from registration batches to phase-III trials. The Company continues to work with the client as it makes its regulatory filings.

GMP clinical and registration batches were delivered for several clients. The notable among them include the successful delivery of GMP clinical supplies of an animal healthcare product for a pharmaceutical major. This complex project was executed through fast-track development and involved overcoming the challenge of limited API availability. Syngene also delivered GMP supplies for another leading pharmaceutical company to support its pilot bioequivalence studies in humans. These products, too, were delivered within aggressive timelines. Another US-based client filed an NDA for immediate-release tablets to the USFDA, the registration batches of which were manufactured at Syngene's GMP facility. In the current fiscal, the Company will be manufacturing and supplying clinical trial batches of monepantel to support Phase 1 and 2 clinical trials in humans, as part of its strategic collaboration with PharmAust. In addition, Syngene received a voluntary license for manufacturing and distributing of Remdesivir, the only drug approved to treat Covid-19. We released the first batch of RemWin® together with our partners from Biocon and Biocon Biologics in November 2020.

In the previous year, the Company had commenced the realignment of the different units of the Development Services and its overall integration with the Discovery Services Division, with the objective to emerge as a solution-provider across the drug delivery continuum. During the year under review, considerable headway was made in this direction, strengthening the Division's capability to work on integrated projects. An important highlight in this regard was the setting up of an Analytical Development function, making the Division's structure similar to that of large pharmaceutical companies.

In terms of capability enhancement, a noteworthy milestone was the setting up and commissioning of the High Potent Active Pharmaceutical Ingredient (HPAPI) laboratory at the Bengaluru site. This facility will be used to develop chemical processes for high potent molecules in a laboratory scale and then transferred to another internal facility for scale-up. The qualification process was completed towards the end of the year under review, while revenues from this enhanced value proposition are expected to be generated in the current fiscal.

Clinical Development was material in establishing Syngene's Covid-19 RT-PCR testing capabilities. Close to 180,000 samples have been tested to support Covid fighting in the local community as well as on Biocon campus. Clinical Development supported the development of a Covid antibody test which later has been marketed together with HiMedia.

MANUFACTURING SERVICES

API Manufacturing

The Mangalore (MSEZ) commercial API manufacturing facility completed the qualification process and is now a GMP-certified facility. Production has commenced in the intermediate areas where equipment has already been qualified. The facility is on track to take on larger volume production in FY 2021-22. The focus remains on ensuring 100% compliance with global manufacturing practices and integrating sustainability into plant operations.

Biologics Development & Manufacturing

The Biologics Development and Manufacturing unit improved its performance from the previous year. However, as client diligence of manufacturing facilities was impeded due to travel restrictions for COVID-19, contract finalisation was delayed, resulting in sub-optimal performance. Several first-time clients have been signed for the Biologics operating unit, many of whom offer prospects of significant future business opportunities. Contracts were also signed for antiviral testing of consumer products.

The Company continues to add scientific capabilities to drive continued innovation. The highlights for the year included completion of construction of the new microbial manufacturing facility, the addition of mRNA technology as a new line of process development and clinical manufacturing service; increase in the capacity of the microbial testing laboratory; a new 5,000 sq. ft. process development laboratory; and a new Quality Control laboratory with the latest biologics infrastructure.

The biologics manufacturing facility can cater to multi-product production campaigns simultaneously based on single-use technology platform. Investments continue to be made to strengthen this capability in alignment with the growing demand for outsourced biologics manufacturing. Since its commissioning in the biologic mammalian manufacturing plant capacity has increased from one 2000L bioreactor to three 2000L bioreactors.

COVID-19 RESEARCH AND PROJECTS

Since the outbreak of the coronavirus pandemic, Syngene has been actively contributing its scientific expertise and resources in the fight against the virus. It has developed high-quality, mammalian derived viral proteins such as S1, RBD, and N protein meant for diagnostic testing and assays. The Company has also developed proprietary antibodies (monoclonal and polyclonal) with high affinity and specificity for use in viral antigen detection and other such tests.

The Company repurposed one of its laboratories in Bangalore to conduct COVID-19 testing using RT-PCR technology. Approved by the Indian Council of Medical Research (ICMR), this centre is one of the largest RT-PCR testing private laboratories in Karnataka. During the year, it has conducted close to 1,85,000 tests and has tied up with over 50 organizations for testing their employees.

The Company developed an IgG based ELISA test kit for COVID-19, ELISafe 19TM, at its research facility in Bangalore. The Company partnered with bioscience firm HiMedia Laboratories for manufacturing and distribution of these kits. Approved by ICMR and the Central Drugs Standard Control Organization (CDSCO), the ELISA test is intended for the qualitative detection of IgG SARS-CoV-2 antibodies in blood samples. It delivers higher throughput and generates faster results than other similar tests.

Syngene collaborated with the Centre for Cellular & Molecular Biology (CCMB) to deliver a high throughput Next Generation Sequencing (NGS) based genomic screening assay that can test 5,000-10,000 samples simultaneously. It has also tied-up with Mylab Discovery Services to manufacture and supply oligonucleotides (primers and probes) for use in their diagnostic kit.

In collaboration with the National Centre for Biological Sciences (NCBS), Syngene is to develop a novel human ACE2 transgenic mouse that is anticipated to phenocopy the full spectrum of human COVID-19. This will be a valuable animal model for in vivo screening of potential COVID-19 therapies and furthering the understanding of SARS-CoV-2 pathogenesis. The project is being funded by the Biotechnology Industry Research Assistance Council (BIRAC). Financial and legal due diligence by BIRAC is in progress.

Syngene has entered into a partnership with the Foundation for Neglected Disease Research (FNDR) to facilitate SARS-CoV-2 in vitro and in vivo research for clients. The Company's multidisciplinary skills in integrated drug discovery and development and FNDR's capabilities in conducting biosafety level 3 (BSL-3) infectious disease research are being combined in a strategic alliance to provide state-of-the-art support for academia and industry involved in COVID-19 research. A project evaluating the in vitro cytotoxic effects of a peptide based anti-SARS-CoV-2 therapeutic has been completed in collaboration with FNDR.

Syngene has collaborated with Sosei Heptares on a program focused on the design and development of compounds for the treatment of infection from SARS-CoV-2 and related corona viruses. The research has made significant progress and the lead compound, suitable for further optimisation as an oral drug, has been identified.

Neutralising mAbs against SARS-CoV-2 is considered a promising candidate for COVID-19 treatment and prevention. Syngene is partnering with IAVI (International AIDS Vaccine Initiative), a non-profit scientific research organization, to develop mAbs against COVID-19. A large sero-surveillance study in which Syngene will play a major role in assessing antibody and T-cell responses to SARS-CoV2 is also underway with the University of Chicago.

Pursuant to the voluntary license agreement signed with Gilead Sciences Inc. and the subsequent technology transfer for manufacturing and sale of its antiviral drug Remdesivir, the Company has successfully completed the process validation and received Market Authorization Approval (MAA) and Manufacturing License under the brand name RemWin. Syngene commenced the manufacturing of this drug from November 2020.

With the broad range of scientific expertise in relevant disciplines, the Company is also working on research projects related to vaccine development.

Syngene has joined a global consortium of 19 organizations from the healthcare industry, led by Bristol Myers Squibb, to help inform, improve and accelerate various aspects of COVID-19 testing, ranging from research to clinical diagnostic applications.

Review of Enabling Functions

The Quality function maintained its focus on driving service delivery through digital transformation. Multiple initiatives such as the Electronic Quality Management System (EQMS), Electronic Document Management System (EDMS) and Laboratory Information Management System (LIMS) have helped to improve compliance, accountability, traceability and better document management .The Quality Control facility for small molecules is slated to become paperless by July 2021, marking another step forward in the Company's digital transformation journey.

The National GLP Compliance Monitoring Authority (NGCMA), India certified the Safety Assessment laboratory for biocompatibility testing in compliance with GLP regulations. Another key highlight was that the Company's COVID-19 testing centre, which uses RT-PCR technology, received the NABL accreditation. With the testing laboratory being set up in less than six weeks, the certification is a validation of the Company's expertise across various scientific disciplines and adherence to best practices.

The company has been quick to respond to the transformed operating environment in wake of the pandemic The IT infrastructure was upgraded to support real-time virtual audits by clients and regulatory authorities. Several virtual audits by clients were successfully carried out and cleared during the year. An integrated, proactive approach for the organization to be 'anytime audit ready' has also been initiated through the combined efforts of the Quality and Operational Excellence teams. To realize this objective, improvement of standard operating procedures (SOPs), recurring internal audits, and a culture of being always prepared for audit are being emphasised.

Significant progress was made in moving the Company's supply chain processes to digitized forms. This has helped to improve transparency, efficiency and traceability in the procurement life cycle. Automation of repetitive manual work in the procurement process has also helped to improve productivity of the procurement function. Another important highlight was the development of a standardised purchase manual that

will act as the guide on all procurement-related activities. The manual will be reviewed periodically so that the procurement operation stays agile while delivering strategic services like planning, forecasting and improved inventory management.

As the shift towards digitalization accelerates, it has also increased the need to have a secure IT framework to protect digital assets. Adherence to best practices and the use of latest technology enable the Company to build robust IT systems that are fully geared to overcome cyber threats and ensure data and IP protection. Multiple cyber security levels are in force and the Company is securing not just its physical servers but also securing the connectivity to other devices, especially mobile phones. To enhance cyber security further, next-generation security platforms based on Artificial intelligence/machine learning are being integrated to detect activities that could bring to light a security lapse or system compromise.

In line with the Company's commitment to ensure full compliance with National and International data privacy laws and to build a robust and well-established information security mechanism, the Data Privacy Office (DPO) was set up during the year. The DPO is responsible for: implementing risk identification and mitigation strategies; planning for data breach response and remediation; developing training and awareness programs; and implementing best global data privacy practices. Syngene's Data Privacy Policy was also updated for adherence to global data privacy laws like the General Data Protection Regulation (GDPR).

The Company is committed to delivering scientific services to its clients as efficiently as possible. In line with this commitment, several new initiatives were rolled out and existing measures continued to gain traction under the operational excellence program LEAP (Leveraging Excellence to Ascend and Perform). The SQDECC (focus on Safety, Quality, Delivery, Efficiency, Compliance and Cost) concept was extended beyond operating units to include enabling functions. While SQDECC has been facilitating problem identification, an analysis tool known as, 'Why-Why Analysis', was implemented to foster a culture of problem-solving. To strengthen the GEMBA Walk initiative (shop-floor walk by managers to drive operational efficiency), the Gemba Academy was created. The Academy strives to improve Lean Management awareness among managers and supervisors through formalised training and certification modules on the Gemba approach. A Gemba walk mobile app was launched during the year to facilitate real-time recording of detailed interactions and observations in the laboratories and on the shop floor.

Awards and Recognition

During the year, the Company received the following awards:

- Bioprocessing Excellence Award 2020 at the 7th Annual Biologics Manufacturing Asia Conference.
- ASSOCHAM CSR and NGO Awards 2020 for 'Excellence in Leveraging Corporate Key Strengths in Fight against COVID-19'.
- 'Dream Companies to Work for Award' at the 29th Edition of the World HRD Congress Awards
- Awarded at the 4th Annual Asia-Pacific Bioprocessing Excellence Awards 2020, Singapore in the 'South Asia-Viral Clearance and Safety Testing' category.

Human Resources

The year under review created a new set of challenges for leaders and managers supported by the HR professionals. From ensuring the safety of employees to receiving the Great Place to Work (GPTW) certification; and from making sure that learning continued while working from home to driving greater engagement, it was an unusual year from a people management perspective

Within 48 hours of the nationwide lockdown, Work from Home (WFH) was successfully implemented for all employees in non-site-dependent roles. These employees, around 40% of the workforce, were supported with the necessary IT infrastructure to make a seamless transition to WFH. Recognizing the toll the pandemic could have on employee well-being, the Company also took steps to address emotional anxieties and boost morale. This included organising wellness webinars and extending counselling support.

Even after lifting of the lockdown and return to near-normal level business operations, employees who could discharge their roles from home continued to do so. This has delivered the dual benefit of ensuring their safety as well as reducing the onsite density of employees. With the WFH model showing good results in all relevant areas - work productivity, employee safety and work-life balance, the Company is assessing the possibility of making WFH a continuing part of its work culture.

For the safety of onsite employees, multiple protection measures have been adopted, such as the creation of 12 zones in the campus to restrict the number of contacts between people, the introduction of multiple shifts to reduce density in laboratories, modified seating to ensure physical distancing, monitoring and recording of temperature twice daily, and proactive COVID testing of employees.

A major highlight for the year was receiving the Great Place to Work certification. Continuing efforts to strengthen people practices and engagement have resulted in a significant jump in the employee trust index and employee connection with the Company from 2014, the year when Syngene first partnered with the GPTW company to baseline the employee experience.

The Company's business performance is derived from the expertise and calibre of its people. To build on this strength further, innovative learning interventions were rolled out by the Learning & Development team which encompassed self-learning webinars, and instructor-led sessions on leading online platforms. Early identification of a 'Learn from Home' (LFH) employee population (almost 2500 employees) helped in designing and delivering relevant programs, resulting in better learning outcomes.

The Company is committed to developing employees to become strong leaders who can drive organizational growth and change. In line with this, leadership and managerial development initiatives were launched for senior leaders. In addition, the 'Leadership Next' program was rolled out for a second wave of senior leaders. This program includes in-depth leadership assessments for participants which for the basis for individual development planning.

The Syngene Training Academy (STA) facilitates a smooth transition for the new campus hires and equips them with essential skills. To meet changing needs, the onboarding process was revamped with a blended approach of training on soft skills, functional skills and Syngene values. In FY 2020-21, campus hiring more than trebled over the previous year. The increased hiring of freshers ensures a flow of young talent to fuel the project pipeline.

The Company is making conscious efforts to promote diversity in the workplace. During FY 2020-21, 31% of employees onboarded were female employees. SHE (Speak, Hear, Empower) Talks – a focused group discussion for women employees - and the launch of a women's committee in the Biologics Division were among the initiatives undertaken to gain insights as the basis for an enabling workplace, encourage women to take up leadership roles and improving retention.

Other key accomplishments for the year include: the launch of 'Botzie', an AI-based 24x7 human resource and administration assistant; revamping of the recognition program to make it more empowering for managers ensure that the Syngene values of excellence, integrity and professionalism lie at the heart of every award; and reinforcement of the safety culture (Kavach) by training 144 subject matter experts (SMEs) across the organization on facilitation skills, to enable them to deliver training programs on safety, effectively.

By continuing to provide opportunities for personal and professional development, engaging with top performers to chart their growth path in Syngene, and fostering a great work environment, the Company reaffirmed its commitment to being a world-class employer. for FY 2020-21 from the previous year. As of 31st March 2021, the Company had ~ 5400 employees.

Financial Performance

(in Rs Mn)

Particulars	FY 2020-21	FY 2019-20	Change (%)
Total Revenue	22,489	20,935	7%
Expenses			
Cost of chemicals, reagents and consumables consumed	5,265	5,194	1%
Employee benefits expense	6,602	5,804	14%
Foreign exchange fluctuation	(171)	(144)	19%
Other expenses	3,429	3,086	11%
Earnings before interest, tax, depreciation and amortisation (EBITDA)	**7,364**	**6,995**	5%
Depreciation and amortisation expense	2,745	2,193	25%
Finance costs	277	346	-20%
Profit before tax and exceptional item	**4,342**	**4,456**	-3%
Exceptional item	350	713	
Profit before tax	**4,692**	**5,169**	-9%
Tax expense	643	1,048	-39%
Profit for the year	**4,049**	**4,121**	-2%
Other comprehensive income	1,906	(1,916)	
Total comprehensive income for the year	**5,955**	**2,205**	170%
Revenue from operations excluding EBITDA Export Incentives	**21,802**	**19,465**	12%
EBITDA from operations (EBITDA excluding Export Incentives, Other Income, Depreciation, Finance Costs, Exceptional items and Tax Expense)	**6,677**	**5,524**	21%
Profit for the year excluding exceptional gains (net of tax)	**3,821**	**3,662**	4%

Revenue

During FY 2020-21, the Company saw a 7% growth in revenue from Rs 20,935 Mn in FY20 to Rs 22,489 Mn. Revenue from operations, before factoring the export incentives is up 12% from Rs 19,465 Mn in FY 20 to Rs 21,802 Mn against last year. Growth was driven by steady performance across all divisions.

Cost of chemicals, reagents and consumables consumed

The cost of materials consumed in FY 2020-21 increased by 1% to Rs 5,265 Mn, accounting for 23.4% of overall expenses. Material costs as a percent of overall revenue decreased by 140 basis points, driven by the change in revenue mix in favour of Discovery Services and Dedicated Services.

Employee benefits expense

The employee costs for the year increased by 14% to Rs 6,602 Mn. The increase in headcount in our existing and new facilities that went live in the last twelve months has driven 10% increase and the rest of the increase came from amortisation impact from the rollout of the new Restricted Stock Option plan. The total employees in the company increased from over 4,900 as of 31st March, 2020 to over 5,400 as of 31st March, 2021.

Foreign exchange fluctuation

The Company earned an exchange gain of Rs 171 Mn during FY 2020-21 as against an exchange gain of Rs 144 Mn in the previous year. The gain in FY 2020-21 was largely on account of the hedge rates being above the prevailing market rates similar to previous year.

Other expenses

The Company's other expenses comprise power and fuel costs, professional fees, selling expenses such as freight outwards, provision for doubtful debts and other general overheads. The Company recorded Rs 3,429 Mn of other expenses in FY 2020-21 reflecting an increase of 11%. The increase in other expenses were mainly due to new ways of doing business during the COVID-19 times and increase in costs associated with maintaining necessary health and safety protocols and additional costs incurred in the new facilities in Mangalore, Hyderabad and Bangalore. Other expenses as a percentage of revenue increased from 14.7% to 15.2% in FY 2020-21.

Depreciation and amortisation expense

Depreciation and amortisation increased to Rs 2,745 Mn from Rs 2,193 Mn in FY 2019-20. This reflects the additional depreciation on the new investments in the Hyderabad facility, expansion at our main Bangalore facility and commencement of the Mangalore commercial API plant.

Finance costs

The Finance costs decreased by 20% to Rs 277 Mn in FY 2020-21 compared to Rs 346 Mn in FY 2019-20, with the average cost of debt being maintained at 2% p.a. The decrease in finance costs is due to low cost borrowing in form external commercial borrowing and foreign currency term loans. Interest coverage is adequate at 17 times during the FY 2020-21.

Tax expenses

Tax expenses for the year stood at Rs 643 Mn in FY 2020-21 in comparison to Rs 1,048 Mn in FY 2019-20. The decrease in effective tax rate in FY 2020-21 is predominantly due to the incremental depreciation impact in the tax books coming from the new units that have gone live, operating losses in the newly set up commercial API plant at Mangalore and decline in the interest income.

Exceptional gain

Pursuant to a fire incident on 12 December 2016, certain fixed assets, inventory and other contents in one of the buildings were damaged. The Company lodged an estimate of loss with the insurance company and the survey is currently ongoing. The Company has recorded a loss of Rs 1,057 Mn arising from such incident and received disbursement approval of Rs 2,120 Mn from the insurance company till 31st March, 2021. The Company has recorded a gain of Rs 350 Mn and Rs 713 Mn on the basis of disbursement approvals in the consolidated financial statements for the year ended 31st March, 2021 and 31st March, 2020 respectively post the recovery on loss of Rs 1,057 Mn. Consequential tax on the exceptional gain is Rs 122 Mn and Rs 254 Mn is included within tax expense in consolidated financial statements for the year ended 31st March, 2021 and 31st March, 2020 respectively.

Profitability

The Company's EBITDA from operations in FY 2020-21 grew by 21% to Rs 6,677 Mn compared to Rs 5,524 Mn in FY 2019-20. EBITDA from operations as a percent of Revenue from operations excluding export incentives increased by 220 basis points from 28.4% in FY 2019-20 to 30.6% in FY 2020-21 reflecting a strong underlying growth.

The Company's reported Earnings Before Interest, Tax, Depreciation and Amortisation (EBITDA) in FY 2020-21 grew by 5% to Rs 7,364 Mn compared to Rs 6,995 Mn in FY 2019-20.

Profit After Tax before exceptional gain increased by 4% from Rs 3,662 Mn to Rs 3,821 Mn driven by underlying operating performance partially offset by increase in depreciation arising from investments made towards expansion. Profit After Tax before exceptional gain as % of revenue declined by 0.5% as a percent of revenue to 17.0%.

Profit After Tax (PAT) declined by 2% to Rs 4,049 Mn, as against Rs 4,121 Mn in FY 2019-20 mainly due to higher exceptional gain in FY 2019-20. PAT as a percent of revenue declined by 170 basis points to 18.0%.

The Company's diluted earnings per share decreased to Rs 10.11 in FY 2020-21 as against Rs 10.35 in FY 2019-20.

Other Comprehensive Income

Other comprehensive income includes re-measurement gains/ losses on defined benefit plans and gains/losses on hedging instruments designated as cash flow hedges. The decrease is primarily due to lower gains on hedging instruments in FY 2019-20 compared to the previous year.

Analysis of the Consolidated Balance Sheet The following table exhibits the Company's balance sheet as on 31st March,2021 (FY 2020-21) and 31st March,2020 (FY 2019-20):

In Rs Mn

Particulars	FY 2020-21	FY 2019-20	Change (%)
Assets			
Non-current assets			
Tangible, Right-of-use and intangible assets	24,382	22,538	8%
Financial assets	4,448	783	468%
Deferred tax assets (net)	891	1,227	-27%
Income tax assets (net)	867	760	14%
Other non-current assets	177	195	-9%
Total non-current assets	30,765	25,503	21%
Current assets			
Inventories	596	252	137%
Financial assets	16,468	15,058	9%
Other current assets	1003	816	23%
Total current assets	18067	16,126	12%
Total Assets	48,832	41,629	17%
Equity and Liabilities			
Equity			
Equity share capital	4,000	4,000	-
Other Equity	24,214	17,758	36%
Total Equity	28,214	21,758	30%
Non-current liabilities			
Financial Liabilities	6,400	2,190	192%
Provisions	520	409	27%
Other non-current liabilities	2,368	1,880	26%
Total non-current liabilities	9,288	4,479	107%
Liabilities			
Current liabilities			
Financial Liabilities	6,124	10,864	-44%
Provisions	465	415	12%
Income tax liabilities (net)	134	117	15%
Other Current Liabilities	4,607	3,996	15%
Total current liabilities	11,330	15,392	-26%
Total	48,832	41,629	17%

Non-current assets

Non-current assets grew by 21% primarily due to:

- investments in tangible assets primarily in Mangalore facility and newly set up research labs at Hyderabad and Bangalore benefiting Discovery services, Dedicated Centers, Development services and Manufacturing divisions.

- Minimum Alternate Tax (MAT) entitlement credits arising on account of tax holiday benefits enjoyed by the Company and other deferred tax items that reverse in subsequent years.

Working Capital (Current assets, less current liabilities)

Working capital increased to Rs 6,737 Mn in FY 2020-21 from Rs 734 Mn in FY 2019-20. The movement is on account of:

- increase in cash and bank balances arising from improvement in customer collections and cash generated from operating activities,

- repayment of USD 50 Mn External Commercial Borrowing (ECB) loan repayment in March 2021 that was classified under other financial liabilities in FY 2019-20, and

- recovery of Mark-to-Market losses accounted in FY 2019-20 improving the position of derivative assets in FY 2020-21;

Other current liabilities primarily include advance from customers that are expected to be recognised as revenue within the next twelve months through delivery of remaining obligations.

Debtors collection significantly improved in FY 2020-21 to 58 days compared with FY 2019-20 at 76 days.

Equity share capital

The Company's equity share capital comprises 4,000 Mn equity shares of Rs 10 /- each.

Other equity

Other equity mainly comprises the share premium, retained earnings, cash flow hedging reserves and other reserves. The total reserves and surplus of the Company increased by 36% in FY 2020-21 as a result of accumulation of profits earned during the year and movement in items of other comprehensive income.

The Company's average return on net worth as on 31st March, 2021, stood at 20% as compared to 21% as on 31st March, 2020.

Non-current liabilities:

Non-current liabilities mainly include:

- Long-term borrowings are in the form of an External Commercial Borrowing (ECB) facility of USD 50 Mn and Foreign Currency Term Loan (FCTL) facility of USD 20 Mn to fund the capital expenditure at the Bangalore, Hyderabad and Mangalore premises of the Company. The borrowings are repayable at the instalments of 15%, 25% and 60% from the end of 3 years, 4 years and 5 years respectively from the date of origination.

- Deferred revenues relating to assets funded by third parties that are to be amortized over the useful life of the assets/period of contract to Other operating Income.

- The debt: equity ratio of the Company as on 31st March, 2021, improved to 0.27 as compared to 0.31 as on 31st March, 2020.

It may be noted that taking account of investments in inter-corporate deposits with financial institutions, deposits with banks, cash and cash equivalents and investments in overnight mutual funds the Company is net cash positive as of 31 March 2021.

Contingent liabilities:

Contingent liabilities include tax and other proceedings that arise from time to time in the ordinary course of business. Contingent liabilities stood at Rs 4,297 Mn as at 31st March, 2021 in comparison with Rs 4,245 Mn as at 31st March, 2020. Of the above, proceedings under income tax matters comprise Rs 4,273 Mn particularly disputing the Company's claim of tax benefits under 10B and 10AA relating to the financial year 2002-03 to 2016-17 pending before various appellate authorities. Income tax matters include Rs 660 Mn that have been settled in favour of the Company from the Honourable High Court of Karnataka against the matters appealed by the tax authorities with respect to financial year 2002-03 to 2008-09. Other than the matters disclosed above, the Company is involved in taxation matters that arise from time to time in the ordinary course of business. Management is of the view that these will not have any material adverse effect on the Company's financial position or results of operations. Also refer note 31 on Contingent liabilities and commitments in the consolidated financial statements

Risks and Concerns

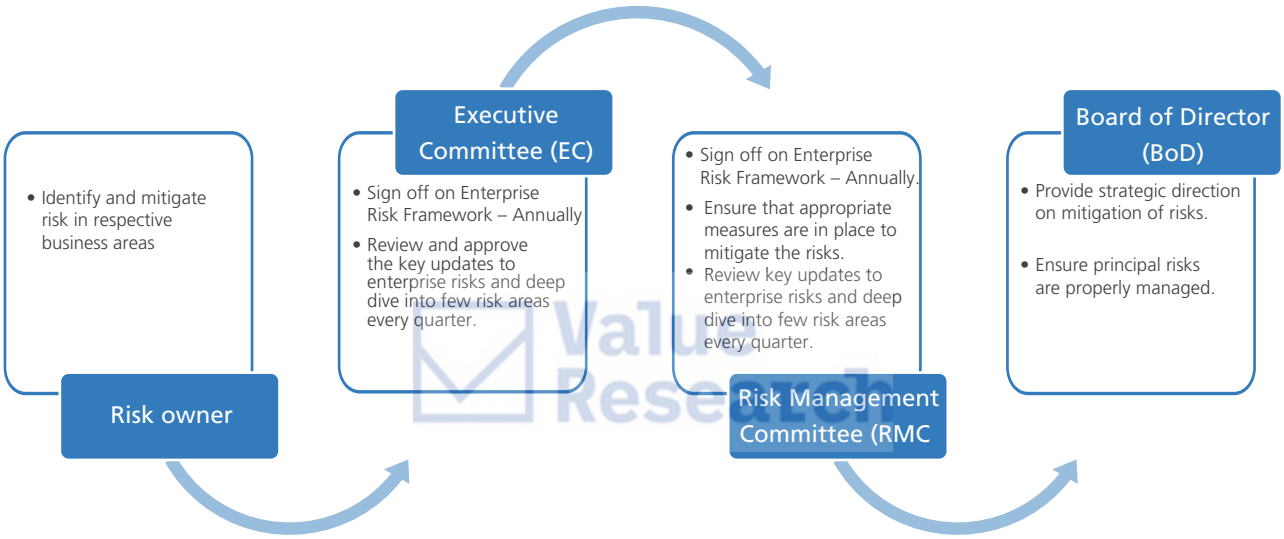
Syngene recognizes that risk is integral to the business. The risk management process is focused on ensuring that risks are identified and addressed through an effective risk management process and that there is a timely process for identifying and dealing with emerging risks. The Company strives to achieve a balance between risk and reward with the aim of ensuring long-term business sustainability, while operating within an approved risk framework. Any emerging risk is immediately

brought to Management's attention and necessary actions are taken The Company has formulated business continuity plans for each of the operating units and enabling functions and is in the process of establishing the recovery strategies defined in the business continuity plans.

Process, roles and responsibilities

Syngene has a risk management framework to identify, monitor, report and manage risk across the business. The risk owners monitor and manage risks relevant to the business. These risks are aggregated and documented in the risk register by the Company risk manager to provide the Board and Executive Committee with a comprehensive overview of the Company's risk profile.

Enterprise risks have been categorized into strategic, financial and other risks and detailed analysis of these risks has been carried out to identify the potential impact on the business and the probability of occurrence. These risks are then addressed with appropriate mitigation measures to either eliminate or reduce the risk. The Company's Executive Risk Committee reviews the risks and the mitigation plans quarterly, and annually signs off on the Enterprise Risk Framework. The Risk Committee undertakes a detailed review of one or two risks every quarter. The risk manager is responsible for supporting business leaders to identify, assess, prioritize and mitigate risks, maintaining the risk registers and ensuring that the reporting process is working effectively.



Risk management process

Risk profiling

Risks	Risk Mitigation strategy
Strategic Risks	
Customer concentration risk leading to rapid / large loss of revenue in the event of the loss of a key customer	Our Risk mitigation strategy consists of • retention of key customers through contract renewals and long term contracts. • increasing customer stickiness by cross-selling additional Syngene services • expanding our customer base by adding new clients and widening the revenue base;
Technology risk arising from failure to keep pace with emerging client technology requirements	Our Risk mitigation strategy consists of • Formation of Syngene wide Scientific Advisory Board to support development and execution of emerging platforms, outside-in view independent of key actions. • Setting up of a Technology Committee that consists of internal members regularly updating the technology trends in the Industry • Ensuring all Syngene employees remain up to speed on new technologies through series of events like quarterly Speaker connect series, Endow a scientific chair at a prestigious institution, Sponsor a Postdoctoral fellowship programme, Exchange visitor program (at a client/ renowned scientist lab)
Commercial manufacturing strategy risk associated with failure of Commercial Manufacturing strategy and execution leading to impairment	Our Risk mitigation strategy consists of • Creating a pathway to obtain regulatory approvals to make the Mangalore SEZ facility attractive for clients who want to get high value molecules manufactured: • Building commercial business pipeline leveraging development stage clients for pursuing commercial manufacturing opportunities at the facility coupled with aggressive pricing strategy. In the interim continue with manufacturing opportunities (non-regulatory) in the generic space.
Potential loss of business opportunities due to failed execution of the Integrated Drug Discovery (IDD) strategy	Our Risk mitigation strategy consists of • Deepening scientific expertise through recruitment of experienced drug discovery leaders responsible for oversight of IDD programs, program governance, client engagement, and coaching/mentoring the IDD team • Enhance sales capability by onboarding experience business development staff • Developing new business / commercialisation models including risk-share and asset development models to augment our current FTE and FFS models to meet the needs of a broader range of customers
Biologics Manufacturing strategy risk associated with inability to make progress in large molecule market leading to potential loss of business opportunities and insufficient Return on Investment	Our Risk mitigation strategy consists of • Delivering robust operating performance through automation, digitization and compliance initiatives to provide world class services. • investing in technology and experience of staff to deliver improved yields, lower COGS, faster cell to clinic timelines, more consistent delivery to time, quality and cost. • Building enhanced sales team capability

Risks	Risk Mitigation strategy
Growth strategy risk due to inability to establish a world class, global sales/ marketing/ commercial operation.	Our Risk mitigation strategy consists of • Establishing a sales team that is experienced and close to customers and highly regarded for customer responsiveness and ability to deliver solutions • Implementing fast, high quality RFI/RFP sales processes • Building positive perception of Syngene brand through brand and communication strategy • Creating effective key account management processes to deliver differentiated customer experience to clients and enable effective cross-selling / upselling and profitability optimization • Regular customer feedback and satisfaction process to gain actionable insights into customer needs earlier and more often
Disruption in operations caused by a) natural calamities especially shortage of water in our locations of operations b) impact of pandemic (both in operations and sales activity)	Our Risk mitigation strategy for (a) consists of (i) 3 campus strategy: Bangalore, Hyderabad and Mangalore to reduce over dependence on one location. (ii) Zero water waste discharge facility: All process, utility and domestic discharges are channelized to the respective collection tanks for further treatment in all Syngene locations by default in design. (iii) Rainwater harvesting approaches are actively deployed in all Syngene locations and is part of the design in all projects. By recycling and rainwater harvesting we reduced freshwater demand by 8% in FY 2019-20 and 21% in FY 2020-21. We targeting to meet 25% of our total water requirement in the next financial year through recycling and water harvesting. (iv) Single-use/disposable technology is already in place and being followed in Biologics Manufacturing facilities (v) Facility expansion where operations are highly water and natural resource dependent in locations that can guarantee supply (vi) Recycling of waste-water where we collect clean utilities from Biologics manufacturing facility to reuse water and reduce fresh water requirement

Risks	Risk Mitigation strategy
	Our Risk mitigation strategy for (b) is as follows: (i) Pandemic Management Strategy is built on the following elements of focus: • As demonstrated from good management of Wave 1: addressing Campus security, Personnel security, Business continuity and Scientific solutions for testing, tracing and treatment • Preparation for the second wave with continued personnel and campus safety protocols, broad and speedy vaccination effort • Provide therapeutic solutions through API manufacturing (ii) Pandemic Management Strategy also addresses the disruption in sales execution through: • Leveraging digital platforms to increase Syngene brand awareness; drive familiarity especially for new customers (prospects) and for services we are not well known for (e.g. Biologics) • Strengthening sales teams by hiring senior and experienced sales staff closer to customers • Tracking of key customer contacts as they move from one company to another; • Science led campaigns; going beyond India advantage for specific problem solving e.g. PROTACS
Infrastructure risk arising due to inadequate infrastructure planning and delayed execution	Our Risk mitigation strategy consists of: • Addressing the infrastructure planning and requirements through Infrastructure Committee with long term planning horizon (5 year on buildings, 10 year on land) where we look to - Integrate building and land demand into operational plans - Create infrastructure Project Management team to ensure timely project delivery - Integrate building demand into Procurement vendor management plan - Create rolling 5 year renovation and/or replacement plan for aging buildings - Explore novel delivery approaches; Build, Operate, Transfer - Create Project Delivery team and Syngene 2.O infrastructure design framework to ensure future infrastructure meets required quality and cost to build requirements
Financial risks	
Tax risk Adverse outcome relating to tax positions (Section 10AA) leading to material financial losses	Our Risk mitigation strategy consists of: • Having an effective appeal / litigation process through good quality documentation to ensure we have justifications for our tax positions • Having high quality legal representation to present our views and facts with conviction before the appellate authorities and court (High Court, Supreme Court) • Continuous monitoring of the situation and respond quickly when there is any development

Risks	Risk Mitigation strategy
Foreign exchange risk due to forex rate fluctuations leading to losses from hedge book and outstanding foreign currency borrowings	Our Risk mitigation strategy consists of: • Having a Forex policy approved by the Audit Committee • Strict adherence to the policy, regular audit to ensure compliance • Review of Forex position in every audit committee
Risk relating to non-compliance to laws due to inadequate governance framework for regulatory compliance management and reporting (domestic & overseas)	Our Risk mitigation strategy consists of: • Identifying all compliance requirements and mapping accountability to ensure compliance • Digital platform to track and record compliance • To ensure continued adherence and real time alignment with laws and regulations, on an ongoing basis • Regular audit for as a part of compliance governance
Contract assurance risk Risk of liabilities, obligations and penalties coming out of failure to manage / mitigate legacy contractual provisions.	Our Risk mitigation strategy consists of: Modernizing, simplifying and standardizing terms across all contracts for onerous provisions and move to market "norm" risk
Business risks	
Data Integrity risk arising by failure to adhere to Standard Operating Procedures / quality requirements leading to data integrity/ confidentiality breaches and regulatory non-compliance, leading to loss of trust and business.	Our Risk mitigation strategy consists of: • Governance mechanism to have a regular confirmation on SOPs being followed in all relevant operations • Reviewing all QMS SOPs vs applicable regulatory guidelines and update as needed. • Reviewing all SOPs to check for compliance to OEM recommendations and industry best practices • To review all SOPs for required language competency and ensure user appropriate.
Project management risk Risk of operational failure to deliver to the desired quality, quantity in a timely manner due to inadequate project management	Our Risk mitigation strategy consists of: • Establish vision and roadmap to become world-class in project management (Syngene way of execution) • Creating a robust and scalable framework for project management across Syngene (SynPro) • Aligning organizational design and upgrade people capabilities to the new framework (PM Academy) • Designing core processes and integrate them into a seamless flow (PM Manual) • Providing appropriate supporting infrastructure to support these world-class (Project Online +)

Risks	Risk Mitigation strategy
People risk arising due to Excess attrition and Potential challenges in sourcing right talent, labour cost inflation	Our Risk mitigation strategy consists of: • Benchmarking total rewards / remuneration to market. Ensure we deliver "fair' pay for each role. • Implementing effective career planning to allow all staff the opportunity for appropriate career advancement • Implementing an effective Learning and Development process to allow all staff the opportunity to enhance their work-related skills to the best of their ability • Implementing an effective Leadership and Management development strategy to equip the company with competent, effective leaders and managers. • Implementing an effective reward and recognition process to ensure all staff have the opportunity to be appropriately recognized for their contribution • Implementing action items identified through Great Place To Work survey for continuous improvement • Reassessing skillset and candidate profile for key roles across the company; can simplification and/or specialisation in role design open roles to need "pools" of candidates • Increasing breadth of recruitment search by adding additional search partners and sourcing from broader range of institutions • Improving recruiting tools and systems • Adopting new technologies to speed up and broaden recruitment search (virtual and AI driven search) • Conduct structural and workload analysis and implementation thereof
Adverse clinical events risk arising out of events resulting in risk to patient safety and consequential financial and reputational consequences	Risk to patient safety and consequent Financial and reputation damage due to adverse clinical events is mitigated using following multi pronged approach. • Identifying risk possibility at protocol/study design stage • Due diligence during volunteer/patient recruitment to ensure protocol compliance • Thorough medical review of adverse clinical events when they occur • Meeting reporting compliances to regulatory authorities/ ethics committee • Providing immediate medical attention to health of patient who suffered such event • Covering financial risk by carrying adequate clinical trial insurance coverage • Monitoring all adverse events to detect possibility of reputational risk.
Environmental/ Health/ Safety regulations compliances risk Risk of non-compliance to Environmental/ Health/ Safety regulations leading to loss of license to operate / reputational damage	Risk mitigation of regulatory non-compliances involves a strategy that involves identification, resolution and escalation: - Implementing Software/tool based approach for tracking compliance to all Environment, health and safety regulations - Working with regulatory authorities to ensure all approvals completed

Risks	Risk Mitigation strategy
Safety risk Risk of safety hazards in operations due to fire and/or due to chemical, biological nature of work performed	Our Risk mitigation strategy consists of: • Infrastructure preventive maintenance and upgradation, audits, alarms and sensors • Improving training and awareness (KAVACH risks reduction programme) • Mindset and behavior improvement • Conduct internal audits and external audits • Continuous upgradation and training through the Emergency Response Team structure • Meet threshold storage limit of flammable chemicals at laboratories across Syngene operations • High risk activity control (Confined space/Hotwork/height work/LOTOTO) through permit to work system
Business Integrity risk Adverse events relating to Business Integrity and Ethics jeopardizing own governance model and putting client relations at risk. a) Failure to comply with regulatory requirements of anti-bribery/complete assessment of vendors before onboarding/complete internal assessment/create awareness on anti-bribery anti-corruption within the organization b) Failure to comply with data privacy requirements /execute data processing agreements with vendors /complete risk assessment of data processing activities/create awareness on data privacy within the organization/prevent and mitigate data breaches	Our Risk mitigation strategy consists of: • Rolling out Anti bribery policy (ABAC) and Code of Conduct for all employees and partners of Syngene • Communicating and creating awareness amongst all employees, especially those in Procurement function, Commercial and all employees dealing with Government departments • Rolling out training module for all employees • ABAC due diligence of all vendors/partners and ensure all vendors and partners sign of Code of Conduct to stay as partners of Syngene • ABAC audit and assessment to ensure compliance • Rolling out Data Privacy policy • Communicating and enforcing the policy across all areas of Syngene • Training and awareness program, formal consent before storing and using of personal data • Risk Assessment to be rolled out for regular assessment of risk areas
Cyber security risk Potential loss of data leading to reputational damage caused by adverse cyber security event	Our Risk mitigation strategy consists of: • Capability building to handle cyber security threats • Pro-active situation management • Stress testing through ethical hacking exercises and taking corrective actions to fix vulnerabilities

Management Outlook

The fundamentals of Global Biopharma industry remain strong. There is good momentum of new chemical entity and new biological entity approvals by regulators underpinned by a strong pipeline of drugs under early stage discovery and development. The continuing drive to reduce the cost of drug discovery and increase productivity is expected to increase outsourcing further, with significant interest in the integrated drug discovery and development model. On the manufacturing side, growing demand for biologics, the capital-intensive nature of the business, and the complexity involved in pharmaceutical manufacturing is further driving demand for outsourcing. We believe Syngene is well positioned to capture many of these market opportunities.

The Company has extended and expanded the Dedicated R&D Centres through the collaboration with BMS where we expect to increase R&D scientists. The Company has laid a strong foundation by expanding our laboratory footprint beyond Bangalore with the ongoing capacity additions in Hyderabad. The Phase 3 of our expansion in Hyderabad will allow us to build additional capacity for another 300 scientists.

In Biologics manufacturing the Company has added capacity to under mammalian capabilities with additional two 2000 L reactors. The construction of another 500 Litre microbial facility has been completed which gets added as a new technology platform to our suite of offerings. This will help the Company cater to the production of a wide variety of biologics drugs ranging from anti-cancer to hormonal disorder therapies and many others. The Company is also planning to invest in a viral vector manufacturing facility and is being supported by BIRAC i.e. the Biotechnology Industry Research Assistance Council in the process. BIRAC has provided a grant to the Company to part fund this project to support the Company's endeavor to be at the cutting edge of cell and gene therapy manufacturing and provide India with landmark scientific capabilities. The plant is expected to be ready for operations in 2 years.

The API manufacturing facility in Mangalore is now a GMP1 certified facility and the Company is working on a multi-pronged approach to obtain regulatory approvals for the plant while adding clients and projects to monetize the asset.

The Company is in the process of strengthening the on-ground sales presence in certain key markets like the US and UK. The Company believes this will lay a foundation for being closer to our clients, driving stronger client relationships and helping us gain market share.

The Company sees growing opportunities in the areas of animal health; virology and vaccine-related services; and cell and gene therapy. Investments are being made to capture these prospects by building relevant capabilities. Syngene is already a leading research provider in animal health. The development of new services that reflect evolving client needs will be a key area to further consolidate the Company's position in this domain. In the context of virology and vaccine-related services, the impetus will be on providing a wide array of solutions that cater to the demands of biotech firms. Finally, with cell and gene therapies being important new modalities in drug development, the Company remains focused on scaling-up its services and entering into strategic partnerships to build its expertise.

Subject to the fact that the Covid-19 pandemic does not cause any further business disruption either through a lockdown, supply chain challenges or through large employee absence from the workplace, the Company sees growth opportunities in the ensuing financial period.

Internal Controls

A robust internal control mechanism is a prerequisite to ensure that an organization functions ethically, complies with all legal and regulatory requirements and observes the generally accepted principles of good corporate governance. It is an extension of the overall corporate risk management framework as well as is an integral part of the accounting and financial reporting process.

Syngene's internal control systems are commensurate with the nature of its business and the size and complexity of its operations. The control mechanism provides for well documented policies/guidelines, authorisations and approval procedures to ensure the orderly and efficient conduct of its business. This includes adherence to Company's policies, safeguarding of its assets, the prevention and detection of frauds and errors, ensuring the accuracy and completeness of the accounting records and the timely preparation and presentation of reliable financial information. The Company believes that its experienced and qualified employees play a key role in fostering an environment in which controls, assurance, accountability and ethical behaviour are accorded high importance.

The Company has engaged Ernst & Young LLP to carry out internal audit of its activities on a periodic basis. The internal auditors also provide an objective view and reassurance of the internal controls as well as simultaneously auditing transactions. They report directly to the Audit Committee of the Board, which ensures process independence. The Audit Committee, comprising of Independent Directors, reviews the adequacy and efficacy of the internal controls, as well as the effectiveness of the risk management process across the Company.

Cautionary Statement

The Management of Syngene has prepared and is responsible for the financial statements that appear in this report. These statements conform to the accounting principles generally accepted in India and include amounts based on informed judgments and estimates. Syngene's projections, estimates and expectations described in this report should be interpreted as 'forward-looking statements' that can be impacted by various internal and external risks. Risks associated with market, strategy, technology, operations and stakeholders can significantly impact the business and the actual results may differ substantially or materially from those expressed or implied.