Management Discussion & Analysis

ECONOMIC OVERVIEW

WORLD

Economic activity worldwide slowed down in 2019 for both advanced and emerging economies owing to trade and tariff-related uncertainties between the global powers, along with tepid consumer and investor sentiments.

The US economy is estimated to have grown by 2.3% in 2019, driven by improved consumer spending, employment generation and manufacturing activity.

Global Growth Trends (%)

	Actual	Projections	
Particulars	2019	2020	2021
World Output	2.9	-4.9	5.4
Advanced Economies	1.7	-8.0	4.8
US	2.3	-8.0	4.5
Eurozone	1.3	-10.2	6.0
Japan	0.7	-5.8	2.4
UK	1.4	-10.2	6.3
Other Advanced Economies	1.7	-4.8	4.2
Emerging Markets and Developing Economies	3.7	-3.0	5.9
China	6.1	1.0	8.2

Source: International Monetary Fund (IMF)

Outlook

The International Monetary Fund (IMF) projects that global economic activity will grapple with unprecedented contraction in 2020, owing to the COVID-19-led lockdown and the consequent suspension of economic activity. As per the IMF's April World Economic Outlook, global growth will contract by 4.9% in 2020, vis-à-vis 2.9% growth in 2019, and subsequently, mark a V-shape normalisation to 5.4% growth in 2021, although half of it will come on a lower base. Further, the global trade volume in goods and services will slip into a degrowth of 11% in 2020 from an already sluggish growth of 0.9% in 2019, before growing by 8.4% in 2021.

INDIA

India continued to be one of the most robust and resilient economies of the world in 2019. During FY20, the economy grew by 4.2%, suffering primarily from inadequate credit availability owing to challenges in the financial sector. The combined impact of muted domestic demand and export markets dragged down capacity utilisation of industries.

The Government of India undertook proactive initiatives such as reducing corporate tax rates and offering credit guarantee for financially sound Non-Banking Financial Corporations (NBFCs). The year also witnessed easing of monetary policy by the Reserve Bank of India (RBI) with significant reduction in the repo rate. Driven by fiscal and monetary policy initiatives, the economy began to show early signs of recovery. However, the COVID-19 outbreak in the fourth quarter of the year made recovery an uphill task.

India's growth pattern (%)

FY16	FY17	FY18	FY19	FY20
8.0	8.2	7.2	6.1	4.2

Source: Economic Survey of India 2019-20; Central Statistics Office

Outlook

The Government of India has already announced a significant relief package of ₹20 trillion, aimed at providing a safety net to the most vulnerable sections of society. Targeted relief measures have also been designed for sectors that are hardest hit by the pandemic such as financial services and micro, small & medium enterprises (MSMEs).

The positive indicators are moderate inflation and low crude prices resulting in declining trade deficit. These factors allow the Government of India adequate room for providing additional fiscal and liquidity support to the economy.

INDUSTRY INSIGHT

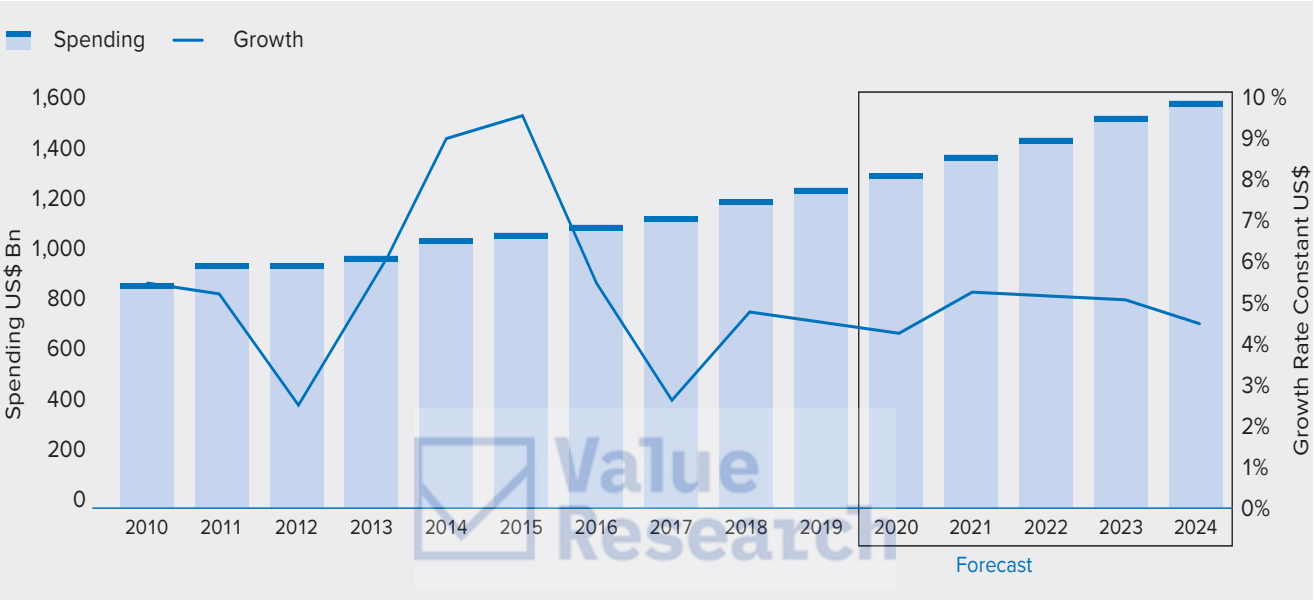
GLOBAL PHARMACEUTICAL INDUSTRY

Globally, the use of medicines has grown considerably in the past decade, particularly in chronic and high-priority segments. The spending for pharmaceuticals registered an invoice value of US$1.25 trillion in 2019, and is expected to grow at 3-6% CAGR through 2024, reaching US$1.5-1.6 trillion. The rise in spending is partly due to increased usage and partly driven by changes in the speciality and innovative product composition of new brands.

Developed markets are expected to see enhanced spending from US$821.6 billion in 2019 to US$985-1,015 billion in 2024, at 2-5% CAGR. On the other hand, pharmerging markets are likely to grow from US$357.7 billion in 2019 to US$475-505 billion in 2024, at 5-8% CAGR.

The front-ranking nations in pharma spending in 2024 are likely to be the US, China, Japan, Germany, Brazil, Italy, France, the UK, India and Spain. (Source: IQVIA)

Global medicine spending and growth 2010-2024



Source: IQVIA Market Prognosis, September 2019; IQVIA Institute, December 2019

Global pharmaceutical spending and growth

US

	2019 (US$ Billion)	2014-2019 CAGR	2024 (US$ Billion)	2020-2024 CAGR
Developed	821.6	3.8%	985-1,015	2-5%
Pharmerging	357.7	7.0%	475-505	5-8%
Rest of the world	71	4.8%	85-95	2-5%
Global	**1,250.4**	**4.7%**	**1,570-1,600**	**3-6%**

Source: IQVIA Market Prognosis, September 2019; IQVIA Institute, December 2019

KEY INDUSTRY TRENDS

Specialty medicines: Specialty drugs are used to treat complex or rare chronic conditions. In developed markets, around 44% of spending in 2019 was focused on specialty products; and is likely to touch 52% in 2024. In pharmerging markets, specialty medicines accounted for 14% of spending in 2019, and are expected to reach 15% in 2024. Of the US$354 billion spent by developed markets on speciality products in 2019, 30% was on oncology products. Oncology spending is likely to be the largest contributor to speciality spending, with a projected increase of 51% through 2024, indicating faster innovation and rapid launch of new pipeline of drugs. Autoimmune therapy spending comprised 17% of total spending in 2019, while HIV accounted for 8% of speciality products; going forward both the segments are likely to witness faster growth.

Biosimilars: Biosimilars are similar versions of biologics, which are made from microorganisms found in plant or animal cells. There has been an ever-increasing demand for pharmaceuticals and for cost effective and more accessible drugs. This makes the biosimilar market an attractive growth proposition in the foreseeable future. The USFDA expects to review more biosimilar applications in 2020, as 66 biologic US patents are expiring within the next five years. This will eventually bolster the growth of the biosimilar segment.

Big data and Artificial Intelligence (AI): Big data and Artificial Intelligence now have a presence in almost every industry. The International Society for Pharmacoepidemiology (ISPE) and its members are working on the roadmap to implement Pharma 4.0 model for the future. Through enhanced digitalisation, Pharma

4.0 will connect the medical fraternity much more cohesively, creating new levels of transparency and speed for a digitalised plant floor. This will not only enable faster decision-making, but also provide in-line and in-time control over business, operations and quality. Robotic technology and Artificial Intelligence (AI) would soon be used to reduce manufacturing floor downtime and product waste. Besides, single-use disposable solutions are gaining momentum, replacing open transfer manufacturing techniques for safer drug storage and transport.

Precision medicine: Precision medicine, also known as personalised medicine, is a process of diagnosing and providing customised medicines and treatment based on an individual's predicted response. Considered niche, these medicines are slowly gaining traction with more and more of such medicines passing the clinical stage and getting ready for the new-age market. In the last five years, investment in personalised medicine has doubled in size and its production is expected to increase by approximately 33% by 2025.

Mergers and acquisitions (M&A): Despite a global slowdown in most other sectors, M&A in the pharma industry remained vibrant throughout 2019. The total value of deals during 2019 stood at US$1.2 trillion. Some of the biggest companies in the industry are consolidating to elevate their position in a highly competitive environment. Increased regulatory pressure from the governments to reduce drug prices and remove potential monopolies is likely to impact margins.

(Source:netscribes.com)

REVIEW OF KEY GLOBAL MARKETS

USA

USA continues to rank at the apex of the world's pharmaceutical spending, contributing about 41% of the total market. The spending is likely to grow from US$510 billion in 2019 to US$ 605-645 billion by 2024, at a CAGR of 3-6%. However, the US market was ranked fourth in overall growth potential, trailing behind high-growth emerging markets such as China, India and Germany. Encouragingly noteworthy is the fact that the country has the highest biological processing quality and is perceived to have the largest growth potential for biologics manufacturing.

With the raging COVID-19 pandemic disrupting supply chains and the government's increased attention on drug pricing, the market is likely to be volatile and margins will be under constant pressure. The US Department of Health and Human Services (HHS) and the USFDA are making concerted efforts to drive speciality product development and expedite regulatory pathways that recognise unmet clinical needs. Besides, support for the generics market will be considerably higher in the forecast period (2020-2024), with the patent expiry of existing drugs.

(Source: IQVIA)

US pharmaceutical spending and growth (US$ billion)

2019	2014-2019 CAGR	2024	2020-2024 CAGR
510	4.3%	605-635	3-6%

Source: IQVIA Market Prognosis, September 2019; IQVIA Institute, December 2019

Europe

In 2019, the total pharma spending in the top five European countries stood at US$174 billion, registering a 4% CAGR over the previous five years. In 2019, the launch of new products in Germany and measures by France to improve biosimilar uptake with an aim to achieve 80% penetration by 2022, have played an important role.

Europe has adopted globally acknowledged standards and the authorities' efforts to seek out new interest to create a more competitive and therefore more accessible market. During the year, the European Union adopted manufacturing waivers to supplementary protection certificates (SPCs), a move supported by generics and biosimilars producers and Active Pharmaceutical Ingredient (API) manufacturers. The manufacturing waiver for SPCs had been a subject of great debate between the generics/biosimilars industry and innovator drug companies. The companies would now be able to start manufacturing under the waiver from July 2022, which provides a positive outlook for the years to come.

EU5 pharmaceutical spending and growth (US$ billion)

2019	2014-2019 CAGR	2024	2020-2024 CAGR
174	4.0%	210-240	3-6%

Source: IQVIA Market Prognosis, September 2019; IQVIA Institute,

Going forward, with a 3-6% CAGR, pharmaceutical spending in the top five European Union (EU5) markets is projected to grow to US$210-240 billion by 2024. The main driver behind this growth would be the launch of latest generation innovative specialty products. However, government led price control initiatives to improve patient access to these specialty products is expected to act as a counter-balancing force to this growth. (Source: IQVIA)

Pharmerging markets

During 2014-19, spending on pharmaceuticals has increased at a CAGR of 7%, reaching US$358 billion by the end of 2019. Pharmerging markets comprised 28% of global pharmaceutical spending in 2019. A significant proportion of this spending and market growth has been driven by enhanced access to chronic and specialty medications, leading to the ramp-up of volumes and adoption of more novel therapies.

Pharmerging markets – Pharmaceutical spending and growth

(US$ billion)

Region/ Country	2019	2014-2019 CAGR	2024	2020-2024 CAGR
Pharmerging markets	358	7.0%	475-505	5-8%
China	142	6.7%	165-195	5-8%
Tier 2*	71	9.4%	90-120	7-10%
Brazil	32	9.9%	45-49	6-9%
India	22	9.5%	31-35	8-11%
Russia	16	8.4%	23-27	8-11%
Tier 3	145	6.2%	195-225	5-8%

Source: IQVIA Market Prognosis, September 2019; IQVIA Institute, December 2019; *Tier 2 includes Brazil, India and Russia

Going forward, pharmaceutical spending in pharmerging markets is expected to account for 30-31% of global pharmaceutical spending in 2024. These markets are expected to continue to grow with a 5-8% CAGR through 2024, as against historical 7% CAGR during the period 2014-19.

The growth in pharmerging markets is likely to be driven by a higher volume growth for branded generics and pure generic medicines. The volume growth would be led by increasing access to the newly introduced medicines by the consumers in these markets. Also, some of the latest generation innovative drugs are likely to be launched in these markets, but expecting that the prices of such products would be high, the rise in their purchases is likely to be limited. (Source: IQVIA)

India

India is now looked upon as the pharmacy of the world. Besides being the largest provider of generic drugs globally, India's pharmaceutical industry meets 50% of the global vaccines demand, 40% of the generic medicine demand in the US and 25% of the entire demand for medicines in the UK.

During 2014-19, the domestic market grew at a CAGR of 9.5% to reach US$22 billion. Presently, over 80% of the antiretroviral drugs being used globally to combat acquired Immunodeficiency syndrome (AIDS), are supplied by Indian pharmaceutical firms. Pharmaceuticals exports from India stood at US$20.6 billion in FY20 up from US$19.1 billion in FY19. Pharmaceutical exports include bulk drugs, intermediates, drug formulations, biologicals, Ayush & herbal products and surgicals.

India's pharmaceutical spending and growth

(US$ billion)

2019 (US$ billion)	2014-2019 CAGR	2024 (US$ billion)	2020-2024 CAGR
22	9.5%	31-35	8-11%

Source: IQVIA Market Prognosis, September 2019; IQVIA Institute, December 2019

Government focus on India's healthcare

The Government of India has been taking several steps to reduce costs of medicines and bring down healthcare expenses. Accelerated introduction of generic drugs into the market has remained in focus, which is expected to benefit both the consumers as well as the Indian pharmaceutical companies.

In November 2019, the Union Cabinet approved the extension/ renewal of the existent Pharmaceuticals Purchase Policy (PPP), with the same terms and conditions, while adding one additional product namely, Alcoholic Hand Disinfectant (AHD) to the existing list of 103 medicines, till the final closure/strategic disinvestment of the Pharma CPSUs.

In the Union Budget 2020-21, the government allocated US$ 9.30 billion (₹650.1 billion) to the Ministry of Health and Family Welfare and US$4.88 billion (₹341.2 billion) towards the National Health Mission to benefit all sections of the society, especially the economically disadvantaged.

Going forward, India's pharmaceutical industry is expected to grow at 8-11% CAGR to US$31-35 billion by 2024. The country has a good mixture of high-end chemistry skills, cost effective labour and the ability to manufacture quality drugs as per the requirements of international regulatory agencies. In addition, there has been a constant focus on rural health programmes, lifesaving drugs and preventive vaccines by the Government of India. India will continue to be an important player in the global generics market. (Source: IQVIA and IBEF)

ABOUT AUROBINDO PHARMA

Aurobindo Pharma Limited (Aurobindo Pharma) is a leading global pharmaceutical company, producing generic formulations and Active Pharmaceutical Ingredients (APIs). The Company is a vertically integrated generic pharmaceutical company focussed on developing a broad spectrum of products including a complex and differentiated product portfolio. The Company's growth is aided by cost-effective product development and substantial execution capabilities. It leverages India's globally competitive cost base and talented team of scientists to successfully launch affordable products and make them accessible worldwide.

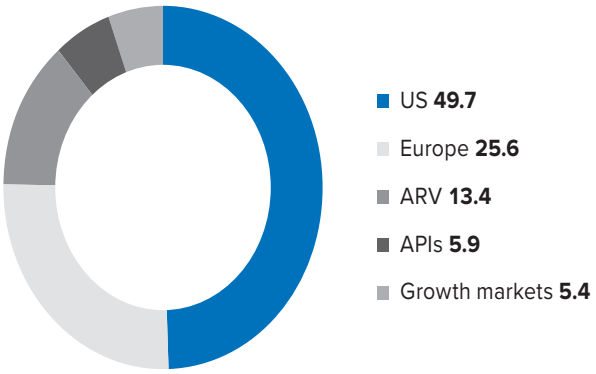
The Company offers a wide range of products and is globally the seventh largest generic company (by revenues) and the second largest listed Indian pharma company (by revenues). It has carved a niche for itself in developing high-quality APIs and finished dosage forms, especially in regulated markets.

With 33 years of experience, eight research facilities and 29 global manufacturing and packaging facilities, Aurobindo enjoys a presence in 155+ markets. Headquartered in Hyderabad, India, it is an Indian MNC that derives 92% of its revenues from international markets.

An empowered workforce of approximately 23,000 people across offices and facilities drives our operations across the globe.

Revenue distribution mix

(%)



Key 2019-20 highlights

- Recorded total growth in revenues by 18.1% y-o-y to ₹230,985 million
- Logged EBITDA of ₹48,643 million, up by 23.1%
- Spent ₹9,580 million (4.1% of revenues) on R&D
- Filed 55 ANDAs with USFDA, of which 19 are injectables and the remaining orals
- Received final approval for 22 ANDAs (including eight injectables) and tentative approval for six ANDAs from the USFDA
- Launched 34 products in the US, including seven injectables
- Filed 12 DMFs with the USFDA, taking cumulative filings to 254 as on 31 March 2020
- Commissioned Eugia Pharma facility for oncology, hormones, injectables and orals
- Started clinical trials for the lead molecule in biosimilar division Bevacizumab and completed clinical trials for the first metered-dose inhaler
- Acquired R&D assets from Profectus BioSicences Inc., USA; the acquisition will provide access to proprietary and innovative technology platforms for prophylactic and therapeutic use, enhancing the Company's research capabilities and expertise in developing newer vaccines from basic discovery research that would culminate in USFDA-approved products.

Formulations business: Integrated manufacturing leverages cost-effective product development

Formulations business contributed 87% to the Company's consolidated revenues in FY20. During the year under review, revenues from this segment clocked in at ₹200,119 million, growing by 23.9% y-o-y.

The Company commands a large portfolio in formulations with 1,200+ products and has 17 formulations manufacturing facilities in India (11), the Netherlands (1), Portugal (1), Brazil (1) and the US (3).

The Company also participates in Antiretroviral (ARV) tenders floated by various independent and government agencies by multi-lateral organisations like United States Agency for International Development (USAID), The President's Emergency Plan for AIDS Relief (PEPFAR) and other health ministries of various countries.

US formulations: Expanding portfolio mix towards differentiated products

As on 31 March 2020, Aurobindo is the second largest generics company in the US in terms of prescriptions (Rx) dispensed as per IQVIA data. The company has significantly strengthened its position over the last five years. The Company's Rx market share increased to 8.5% for 12 months ending April 2020, as against 7% for the 12 months ending April 2019 and 3.8% for the 12 months ending April 2016 as per IQVIA data. The Company has a presence across various segments such as generics (oral, injectable and OTC), branded (injectables) and dietary supplements. During the year, the Company registered a growth of 27.2% at ₹114,835 million.

Filings and approvals in the US

Filings				
FY16	FY17	FY18	FY19	**FY20**
21	30	46	63	**55**

Approvals				
FY16	FY17	FY18	FY19	**FY20**
50	61	50	48	**22**

Oral solids: During FY20, Aurobindo's oral solids segment in the US, reflected a significant growth of 18% that was largely driven by improvement in the volumes of existing products. The oral solid prescription sales increased by 30% (Source:IQVIA data), and the market share of prescription dispensed improved to 9% (Source:IQVIA data), during the financial year. Aurobindo actively markets 190 products, of which 83% rank among the top 4 in the US market. The Company is awaiting final approval for 120 ANDAs as on 31 March 2020, and is in the process of creating an incremental portfolio across the therapies, which will drive growth in the oral solids business.

Injectables: This segment witnessed a robust growth of 31% led by new product launches, pickup in volumes and gain in the market share of existing products. As per IQVIA's 12 months ending March data, the number of eaches have increased by 12% year-on-year. The Company actively markets 47 products, of which 74% rank among the top 4 in the US market. The Company is awaiting final approval for 58 ANDAs as on 31 March 2020. It is on the path of building a future pipeline of complex injectables including depot injections.

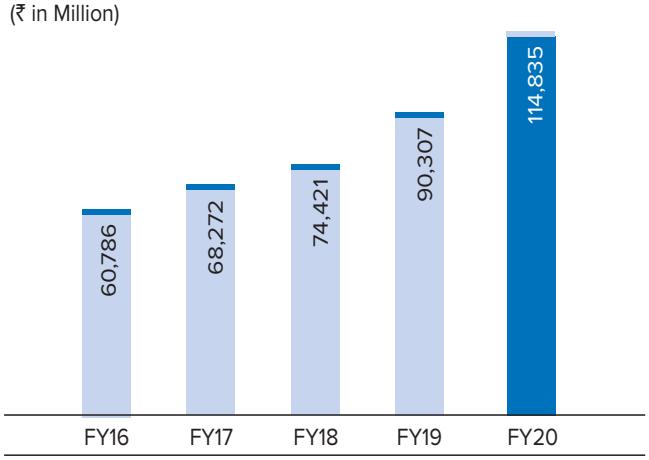
Over-the-counter drugs (OTC): The OTC segment recorded a strong growth of 15% and its contribution to the US revenues increased to 3% in 2019-20. Going forward, the switchover of certain medications from Rx to OTC would strengthen the portfolio of branded OTC products.

Branded oncology injectable: Aurobindo completed the acquisition of seven marketed branded oncology injectables in March 2019, which allows the Company to enter the branded space with a portfolio of well-known products. Acrotech Biopharma (Aurobindo Pharma's subsidiary) will continue building its commercial infrastructure to maximise the value of its current and future products.

Dietary supplements: Natrol posted a growth of 22% and accounted for 10% of the US revenues. It maintained the growth momentum through new product introduction and geographical expansion.

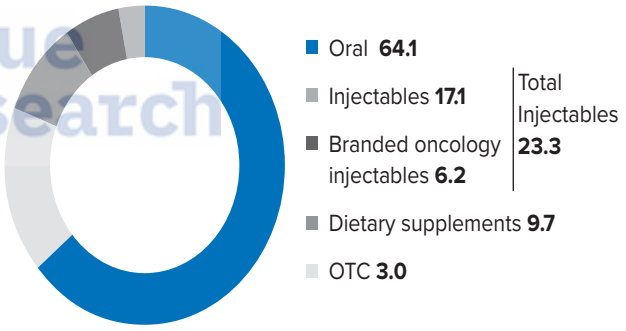
US formulations revenue trend

17.2% 5-year CAGR
(₹ in Million)



Revenue mix of the US formulations segment

(%)

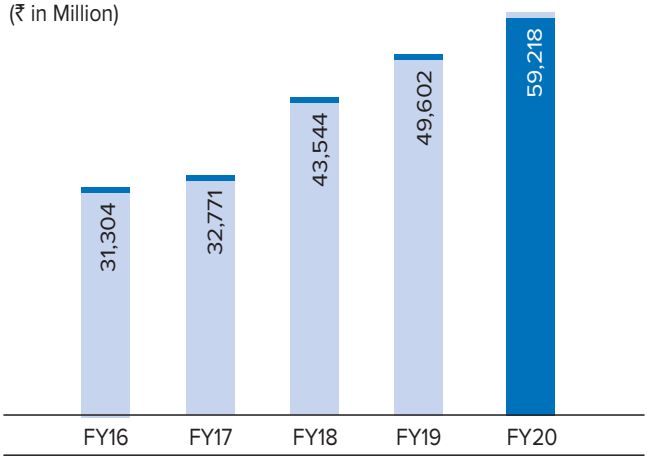


Europe formulations: Deepening the European footprint

Aurobindo is ranked among the top 10 generics companies in 7 out of 11 countries in which it operates. This business vertical delivered a robust performance during the year, with a growth rate of 19% year on year. Its contribution to the total revenues was 26%. The markets of France, the UK, and Italy primarily drove this growth. The Apotex business acquisition has helped the Company to leverage synergies in the European markets. The Company has completed the integration of acquired businesses and is in the process of restructuring the businesses to draw synergies.

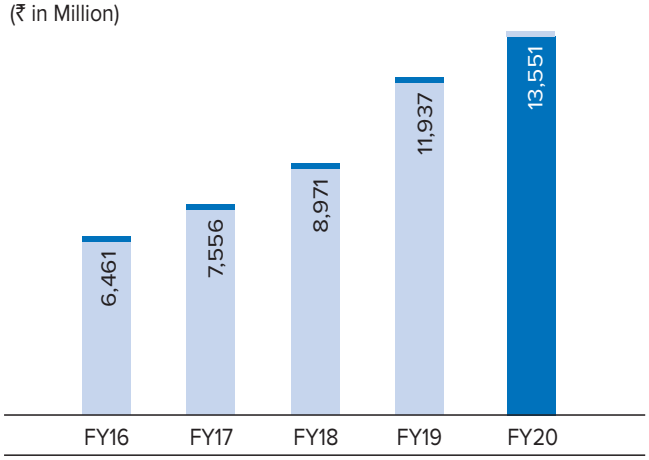
Europe revenue trend

17.3% 5-year CAGR
(₹ in Million)



Growth Markets formulations revenue trend

20.3% 5-year CAGR
(₹ in Million)



Growth Markets formulations

The growth markets formulation business expanded by 14% to reach ₹13,551 million, contributing 5.9% to the Company's total revenues. Key markets include Canada and Brazil. The segment aims to build its presence in branded generics in select growth markets and is deepening its footprint in specific countries, with the Canadian market being the key growth driver.

In Canada, the company has launched 13 products during the year taking total launches to 113. The market share of the Company in value terms increased from 1.7% to 2.4%[1]. During the year under review, the company has filed 13 dossiers and plans to file another 25 products in FY21. Over the next two to three years, the company is aiming to introduce products in Inhalers and Biosimilars.

China is the world's second largest pharmaceutical market with a market size of US$142 billion in 2019 and estimated to reach US$165-195 billion by 2024, indicating a growth of 5-8% (Source: IQVIA). The Company has identified a basket of products for this market and started filing from India. As on 31 March 2020, the Company has filed 15 products. It is also setting up an oral solids formulation facility. The Company has also entered into a joint venture for developing and marketing products.

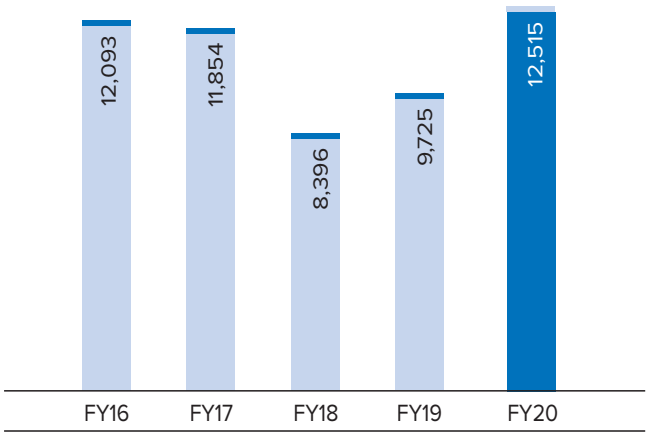
[1]Source: IQVIA

ARV formulations

The Company focuses on global tenders floated by multi-lateral organisations like Global Fund, USAID, PEPFAR and country-specific Ministry of Health tenders. Aurobindo's ARV division delivered a y-o-y growth of 28% in FY20. The segment recorded ₹12,515 million in revenues during the year on the back of its early mover advantage in TLD (Tenofovir + Lamivudine + Dolutegravir) tablets. A growing single-pill regimen, along with rapid conversion of TLE (Tenofovir + Lamivudine + Efavirenz) to TLD in the institution segment, has contributed towards this growth.

ARV revenue trend

(₹ in Million)



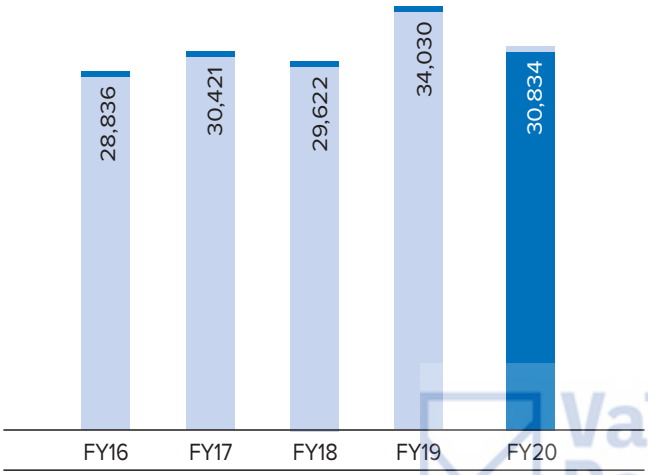
API business: Sustained growth in advanced regulated markets

Aurobindo's API business is a strategic segment in terms of vertical integration and supply reliability. The Company has been investing in this division for capacity creation and capability building. Key customers for this business unit include innovator and large generic companies. The business unit

continues to focus on complex products with varying volumes, while continuously improving its manufacturing processes to meet market needs. The Company manufactures and markets Betalactum and non-Betalactum at its 11 API and intermediate facilities. The revenue from the API division was ₹30,834 million and it contributed 13.4% to the consolidated revenues of the Company.

API revenue trend

(₹ in Million)



FINANCIAL REVIEW – CONSOLIDATED

During 2019-20, Aurobindo's consolidated revenues increased by 18% to ₹230,985 million from ₹195,636 million in the previous year. Its EBITDA grew by 23.1% to ₹48,643 million, whereas the EBITDA margin stood at 21.1%. The Company's research and development expenses stood at ₹9,580 million, i.e. 4.1% of its total revenues. Aurobindo reported Profit after Tax (PAT) of ₹28,310 million, an increase of 19.7% year-on-year and Earnings per Share (EPS) of ₹48.32.

Key ratios

	As on 31 March 2020	As on 31 March 2019
Debtors turnover	5.1	4.5
Inventory turnover	3.1	3.0
Interest coverage ratio	24.9	20.9
Current ratio	1.4	1.2
Debt equity ratio	0.16	0.36
Operating profit margin (EBITDA Margin %)	21.1%	20.2%
Net profit margin (%)	12.3%	12.1%
Return on net worth (%)	18.4%	18.4%

Manufacturing review

Aurobindo continues to strengthen its manufacturing operations. Aurobindo has 29 manufacturing and packaging units spread across USA (4), India (22), Portugal (1), the Netherlands (1) and Brazil (1). Its well-equipped production facilities have approvals from international regulatory agencies such as the US Food and Drug Administration (USFDA), UK Medicines and Healthcare products Regulatory Agency (MHRA), World Health Organisation (WHO), Health Canada, EU's European Medicines Agency (EMA), Portugal's INFARMED and Brazil's ANVISA for both APIs and formulations. The Company largely backward integrated and ensures seamless production schedules with on-time availability of raw materials. Going forward, the Company will enhance capacities of its existing units and set up new facilities.

During the year under review, Eugia Pharma's facility has been commissioned. The facility was inspected and approved by various regulatory authorities, including the USFDA, EMA and INFARMED. This unit has a total installed capacity of 6 billion units and can manufacture various dosage forms such as capsules, tablets and injectables. The Company also added capacity at Unit VII and Unit X; and expanded its API capacity in Unit XI and Unit XIV. Aurobindo also invested in expanding its solar power plant capacity in one of the API units.

SCORE ANALYSIS

Strengths	Challenges	Options	Responses	Effectiveness
• Vertically integrated manufacturing	• Competitors with similar offerings and business structures	• Vaccines for new diseases	• Capacity creation and capability building measures	• Audited by regulatory agencies
• Presence in multiple therapeutic areas	• High mobility of workforce within the industry	• Rise in demand for lifestyle products and geriatric care	• Expanding into new areas like biologics, dermatology, transdermal patches and respiratory medicines	• Earned shelf space on a global scale
• Global footprint	• Pricing pressures	• Global response to pandemic/s		• Control over raw material sourcing
• Strong R&D				• Dominant API player
• Skilled workforce				• In-house R&D capabilities; strong technological implementation in manufacturing and robust marketing infrastructure
• Capability of delivering high-quality, cost effective generics				

PEOPLE AT AUROBINDO

Aurobindo is cognisant of the fact that its success is dependent on the experience, expertise and executional capabilities of its people; and this is why the Company considers them strategic business partners.

The Company's ideology is 'committed to healthier life', and it reiterates the idea in terms of its people policies by promoting work-life balance. Aurobindo offers an empowering and enabling work environment for its people, with various learning and development programmes across almost all functions of the business.

THE COMPANY AIMS TO:

- Attract, build and retain talent
- Create and nurture a performance culture through capability building, performance measurement and leveraging IT
- Foster leadership at all levels through trust, empowerment, inclusion and openness
- Promote a collaborative approach for business excellence
- Encourage a vibrant work culture based on innovation and incentivise people based on their productivity/outstanding performance

Aurobindo's focus on the wellbeing of its people remains steadfast. The Company is ensuring utmost care through the newly developed 'human touch lifecycle' process, to enhance work environment in a post-COVID world.

SUSTAINABLE AT THE CORE

Aurobindo never loses sight of health, safety and the environment while executing its operations. It follows international guidelines, and continuously works towards improving safety across all its facilities and processes. The Company enjoys cordial industrial relations, and is incessantly evolving its systems and processes to enable better work-life for its people.

The Company upgrades its plants and treatment systems every year to remain a frontrunner in promoting sustainability. It continues to work with the Access to Medicine Foundation and is participating in the 2020 AMR Benchmark. Aurobindo has also joined the AMR Industry Alliance.

Aurobindo strives to minimise waste generation, optimise the use of available resources, reduce its carbon footprint and ensure minimal impact of its activities on the environment.

A RESPONSIBLE ORGANISATION

Aurobindo's philanthropic arm Aurobindo Pharma Foundation builds on the organisation's commitment towards sustained excellence. It includes the Company's citizenship efforts that benefits communities.

The Foundation invests a large part of its resources into building social assets like schools, hospitals and toilets that help in improving the quality of life in the society. It works towards providing basic amenities such as potable water and nutritious food to the underprivileged. The Foundation has a team of over 11 people, who monitor the implementation and impact of each project.

The Foundation's key areas of activity for 2019-20 were:

- Promoting quality education
- Supporting preventive healthcare and sanitation
- Sustaining ecological balance and conserving natural resources
- Promoting road safety
- Providing safe drinking water
- Elevating hunger and malnutrition
- Supporting rural sportspersons

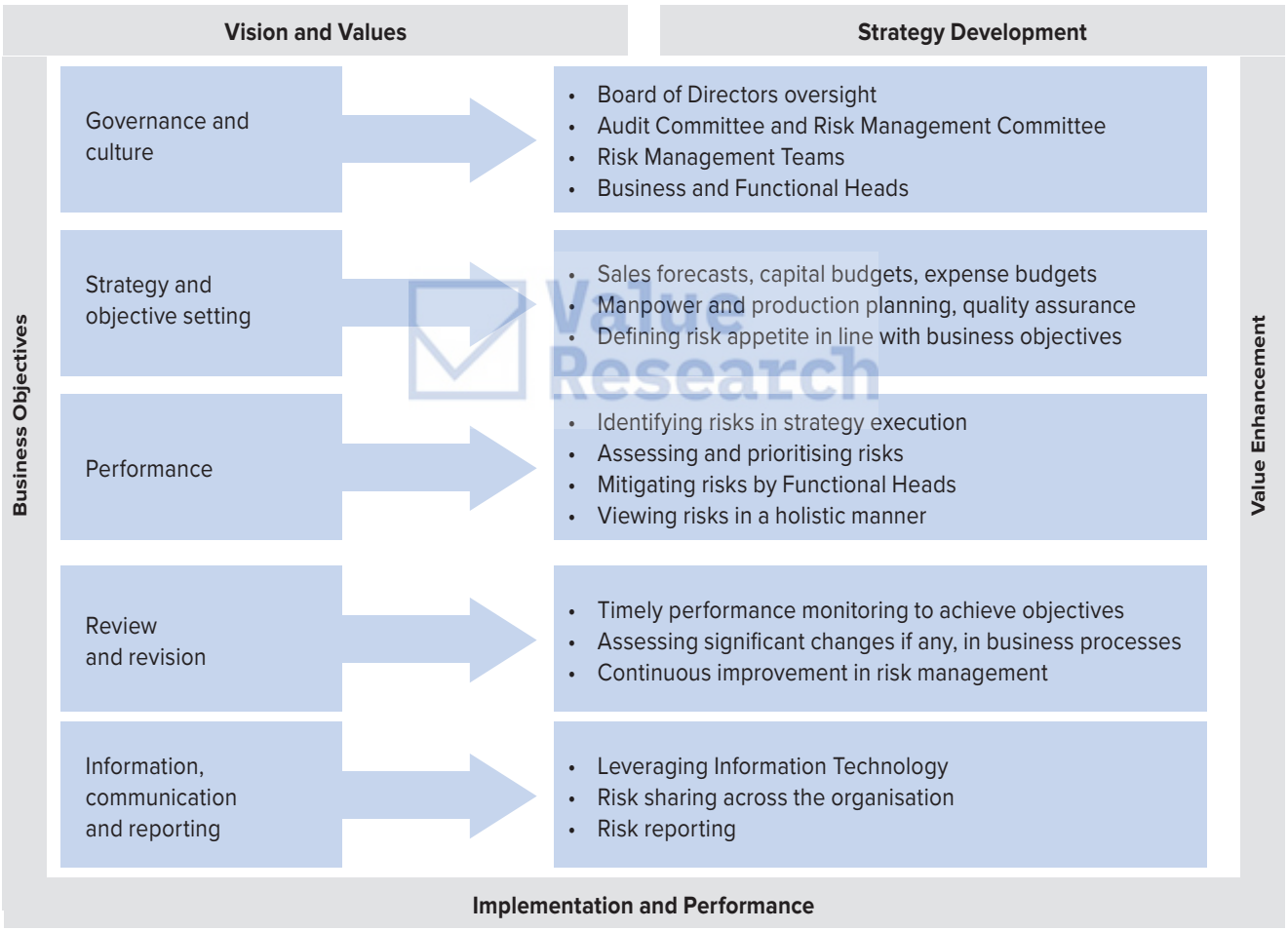
Risk Management

OVERVIEW

The objective of the Aurobindo Enterprise Risk Management (ERM) framework is to address all major risks in a proactive manner and to sustain business growth. The Company has an effective and robust ERM function, which enables the achievement of strategic objectives by identifying, assessing, mitigating and monitoring any risk or potential threat to the Company's objectives. While achievement of strategic objectives is the key leading factor, Aurobindo's values, culture, obligation and commitment to customers, investors and regulatory bodies are the foundation on which the ERM framework is developed. Systematic and proactive identification of risks and the mitigation thereof, enables effective and quick decision-making and boosts the Company's performance.

The design of the Aurobindo's ERM framework is based on the internationally recognised standard 'Enterprise Risk Management Integrating with Strategy and Performance' (COSO ERM Framework 2017), developed by the Treadway Commission. The ERM Framework would highlight the importance of considering risk in both the strategy-setting process and in driving performance across all functions. Further, it would focus on integrating risk management practices throughout the organisation and help in enhancing the growth and performance of the Company.

Enterprise Risk Management framework at Aurobindo



The Aurobindo ERM Framework begins with an underlying premise that the Company exists to provide value for its stakeholders and faces uncertainty in the pursuit of that value. 'Risk' is considered to be the effect of such uncertainty on the formulation and execution of the business strategy and achievement of business objectives.

As a strategic function, the ERM framework would focus on:

- Providing insight into strategy setting and its execution in line with the Company's vision
- Enhancing alignment between the Company's performance and risk management practices
- Recognising and expanding the globalisation of markets and operations coupled with applying a tailored approach across geographies
- Presenting fresh ways to view risk in the context of greater business complexity
- Expanding risk reporting to address expectations for greater stakeholder transparency
- Leveraging information technologies, automating business processes and using data analytics in supporting decision-making

Risk governance structure

Board of Directors	• Setting and evaluating strategies and risks associated with it • Defining the role of risk management committee (RMC) • Assessing management abilities and performance vis-à-vis Company's objectives
Risk Management Committee (RMC)	• Monitoring the risk management practices for its effectiveness • Evaluating significant risks, impacts and risk mitigations • Providing direction to risk teams and functional heads for improvement
Risk Management Head (RMH)	• Formulating and implementing risk management policies and procedures • Facilitating the execution of risk management practices • Providing periodic updates to MD and CFO and quarterly updates to the RMC on risks to key business objectives and their mitigation • Working closely with functional heads for implementing risk mitigation actions
Business and Functional Heads	• Adhering to risk management policies and procedures of the Company • Identifying and managing risks proactively in respective business functions • Implementing agreed upon risk mitigation actions

Risk categories

Strategy and its execution risks: Arise out of the choices made and key decisions taken in defining the Company's strategies and the risks to the successful execution of these strategies – for example new markets, product & process development, resources, business growth & revenue model, M&A, industry changes, investment model, etc. can impact business objectives. **(Risk ownership: Key management personnel)**

Operational risks: Indicate gaps in existing processes, which could potentially weaken the process and make it vulnerable to exploitation, impacting the business adversely. The gaps could relate to under-utilisation of resources, production capacities, material availability, human safety etc. **(Risk ownership: Operations team)**

Legal and Compliance risks: Arise out of non-compliance with applicable laws, regulations, standards and policies that could impact the Company's reputation and business. **(Risk ownership: Functional heads)**

Financial risks: Include uncertainties and untapped opportunities in effective and efficient utilisation of financial resources as well as uncertainties in currency fluctuation, liquidity & funding, capital management and credit risk. These risks could impact the Company's financials and in turn the transmission of accurate financial information to stakeholders. **(Risk ownership: CFO and Finance & accounts team)**

Information Technology (IT) risks: Could have potential impact on information assets and processing systems. For example: system failures, virus attacks or breach of cyber security. **(Risk ownership: CIO)**

OTHER COMPONENTS OF RISK MANAGEMENT

Risk/Opportunity identification: Risks/opportunities are identified through structured interviews, brainstorming sessions and risk questionnaires. Risk registers are updated for all the risks.

Risk assessment: Scenario-based assessments are done to determine likelihood of risk occurrence and impacts and to prioritise risks and mitigate them. Risk management is the primary responsibility of the respective Business Heads and Functional Heads. The Risk Team is the custodian and facilitator in the risk management process.

Risk mitigation: Risk mitigation actions are undertaken by the Business Heads and the Functional Heads responsible for treating risks appropriately in a time-bound manner and the progress of risk treatment actions reviewed periodically. Risk Teams help identify risks and take necessary steps to mitigate the same.

Risk reporting: Risk reports are submitted to the RMC on a periodic basis for its review. The reports highlight identified key risks, their impact on business and the control measures as well as risk mitigations agreed upon by the Business Heads. The RMC reviews the risk reports, provides direction to the Risk Team and the Functional Heads on risk rating levels and controls measures that are to be undertaken by the Business Heads.

INTERNAL FINANCIAL CONTROLS (IFC) HIGHLIGHTS FOR THE YEAR

In accordance with Section 134 (5) (e) of the Companies Act 2013, the Board of Directors of the Company are responsible for establishing and implementing Internal Financial Controls (IFC), which are adequate and operate effectively. The Company's statutory auditors are required to provide an independent opinion on the adequacy and operating effectiveness of such controls during the financial year. The IFC system encompasses the following elements, which have been properly established across all key business processes:

- Orderly and efficient conduct of business
- Safeguarding of its assets
- Adherence to Company's policies
- Prevention and detection of frauds and errors
- Accuracy and completeness of the accounting records and timely preparation of reliable financial information

Aurobindo is continuously leveraging information technology to enable significant improvement in the business process. The IT teams and business teams continue to work together for automating business processes and to reduce dependency on manual controls. The Company has a strong maker-checker principle of authorising transactions, which reinforces the necessity of initiation and authorisation of every transaction by atleast two individuals. Proper segregation of duties (SOD) is also established in every transaction to prevent and address fraud risks and errors.

Physical verification and reconciliation of fixed assets and inventory are performed on a periodical basis. Management Review Controls (MRC) is conducted by competent key personnel in real-time to ensure that the controls are operating as intended. For example, the comparison of budget to actual, examining reports generated by IT systems, analysing estimates of sales, expenses and project costs.

Process walk-throughs have been carried out during the year 2019-20 to re-assess the design effectiveness of controls such as Entity Level Controls (ELC), Information Technology General Controls (ITGC) and Process Level Controls (PLC). Process control changes if any, have been properly documented and tested. Also, transaction auditors have tested all the controls for their operating effectiveness during the year.

BUSINESS RISKS AT AUROBINDO

Some of the key existing and emerging risks affecting Aurobindo's business are listed below:

Key business risks emerging from Novel Coronavirus (COVID-19)

The COVID-19 has spread rapidly all over the world, infecting millions of people in several countries, causing great suffering to humanity, and impacting lifestyles, businesses and economies. In the ensuing months, the resultant nationwide lockdown in several countries, including India, led to the shutdown of business operations and logistics systems, while travel movements came to a halt. The situation was further aggravated by demand, supply and liquidity issues. Aurobindo has been proactively managing the risks arising from the COVID-19 situation and made concerted efforts to overcome these challenging times.

Like many other pharmaceutical companies, Aurobindo, being a generic drug company with a business presence in the domestic and international markets including USA, Europe and other markets (over 155 countries), and having 29 manufacturing and packaging facilities worldwide, was also exposed to some significant risks emerging from the COVID-19 pandemic, which have had an adverse impact on operations and revenues.

- **Supply Chain disruption risk:** Raw material shortages in China and other markets including India, extended shutdown of manufacturing facilities
- **Logistics risks:** Severely affected the flow of imports of Key starting materials, Intermediates and APIs, packing material, travel restrictions, airlines cancellations, local transportation constraints etc.
- **Production decline at manufacturing facilities:** Shortage of labour due to local lockdown
- **Demand and Supply risks:** Dependency on certain geographies for raw material imports and price variances
- **Customer delivery risks:** Delays in delivering products to customers, cancellation of orders by customers
- **Sales volumes and cash flow constraints:** Liquidity pressures and loan commitments

Supply chain disruption risks

Due to the COVID-19 outbreak, there could be a significant risk to Aurobindo in procuring raw-material from China and other markets, including the domestic market. The Company continues to have a high dependence on the China market for import of Key Starting Materials (KSMs), Intermediates and Active Pharmaceutical Ingredients. The COVID-19 outbreak could create severe disruption on the entire supply chain process in terms of sourcing, production, inventory management and logistics & distribution.

India is heavily reliant on China for imports of KSMs, intermediates and APIs used in making an array of drugs and medicines. This is largely for drugs like antibiotics – crucial among them being 6 APA (and other products based on it such as amoxicillin and ampicillin), tetracycline and for vitamins such as vitamin C and D. All of these are based on drug ingredients made using a fermentation-based process, an area where China has achieved global dominance. But restrictions on trade and production, in the wake of the outbreak, have majorly curbed supply, sending shock waves through the industry.

Though India is one of the top formulation drug exporters in the world, the Indian Pharma industry relies heavily on imports of KSMs, intermediates and APIs. As per the Confederation of Indian Industry (CII) report, India imported around US$ 3.5 billion worth of KSMs, APIs and Intermediates in FY19 that accounts for approximately 40% of the overall domestic consumption. This is a year-on-year increase of around 30% from FY18. Imports from China have been on a steady rise over the years (from 62% in FY12 to 68% in FY19) due to the low-cost advantage enjoyed by Chinese manufacturers. In FY19, India imported US$ 2.4 billion worth of APIs.

With India's API imports from China averaging almost 70% of its consumption by value, importers are at the risk of supply disruptions and unexpected price movements. For many critical antibiotics dependency on imports from China is close to 100%.

Aurobindo's high dependency on China for raw-material imports could lead to risk of import disruptions, short supplies and production bottlenecks. Out of the total raw-material requirement of Aurobindo India, about 45% of the material is procured from China and 7% is procured from other countries and the remaining 48% is procured from the domestic market, which may have inputs being sourced from China. The creation of a stable sourcing platform is a challenge and critical for the Company in material procurement, and the supply chain team has been taking necessary steps in ensuring long-term supply sustainability.

Mitigation strategy

Supply Chain Management (SCM) teams have managed the supply disruptions effectively over the past few months through available inventory and keeping adequate stock quantities by developing effective 1+3 months rolling plans, considering production requirement and material availability. As China nears a return to full production, raw material supply disruptions should ease out in future. Procurement teams are exploring ways of identifying alternative suppliers globally for procurement of material to minimize geographical concentration risk.

Procurement teams are continuously monitoring supply of key starting material, APIs and other materials from China and other markets to ensure timely supplies. The Company continues to focus on de-risking of single sourced material and reducing geographical concentration risk for raw material, on account of cost escalations and environmental issues.

Aurobindo believes in effective demand planning and takes into consideration the market requirement, existing stock levels, API in-house commitment and external suppliers' commitment. Aurobindo is committed to serving customers as per their requirement and executing the orders 'Just in Time'. The logistics department maintains a good relationship with forwarders to ensure pickups (ground operations) are done on priority, and with airlines and ocean liners to ensure that goods have been picked up by the first available aircraft or vessel.

Merger and Acquisition risks (R&D Investments)

During FY20, the Company has acquired certain business assets used for R&D from Profectus BioSciences Inc. USA, a clinical-stage vaccine development company through Auro Vaccines LLC, a 100% subsidiary of Aurobindo Pharma USA Inc., which in turn is a 100% subsidiary of Aurobindo Pharma Limited, India. The acquisition would provide access to proprietary and innovative technology platforms for prophylactic and therapeutic use, along with a R&D centre.

It is a widely accepted fact that technological expertise and quick innovation are crucial corporate assets for facing increased competition. In order to maintain the current growth rate and gain a strong foothold in the export market, it is imperative that Aurobindo builds a strong product pipeline through continuous investment in R&D. The acquisition of R&D assets would lead to enhancement of R&D capabilities and expertise in developing newer products. However, the return on R&D spending may have longer gestation period. The Company may be unable to realise the anticipated benefits of such acquisitions within the defined period.

Mitigation strategy

Aurobindo has a full-fledged R&D Division, which is continuously engaged in research on new products and process improvement on existing products as part of continuous improvement. The R&D Division has a dedicated team of scientists and analysts, who work on developing a wide range of medications, including specialty products. Innovation is fostered by a different approach towards cost, time, quality and complex product development by adopting cutting-edge technology. The Company's philosophy is to continuously upgrade the technology to provide a broad basket of products, and to manufacture cost effective higher quality products. In order to get returns on the R&D investment, the Company has developed a robust M&A process, which includes focusing on clearly defined areas for acquisitions, exhaustive due diligence and a well-structured integration process.

Aurobindo's focus has been on extending R&D spending into areas that provide opportunities available in the market, particularly those pertaining to untapped medical needs.

Economic and geopolitical risks

The regulatory landscape of the global pharmaceutical industry is complex and dynamic, which could be significantly influenced by the external macro environment such as the political, economic, social and technological factors (PEST). Aurobindo's products are marketed in most of the international pharma markets including USA, Europe and Emerging markets. Major revenues come from USA and the European countries, which together constitute about 75% of the total revenues of the Company in FY20. Due to the recent COVID-19 pandemic, international trade and the supply chains have been disrupted severely, and these macro-economic uncertainties could affect the Company's revenues coming from the international market.

Due to the onset of the COVID-19 pandemic, there could be issues such as problems of liquidity, cash flow, demand and other issues in the short term within the countries where we are selling our products. The consequences of the health ministry's reducing/cancelling supplies or imposing penalties might also exist.

USA is the largest market for the Company, with around 50% of the revenue generated in FY2019-20. Europe is the second largest market in which the Company sells formulations, accounting for approximately ~26% of revenues in FY20.

The consolidated revenue breakup of the Company for FY20 is as given below:

- International sales constitute about 92% of the Company's total revenue, with the remaining 8% being domestic sales
- The formulations business contributes 87% to the Company's total revenue, while 13% comes from active pharmaceutical ingredients (APIs)
- About 57% of the formulations sales come from USA, about 30% from Europe, 6% from the anti-retroviral (ARV) business segment and the balance 7% from growth markets

Mitigation strategy

Although pharmaceutical companies faced issues related to the COVID-19 pandemic, the challenges faced by the Company would have a short-term impact. Mitigation strategies would include discussions and in the medium-term, with improved conditions and streamlining of supply and demand, the situation would ease out.

As one of India's largest vertically well-integrated pharmaceutical companies with 70% of API manufactured in-house, the Company's strength lies in developing quality Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs). These products are manufactured across facilities that have been inspected by various regulatory authorities such as the USFDA, UK MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa, and ANVISA Brazil.

In some countries like Africa, the Middle East and Russian countries, PEST influence is high, which might lead to business risk to the Company. Government authorities are encouraging local manufacturers, restricting imports and levying conditions to buy medicines only through government tenders. As part of its de-risking strategy, the Company is aggressively participating in government tenders and appointing approved distributors. The sales and marketing team is insisting on a 100% advance payment before shipment from local distributors, and focusing more on the high margin range of products.

Over the years, Aurobindo has been expanding its business presence through business and R&D acquisitions in the USA and Europe markets and is focusing on other untapped and potential markets like Japan, Brazil, Africa, Canada etc.

Competition risks

As there are a large number of competitors present in the generic drugs market of India and abroad, Aurobindo is exposed to tough competition from other pharmaceutical companies in most therapeutic areas. The generic drug competitors can enhance competition by offering more product choices which may impair the Company's competitive advantage and lead to loss of market share.

The pharmaceutical industry is heavily competitive and has become even more in the recent years, both in the branded and generic product segments. Therefore, understanding the competition becomes imperative for the Company, especially during the drug development process. The entire process for establishing successful products within a market would involve analysing the market and identifying competitors using novel technologies, offering innovative product choices, and having structured business models, each of which may challenge Aurobindo's market share and growth.

Mitigation strategy

The Company's R&D team continues to develop innovative processes and specialised products that allow the Company to capitalise on competitive market opportunities. In order to face competition from other pharmaceutical companies, Aurobindo continues to adopt and implement the following innovative and systematic approaches.

- Analysing and understanding all potential markets and competitors in key therapeutic areas
- Targeting the right customers in terms of pricing, sales volumes and payment history
- Market potential forecasting
- Gathering competitor's pricing and product tracking
- Expanding product portfolios through business acquisitions in key markets
- Ensuring timely delivery to customers
- Producing products at competitive costs by developing new processes, upgrading existing processes
- Timely launch of new products
- Enhancing manufacturing facilities with new products to ensure sufficient levels of production by talented R&D teams to build market share

Pricing risks

The drug pricing concerns and pressures in the domestic and global markets due to government regulations and stringent measures to reduce drug prices for customers could have an adverse impact on Aurobindo's business and profits. Customer expectations and competitors' tactics can lead to pricing pressures, which can bring down top-line and operating margins.

Due to generic drug pricing pressures, the drug manufacturers including Aurobindo are facing tougher market conditions, and the pricing concerns are expected to remain in all key markets. The US government is establishing new measures to enhance competition, promote access and lower drug prices. Therefore, it is approving an increased number of generic drug applications.

Further consolidation in distribution channel may continue to adversely affect pharmaceutical manufacturers and such consolidations have resulted in increasing the product pricing pressures. Drug pricing is influenced by global trends in terms of availability and cost of imported raw material. The Company's net sales realisations could get affected due to discounts offered to customers for benchmarking and competing with the pricing of other competitors.

The Company also sells ARVs to over 125 countries by participating in Global tenders floated by International Organisations such as Global Fund, USAID/PEPFAR and country specific Ministry of Health (MOH) and in such an environment, drug prices are marginally controlled and profit margins are affected. Domestic pricing is influenced by global trends in both availability and price of imported active ingredients. The Company continues to face challenges within the industry in terms of price cuts or increased price controls.

Mitigation strategy

In an environment that is laden with pricing pressures, the Company, as part of its mitigation strategy, continues to adopt negotiation tactics to market and sell products to customers. With a continued focus on stable supplies, day-1 launches, and a diversified product portfolio, the Company is handling pricing pressures by launching value- added products and focusing on other markets where there are better margins.

Moreover, the Company's vertically integrated manufacturing facilities, high quality products and differentiated services, combined with R&D expertise, would help the Company manage pricing pressures. The R&D team continues to develop cost-effective products by alternative production process. The Company is able to cope with price pressures by increasing volumes, improving efficiencies, optimising costs and strengthening its supply chain. The SCM team is continuously putting in efforts to de-risk global procurement issues and is ensuring timely services to important customers in all key markets.

Market risks

Over the years Aurobindo has been doing large business in generics in the USA and Europe markets, and there are many pharmaceutical companies that are competing with Aurobindo in both the markets. The Company might be exposed to significant risk if it is unable to offer a wide range of products across multiple therapeutic segments and bring products to market in a timely manner, which could ultimately affect the business growth strategy. While the Company is significantly dependent on the US and Europe markets for its business, any failure to conduct profitable operations in those markets, could adversely affect the Company's business and financial condition.

With the COVID-19 crisis spreading in all key pharma markets, including the US and European markets, which are badly affected, where the economic impact is larger and there are supply issues to customers and partners, it is highly critical for the Company to retain the existing market share and enhance the market size in the days to come. Any kind of delay in supplying material to customers and deviations in customers' specifications could have an adverse impact on customer relationships and loss of revenues. This would be aggravated by issues like liquidity, cash flow, demand and other issues in the short-term. Also, the situation might lead to reducing/cancelling supplies or imposing of penalties by customers and health ministries.

Any failure to market and cater to key customers in the markets due to this unprecedented situation may also result in reputational damage to the Company.

The EU market has differences across EU member states, and this can influence the Company's revenue strategy. Customer consolidation/integration continues to happen among wholesalers, pharmacists and buying groups, thereby increasing the customer concentration risk for the Company. Therefore, it is imperative for the Company to offer a wide range of products as well as a product pipeline, in order to fulfil customer needs.

Mitigation strategy

The Company continues to enlarge its market share through business acquisitions in the US and European markets, and diversifying its product portfolios. In FY20, the Company has acquired certain business assets used for R&D from Profectus BioSciences Inc. USA, a clinical-stage vaccine development company, which would provide access to proprietary and innovative technology platforms for prophylactic use and therapeutic use along with a R&D centre.

Through continued investment in R&D, the Company is able to constantly build a portfolio of value-added products for the future. Some of the new therapeutic areas are biologics, dermatology, respiratory, peptides, and vaccines. As part of the product portfolio growth strategy, the Company sells dietary supplements in the US and other markets, which enhance

revenues. New launches and a well-diversified product portfolio have enabled the Company to maintain steady growth in the US and Europe markets.

As a significant global player, the Company continues to focus on leveraging its market-leading, vertically integrated manufacturing base to enhance market share in untapped markets. Also, to enhance presence in therapeutic areas like oncology and dermatology, the Company is focusing on every product segment in all markets. Such a well-rounded approach would help consolidate the Company's revenues over long-term, thereby spreading the risk portfolio and increasing market share.

In order to mitigate the risk of customer concentration, the Company is continuously making focussed efforts to enhance its customer base through an effective marketing strategy. The Company continues to focus on customer service by improving OTIF (On time in Full). In the ARV business, customers are government organisations and the Company is necessarily dependent on those customers, as the Company sells ARV products by participating in Global tenders floated by international organisations such as the Global Fund, USAID/ PEPFAR and the Ministry of Health (MOH).

In order to minimise the risk of country concentration, the Company continues to spread its business into Europe, Japan and other emerging markets. Aurobindo, with its effective marketing strategy, is able to augment sales volumes in existing markets and continues to widen geographical spread by entering into large potential markets in Latin America and emerging markets. The Company has dedicated commercial and business development teams focusing on developing new partnerships.

Regulatory, Statutory and Legal compliance risks

Large-scale geographical footprints, complex product portfolios and processes could increase Aurobindo's vulnerability to regulatory issues and compliance delays and oversights, including late filings, registrations and ANDA approvals and these vulnerabilities could be further affected by the recent COVID-19 crisis. Compliance deviations in any geography due to changing regulations can lead to business and reputational impact on the Company. It is of utmost importance for the Company to ensure compliance with regulations and applicable laws relating to patient health and safety to avoid legal penalties and to have smooth and continued business operations.

Aurobindo, being part of a highly regulated industry, faces the challenging task of complying with a large number of rules and regulations across all aspects of the business. In recent years, the number and complexity of regulatory requirements has increased substantially, and will become even more stringent in the days to come. The Company is particularly challenged with responding to this ever-changing regulatory environment since non-compliance has a profound effect on cost, reputation, and ultimately the lives of patients.

Various regulatory agencies are constantly overseeing compliance activities in terms of increased scrutiny, sophisticated risk-monitoring techniques across the globe and forcing pharmaceutical companies to identify and correct quality issues upfront before impacting production. Therefore, it is very critical for the Company to have the best compliance practices to conform to changes in regulations and other applicable laws. The regulations require registration, filings and data submission to allow the Company to enter diverse markets. Therefore, the Company continues to establish and strengthen systems and controls to monitor and upgrade registrations, as and when required. The Company continues to take extraordinary care in conducting business in accordance with regulations and applicable laws and maintaining its core values.

Mitigation strategy

The Company strives to maintain the balancing act of driving business innovation and achieving business goals, while simultaneously mitigating compliance risks, if any, and conforming to regulatory and compliance standards to meet stringent requirements of regulators. Robust quality systems and control measures are available to ensure that quality is ensured by process design. The Company continues to adopt an enterprise-wise compliance review and data analytics by senior management in quarterly Quality Review Meetings (QRM), which reduces potential risks. There are separate and dedicated teams which take care of regulatory filings and timely submission of dossiers, besides ensuring timely product availability. The regulatory team do a regular follow-up of pending approvals and queries raised by regulatory authorities.

The Company is constantly improving compliance practices by imposing strict adherence to its Code of Conduct that is focused on ethics and integrity, which reduces risk of non-compliance. The ethics and integrity driven approach fulfill the needs of the business with the needs of regulators.

Through the 'Compliance Management System' (for statutory) (Vision 360 Tool), the Company continues to ensure compliance with all applicable laws, and it is designed to cover all compliance aspects of key functions in the entire organisation. Periodic compliance updates to the system are made whenever there is a change in any applicable laws. Quarterly compliance declarations, as provided by functional heads and generated electronically from the Vision 360 system, are submitted to the compliance officer of the Company. Quarterly compliance audit is done by the transaction auditors to ensure that compliance is mapped with applicable laws. In case of any non-compliance, necessary steps are taken by the concerned functional heads to correct the deviation.

Aurobindo has a talent pool of over 1,600 scientists and analysts, who have proficiency and experience in handling complex chemistry and filing applications with the regulatory authorities. The strong scientist pool has helped Aurobindo receive a total of 425 ANDA approvals (397 final approvals and 28 tentative approvals) from the USFDA as on 31 March 2020. Cumulative filings totalling to 586 ANDAs.

Similarly, as on 31 March 2020, the team has filed over 3,350 DMFs (multiple registrations) including 254 with the USFDA. So far, 135 patent applications are pending with various authorities and 127 have been granted patents.

Environment, Health and Safety (EHS) risks

Ensuring valid EHS permits and approvals from concerned government authorities on a timely basis is a top priority for Aurobindo. Any failure to obtain, renew or maintain the required permits or approvals may result in the interruption of operations and may have an adverse impact on the Company's business. Aurobindo handles a large number of chemicals with various hazardous properties. Failure to handle chemicals in a safe manner may pose safety and health risks to employees.

Compliance with various terms and conditions of EHS permits and approvals is made part of a structured corporate tracking and review mechanism that includes timely actions for renewals of permits. The Company is focusing on identification and strategies for mitigating EHS risks beyond permits and regulatory compliance. While the manufacturing facilities are equipped with adequate engineering and administrative controls of operations to mitigate EHS risks, the Company is making all efforts in addressing certain EHS concerns like Pharmaceuticals in Environment (PiE) and Antimicrobial Resistance (AMR) etc. Aurobindo is collaborating with reputed international agencies like Access to Medicine Foundation, AMR Industry Alliance, etc. The Company is also engaging reputed organisations like Ecovadis for independent EHS evaluation and assessment.

Mitigation strategy

Aurobindo's facilities have already established processes for deactivation of API residues in wastewater. Significant investments were made in the upgradation and expansion of wastewater treatment projects in our facilities for an improved and additional treatment of wastewater. The solid and liquid hazardous wastes are being disposed of to Treatment, Storage and Disposal (TSD) facilities or cement units that mitigate the risk of PiE or AMR effectively.

Extensive and massive plantation, within and around manufacturing facilities, is taken up to offset environmental impact to some extent. The Company is committed to providing a safe and healthy working environment to all its employees and contract workers. To manage the safety and health risk, risk identification and assessments are performed before scaling up. A hazard and operability study (HAZOP) is performed before a chemical process is taken up in the manufacturing area. Training is provided to operating personnel on precautions to be taken, and suitable personal protective equipment is provided.

Patent protection risks

Aurobindo's success to a great extent depends upon the Company's ability to obtain IP Rights such as patents and trademarks, protect trade secrets and other proprietary information, and operate without infringing the intellectual property rights of the other companies. Aurobindo's inability to obtain timely ANDA approval and/or launch a product immediately upon approval due to patent litigation issues or due to settlement for a late market entry date may affect the revenue.

Aurobindo has a dedicated team of IP professionals, whose primary task is to ensure that the products are manufactured using essentially non-infringing composition and processes to the best possible extent and in compliance with IP-related requirements by reviewing and monitoring IPR issues continuously.

Mitigation strategy

The IPR team evaluates and provides stage-wise IP clearances during product/process developmental activities. The IP team also provides frequent updates and alerts on all relevant IP matters (such as patent, trademark, etc.) to R&D scientists for the products and suggests suitable measures to deal with IP-related issues. The IP team is also involved in product selection to ensure that opportune products are identified for development. Further, the IP team has been proactively exploring early launch opportunities based on the changing IP scenario in specific countries and conveying the same to the corresponding country heads/business teams with the objective of enhancing revenues.

As on 31 March 2020, the Company had filed several patent applications, of which 127 patents had been granted and 135 patent applications are pending for prosecution with various authorities globally. Aurobindo takes adequate care to protect its trade secrets, know-how and other proprietary information, and ensures that the employees, vendors and suppliers associated directly or indirectly with the Company sign appropriate confidentiality agreements prior to disclosure of any such confidential information.

Financial risks

In view of the large scale of exports, raw material imports and borrowings, there exists potential financial risks to the Company, which include foreign currency risk, credit risk, liquidity risk and interest rate risk. This could be aggravated by the recent COVID-19 crisis resulting in revenue decline, cash flow constraints, liquidity pressures, loan commitments, currency fluctuations and interest rate changes, all of which could have major impact on operating results and the financial condition of the Company.

In the current COVID-19 crisis, global economic activity and financial markets around the world are on slowdown mode. Since Aurobindo's major share of revenues comes from the US and European countries, which are badly impacted, managing cash pressure are crucial for the Company. This situation could lead to a drop in sales, cash flow constraints, and reduction in cash collections in the short-term, which could result in a liquidity crunch. As a result, the Company would not be able to duly meet its financial obligations, such as making import payments and discharging loan commitments.

The exchange risk arises from its foreign currency revenues, imports and borrowings and major portion of the Company's revenues are in foreign currencies. As the rupee value is presently depreciating, the Company's revenue could increase while the burden of foreign payments towards imports and borrowing may increase. In times of a slowdown, the Company would have to face and overcome interest rate changes to avoid adverse impact on cash flows.

Mitigation strategy

The Company continues to focus on countering the unpredictability of financial markets so as to minimise any adverse impact on financial performance and also effectively uses derivative financial instruments, i.e. forward contracts, to mitigate foreign exchange related exposure. The Company's growing exports and its collections provide natural hedging to imports, loan commitments and working capital against exchange fluctuations. The forex position is reviewed daily by department head and quarterly by audit committee and board.

The Company's credit control policies and procedures are robust enough to mitigate the credit risk relating to sales and customer collections. The treasury team and Business Heads continue to evaluate customer credit worthiness and define credit limits for individual customers which are uploaded in the ERP system. In the event of any customer overdue balances and credit limits being in excess, auto-controls are established in the ERP system to block further sales to such customers. As part of effective financial risk management, the Company's treasury team performs the following tasks:

- Assessing regularly the available cash and liquidity position
- Reviewing periodically the customers' overdue receivables and committed collections and following up with the Sales and Marketing team to expedite the collections process
- Ensuring reduction in borrowing costs by effectively negotiating with banks
- Monitoring day-to-day fund requirements and making timely import payments
- Keeping track of changes in the financial market and taking appropriate decisions on financial instruments to avoid any financial loss
- Establishing strong maker-checker controls and proper segregation of duties within the finance team to ensure that no one person has entire control over processing of financial transactions

People risks

It is essential to establish and promote a culture of excellence in the execution of all operations and processes to support the sustained growth of Aurobindo. The Company may be facing many challenges relating to talent acquisition, strategy setting, employee cost controlling, learning and development, succession planning and employee retention as well as labour compliances and disputes, which can have an adverse impact on operations and revenues.

In the current COVID-19 crisis, the Company's operations at some locations could be disturbed to some extent due to shortage of labour resulting from the local lockdown of respective nations. The pharmaceutical industry is human capital intensive with a high rate of attrition, and it is a challenge for the Company to maintain good industrial and employee relations, especially since any labour unrest could impact the Company's operations.

Mitigation strategy

In response to the mitigation of people risks and to face unforeseen challenges, the Company continues to adopt the following measures:

Process automation

Aurobindo is focusing constantly on process automation and integrating technology with people processes, which makes process effective, streamlines systems and ensures timely execution of projects. The Company as a part of new initiatives has automated the following processes during the year:

- Learning management system to ensure that compliance and behaviour focused programmes are being attended by all employees
- Employee full and final settlement process to ensure accurate and integrated compensation practices
- Contract labour training – RFID based contract labour training – to ensure that only trained contract manpower is authorised to enter into a specific area of operations at the manufacturing plant.

Leadership development

A system of second-line development, an integrated approach with a focus on seamless operations, feedback and competency aspects, has been implemented. All critical positions are mapped, and second-line development plans are being initiated with focus on various plants on a priority basis. An Integrated Business Excellence System to build shop floor capabilities focusing on asset care, process care and people care is being extended to all formulation units. The Company continues to strengthen NALANDA, an online academy that

facilitates leadership and talent development, and supports the management philosophy of second-line development, in line with the Company's leadership competency model.

Statutory Compliance and Safety/Health Management
New Social Audit process called the AMFORI Business Social Compliance Initiative is rolled out at some of the Formulation units. More and more manufacturing facilities are coming under the scope of Social Audits to reduce or mitigate the risks associated with HR compliances and safety management. An outcome-based technical training to improve productivity and right handling of sophisticated equipment is provided for operators and supervisors on the shop floor.

Talent engagement and empowerment
The Company is striving to create a culture of employee engagement as a method to retain talent. It is a proactive approach and employees are given both responsibility and authority. Emphasis is on leadership accountability with a clear mandate to develop critical talent and successors for all key roles as part of employee performance models and employees are encouraged to perform to their optimal potential. Regular feedback and counselling are provided to help the personnel update and upgrade their knowledge and skills, so as to minimise operational risks.

Multi-skilling and Quality programmes
The Company continues its focus on its multi-skilling programme, which promotes job enrichment of talent at the operational level. Also, adopting the Quality Marshal program continuously instils a quality culture on the shop floor.

Employee performance appraisals
The Company's online employee appraisal system is robust for measuring performance vis-à-vis KRAs defined for the employees. The HR team strives to ensure that annual performance assessments are conducted effectively with necessary feedback and counselling. Talent risk mitigation features included in Performance Management System (PMS) are Talent identification, Retention and Development, besides helping other talents to scale up their performance.

Harmonious industrial relations
The Company has been able to move the entire grievance handling system online. The system ensures that all concerns are handled in a time-bound manner along with solutions, apart from helping prevent and settle issues in a peaceful manner. The Industrial Relations team works continuously to maintain a cordial relationship with employees with a view to achieve the best performance. Further, the management has established Social Accountability Standards (SA 8000 series) to maintain its commitment towards fair and progressive people management and EHS systems. The Company ensures that there is full adherence to the code of business conduct, and fair business practices are followed by employees.

Information technology (IT) and Cyber security risks
In the current environment of the COVID-19 outbreak, business continuity demands working remotely, that requires additional focus and hardening of the IT infra security as well as Cyber Security. BYOD (Bring your own device) has become a norm, and therefore providing data access remotely in a secured manner is a major requirement. The Company faces cyber security challenges in terms of data confidentiality, integrity and availability as more collaboration technologies (web conferencing, video conferencing, file sharing and collaboration, mobile computing, cloud computing etc.) for internal and external virtual meetings are adopted. Any vulnerability in information security and regulatory compliance management, may have an impact on business continuity and may lead to legal consequences and penalties.

Aurobindo's IT infrastructure, data availability, data storage and processing and security aspects are continuously scaled-up and upgraded to support the growing business and enable it to stay competitive. Aurobindo continues to ensure compliance with applicable provisions of the European Union General Data Protection Regulation (EU GDPR). To ensure GDPR compliances, the Company has established policies and procedures, which include training of employees and investing in adequate technologies to safeguard personal data collected from EU data subjects. The Company has a tie-up with the Enterprise DPO (Data Protection Officer), who closely works with the country specific DPO, IT, HR, Legal etc. for ensuring compliance.

Mitigation strategy
The Company is improving process efficiency by way of controls, automation and internal workflows for ERP Oracle applications and other applications supporting the operations. The Company has robust IT controls related to backup, storage and system access, including role-based access and change management controls. For all critical IT applications and services, the Company has built highly stringent and secured infrastructure. For business continuity, the Company continues to maintain a disaster recovery site, which hosts backup ERP applications. For any business process automation and regulatory compliance-related solution, the IT team works very closely with business process owners for effective and timely implementation. Periodic reporting of all critical IT projects to the leadership team is done by the Chief Information Officer (CIO). The IT team conducts a periodic evaluation of IT processes, and in the contingency of any gaps and concerns, corrective measures are taken.

The IT Governance Committee continues to review IT-related matters around policies and practices, budgets, proposals for procurement of new applications and hardware, renewal of licenses, process automation to support the business functions etc. and advises the Board for its consideration. The Company has an experienced IT operations team, which ensures smooth day-to-day functioning of IT infrastructure and applications including network infrastructure, server and

device management, computer operations, and helpdesk services. Some of the new initiatives taken during the year are given below:

- Implementation of Application object management to automate the process of change management control and object migration and thereby automate the release management for ERP
- Upgrading operating systems, database and applications to latest versions to provide better performance and enhanced features to the business
- Tech refresh of Oracle ERP to Exadata for improved performance
- Implementation of additional user access controls in ERP, in line with Attendance Management System and HR Management system. Resignation process made online in all divisions

Aurobindo leverages industry best standards to secure its IT infrastructure environment. Some of the preventive measures in place are the Intrusion System enabled perimeter firewalls, content filtering gateways, robust logical access controls for laptops and critical data at rest, regular software patching etc. The IT team conducts a periodic review of the Company's cyber security posture and penetration tests to ensure effectiveness. In addition, the following control measures are taken to mitigate cyber security risk.

- Training and awareness sessions for users about common and new cyber vulnerabilities and attacks
- Hardening of IT Infra security by implementing technology solutions
- Regularly reviewing access levels and tracking them appropriately

Monitoring logs related to IT infrastructure – Firewall, Mail gateway, AD server, Proxy server, AV Server, Email Server and ERP Server, besides taking appropriate action on incidences, if any.