Management
Discussion and Analysis

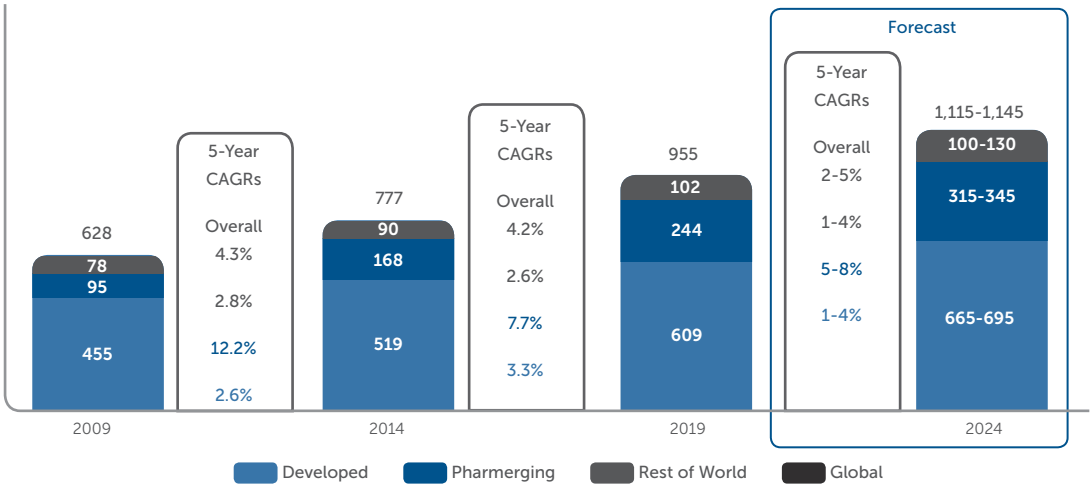
A Growing Industry in a Volatile Global Growth Environment

As per the International Monetary Fund, global economic growth was expected to rise from 2.9 percent in 2019 to 3.3 percent in 2020, slightly weaker than earlier projections. Economic weakness in certain emerging market economies, especially India led to this revision of growth prospects. Stronger multilateral cooperation, more balanced policy mix at national levels and impact of monetary policy easing could help strengthen economic activity and prevent downside risks.

However, the coronavirus (COVID-19) outbreak has brought considerable human suffering and major economic disruption with the growth prospects of the global economy becoming highly uncertain. Adverse impact on global business confidence has been witnessed in the first quarter of 2020, with financial markets demonstrating high volatility and capital flight, especially in emerging market economies where investors have been major sellers in stock markets. IMF predicts that global growth is expected to fall below 2019 levels[1].

Economic growth, an expanding global population, rise in incomes and technological change are expected to contribute to growth in the pharmaceutical industry. However, social, economic and political challenges remain in meeting unmet medical needs. The global healthcare market continues to grow, despite signs of economic slowdown in some countries. Global medicine spending is expected to rise from US$955 billion in 2019 to over US$1.1 trillion by 2024, per IQVIA.

Figure 1. Global Medicine Net Market Size and Growth 2009–2024, Constant US$Bn



Source: IQVIA Therapy Prognosis, Sep 2019; IQVIA Institute, Dec 2019

Notes: Net Market Size after estimated off-invoice discounts and rebates, estimated at country level

The rise in spending is expected to be driven by the increased access globally and the anticipated launch of novel therapies, including gene and cell therapy addressing key unmet needs. Payer scrutiny, government prescription drug policies and sales losses from genericization and biosimilar competition are expected to result in reduction in the global growth rate of medicine spending.

1 Source: https://blogs.imf.org/2020/03/04/potential-impact-of-the-coronavirus-epidemic-what-we-know-and-what-we-can-do; accessed on March 23, 2020

Trends Impacting the Global Pharmaceutical Sector

1. Growing and Ageing Populations
2. Advances in Science & Technology and Key R&D Focus Areas
3. Growing Adoption of Digital Technologies
4. Pricing and Access
5. Regulatory Environment & Geopolitical Uncertainties
6. Impact of COVID-19 on the Global Pharmaceutical Industry Landscape

Growing and Ageing Populations

The world's population is rising and more people are living longer. This demographic change is driving demand for both preventive and therapeutic healthcare products. While there is increased affordability due to increased wealth, there are also increased healthcare challenges and costs. An ageing population and changes in society are contributing to steady increases in non-communicable diseases (NCDs). These diseases include cancer and cardiovascular, metabolic and respiratory diseases often associated with lifestyle choices, including smoking, diet and lack of exercise.

As the burden of NCDs grows, so do public expectations, while the Governments' ability to address these is constrained as finances are under stress. Low and middle-income countries that are disproportionately affected by increased burden of NCDs are also impacted by issues such as nutrition, hygiene, air pollution and climate change, thereby worsening social, economic and demographic inequalities.

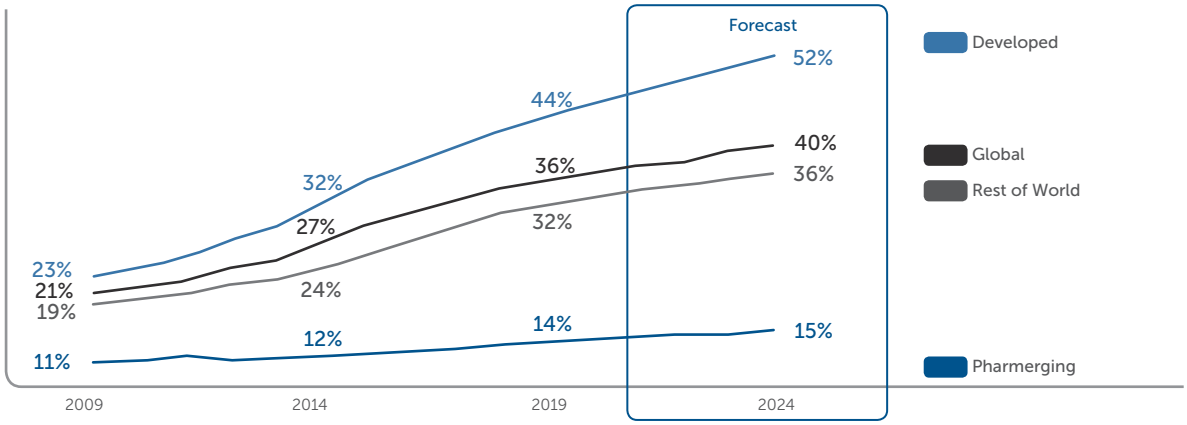
Advances in Science & Technology and Key R&D Focus Areas

Scientific innovation is critical to addressing unmet medical needs. Rapid advances made in this area are transforming development of newer medical therapies. Greater understanding of the biology of human disease and the use of new technology and approaches is enabling scientists to identify and develop novel targeted treatments. Innovation is being accelerated through the use of large volumes of biological data from disease biology and genomics which is driving precision medicine, while advances in data management and data integration are accelerating scientific discovery, improving health through technology and improving the speed and quality of clinical trial processes. Such advances have resulted in increased numbers of FDA Priority Reviews and Breakthrough designations.

The growth therefore over the last few years which is being enjoyed by the biopharma sector has been facilitated by an increasingly cooperative and flexible United States Food and Drug Administration (FDA). The positions adopted by the FDA play a key role in the success of new specialty medicines (medicines for chronic, complex or rare diseases) given that United States is the biggest acquirer of medicines globally. The sector's focus on rare diseases or poorly served niches in the oncology world has a lot to do with this focus, which the FDA has rewarded with very fast decisions. At the same time, enabled by technology, patients are becoming more engaged and willing to take greater control of their health and treatment choices.

Adoption of specialty biopharmaceuticals is driving spending increases and these products now account for 36% of spending globally. Specialty spending is projected to account for 40% of global spending in 2024. In developed markets, spending on specialty products is expected to reach 52% in 2024.

Table 2: Global Medicines Specialty Share of Invoice Spending by Region



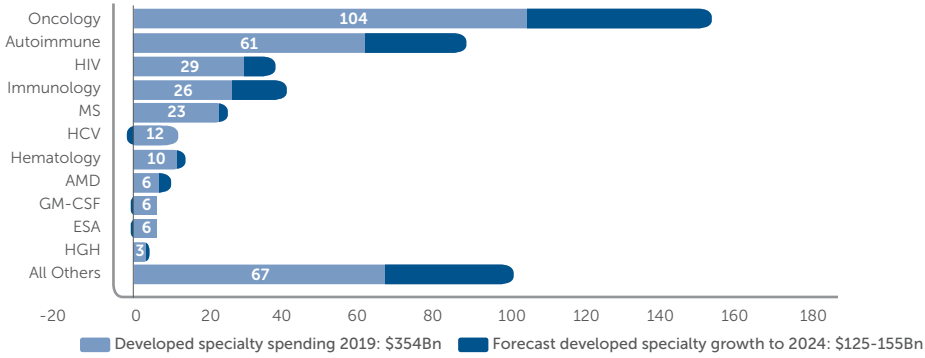
Source: IQVIA Therapy Prognosis, Sep 2019; IQVIA Institute, Dec 2019

Notes: Specialty medicines are defined by IQVIA as drugs for chronic, complex or rare diseases which meet a majority of defined characteristics

Analysis shown is based on invoice price level, not reflecting rebates. Regions are based on country estimates including 219 countries in IQVIA Market Prognosis

Spends on Oncology therapies is expected to be the largest contributor to global spending, growing 51% through 2024. This is expected to be followed by spends on Autoimmune, Immunology and HIV drugs.

Table 3: Specialty Invoice Spending by Therapy Area in Developed Markets, Constant US$Bn



Source: IQVIA Market Prognosis, Sep 2019; IQVIA Institute, Dec 2019

Notes: Leading specialty therapy areas and total others. All others are classes with 2019 spending smaller than those shown. Analysis shown in constant US$. Data is based on the eight developed markets available in IQVIA Therapy Prognosis (see Notes on Sources), does not include the developed markets Australia or South Korea.

Growing Adoption of Digital Technologies

The life sciences sector is an inflection point. While the promise of cell and gene therapies is being delivered to patients, artificial intelligence (AI) and machine learning (ML) approaches are raising expectations that discovery and development may not only be more innovative, but cheaper and more time efficient. Data-driven approaches have the potential to create value across manufacturing, supply chain, and the entire health care ecosystem.

Creating new value for all stakeholders and themselves: To create value for patients, organizations are expected to focus on providing a holistic patient experience - mapping all the touchpoints that patients may experience throughout their journey with their caregivers. Patients and caregivers could connect digitally and address needs ranging from diagnosis to maintenance. Medical device companies could develop more user-friendly devices and look at ways to offer patient-centered services in nonclinical settings, driven by technology and connectivity. From a workforce standpoint, organizations can leverage technologies for meaningful work with flexible work models revolving around human-machine collaboration.

To create value for themselves, organization lacking such capabilities are expected to make technology investments either through acquisitions or via in-licensing of software applications. Such technology investments are expected to play a key role across compliance, risk management, and to enhance real-world evidence and drug discovery, among others.

Leveraging opportunities and increasing efficiencies: AI is ushering in a new era of intelligent drug discovery and is expected to lead to new developments. Demand for personalized treatments is driving operations away from large scale factories to smaller but many facilities. Data-driven manufacturing is helping companies with renewed focus on quality and compliance and helping companies become more agile and reduce the number of days it takes to release a drug product. With AI and augmented reality (AR), organizations could track productivity in real time, as well as reduce the risk of human error.

Building blocks for the future: New therapies coming to the market such as cell and gene therapies, as well as therapies for orphan indications address high unmet need but carry high treatment costs. Healthcare systems are unlikely to be able to absorb the costs of such expensive treatments. As a result, drug manufacturers are expected to move beyond just selling their products and also look at innovative pricing and reimbursement models to promote market accessibility.

Device generated data and analytics would help in real time and personalized decision making and help improve patient outcomes. Collaborations between drug manufacturers, technology companies and medical device manufacturers could pave the way for greater patient centricity as the traditional business models of the industry are challenged.

Beyond this, stakeholders including shareholders are scrutinizing companies on non-financial aspects such as environmental and social facets. Companies are likely to look at ways, including public-private partnerships, to more closely align their corporate social responsibility (CSR) with innovation and patient programs, as it will not just benefit them but society as well.

Pricing and Access

The growing demand for healthcare due to demographic change is further constraining healthcare providers with push for universal healthcare coverage. As difficult economic conditions are burdening, patients with out-of-pocket expenses relating to medicines, Government and payer budgets remain subject to increasing reviews.

The pricing of biopharmaceutical products continues to draw significant attention from Governments and the public, with calls for better transparency on how prices are set and a greater emphasis on health outcome-based pricing. Specialty drugs are increasingly being used for treatment of complex, chronic or rare conditions, and pricing for these products reflects the higher value they bring to patients and payers, as well as the smaller patient numbers as a result of targeted treatment options.

Pricing controls and transparency measures remain a priority in many markets, including key markets such as China, Europe and several emerging economies. In China, the authorities accelerated progress towards bringing innovative treatments to market. This included increasing the pace and frequency of reimbursement coverage, especially for oncology drugs. Governments elsewhere pursued implementation and expansion price control measures for medicines. International reference pricing continued to gain traction, although many countries engaged in negotiation of confidential contracts with manufacturers.

There continues to be pressure on pricing in the United States, where Federal and State policymakers are considering legislative and regulatory efforts to lower drug prices and to implement transparency measures. The current administration is undertaking a comprehensive review of drug pricing and its reimbursement, and along with the Congress, remains focused on healthcare policy priorities, including efforts to increase competition and generic drug use in Government programs. This is likely to create downward pressure on pricing. Federal agencies in the United States remained on course with proposing and implementing policies & programs with the goal of reducing costs, increasing transparency, transforming the delivery system, and improving quality and patient outcomes.

Rhetoric around drug pricing is only going to increase as the US presidential election gets closer, keeping a sector already unpopular with voters under the spotlight. While the political stand-off would mean that US lawmakers may not agree on any new measures any time soon, it is evident that the cost of medicines will remain a live issue in 2020.

Despite this, therapies that are clearly differentiated in areas of unmet medical need will continue to attract strong coverage and funding globally. To expand access to drugs, cell and gene therapies, life science companies may need to align their commercial models with changing market dynamics in advanced markets such as the United States and Europe.

Regulatory Environment & Geopolitical Uncertainty

The biopharmaceutical industry is highly regulated with public expectations that available medicines be safe, effective and of high quality. We are also witnessing introduction of Government policy and regulation to accelerate innovation in drug development. Regulatory health authorities are implementing programs intended to speed up patient access to transformative medicines. These include China, Japan and the United States. Other countries are also working on work sharing processes wherein review pathways relying on assessment conducted by reference agency have been introduced in many countries to speed up patient access to medicines.

Several uncertainties are also present in the industry; disputes over healthcare policies in the United States are expected to continue and rhetoric rise with the upcoming Presidential elections scheduled during this year. The election is is expected to cause uncertainty for all market players' with financial markets expected to display volatility for larger section of listed biopharmaceutical companies. In Europe, they include how the United Kingdom (UK) might work with the EU regulatory system after the expiry of the transition period, following its exit from the EU in January 2020 and the approach the UK might take to establishing its own regulatory system outside of the EU. The relocation of the EMA from London to Amsterdam, Netherlands has resulted in some delays and disruption to regulatory processes.

In biosimilar development, regulatory requirements for registration of products are now well established. However, significant areas of regulatory policy are still evolving including transparency of data regarding level of evidence to support approval of claims for biosimilarity in labelling, standards for interchangeability & pharmaceutical substitution, and traceability of pharmacovigilance reports through naming conventions that permit differentiation of products. Furthermore, transparency in data used for regulatory decision making is an area of increasing interest among global regulators such as that of US and EU.

Impact of COVID-19 on the Global Biopharmaceutical Industry Landscape

While the human cost and economic disruptions of the global pandemic have created shock waves, the mission of the pharma industry to maintain a steady supply of vital medicines and deliver new innovation has remained a steady focus. While other sectors may be more threatened by the pandemic, the business challenges facing pharma are urgent, like ensuring that supply chains are functioning so patients can get needed prescriptions filled and remain on critical therapies. As a result, companies are moving decisively to ensure patient health, manage disruptions and lead the development of a vaccine, antiviral or other therapeutic solution for COVID-19.

Companies have faced disrupted supply chains, delayed clinical trials and lack of access to physicians and other medical forums. During the course of this pandemic, patients either have been unable or unwilling to visit physicians for new diagnoses or prescriptions or refills. This trend could continue in the coming months as well and could result in fewer prescription and potential reduction in offtake. Companies will have to innovate to alleviate such situations by working with payers, providers and patients and increase the use of digital mediums and technology and facilitate interactions among physicians and patients and clearing of backlogs for diagnoses and fulfilment of prescription requirements.

Product launches by pharma companies may be delayed, and those that go ahead may fall short of expectations, given the impediments to commercializing drugs at the same speed and scale in the current environment. Once the public health crisis is over and business operations return to normal, pharma executives will need to adjust go-to-market strategies for previously planned product launches. Leveraging digital tools would be one way improving productivity of the field force which is currently unable to meet with physicians in their office to promote the products being launched by the pharma companies.

The COVID-19 crisis also will have indirect effects for the broader pharma environment, including reduced funding for early-stage biotech companies and diminished demand for contract research organizations. Research funds will also be diverted towards finding a cure for COVID-19, both at government level as well as at the level of private enterprise. Importantly, the underlying economic crisis triggered by the COVID-19 pandemic will have a significant ripple effect on state and national budgets. Urgent and costly measures to shore up businesses and support individuals will force governments to contain outlays in every category, including healthcare. This will result in pricing pressure on both commodity as well as specialty drugs and the bar of incremental innovation required for premium-price drugs will continue to rise.

In this backdrop, while the industry does not face a crisis, it needs to effectively respond to the challenges posed to ensure short to medium term visibility of not only its financial performance but also of its pipeline on which rests the long term potential of the sector. Companies therefore may have to be prudent to allocate spend, including deferment of some projects, to offset any such potential headwinds to in the current business environment. If the impact of this pandemic lingers for much longer, it could negatively influence the outlook that has been laid out in the sections earlier.

Our Strategic Response

At Biocon, our strategy is to bring differentiated, high-quality affordable products with high unmet need to the global marketplace and make these products available to patients, partners and healthcare systems across the globe. Our long-term priorities involve a specialty play underpinned by scientific and technical know-how, vertical integration, talented people, quality culture, strong global partners and customers. We remain confident to deliver on our goals across various business segments.

We believe the choices we made in the past, which revolve around complexity of development and involve breadth and depth of various technology platforms, are the key differentiators giving us a competitive advantage in all our business segments. We continue to invest in enhancing our quality management systems, developing products in our portfolio and manufacturing and research infrastructure to cater to our existing and new products pipeline.

Business Review

Small Molecules API and Generic Formulations

Our Small Molecules business is built on our unique strength in fermentation technology and entrenched presence in the chronic therapies. Our differentiated portfolio spans complex molecules ranging from cardiovascular and anti-obesity agents to immunosuppressants and narrow spectrum antibiotics. We will continue to invest in and grow our portfolio of differentiated Active Pharmaceutical Ingredients (APIs) which may have technical barriers to entry, e.g. complexity in manufacturing, potent compounds or a mix of both.

Over the years we have built a good track record with the leading regulatory agencies across the globe including FDA and EMA. Our global scale coupled with our good compliance record at our manufacturing facilities has made us a preferred global partner for APIs for our customers. By investing further in expanding capacities of our complex APIs and by investing in newer and complex molecules, we believe there is much promise for continued growth based on our selected portfolio.

Table 4: API Sample Portfolio –

Statins Basket	Simvastatin, Pravastatin, Atorvastatin, Rosuvastatin, & Fluvastatin
Immunosuppressant Basket	Tacrolimus, Sirolimus, Everolimus, Mycophenolate Mofetil & Mycophenolate Sodium
Other Key Products	Orlistat, Fidaxomicin

Currently, the API business contributes significantly to the Small Molecules business segment. , However, going forward, the growth in this segment will increasingly be driven by building on the generic formulations opportunity across global markets, notably United States.

A few years ago, we started developing generic formulations pipeline primarily focused on developed markets and targeting niche therapeutic areas such as oncology, diabetes, autoimmune diseases and immunology. The product pipeline was focused on leveraging in-house APIs to ensure supply reliability due to vertical integration in the chronic areas. Over the next five years, we aim to continue to leverage our strengths in fermentation technology and characterization techniques to build on this vertically integrated pipeline in the niche formulations space. The strategy is to build a robust pipeline of difficult-to-make, technology-intensive molecules which can be commercialized in several global markets including the United States. The combination of a strong R&D team, world-class manufacturing facilities approved by international regulatory agencies and a dynamic commercial team have helped this fully integrated business expand the available commercial opportunities globally.

We continue to be judicious in pursuing the generic formulations opportunity, which is reflective of the current and expected market dynamics in the United States. We will continue to pursue select opportunities which meet our internal selection bar for complexity in manufacturing or development and vertical integration.

Table 5: Generic Formulations Sample Portfolio –

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

FY20 Highlights:

Geographic expansion into China: Biocon extended its footprint to China, the world's 2nd largest pharma market through a license and supply agreement with a subsidiary of China Medical System Holdings Limited (CMS) for three generic formulations products. This agreement will allow Biocon to take its US approved generic formulations to patients in China, allowing an early entry into the Chinese market. Biocon will be responsible for the development, manufacturing and supply of the products while CMS will be responsible for registration and commercialization. The total addressable market size for the three products in Mainland China is a little under $1 billion as per IQVIA data.

API capacity expansion: During FY20, we started work on a greenfield fermentation-based manufacturing facility in Visakhapatnam, Andhra Pradesh to cater to strong volume growth anticipated in the small molecules APIs business. This expansion will enable us to deliver on our vertically integrated strategy of developing and commercializing our own ANDAs and also service the needs of our global API customers. Expected investment in this capacity is roughly ₹ 600 Crores and the facility is expected to be operational over the next three years, followed by commercialization based on regulatory approvals in major markets.

DMF and API Filings: During the year under review, we filed new Drug Master Files (DMFs) and equivalent for multiple APIs, mostly in the regulated markets.

Regulatory compliance and recognition: At Biocon, we remain committed to global standards of Quality and Compliance and are proud of our track record. We had a number of key inspections during the financial year, including those conducted by the FDA.

Biocon's Oral Solid Dosage Manufacturing Facility completed a Pre-Approval Inspection (PAI) conducted by the FDA with no observations in January 2020. This fiscal, we also received approval from Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom for this facility as well.

On the API side, the FDA conducted a PAI and GMP inspection of the Small Molecules API Manufacturing Facility in January 2020. At the conclusion of the inspection of the Bengaluru facility, which took place between January 20 and January 24, 2020, the agency issued a Form 483, with five observations. We responded to the FDA with a Corrective and Preventive Action Plan (CAPA). In May 2020, the FDA issued an Establishment Information Report (EIR) for the same and closed the inspection.

Health Canada conducted a GMP inspection of our Small Molecules API Manufacturing Facility in January 2020. At the conclusion of the inspection, we received multiple observations. We responded to Health Canada with a Corrective and Preventive Action Plan (CAPA) and are working to address these observations expeditiously.

In February 2020, the FDA conducted a post-approval and GMP inspection of another Small Molecules API Manufacturing in Bengaluru and issued two observations on Form 483. Biocon responded to those observations. In March 2020, the FDA issued an Establishment Information Report (EIR) for the same and closed the inspection.

Apart from the FDA, our API manufacturing facility in Bengaluru successfully underwent an inspection by COFEPRIS, the Mexican health regulatory agency and reported zero observations and our Vishakhapatnam site was also inspected by KFDA, South Korea without any major observations.

Our Small Molecules APIs manufacturing facility in Hyderabad won the 'Annual Greentech Environment Award 2019' for 'Outstanding Achievements in Environment Management in the Pharmaceutical Sector'.

The API Manufacturing facility at Visakhapatnam was recognized for 'Outstanding Achievements in Safety Management' in the Pharmaceuticals sector during the Annual Greentech Safety Award' Program in New Delhi.

Performance of Small Molecules Segment in FY20 - Small molecules is the largest segment for our Company, contributing 32% of consolidated revenues from operations in FY20. Revenues were ₹ 20,937 mn in FY20, as compared to ₹ 17,728 mn in FY19, reflecting a growth of 18%. The performance in FY20 over the previous fiscal was driven by a strong performance of our generic formulations in the US on the back of consistent client acquisitions and increased market share for all our products. This was aided by API business performance driven by a better product mix and an overall better pricing environment over last fiscal.

Biologics (Biosimilars & Novel Biologics)

Biosimilars

Biocon's subsidiary Biocon Biologics India Limited is uniquely positioned as a fully integrated 'pure play' biosimilars organization in the world. It aims to be the 'Most Inspiring Global Leader in Biologics' delivering affordable access to innovative and inclusive healthcare solutions, transforming patient lives. It is engaged in developing high quality, affordable biosimilars that can expand access to a cutting-edge class of therapies to patients globally.

Biocon Biologics is an established and vertically integrated global biologics player that has invested ahead of peers in this exciting field. Over 40 years of experience in science and manufacturing at Biocon laid the foundation for Biocon Biologics. It entered this area over 15 years ago with focus and determination to take the path less travelled, which has enabled it to be an early mover in biosimilars.

Its rich pipeline of differentiated assets aims at serving unmet patient needs associated with non-communicable diseases in emerging as well as developed markets. Biocon Biologics' therapeutic focus is in developing molecules in the area of diabetes, oncology, immunology, dermatology, ophthalmology, neurology, rheumatology and inflammatory diseases. Five of the portfolio of molecules have been taken from lab to market, of which three of them having been commercialized in developed markets like EU, Australia, United States, Canada and Japan. Biocon Biologics' expects a steady stream of launches every year in these developed markets over the next few years. Biocon Biologics aims to touch touching 5 million patient lives by FY22 and cross a revenue milepost of US$1 billion.

Biocon Biologics' unique position as it aims to be the 'Most Inspiring Global Leader in Biologics' is highlighted in the few points in paragraphs below.

High barriers to entry: The development of biosimilars requires the confluence of multiple high-end skills 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 for developing biosimilars are significantly high and the time for their development is long in comparison to the cost and time for development of conventional chemical synthesis-based "small molecule" generic pharmaceuticals. Technical know-how needs to be well supported by infrastructure investments of global scale, coupled with a strong focus on profitable commercialization, to support a long term play.

Along with our partners, we have invested over a billion dollars to develop our portfolio assets, and in creating commercial scale manufacturing capacities to address global volume requirements across multiple manufacturing platforms. We remain committed to making additional investments in R&D and in enhancing our manufacturing capacities. We are now building strong commercial, policy and access expertise to build differentiation and providing further credence to our unique position as a fully integrated 'pure

play' biosimilars organization in the world. We expect this to help us move closer to our aspiration of being the 'Most Inspiring Global Leader in Biologics', delivering affordable access to innovative and inclusive healthcare solutions, transforming patient lives.

Quality focus and global scale: Biosimilars are expected to provide affordable and accessible alternatives to originator biologics for patients and an opportunity for Governments across the world to rein in burgeoning healthcare spends. By nature, development of biosimilars requires quality focus and global scale to deliver these efficacious therapies across the world. Biocon Biologics has been an early mover in the development and commercialization of biosimilars and has become the leading player based out of India (based on number of US and EU biosimilar approvals) and in other key markets, like Brazil. Biocon Biologics would like to feature itself as a true global player. Its commitment to provide access to high quality, yet affordable, biosimilars to a global patient pool led it to develop the technology, critical mass and skillsets for producing these complex molecules at a time when there were few credible global players.

Focus on access: Improving patient access to high quality, affordable products in chronic conditions such as diabetes and oncology are core to Biocon Biologics' mission to be the 'Most Inspiring Global Leader in Biologics'. With its "Mission <10 cents" Biocon Biologics wants to enable equitable access to recombinant human insulin (rh-Insulin) by offering it at less than 10 US cents/day for low and middle-income countries to address the growing incidence of diabetes. Chairperson Kiran Mazumdar-Shaw announced this initiative on the side lines of the 74th Session of the United Nations General Assembly in September 2019 with the intention to improve access in geographies with high unmet need. The announcement has been very well received and Biocon Biologics is working now with various governments to deliver on this commitment.

Focus on digital: As part of its vision of 'Transforming healthcare, Transforming lives' and to become the "Most Inspiring Global Leader in Biologics", Biocon Biologics' initiatives include a huge emphasis on using digital innovation to deliver value to Patients, People, Partners and Business. These include shaping the digital healthcare ecosystem, leveraging cutting-edge technology across R&D to achieve scientific excellence, global scale manufacturing with AI/ML equipped systems to enable innovative delivery and archetype-based technology-driven operating models that will allow it to serve patients at the center of the income pyramid. While these are early days, work on such initiatives has started and should help Biocon Biologics to be able to continuously innovate and differentiate as a global leader in Biologics.

Strategic partnerships: To become the 'Most Inspiring Global Leader in Biologics' delivering affordable access to innovative and inclusive healthcare solutions, transforming patient lives required the company to have marquee partnerships with large global companies to help develop and make accessible its disruptive and differentiated portfolio of biosimilars consisting of 28 molecules across the globe. Of the 28 molecules in the pipeline, 11 are partnered with Mylan, a global generics major and, several partnered with Sandoz, the current global leader in biosimilars by revenue. These major partnerships are well supported with strategic tie ups with major local commercialization players in key emerging markets. The balance portfolio is being developed independently by Biocon Biologics while trying to maximise innovation.

Evolution of Development and Commercialization Models: Biocon Biologics has taken a step-wise approach to move up the accountability and capability curve with the ultimate goal of carrying independent global development and commercialization of biosimilars under the Biocon Biologics label in the years ahead. This will help the company to address the opportunity from the third wave of biosimilar patent expirations. Biocon Biologics is therefore also beginning to expand its presence in markets outside of India (including the US) in order to more closely collaborate with partners and to open opportunities for direct commercialization and to leverage digital technologies and innovative access models where appropriate. This unique position of Biocon Biologics should help it deliver affordable access to innovative and inclusive healthcare solutions, transforming patient lives in the years ahead.

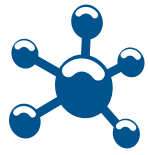
Several firsts to our credit in the area of biosimilars:

- 1st biosimilar Trastuzumab to be approved anywhere in the world developed and launched in India by Biocon Biologics (2014). With regulatory approvals secured in more than 75 countries globally, we are on our way to becoming a true global player.
- 1st company from India to launch a biosimilar in Japan: Insulin Glargine (2016). We have received more than 40 regulatory approvals for Glargine. The product has been launched in EU, Australia and several emerging markets.
- 1st company globally to get FDA approval for biosimilar Trastuzumab; 1st company from India to have a biosimilar approved in the U.S. (2017). Launched in U.S. in December 2019.
- 1st company from India to have a biosimilar commercialized in U.S.; 1st biosimilar Pegfilgrastim approved by FDA (2018)
- 1st Company from India to launch biosimilar Trastuzumab in Europe (2019)

- Ogivri™, co-developed by Biocon Biologics and Mylan, is the first trastuzumab biosimilar approved and launched in Australia as well as Canada.
- Semglee, co-developed by Biocon Biologics and Mylan, is the first Glargine biosimilar approved and launched in Australia

BIOCON BIOLOGICS' GLOBAL BIOSIMILAR PORTFOLIO

PIPELINE OF **28** MOLECULES



Biocon Biologics
Transforming Healthcare. Transforming Lives.

BIOCON BIOLOGICS is independently developing many biosimilar assets

Mylan®

With **MYLAN**, 11 biosimilars being co-developed for global markets

SANDOZ A Novartis Division

With **SANDOZ**, set of next-gen immunology, oncology biosimilars being co-developed for global markets

STATUS OF BIOCON BIOLOGICS-MYLAN PARTNERED PORTFOLIO (May 2020)

Biocon's strong development & manufacturing capabilities

+

Mylan's regulatory & commercial excellence

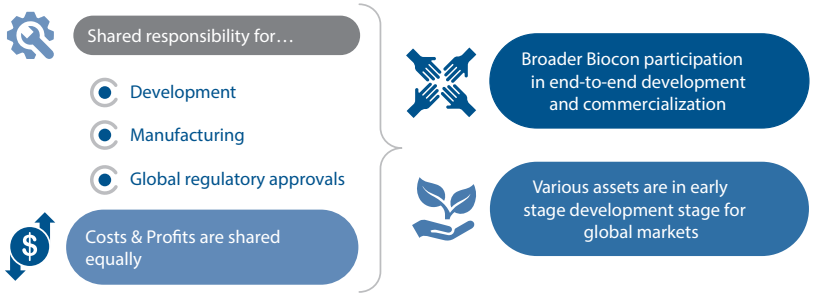
Cost and profit share model

THERAPEUTIC AREA	MOLECULE	STATUS		
		US	EU	MoW
Oncology	Trastuzumab			Launched in Australia, Canada & Emerging Markets.
	Pegfilgrastim			Approved in Canada and Australia
	Bevacizumab	Under Review	Under Review	Launched in India
	Filgrastim			-
	Pertuzumab			-
Diabetes	Glargine 100 IU/ml	Under Review		Launched in Australia, Japan* & Emerging Markets. Approved in New Zealand.
	Glargine 300 IU/ml			-
	Aspart	Mid CY20	Under Review	-
	Lispro			-
Autoimmune	Adalimumab**			-
	Etanercept**		+ CHMP opinion	-

Early Development/ Preclinical | Planned Submission/ Filed | Approved | Marketed

* Japan is outside of Mylan partnership, ** Partner Mylan has in-licensed product (Biocon benefits from economic interest)

BIOCON BIOLOGICS - SANDOZ EXCLUSIVE PARTNERSHIP



FY20 highlights: FY20 has been another great year for our biosimilars business. We launched products across markets, received and also filed for regulatory approvals across developed and most of the world markets. We also enhanced capacity for two of our major products and launched our 10 cents mission in human insulin.

Biosimilars: Highlights FY20

Product Launches: Ogivri™, biosimilar Trastuzumab, co-developed with Mylan was launched in the United States during FY20. Ogivri™ had already received approval in the United States in December'17, where it was the first biosimilar Trastuzumab to be approved. It is the second biosimilar from our partnered portfolio commercialized in the United States after Fulphila®, biosimilar Pegfilgrastim which was launched in FY19. Ogivri™ was also commercialized in Australia, Canada and additional EU markets by Mylan. It was launched in Europe towards the end of FY19. Through our biosimilar Trastuzumab, we continued to enhance access to a critical biologics therapy for cancer patients in several emerging markets as well.

Semglee®, our biosimilar Insulin Glargine co-developed with Mylan, was launched in Europe during FY19. During FY20, Mylan expanded access for Semglee® in more markets within Europe. The FDA conducted a pre-approval inspection (PAI) at our Malaysia facility in February'20 as part of the review process of our application for the US market. At the conclusion of this PAI, the agency issued a Form 483 with three observations which were procedural in nature. We responded to the observations within stipulated timelines and have received the Establishment Inspection Report (EIR) from the US FDA with a "VAI" (Voluntary Action Indicated) classification indicative of a successful closure. The closing of the Malaysia facility inspection is an important milepost in our journey of making available our Insulin Glargine product in the United States in the second half of CY'20.

Transition of insulins to be regulated as Biologics from March 23, 2020 – In the United States, although the majority of therapeutic biological products have been licensed under section 351 of the Public Health Service Act (PHS Act), some protein products (which also include insulins) historically have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). As per the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), insulins transitioned to be regulated as a Biologic from March 23, 2020. This transition would have caused problems for generic insulin developers who had filed their application for review but had not received their final approval before the transition date, including Biocon Biologics/ Mylan. However, a legislation was passed into law in December'19 mandating the FDA to continue review of pending insulin marketing authorization applications under section 505 of the Federal Food, Drug and Cosmetics Act even after the transition. As a result, the transition did not affect our application review by the FDA. The continued review is expected to help Biocon Biologics and Mylan enable access to Semglee® to patients in the United States at the earliest. With the target action date for our application in June'20, our partner Mylan expects to launch Semglee® in the United States in the second half of CY'20.

Mylan commercialized biosimilar Adalimumab (Brand name Hulio™, in-licensed from a third party - Fujifilm Kyowa Kirin Biologics) in FY19 in Europe in which Biocon Biologics receives economic benefit. It extended the commercial footprint of Hulio™ to additional markets in Europe during the year under review and Biocon Biologics benefitted from higher sales and market shares of Hulio™ across key markets. Mylan also extended the commercialization rights for Hulio™ from Europe to global markets and Biocon Biologics under the terms of its global partnership with Mylan for monoclonal antibodies, retains its economic interest in this expanded in-licensing arrangement, and will gain a share of profits from global markets.

Pipeline development updates: On the development front, our partner Mylan filed a Biologics License Application (BLA) for our proposed biosimilar Bevacizumab in the United States and a Marketing Authorization Application in Europe. In the United States, FDA has accepted Mylan's BLA for review under the 351(k) pathway. The FDA goal date set under the Biosimilar User Fee Act (BsUFA) is December 27, 2020. The European application has also been accepted and is under review.

Nepexto®, brand name of an etanercept biosimilar, in-licensed by partner Mylan from a third party (Lupin) for Europe and other markets, gained a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP), recommending use of the product. Biocon Biologics retains its economic interest in this arrangement vis-a-vis Mylan in accordance with our existing collaboration agreement.

Our biosimilar Insulin Aspart program also continues to make progress with BLA filing in the United States expected in mid-CY'20. The Marketing Authorization Application has also been filed in the EU and the file is currently under review.

From our independent portfolio, we are developing recombinant human insulin for the US market which made good progress in Phase-I PK/PD clinical trials. The Phase I studies were successful and we expect the study reports to be available in the next few months, post which we expect to start Phase-III trials, for which advice is being sought from the FDA.

Biocon Biologics also in-licensed an early stage preclinical biosimilar asset from Just - Evotec Biologics, a subsidiary of Evotec SE and will develop, manufacture and commercialize the biosimilar under the Biocon Biologics label in global markets. Just - Evotec, received an undisclosed license fee and will receive milestone payments.

Capacity enhancements: Our investment strategy for manufacturing has been to build capacity in a modular manner, in-line with our projections of the market opportunity. This has allowed us to scale up capacity in response to higher-than-expected demand, even as we balance exposure to any underutilized capacity and costs in the early phase. We will continue to invest in expanding our manufacturing capacities to address volume growth on account of increased penetration of our products in developed and emerging markets and also to support new biosimilar pipeline development and launches.

In October'19, Biocon Biologics and Mylan received US FDA approval for the supplemental Biologics License Application for an additional production line to manufacture Ogivri™ 150 mg per vial drug product. The same manufacturing line is also certified by the EMA and significantly enhances our drug product capacity for supplying Trastuzumab to the US, EU and other markets. The approval follows a pre-approval inspection of Biocon Biologics' new drug product facility as what we refer to as the B2 biologics facility that was conducted in September'19.

In November'19, Biocon Biologics and Mylan's supplemental Biologics License Application (sBLA) for Pegfilgrastim drug substance to be manufactured at Biocon Biologics' new Biologics manufacturing facility was approved by the FDA. This approval enables Mylan and Biocon Biologics to scale up capacity multi-fold and address the growing market opportunities in the United States and other global markets for the product.

The first phase of our state-of-the-art, new 250,000 square feet Drug Substance facility for monoclonal antibodies at Biocon Park, Bengaluru has been commissioned in late FY20 and is undergoing qualification which will be followed by validation activities. Commercial operations from this new facility are expected to start late FY21 or early FY22. This facility once fully ready for commercialization will expand our capacities significantly and will enable us to address the growing patient needs across markets.

Expansion of R&D footprint: Biocon Biologics expanded its R&D footprint during the year by acquiring Pfizer Healthcare India Limited's R&D capital assets to set up a 60,000 square feet world-class integrated R&D facility at TICEL Bio Park in Chennai. The high end facility will enable Biocon Biologics to expand its R&D capability and fast forward the development of its biosimilars from lab to pilot scale. The facility, post qualification has the capacity to house over 200 scientists.

Value unlocking of the biosimilars business: An important development during the financial year was the investment of $75 million by Activ Pine LLP, an affiliate of True North Fund, in Biocon Biologics India Limited. This was a primary equity infusion for a 2.44% stake at an equity valuation of $3 billion and an enterprise valuation of $3.5 billion on a pre-money basis. Biocon Biologics will deploy the money towards CAPEX investments as well as on R&D. The investment validates Biocon Biologics'science, scale, scope, strategy and its current business and future prospects. It also reflects a high level of conviction in Biocon Biologics' status as a global frontrunner in biosimilars that is leveraging its large scale manufacturing capabilities to shift the access paradigm for these life-saving therapies.

Novel Biologics

The Novel Biologics portfolio has both in-house as well as partnered and in-licensed products targeting diabetes, immunology inflammation and oncology including immuno-oncology. Biocon's focus on innovation for global markets continues to be strengthened by directing efforts at increasing scientific depth and emphasis on bolstering our in-house research capabilities – including access to novel IP, therapeutic modalities, in-vivo and in-vitro models, toxicology studies, early regulatory filings, academic collaborations etc. In the development phase, broader global advancement of our novel program assets will likely be driven via external collaborations to further fund the larger studies required to bring these novel molecules to market and realize the full value of our innovations.

Our basket of novel assets under development, represent an interesting combination of early and advanced stage programs, comprised of therapeutics that aim at treating diabetes, oncology and auto-immune/inflammatory diseases. These therapeutics span across multiple modalities - including recombinant proteins, novel fusion antibodies and monoclonal antibodies (mAbs),

BIOMAb EGFR® (Nimotuzumab) was India's first indigenously produced novel monoclonal antibody for the treatment of head and neck cancer, launched by Biocon in 2006.

We also launched ALZUMAb™ (Itolizumab), world's first novel anti-CD6 monoclonal antibody, in India, for psoriasis in 2013. It was the second novel biologic we had taken from 'lab to market' after Nimotuzumab.

We continue to pioneer 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	India Phase II in T2D completed, Phase Ib multiple ascending dose study in T1D patients initiated in Germany
Immuno-Oncology	EGFR mAb + TGFßRII* (FmAb2) (Tumor-Targeted Fusion mAb)	IND filed, received "study may proceed" advice from FDA
Inflammation	Itolizumab* (Novel, humanized CD6 Antibody)	U.S., CA, AUS and NZ rights out licensed to US based Equilluim, clinical trials ongoing in aGVHD. Uncontrolled asthma and lupus nephritis trials – patient recruitment paused due to COVID-19 pandemic.
	BVX20# Novel, humanized CD20 Antibody	Path to IND mapped out

* In - house program, # partnered with Vaccinex

In diabetes, Biocon's Insulin Tregopil, is a first-in-class oral prandial insulin molecule for post-prandial glycaemic control. A Phase II study in Type 2 diabetes patients in India was initiated in FY18. The India study has been completed and report on the outcome is being prepared. Based on encouraging safety and efficacy data highlighting effective control of 1 hour and 2 hour post prandial glucose (PPG) excursion across multiple studies, we plan to submit a marketing authorization application to DCGI, India's drug regulator. The marketing application is aimed at gaining approval for a limited indication to treat Type 2 diabetes (T2DM) patients who cannot adequately control their PPG excursion following meal intake. Additionally, for Type 1 diabetes (T1DM) patient population, a multiple ascending dose study, in partnership with the US based JDRF, a leading global organization funding Type 1 diabetes research and advocacy worldwide, has commenced in FY20 in Germany. The outcome from these studies in different diabetic patient populations will form the foundation of a broader global program envisioned for Insulin Tregopil.

Bicara Therapeutics: Biocon's Immuno-oncology program focusing on development of novel bi-functional fusion antibodies is housed in its wholly owned subsidiary Bicara Therapeutics, based out of Boston in the United States.

FmAb2, Bicara's lead program, which comprises EGFR and TGFß, is currently ready to initiate a Phase I study in the US and Canada. This bifunctional fusion antibody works on the concept of preferentially targeting the tumor micro-environment. We received "study may proceed" advice from the FDA to initiate a Phase I safety trial in the US following a successful Investigational New Drug (IND) application in late FY20. We are also using the fusion antibody platform to generate other novel bi-functional antibodies.

Out-licensing partnership with Equillium: Biocon is the first global company to biologically and clinically validate CD6 as a target for autoimmune diseases. In May 2017, Itolizumab, our novel humanized CD6 antibody was out licensed for the United States and Canada markets to US based biotechnology company Equillium. During the fiscal year under review, we expanded the scope of our licensing agreement with Equillium for Itolizumab, to include Australia and New Zealand. Itolizumab holds broad potential 'pipeline in a product' with multiple high-value indications applicable with three clinical studies underway across the globe in aGVHD, uncontrolled asthma and lupus nephritis.

Table 7: Summary of developments status EQ001 (Itolizumab):

Pulmonary		Phase I	Phase I b/ 2	Phase III
uncontrolled asthma	EQUIP Phase 1b uncontrolled moderate to severe asthma trial initiated June 2019 Initial data expected 2H 2020	Phase I b		
Transplant Science		**Phase I**	**Phase I b/ 2**	**Phase III**
aGVHD	EQUATE Phase 1b/2 aGVHD trial initiated March 2019 Data to inform further development in GVHD, e.g. GVHD prevention, cGVHD	Phase I b / 2		FDA Fast Track Orphan Drug Designation
Renal Disease		**Phase I**	**Phase I b/ 2**	**Phase III**
lupus nephritis	EQUALISE Phase 1b trial initiated September 2019 Data to inform development in lupus	Phase I b		FDA Fast Track

Note: aGVHD trial is actively recruiting patients. However, due to Covid-19 pandemic, the patient recruitment is paused for uncontrolled asthma and lupus nephritis.

To fund the clinical trials, Equillium raised US$65 mn in its maiden public offering, and listed on Nasdaq on October 12, 2018. Biocon holds a ~13.1% stake in Equillium, among other rights as part of the out licensing agreement.

Performance of Biologics Segment in FY20 – This year saw the biologics segment deliver an encouraging performance and once again being the strongest performing segment for Biocon, with revenues growing 29% over last year to ₹ 19,513 mn, representing 30% of consolidated revenues from operations. Growth was led by higher revenues from Pegfilgrastim in the United States and Trastuzumab in developed markets.

Strong revenue growth did not translate into improvement in segment profit margins as this was negated primarily by increased cost of operations with respect to remediation costs in Malaysia.

Branded Formulations (India and UAE)

Branded Formulations business segment comprises products sold under Biocon brand in the regional markets, currently in India and the UAE. This business focuses on specialty brands in critical therapies offering affordable and differentiated medicines of world-class quality to thousands of patients in India and UAE. 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, autoimmune diseases among others.

Branded Formulations India (BFI) – BFI is our flagship business because it represents our home country. Our primary focus is to serve patients and healthcare systems by delivering high quality biosimilars and medicines at an affordable price.

Despite many headwinds in FY20 our strategic products represented 70% of our sales. Although the overall business declined by 6% this was driven primarily by i) Significant downward pricing pressures, in our leading assets, and increased competition for both insulins and CANMAb™, our biosimilar trastuzumab in India ii) Supply issues related to the well-known challenges with the Malaysia plant also impacted the business and iii) In Q4 FY20 (Jan-March 2020), we were impacted by the COVID-19 situation but not as much as expected. Team BFI rose to the challenge to do everything to support its patients and everyday were innovating to partner with physicians to support patients and to innovate to ensure that patients that needed medicines received them. We even leveraged military cargo flights, rented cold chain trucks to ensure patient supply.

UAE – Our UAE is well diversified across a portfolio of products that include, biosimilars in-licensed second brands and branded generics. The business operates across therapy segments with key focus on cardiovascular, diabetes, gastrointestinal and respiratory therapy. Our top brands contributed to around 69% of sales.

FY20 was the first full year of sales post launch of our world's first biosimilar Trastuzumab Canhera™ in UAE. Within a span of a year Canhera™ has cornered a 30% volume market share in UAE retail market. Similarly, in FY20 our in-licensed second brands Jalra range and Imprida range have shown a substantial growth. With products like Jalra and Glaricon™, our diabetes franchise is ranked at 8th position in UAE diabetes market, clocking a 30% growth during the year under review.

While in FY20 volume for our branded generic products increased, this business faced strong headwinds as UAE Ministry of Health has effected a price revision across a range of our products. Overall there was a 40% price reduction across 60% of our product range. This resulted in a subdued performance for the business during the year under review.

Performance of Branded Formulations Segment in FY20 - In FY20, the Branded Formulations segment revenues declined 18% from ₹ 6,564 mn to ₹ 5,362 mn due to subdued growth in India and UAE. The UAE business continues to be impacted by re-pricing of branded generic products mandated by the Ministry of Health.

Research Services (Syngene)

Contract Research Organisations (CROs) undertake R&D activities on a contract basis for other organisations. Over the past decade, the contract research industry has witnessed rapid growth as companies increasingly outsource R&D activities to improve productivity and efficiency across their value chain.

The global CRO market is estimated to grow at a CAGR of over 7.6% during 2019 to 202 , to surpass $61 billion in terms of value by the end of this period[2]. Rising R&D investment, along with the increased focus on novel drug development for the treatment of cardiac diseases, cancers, neurological and infectious diseases, will be a major factor in driving the demand for CRO services.

Syngene was established in 1993 and is an innovation-led leading global contract research organization providing integrated research solutions spanning the discovery, development and manufacturing continuum for small and large molecules, antibody drug conjugates, and oligonucleotides.

Syngene operates in a range of collaboration models from long-term relationships and dedicated R&D centres to contracts based on number of scientists Full-Time Equivalent (FTE) and Fee-for-Service (FFS) arrangements. Clients can select any one – or a combination – of these models to deliver their R&D programs. It has three business divisions – Dedicated R&D Centre; Discovery Service, Development and Manufacturing Services.

FY20 highlights:

Dedicated Centres: Syngene operates four dedicated R&D centres for Bristol-Myers Squibb (BMS), Baxter Inc., Amgen Inc., and Herbalife. The long standing collaborations with these global leaders, extending between five and fifteen years, reflect the confidence Syngene has secured for its services. During the year, the Company achieved steady performance in its dedicated R&D Centres.

The Discovery Services division, comprising the scientific disciplines of chemistry, biology, safety assessment, and research informatics, delivered robust growth throughout the year as the result of contract renewals and expansion of partnerships with existing clients, as well as the onboarding of new clients. Several FFS-based collaborations moved to an FTE-based model, reflecting the maturing of these partnerships and affording additional value. In addition to expanding Syngene's presence in the human life sciences sector, the division saw growing demand from clients in other sectors, particularly animal health.

Robust integration of the core discovery-related disciplines, as well as enhanced collaboration with Development Services, has augmented Syngene's position as a service provider for fully-integrated therapeutic discovery. Syngene's range of capabilities and extensive drug discovery knowledge, spanning from early stages of target identification and validation, through to preclinical evaluation and preparation of drug substance and drug product for clinical testing, makes the Company a very attractive partner and offers opportunities to provide services to new customer groups such a start-ups, academia, venture capital, government and non-profit organizations.

A key highlight of the Discovery Services during the year was the opening of a state-of-the-art research and development centre in Hyderabad, India; a location that offers a strategic advantage due to its excellent infrastructure, good connectivity, and extensive scientific talent pool. With strong environmental credentials, the first phase of the centre will house 150 Discovery Chemistry scientists. It is equipped with an anytime, anywhere automated control system and electronic laboratory notebooks – an important step towards digitization.

A key scientific advance for the year was the extension of the company's cellular and gene therapy research capabilities into CAR-T therapy, an innovative and leading-edge approach to treating cancer. Several projects within Discovery Biology covering hypothesis-testing and validation of new biological targets, as well as the exploration of novel mechanisms related to CAR-T therapies, are underway.

The Development Services sub-division delivered steady performance during the year. New client projects were undertaken across the full range of services and multiple modalities. In particular, two new strategic collaborations in animal health increased the focus on that sector.

2 Source: https://www.globenewswire.com/news-release/2019/10/28/1936031/0/en/CRO-Market-value-to-cross-61-billion-by-2025-Global-Market-Insights-Inc.html

Notable scientific achievements during the year included the delivery of registration batches of multiple, modified-release tablet formulations of a drug that treats symptoms of multiple sclerosis for a Russian client — the result of a four-year collaboration. The Company also developed and validated a Human Papilloma Virus (HPV) assay, a test system increasingly being used for cervical cancer screening.

Manufacturing Services: The construction of the API manufacturing facility in Mangaluru, India, was completed on schedule and the facility will undergo qualification testing in the coming year. Once fully operational, it will allow the Company to offer commercial-scale manufacturing for small molecules.

For Biologics development and manufacturing, Syngene has invested in the latest R&D technology for large molecules and the Company's Biologics unit is an emerging capability. Two 2KL bioreactors were commissioned during the year, and a microbial manufacturing facility is being set up, strengthening the biologics manufacturing capacity. New client wins were recorded in the year to add to the expansion of renewal of contracts with existing clients. It also entered into contracts with leading industry players for the development of biologics in animal health.

Syngene has implemented a variety of initiatives to further improve its track record in the area of quality and compliance. Business specific quality manuals were introduced to enhance the focus on standards and industry regulations. Significant progress was made towards the total digitization of its Quality Management System. Digitization has brought in a high degree of visibility and control over operations and will be fully rolled out in FY21.

Syngene's commitment to complying with global quality and regulatory standards was reflected in the positive outcome of the inspections conducted at its facilities during the year. The Human Pharmacology Unit (HPU) and an analytical laboratory for general Good Manufacturing Practices (GMP) coverage successfully completed United States Food and Drug Administration (US FDA) inspections. The Company received approval from the Ministry of Health of the Russian Federation for compliance with current Russian GMP standards. The Company's viral testing facility received Good Laboratory Practice (GLP) certification from the National GLP Compliance Monitoring Authority (NGCMA), making it India's first and only GLP-certified viral clearance study service provider. Several client audits were also successfully completed, thereby reinforcing confidence in the Company's systems and processes.

Performance of Research Services Segment in FY20 - During the year under review, Syngene's revenues grew 10% to ₹ 20,119 mn. The performance was driven by a broad based growth across all business units, with improved traction in Discovery Services. Segment margins improved over last year driven by lower material costs and forex gain during the year.

Operational Performance

Overview of the financial performance of the Company 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, 2020 (FY20) and March 31, 2019 (FY19)

All Figures in ₹ Million

Particulars	FY'20	FY'19	Change
Assets			
Non-current assets			
Tangible, intangible and right- of- use assets	81,671	63,699	28%
Investment in associates and a joint venture	142	431	(67)%
Financial assets	1,764	2,495	(29)%
Income- tax assets (net)	2,417	1,693	43%
Deferred tax assets (net)	3,680	3,247	13%
Other non-current assets	1,514	1,474	3%
	91,188	73,039	25%
Current assets			
Inventories	14,359	10,316	39%
Financial assets	35,496	36,424	(3)%
Other current assets	3,395	2,145	58%
	53,250	48,885	9%
Total	1,44,438	121,924	18%

All Figures in ₹ Million

Particulars	FY'20	FY'19	Change
Equity and Liabilities			
Equity			
Equity share capital	6,000	3,000	100%
Other equity	61,058	57,980	5%
Non-controlling interests	6,773	6,089	11%
	73,831	**67,069**	**10%**
Non-current liabilities			
Financial liabilities	19,877	15,757	26%
Provisions and other non-current liabilities	10,650	8,713	22%
	30,527	**24,470**	**25%**
Current liabilities			
Financial liabilities	32,795	24,651	33%
Income- tax liability (net)	1,279	1,238	3%
Provisions and other current liabilities	6,006	4,496	34%
	40,080	**30,385**	**32%**
Total	**1,44,438**	**1,21,924**	**18%**

Non-current assets

Non-current assets grew 25%, primarily due to additions in tangible assets and capitalization of product development expenses. Additions to tangible assets pertain primarily to Biologics facility, Research Services (Mangalore facility), and other manufacturing facilities. Decrease in Financial assets is due to fair value of investments in Equillium Inc. and mark to market loss on derivative instruments, primarily driven by Research Services.

Other equity

Other equity majorly comprises of securities premium, treasury shares, retained earnings and other reserves. The total other equity of the company increased by 5% in FY20, due to profit accumulation during the year.

Non-controlling interests

The profit attributable to minority shareholders increased 11% in FY20, attributable to accumulation of profits of current year.

Non-current liabilities

Non-current liabilities increased by 24% in FY20, primarily due to an increase in other financial liabilities and deferred revenue. During the year, Biocon Biologics India Limited had approved a primary investment from Activ Pine LLP ("Investor") for ₹ 5,363 mn that translates to a 2.44% minority stake for the Group. As per applicable Accounting Standards, this has been recorded as financial liability in the consolidated financial statements. Increase in deferred revenues 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)

Working capital as at March 31, 2020 stood at ₹ 13,170 mn, down by 29% as compared to FY19 due to an increase in current maturities of long term borrowings, short term borrowing,advance from customers, and payables for capital goods offset by an increase in inventory. Borrowings are primarily in Biologics and Research Service businesses.

Debt equity

Total debt as at March 31, 2020 stood at ₹ 24,923 mn and the debt equity ratio stood at 0.37. No material changes that may affect the financial position of the Group, have occurred after the close of the year, until date of Directors 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, 2020 (FY20) and March 31, 2019 (FY19)

All Figures in ₹ Million

Particulars	FY'20	FY'19	Change
Total revenue	65,286	56,588	15%
Expenses			
Cost of materials consumed	20,522	18,966	8%
Employee benefit expense	13,279	10,617	25%
Finance costs	649	709	(8)%
Depreciation and amortization expense	5,522	4,478	23%
R&D expenses, net of recovery from co-development partners	4,392	2,899	52%
Other expenses	9,448	8,725	8%
Total expenses	**53,812**	**46,394**	**16%**
Share of profit of joint venture and associate (net)	(289)	9	(3,311)%
Profit before tax and exceptional item	**11,185**	**10,203**	**10%**
Exceptional item	675	1,946	(65)%
Profit before tax	**11,860**	**12,149**	**(2)%**
Tax expense	2,495	1,939	28%
Tax on exceptional item	656	184	259%
Profit for the year	**8,709**	**10,026**	**(13)%**
Non-controlling interest	1,227	973	26%
Profit attributable to shareholders of the Company	**7,482**	**9,053**	**(17)%**
Other comprehensive income attributable to shareholders	(1,314)	(552)	138%
Total comprehensive income attributable to shareholders of the Company	**6,168**	**8,501**	**(27)%**

Revenue

During the year under review, revenues grew by 15% on a consolidated basis from ₹ 56,588 mn to ₹ 65,286 mn. The Small Molecules segment revenues increased 18%, as it benefited from the launch of generic formulation products in the U.S., better product mix in APIs and an overall better pricing environment over last fiscal. The Biologics segment revenues grew by 29% primarily due to higher revenues from Pegfilgrastim and the launch of biosimilar Trastuzumab in the developed markets. Branded Formulations segment contracted 18% due to subdued growth in India and UAE. The UAE business continues to be impacted by re-pricing of branded generic products mandated by the Ministry of Health, while Contract Research segment (Syngene) turnover grew 10% driven by discovery services and development centers.

The Total Revenue composition for FY20 and FY19 is detailed below:

Table 3

Particulars	FY20		FY19	
	(₹ mn)	(%)	(₹ mn)	(%)
Small Molecules	20,937	32	17,728	31
Biologics	19,513	30	15,169	27
Branded Formulations	5,362	8	6,564	12
Research Services	20,119	31	18,256	32
Less:- Inter-segment revenue	(2,259)	(3)	(2,573)	(5)
Revenue from operations	**63,672**		**55,144**	
Other income	1,614	2	1,444	3
Total income	**65,286**		**56,588**	

Cost of materials consumed

Material costs for the year comprised of raw materials, packing materials, traded goods and change in inventories. In FY20, material costs, as a percentage of revenue from operations ex-licensing, decreased by ~3% as compared to FY19.

Employee benefit expenses

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 25% in FY20, driven by growth in business and annual increments.

Research and development expenses

The net R&D expenditure for FY20 increased 52% to ₹ 4,394 mn (₹ 2,899 mn in FY19). Total spend was at ~10% (8% on FY19) of revenue ex-Syngene. We capitalized ₹ 877 mn, taking gross R&D spend to ₹5,271 mn for the year compared to ₹ 4,796 mn in FY19. 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.

Depreciation and amortization

During this fiscal, depreciation and amortization increased 23% to ₹ 5,522 mn from ₹ 4,478 mn in FY19, primarily due to amortization of intangibles capitalized during the year in Biologics and commissioning of new facilities in Syngene.

Finance costs

The finance cost for FY20 at ₹ 649 mn (₹ 709 mn in FY19), primarily comprises interest cost on borrowings for Biologics and Research Services business The decrease is due to repayment of long-term borrowings

Tax expenses

Effective tax rate (ETR) for the year before exceptional item was 22% (19% in FY19). Lower effective tax rate in FY19 was primarily due to one-time benefit of carry-forward losses in BUK.

Exceptional items (net)

The Exceptional items during the year (FY'20) comprised the following:

1. Pursuant to the claims in relation to the fire incident on December 12, 2016 at Syngene, receivable and the disbursements from the insurance claim has been presented on a net basis as ₹ 713 mn under Exceptional items in the financial statements.
2. During the year, the Company entered into a License Agreement with Bicara granting license to develop, manufacture and commercialize fusion proteins. This sale resulted in a gain of ₹ 550 mn that has been recorded as an exceptional income in the standalone financial results of the Company. Related tax is included within tax expense in the standalone and consolidated financial statements.
3. During the year, the Company sold its investment in the equity shares of Biocon Biologics Limited, United Kingdom (BUK) to Biocon Biologics India Limited for a consideration of ₹ 10,810 mn and received dividend of ₹ 456 mn from BUK. Gain arising from such sale of equity shares, including dividend income have been included as an exceptional item in the standalone financial results. Related tax is included within tax expense in the standalone and consolidated financial statements.

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 fair value of investment in equity through FVOCI. The decrease is primarily due to lower gains on hedging instruments in FY'20 as compared to the previous year and loss on fair value of investment in equity of Equillium.

Key financial ratios

Particulars	FY20	FY19	Change
Debtors turnover	4.91	3.83	28%
Inventory turnover	2.35	2.87	(18)%
Interest coverage ratio	25.88	20.06	29%
Current ratio	1.33	1.61	(17)%
Debt equity ratio	0.37	0.39	(6)%
Operating profit margin (%) #	18%	18%	–
Net profit margin (%)*	11%	13%	(11)%
Return on net worth^	12%	13%	(13)%

 # Operating margin is defined as profit before taxes and interest

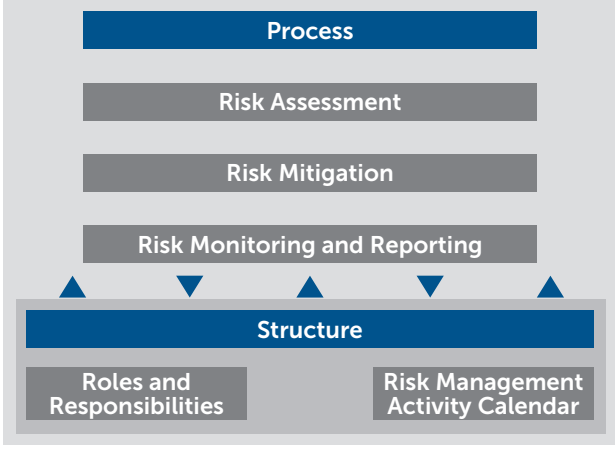
** Net Profit before exceptional income and tax thereon*

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

Risks, Threats and Concerns

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. A risk could be categorized into financial, operational, strategic, regulatory/ statutory, reputational, political, catastrophic/ pandemic etc.

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 it is focused at ensuring that these risks are known and addressed through a pragmatic and effective risk management process.

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

1. Risk 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 risks which the organization faces from time to time gets identified and prioritized.

Risk mitigation is the process of initiating responsive action for managing the key risks which 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 is aimed at assuring the management that risks have been adequately identified and prioritized and significant risks are well managed. The Risk Committee reviews the critical risks, gross exposure, mitigation action status and their net exposure on a periodic basis.

The global pharma industry due to the nature of business carried out is potentially exposed to inherent risks such as product safety & quality issues, intellectual property tangles, inappropriate marketing practices etc. thereby leading to penalties, product recalls, brand 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 regulatory approach to patient protection may vary from market to market. Besides rapid change what also impacts the industry landscape is increased scrutiny, sophisticated risk-monitoring techniques and coordination across agencies & regions. In such a context, it is imperative to respond with a holistic risk mitigation framework.

The Company is committed to conducting business in accordance with all applicable statutory laws, government notifications and regulations, and pursuing its core organizational values. Our established risk management framework addresses financial, operational, strategic, regulatory/ statutory, reputational, political, catastrophic/ pandemic risks that are inherent to the pharma business and impact our strategic goals. Risk management, coupled with a robust internal control framework, help the Company emphasize qualitative consistency, employee safety and long-term sustainability.

The global pharma business is marked by a variety of risks. Pharmaceutical companies struggle to globally enforce IP protection, particularly in some emerging markets. 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 information assets, particularly protected/patient health information and intellectual property. 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.

Although the comprehensive eradication of risks associated with the business of the Company is unfeasible, constant efforts are made to analyze their potential impact, assess the changes to risk environment and define actions to mitigate their adverse impact. The Company has implemented a precise methodology entailing the timely identification, analysis and assessment of risks and their 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 Committee and Board of Directors.

In addition to the above, 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 pandemics, 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

During these unprecedented times, pharma companies are required to respond to the challenges or risks arising due to COVID-19 pandemic. If the current COVID-19 pandemic lasts for a medium/long span of time, it can potentially have a negative impact on operations resulting from reasons such as extended lockdown impacting manufacturing and R&D operations, forced shutdown in case our employees contact the disease, restrictions of inter-state and international logistics, non-availability of materials from China or other countries, inability to generate demands from our customers due to significantly reduced business development

activities, challenges in adhering to the good manufacturing practices due to skeletal staff as well as delay on projects/programs not related to the core supply chain operations. Potential for critical data loss/ cyber-attacks also have increased, considering remote working option adopted by most of the companies. While Pharma industry is considered as essential services and allowed to have minimal number of personnel continue the operations, it is imperative to adhere to all precautionary measures to ensure safety of the employees attending operations and avoid any contamination. While the full impact of the global pandemic is still unknown, pharma companies need to respond, recover and thrive.

At Biocon, an assessment of risks triggered due to COVID-19 pandemic was carried out and critical levers to support enterprise resilience were identified. These included focus on overall people safety, transparent communication, focus on continued critical operations such as procurement, production, sales and disposal of waste, focus on compliance and governance, relooking at cash and liquidity management in the changing circumstances and prioritization/ rationalization of spends. Furthermore, remote working and cyber security, 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 implementation of 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 in accordance with a broad criteria that it has set for itself.

A robust, comprehensive internal control system is a prerequisite for an organization to function ethically which is commensurate with its abilities and objectives. We have established a strong internal control system for the Company, which is comprised of policies, guidelines and procedures adopted by the Company to ensure the 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 is aimed at providing assurance of 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 on a regular basis and status of rectification measures to ensure that risks are mitigated appropriately on a timely basis.

Outlook

The new financial year comes with a new set of challenges in the midst of the ongoing COVID-19 pandemic. However, we are confident of emerging from the current situation stronger and more determined than ever to deliver on our commitments to our partners and patients. While uncertainties remain, the Biologics segment will continue to lead overall revenue growth on a consolidated basis with steady growth expected from both Small Molecules as well as Research Services. Biologics segment is expect to deliver strong growth in FY21 and remains steadfast in achieving its aspirational revenue guidance on $1 bn by FY22.