Management Discussion and Analysis

Anticipating a Global Reboot of the Economy

As per the International Monetary Fund (IMF), the global economy is estimated to grow by 5.5% in 2021 and 4.2% in 2022. The projection comes on the back of vaccine approvals, which is expected to spur the economy later this year. However, the effectiveness of policy support and access to medical interventions will determine the extent of recovery in different countries.

This year's estimated growth follows a severe economic collapse in 2020 that has adversely impacted people globally. Based on the World Economic Outlook Update[1], the global growth contraction for 2020, estimated at -3.5%, was 0.9 percentage point higher than the growth estimated in the previous forecast, driven by a stronger than expected reboot in the second half of 2020.

We believe strong multilateral cooperation will form the basis of bringing the pandemic under control everywhere. Increasing funding for equitable access to COVID-19 vaccines for all countries, ensuring global distribution, and facilitating the therapeutics at affordable rates are essential measures to rein in COVID-19. Several countries, mainly the low-income developing economies, set foot into the crisis with a huge debt, which is expected to rise even further due to the pandemic. Therefore, there is a need for the global community to work collaboratively and ensure adequate access to international liquidity to help these countries.

The Pharmaceutical Market Amid COVID-19

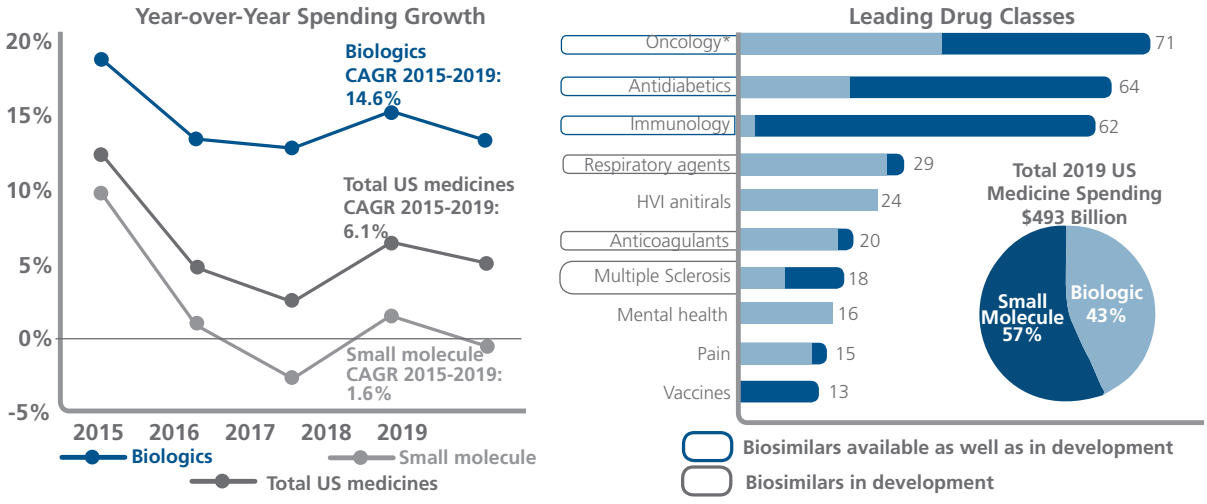
As per IQVIA[2], the global medicine net market size is estimated to reach more than $1 trillion by 2024, growing at a 5-year CAGR of 2-5%. The healthcare sector is projected to account for the highest R&D spend in a few years. In the past, the surge in healthcare spending was driven by treatment for chronic diseases and untreatable disorders. However, the emergence of COVID-19 temporarily redirected the R&D spending and shifted focus towards controlling the virus's spread. In the long term, the market will reward organizations that reinvent their R&D functions and adapt to changes in consumer preference.

The announcements on several promising COVID-19 vaccines were a much-needed shot of optimism after a period beset with challenges. Although there have been challenges in the distribution of these vaccines, that doesn't lessen the accomplishment. To manage the crisis, governments worldwide have formulated emergency response strategies, and many of these measures are likely to be continued even after the pandemic subsides. One of these measures is an increased focus on boosting national competitiveness and localized manufacturing, as COVID-19 has reinforced the significance of these policies to business continuity and economic sustainability. The governments are favouring domestic production in strategic sectors like pharmaceuticals, healthcare, and medical equipment. The Supply Chain Resilience Initiative (SCRI), announced by Australia, Japan, and India, will be implemented in phases in 2021. The SCRI will also accelerate the development of COVID-19 vaccines and is a broader attempt to reduce supply chain dependence on China in the pharmaceutical sector. The Government of India has also announced several schemes to strengthen the pharmaceutical sector and incentivize global and domestic players to enhance investment and production capacities in Active Pharmaceutical Ingredients/Key Starting Materials, biopharmaceuticals, complex generic drugs, patented drugs or drugs nearing patent expiry, cell-based or gene therapy drugs. These initiatives are also intended to ensure higher resilience of the Indian industry to external events and contribute meaningfully to achieve affordable healthcare.

Further, pharmaceutical drug spending remains an important element of the total healthcare cost. From a molecule perspective, biologics continue to drive a significant portion of the overall spending in leading global markets. In the US, biologics spending has increased considerably between 2015 and 2019, growing at a CAGR of 14.6%, outpacing small molecules that have been growing at a CAGR of 1.6% during the same period, as per IQVIA.

1 https://www.imf.org/en/Publications/WEO/Issues/2021/01/26/2021-world-economic-outlook-update
2 Global Medicine Spending and Usage Trends: Outlook to 2024 by IQVIA | March 2020

Exhibit 1 Total U.S. Invoice Spending Growth by type and Leading therapy Areas by 2019 Spending, US$Bn,



Source: IQVIA MIDAS; IQVIA Institute, June 2020'

More importantly, biosimilars and their originator products accounted for $40 billion in spending in 2019. This expenditure was across several key therapy areas where further biosimilar entry would significantly impact healthcare costs. Biosimilars have the potential for substantial system savings. Therefore, biosimilars spending is expected to reach $16-36 billion by 2024. The recent upsurge in approval and launches of biosimilars, mainly in oncology, has boosted biosimilar penetration. Moreover, regulatory bodies like the US FDA are supporting innovation and competition in biologics and biosimilar development, with an intent to raise awareness and acceptance for biosimilars.

Besides, small molecules continue to play a significant role in innovative treatments in oncology, diabetes, respiratory and autoimmune diseases and represent close to 60% of the total medicine spending compared to biologics. Even as this landscape is evolving in terms of drug complexity, manufacturing trends, and molecule potency, more than 80% of all the drugs prescribed in the US are generic drugs due to the cost benefits they offer, compared to their brand equivalents.

These changes are expected to establish a healthier competitive market in the coming years, with originator manufacturers also pursuing competitive measures.

The COVID-19 pandemic has been a thought-provoking revelation on the importance of health research and science. 2020 was not just a year full of challenges and tragedies but also acted as a catalyst for positive change, prompting the need for improved healthcare delivery using virtual engagements, digitized clinical trials, and new, disruptive business models, coupled with radical or innovative collaborations. The effects of these positive changes will be witnessed globally in the world of healthcare for years to come.

Trends Impacting the Global Pharmaceutical Sector

COVID-19 has impacted health and disease patterns and brought changes to several aspects of the pharmaceutical industry. Some of the emerging trends are highlighted below:

1. Demand for digital transformation
2. Advancements in technology and increasing R&D spends
3. Need for a new understanding of diseases
4. Affordable pricing and improved market access
5. Building a cohesive regulatory framework

Demand for Digital Transformation

Since the onset of artificial intelligence (AI) and the data science revolution a few years ago, healthcare has consistently lagged in adoption, compared to other sectors, in leveraging these technologies.

Noticeable trends that underscore the need for digital healthcare are evident, with COVID-19 further proving that health consultations can be

executed effectively through telehealth.

Readiness to adopt telehealth: Many health visits can be potentially replaced with telehealth, which saw a significant spurt amidst COVID-19. As per McKinsey, consumers using telehealth increased from 11% in 2019 to 76% of the consumers interested in adopting telehealth last year. Telehealth will create stability for patients in the short and long term and increase preparedness for future health crises. However, this evolution will require a supportive policy framework that includes investment in interoperable data infrastructure and coherent legislation, including data protection and well-regulated networks.

Low and middle-income countries benefit the most: Advancements in digital healthcare hold tremendous potential to bring much-needed medical innovation and care to low and middle-income countries and underserved patients. Moreover, these countries have been outpacing the rest of the world in embracing and scaling digital care models.

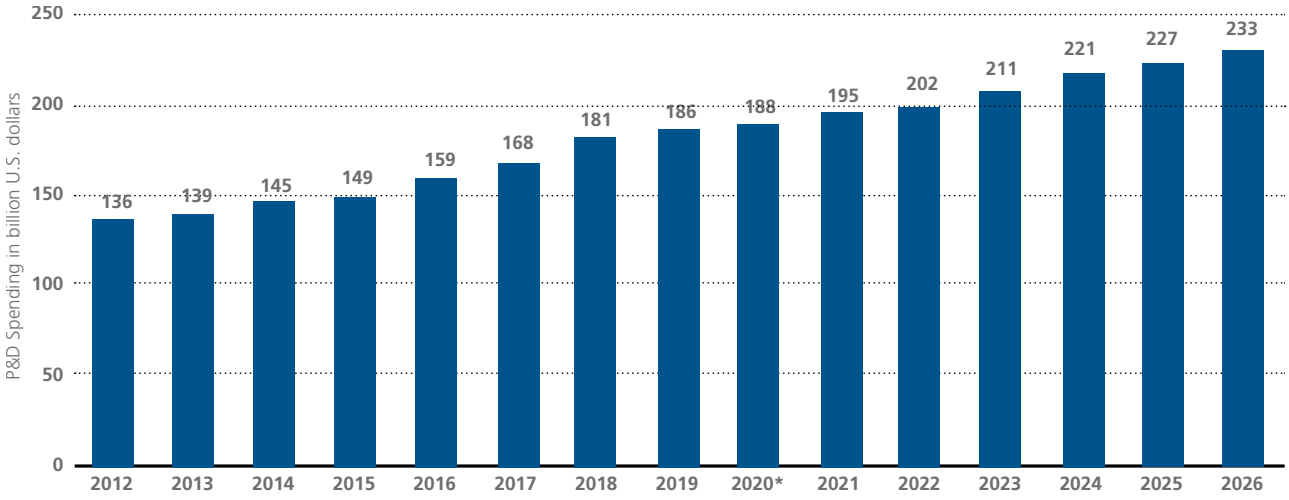
For example, Brazil came up with one of the first integrated countrywide AI platforms that can predict dengue outbreaks, with 80% accuracy and 30 days ahead of time. The platform even goes to the extent of recommending where and how much larvicide, insecticide, and human resources should be deployed to contain the outbreak. The platform has been used in the Philippines, Brazil, and Malaysia to help aid COVID-19 tracing and case detection. The prospects to reimagine global health with digital solutions are endless.

Besides telehealth, many pharma companies are now recognizing the potential benefits of cloud computing that enable cost savings and higher efficiencies and drive competitive advantages without compromising security and compliance. Implementation of cloud computing can improve data quality to support the sales and marketing of drugs. It can further provide new ways for clinical trial site managers to communicate effectively across countries.

Advancements in Technology and Increasing R&D expenses

New medicines offer an improved quality of life for patients, with fewer side effects, increased productivity, and, most importantly, extended lives. However, developing therapies is a complex and lengthy process. Companies often focus their R&D on areas where science is complex and risks of failure are high. Therefore, even though the rapid pace of scientific advances enables a better understanding of diseases at the molecular level, the scientific, technical, and regulatory challenges that come with it create complexities, making drug development difficult and more time-consuming. Clinical trials take six to seven years; hence, a new medicine takes at least ten years on average to complete the journey from discovery to the marketplace. Compared to other industries, pharmaceutical companies have a bigger drive to manufacture innovative products and invest substantially in R&D. This is because of the time-limited patent protection of drugs, coupled with the threat of sales erosion through generic and biosimilar competition. Moreover, patent expirations in the pharma industry give way to high R&D requirements and specialty drug development to diversify the product portfolio. In 2019, the global pharmaceutical industry spent $186 billion on R&D. It is expected to reach $233 billion by 2026.

Table 2: Global Pharmaceutical R&D spending, in US$ billion



Source: Evaluate Pharma - World Preview 2020

For the past several years, the R&D landscape has witnessed significant developments. To reduce R&D costs, many drug manufacturers have started outsourcing parts of R&D, primarily to Contract Research Organizations (CROs). Another significant development has been the use of big data in clinical research. Therefore, clinical and molecular data can build a predictive model to develop safer and more efficient drugs. Real-time or real-world evidence (RWE) attracts greater interest, increasing the need for collaboration with technology companies to gather

data from various sources, even social media.

Need for a new understanding of diseases

The pandemic has prompted the emerging understanding of health and diseases as indicators of complex clinical and non-clinical factors across biology, genetics, age, gender, and economic, social, and environmental dimensions. It has further helped uncover problems related to multi-disease, co-morbidities, and interconnections between conditions. There has been an urgency of moving 'upstream' to explore prodromal diseases to enable early diagnosis and interception of disease. Hence, this emerging understanding of the complexities of diseases is expected to challenge the siloed structure of healthcare provider systems and traditional distinctions of medical specialties.

Affordable Pricing and Improved Market Access

In response to the rising healthcare costs, payers have started demanding information on a drug's efficacy and safety. They also look for the economic justification for a given drug, compared with alternative medications, biosimilars, and generics. Earlier, market access for a drug depended exclusively on safety and efficacy. While these factors are still important, cost-effectiveness – built on clinical differentiation – has become critical and gaining importance. As more drugs lose patent protection and generic alternatives prosper, pharma companies will have to absorb the double blow of lost revenue and greater scrutiny from payers, who will have even more choices.

Acknowledging these concerns, companies have launched efforts to collect more data on the payers' decision-making processes. However, given the scope of market access challenges faced by pharmaceutical companies today, these efforts are expected to have incremental benefits only. To overcome this, organizations need to make market access an essential part of their organization. The economic value attained from the product should be pivotal during drug development and commercialization activities. Pharma companies may have to reallocate resources on a massive scale to implement this.

Building a Cohesive Regulatory Framework

Regulators worldwide have been working together to build a cohesive framework that increases the likelihood of a product getting rejected in one region, being banned in others. To boost transparency and public trust, the regulators have become more proactive as patients become more demanding. This has brought the pharma sector under extreme scrutiny. The way the sector conducts trials, the partnerships with providers and payers, contracting strategies, pricing agreements, digital marketing, and how it handles patient safety will attract more attention in the coming years.

Therefore, every Company is expected to make sure it works ethically and establish itself as an organization with which others would like to collaborate. This means being open and transparent instead of treating compliance as a cost of doing business.

Biocon's Strategy for Sustainable Growth in the Evolving Pharmaceutical Landscape

At Biocon, our strategy revolves around four pillars: accessibility, affordability, availability, and assurance. We aim to use our expertise and scale to address the underserved or the unserved markets by enhancing access to essential drugs. With an increased focus on generics and biosimilars, we continuously innovate to offer affordable medicines and quality alternatives to expensive drugs to patients globally. Our continuous focus on building strategic partnerships and simultaneously creating a diverse portfolio of drugs help us increase medicine availability to a great extent. Furthermore, we exhibit the highest standards of ethics and are committed to providing high-quality products in compliance with international regulatory standards. As a global innovation-led company, our strength lies in our technical & scientific expertise, vertical integration, a skilled team, quality culture, and a vast network of global partners and customers.

Biocon has four distinct business segments:

a. **Generics**

b. **Novel biologics**

c. **Biosimilars** (Under Biocon Biologics Limited)

d. **Research services** (Under Syngene International Limited)

Business Review

Generics

The Generics business has been a key pillar of success for Biocon. Over the past couple of years, we have sharpened our focus on the generics segment and identified strategic priorities, which will enable us to realize significant growth opportunities globally. Our strategy is to continue building a differentiated Active Pharmaceutical Ingredients (APIs) portfolio and vertically integrate it where possible to manufacture and supply generic formulations for the global markets. We also continue to explore asset acquisition, external development, and select in-licensing opportunities to bolster our formulation portfolio.

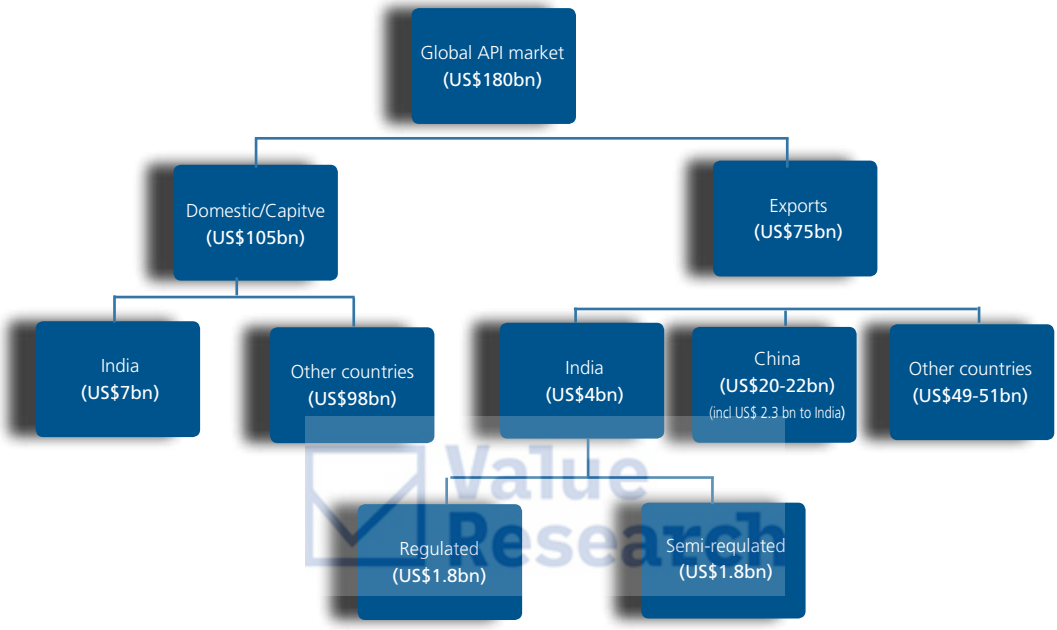
Over the past decade, we have established ourselves as a reliable manufacturer and supplier of APIs derived from fermentation and synthetic chemistry. We will continue to build upon our expertise in these technologies. We initiated our formulations journey with the US markets a few years ago, leveraging our in-house APIs to ensure continuity of supply and price competitiveness. Today, we have four commercial products in

the US, broadly tracking mid to high teens market share

While we expand our API portfolio in differentiated areas such as peptides and high potent APIs, we are confident of replicating the success of our APIs with our formulations, driven by the quality, reliability, and affordability of our products.

Active Pharmaceutical Ingredients (API)

Table 3: Breakdown of the Global API market across key segments/regions



Note: excludes KSMs/intermediates
Source: KPMG CII API industry report, DGCIS, Macquarie Reserach, October 2020

The Indian pharmaceutical industry has advanced steadily and evolved into a preferred destination for high-value and complex APIs for drug manufacturers worldwide. India, however, lags behind China in scale considerably. As per industry estimates, China's API exports stood at $20-22 billion in 2019, compared to ~$4 billion for India. The Indian API manufacturers are gearing to leverage the growing market opportunity, which will be driven by steps taken by the government to achieve self-sufficiency for APIs, promote domestic manufacturing, and India's competitive advantage to offer scientific skills and quality products.

Biocon is amongst the global leaders in fermentation-derived and chemical synthesis-based, high-value APIs. Our success in the global markets largely driven by our API portfolio selection, which aligns with our scientific skills and manufacturing capabilities. We have successfully built a good track record with leading regulatory agencies worldwide, including the US FDA, EMA, and MHRA. We owe our reputation as a trusted global supplier for APIs to our global footprint and good compliance record at our manufacturing facilities. Our differentiated product portfolio includes focussed therapies such as Cardiology, Anti-diabetics, Immunosuppressants, Multiple Sclerosis, and Oncology. We cater to over 1,000 pharmaceutical companies in 100+ countries, including the US, Europe, and other developing countries.

While we have created manufacturing capacities to deliver scale, speed, and quality for our commercial APIs, the ongoing investments will help us build additional capacity, cement our global positioning as a reliable partner for high-quality products, and secure potential growth opportunities in the future. An enhanced presence in adjacencies is a critical growth driver for us, as we witness increased demand from existing customers and expand the customer base. We have also stepped up our efforts to develop new fermentation-derived and chemical synthesis-based molecules, coupled with a focus on peptides and high potent APIs

Table 4: Our API Portfolio

Cardiology	Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, Fluvastatin, Dabigatran, Apixaban and Rivaroxaban
Anti-Diabetics	Sitagliptin, Vildagliptin, Linagliptin, Dapagliflozin, Empagliflozin, and Repaglinide
Peptides	Liraglutide and Semaglutide
Immunosuppressants	Tacrolimus, Sirolimus, Everolimus, Pimecrolimus and Mycophenolate Mofetil and Mycophenolate Sodium
Multiple Sclerosis	Glatiramer Acetate, Fingolimod and Teriflunomide
Oncology	Dasatinib, Lenalidomide, and Pazopanib
Other Key Products	Orlistat, Mirabegron, Posaconazole, Micafungin, Anidulafungin and Brinzolamide

Generic Formulations

As per industry estimates, the global generics drug market is expected to reach $675.2 billion by 2030, with the US market accounting for the lion's share of the spending. The US generic-drug market is expected to grow at a CAGR of 4% and generate revenues worth $86 billion by 2022, as per IQVIA.

Despite intense competition and pricing challenges, the generic formulations business offers attractive growth opportunities, with several products nearing patent expiry in 2023. Expansion of the market will be further driven by an increased generics penetration due to pressure in government healthcare spending, an ageing population, and expanded patient access.

At Biocon, we are committed to providing a continuous supply of affordable, high-quality medicines to patients across geographies by developing a pipeline of differentiated generic finished dosages. The strength of our generic formulations business lies in our portfolio selection -formulations, or even the constituent APIs, which are complex to develop. This is further augmented through our supply reliability due to the vertical integration and compliance on quality. On the commercial front, we are expanding our global footprint through select direct-to-market entry strategies as well as strategic B2B partnerships.

As we scale our business further, we are making investments to enhance our R&D capabilities and bolster our portfolio to include niche, difficult-to-make, complex molecules with relatively higher entry barriers.

Table 5: Our Generic Formulations Portfolio

Molecule	Status
Rosuvastatin Calcium	Launched – United States & EU
Simvastatin	Launched – United States
Atorvastatin	Launched – United States
Tacrolimus	Launched- United States
Everolimus	Approved (United States)
Fingolimod	Approved (United States)
Pemetrexed	Tentative Approval (United States)
Dapagliflozin	Tentative Approval (United States)

Currently, APIs make up for a significant portion of the Generics business. However, growing opportunities in formulations will drive this segment's growth.

FY21 Highlights

Steady growth in US formulations business: Despite intense competition and a challenging pricing environment, we demonstrated significant growth for our formulations business in the US. Our key statin formulations have successfully retained their mid to high teens market share. We also achieved another key milestone in our formulation journey, with the launch of Tacrolimus capsules, a vertically integrated drug, in the US. Tacrolimus is an immunosuppressant and a life-saving drug used to prevent organ rejection in a transplant patient, to be used for chronic conditions. We also received US FDA approval for Everolimus (gAfinitor), a kinase inhibitor drug indicated to treat various forms of cancer such as advanced hormone receptor and Breast Cancer (Advanced HR+BC), primitive neuroectodermal tumor (PNET), Renal cell carcinoma (RCC), and tuberous sclerosis complex (TSC). Everolimus is another example of our vertically integrated portfolio strategy.

Expansion of Generic Formulations business to new geographies: Biocon received licenses from the MHRA, UK, to import and distribute products. This will enable Biocon to commercialize its formulations directly in the UK. Biocon has multiple DCPs (Decentralized Procedure) ongoing in Europe to build its portfolio and support its European expansion. These developments align with Biocon's regional expansion strategy of direct-to-market initiatives and licensing / distribution deals in identified markets outside the US. Our subsidiary, Biocon Pharma and DKSH – a leading market expansion services provider – signed an agreement wherein DKSH will sell and distribute seven of Biocon's generic formulations in Singapore and Thailand. DKSH will also manage the logistics and help drive sales growth with its capabilities and strengths in

the pharmacy and medical channels. Biocon Pharma also partnered with Libbs Farmaceutica, a leading pharmaceuticals company in Brazil, to launch generic drugs in the world's sixth most populous country.

DMF Approvals Received for APIs: Biocon received its first anti-diabetic Drug Master File (DMF) approval in China with Sitagliptin API, used in medicines that treat Type 2 diabetes. We also entered new geographies, received 14 DMF approvals, and filed 33 DMFs for APIs in the US, Europe, and MoW markets.

Continued capacity expansion: Last year, we began constructing a greenfield, fermentation-based manufacturing facility in Visakhapatnam, Andhra Pradesh, to accelerate the growth of fermentation-derived APIs. This facility will allow us to meet the increasing needs of our global API customers and deliver on our strategy of developing and commercializing vertically integrated generic formulations. Due to delays on account of COVID-19, the construction of this facility has been impacted and is expected to be commissioned by CY2022. Additionally, various other expansion projects and contract manufacturing arrangements have been identified for APIs that need higher capacities in the future.

Moving towards Digitization: Biocon embraced digitization to reduce human interventions and strengthen our quality and compliance across the organization. To achieve this, we implemented various digital tools such as Quality Management System (QMS) Software, Laboratory Information Management Systems (LIMS), and Electronic Learning Management systems. Further, dedicated training programs were rolled out to augment a quality excellence mindset.

Further progress to the de-risk supply chain: We made progress in de-risking and stabilizing the supply chain for our key products. Steps have been taken to reduce our single-source dependency on specific geographies and the consequent procurement risks.

Continued Compliance: Our Generics API manufacturing facility at Biocon Park, Bengaluru, received an Establishment Inspection Report (EIR) with a Voluntary Action Indicated (VAI) status from the US FDA in May 2020 for the pre-approval and GMP inspection conducted in January 2020. We also received a GMP compliance certificate from the MHRA, UK, for our manufacturing facility at Biocon Park in March 2021. Biocon UK Ltd received the Manufacturing Import Authorization (MIA) and Warehouse Distribution Authorization (WDA) certifications from UK MHRA. This certification now allows us to sell our products in UK territory.

FY21 Financial Performance

Generics is the second biggest segment for our Company, contributing 33% to consolidated revenues in FY21. Our revenues stood at ₹ 23,359 million in FY21 compared to ₹ 22,070 million in FY20, reflecting a growth of 6%. The generics segment reported a modest performance against the backdrop of COVID-19 related challenges, increasing competition, and pricing pressure in some of our commercialized formulation products.

In APIs, the demand for immunosuppressants remained strong, while we faced a challenging pricing environment in key established cardiovascular products due to increased competition. With the completion of our ongoing capacity expansion projects, we shall see a ramp-up in the immunosuppressant APIs, along with the novel API portfolio.

Our formulations business saw a pricing pressure on some of the key statin products in the US. We have undertaken several initiatives to drive efficiencies, including cost improvement, to strengthen our position in price-sensitive products and segments. These initiatives will lead to improved cost structures and enable us to price our products competitively, without compromising margins. The formulation revenues were also impacted by the absence of new product launches caused by delays in facility inspections due to COVID-led travel restrictions.

In summary, the generics business remains in the investment phase as we continue to deploy capital to create capacity and introduce new products through our R&D efforts. We expect this segment to demonstrate modest growth over the next couple of years. In the future, our growth will be determined by new product approvals, foray into new geographies, relentless focus on cost competitiveness, operational excellence, and seamless execution of our existing business.

Novel Biologics

The Novel Biologics business of Biocon is a combination of in-house, partnered, and in-licensed products, targeting therapeutic areas such as diabetes, immunology inflammation, and oncology, including immuno-oncology.

The global advancement of our programs will be driven by our inherent capabilities and external collaborations to fund more extensive studies required to bring these novel molecules to market and realize their true potential.

Our basket of novel assets under development represents an exciting combination of early and advanced stage programs, comprising therapeutics to treat diabetes, oncology, and autoimmune/inflammatory diseases. These therapeutics span multiple modalities, including recombinant proteins, novel fusion antibodies, and monoclonal antibodies (mAbs). We continue to pioneer the development of novel molecules, a summary of which is given in the table below:

Table 6: Lead Novel R&D Assets

Disease Area	Asset	Status
Diabetes	Insulin Tregopil- first in-class oral, prandial Insulin	Phase I multiple ascending dose studies in Type 1 DM patients making steady progress in Germany
Immuno-Oncology	BCA101- (formerly FmAb2, a tumor-targeted fusion mAb). This program is part of Bicara	Phase 1/2 clinical trial initiated in July 2020. Based on the current progress, transitioning to dose expansion studies anticipated in the second half of 2021
Inflammation	Itolizumab - A novel humanized CD6 antibody	The US, Canada, Australia, and New Zealand rights out-licensed to the US-based Equillium Inc. Itolizumab holds the potential for multiple high-value indications. Equillium is a clinical-stage biotechnology company developing itolizumab for multiple severe immuno-inflammatory diseases, including acute graft-versus-host-disease (aGVHD), lupus and lupus nephritis and uncontrolled asthma. We are awaiting clinical data from all the studies in CY 2021.

In diabetes, Insulin Tregopil is a first-in-class oral prandial insulin molecule for post-prandial glycemic control. A clinical study report (CSR) on the phase 2 component of a study in India, evaluating higher doses (up to 45 mg TID) of Insulin Tregopil, was submitted to the DCGI and the FDA, as per regulatory requirements. While our Type 2 DM study data is encouraging for safety and Postprandial Blood Glucose (PPG) control, the marketing authorization application has been deferred because of the COVID-19 pandemic. Additionally, we commenced multiple ascending doses (MAD) study for Type 1 DM in Germany in FY20. This trial is in partnership with the US-based Juvenile Diabetes Research Foundation (JDRF), a leading non-profit organization funding research on Type 1 diabetes. The T1DM trial is progressing well. The Part 1 component of this trial is expected to be completed in FY22.

Our Second program, Itolizumab, has seen multiple developments in FY21. Under the brand ALZUMAb™, Itolizumab was launched in India to treat chronic plaque psoriasis in 2013. In 2020, Itolizumab was repurposed for the prevention and treatment of COVID-19 complications. Biocon was granted Restricted Emergency Use approval for Itolizumab in July 2020 for the treatment of Cytokine Release Syndrome (CRS) in moderate to Severe Acute Respiratory Distress Syndrome (ARDS) patients in India. Following this, Biocon stepped up its efforts to provide Itolizumab to COVID-19 patients in India.

Additional data is being collected as part of Phase 4 (post-marketing study) and Real-World Evidence (RWE) from COVID-19 patients. Itolizumab's unique mechanism of immunomodulation involves binding to the CD6 receptor and blocking T lymphocytes activation. This, in turn, suppresses pro-inflammatory cytokines, thus reducing inflammation. We trust our unique mechanism of action that could help prevent and treat CRS, a leading cause of death in COVID-19 patients. We have seven years of post-marketing safety data on this product for psoriasis treatment.

Bicara Therapeutics: Biocon's immuno-oncology program focused on developing novel bifunctional fusion antibodies is housed in Bicara Therapeutics (Bicara), based in Boston, US. Bicara is a clinical-stage biotechnology company, which develops dual-action biologics designed to spur a durable and potent immune response in the tumor microenvironment.

Bicara's bifunctional approach combines the power of immunomodulators and the precision of tumor-targeted antibodies. BCA101, Bicara's lead program, a first-in-class EGFR / TGFß-trap bifunctional antibody, entered a Phase 1/2 study at leading US and Canadian cancer centers in July 2020. BCA101 is under evaluation, both in combination with the checkpoint inhibitor Pembrolizumab and as a single agent, in patients with advanced EGFR-driven solid tumors who have stopped responding to the standard of care. Based on the current progress, the Company anticipates transitioning to dose expansion studies in the second half of 2021.

During the year, Biocon ceded control over the Board of Directors and operations of Bicara. Consequently, Bicara has now been classified as an Associate, from a Subsidiary, under IND-AS, and gain of ₹1,597 million arising on the fair valuation of Bicara due to loss of control is reported under "Other income" for the year. So far, Biocon has invested $40 million in Bicara to fund its growth programs. On a go-forward basis, Biocon does not have financial obligations towards Bicara, and all the future funding will be raised directly through a combination of various funding rounds.

Biosimilars (Biocon Biologics Limited)

Biocon operates its biosimilar business through a subsidiary, Biocon Biologics Limited (Biocon Biologics). It is engaged in developing high-quality, affordable biosimilars that can expand access to cutting-edge therapeutics for patients globally. The R&D, manufacturing, commercial, and essential business functions for Biocon's biosimilars business are housed under Biocon Biologics. Besides, the Branded Formulation India (BFI) business is also a part of Biocon Biologics.

Biocon Biologics is an established and vertically integrated global biosimilar player that has invested ahead of its peers in this exciting opportunity. Biocon's more than 40 years of experience in science and manufacturing laid the foundation for Biocon Biologics. Biocon's early entry into the biosimilar segment, more than 15 years ago, has enabled it to become a frontrunner in biosimilars.

Biocon Biologics has strong competency in developing high-quality biosimilars at its R&D sites in Bengaluru and Chennai (India) and manufacturing cost-efficient biosimilars at scale for both developed and emerging markets, in Bengaluru (India) and Johor (Malaysia). As of March 2021, Biocon Biologics has a global commercial footprint through a hybrid commercial model, wherein it has a direct commercial presence in some countries and leverages regional partners in others. Biocon also has a global partnership with Viatris for some products wherein Viatris has exclusive commercial rights in developed markets.

Biocon Biologics' therapeutic focus includes diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology, and inflammatory diseases. So far, it has taken five products from lab to market, of which three have been commercialized in developed markets like the US, EU, Australia, Canada, and Japan.

Biocon Biologics has several first-in-class achievements to its credit, such as:

- 1st biosimilar Trastuzumab to be approved anywhere in the world; developed and launched in India (2014)
- 1st company globally to get US FDA approval for biosimilar Trastuzumab (2017)
- 1st biosimilar Pegfilgrastim approved by the US FDA (2018)

The market dynamics for biosimilars are evolving by the day. Initially, only a few players invested in this space, but we have seen a growing interest in this space among several companies. In the following decade, a strong growth is expected in the biosimilar market, with ~$90 billion worth of biologics revenue expected to lose exclusivity, as per industry estimates. This would increase further, given that large number of pharmaceutical products under development today are biologics and would lose exclusivity at some point. We believe the experience which Biocon Biologics has accumulated over the years and the competitive dynamics of the biosimilar market, as mentioned below, positions it well to capitalize on this opportunity.

High barriers to entry: The development of biosimilars requires the confluence of multiple high-end capabilities in physicochemical and biological characterization, sensitive orthogonal analytical techniques for demonstrating biosimilarity at the molecular level, pharmacokinetic (PK) and pharmacodynamic (PD) studies against the chosen reference product as well as extensive human clinical trials. Thus, R&D costs and time taken for developing biosimilars are significantly high as compared to conventional chemical synthesis-based "small molecule" generic pharmaceuticals.

Quality focus: By nature, biosimilar development requires a strong focus on quality at global scale. Being protein products administered by injection, it is critical to have consistency in product quality, which comes with experience and investments in high quality manufacturing and testing infrastructure.

Manufacturing capabilities at scale and a global reach: Biosimilars are designed to make healthcare affordable by improving access to high-value therapeutics and saving costs for healthcare systems worldwide. The ability to provide products to both developed and emerging markets enables us to manufacture high volumes and benefit from economies of scale. Moreover, it shields our business from the cyclical market dynamics of individual countries.

We have a large portfolio of molecules targeting sizable opportunities, of which 11 are in partnership with Viatris (originally Mylan, which got merged with Pfizer's Upjohn business in 2020), and a few in partnership with Sandoz (a subsidiary of Novartis). The Viatris collaboration is a cost-share and profit-share model wherein we participate in about one-third of the economics from developed markets where Viatris has exclusive commercial rights. We share equal economics in emerging markets where we have co-commercialization rights. We are responsible for developing, manufacturing, and supplying the products globally. The Sandoz partnership is structured based on an equal economic share with Sandoz having commercialization rights in developed markets and the responsibility for development and manufacturing is shared between the partners.

Table 7: Status of Biocon Biologics Portfolio (April 2021)

Global Biosimilars Pipeline

Biocon Biologics

Therapeutic Areas	Molecule	Product Status: US	Developed Markets: ex-US	MoW^^
Oncology	Pegfilgrastim#		EU, CANZ	
	Trastuzumab#		EU, CANZ	
	Bevacizumab#		EU	
	Pertuzumab#			
Immunology	Adalimumab*#		EU, CA, Japan	
	Etanercept*#		EU	
Diabetes	Glargine**# 100U		EU, ANZ, Japan	
	Glargine# 300U		EU	
	Aspart#		EU	
	RHI^			
Undisclosed	7 Assets			

Early Dev./ Preclinical | Clinical | Filed | Approved

In partnership with Viatris; *Partner Viatris has in-licensed product (Biocon benefits from economic interest); **Japan is outside of Viatris partnership; ^RHI non-partnered asset completed Ph 1 and considering potential Ph 3 waiver to be confirmed with US FDA advice, shown as Planned submission;
^^MoW represents Most of the World markets. Chart represents the status of the country where the product is in most advanced stage. Every country has a different status. CANZ stands for Canada, Australia and New Zealand. CA - Canada, AUS - Australia and NZ - New Zealand. Status as of April 2021.

The Branded Formulations India (BFI) business focuses on specialty brands in critical therapies, offering affordable and differentiated medicines of world-class quality to thousands of patients in India. These include biologics (including biosimilars, novel molecules, and others), in-licensed products, and branded generics for acute and chronic conditions. The business focuses on therapeutic areas such as metabolics (diabetes, cardiovascular), oncology, nephrology, and autoimmune diseases.

FY21 Highlights

COVID-19 has resulted in significant disruption to several businesses globally, including biosimilars. While our teams have done remarkably well to ensure our products reach patients worldwide, there have been circumstances beyond our control that have restricted our ability to deliver as per plan. That said, we have seen good growth and several positive developments around our business.

Biocon Biologics revenues have grown by 21% over last year to ₹28,002 million, representing 38% of consolidated revenues from operations with an EBITDA margin of 27%. The growth in revenue were primarily driven by improved performance in both developed and emerging markets.

- bPegfilgrastim: We have seen a resilient market share of Fulphila® throughout the year in the US despite competitors entering the market. Through our partner Viatris, we had launched bPegfilgrastim in Australia and Canada in April 2020.
- bTrastuzumab: In the US, Ogivri® was launched in December 2019 through our partner Viatris, where it has seen a steady increase in market share. Besides, we have also seen a strong performance of Ogivri® in Canada and Australia.
- bBevacizumab: We have commercialized bBevacizumab in select emerging markets. In India, it is marketed under the brand name Krabeva®. Our partner, Viatris, has filed a Biologics License Application (BLA) in the US under the 351(k) pathway. In April 2021, Biocon Biologics and Viatris received approval from European Commission for Abevmy® in the EU. Also, we received approval for bBevacizumab from the National Pharmaceutical Regulatory Agency (NPRA) in Malaysia.
- bAdalimumab: We have an economic interest in Hulio™ as a part of our three-way collaboration with Viatris and Fujifilm Kyowa Kirin Biologics. Hulio™ has been launched in the EU and has been approved by the US FDA, with launch expected in July 2023.
- bEtanercept: We have an economic interest in Nepexto® due to our three-way collaboration with Viatris and Lupin. Nepexto® was launched in the EU in August 2020.
- bGlargine: Semglee® was launched in the US in August 2020 through our partner Viatris. Semglee® has also been commercialized in the EU and Japan.
- bAspart: In February 2021, Biocon Biologics and Viatris received European Commission approval for Kixelle® in the EU. Also, we received approval for insulin Aspart from the National Pharmaceutical Regulatory Agency (NPRA) in Malaysia. The BLA filing for insulin Aspart in the US is under review.
- Recombinant Human Insulin (rHI): We have commercialized recombinant human insulin in several emerging markets worldwide. We are developing the product for the US market, considering the positive FDA draft guidance for insulin biosimilars under the 351(k) pathway.

Improving patient access to high-quality, affordable products for chronic conditions such as diabetes and oncology are core to Biocon Biologics' mission. We are working on the "Mission 10 cents" initiative, which aims to enable equitable access to rHI by offering it at less than 10 US cents a day for Low/Middle-Income Countries (LMICs). In FY21, we signed agreements with two municipalities in the Philippines. Besides, we signed an MoU with the Christian Social Services Commission (CSSC), a faith-based organization active in Africa that works closely with the government and international and national partners to facilitate health and education services. Tanzania will be the first country in Africa to benefit from this collaboration between Biocon Biologics and CSSC.

Moreover, Biocon Biologics partnered with The International Diabetes Federation (IDF) as the first biosimilar insulins company to promote and support IDF's Core Mission initiative and activities. Biocon Biologics has also signed an agreement with the Clinton Health Access Initiative (CHAI) to expand access to life-saving cancer biosimilars as a part of the Cancer Access Partnership (CAP). Biocon Biologics aims to deliver substantial savings to healthcare systems by enhancing access and availability of these high-quality, affordable biosimilar cancer therapies in 25 countries in Africa and five countries in Asia. We will initially supply bTrastuzumab and bPegfilgrastim as a part of this agreement.

In FY21, we collaborated with Voluntis, a digital therapeutics leader, to develop and distribute innovative digital therapeutics, supporting people with diabetes on biologics therapy. It enables us to offer a US FDA-cleared and CE-marked digital therapeutic product, Insulia®, to Type 2 diabetes patients. Insulia® provides automated insulin dose recommendations enabling people with diabetes to self-manage their condition and healthcare teams to monitor progress remotely. It is the first digital therapeutic with regulatory clearance to provide automated titration recommendations for all basal insulins.

In manufacturing, our investment strategy is to build capacity in a modular manner, in-line with our projection of market opportunity. This has allowed us to scale up capacity in response to a higher-than-expected demand, even as we balance exposure to any underutilized capacity and costs in the early phase. We will continue to expand our manufacturing capacities to address volume growth on account of increased penetration of our products in developed and emerging markets and support new biosimilar pipeline development and launches. Our manufacturing facilities in Bengaluru and Johor are already approved by several key regulatory agencies including the US FDA, EMA, etc. In May 2020, we received EU GMP certification for our manufacturing facility at Bengaluru's Biocon Park, which is used to manufacture

Pegfilgrastim, Trastuzumab, and Bevacizumab Drug Substance and Drug Product. In the beginning of FY21, US FDA had closed the inspection of our Malaysia facility for insulin glargine, following which the New Drug Application (NDA) was approved in June 2020. We have built a 340,000-square feet mAbs Drug Substance facility located in Biocon Park (B3) which is one of the largest mAbs manufacturing facility in India in terms of built area for a single building/site, wherein we have invested ~$120 million. We have built this facility in a sustainable manner to ensure maximum energy conservation.

In continuation to the investment of $75 million by Activ Pine LLP, an affiliate of True North Fund, in Biocon Biologics Limited in FY20, we received additional investments of $255 million from Tata Capital Growth Fund II, Goldman Sachs India AIF Scheme – 1 and Beta Oryx Limited, an affiliate of ADQ in FY21. Activ Pine's equity infusion was for a 2.44% stake at an equity valuation of $3 billion on a pre-money basis. In July 2020, Tata Capital Growth Fund invested ₹225 crore (~$30 million) for a 0.85% stake, valuing Biocon Biologics at an equity valuation of ₹26,250 crore (~$3.5 billion). Goldman Sachs issued Optionally Convertible Debentures (OCD) worth ₹1,125 crore (~$150 million) at a post-money equity valuation of $3.94 billion.

Abu Dhabi-based ADQ invested ₹555 crore (~$75 million) for a 1.80% stake, valuing Biocon Biologics at a post-money valuation of ~$4.17 billion. Biocon Ltd will hold an 89.89% stake in Biocon Biologics on a fully diluted basis after completion of these transactions. The capital raised is being used for investment in capex, R&D, operational expenses, and redemption of Biocon Limited's preference shares in Biocon Biologics.

The investment validates Biocon Biologics' science, scale, scope, strategy, and business prospects. It also reflects a high level of conviction in Biocon Biologics' position as a global frontrunner in biosimilars, which leverages its large-scale manufacturing capabilities to shift the access paradigm for these life-saving therapies.

Research Services (Syngene)

As per MarketsandMarkets analysis, the global Contract Research Organisation (CRO) market is estimated to grow at a CAGR of 9.1% and increase from $47.77 billion in 2020 to $73.77 billion by 2025. The APAC region is likely to offer significant growth opportunities during the forecasted period. Over the years, R&D outsourcing has gradually transitioned from being a cost arbitrage initiative to enhancing R&D productivity, speed-to-market, and helping innovator companies concentrate on their core competencies. The interplay of several factors like expertise to manage complexities, innovation in newer areas, and driving flexibility in costs position the CRO industry to grow steadily in the coming years.

Established in 1993, Syngene International Limited (Syngene) is India-based integrated research, development, and manufacturing organization providing scientific services. Driven by an experienced leadership team, expertise of a highly qualified team of 5000 employees, supported by market-leading technology and world-class infrastructure, Syngene provides end-to-end services spanning a wide section of modalities, including small and large molecules, antibody-drug conjugates (ADCs), and oligonucleotides. The scientific services are accessed mainly by the global pharmaceutical and biotechnology industry. Nutrition, consumer goods, animal health, and specialty chemicals are among the other sectors being served by the Company. During the past year, the Company engaged with over 360 clients from multiple industry verticals.

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. This, along with being a one-stop solution provider, has enabled it to build relationships of trust with its clients and extend the scope of engagement. Syngene is involved in the discovery, development, and manufacturing of small and large novel molecules. Hence, its business is divided into four segments:

- Discovery Services: Conducts early-stage research that spans from target identification to delivery of drug candidates for further development
- Development Services: Involves activities from preclinical to clinical trials that include drug substance development, drug product development, and allied services to demonstrate safety, tolerability, and efficacy of the drug
- Manufacturing Services: Includes manufacturing of small and large molecules
- Dedicated R&D Centres: Ring-fenced infrastructure and exclusive multi-disciplinary scientific team and support personnel provided for client's research program.

Collaboration Models

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

FY21 Highlights

New Collaborations: Syngene recently collaborated with Deerfield Discovery and Development (3DC) to advance integrated drug discovery projects, from early target validation to preclinical evaluation. This year, 3DC awarded four antibody discovery projects to Syngene in oncology and autoimmune diseases that will be executed in 2021.

Syngene International and HiMedia Laboratories, a bioscience company with expertise in media manufacturing and diagnostics, have collaborated to manufacture ELISafe 19TM, an IgG-based ELISA test kit for COVID-19 that has been approved by the Indian Council of Medical Research (ICMR). The ELISafe 19TM antibody test kit has a sensitivity of 100% and a specificity of 99%.

Syngene International has collaborated with PharmAust Limited to manufacture and supply 10 kg of GMP-grade monepantel (MPL) to support clinical trials in humans. These trials will examine the effects of MPL in humans with motor neuron disease (MND) and the effects of MPL tablets in individuals with selected cancers. The synthesis of the GMP-grade MPL will be completed by June 2021; however, the manufacturing will begin after Syngene has conducted a feasibility study.

Capacity Expansion: Syngene has expanded its research facility in Genome Valley, Hyderabad, India, and added capacity for additional 90 scientists. The initial capacity of the facility was 150 scientists and was commissioned in February 2020. The Discovery Services division received NABL (National Accreditation Board for Testing and Calibration Laboratories) accreditation to provide safety assessment services for testing medical devices from its Bengaluru facility.

Improved Credit rating quality: In a further boost to Syngene, CRISIL upgraded its credit rating from AA to AA+ with a stable outlook. ICRA upgraded its credit rating in August to AA+ Stable from AA Positive. This is a further affirmation of Syngene's robust business model and strong fundamentals.

Fighting COVID-19: Continuing its contribution in the fight against COVID-19, Syngene has set up a new RT-PCR testing facility approved by NABL and ICMR that complies with the BSL-2 criteria. It has further completed testing of more than 100,000 samples at its COVID-19 testing facility. 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.

Syngene and Gilead also signed non-exclusive voluntary licensing agreements to expand the further supply of Remdesivir, an intravenous nucleotide prodrug of an adenosine analog. Remdesivir combines with the viral RNA-dependent RNA polymerase, constraining viral replication through premature termination of RNA transcription. Therefore, it has confirmed in vitro activity to have worked against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Syngene commenced the manufacturing of the product from its Bengaluru facility and launched Remdesivir during the year.

FY21 Financial Performance

During the year under review, Syngene's revenue from operations grew 9% to ₹21,843 million. The performance was driven by broad-based growth across all business units, with improved traction in Discovery Services. Segment margins improved over the last year, driven by lower material costs.

Operational Performance

An overview of the Company's financial performance is given on the next page, which forms part of the MDA.

Financial Performance - An Overview

Consolidated Balance Sheet

The following table highlights the Consolidated Balance Sheet as on March 31, 2021 (FY21) and March 31, 2020 (FY20)

All Figures in ₹ million

ASSETS	Mar-21	Mar-20	Change
Non-current assets			
Tangible and intangible assets	91,641	81,671	12%
Investment in associates and a joint venture	1,795	142	1164%
Financial assets	8,302	1,764	371%
Assets for current tax (net)	2,648	2,417	10%
Deferred tax assets (net)	3,077	3,680	(16)%
Other non-current assets	1,756	1,514	16%
	1,09,219	**91,188**	**20%**
Current Assets			
Inventories	18,666	14,359	30%
Financial assets	53,178	35,496	50%
Other current assets	3,638	3,395	7%
Assets held for sale	522	-	100%
	76,004	**53,250**	**43%**
Total	**1,85,223**	**1,44,438**	**28%**
EQUITY AND LIABILITIES			
Equity			
Equity share capital	6,000	6,000	0%
Other equity	70,269	61,058	15%
Non-controlling interests	8,807	6,773	30%
	85,076	**73,831**	**15%**
Non-current liabilities			
Financial Liabilities	46,408	19,877	133%
Provisions and other non-current liabilities	11,638	10,650	9%
	58,046	**30,527**	**90%**
Current liabilities			
Financial Liabilities	33,269	32,795	1%
Income tax liability (net)	1,524	1,279	19%
Provisions and other current liabilities	6,904	6,006	15%
Liabilities directly associated with assets held for sale	404	-	100%
	42,101	**40,080**	**5%**
Total	**1,85,223**	**1,44,438**	**28%**

Tangible and intangible assets

Tangible and intangible assets grew 12%, primarily due to additions in the tangible assets and capitalization of product development expenses partly offset by depreciation and amortization for the year. Additions to tangible assets pertain primarily to the Biosimilars facility, Research Services, and other manufacturing facilities.

Non-current financial assets

The increase in Financial assets is due to investment in inter-corporate deposits for more than 12 months by ₹ 6,267 million and an increase in fair value of Equillium Inc. investment by ₹739 million. Such increase in fair value of investments is through other comprehensive income (OCI).

Other equity

Other equity majorly comprises securities premium, treasury shares, retained earnings, and further reserves. The Company's total other equity increased by 12% in FY21 due to profit accumulation.

Non-controlling interests

The Profit attributable to minority shareholders increased by 20% in FY21, attributable to the current year's profits accumulation.

Non-current liabilities

Non-current liabilities went by 105% in FY21. During the year ended March 31, 2021, Biocon Biologics has entered into an agreement with Goldman Sachs India AIF Scheme-1 (Goldman Sachs) whereby Goldman Sachs has infused ₹11,250 million against the issuance of Optionally Convertible Debentures. The debentures have been accounted in the consolidated financial statements as a compound financial instrument in line with Ind AS, given that it has both financial liability and equity features.

Biocon Biologics has also received an equity investment from Activ Pine LLP, Tata Capital Growth Fund II, and Beta Oryx Limited, amounting to ₹ 5,363 million, ₹2,250 million, and ₹5,550 million, respectively, for a minority stake of 2.44%, 0.85%, and 1.87%. The gross obligation for such investment is ₹14,966 million as at March 31, 2021. As per applicable Indian Accounting Standards, this has been recorded as a financial liability in the consolidated financial statements.

The increase in deferred revenue is mainly from Biosimilars, which is partially offset by repayment of long-term borrowings in Biologics and Research services.

Working capital (current assets less current liabilities)

As at March 31, 2021, working capital stood at ₹ 37,279 million, up by 183% compared to FY20 due to an increase in inventories, unbilled revenue, and cash balance partly offset by a decrease in current maturities of long-term borrowings, short term borrowing. Borrowings are primarily in Biologics and Research Service businesses.

Assets and liabilities held for sale

Pursuant to the Board of Directors' approval on May 14, 2020, Biocon is in the process of disposing of its interest in the JV entity and related UAE operations. Accordingly, the share of profit / (loss) from the JV and the results of its related business have been disclosed as discontinuing operations in the consolidated financial statements. Assets and liabilities associated with the business are disclosed separately as held for sale. Due to regulatory challenges, Biocon has not been able to exit, and it continues to evaluate its option concerning exit.

Debt and equity

Total debt at March 31, 2021, stood at ₹58,619 million, and the debt-equity ratio stood at 0.77. No material changes that may affect the financial position of the Group have occurred after the close of the year, until the date of the Director's Report.

Consolidated Statement Of Profit And Loss

The following table highlights key components of the statement of Profit and Loss for the fiscal years ended March 31, 2021 (FY21) and March 31, 2020 (FY20)

All Figures in ₹ million

Particulars	FY 21	FY 20	Change
Total revenue	73,603	64,619	14%
Expenses			
Cost of materials consumed	22,085	19,895	11%
Employee benefit expense	15,657	13,279	18%
Finance costs	577	649	(11)%
Depreciation and amortisation expense	7,151	5,522	30%
Research and development expenses, net of recovery from co-development partners	5,531	4,392	26%
Other expenses	11,259	9,408	20%
Total expenses	62,260	53,145	17%
Share of profit / (loss) of joint venture and associate (net)	(695)	-	
Profit before tax and exceptional item	10,648	11,474	(7)%
Exceptional items, net	126	675	(81)%
Profit before tax	**10,774**	**12,149**	**(11)%**
Tax expense	2,120	2,495	(15)%
Tax on exceptional item	95	656	(86)%
Profit for the year from continuing operations	**8,559**	**8,998**	**(5)%**
Loss for the year from discontinuing operations	**(97)**	**(289)**	**(67)%**
Profit for the year	**8,462**	**8,709**	**(3)%**
Non-controlling interest	989	1,227	(19)%
Non-controlling interest on exceptional item	68	-	0%
Profit attributable to shareholders of the Company	**7,405**	**7,482**	**(1)%**
Other comprehensive income attributable to shareholders	1,582	**(1,314)**	(220)%
Total comprehensive income attributable to shareholders of the Company	**8,987**	**6,168**	**46%**

Revenue

During the year under review, revenues grew by 14% on a consolidated basis from ₹64,619 million to ₹73,603 million. Our Biosimilar revenues have increased by 21% over last year to ₹ 28,002 million, representing 38% of revenues from operations with an EBITDA margin of 27%. We have seen strong sales growth from our partnered program driven by improvement in market share in developed markets and the launch of Semglee in the US. We have seen a marginal improvement in the non-Viatris sales in emerging markets and BFI business. The Generics Revenues were ₹23,359 million in FY21 compared to ₹22,070 million in FY20, reflecting a growth of 6%. The generics segment reported a modest performance against the backdrop of COVID-19 related challenges, increasing competition, and pricing pressure in some of our commercialized products. The Research services grew 9% to ₹21,843 million. The performance was driven by broad-based growth across all business units, with improved traction in Discovery Services. The Total Revenue composition for FY21 and FY20 is detailed below:

Particulars	FY21		FY20	
	(₹ million)	(%)	(₹ million)	(%)
Generics	23,359	32	22,070	34
Biosimilars	28,002	38	23,151	36
Novel Biologics	-	-	-	-
Research Services	21,843	30	20,119	31
Inter-segment	(2,146)	(3)	(2,335)	(4)
Revenue from operations	**71,058**		**63,005**	
Other income	2,545	3	1,614	2
Total income	**73,603**		**64,619**	

Other income

Other income comprised of Interest on surplus funds and export incentives. Further, to enable Bicara to raise further funding for R&D plans, the existing shareholder arrangements (voting rights & Board composition) of Bicara were amended, which resulted in loss of control over the subsidiary. Accordingly, the Company fair valued its investment in Bicara on the date of loss of control, which resulted in a dilution gain of ₹1,597 million.

Material & Power costs

Material & power costs comprised raw materials, packing materials, traded goods, and change in inventories. In FY21, material costs, as a percentage of revenue from operations ex-licensing, decreased by ~1% compared to FY20.

Staff costs

Our employee benefit expenses comprise the following items:

- Salaries, wages, allowances, and bonuses
- Contributions to Provident Fund
- Contributions to gratuity provisions
- Amortisation of employees' stock compensation expenses and welfare expenses (including employee insurance schemes)

These expenses increased by 18% in FY21, driven by business growth, increased headcount, and stock compensation costs.

Research and development expenses

The net R&D expenditure for FY21 increased by 26% to ₹5,531 million (₹4,394 million in FY20). Total spend was at 13% (~10% in FY20) of revenue ex-Syngene. We capitalized ₹739 million, taking gross R&D spend to ₹6,270 million for the year compared to ₹5,271 million in FY20. The gross R&D spend increased due to higher spend in the biosimilar development programs, ANDA programs, and expenditures related to in-house novel programs.

Interest & Finance charges

The finance cost for FY21 at ₹577 million (₹649 million in FY20) primarily comprises interest cost on borrowings for Biologics and Research business.

Depreciation & Amortisation

During this fiscal, depreciation and amortization increased 30% to ₹7,151 million from ₹5,522 million in FY20, primarily due to amortization of intangibles capitalized in Biologics and commissioning of new facilities in Syngene.

Tax expenses

The effective tax rate (ETR) for the year before the exceptional item was 20% (22% in FY20). Lower tax rate is mainly due to profits from exempted units.

Exceptional items (net)

The Exceptional items during the year (FY21) comprised the following:

a) Pursuant to the claims related to the fire incident on December 12, 2016, at Syngene, receivable and the disbursements from the insurance claim have been presented on a net basis as ₹ 350 million under Exceptional items in the financial statements.

b) During the year ended March 31, 2021, Biocon Biologics has paid severance of ₹ 224 million to the erstwhile leadership team.

Other comprehensive income

Other comprehensive income includes re-measurement gains/losses on defined benefit plans, gains/losses on hedging instruments designated as cash flow hedges and exchange differences on translation of foreign operations, gains/losses on the fair value of the investment in equity through FVOCI. The decrease is primarily due to lower gains on hedging instruments in FY20 compared to the previous year and loss on the fair value of the investment in the equity of Equillium.

Key financial ratios

Particulars	FY21	FY20	Change
Debtors turnover	4.73	4.96	(2)%
Inventory turnover	2.02	2.31	(12)%
Interest coverage ratio	12.90	26.41	(51)%
Current ratio	1.81	1.33	36%
Debt equity ratio	0.77	0.39	96%
Operating profit margin (%) #	16%	19%	(14)%
Net profit margin (%) *	10%	12%	(13)%
Return on net worth^	10%	12%	(12)%

Operating margin is defined as Profit before taxes and interest

* Net Profit before exceptional income and tax thereon

^ Net Profit before exceptional income and tax thereon as a percentage of equity

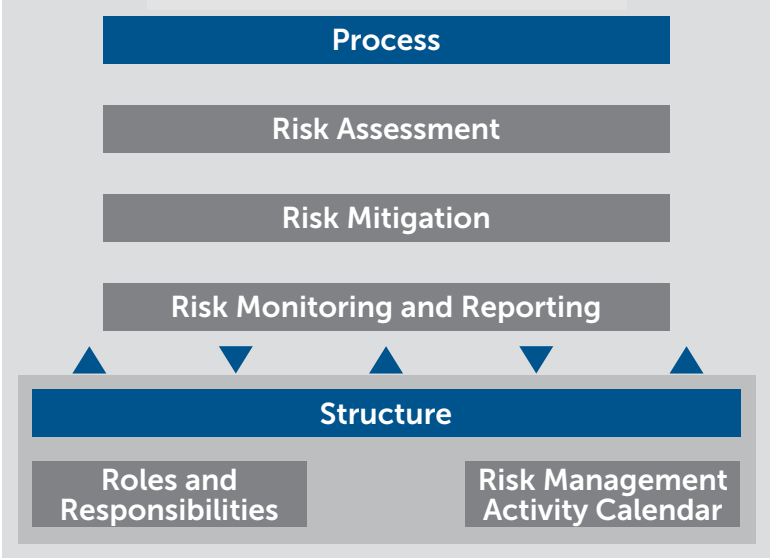
Risks, Threats, and Concerns

A key factor for a company to create sustainable value is the risks it is willing to take (at strategic and operational levels) and its ability to manage them effectively. Therefore, the ability to identify and manage risks promptly is a critical aspect of Corporate Governance for a company.

A risk is a potential event or non-event, the occurrence or non-occurrence of which can adversely affect the objectives or strategy of the Company or result in opportunities being missed. Risk is measured in terms of likelihood of occurrence and potential impact if it materializes. A risk could be categorized into financial, operational, strategic, regulatory/statutory, reputational, political, catastrophic/pandemic.

Amongst the risks discussed above, regulatory/statutory, operational, strategic, and financial are mostly controllable, while political and catastrophic/pandemic (impacting business continuity) risks are mostly uncontrollable.

Table 8: Our Risk Management Process



Risk management is a structured, consistent, and continuous process across the entire organization for identifying, assessing, deciding on responses to, and reporting on opportunities and threats that may affect the achievement of its objectives.

Risk management does not aim at eliminating the risks, as that would simultaneously eliminate all chances of rewards/opportunities. Instead, constant efforts are being made to analyze their potential impact, assess the changes to the risk environment, and define actions to mitigate their adverse impact. The Company has implemented a precise methodology that entails timely identification, analysis, and assessment of risks and potential consequences, formulation of specific mitigation strategies, and seamless execution. An enterprise-wide risk evaluation and validation process is conducted regularly and reviewed by the Risk Management Committee and Board of Directors.

With time, the practice of risk management has shifted fundamentally. In the past, risks were managed in "silos." Over time, the risk management framework recognized that risks are highly interconnected and interdependent. This evolved approach views all risks together, within a coordinated and strategic framework integrated throughout the organization.

The risk management process at Biocon consists of the following three steps:

1. Risk Identification and Assessment
2. Risk Mitigation
3. Risk Monitoring and Reporting

An effective risk management process entails these three steps being aligned with regular operations of the enterprise to ensure relevant and timely reporting and action on all risks which the organization faces. In the process of risk assessment, the organization's risks from time to time get identified, analyzed, and prioritized.

Table 9: Our Risk Management Structure

Board of Directors	• Reviews the risk management and internal control framework, key risks, and mitigating controls
Risk Management Committee	• Reviews and assesses the effectiveness of risk management framework • Recommends changes to the risk management and/or associated frameworks, processes, and practices Company
Senior Leadership Team	• Providing direction and ensuring sustainable implementation of the risk framework • Reporting to the Board of Directors & Risk Management Committee, the outcome of its periodic review of the risk management process
Chief Risk Officer	• Coordinates with senior leadership team and functional heads and assists in carrying out risk identification, assessment, prioritization, and mitigation activities • Preparation of consolidated risk reports and present to senior leadership/Risk Management Committee.
Department/ Functional Heads	• Directing and implementation of the risk management initiatives pertaining to their team/ department • Continuous risk assessment, review of risk mitigation procedures etc.

Risk mitigation is initiating responsive action for managing the key risks that the organization faces and restricting them at a tolerable level. The entire process can be broken down into "4T":

1. Treat (Mitigation)
2. Terminate
3. Transfer
4. Take (Acceptance)

The risk monitoring and reporting process aims to assure the management that risks have been adequately identified and prioritized and significant risks are well managed. The Risk Management Committee reviews the critical risks, gross exposure, mitigation action status, and net exposure periodically.

The pharmaceutical industry is growing day by day due to an ever-increasing demand for its services. Due to the nature of business, the global pharma industry is potentially exposed to inherent risks such as product safety & quality issues, intellectual property tangles, inappropriate marketing practices, etc. This leads to penalties, product recalls, brand/reputation loss, and revenue loss. The regulatory landscape of the

international pharma industry is complex and dynamic, which poses additional challenges. The primary industry driver is patient health and safety, even as a regulatory approach to patient protection may vary from market to market. Besides, increased regulatory scrutiny, sophisticated risk-monitoring techniques, and coordination across agencies & regions are some of the changes that impact the industry. In that context, it is imperative to respond to risk with a holistic risk mitigation framework. In today's world, a patient-centric approach is considered the only right way to do good business and serve citizens.

The Company is committed to conducting business following all applicable statutory laws, government notifications, and regulations across various locations where it has operations and pursuing its core organizational values. Our established risk management framework addresses financial, operational, strategic, regulatory/statutory, reputational, political, catastrophic/ pandemic risks inherent to the pharma business and impacts our strategic goals. Risk management, coupled with a robust internal control framework, helps the Company maintain qualitative consistency, employee safety, and long-term sustainability.

A variety of risks marks the global pharma business. Pharmaceutical companies struggle to enforce IP protection, particularly in some emerging markets globally. Enhanced regulatory scrutiny is set against a backdrop of increasing patient advocacy, social media, and affiliate marketing programs. The digitization and proliferation of electronic medical records, networked medical devices, mobile health applications, cloud-based technologies, and data-sharing among industry stakeholders have increased the complexity of managing and ensuring the safety of information assets, particularly protecting patient health information and intellectual property. However, with digitization, Company can control quality and operations, bring in flexibility and adaptability, and improve management effectiveness.

The success of new products in the global pharmaceutical industry will more than offset global pricing pressures, supporting an outlook change from stable to positive for the industry.

In 2017, the US FDA began a push to get lower-cost generic drugs out to the market faster. Efforts of the regulator to clear generic applications have led to cheaper versions of high-cost drugs, which will impact the overall profitability of the generics business. As per US FDA's 2019 report on Generic Competition and Drug Prices, drug products with a single generic producer saw a 39% reduction in the price of the brand name. There was a reduction of more than 95% for products with six or more competitors.

The key risks relating to our current operations, which we believe could cause our actual results to differ materially from expected and historical results, include human capital risk such as loss of key personnel, timely non-replenishment of critical vacant roles with the apt skillset, concentration or reliance on third-party sole suppliers or service providers including regional supplier reliance, risk of our R&D programs failing or not getting completed in a timely manner, risk of inability to address the regulatory queries on various filings made, risk of non-adherence to good manufacturing practices on an ongoing basis, risk arising out of strategic co-development arrangements with a partner, disruption of operations or loss of information from natural disasters or pandemic, risk arising out of strategic projects where significant investments are made, foreign exchange fluctuations, changing global political and regulatory landscape, continued adherence to environment & safety-related requirements, critical information loss or cyber-attacks, losses due to treasury activities, failure to report accurate financial information in compliance with accounting standards and applicable legislation, change in company strategy amongst others.

Note on COVID-19 related risks

There's hardly any industry that hasn't been affected by COVID-19. The pharmaceutical manufacturing sector is no exception.

While pharma companies have been at the forefront of the fight against the COVID-19 pandemic, they have also been tackling a new wave of ransomware attacks and extortion demands since the last quarter of 2020, as per 'Turn the Page – Predictions for 2021 and Beyond' report released by Seqrite, an enterprise security solutions brand by Quick Heal Technologies. Ransomware attacks, which were earlier used to encrypt files and demand a ransom payment against the decryption key, are now gaining access to private and sensitive information of the Company. This has made it mandatory for pharma and research companies to adopt a comprehensive set of security solutions. Moreover, under the remote working model, employees use various tools, including video conferencing and chat applications, to communicate. This has made companies prone to critical data loss/cyber-attacks. Therefore, any new vulnerability in such widely used applications could be used by malware authors as soon as they are discovered, further emphasizing the need for a strong IT administration. While vaccine campaigns have been running globally, the recent spurt in the new COVID-19 infections worldwide has given way to stricter social distancing norms and extended lockdowns. Thus, experts have revised their forecasts and are claiming COVID-19's impact to last for "years to come." While the pharma industry is categorized as essential services and has been allowed to have minimal personnel on-premises to continue operations, it is imperative to adhere to all precautionary measures to ensure the safety of the employees at work and avoid any contamination. The full impact of the global pandemic is still unknown. Pharma companies, therefore, need to respond, recover, and thrive.

At Biocon, an assessment of risks triggered due to the COVID-19 pandemic was carried out, and critical levers to support enterprise resilience were identified. These included a focus on overall people safety, transparent communication, a focus on continued critical operations such as procurement, production, sales, and disposal of waste, a focus on compliance and governance, relooking at cash and liquidity management in the changing circumstances, and prioritization/rationalization of spends. Furthermore, remote working and cybersecurity, safe plant operations, impact assessment on R&D, and availability of insurance coverage and contract liabilities were evaluated. Key mitigation actions were put in place to support business continuity plans and continued safe operations.

Internal Controls

The Company is responsible for establishing and maintaining adequate and effective internal controls and the preparation & presentation of financial statements, including assertions on the internal financial controls following a broad criterion that it has set for itself.

A robust, comprehensive internal control system is a prerequisite for an organization to function ethically, commensurate with its abilities and objectives. We have established a strong internal control system for the Company, which comprises policies, guidelines, and procedures adopted by the Company to ensure orderly and efficient business conduct, including adherence to policies, asset safeguarding, fraud cum error prevention & detection, accounting records accuracy & completeness, and the timely preparation and presentation of reliable financial information.

This internal control system aims to assure our operational effectiveness and efficiency, compliance with laws & regulations, asset safeguarding & reliability of financial and management reporting.

The Company is staffed by experienced, qualified professionals who play an important role in designing, implementing, maintaining, and monitoring the internal control environment.

An independent firm of chartered accountants performs periodic internal audits to provide a reasonable assurance of internal control effectiveness and advises the Company on industry-wide best practices. The Audit Committee, consisting of Independent Directors, reviews important issues raised by the internal and statutory auditors regularly and the status of rectification measures to ensure that risks are mitigated appropriately on a timely basis.

Outlook

FY21 was a challenging year testing our resilience, agility, and adaptability to the new business paradigm caused by the outbreak of COVID-19. At Biocon, we are conscious that the pandemic is far from over, and it will continue to assess with new challenges at regular intervals. We have transitioned to FY22, adapting to the new normal, and have prepared ourselves to tide past eventualities in the future.

We are confident of the long-term opportunities in every segment where we operate and our ability to deliver value to patients the world over. In FY22, we expect to retain the growth momentum, led by higher revenues across the segments. We will continue to focus on the portfolio, strengthening the development pipeline, and fast-track capacity enhancement. These initiatives will bolster our pursuit of enabling access to affordable therapies to patients worldwide and will have us positioned well to deliver our partners' and stakeholders' expectations.