Cautionary Statement

Statements in the Annual Report, particularly those, which relate to Management Discussion & Analysis, describing the Company’s objectives, projections, estimates and expectations, may constitute forward-looking statements within the meaning of applicable laws and regulations. Although the expectations are based on reasonable assumptions, the actual results might differ significantly.

Key Economic and Industry Trends

As per the International Monetary Fund (IMF), the global economy is expected to grow at 3.2% and 3.5% in 2019 and 2020. Within this, the US, European Union (EU) and China are expected to witness slowdown in growth in 2019. Governments and central banks in the US, EU and China are adopting stimulus measures along with accommodative monetary policies to support economic growth to tide over growth concerns in their respective regions.

As per IMF, India’s Gross Domestic Product (GDP) in FY 2020 and FY 2021 is expected to grow at 7.0% and 7.2%, respectively. The GDP growth is expected to be driven by continued strengthening of investments, improvement in exports performance, an expansionary monetary policy stance and expected impetus from fiscal policy. The implementation of structural reforms such as the Goods and Services Tax (GST) is expected to support the long-term growth trajectory of the country.

According to Evaluate Pharma, the global pharmaceuticals market is expected to grow at 6.4% Compound Annual Growth Rate (CAGR) between 2018-2024 to reach US$ 1.2 trillion in 2024. This growth is expected to be led by novel therapies addressing key unmet needs, growth in core therapeutic areas and increase in access to medicines globally. The orphan drugs sector is expected to outperform the market, almost doubling in size over 2018-2024 and peaking at US$ 262 billion in 2024, accounting for approximately 20% of prescription sales.

The Indian pharmaceutical industry, which is the largest exporter of generic drugs in the world, accounts for about 20% of the global generic drug exports. India is also the second largest contributor of global biotech products and the pharmaceutical workforce and labor costs here are lower than other manufacturing hubs. Exports from India, the third largest pharmaceutical market globally in volume terms, grew by 11% YoY to over US$ 19 billion in FY 2019.
According to a report by Federation of Indian Chambers of Commerce and Industry (FICCI), the Indian crop protection chemicals industry is estimated to witness a CAGR of 8.3% to US$ 8.1 billion by FY 2025, with exports growing at a higher rate of 8.6% to US$ 4.2 billion in 2025. According to an Industry report, the global animal nutrition market is estimated to grow at a rate of 6.5% to reach US$ 21.4 billion by 2022.

Our Business Strategy

We are focused on maintaining global leadership position in our chosen areas of business and to continuously create new opportunities to ensure sustainable growth. Our core business strategy is to create a robust integrated global pharmaceuticals and life sciences company. Healthy demand in our Pharmaceuticals segment and continuous value-addition in our Life Science Ingredients (LSI) segment’s offerings is expected to drive sustainable business performance, going forward.

Our business is classified into three broad segments:

1. Pharmaceuticals
2. Life Science Ingredients
3. Others (Drug Discovery & Development Solutions and India Branded Pharmaceuticals businesses)

In the Pharmaceuticals segment, our strategic objective is to continue to maintain and establish leading market positions in our key business lines to drive profitable growth. As such, we have implemented the following core strategies:

(1) **Continue to strengthen leadership positions in our key business segments**

We have established leadership positions throughout our diversified portfolio in all our three business lines, namely (i) Specialty Pharmaceuticals, comprising Radiopharma (including Radiopharmaceuticals and Radiopharmacies) and Allergy Therapy Products, (ii) Contract Development and Manufacturing (CDMO) comprising Contract Manufacturing of Sterile Injectables and Non-Sterile Products (CMO) and Active Pharmaceutical Ingredients (APIs) and (iii) Generics comprising Solid Dosage Formulations. We intend to continue to strengthen our leadership positions by focusing on the following:

A. **Radiopharma**

We are the third largest player in the nuclear medicine industry and the leading player in the United States based on market share of certain products, namely, MAA and DTPA. We believe we are well-positioned in the high value niche business of Radiopharmaceuticals, offering quality diagnostic imaging and therapeutic radiopharmaceutical products. We specialise in lung, thyroid, bone and cardiac imaging products as well as thyroid disease therapy. For diagnostics, our key products include MAA and DTPA, for both of which we are sole suppliers in the United States. For therapeutics, our key products include iodine-131 (‘I-131’), of which we are one of only three manufacturers globally. Our goal is to achieve market leadership in the nuclear medicine industry by increasing our market share of RUBY-FILL® generators and RUBY Rubidium Elution System™ - cardiac position emission tomography (‘PET’) imaging, as well as focusing on value-based pricing and expanding our product portfolio through the launch of niche and differentiated products, including a few niche 505(b)(1) or 505(b)(2) filings. We also plan to consider expanding our portfolio by in-licensing new products within or adjacent to our current portfolio such as products in the medical device area and the adjacent nuclear medicine supply space. We are also considering increasing our product portfolio of devices and complementary imaging products.

In September 2017, our acquisition of substantially all of the assets of Triad’s Radiopharmacy business, including its network of radiopharmacies, was part of our strategy to get closer to customers. We are the second largest centralised commercial radiopharmacy network partner in the United States with over 50 radiopharmacies across 22 states. We aim to build the nation’s premier centralised radiopharmacy network. We continue to seek opportunities to expand or enhance the efficiency of our Radiopharmaceuticals business by optimising the coverage of our Radiopharmacy network including through further additions and improvements or consolidation of locations, which may include geographic expansion of our Radiopharmacies in the United States and Canada by opening new pharmacies. In this regard, we are working on making ‘Jubilant’ a well-known and respected brand among hospital networks in the United States and Canada. Combined with our radiopharmaceuticals manufacturing capabilities, a wider distribution network of radiopharmacies ensures synergies within the Radiopharma business line. We
believe we are a strong partner to major US healthcare providers and have deep relationships with our current customers and organisations [Group Purchasing Organisations (GPOs) and regional networks] that influence the industry, and we will look to enhance our customer offerings to renew and extend existing agreements with our customers. We also plan to look for opportunities to establish new distribution channels through collaboration and contractual arrangements with our strategic partners.

B. Allergy Therapy Products

We are one of the leading allergenic immunotherapy companies in the United States with 90 years of experience and a service provider to allergists and the medical community, with a product range of over 200 different allergenic extracts, six insect venom products and exclusive skin diagnostic testing devices. We also distribute our products to other markets including Canada, Europe, Australia and New Zealand through distributors. We are one of the top three players in the allergenic extract market in the United States and are currently the sole producer and supplier of venom products for the treatment of allergies in the United States. In addition, we expect to benefit from barriers to entry as Allergy Therapy Products operate in a niche US allergen extract market and most products in this market are biological products with grandfather status requiring a Biologics License Application from the USFDA for any new approval for manufacturing and commercialisation. Our strategy is to build on our leadership in the North American market and at the same time deepen penetration in other markets by continuing to offer differentiated products such as venom and extracts. We aim to continue to drive growth and profitability through our strong customer commitment to be the partner-of-choice in the US allergy market and leveraging the strong brand recognition of the ‘HollisterStier’ brand. We believe we can achieve this through long-term strategic partnerships, adding to our product portfolio by launching new, differentiated products and/or processes along with expanding our capacities for our venom and extract products, improving supply reliability, and expanding our customer base into new markets.

C. Contract Manufacturing of Sterile Injectables and Non-Sterile Products

We are fully integrated, providing a broad range of capabilities including sterile liquids and lyophilised products, ointments, creams, lotions (OCL) and biologics. We serve seven of the top 20 pharmaceutical companies globally. We have an established market position in the sterile injectables and non-sterile products markets in North America, with deep and long-term relationships. We expect to further benefit from barriers to entry in this segment, including the level of technical expertise required to develop products, obtain licensing and regulatory approvals and manufacture of such products. In particular, there is a growing demand for sterile injectables capabilities, which generally involve complex processes, and we believe we are one of a limited number of manufacturers with the requisite know-how. Due to consolidation activities across the Contract Manufacturing (CMO) space and our compliant regulatory status, we have seen an influx of new clients at both our Spokane, Washington, United States and Montreal, Canada sites, which creates opportunities for us to capture greater market share. We believe we are in a position to grow the CMO business by continuing to focus our efforts on strengthening our industry position by enhancing; and expanding our capacity, including through focusing on consistent and ‘First Time Right’ customer service, extending and deepening our relationships with leading innovator pharmaceutical companies; focusing on long term high value contracts; building new customer relationships including identifying new customer targets for ampoules, semi-solids and non-sterile liquids, finding opportunities to strategically extend our product portfolio, and evaluating opportunities for new product launches. We are also exploring opportunities to increase capacity by reducing unutilised production capacities and establishing new lines within our current capabilities, including lyophilisation. In addition, we plan to expand capacities through debottlenecking, including operating Spokane facility on a 3-shift 7-day basis to achieve greater sales volumes. Our production efficiency measures are also aimed to increase our product filing yield and reduce the time cycle between product releases.
D. Active Pharmaceutical Ingredients (APIs)

We develop and produce APIs in the therapeutic areas of the Cardiovascular System (CVS), Central Nervous System (CNS), Gastrointestinal (GI), Anti-infectives and Anti-depressants. We believe our forward integration with our Solid Dosage Formulations business line, focus on developed markets, strong emphasis on cost and in-house R&D helps drive consistent growth and profitability in this business line. We believe our strong presence and extensive experience in operating in highly regulated markets help us with customer retention and price realisation of our APIs products. Our strategy is to continue to be a preferred supplier to our customers with expansion in this business line, through streamlining our product selection, new product launches and increasing market share of our existing products. We believe that we are well placed to achieve sustainable growth through a well differentiated strategy of products and markets, a strong set of capabilities focused on product selection and cost optimisation and a highly capable team with a proven track record. Our forward integration with our Solid Dosage Formulations business also helps to ensure high capacity utilisation. To drive growth, we plan to focus on initiatives aimed at increasing the range of products that our customers purchase from us in key markets such as the United States and Europe, as well as expanding our geographical reach in select emerging markets such as Turkey, Brazil, Mexico, Russia, China and South Korea. We expect to continue to invest in R&D to build up our product pipeline, using our chemistry capabilities to develop new processes to bring products to the market and contribute to our growth, and pursue capacity expansion to take advantage of pipeline opportunities.

E. Solid Dosage Formulations

We believe we have a strong product portfolio and are one of the market leaders in the United States based on market share of several key products, namely, Prochlorperazine, Methylprednisolone, Prednisone, Donepezil and Olanzapine ODT. We focus primarily on the manufacture and sale of solid dosage formulations for Cardiovascular System (CVS), Central Nervous System (CNS), Gastrointestinal (GI) and Anti-allergy therapeutic categories. Our Solid Dosage Formulations business derives benefit from backward integration into our APIs business, supported by our in-house R&D facilities for formulation development, and extensive regulatory filings capabilities and cost effective manufacturing. These capabilities allow us to flexibly target attractive product development opportunities. Additionally, our in-house APIs capability allows us to better control the development of certain products from formulation through commercialisation and provides a stable source of APIs supply for these products at competitive prices. Our aim is to be first to enter and last to exit, using our chemistry and R&D capabilities and manufacturing expertise to drive growth in our Solid Dosage Formulations business line. We intend to focus on continuous investment in R&D in order to increase our Abbreviated New Drug Application (ANDA) filings and approvals, as well as complex, limited competition products using our in-house chemistry capabilities. We are also diversifying our business geographically and we intend to continue expanding our business into emerging markets by leveraging our existing US filings.

(2) Be closer to the customer to provide high quality products and services

We aim to be closer to our customers to provide them with high quality products and services. We have established strong and long-standing customer relationships across our business lines and we intend to capitalise on the strength of these relationships to create and pursue additional growth opportunities. Approximately 70% of our assets, including four manufacturing facilities (CMO Spokane facility, CMO Montreal facility, Radiopharmaceuticals Montreal facility and Solid Dosage Formulations Salisbury facility) and our network of more than 50 Radiopharmacies are based in North America. This ensures better service to our customers.
customers, a majority of which are based in North America. We will continue to leverage the insights we have gained from successfully bringing products to market in the highly regulated US market to launch products in other markets like Europe, Japan, Australia and other emerging markets. However, we expect revenues and profitability in North America will continue to account for a significant portion of our future consolidated revenues as we continue to focus on growth in this market.

(3) **Diverse sources of revenue with a de-risked business model**

Our de-risked business model comprises a global manufacturing and marketing footprint with diversified product offerings, including products in niche areas and product sourcing capabilities as well as a broad customer base. We are positioned across a range of geographic locations enabling us to capture different market segments, which offers opportunities for us to achieve higher revenue and margins, while minimising concentration risk. We expect to grow our diverse product and service portfolio both by increasing penetration in existing markets and expanding product portfolio.

We believe that we will have a higher likelihood of increasing our penetration in existing markets by offering new product innovations to our customers to meet their demands. We also intend to expand our product portfolio by utilising our market expertise in the United States, Europe, Canada and other targeted countries to identify new product development and marketing opportunities. We aim to deliver high quality products and services by maintaining efficient and regulatory compliant manufacturing facilities. We believe that we are proactive in maintaining good relationships with key regulatory agencies in North America, Japan and Europe and that our track record of compliance with global standards and regulations is an important factor in obtaining timely regulatory approvals and in maintaining long standing customer relationships.

**Products and Product Supply:** As on March 31, 2019, we had a diversified product portfolio including diagnostic and therapeutic radiopharmaceuticals, a broad range of sterile injectables and non-sterile products, over 200 different allergens and standard allergy vaccine mixtures, 55 commercialised generic solid dosage formulations and 42 commercialised
APIs sold across markets globally. As a result of our diversified product portfolio, we benefit from diversified revenues between three differentiated businesses. Our Specialty Pharmaceuticals business line, contributed 53% of total Pharmaceuticals segment revenue for the financial year ended March 31, 2019, while our CDMO and Generics business lines contributed 28% and 19% of revenue respectively in the Pharmaceuticals segment.

Customers: We have a broad and diversified customer base and with the top 10 customers (excluding GPOs but including customers purchasing goods and services through such GPOs) contributing 30% of the total Pharma revenues as on 31st March 2019.

Geographic diversification: We had sales in over 80 countries as on March 31, 2019 with revenues from North America contributing over 80% of the total Pharmaceuticals segment revenues. We believe that our established footprint in stable and regulated markets such as North America demonstrates the sustainability of our revenue generation and margins going forward.

Manufacturing facilities, R&D centers and Radiopharmacy distribution network: We benefit from a global and diversified manufacturing footprint. We have two manufacturing facilities located in Kirkland, Montreal, Canada, including our Radiopharmaceuticals facility, and our CMO facility, which produces sterile injectables and non-sterile products. Our US facilities include our Salisbury facility and Spokane facility which produce Solid Dosage Formulations and sterile injectables, respectively. In India our Nanjangud facility and Roorkee facility produce APIs and Solid Dosage Formulations, respectively. We are able to manufacture sterile injectables and solid dosage formulations at more than one facility and the location of our facilities provides us with an advantage of enabling us to be closer to our customers in North America. We also have R&D centers in Noida, India, Montreal, Canada, Nanjangud, India and Spokane, US which focus on innovation and provide support for new products. In addition, we have a distribution network of more than 50 Radiopharmacies in the United States.

Strong product pipeline with deep R&D capabilities

We believe we are well-positioned for future growth with a strong pipeline of products under development and across all of our business lines. Two of our radiopharmaceutical products have received 505(b)(2) approvals from the USFDA, namely Drax Exametazime™ and RUBY-FILL® Rubidium Rb82 Generator and Elution System. In addition to Drax ExametazimeTM and RUBY-FILL® Rubidium Rb82 Generator and Elution System, our Radiopharmaceuticals business line is in the process of developing certain products such as I-131 metabolobenzylguanidine (‘mIBG’) for which we plan to make a New Drug Application (‘NDA’) filing. In addition, we have six other products in different stages of development for which we may consider making 505(b)(2) filings. For Allergy Therapy Products, subject to the completion of relevant approvals from the United States Department of Agriculture (’USDA’), we plan to register our venom products and allergenic extracts for use in animals. We also have a strong pipeline in our APIs and Solid Dosage Formulations businesses.

Our captive value chain in our business lines and our large scale of production allow us to build and retain leadership through product innovation and new product launches. Our R&D continues to lead to new, innovative processes and new knowledge-driven products that increase the efficiencies of our production and allow us to capitalise on opportunities for growth in competitive markets. We have R&D centers located in North America and India and employ a team of over 400 R&D professionals with expertise in the development of non-infringing processes for APIs and Solid Dosage Formulations, as well as specialised and/or niche formulations and designs for radiopharmaceuticals and other products, which have been taken to commercialisation.

Global competitive edge due to integrated and efficient manufacturing operations

Integration across the value chain enables us to benefit from cost competitiveness advantages and better capacity utilisation due to captive demand. We believe our large scale capacity manufacturing sites in India provide us with cost advantages in terms of wages and raw materials prices as compared to many of our global competitors, as well as economies of scale. In addition, our integrated operations ensures competitive advantages through cost efficiencies by producing across the
value chain. This reduces our dependence on third parties for supply of feedstock and helps to insulate us from significant volatility in raw materials prices. The APIs from our manufacturing facilities are used for solid dosage formulations under our Generics business. Such integration between our Solid Dosage Formulations and APIs businesses allows us to continuously improve our cost of production. Multiple products in our Radiopharmaceuticals and Allergy Therapy Products businesses are manufactured in our CMO facilities. For example, our CMO Montreal facility is used to manufacture cold products (non-Radioactive products that may be later complexed with Radioisotopes) such as DRA\XIMAGE\® MAA and DRA\XIMAGE\® MDP-25 for our Radiopharmaceuticals business and our Spokane facility is used to manufacture products for our Allergy Therapy Products business line. Additionally, our radiopharmaceutical products are distributed through our more than 50 radiopharmacies.

We operate our plants in accordance with current Good Manufacturing Practices (‘cGMPs’) and/or other applicable requirements. We currently operate four USFDA approved manufacturing facilities in North America and two USFDA approved manufacturing facilities in India. As the USFDA has heightened standards for and increased its monitoring of pharmaceutical manufacturers significantly over the last decade, we intend to continue to adhere to USFDA regulations to assure our customers of the quality of our manufacturing processes and products.

Our Roorkee, India facility received a Warning Letter and our Nanjangud facility received an Official Action Indicated classification from the USFDA during the financial year. In both cases, we expect to continue to service our current operations but new product approvals from the facilities maybe delayed. We are committed to the highest level of compliance and quality and are taking steps to ensure further stringent controls at all our facilities. We have submitted comprehensive responses to the USFDA and have engaged with 3rd party consultants to help in the remediation activities.

In addition to inspections by the USFDA, our sites are also inspected by a number of other regulatory agencies, including, Health Canada, Central Drugs Standard Control Organisation in India, ANVISA Brazil and RP Darmstadt Germany.

(6) Offer an integrated business model that provides products and services which are cost-effective

We expect to continue to optimise margins by enhancing efficiencies in our integrated operations. We believe the integrated business model we have in place makes us well-positioned to deliver products and services which are cost-effective. For example, our Radiopharmaceuticals and Allergy Therapy Products businesses are supported by our CMO operations. We are also able to utilise our network of Radiopharmacies to distribute our radiopharmaceutical products in the United States. Our multi-site manufacturing capabilities in North America and India gives us flexibility and provides us with cost advantages. In addition, our Solid Dosage Formulations business line is supported by R&D from India and is integrated into our low cost APIs manufacturing in India. We aim to continue to increase the share of solid dosage formulations manufactured with the Company’s cost-competitive in-house APIs manufactured in India. We also plan to continue our focus on methods to optimise our margins through business excellence programs involving Lean Six Sigma initiatives, which are aimed at productivity enhancement. In this regard, we expect to achieve higher gross margins for many of our new products and to improve our yields on existing products by increasing capacity utilisation for these products. We also aim to improve our operating margins by leveraging our existing sales capabilities and administrative functions across an expanded revenue base as a result of expected growth in our product portfolio, thereby gaining scale in operations.

(7) Continue to pursue strategic acquisitions to further consolidate leadership positions and accelerate growth

We have historically grown the Pharmaceuticals segment through a series of organic and inorganic initiatives. For example, we completed the acquisition of our Nanjangud facility, followed by multiple acquisitions in the United States, Canada and Europe. Most recently, in September 2017, we acquired substantially all of the assets which
comprised Triad’s Radiopharmacy business. While we remain focused on driving the growth of our business organically, we intend to continue to pursue sizeable, strategic acquisitions to further strengthen our portfolio, gain competitive advantage, consolidate leadership positions and accelerate growth within our existing businesses, and achieve higher than industry growth.

In the Life Science Ingredients (LSI) segment, our Company has built global scale and has global leadership in our chosen businesses. Following are our key strengths in this segment:

- **Leadership positions in key products** – The Company is a global leader in Pyridine and its derivatives (Fine Ingredients), Vitamin B3, Acetic Anhydride and Ethyl Acetate.
- **Strong R&D ethos** – LSI segment leverages strong R&D capabilities, which enables development of superior processes and catalysts resulting in a strong pipeline of Specialty Ingredients products. The Company has a broad product portfolio of over 90 products driven by R&D capabilities and chemistry expertise.
- **Longstanding client relationships** – The Company has strong and established business relationship with clients across pharmaceuticals, personal care, agrochemicals, nutrition and specialty ingredients industries.
- **Optimal utilisation of resources** – We have undertaken strategic initiatives to increase capacity utilisation of our multipurpose plants by retrofitting and debottlenecking existing plants. In addition, six sigma and lean initiatives program will continue to further improve our operations with focus on reducing costs and improving yields.

- **Integrated Value Chain** – Vertical integration across the value chain enables cost competitive advantage. Intermediates produced by our Ethanol business are used as feedstock by downstream business units and similarly Advance Intermediates products like Pyridine and Beta Picoline are used by Fine Ingredients, Crop Science Ingredients and Vitamins businesses.

In the ‘Others’ segment, for our Drug Discovery & Development Solutions (DDDS) business we are focusing on an integrated approach from Drug discovery services, Chemistry services to Good Manufacturing Practice (GMP) scale-up of intermediates and actives which complements well with our Contract Development and Manufacturing (CDMO) offerings of large scale GMP and non-GMP manufacturing through LSI business. This provides our pharmaceuticals and other life science customers with a one stop solution from early phase development to commercialisation of their molecules. We also have a strong commitment to innovation through in-house investments to partner with our clients. This has generated a strong portfolio of discovery assets both in early as well as late stage in the area of Epigenetic, Inflammation and Diabetes. We continue to evaluate further licensing opportunities from our existing pipeline.

During the year, Jubilant Pharma Limited (JPL), Singapore, a material wholly owned subsidiary of the Company fully redeemed the outstanding zero coupon convertible loan of International Finance Corporation (IFC), Washington, on a one-time settlement of US$ 135 million based on mutual agreement. With this all loans outstanding to IFC have been fully paid and the obligation to provide an exit to IFC by equity conversion of the convertible loan has been cancelled. This payment was made from the rated unsecured bonds of US$ 200 million raised by JPL, Singapore in March 2019.
Financials

<table>
<thead>
<tr>
<th>Consolidated Income Statement</th>
<th>FY 2018 (₹ million)</th>
<th>FY 2019 (₹ million)</th>
<th>% Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Revenue from Operations</strong></td>
<td>75,578</td>
<td>91,108</td>
<td>21%</td>
</tr>
<tr>
<td>Other Income</td>
<td>400</td>
<td>357</td>
<td>(11%)</td>
</tr>
<tr>
<td><strong>Total Income</strong></td>
<td>75,978</td>
<td>91,465</td>
<td>20%</td>
</tr>
<tr>
<td>Material Cost and Change in Inventory</td>
<td>26,259</td>
<td>32,809</td>
<td>25%</td>
</tr>
<tr>
<td>Purchases of Stock-in-trade</td>
<td>2,428</td>
<td>2,409</td>
<td>(1%)</td>
</tr>
<tr>
<td>Excise Duty on Sales</td>
<td>400</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employee Benefits Expense</td>
<td>15,559</td>
<td>19,260</td>
<td>24%</td>
</tr>
<tr>
<td>Power and Fuel Expense</td>
<td>4,249</td>
<td>4,664</td>
<td>10%</td>
</tr>
<tr>
<td>Other Expenditure</td>
<td>11,499</td>
<td>14,576</td>
<td>27%</td>
</tr>
<tr>
<td><strong>Earnings Before Interest, Taxes, Depreciation and Amortisation (EBITDA)</strong></td>
<td>15,584</td>
<td>17,747</td>
<td>14%</td>
</tr>
<tr>
<td>Depreciation, Amortisation and Impairment Expense</td>
<td>4,150</td>
<td>3,709</td>
<td>(11%)</td>
</tr>
<tr>
<td>Finance Cost</td>
<td>2,843</td>
<td>2,198</td>
<td>(23%)</td>
</tr>
<tr>
<td><strong>Profit Before Exceptional Items and Tax</strong></td>
<td>8,591</td>
<td>11,840</td>
<td>38%</td>
</tr>
<tr>
<td>Exceptional Item – Charge on Stock Settled Instrument</td>
<td></td>
<td>2,802</td>
<td></td>
</tr>
<tr>
<td><strong>Profit Before Tax</strong></td>
<td>8,591</td>
<td>9,038</td>
<td>5%</td>
</tr>
<tr>
<td>Tax Expenses</td>
<td>2,247</td>
<td>3,268</td>
<td>45%</td>
</tr>
<tr>
<td>Minority Interest</td>
<td>25</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Profit After Tax (PAT)</strong></td>
<td>6,428</td>
<td>5,745</td>
<td>(11%)</td>
</tr>
</tbody>
</table>

**Revenue**

Total Revenue from Operations during the year stood at ₹ 91,108 million as compared to ₹ 75,578 million in FY 2018. Revenue from Pharmaceuticals segment grew 33% YoY at ₹ 53,240 million contributing 58% to overall revenue. Revenue from Life Science Ingredients segment stood at ₹ 35,452 million in the year, up 5% YoY and contributing 39% to the total revenue. Revenue from ‘Others’ segment stood at ₹ 2,416 million in the year contributing 3% to the total revenue.

**Total Expenditure**

Total expenditure stood at ₹ 73,718 million in the fiscal year ended 31st March, 2019 from ₹ 60,394 million in the fiscal year ended 31st March, 2018. Materials cost stood at ₹ 32,809 million in the fiscal year ended 31st March, 2019 from ₹ 26,259 million in the fiscal year ended 31st March, 2018. Power and Fuel expense was at ₹ 4,664 million as compared to ₹ 4,249 million in the year ended March 2018. Employee benefit expenses increased to ₹ 19,260 million in the fiscal year ended 31st March, 2019 from ₹ 15,559 million in the fiscal year ended 31st March, 2018. Other expenses stood at ₹ 14,576 million during the year, increasing 27% from ₹ 11,499 million in the fiscal year ended 2018. Employee benefits expenses and other expenses were higher on account of acquisition of Triad in addition to annual increase in employee benefits.

**Earnings before Interest, Taxes, Depreciation and Amortisation (EBITDA)**

The overall EBITDA in FY 2019 grew by 14% YoY to ₹ 17,747 million translating to EBITDA margin of 19%. The EBITDA of Pharmaceuticals segment was at ₹ 13,858 million as against ₹ 10,042 million in FY 2018 with margins of 26% as against 25% in FY 2018. Life Science Ingredient segment’s EBITDA was at ₹ 4,451 million as compared to ₹ 6,322 million in FY 2018, translating to EBITDA margin of 13% compared to 19% in previous year. ‘Others’ segment EBITDA was at ₹ 43 million as compared to (₹ 92) million in FY 2018, translating to EBITDA margins of 2%.

**Finance Cost and Depreciation**

Depreciation and amortisation in FY 2019 was lower at ₹ 3,709 million compared to ₹ 4,150 million in FY 2018. Finance cost in FY 2019 was at ₹ 2,198 million as compared with ₹ 2,843 million in FY 2018. The blended interest rate for the borrowing stood at 6.18% with the rupee rate of borrowing at 8.4% and the foreign currency borrowing at 4.91%.
Profit Before Tax
Profit Before Tax for the fiscal year ended 31st March, 2019 stood at ₹ 9,038 million.

Tax Expense
Tax Expense was at ₹ 3,268 million in the fiscal year ended 31st March, 2019 from ₹ 2,247 million in the fiscal year ended 31st March, 2018.

Profit After Tax
The Profit After Tax stood at ₹ 5,745 million with an Earnings Per Share (EPS) of ₹ 36.86 per equity share of ₹ 1 each.

Review of Operations
Our operations comprise products and services across Pharmaceuticals, Life Science Ingredients and Others segments.

1. During the year, we re-classified our Pharmaceuticals segment under the following:
   (i) Specialty Pharmaceuticals, comprising Radiopharma (Radiopharmaceuticals and Radiopharmacy) business and Allergy Therapy Products
   (ii) CDMO, comprising Contract Manufacturing of Sterile Injectables and Non-Sterile Products and Active Pharmaceutical Ingredients
   (iii) Generics, comprising Solid Dosage Formulations

2. Life Science Ingredients segment includes the following:
   (i) Specialty Intermediates & Nutritional Products
   (ii) Life Science Chemicals

3. ‘Others’ comprising Drug Discovery & Development Solutions and India Branded Pharmaceuticals businesses

<table>
<thead>
<tr>
<th>Segmental Revenue Analysis</th>
<th>Revenue (₹ million)</th>
<th>YoY Growth (%)</th>
<th>Revenue Mix (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>FY 2018</td>
<td>FY 2019</td>
<td></td>
</tr>
<tr>
<td>Specialty Pharmaceuticals</td>
<td>19,904</td>
<td>28,300</td>
<td>42%</td>
</tr>
<tr>
<td>Radiopharma</td>
<td>17,092</td>
<td>24,677</td>
<td>44%</td>
</tr>
<tr>
<td>Allergy Therapy Products</td>
<td>2,812</td>
<td>3,623</td>
<td>29%</td>
</tr>
<tr>
<td>CDMO</td>
<td>12,049</td>
<td>14,698</td>
<td>22%</td>
</tr>
<tr>
<td>CMO</td>
<td>6,483</td>
<td>7,844</td>
<td>21%</td>
</tr>
<tr>
<td>Active Pharmaceutical ingredients</td>
<td>5,566</td>
<td>6,854</td>
<td>23%</td>
</tr>
<tr>
<td>Generics (Solid Dosage Formulations)</td>
<td>8,034</td>
<td>10,242</td>
<td>27%</td>
</tr>
<tr>
<td>Life Science Ingredients</td>
<td>33,649</td>
<td>35,452</td>
<td>5%</td>
</tr>
<tr>
<td>Specialty Intermediates &amp; Nutritional Products</td>
<td>15,426</td>
<td>14,218</td>
<td>(8%)</td>
</tr>
<tr>
<td>Specialty Intermediates</td>
<td>9,770</td>
<td>10,113</td>
<td>4%</td>
</tr>
<tr>
<td>Nutritional Products</td>
<td>5,656</td>
<td>4,105</td>
<td>(27%)</td>
</tr>
<tr>
<td>Life Science Chemicals</td>
<td>18,223</td>
<td>21,235</td>
<td>17%</td>
</tr>
<tr>
<td>Others</td>
<td>1,942</td>
<td>2,416</td>
<td>24%</td>
</tr>
<tr>
<td>Total Revenue from Operations</td>
<td>75,578</td>
<td>91,108</td>
<td>21%</td>
</tr>
</tbody>
</table>

Key Financial Ratios (Consolidated)

<table>
<thead>
<tr>
<th>Particulars</th>
<th>Unit</th>
<th>FY18</th>
<th>FY19</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debtors Turnover</td>
<td>'times'</td>
<td>6.99</td>
<td>7.49</td>
<td>7%</td>
</tr>
<tr>
<td>Inventory Turnover</td>
<td>'times'</td>
<td>5.72</td>
<td>6.41</td>
<td>12%</td>
</tr>
<tr>
<td>Interest Coverage Ratio</td>
<td>'times'</td>
<td>5.48</td>
<td>8.07</td>
<td>47%</td>
</tr>
<tr>
<td>Current Ratio</td>
<td>'times'</td>
<td>1.59</td>
<td>2.19</td>
<td>38%</td>
</tr>
<tr>
<td>Debt Equity Ratio</td>
<td>'times'</td>
<td>0.81</td>
<td>0.73</td>
<td>(10%)</td>
</tr>
<tr>
<td>Operating Profit Margin</td>
<td>%</td>
<td>20%</td>
<td>19%</td>
<td>(5%)</td>
</tr>
<tr>
<td>Net Profit Margin</td>
<td>%</td>
<td>8%</td>
<td>6%</td>
<td>(25%)</td>
</tr>
<tr>
<td>Return on Net Worth</td>
<td>%</td>
<td>17%</td>
<td>13%</td>
<td>(24%)</td>
</tr>
</tbody>
</table>

1. Improvement in Interest coverage ratio was on account of higher EBITDA and lower finance costs vis-à-vis last year.
2. Current ratio was higher due to higher cash, which was a result of increase in cash generation from business and funds raised through bond issuance by the wholly owned subsidiary of the company.
3. Net profit margin was lower as compared to last year due to the exceptional expense related to one-time settlement of the IFC convertible loan.
The Pharmaceuticals segment is engaged in the manufacture, supply and distribution of Radiopharma products, Allergy Therapy Products, Contract Manufacturing (CMO) of Sterile injectables and Non-sterile products, APIs and Solid Dosage Formulations, through six USFDA approved facilities in the US, Canada and India and contributes 58% to our Total Revenue from Operations. Revenue from this segment has improved 33% YoY to ₹ 53,240 million from ₹ 39,987 million last year.

Specialty Pharmaceuticals
Our Specialty Pharmaceuticals business includes our Radiopharma (Radiopharmaceuticals and Radiopharmacies) business and Allergy Therapy Products business. Revenues from this business stood at ₹ 28,300 million in FY 2019 vs ₹ 19,904 million in FY 2018, growth of 42%, with 53% contribution to total Pharmaceuticals segment revenues.

Radiopharma
We manufacture, supply and distribute radiopharmaceutical products, which are used in the diagnosis, treatment and monitoring of various diseases. We specialise in cardiac, lung, thyroid, kidney and bone imaging as well as thyroid disease therapy. We have made healthy progress and are operating a differentiated business in a very niche segment. Our Radiopharma business saw revenue growth of 44% YoY to ₹ 24,677 million in FY 2019 as compared to ₹ 17,092 million in FY 2018, due to growth in existing products, new product launches and higher contribution from acquired radiopharmacy business. It is our vision to be a leading player in nuclear medicine by demonstrating robust quality, value to our customers, sustainability to physicians / their patients and by building a healthy pipeline of products.

The Radiopharma business comprises the Radiopharmaceutical manufacturing business and the Radiopharmacy distribution business. Jubilant’s Radiopharmacy business is the 2nd largest radiopharmacy network in the US with over 50 pharmacies distributing nuclear medicine products to the largest national Group Purchasing Organisations (GPOs), regional health systems, stand-alone imaging centers, cardiologists and hospitals. The Radiopharmacies complement the Company’s niche Radiopharmaceuticals business and provides us with direct access to hospital networks with ability to deliver more than three million patient doses annually through around 1,700 customers.
We continue to expand our RUBY-FILL ® installation base in the US and Canada. We also continue to see growth in our Drax Exmetazime, a product used in SPECT scan in identifying of white blood cells in intra-abdominal infection.

Our Company has successfully built an integrated ecosystem including a dedicated Research and Development team, specialised manufacturing facilities, best-in-class regulatory affairs, sales and marketing operations. This business has promising growth through our own vertically integrated Radiopharmacies as well as our Radiopharmacy customers. Our Company is working on several active pipeline projects.

We are well positioned in the North American nuclear medicine market, which is expected to grow across the therapeutic segments of Oncology, Neurology and Cardiology over the next five years. We aspire to be the leading manufacturer of nuclear medicine products in North America. We are evaluating to further expand into markets such as Latin America, Europe and Asia.

**Allergy Therapy Products**

The Allergy Therapy Products business provides allergy immunotherapy products in the US. We aim to supply bulk extracts to physicians who can use the same for diagnostic testing and also to administer treatment. Allergenic extracts in our portfolio are offered in the form of consistent, high-quality, differentiated products along with a range of specialised diagnostic devices for skin testing.

This is a highly differentiated business of manufacturing and marketing allergenic extracts, which is backed by one of the oldest and most trusted brands in this business. Our Company has been focusing on expanding market coverage and this has been bearing fruit with better performance. In addition, we are increasing capacities in Lyophilisation in the Allergy Therapy Products manufacturing facility to ensure consistent and reliable supply of our insect venom products as the sole producer and supplier of venom in the US.

During FY 2019 revenue in the business improved by 29% YoY to ₹ 3,623 million as compared to ₹ 2,812 million in FY 2018, due to enhanced business performance.

The business continues to stress on innovation wherein emphasis is to develop innovative products to address allergies. It is our endeavor to expand the leadership that our products enjoy on the back of a robust product pipeline backed by hands-on production and an extensive presence in important markets. Our Company is expanding its footprint beyond the US and is building network in other countries such as Canada, France, Australia, New Zealand and South Korea, to drive sales of our brands. We are also evaluating strategies to expand coverage mix, having filed submissions to register venom Subcutaneous Immunotherapy (SCIT) for use with animals during the year.

**CDMO**

Our CDMO business includes our Contract Manufacturing of Sterile Injectables & Non-Sterile Products (CMO) and also our Active Pharmaceutical Ingredients (APIs) businesses. CDMO revenues were at ₹ 14,698 million in FY 2019 as against ₹ 12,049 million in FY 2018, a growth of 22% YoY.

**Contract Manufacturing of Sterile Injectables & Non-Sterile Products (CMO)**

We are a fully integrated leading CMO player based out of North America with operations in Montreal, Canada and Spokane, US. The facilities offer manufacturing services including sterile injectables (both liquid and lyophilisation), ampoules and sterile ointments, creams and liquids and also non-sterile ointments, creams, and liquids. We are among the leading Contract Manufacturers in North America for sterile injectables. Our facilities are approved by regulators across the world including USFDA, Health Canada, ANVISA Brazil, PMDA Japan, Russia, UK MHRA and others. The products manufactured at both sites are sold in over 50 countries across the globe. We lay strong emphasis on compliance and Intellectual Property Rights (IPR). We will continue to focus on highest level of compliance with a lean operation setup and supply of right quality products in a timely manner.
manner to our customers which help us further grow the order book. Injectables form an increasing proportion of new approvals by innovators for which there is shortage of capacity for high quality manufacturing sterile sites as available with us. In view of the robust business demand, Spokane site is expanding its operations to run 24*7 across all areas of operations.

Our analysis suggests that another area of growth is sterile ophthalmic. With ageing population across the globe, eye ointments are gaining popularity. We are witnessing a lot of Request For Proposals (RFPs) in this area as well. Basis this assessment, we have decided to set up a 200 bottles per minute ophthalmic line in Montreal. The line once operational is expected to further drive growth for the CMO business.

We are also continuing to invest on sites to address future growth opportunities. Significant amount has been invested in Spokane facility in adding another Lypholisation equipment on one of the sterile injectable lines to increase available capacity. The sites are also creating a master plan to initiate investments in new areas of growth.

Revenues for FY 2019 were at ₹ 7,844 million as compared to ₹ 6,483 million in FY 2018, a growth of 21% YoY.

**Active Pharmaceutical Ingredients (APIs)**

APIs are also known as bulk drugs or drug actives and are responsible for rendering therapeutic action in the final formulation. We are one of the world’s reputed manufacturers of Active Pharmaceuticals Ingredients (APIs) and partner with several leading generic formulation companies across the globe to fulfill their requirements of high quality APIs at affordable prices. We are one of the leading players globally in Cardiovascular System (CVS), Central Nervous System (CNS) and Anti-infective APIs along with several other therapeutic areas. We also add further value to the organisation by virtue of supplying cost effective and high quality APIs to Jubilant’s Solid Dosage Formulations business in US, Europe and Rest of the World (RoW).

The goal of APIs business is to develop leadership positions in chosen products and delivering high quality products. Our aim is to have sizeable capacities and dedicated lines for high volume molecules further optimising costs. This will also help in sustaining our long-standing relationship with generic formulation companies in global markets with our world-class product offerings.

Revenue from this business was at ₹ 6,854 million in FY 2019 as compared to ₹ 5,566 million in the previous year, a growth of 23% YoY.

As of 31st March, 2019, we have 42 commercial products and have filed 94 Drug Master Files (DMFs) in the US, 15 filing in Japan, 43 certificates of suitability to the monographs of the European Pharmacopoeia (CEPs) in Europe and 14 filings in Australia. We practice best regulatory and quality compliance in APIs Industry, with successful inspections track record of years by various regulatory agencies. Our facility at Nanjangud, India is approved by key regulators including USFDA, AFSSAPS France, PMDA Japan, ANVISA Brazil, KFDA Korean, Cofepris Mexico and TGA Australia. During the year, our facility was inspected by various regulatory agencies, including USFDA. USFDA informed us that basis the inspection, the Nanjangud facility has been classified as ‘Official Action Indicated’ (OAI). We are currently in the process of engaging with the concerned regulatory agencies to remediate the concerns with our corrective and preventive actions.

We are taking various initiatives to reduce cost through higher efficiencies and also through input material cost optimisation. Several cost improvement and process innovation programs have been undertaken during the year, for some large commercial APIs as part of product life cycle management. This improves profitability as well as maintains market share in the event of market and competition pricing pressures.

Sustainable manufacturing is also an important aspect of our APIs business. For our large commercial products, we focus on improvement programs for YoY reduction of resource use (energy, water, raw material etc.) per unit of product.

We also undertook price optimisation exercise to harmonize our product pricing in line with market scenario and prevalent supply-demand situation. This helped us to improve the profitability of certain products and add value to the organisation. The philosophy of our new product development for APIs is innovation-led affordability and quality by design giving our customers access to cost effective affordable APIs, while maintaining a consistent global quality standard. Aided by strong process and analytical chemistry skills and IP and regulatory expertise, we will continue our focus on new product development and filings for focused markets. Our APIs development efforts will also enable our own
Solid Dosage Formulations business to developed new formulations pipeline using in-house APIs. This helps achieve faster ANDA / dossier filings, and assures supplies of cost competitive and fully compliant APIs in future.

**Generics**

The Generics business includes our Solid Dosage Formulations business. Total revenue from this vertical at ₹ 10,242 million in FY 2019 as compared to ₹ 8,034 million in FY 2018. Our performance in this business was helped-in the US by market share gains and improved pricing in select products.

The Solid Dosage Formulations business includes manufacturing and marketing of formulations in the generics space. We have traditionally focused on the key US market, which is the largest market for generics. In addition, we are also rapidly expanding in RoW markets like Asia, Middle East, Latin America and Africa and we have aggressive plans to grow in markets of Europe, Canada, Australia and Japan in the near future.

The business derives benefit of backward integration with a part of our commercial Solid Dosage Formulations backward integrated to in-house APIs. This helps us reduce costs and maintain optimal efficiency. The broad therapeutic areas covered include Cardiovascular System (CVS), Central Nervous System (CNS) and Gastrointestinal (GI). Currently, we are leaders in the US for Prochlorperazine, Methylprednisolone, Risperidone and Terazosin and we rank among the top three in the US for a few other products.

We manufacture our products in Salisbury, US and Roorkee, India. A few products are also in-licensed from external partners. Both our Salisbury, US and Roorkee, India facilities are USFDA approved. Our Roorkee, India facility has also been approved by UK MHRA, ANVISA Brazil, PMDA Japan, TGA Australia and MCC South Africa. During the year, our Roorkee, India facility received a Warning Letter from the USFDA. We are currently in the process of implementing remediation measures at the facility and are hopeful of resolving the issue at the earliest.

As on 31st March 2019, the business had 55 products commercialised, including 31 in US, 15 in Canada, 29 in Europe and 28 in RoW. Also, we had filed a total of 96 ANDA filings in US, 36 filings in Europe, 23 filings in Canada and 42 filings in other RoW countries so far. As on 31st March, 2019, we have received 61 ANDA approvals in the US, 33 in Europe, 23 approvals in Canada and 35 approvals in RoW markets.

We have recently increased the oral solid dosage capacity at our manufacturing facility in Roorkee, India by one billion doses to meet the anticipated future growth requirements. We are expanding our product portfolio in oral solids and certain niches in Novel Drug Delivery System (NDDS) with an objective of increasing the contribution to revenue as we grow beyond the traditional regulated markets. We will continue to enhance our focus in the key RoW markets, wherein we foresee significant growth opportunities. We currently have approvals in key markets of Asia and Africa—including South Africa, Philippines, and Malaysia, and a large number of these approved products are already commercialised. In Latin America and Commonwealth of Independent States (CIS) markets, our growth would be driven by new filings and new product launches in key markets, including Brazil, Chile, Mexico and Ukraine.

Further, we continue to expand our operations in Europe, which has been a consistent revenue contributor for our global business over the years. We have built a strong customer base of more than 35 customers in Europe and we are continuously strengthening our product portfolio with them. Further, our business in Canada and Australia is expected to see significant growth based on new launches and new partnerships. In the US market, we are seeing product specific opportunities due to rationalisation of product portfolio and plants by some of our peers.

The business derives benefit of backward integration with a part of our commercial Solid Dosage Formulations backward integrated to in-house APIs. This helps us reduce costs and maintain optimal efficiency.
Revenue contribution from the Life Science Ingredients segment to Total revenue from operations stood at 39%. During the year revenue in the segment were at ₹ 35,452 million as against ₹ 33,649 million in FY 2018, a growth of 5% YoY. The improvement in revenue is attributable to better pricing in Life Science Chemicals business.

**Specialty Intermediates**

This business comprises Advanced Intermediates like Pyridine, Picolines, Cyanopyridines, Piperidine and their value added derivatives known as Fine Ingredients and Crop Science Ingredients. The Company is one of the few global companies in this business space, fully integrated both upstream and downstream. We have leveraged backward integrated feedstock of Acetaldehyde produced from Ethanol, coupled with global expertise in Pyridine chemistry to achieve global leadership position in Pyridine business.

We have forward integrated this Pyridine and Picolines platform to develop more than 60 commercial products, with global leadership position in 10 value added products. The Specialty Intermediates products of the Company are used in pharmaceutical, agrochemicals, food, personal care, healthcare and nutrition products, Oil & Gas and various other life science industries.

During the year, the Company has started producing Alpha and Gamma Picolines. The key derivative of Gamma picolone is 4-Cyanopyridine, which finds application mainly in Anti-tuberculosis drugs. The Company has made significant presence in supply of 4-Cyanopyridine.

We are also serving the demand of Formaldehyde in northern India. Customers see significant value in sourcing Formaldehyde from the Company on account of consistency in supplies.

The Company has started supplying two products in Oil & Gas Industry. These products are used as corrosion inhibitors and clay stabilisers. Supplies are made to customers in India, UAE and North America.

Revenue from this business was at ₹ 10,113 million during the year as against ₹ 9,770 million in FY 2018, a growth of 4% YoY.

Our business has strong enablers in place to ensure successful execution, including differentiated strategy, scale, cost effectiveness, strategic tie-ups and an experienced and dedicated team.

This year, we focused on strengthening our processes and capabilities as well as new products’ portfolio for
long-term growth and sustainability of Specialty Intermediates business. We have also invested to reduce our carbon footprint through effective effluent management for complex chemistries, as well as improving process safety.

We enhanced capacities of three products by 25-30% through debottlenecking initiatives and also by working with external manufacturers for outsourcing of few products. A new GMP multipurpose plant for pharma intermediates and a multipurpose plant for agro chemical intermediates was commissioned during the year. Additionally, another facility has been setup for fluorinated derivatives to be launched in FY 2020. We also undertook projects to optimise product costs and stay competitive in the market.

Due to Chinese government actions with respect to environmental challenges, demand for our products has been positive. We are continuously exploring opportunities to get long term benefits from this situation and look into products that are key raw materials as an intermediate for agrochemicals and other associated industries. We also entered markets of Brazil, Argentina, Mexico, Australia, Oman and Bahrain with new biocide derivatives.

We successfully developed and commercialised seven new products in FY 2019 having a good global potential and rapid growth in near term. We are working on five more new products to be launched in FY 2020.

**Nutritional Products**

In this business, we primarily cater to Human Nutrition, Animal Nutrition, Pharmaceuticals and Personal Care segments. One of our key products in this segments is Vitamin B3 (Niacinamide and Niacin) for which we hold a global leadership position. The product is typically used in the food, animal feed, pharmaceuticals and personal care industries. Our Vitamin B3 business is fully backward integrated with feedstock raw material (i.e. Beta Picoline and 3-Cyanopyridine) which is produced by our Specialty Intermediates business as a by-product. We have recently received World Health Organisation's (WHO) Good Manufacturing Practice (GMP) certification for our Vitamins facility which will help us increase our footprint in the premium food, personal care and other value added applications.

Shortage of Vitamins A and Vitamin E during most of the year had adverse impact on the vitamins premix market leading to shrinkage in consumption of Vitamins B3 that led to high inventories of the product. Also, integrated producers of Vitamin B3 in China resorted to predatory pricing to garner market share, which led to sharp drop in prices. This situation has now normalised and demand is catching up.

Through our Animal Nutrition business, we offer high quality specialty feed supplements and additives and premixes in the category of vitamin and mineral premixes, Betaine, Acidifier, Toxin Binders, encapsulated products, Growth Promoters, Liver Nourishment Products and Emulsifiers to integrators, feed millers and commercial farmers across the globe. We cater to various segments of industry like poultry, dairy, aqua and pet food.

In Nutritional Products business we have recently entered into Human Nutrition offering nutritional and functional ingredient solutions and tailored premixes for use in food, nutrition and fortification markets. We are the right partner of choice for developing client’s business in today’s ever-conscious clean label market by providing natural, minimally processed and familiar ingredients.

Revenue from this business was at ₹ 4,105 million during the year as against ₹5,656 million in FY 2018.

Our association with customers across the world is based on trust and reliability. Our facilities adhere to best practices and processes including ISO, cGMP, FAMI-QS, FSSC: 22000, Kosher & Halal certifications. We are associated with globally renowned analytical equipment manufacturers for providing nutritional services to our customers.

Vertically integrated value chain and low cost manufacturing are our key competitive advantages. The green route production with delivery of high quality product will help us increase our market share in better margin segments such as food, cosmetics and pharmaceuticals.

**Life Science Chemicals**

This business deals in Acetyl range of products like Acetic Anhydride, Ethyl Acetate, Acetic Acid, Anhydrous Alcohol, with a streamlined production process. Acetic Anhydride finds usage in cellulose acetate, pharmaceuticals, agrochemicals, aromatics, dyes intermediate, wood acetylation etc. We are the market leader in India and enjoy a substantial share in global markets. The demand of Acetic Anhydride has been growing consistently both in domestic and international markets and we are competitively placed to capture this growth in global markets. We also have a significant presence in Ethyl
Acetate - an environment friendly solvent, which is used by the pharmaceutical, packaging, coating and ink industries. We are the market leader across India and have been increasing our presence in international markets like Europe and South East Asia. During the year, our capacity utilisation of Ethyl Acetate has been better than last year due to better market demand in India as well as in international markets.

We have optimised the manufacturing process over a period, aligning with operational excellence and thereby achieved cost competitiveness in the market place. We have strong enablers to succeed, with competitive advantages such as backward integration, global sales and distribution networks, reliable customer base, a strong cost control from continuous capacity debottlenecking and with the highest commitment towards environment and safety.

Over the last year, we have become the largest Ethanol supplier to Oil Marketing Companies (OMCs) among standalone distilleries. Our Ethanol business is vigorously supporting ‘Ethanol Blending Program (EBP)’ of Government of India. In the current EBP tender from December 2018 to November 2019, the Company has been successfully awarded a significant contract for supplies in Uttar Pradesh, Delhi and Maharashtra states. With these expected supplies, we will become the 4th largest supplier in the EBP program. The business is focused on improving production capacities with continuous investments and operational excellence; this will eventually help us in being one of the largest contributors in the EBP programs.

The Company is the global leader in production of green Acetaldehyde made from bio-route of cane or corn based Ethanol. Off-late the Company’s Acetaldehyde has found place in end applications such as pharma intermediates, paint binders, food and flavor ingredients, etc. The Company has successfully commenced exports to Europe, besides meeting domestic demand.

Revenue for FY 2019 stood at ₹ 21,235 million as compared to ₹ 18,223 million in the previous year, up 17% YoY, due to firm pricing for our key products.

Going forward, to further strengthen our global positioning in Acetic Anhydride market, we are expanding capacity of Acetic Anhydride by building a new plant at our Bharuch manufacturing facility. This is expected to be commercialised during FY 2020 and make us the largest merchant market supplier of Acetic Anhydride globally.

‘Others’ Segment

The Others segment includes our Drug Discovery & Development Solutions and the India Branded Pharma businesses. Revenues in FY 2019 were at ₹ 2,416 million as compared to ₹ 1,942 million in the previous year, up 24% YoY.
In our Drug Discovery & Development Solutions business, we focus on offering our integrated solutions to our customers which maximises speed to develop a new lead. Our broad service offering from early Drug Discovery Services, GMP scale up of Intermediates and New Chemical Entity (NCE’s), complements very well with our Contract Development & Manufacturing (CDMO) offering of large scale GMP and non-GMP manufacturing through our Life Science Ingredients business. This provides an integrated solution (from early phase discovery & development to commercialisation of the molecule) to our pharmaceutical and other life science customers.

The operation comprises two subsidiaries; Jubilant Biosys and Jubilant Chemys. In addition to these service offerings, we have started development of a set of early stage pre-clinical assets which we will then offer for out-licensing or collaboration to the pharmaceuticals innovator industry. This is accomplished by leveraging our therapeutic expertise and technology platforms in advanced biology and medicinal chemistry expertise.

It is our objective to provide solutions and services to the pharmaceutical and biotechnology industry as well as academic institutions during the research and pre-clinical phases of drug development. Our therapeutic areas of expertise include Oncology, Metabolic Disorders, Central Nervous System (CNS), Pain and Inflammation.

We are continually expanding our relationships in this sector and expanding our service offering by investing in new technologies and capabilities which enhance our knowledge in select therapeutic areas. The business presents a cost-effective alternative to customers seeking world-class research and development services which are designed for speed to reach critical milestones. Our chemical development facility adheres to GMP and is capable of conducting multi-kilogram manufacturing campaigns for both pre-clinical toxicology and early clinical stage requirements.

During FY 2019, the business reported revenue of ₹ 2,168 million from ₹ 1,763 million in FY 2018. The business continues to strategically invest in creating a portfolio of novel products that can, in the future, be suitably monetised. Our focus also remains on integrated programs as well as discrete Full Time Equivalent (FTE) and Free For Service (FFS) services.

We will further strengthen the in-house proprietary discovery research for out licensing of new molecules to speed up the process for our innovator customers and add more value.
In this business, we target the local formulations market in India. The chosen therapeutic areas include chronic specialties like Cardiology and Diabetes. This is underlined by combination of enabling growth factors, including higher awareness, longer life spans, enhanced propensity to spend and evolving lifestyles.

During FY 2019, revenue in the business were at ₹ 247 million as compared to ₹ 179 million in FY 2018.

Our portfolio includes high growth molecules and combinations like Rosuvastatin, Telmisartan, Teneligliptin, Glimepiride, Cilnidipine and Azilsartan. These primary therapies are supported by supplementary or nutritional formulations like Vitamin B12, Vitamin D3, Proton Pump Inhibitor (PPI) & multivitamin preparations. The growing portfolio is backed by an increasing distribution network covering 30,000 retail points and robust field force of more than 230 sales representatives that serve 20,000 cardiologists, diabetologists, nephrologists, neurologists and consulting physicians across the country.

We see ample growth opportunity and will evaluate additional products where we believe we can make an impact in our preferred segments of therapy.

In FY 2019, IBP was amongst the fastest growing Cardiovascular Diseases (CVD) divisions in India. We shall continue launching relevant products in the CVD domain and at the same time, evaluate interesting opportunities in other segments/therapies to tap potential growth opportunities.
Research & Development and Intellectual Property

**Pharmaceuticals**

At Jubilant, Research & Development (R&D) is the manifestation of our belief in innovation and quality that fuels our business aspirations.

The focus of R&D is to enhance innovation level, scientific efficiency, effectiveness in compliance with Jubilant core values and support the execution of business strategies.

In Pharmaceuticals segment, the multi-skilled R&D team specialised across value chain of pharmaceuticals focuses on generics research including APIs and across dosage forms, novel drug delivery systems research, radiopharmaceuticals, allergenic extracts research, analytical research and biological support including pharmacokinetics and Bio Availability (BA)/Bio Equivalence (BE) research. R&D supports the activities of various businesses through developing new breakthrough products, process development, technologies, process intensification and establishing technologies at commercial scale. All R&D centres are process driven and have disciplined work culture. We have a strong internal audit frame-work in place which ensures overall R&D regulatory compliance. The R&D keeps itself updated with the regulations, upcoming technological changes and trends and proactively aligns with pharmacopeia methods and industry best practices. Our R&D continues to lead to new, innovative processes and new knowledge-driven products that increase the efficiencies of our production and allow us to capitalise on opportunities for growth in competitive markets. R&D set up at various plant locations continuously work on cost optimisation of products.

APIs R&D is focused on developing commercially competitive, robust and eco-friendly technologies. The APIs R&D is capable of developing difficult to handle complex multi-step synthesis of APIs having many chiral centres and has outstanding capabilities of carrying out PolyState studies of APIs. Our APIs R&D thrives on ‘green chemistry culture’ and has developed various environmental friendly and disruptive technologies wherein many batch processes have been replaced by continuous processes and chemical processes with enzymatic / chemo catalysis processes. APIs R&D also keeps on developing NCE-1 molecules meant for FTF opportunities and continue evaluating options for 505(b) (2) and Day 1/181 launches. Focusing on sustainable and competitive offerings to customers, APIs R&D is critical in ensuring development of Key Starting Materials (KSMs) to enhance the overall control over process, quality and compliance.
We have a dedicated and agile team of scientists focusing on development of variety of niche generic products across the spectrum of available dosage formulation technologies. Our product development pipeline comprises dosage formulations ranging from immediate release oral formulations to more complex generics based on matrix, reservoir, multi-unit particulate (MUPS) technologies and powder or granules for oral suspension. Dosage R&D skill set includes development of various forms of immediate release of tablets / capsules / powder for oral suspensions, multi-unit particulate dosage forms, modified release dosage forms, inlay tablets, oral liquids, sterile dosage forms including prefilled syringes and lyophilized powders for injection, ophthalmic dosage forms, topical dosage forms and veterinary products.

Our Radiopharmaceuticals business has a focused R&D team with radiochemical expertise, based in Montreal, Canada and the team works on Nuclear Medicine for the diagnosis, treatment and monitoring of various diseases. It serves hospital-based customers (Nuclear Medicine Physicians and Technologists) in addition to specialised Radiopharmacies and through them patients, globally with high quality and reliable specialty products. The business is backed by a dedicated R&D team, specialised manufacturing, strong regulatory and medical affairs and commercial operations using radiation safety protocols. The areas of specialisation include cardiac, lung, bone and thyroid diseases. This team supports existing products and leads the development of new products using its own resources, and also collaborating with our R&D team in India. In Radiopharmaceuticals, we are continually engaged in the development of new products that have yielded a pipeline of products that can be introduced in the future. Also, the Radiopharmaceuticals focused area of development is to enhance the product offerings across the diagnostics, therapeutics and theragnostics to increase the bandwidth of products and their applications.

Jubilant is also working in the space of allergy diagnostics and therapeutics for treating allergies caused by companion animals (cats & dogs). Allergy R&D has expertise in biopharmaceuticals – specifically sterile liquid vaccines. Core focus is on allergen (natural) extracts for immunotherapy – range of vaccines to immunise patients against IgE mediated allergen specific hypersensitivity. The Allergy Therapy products business has evolved into a global player in providing high quality products to the global immunotherapy market for the diagnosis and treatment of allergies. Its cGMP facility manufactures products to meet the high quality standards followed in the allergy industry. Over the years the company has extended its customer base to include allergists, ENT doctors and clinics, primary care physicians, hospitals and pharmacies in the US, Canada, Australia and many other international markets. It currently has over 200 allergenic extracts (standardised grass pollen extracts, non-standardised tree, grass and weed pollen extracts, Acetone Precipitated (AP) product line of extracts, standard mite extract, standardised venom, mold extracts and foods (resale item for diagnostic use etc.) and mixes and a line of specialised skin test devices in the market.

We have evolved our production technologies including specialised proprietary know-how over a period of time with the help of R&D. We keep our options to licence-in/licence-out technologies/know-how to accelerate businesses of interest.

Our Intellectual Property (IP) - enabled innovative R&D efforts have helped us avoid IP disputes after developing outstanding designing around capabilities around third party IP by identifying newer opportunities, better understanding of emerging challenges, developing alternative/innovative research strategies and creating intellectual property which is well protected in defined geographies of our business interests. Our efforts have fructified into intellectual properties, which have grown over the years creating a strong position for the generic pharmaceutical business in regulated markets.

We protect our inventions by filing patent applications in India, US, Europe, Canada, Australia, China, International Patent Applications (PCT) and other countries. We pursue them till grant and maintain them in countries of business interest. Following is the list of Company’s Patent Portfolio as on 31st March, 2019.

<table>
<thead>
<tr>
<th>R&amp;D</th>
<th>Inventions Filed</th>
<th>Patent Applications Filed</th>
<th>Patents Granted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiopharmaceuticals</td>
<td>38</td>
<td>345</td>
<td>222</td>
</tr>
<tr>
<td>Active Pharmaceutical Ingredient (APIs)</td>
<td>164</td>
<td>328</td>
<td>79</td>
</tr>
<tr>
<td>Solid Dosage Formulations</td>
<td>94</td>
<td>177</td>
<td>13</td>
</tr>
<tr>
<td>Allergy Therapy Product</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>298</td>
<td>852</td>
<td>315</td>
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</tbody>
</table>
In addition, we have various trademarks in our Company’s name and in the names of our subsidiaries, in India and outside.

**Life Science Ingredients**

Research & Development (R&D) is a key driver for innovation and plays a vital role in developing and adopting new technologies in the technologically intensive life sciences industry. In Jubilant, a team of well qualified and experienced professionals in R&D centres spread across multiple locations are specialised across the value chain of chemical research, chemistry/process development of advance intermediates, fine ingredients and contract research. Our R&D centres conform to international standards and are well equipped with world-class infrastructure managed by best-in-class manpower. Each R&D centre has dedicated unit integrated with relevant business. Our consistent endeavors to invest in R&D have helped to create a robust product pipeline ensuring sustainable growth.

Our R&D performance hinges on the coherence and cohesiveness among our R&D centres where rapid exchange of knowledge takes place to keep pace with competition and to develop disruptive technologies for future. The R&D team focuses on process intensification, absorption of technologies and establishing technologies at commercial scale.

A dedicated team of scientists focuses on product/process development in the area of Pyridine and its derivatives and related heterocyclic chemistry, development of advance heterogeneous catalysts, extension of chemistry skills to non-heterocyclic compounds, value creation in existing key products through process improvements/process intensification, chiral compounds, technology development of vitamins and especially Vitamin B3 and development of animal health care products.

We develop new technologies at the lab scale and the scientists and manufacturing engineers work in close coordination to ensure parameters established during lab development are within the determined design space leading to seamless rampup to commercial scale without losing on the proficiency of the process with a lead-time comparable to the best in the industry. Six Sigma initiatives at plants and R&D support the adoption of new technologies and enhancing the efficiencies of our manufacturing facilities to provide better services to our customers.

Through our investment in R&D, together with our implementation of management tools and strategies in manufacturing, design and project management, we continue to improve our cost competitiveness and quality of production by improving the efficiency of our supply chain management and developing better processes and product development and manufacturing capacities to reduce process inefficiencies, process variations, plant inefficiencies, assets under-utilisation and the time required for product and process development.

We continually develop new products that provide our customers with better solutions for existing problems and new solutions for emerging problems. This requires us to undertake significant effort on research, development, manufacturing and marketing. To preserve the value of our investment, we rely on the patent laws of the jurisdictions where we do business. In addition, we need to continuously improve our production efficiencies.

Our production technologies typically incorporate specialised proprietary know-how. We have both developed intellectual property internally and acquired intellectual property through acquisitions. From time to time, we may grant licenses to third parties to use our patents and know-how, and may obtain licenses from others to manufacture and sell products using their technology and know-how.

We have designed a successful R&D, which continues to ensure delivery of a sustainable pipeline of high-value products of Fine Ingredients and Intermediates. Our R&D

We continually develop new products that provide our customers with better solutions for existing problems and new solutions for emerging problems. This requires us to undertake significant effort on research, development, manufacturing and marketing.
strategy is centered on improving the speed and yield. Our R&D continues to lead to new, innovative processes and new knowledge-driven products that increase the efficiencies of our production and allow us to capitalise on opportunities for growth in competitive markets.

Fine Ingredients business faces significant competition from China and other competitors. R&D has taken a proactive approach to introduce new products in Pyridine chemistry and also in Non-Pyridine chemistry. This is being done by deploying our various technological capabilities. New products continue to get developed by experienced and talented R&D teams which work to deliver in-line with the marketing strategy by developing new cost effective processes/products. Further, in order to ensure that cost competitiveness is maintained, R&D is working on the improvement of existing processes including atom economy.

Following is the list of Patent Portfolio as on 31st March, 2019

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<thead>
<tr>
<th>R&amp;D</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Life Science Ingredients</td>
<td>54</td>
<td>147</td>
<td>83</td>
</tr>
</tbody>
</table>

**Drug Discovery & Development Solutions**

Drug Discovery & Development Solutions in Jubilant offers state-of-the-art capabilities in small molecule discovery and preclinical development. These include capabilities in Discovery Informatics, Molecular Modelling, Structural Biology, Medicinal Chemistry, in vitro and in vivo Biology, DMPK studies, Pharmacology, and Toxicology. Our disease biology expertise spans across multiple therapy areas including oncology, metabolic disorders, neurological disorders and inflammation.

Drug discovery at Jubilant is driven by the passion of its personnel, to provide affordable drugs to patients worldwide in areas of unmet needs. Jubilant scientists collaborate across technology and therapeutic platforms to identify and validate novel small molecules and platforms that will enable first or best in class healthcare efforts of our collaborators. The competence of this team has been demonstrated by the progression of molecules to candidates starting from targets in a span of three years or less. Jubilant’s ISO 27001-certified facility is designed to firewall collaborations for scientific, operational and data exclusivity.

FY 2019 was a turnaround year for the Drug Discovery & Development Solutions business. On the operations side, the year was marked by the acquisition of state of the art instruments such as SPR, initiation of work on new technology such as flow chemistry and various Artificial Intelligence (AI) initiatives. Electronic lab notebooks will be introduced to significantly increase productivity and strengthen data management capabilities. In parallel, numerous investments were made to enhance EHS standards in our laboratories. All these investments and initiatives will provide a solid basis for the growth of the business in the coming years.

In FY 2019 Jubilant Biosys filed six patent applications and enabled the filing of patents for various clients. 11 research articles were published in high impact journals and oral and poster presentations were made at numerous international and national conferences.

With regard to project achievements, the highlights were the delivery of a preclinical candidate for IND application that was optimised after only 18 months of work starting from a hit compound identified from in silico screening carried out by the Jubilant computational chemistry group, and the identification of a preclinical candidate in another collaboration that has led to the expansion of the project into other therapeutic areas.

Drug discovery is inherently a risky venture with a high failure rate. To mitigate this, we maintain a pipeline of
client programs that can help offset attrition of client programs and we continue our efforts to expand this business base.

**MANUFACTURING Pharmaceuticals**

Jubilant Pharma’s manufacturing operations continue to strengthen with strong focus on the following key enablers.

- **Compliance**: Compliance with diverse international regulations to maintain high quality standards and global customer base
- **Customer service**: Heightened awareness of our customer needs and striving towards delivering a quality product in a timely manner
- **Capacity and Capabilities enhancement**: Sufficient capacity to meet demand as well as respond to market opportunities. Capabilities enhancement to keep up with technology advancements
- **Cost leadership**: Continue to improve our conversion cost to be more competitive and to stay longer in the market place
- **Continuous improvement**: Continually improve our processes using Business Excellence models
- **Continuity**: Business continuity through risk mitigation and sustainability measures

**Compliance**: We continue to improve our quality systems to ensure compliance with ever evolving regulations. Jubilant always strives to stay ahead of the curve to ensure compliance with regulations and meeting patient needs. We have implemented ‘Track and Trace’ system in compliance with EU-FMD requirements on the packaging of medicinal products at Roorkee, India. The EU-FMD Track and Trace System will enhance the EU countries ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. The system will improve detection and removal of potentially dangerous drugs from the supply chain to protect consumers. Jubilant is fully compliant to this regulatory system and all applicable finished dosage form manufacturing facilities had gone live in February 2019 with ‘Track and Trace’ systems for the EU. Compliance wire, a Learning Management System was launched across the pharma sites to enhance training and compliance.

During FY 2019, the manufacturing facilities of Jubilant Pharma underwent several regulatory inspections. USFDA has inspected our Jubilant Cadista facility at Salisbury, Maryland, US and provided Establishment Inspection Report (EIR) designating the site as No Action Indicated (NAI), denoting high confidence in its GMP compliant state and complete closure of all observations from any prior inspections. USFDA has inspected our Jubilant HollisterSteir facility at Spokane, Washington, US; Jubilant HollisterSteir, Montreal, Canada and Jubilant Generics APIs facility at Nanjangud, India. Health Canada has inspected our Jubilant HollisterSteir facility at Montreal, Canada and Jubilant Generics facility at Nanjangud, India (Joint inspection with USFDA). Our Nanjangud facility received observations from the USFDA as well as Health Canada in their joint inspection. We are working with both agencies to address all concerns. We have engaged 3rd party expert consultants to help us with the remediation. Jubilant Generics facility at Roorkee, India was inspected by USFDA in July, 2018. Based on the observations, site received an OAI followed by issuance of Warning Letter. However, site is working on the remedial actions along with regulatory consultants and providing periodic updates to USFDA on corrective actions. MOH, Belarus has inspected our Jubilant Generics facility at Roorkee, India in February 2019.

For Jubilant Pharma, we have always included Environment, Health & Safety (EHS) as one of the key decision enablers for any process implementation. Awareness sessions have been timely conducted to keep our employees, community and other stakeholders informed on key EHS aspects relevant to their operations. Status of the EHS compliance with respect to various statutes, rules and regulations applicable to the Company is governed through an intranet based application ‘Statutory Compliance Reporting System’ (SCRS) for Indian manufacturing facilities and we are in the process of conducting compliance audit to create a baseline on regulatory requirements for the North American manufacturing facilities considering the regulatory requirements applicable to the different sites and regions. Compliances are reported and reviewed by the Board on a periodic basis. The intent is to ensure that the compliances are effectively managed and controlled and that they support the Company’s business objectives and corporate policy requirements.

At Nanjangud manufacturing facility, there has been a minimisation of the hydraulic load and treatment cost on ETP from the lean effluent (generated from main steam condensate, supplied from neighbouring industry) by treating only through Reverse Osmosis (RO) system based on its characteristics rather taking through primary, biological followed by RO system.
The process for open unloading of major quantity of hazardous solid process residue generated, has been minimised by in-line dilution with stripper solvent and sent to cement industry as an ancillary fuel, which has substantially reduced the safety hazard in the process and improved the calorific value.

**Customer service:** Jubilant operations fundamentally focuses on Supply Level Adherence (SLA) and Right First Time (RFT). By achieving excellence in these two key metrics, high levels of customer service is automatically achieved.

**Capacity and Capabilities expansion:** Our Roorkee, India manufacturing facility completed the expansion to increase its capacity to manufacture multiple dosage forms. With state-of-the-art facility and machinery, plant capacity will increase by one billion doses with large batch sizes. Our manufacturing facility in Salisbury, US has made major capital investment to increase our capacity and capabilities for Roller Compaction, in order to scale up for potential market opportunities requiring this technology.

At our manufacturing facility in Nanjangud, India we have established effluent treatment capability with advanced technology like DAF (Dissolved Air Flotation system) in the primary treatment and Ammonia stripping, Anoxic system and MBR (Membrane Bio Reactor system) in the biological treatment in view of improving the treatability.

We have added Isolator technologies at our Montreal, Canada manufacturing facility to ensure sterility of the product as well as reduce radiation exposure to our employees. We also have automated our RUBY- FILL® manufacturing processes by installing automated loading stations resulting in efficiency gains and capacity expansion and improved compliance. We are investing to automate several other manual processes to enhance efficiencies, compliance as well as health and safety of our employees.

At our CMO Operations in Spokane, US, we are increasing our Sterile Liquid and Lyophilisation capacity and are also undertaking a site master planning to plan future expansions to further augment our capacities and capabilities. Additionally, another new filler and Lyophiliser are in the process of procurement to replace older equipment at our Allergy Therapy Products manufacturing facility to further improve operations reliability and capacities. At our CMO operations at Montreal, Canada we have completed upgrades of our filling line and Lyophiliser and we are in the process of procuring additional Ophthalmic manufacturing and filling capacities.

Several capacity de-bottlenecking projects have been implemented and facilities upgraded to enhance GMP at our formulations and APIs manufacturing facility at Roorkee and Nanajangud, India.

At Nanjangud, various capacity enhancement projects (Oxcarbazepine, Tramadol and Azithromycin Dihydrate) have been implemented in view of minimising the COGM and improving the capacity utilisation and for capability building.

**Cost leadership:** Our focus has been on conversion cost optimisation without compromising our quality and customer service standards. Several initiatives have been undertaken to reduce the conversion cost. Our manufacturing facility in Salisbury has led structured improvement projects that have delivered significant conversion cost savings, while at the same time improving safety rate, deviation rate, productivity, batch rejections, and service level. We have undertaken several energy saving projects to reduce our utilities costs. Several automation projects and increased batch sizes in our operations are leading to head count rationalisation. Our bottoms-up Business Excellence initiative named ‘Eureka’ in North America and ‘Sankalp’ in India has allowed employees to come up with suggestions to reduce or eliminate waste in our processes. Our focus on training and process improvements have led to reduction of discards and improved ‘Right First Time’ (RFT).

At Nanjangud, as part of continuous improvement journey towards cost leadership / cost optimisation, our business excellence team along with CFT (Production, Technical services and R&D) have executed yield improvement projects for major volume contributing products.

**Continuous improvements:** In Jubilant Pharma, Business Excellence function is proactively creating the framework for new improvement strategies which drives the competitive advantage backed by a strong execution mechanism and capability. These improvement strategies pertain to all three critical pillars of the organisation – customer, process and people.

The continual effort of Business Excellence function is to understand processes and systems, model them by transfer functions and define crucial measurements which results in a superior co-ordination and integration of processes, learning and reconfiguration and transfiguration. This leads to a competitive advantage, which can be effectively used to leverage Company’s competitive strategy.
During this journey of continual improvement, we have adopted various improvement methodologies in line with organisation priorities like Lean Six Sigma, Total Productive Maintenance (TPM) and Business Intelligence (BI) tools etc. This year also Business Excellence function has added competencies like Lean Lab deployment for optimising the efficiencies in Quality Labs.

The Business Excellence infrastructure element helps in creating a self-driven / mission directed team (MDT), which drives their operational area towards excellence in alignment to business objective through right accountability and training. This sustained culture of innovation and excellence is the result of deep commitment of Jubilant employees.

Our Technical Services function is conducting more technology transfers than ever before. We understand that process robustness is critical success factor for ensuring reliable supply chain and product quality. Key emphasis has been laid by senior management on ‘Right First Time’ transfers from R&D to manufacturing facilities or from one manufacturing facility to another. As part of its commitment to continuous improvement, knowledge transfer and enhanced product and process understanding, Jubilant has established technology transfer groups at its manufacturing and corporate sites as part of its commitment to new product introduction, product launches and continuous process improvement.

The Technical Services groups interface with key functions like R&D, Regulatory, Quality, Business, Supply Chain and Operations to ensure realisation of business objectives. Most importantly, the Technical Services functions ensure that fundamental knowledge gained during the development is transferred to the manufacturing scale using a robust Quality by Design (QbD) approach.

The Business Excellence team at Nanjangud facility is focused on continuous improvement and has taken up five yield improvement projects in FY 2018-19 and various projects for OPE enhancement and capacity building. In Feb 2019, SS+1S concept has been initiated at the site.

Also as part of green energy initiative at Nanjangud, solar power is under implementation.

The Nanjangud team participated in QCFI, Mysore chapter and won four golds in different categories.

**Continuity:** Business continuity is key for sustenance for which sound strategy is already in place. We also executed several risk mitigation projects to qualify alternate sites for key products, qualification of alternate sources for key active ingredients, excipients and components. We see our sustainability programs a key enabler for ensuring business continuity. At Nanjangud, four units of an RO water treatment facility have been constructed (in coordination with the Municipal Corporation) to supply purified water to the surrounding area.

A new initiative (World on Wheels) has been implemented at Nanjangud. This comprises a mobile computer lab which is taken to surrounding villages, schools and colleges to train students, youth and villagers on basic computer skills.

A government school (with two class rooms) has also been constructed near Mysore by Jubilant.

Jubilant Generics has been conferred with the FICCI Corporate Social Responsibility (CSR) Award for the commendable work done in the area of women empowerment in the community around Nanjangud site.

**Life Science Ingredients (LSI)**

Manufacturing function has played an important role in supporting business competitiveness by creating a cost leadership position in a highly competitive market. We have established high production benchmarks across all the sites with significant improvements by savings in raw material and energy norms. Our operations continue to be driven by the manufacturing strategy of ‘Transforming Manufacturing for Operational Excellence and Sustainability’ with ‘zero tolerance to any non-compliance’ as the core focus of LSI Manufacturing and EHS functions in continuation to last year. All LSI Manufacturing facilities have accelerated their initiatives on capacity enhancements, capability improvements, production efficiency improvement, Environment, Health & Safety (EHS) improvement and cost reduction to further improve operating parameters. During the year, we have made considerable investment across the manufacturing facilities, which has enabled facilities to significantly improve in the areas of environment, energy conservation and recycling of water including water security. Our multi-purpose GMP plant has been operating with good efficiency levels. Agro-chemicals plant has been commissioned at Bharuch manufacturing facility to further enhance LSI manufacturing capability.

Continuous focus on manufacturing excellence, enhancement in automation levels, Business Excellence initiatives, EHS improvements and natural resource conservation has enabled LSI to save on operating costs and improve the overall statutory and regulatory compliances. Energy conservation and effluent reduction
efforts have been intensified during the year and will be carried forward more aggressively in the coming years. Asset reliability and integrity improvement including structural integrity and infrastructure renovation and aggressive deployment of Total Productivity Management (TPM) concepts across all Strategic Business Units (SBUs') has enabled the sites to improve on the OPEs' and plant efficiencies, visual make-over, industrial safety and culture building towards a high performance organisation.

Following the approach of triple bottom line (Environment, Economic and Social) factors, we have marched ahead towards creating a Sustainable environment and have achieved the coveted Responsible Care® logo usage approval for Bharuch, India. This is over and above the existing certification for Corporate Office at Noida, Uttar Pradesh, India and plant at Gajraula, India under the American Chemical Council’s (ACC) Responsible Care® program.

**Accreditations/Certifications:**

- Animal Nutrition manufacturing facility at Savli, India and Vitamins plant at Bharuch, India is certified for FAMI-QS Code Version 5.1 in Feed Safety Management System
- Vitamins manufacturing facility of Bharuch, India is certified to Kosher, Halal-India, Halal-Malaysia, Halal Indonesia, Food Safety System Certification (FSSC) 22000 (Global Food Safety) compliance and has been licensed by Food Safety and Standards Authority of India (FSSAI)
- Gajraula Quality Control Laboratory has also been accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) for chemical testing in accordance with the ISO/ IEC 17025:2005, Gajraula, India
- Gajraula, India manufacturing facility has been Kosher approved for Nine core products in the Fine Ingredient business and also Halal certified for eight core products
- The Carbon Dioxide plant at Gajraula, India manufacturing facility has been certified for FSSC 22000:2005 also against TS22002-01:2009 (Food Safety System Certification) for production and dispatch of food grade Carbon Dioxide for beverages. This facility is also approved by FSSAI
- At Nira, India manufacturing facility Ethyl Acetate and Acetic Anhydride are certified for Food Safety System Certification (FSSC) ISO-22000:2005 for production and dispatch of these food grade products
- Glacial Acetic Acid from Nira, India manufacturing facility has been certified FSSC /ISO-22000:2005 for storage and supply of food grade Acetic acid
- Manufacturing facility at Nira, India has been Kosher approved for four products i.e. Ethyl Acetate, Acetic Acid, Acetic Anhydride and Ethyl Alcohol. The facility is also Halal Certified for Acetic Anhydride, Ethyl Acetate and Acetic Acid
- FICCI Chemicals & Petrochemicals award 2018 for Excellence in Safety in Chemical Sector for Gajraula, India
- Certification of EnMS ISO 50001:2011 for Gajraula, India
- Up-gradation RC 14001:2013 to RC 14001:2015 for Gajraula, India
FICCI Chemicals & Petrochemicals Awards for ‘Efficiency in Water Usages in Chemicals’ for Gajraula, India


Awarded 4-Star (Good) rating by MPCB (Maharashtra Pollution Control Board) for maintaining good air quality index from operations at Nira, India

Supply Chain

Pharmaceuticals

Cost optimisation through consolidation of spend across organisation continued to be the focus area for supply chain. We continued our efforts to improve working capital by reducing inventory through the value chain. With maturity of SAP in our processes, we have been able to take advantage of planning and procurement optimisation that has positive impact on capacity utilisation and cost optimisation.

FY 2019 was an year of several niche initiatives taken by supply chain – automation of supply chain performance dashboard through Qlikview applications, global spend consolidation initiatives, de-risking of single sourced items and many more. Due to environment control in China, prices of many of the Active Pharmaceutical Ingredients (APIs) and Key Starting Material (KSM) increased. Further there was availability constraints that supply chain had to navigate through by strategic negotiations and securing required quantities even at higher prices to ensure business continuity. This was a major challenge for Supply Chain Management (SCM) to keep spend within the budget. We advanced our initiative for alternate vendor development for critical APIs and KSMs to ensure security of supply. Plans are in place to come out of this dependency by outsourcing model developing our own processes.

Initiatives like outsourcing the Advance Intermediates helped in releasing in-house capacities and generating more sales revenue. Consolidation of spend with other businesses helped us in achieving saving and better service levels to internal customers.

We have coordinated and supported the timely filing of new DMFs and ANDAs which are critical for business growth. Plant expansion projects were taken up and successfully completed on time during the year through excellent coordination and delivery adherence.

In our journey of excellence and to de-risk supply chain from single sourced components, for short term we augmented components inventory to minimise business disruption risks and embarked on focused Alternate Source Development (AVD) program for long terms business sustainability. Plans are in place to come out of dependency on single sourced components.

Many green supply chain initiatives were taken like disposing of solid waste and spent solvents to cement industry thereby reducing burden on land filling. Usage of Bio-Diesel as a boiler fuel. Power trading through Indian Energy Exchange (IEX) giving good savings.

Life Science Ingredients

The year FY 2019 was another challenging year for Supply Chain in Life Science Ingredients. The international and domestic macro-economic activities affected our Supply Chain immensely. Last year GST was implemented across India, however continuous changes in GST rules put pressure on team to update the system as per the new requirements. The team did a splendid job in this regard.

On the commodity front, volatility in Crude oil, Solvents and other chemicals severely impacted the procurement in entire chemical industry. However, the Supply Chain closely monitored the market condition and acted to protect the interest of the Company by not taking any long term exposure.

This year, supplies from Coal India were severely affected despite the company having long term Fuel Supply Agreement (FSA) with Coal India Limited. This situation forced us to procure coal from international market at much higher price. This ensured that the sales were not affected though some impact was felt on bottom-line.

Supply Chain was also actively involved in execution of many capacity expansion projects of the business including green field Acetic Anhydride project at Bharuch, India.

We went live with some of our digitalisation projects and also created pipeline of around four projects which should help in improving the productivity, efficiency and customer experience.

Going forward, we shall continue to target and achieve higher levels of efficiency across categories with a primary focus in the area of raw material and logistics while ensuring delivery of value to our end customer.
'OTHERS'

Drug Discovery & Development Solutions

For the first time in FY 2019 a new purchase concept ‘Just in Case’ for crucial lab needs was introduced, allowing execution through contingency plans.

Better networking with neighbouring pharma firms have helped good purchasing techniques that slashed negotiation cycle times for high value capital procurements. Supply chain representing during business process review meetings has brought greater level of understanding that enabled supply chain as contributors to the value proposition of speed as well as EBIDTA was a major paradigm shift.

Developing agile modes of working became the facet amongst other supply chain objectives and that helped next level project results and time saving. Judicious decisions on categorical spend realisation from in-house materials distribution has brought in awareness on cost saving methodologies. Increased scrutiny at customs statutory continue to dominate the import/export norms whilst supply chain continues to endeavor to bridge the gap to match its stakeholders need for speed. Several forms of revision to GST governance tightened the compliance at every strand of supply chain activities.

For the upcoming fiscal year, DDDS plans to re-design the entire procurement cycle, paving the way for higher performance results; at DDDS we are aware that supply processes are directly tied to its business performance.

Business Excellence

Business Excellence continuously strives to build excellence in our Management Systems, to facilitate organisation’s growth, meet financial goals and create value through a culture of continuous improvement. Value is derived by deployment of state-of-the-art transformational methodologies backed by strong execution capabilities. At the same time, involvement of all employees through initiatives like training, certification and Sankalp helps to build the cultural DNA of the organisation.

Pharmaceuticals

Along with process owners the team is engaged in enhancement of efficiencies through reduction in process lead times in operations, supply chain, quality as well as R&D. Reduction of losses in the production processes, improvement in planning process have increased Overall Plant Effectiveness (OPE) leading to enhanced capacities and ensuring reliable and repeatable output. At the same time, we have worked on product quality drastically reducing discards and improving yields. All this has been done by using the latest tools and technologies.

Engagement in North American sites has being enhanced to identify more opportunities to add substantial value to our organisation. We have increased our engagements with all Business Units, including the new area of Radiopharmacies, which will bring us substantial benefits in the future.

Every cost element is analysed for improvement opportunity. Site level profitability will be increased by mapping and reducing internal costs.

Life Science Ingredients

A very strong culture of deploying process improvement tools and techniques has been established in operations. Projects leading to capacity enhancements, yield improvements, energy savings and effluent reduction have significantly contributed to the operating margins. While we sustain and enhance these gains in operations, we have extended engagement of Business Excellence to supply chain and office functions through deployment of lean methodologies. This year we brought strong focus to establishing a safe and clean workplace by deploying methodologies like SS and Visual Management.

We will continue to aggressively deploy TPM across all manufacturing facilities, leading to enhancement in asset reliability, reduction in production losses and improvement in Overall Plant Effectiveness (OPE).

Drug Discovery & Development Solutions

Last financial year has been a year of some major initiatives on Business Excellence fronts to improve upon various functions within Drug Discovery & Development Solutions to the next level. At DDDS we believe that the scientific services organisation can only excel by creating a culture of excellence in the organisation by continuously seeking to enhance people, processes and systems.

Initiatives on the supply chain front included inventory and cost optimisation projects, harmonisation of contracts for products and services areas Jubilant lead to the significant reduction on Turn Around Time (TAT) to the internal customers which in turn improved the prompt delivery to the clients.

At DDDS, much like the parent organisation, continuous improvement is the mantra and with the induction of
seven new green belts we have a larger project on hand to add to this process in the current year.

**Human Resource Management**

Digitisation is the buzzing concept in the corporate world, which is evolving rapidly in the dynamic and competitive environment. Digitisation is not only about technological shift but also about a change in organisation intersecting technology, business and people.

At the helm of any transformation, it’s the employee who is leading and bringing the change across the organisation. This transformation that we are witnessing at Jubilant is futuristic where we will utilise the big data, analyse it, draw inferences and conclude to predict the future.

To make the organisation ‘Digital Ready’, we partnered with Singularity University to provide high quality education on scientific progress and ‘exponential’ technologies to our leaders. In addition, ‘Digital Day’ workshop with Bain & Company and AT Kearney helped prioritise some of the focus areas for Jubilant.

Our employees remain at the core of the Company’s growth strategy and play a vital role in ensuring sustainable business growth and future readiness. The Company has been focusing on strengthening its talent management and employee engagement processes through clear role expectations with specific and well-defined Key Performance Indicators for each role.

We believe in creating a culture of high performance and meritocracy that provides all our employees with opportunities to excel, learn and progress. We have introduced mid-year performance discussion for all employee to take a stock of their performance and do course correction of any during the year. We have also revamped the look and feel of Key Responsibility Area (KRA) setting and annual performance review where an employee is assessed against the performance milestones set at the beginning of the year.

With the endeavour to strengthen the talent pipeline, we have been focusing on attracting the best talent from India’s leading campuses to have a steady flow of fresh talent, thereby creating a strong pool of internal talent. We have engaged with management and engineering colleges across India in quiz competition ‘Mind Fizz’ to increase our visibility. We have been focusing on digitisation our talent attraction and hiring platform by revamping and simplifying our internal talent acquisition process. We also ensure strong media presence, advertisement of position internally and externally to attract right talent.

In the learning and development space, we are leveraging our ‘Learning Management System’ (LMS) which provides online training courses on business, functional, management and leadership skills to hone and foster a culture of continuous learning in the organisation. The LMS has about 80% employee usage. Additionally, we have mandatory programs for employees on the Code of Conduct, Whistle Blower policy and policy on Prevention of Sexual Harassment at workplace to reinforce our commitment to governance and adherence to the code of conduct and fair business practices.

Our well defined leadership competency framework continues to be the bedrock of our developmental activities. It forms the basis for the annual training calendar which has programs with standard curriculum that are offered across the company sites. The talent management program lays the foundation for identification of talent at different levels within the organisation and their development, for building of an internal talent pipeline.

Every great organisation stands on a strong foundation of its values. At Jubilant, it is the thread, which connects all of us together - cutting across the boundaries of businesses, sites and levels. With the intent to be better equipped to ‘live’ the ‘values in action’ and inspire others, an organisation wide values cascade through ‘Jubilant Values’ workshops has been done by all businesses to make all the employees internalise the Jubilant values and their associated behaviours. The values will also be a part of the annual performance evaluation from this year.

In our journey towards building the employee experience, we have launched multiple priority initiatives at organisational and business levels. We have also conducted the Employee Experience survey in 2019 to understand the ‘pulse’ and the impact of the initiatives taken so far. The employee Net Promoter Score (eNPS) has become a part of the performance KRAs of the business leaders and will encourage them to strive towards creating superior employee experience within the company.

As on March 31, 2019, a total of 355 employees at our manufacturing plants at Savli, Nira and Gajraula were either members of unions or had collective bargaining capabilities. During the year, we enjoyed cordial relations with our employees and there have been no instances of labour unrest or disputes at any of the manufacturing sites.
Risk-taking is an inherent trait of any enterprise. It is essential for growth or creation of value in a company. At the same time, it is important that the risks are properly managed and controlled, so that the Company can achieve its objectives effectively and efficiently.

**Internal Financial Control Framework**

Section 134(5)(e) of the Companies Act, 2013 requires a company to lay down Internal Financial Controls (IFC) system and to ensure that these are adequate and operating effectively. Internal Financial Controls, here, means the policy and procedure adopted by the company for ensuring the orderly and efficient conduct of its business including adherence to Company’s policies, the safeguarding of its assets, the prevention and detection of frauds and errors, the accuracy and completeness of the accounting records and the timely preparation of reliable financial information.

The above requirement has the following elements:

1. Orderly and efficient conduct of business
2. Safeguarding of its assets
3. Adherence to Company’s policies
4. Prevention and detection of frauds and errors
5. Accuracy and completeness of the accounting records and timely preparation of reliable financial information

At Jubilant Life Sciences Limited, the Internal Financial Controls (IFC) system has been established and incorporates all the five elements as mentioned above. In addition, the Company has a transparent framework for periodic evaluation of the Internal Financial Controls in the form of internal audit exercise carried out through the year and online controls self-assessment through Controls Manager software, thereby reinforcing the commitment to adopt best corporate governance practices.

Policy and procedure adopted by the Company to adhere to IFC elements is given below:

**Orderly and Efficient Conduct of Business**

The Company has a well laid down organisational structure which defines the authority-responsibility relationship. The Company has a formal financial planning and budgeting system encompassing short term as well as long term planning. In order to ensure that decisions are made and action taken at an appropriate level, the Board of Directors of the Company has formulated the
Delegation of Authority which has been designed to ensure that there is judicious balance of authority and responsibility. The adherence to Delegation of Authority is part of Internal Audit Plan. The Company also has a risk management framework which has been discussed under the heading ‘Our Vision on Risk Management’.

Compliance with respect to various statutes, rules and regulations applicable to the Company is managed by the Secretarial Department. Status of compliance is governed through an intranet based application. Respective control owners certify the compliances on a quarterly basis and a compliance report is prepared. The objective of the certification is to ensure that the compliances are effectively managed and controlled and that they support the Company’s business objectives and corporate policy requirements.

**Safeguarding of its Assets**

The Company has taken an All Industrial Risk Policy for its plants as well as Fire policy for Corporate Office to safeguard its assets. The Company also carries out a physical verification of its assets.

**Adherence to the Company’s Policies**

The Company has two tier policies and procedures viz. Entity Level Controls and Process Level Controls. The entity level controls include a comprehensive Code of Conduct. The Company also has a Whistle Blower policy and any employee of the Company can directly write to the Ombudsman. We also have process level controls which cover a wide range of key operating financial and compliance related areas like Accounting, Order to Cash, Procurement to Payment, Inventory and Production, Treasury, Legal, Forex, Fixed Assets, Direct and Indirect Tax, R&D, ITGC etc.

Self-assessment certification of controls is being done by the control owners through a verifiable and transparent process and such certification is reinforced by activity and location owners, as they give in-principle approval to the self-assessment by the control owners. Result of controls manager certification is prepared and presented to the audit committee every quarter by the Chief Financial Officer (CFO) for exception review.

Controls certification is also being validated by the in-house team through review of the assertions certified by the Control Owners on sample basis regularly across business units, plants, branches and corporate office and validation results of Controls Manager certification are prepared and presented annually to the audit committee. The above policies are periodically reviewed and refreshed in line with the changes in business and regulatory requirements.

The audit committee, on a quarterly and annual basis, reviews the adequacy and effectiveness of the internal controls being exercised by various business and support functions.

**Prevention and Detection of Frauds and Errors**

Due to the presence of strong Code of Conduct and Whistle Blower policy, it is generally expected that serious frauds will not take place. In order to prevent and detect frauds and errors, perpetual internal audit activity is carried out by Ernst & Young LLP. Action points and suggestions made by them are discussed in sub-audit committee meeting before presenting the same to the audit committee. Subsequently, follow-up audits are also carried out by in-house internal audit team to ensure implementation of the suggestions. In addition, special audits are carried out by Ernst & Young LLP in areas that may be vulnerable to fraud.

**Accuracy and Completeness of the Accounting Records and Timely Preparation of Reliable Financial Information**

The Company has a well-documented accounting manual. The accounting manual contains detailed guidelines on all aspects of accounting which helps in ensuring that the accounts and finance team is well updated on the accounting requirements. Financial consolidation is carried out through an Enterprise Resource Planning system called Hyperion thereby minimising the chances of manual errors. The financial information is verified by the statutory auditors on a periodic basis as per the requirements of Companies Act, 2013, Securities and Exchange Board of India (SEBI) (Listing Obligations and Disclosure Requirements) Regulations, 2015 (the ‘Listing Regulations’), ICAI guidelines, etc. The Company provides structured training to the accounts and finance team on a wide range of topics covering Ind AS (Indian Accounting Standards), IFRS (International Financial Reporting Standards), Companies Act, 2013, Direct & Indirect taxes, etc. through in-house and outside experts.

**Implementation of Internal Financial Controls**

To compete globally, world class Corporate Governance and financial control over operations is a must for the Company. The Internal Financial Controls as mandated by the Companies Act, not only require a certification from CEO-CFO but also put an obligation on the Board
of Directors to ensure that the Internal Financial Controls are adequate and operating effectively. Besides this, the statutory auditors are also required to give an opinion on the adequacy and effectiveness of Internal Controls over Financial Reporting (ICFR).

To make the Internal Financial Controls framework robust, we have worked on three lines of defence strategy which is as under:

- **First Line of Defence: Build internal controls into operating processes** – To this end, we have ensured that a detailed Delegation of Authority is issued, Standard Operating Procedures (SOPs) for the processes are created, financial decision making is done through Committees, IT controls are built into the processes, segregation of duties is done, strong budgetary control framework exists, the entity level controls including Code of Conduct, Ombudsman office etc. are established.

- **Second Line of Defence: Create an efficient review mechanism** – We created a review mechanism under which all the business units and functions are reviewed for performance at least once in a month by the respective CEOs and once in a quarter, by the corporate team. The formats for these reviews are detailed and finalised with the help of global consulting firms.

- **Third Line of Defence: Independent assurance** – We have appointed a Big Four firm as our internal auditors to perform systematic independent audit of every aspect of the business to provide independent assurance on the effectiveness of the internal controls and highlight the gaps for continuous improvement.

We have implemented a program under which more than 2,500 financial controls are established and certified on a quarterly basis by the relevant process owners before the financial results are closed for the quarter. A quarterly certification process is at least once through a work flow based IT tool called ‘Controls Manager’ and this certification is the basis of the ‘CEO-CFO certification’ of internal controls as per Regulation 17(8) of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015 (the ‘Listing Regulations’)

The Company regularly updates the control library and risk and control matrix. The exercise of review of controls was conducted during the year by in-house process owners with the help of a Big Four firm. The revised control framework after such review was tested for operational effectiveness by the statutory auditors and they have given an affirmative opinion about the adequacy and effectiveness of Internal Controls for financial reporting in the Company.

The Company has three business segments namely:

a) Pharmaceuticals
b) Life Science Ingredients
c) Others. The segments have a complete management set up with CEO, CFO and other functional heads who are responsible for running the operations and report to the Chairman/ Co-Chairman and Managing Director (CCMD) and the Corporate Committee.

To improve the controls in operations, we have established, for each line of business, the concept of financial decision making through operational committees. The entire purchase, credit control and capital expenditure decisions are taken jointly in committees. The key roles of these business committees are as under:

- **Purchase Committee** which ensures high quality purchases at economical cost and maintains reliability of supplies from reputed suppliers with long-term relationships. This committee includes CEO, CFO, Head of Supply Chain and the relevant SBU (Strategic Business Unit) / functional head.

- **Capex Committee** which ensures cost reduction with proper negotiation and monitors time & cost overrun. This committee includes CEO, CFO, Head of Project, head of Supply Chain and the relevant SBU head/ functional head.

- **Credit Committee** which evaluates the credit risk and approves the maximum credit which can be provided to a customer. This committee approves the credit limits at the beginning of the year and is empowered to make changes as and when required. This committee includes CFO, CEO and the SBU head.

- **Business Performance Committee** which reviews the business performance on a monthly basis. This committee includes CEO, CFO, functional heads and the relevant SBU head.

In addition to the above, to maintain periodic review and control, we have a structured weekly meeting between the corporate team and the business leadership team. Through this meeting, the corporate team keeps itself abreast of the latest business developments and guides the business team to undertake mid-course corrections, if required. This meeting also provides a forum for obtaining the relevant approvals required from the Corporate team as per Delegation of Authority. Participants at this
meeting are Chairman/ CCMD/ Executive Director/ Chief Scientific Officer from Corporate side and CEOs and CFOs from the Business side.

Further, a detailed quarterly review of the business performance with the Chairman/ CCMD and the Corporate committee is organised to identify any gaps in performance and to consider mid-course corrections.

**Our Vision on Risk Management**

To establish and maintain enterprise wide risk management capabilities for active monitoring and mitigation of organisational risks on a continuous and sustainable basis.

**Risk Management Strategy**

We have a strong risk management framework that enables regular and active monitoring of business activities for identification, assessment and mitigation of potential internal or external risks. We have established processes and guidelines, along with a strong overview and monitoring system at the Board and senior management levels.

Our senior management team sets the overall tone for risk minimisation culture through defined and communicated corporate values, clearly assigned risk mitigation responsibilities and appropriately delegated authority. We have laid down procedures to inform Board members about the risk assessment and risk minimisation procedures. As an organisation, we promote strong ethical values and high levels of integrity in all our activities, which by itself significantly mitigates risk.

**Risk Management Structure**

Our risk management structure comprises the Board of Directors and Audit Committee at the apex level, supported by Executive Director (ED), Chief Executive Officers (CEOs), Business Chief Financial Officers (CFOs), functional Heads, Strategic Business Heads (SBUs) Units and heads of Management Assurance function. As risk owners, the heads are entrusted with the responsibility of identification and monitoring of risks. These are then discussed and deliberated at various review forums chaired by the Executive Director and CEOs and actions are drawn upon. Progress against the risk management plan is periodically monitored.

The Audit Committee, Executive Director, CEOs, CFOs and heads of Management Assurance act as a governing body to monitor the effectiveness of the Internal Financial Controls framework.

**Risk Mitigation Methodology**

We have a comprehensive internal audit plan and a robust Enterprise Risk Management (ERM) exercise which helps to identify risks at an early stage and take appropriate steps to mitigate the same.

Each SBU head updates the risk register and identifies top three to five risks for the business. The CEO then consolidates top 10 risks of the Life Science Ingredients segment and reports the same on a periodic basis to the Board of Directors along with mitigation plan.

We have a quarterly certification process wherein, the concerned control/ process owners certify the correctness of entity level and process level controls. The certification process has been in operation for more than 12 years and covers over 2,500 controls. The process level controls cover a wide variety of key operating, financial and compliance related areas while entity level controls cover integrity and ethical values, adequacy of audit and control mechanism and effectiveness of internal and external communication, thereby, strengthening the internal financial control systems and processes with clear documentation on key control points. This has made our internal controls and processes stronger and serves as the basis for compliance with the provisions of the ‘Listing Regulations’.

**Management’s Assessment of Risk**

The Company identifies and evaluates several risk factors and draws out appropriate mitigation plans associated

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We have a strong risk management framework that enables regular and active monitoring of business activities for identification, assessment and mitigation of potential internal or external risks.
with the same. Some of the key risks affecting its businesses are laid out below:

**Competition, Cost Competitiveness & Pricing**

Competition we face in some of our business lines is described in detail below.

**Specialty Pharmaceuticals**

We face extensive competition in our Specialty Pharmaceuticals segment. Many of our competitors have substantially greater experience in the development and marketing of branded, innovative and consumer oriented products. New competitors, including large pharmaceutical companies, have also recently entered the specialty pharmaceuticals market. They may be able to respond more quickly to new or emerging market preferences or to devote greater resources to the development and marketing of new products and/or technologies than we can. As a result, any products and innovations that we develop may become obsolete or non-competitive before we can recover the expenses incurred in connection with their development. In addition, for these product categories we must demonstrate to physicians, patients and third party payers, the benefits of our products relative to competing products that are often more familiar or otherwise more established. If competitors introduce new products or new variations on their existing products, our products may be replaced in the marketplace or we may be required to lower our prices. In our Radiopharmaceutical business, the market for diagnostic medical imaging agents is highly competitive and continually evolving. Our principal competitors in the Radiopharmaceutical business include, but are not limited to, Lantheus Holdings Inc., GE Healthcare Inc., The Bracco Group and Curium, as well as Cardinal Health Inc. in the Radiopharmacy business. We cannot anticipate their actions in the same or competing diagnostic modalities, such as significant price reductions on products that are comparable to our own, development or introduction of new products that are more cost-effective or have superior performance than our current products. Other risks are the introduction of generic versions when our proprietary products lose their patent protection or any new entrants into a Generics market in which we are already a participant. In addition, distributors of our products could attempt to shift end-users to competing diagnostic modalities and products. Our current or future Radiopharmaceutical products could be rendered obsolete or uneconomical as a result of these activities.

**Contract Development and Manufacturing (CDMO)**

For our CMO business, pricing is a key driver to gain market share. We are under pressure to either engage in competitive pricing or to differentiate our services by other means. We aim to differentiate through improvement in our service quality, provision of added services such as product development, targeted formulation, laboratory analytical services as well as superior technical expertise. If we fail to implement our CMO strategy, our business, financial condition and results of operations will be adversely impacted.

We face intense competition in the market for APIs business. Once we develop API, we need to identify and partner with a generic drug manufacturer that will use our APIs in their formulation or wait for our solid dosage formulations to receive the requisite approvals. The regulatory approval process for new suppliers of APIs to generic manufacturers imposes significant timing constraints in bringing products to market. Suppliers who can gain early approval for their products have a competitive advantage for that API product. There is also no assurance that we will be able to continue identifying generic drug manufacturers as suitable partners.
Many of our competitors have greater financial resources, marketing capabilities and greater experience than we do in the testing and production of APIs, obtaining regulatory approvals, manufacturing and marketing. If our competitors who are developing APIs, which are coming off patent for sales in regulated markets, are able to gain early approval and commercialise their products before we can, we will lose market share for such API products, and we may not be able to generate sufficient revenue and profit to offset our development costs for those APIs. Our competitors may also have long-term relationships with customers such as global generic companies in the field of APIs, which we are in the process of developing. As a result, we will have to commit resources in such a way as to inspire the trust and confidence of new customers, particularly in relation to our API business. If we are unable to obtain new customers or maintain our relationships with existing customers, we may be unable to successfully commercialise the APIs currently in the development phase.

**Generics – Solid Dosage Formulations**

We also face intense competition in the market for Solid Dosage Formulations. The Generics segment of the Pharmaceutical market is characterised by a high level of price competition, as well as other competitive factors including reliability of supply, quality and enhanced product features. To the extent that any of our competitors are more successful with respect to any key competitive factor, including but not limited to greater financial resources, marketing capabilities and greater experience in the testing and production of Solid Dosage formulations, obtaining regulatory approvals, long term relationship with customers, our business, financial position and results of operations could be adversely affected. Pricing pressure could arise from, among other things, limited demand growth or additional competitive products being introduced into a particular product market, price reductions by competitors, the ability of competitors to capitalise on their economies of scale to create excess product supply, the ability of competitors to produce or otherwise secure APIs at lower costs than what we are required to pay to our suppliers and the access of competitors to new technology that we do not possess.

In our Solid Dosage Formulations business, any delay due to failure in bioavailability and bioequivalence studies or regulatory approvals may significantly reduce our capability to gain market share in this business. Our competitors in Solid Dosage Formulations include major pharmaceutical and chemical companies that develop or may develop products within the same therapeutic areas as our current and future products, specialised Contract Research Organisations (CROs), R&D firms, universities and other research institutions.

In order to combat the risk of rising competition and to ensure that cost competitiveness is maintained, we continue to explore all options viz.

- New products continue to get launched by experienced and talented R&D teams which work to deliver on the marketing strategy by focusing on quality assurance through the development of new cost effective processes/ products to meet customer demand, build market share and minimise the possibilities of commoditisation. The in-house R&D team further develops cost effective products by redefining the production process.
- For some of our generic formulations, we have captive manufacturing of APIs to ensure timely material availability and effective cost control to focus on improving profit margins
- The competitive strengths of our manufacturing expertise across different businesses of our Pharmaceuticals segment along with our market lead in North America in sterile vial manufacturing and active relationships with global pharmaceutical companies allow us to compete effectively against our competitors.

**Life Science Ingredients**

In the Life Science Ingredients segment, a significant share of our business comes from exports and it faces stiff competition in both domestic and international markets. Manufacturers in China, who gain from economies of scale, favourable policies and lower cost along with other advantages, may adversely affect our ability to maintain market leadership, achieve planned growth and generate planned margins.

Additional risk of competition exists in the form of (i) certain competitors being suppliers of core raw materials for Life Science Chemicals business of the Company, (ii) new entrants resorting to penetration pricing to make inroads, (iii) Chinese manufacturers’ strategy to initiate price wars with Indian manufacturers. These competition risks and excess capacity, amongst others, can force a decrease in prices and consequently affect margins.

Our Advance Intermediates business comprises Pyridines and Picolines. While we continue to retain our global
leadership position, the industry is having excess capacity, primarily due to new players coming up in China. Over the last few years, China has been focussing more on its environmental standards and requirements, which forces industry to financially invest more on compliance related matters. This is expected to continue for few more years, which means that the cost structure in China would go up and might also lead to potential supply disruptions. Further though Paraquat, which is the primary end use of Pyridine, has been officially banned in China since 2016, a stricter implementation mechanism has been put in place now. While Vietnam and Taiwan have completely banned the use of Paraquat since Q1 2018, ban in other countries such as Thailand and Brazil is yet to be formally announced. Demand in countries such as US and those in Western Africa is increasing. This would result in some short term increase in Pyridine demand, but eventually the demand will even out. This will have a proportional impact on demand and supply of Beta Picoline. We continuously focus on cost of key raw materials, consumption norms of both starting raw materials and energy so as to remain competitive. The Company is also making Alpha Picoline and Gamma Picoline on the same assets as well as selling the upstream in-house products like Acetaldehyde and Formaldehyde in merchant markets, with a view to broad base the asset utilisation thereby driving overall cost competitiveness.

Fine Ingredients business faces significant competition from Chinese players both in the Indian as well as international markets. The competition has intensified due to the entry of manufacturers of Pyridine and its derivatives in the Fine Ingredients market. At the same time, China has significant advantages in terms of excess capacity, low cost capital and availability of raw materials. This poses a risk of downward pressure on the prices of Fine Ingredients products and may lead to supply of material at low prices by Chinese companies in the Indian market adversely affecting our market share. We recognise the risk and have engaged in proactive mitigation by doing continuous improvement in processes, promoting our products into new applications, entering into long term contracts with customers and maximising the utilisation of existing assets through forward integration of existing products to improve margins. Due to reduction in the lifecycle of new products, we are working towards creating new building-blocks and new chemistry platforms to increase the product portfolio and market offerings.

In Vitamin B3 market, capacity far exceeds demand and there has been emergence of new vertically integrated competitors. This could result in downward pressure on Vitamin B3 pricing if these players resort to aggressive pricing to gain market share, however their capacity utilisation is restricted by availability of a critical raw material i.e. Beta Picoline, which is evident from the current market situation where Beta Picoline availability is low. We plan to mitigate this risk by focusing our effort on more profitable market applications which are less price sensitive.

In the Animal Nutrition business, we are facing stiff competition. High fluctuation in demand and supply continued to exert pressure on prices of broiler and eggs, leading to unpredictable price trends in domestic poultry market during FY 2018-19. Diversification to other species’ feed markets such as aqua and exploring export markets are primary risk mitigation measures being undertaken by us.

There has been strong demand for crop protection intermediates because of environmental issues in China which the factories in China are not able to fulfil. Hence, there is a good opportunity for our Crop Science Ingredients business to develop and launch new products. We plan to launch four new products in the near future. However, we may face Chinese competition in these products once Chinese producers shift their plants to new locations to increase manufacturing capacity. We plan to mitigate this risk by planning alternative products using the same assets (i.e. our multipurpose plants) and continuously improve on product costs to protect our margins.

The Ethanol business is vigorously supporting the Ethanol Blending Program (EBP) of the Government of India. In the current EBP tender from December 2018 to November 2019, we have been successfully awarded a tender for supplying 70 million litres of Ethanol in the states of Uttar Pradesh, Delhi and Maharashtra in India. With these expected supplies, we will be the fifth largest supplier for EBP nationally. Moreover, a price increase based on Government’s new policy has improved our business margins. The business is focused on improving our production capacities with continuous investment and operational excellence. This is expected to eventually help us in maintaining our position as one of the largest contributors to the EBP.

In order to combat the risk of rising competition and to ensure that cost competitiveness is maintained, we continue to explore all options viz.

• Increasing penetration in other geographical regions and strengthening our supply position...
with our existing strategic customers through competitive offering to achieve a higher share of customers’ business. Wherever feasible, we enter into long term contracts with volume commitments and prices which are linked to key input material prices to mitigate risks

- Building long term relationships with key customers by offering improved quality and service experience. Passing-on the increase in the raw material prices to customers on the strength of excellent customer relationships and sales and distribution network
- Building economies of scale in manufacturing, distribution channels and procurement to maintain cost advantage and sustained entry barrier
- Introducing cost improvement initiatives and manufacturing efficiency improvement plans at plants by undertaking projects under Business Excellence program and by applying many tools and techniques e.g. Lean, Six Sigma and Total Productive Maintenance
- Developing economical alternatives and re-engineering costs to counter increase in input cost. Cost optimisation has enabled us to counter international competition
- Significant R&D has been done to improve raw material and utilities consumption and increase manufacturing efficiency
- Developing external manufacturing facilities to make the products expeditiously and at lower cost
- Developing new suppliers to mitigate the risk of higher input prices and non-availability of raw material in time. Micro level planning of inventory also places focus on handling inventory costs

Others

Drug Discovery & Development Solutions

In the Drug Discovery & Development Solutions business, the pharmaceutical industry is facing significant challenges such as escalating cost of R&D, patent expirations, pricing pressure, increased regulatory and safety hurdles as well as lower productivity. The pharmaceutical industry as a whole has been constantly re-evaluating its business model across the entire R&D value chain. This has resulted in a drive towards cost reduction which has increased the industry’s appetite for externalisation of more R&D processes. This increased outsourcing has benefited us as well as the entire drug discovery and development market place which has resulted in a better market, albeit with increased competition from CROs around the world and notably from China. A further risk in this business is the intrinsic discovery and development risk when programs fail to meet efficacy which leads to suspension of the efforts and short term decline in revenue till other compensatory programs are developed. To mitigate this risk, we are constantly reviewing our internal processes and organisational structure to ensure higher efficiency, increased scientific output and cost effectiveness. In addition, the pharmaceutical industry is investing increasingly in new modalities such as cell and gene as well as monoclonal antibodies which are outside the scope of the Company. To mitigate this risk, we are expanding our geographical reach to South Korea, Japan and Australia while improving our business model for biotech companies in the key markets of US and Europe.

We have also evolved our business model to include a portfolio of proprietary drug discovery projects which we can out-license to the pharmaceutical industry to generate revenue in the form of milestone based fees and royalties along with research funding. We perform the role of traditional CROs, by delivering small molecule drug discovery services to our clients. We also develop our own portfolio of proprietary Pre-clinical drug discovery programs that we use to initiate discovery collaborations with our clients through out-licensing or partnership models.

Dependence on Certain Key Products and Customers

The Company depends on certain key products and key long-term contracts with customers for a significant portion of its total revenue, cash flows and earnings and any events that adversely affect the markets for key products or key contracts may adversely affect its financial condition, results of operations and profitability. If the volume or pricing of our largest selling products declines in future or the Company is unable to satisfy market demand for these products, its financial condition, results of operations and profitability could also be adversely affected. Any event that adversely affects any of these products or their markets could have a material and adverse effect on our business, financial condition and results of operations. While we are not dependent on any single customer and have a broad and diversified customer base across businesses, if any of our long-term customers terminate their contracts, delay payments or breach payment obligations, reduce the volume of business we receive under the contracts, do not renew
such contracts on favourable terms or at all, our revenues and profitability may be adversely affected.

We continue to launch new products with the help of R&D teams, which help in developing new cost effective processes/products to meet customer demand and build market share. We may also change our product mix appropriately.

In the Drug Discovery & Development Solutions business, we have several large collaborations with key pharmaceutical and biotech companies that provide a large portion of the revenue each year. If these collaborations were to end abruptly there would be an impact on our revenue and profitability. To mitigate this risk, we have a team of business development professionals in the field who interact with clients on a constant basis to generate additional business. These interactions include the development of new clients as well as strengthening of relationships with existing clients. We have a strong brand and reputation in the industry that helps us to attract and retain our clients. In addition, our mixed business model with our portfolio of proprietary programs is also an attractive marketing tool to bring in larger deals and to develop our long-term interaction with key clients.

**Foreign Currency and Interest Rate Exposures**

There has been significant movement in exchange rates over many years. Due to our global operations, we have significant foreign currency exposures. An increasing amount of our sales, particularly in US, Canada and European countries, is recorded in local currencies, which exposes us to the direct risk of exchange rate fluctuations. We may also be exposed to credit risks in some of these markets. The imposition of price controls or restrictions on the conversion of foreign currencies could also have a material adverse effect on our financial results.

We borrow funds in the domestic and international markets from various banks, financial institutions and Public Financial Markets to meet the long-term and short-term funding requirements for operations and growth initiatives at fixed and floating rates of interest. Any increase in interest rates may increase the cost of any floating rate debt that we incur.

The Company does not use any derivative financial instruments or other hedging techniques to cover its potential exposure since net foreign exchange exposure is not significant.

**Capacity Planning and Optimisation**

Our production capacity may not be aligned with market demand. Insufficient capacity threatens our ability to meet demand and be competitive and excess capacity threatens the organisation’s ability to generate competitive profit margins.

We ensure that capacities are well planned and optimised to respond to market realities in the following ways:

- The Company continues to invest in the optimisation of our manufacturing capacity utilisation. Such optimisation is driven by continuous de-bottlenecking of our manufacturing plants and by value engineering through the application of Six Sigma, Lean Sigma and other value-added tools for productivity enhancement. In addition, we also build new capacities as per our commercialisation plans based on customer approvals and patent expiry of various molecules. We intend to continuously increase production capacity for several of our APIs.

- The business teams regularly track the trends for each product to ensure that there is sufficient capacity to meet demand. We have robust processes to continuously monitor plant capacities and utilisation, drive improvements aligned with good manufacturing practices such as preventive maintenance schedules and modify plant designs
in case of repeated breakdown. We periodically undertake de-bottlenecking and other initiatives to improve efficiency in terms of throughput, cost reduction and to also build additional capacities without committing significant capital outlay thereby generating better return on investment. We have proactively improved capacities of key Fine Ingredient products by 25-30% by debottlenecking and outsourcing, hence gearing up for the growing demand for their end products.

- We have developed a dedicated external manufacturing team which can help to outsource some capacities and capabilities in order to ensure quicker response to unforeseen market demand.

- To mitigate excess capacity situations or lower asset utilisation, we continuously evaluate manufacturing of new intermediates by using existing assets thereby making the plants multi-purpose, thus improving flexibility. We have commenced commercial scale production of ‘Alpha Picoline’ and ‘Gamma Picoline’, on our existing assets which caters to our captive requirements, besides meeting market demand. As a derivative of Gamma Picoline, we have started making ‘4-Cyano Pyridine’ which is used in Pharma and industrial applications.

- In order to maximise asset utilisation, the Company has started focusing on selling both Acetaldehyde and Formaldehyde in merchant market. As we are the largest bio-based Acetaldehyde manufacturer, there is an increasing interest among domestic as well as overseas customers.

- We have retrofitted our existing multi-purpose plants to manufacture new Pyridine derivatives for pharmaceutical and biocide applications. We are also doing forward integration to create value added Fine Ingredients products from our current Good Manufacturing Practices (cGMP) multi-purpose facility for global customers.

**Manufacturing Operations**

As a pharmaceutical manufacturer, our manufacturing facilities are required to comply with extensive USFDA and comparable foreign regulatory authority requirements, including ensuring that quality and manufacturing processes conform to Good Manufacturing Practices (cGMP).

One of our key strengths is excellence in carrying out manufacturing activities with utmost efficiency. Hence, any risk that challenges the manufacturing operations would be a cause of concern as extensive time, money, and effort is expended in all areas of regulatory compliance, including manufacturing, production and quality. We have made an effort to identify such risks and are prepared to mitigate the same to avoid significant additional regulatory compliance expense and/or regulatory penalties.

We are committed to business process improvement by means of automation and providing timely training to workers, establishing clear Standard Operating Procedures (SOPs) and process guidelines which will lead to reduction in cycle time and improvement in productivity.

Any inconsistency in the availability of water may pose a threat to our manufacturing operations in India. As a proactive approach, our operations team has been working on maximising the recycling of water from effluent streams and reduction of water intake at source.

In the Pharmaceuticals segment, manufacturing problems could cause inventory shortages and delay product shipments and regulatory approvals, which may adversely affect the Company’s financial condition, results of operations and profitability. In order to generate revenue from our products, we must be able to produce sufficient quantities of our products to satisfy demand. Many of our products are the result of complex manufacturing processes and subject to regulation by various governmental authorities. Failure to comply with these requirements may lead to delays in the submission or approval of potential new products or financial penalties. In order to distribute our products in US, we must register our facilities, whether located in US or elsewhere, with the USFDA as well as regulators outside the US. Our products must be made in a manner consistent with cGMP or similar standards in each territory in which we manufacture. We may have to write-off the costs of manufacturing any batch that fails to comply with approved specifications. Furthermore, the USFDA or other regulatory authorities may inspect our facilities and identify deviations from cGMPs. The deviations are reported by the USFDA investigators on a Form 483 and may result into subsequent regulatory actions such as Warning Letter, Import Alert and Seizures.

During the financial year ended March 31, 2019, our facilities were inspected by various regulatory authorities e.g. the Jubilant Cadista Pharmaceuticals Inc.- Salisbury, US facility was inspected in April 2018, the Jubilant HollisterStier General Partnership - CMO Montreal, Canada facility was inspected in May 2018 and the Jubilant Generics Limited - Roorkee, India facility
was inspected in August 2018. Recently, our Jubilant HollisterStier LLC - Spokane, US facility was inspected by the USFDA and the CBER USFDA in October 2018, and our Jubilant Generics Limited - Nanjangud, India facility was jointly inspected by the USFDA and Health Canada in December 2018. Some of these inspections resulted in the issuance of Form-483 inspectional observations for Jubilant Generics Limited - Roorkee, India facility and Nanjangud, India facility, Jubilant HollisterStier LLC - Spokane facility and Jubilant HollisterStier General Partnership - CMO Montreal, Canada facility. Our Radiopharmacy in Kansas City (part of Jubilant DraxImage Radiopharmacies Inc.) was also inspected in June 2017, before we acquired it in September 2017, for which Form-483 inspectional observations were issued.

Upon receipt of a Form-483, we work to address any inspectional observations in a timely manner to obtain the EIR (Establishment Inspection Report) from such inspections, which indicates formal closure of the inspection. As of March 31, 2019, we have not received the EIRs from the most recent inspections of the Jubilant HollisterStier LLC - Spokane, US facility and the Jubilant Generics Limited - Nanjangud, India facility or the Kansas City, US Radiopharmacy (part of Jubilant DraxImage Radiopharmacies Inc.) was also inspected in June 2017, before we acquired it in September 2017, for which Form-483 inspectional observations were issued.

Research and Development (R&D) Effectiveness

As a pharmaceutical manufacturer, we are dependent on our R&D to effectively improve and enhance our existing products, develop commercially viable and sustainable new products along with process improvements that can improve time, quality and cost efficiency. To that end, we have an effective strategy to mitigate potential risks and ensure R&D effectiveness with earmarked budgets and investments in R&D commensurate with the business plans. R&D set up at various plant locations continuously works on cost reduction of existing products and development of new products using the same assets.

In the Pharmaceuticals segment, the R&D team primarily focuses on APIs & Generics research including APIs, Solid Dosage Formulations and Radiopharmaceuticals. R&D supports the activities of various businesses through new product and process development, process intensification, absorption of technologies and establishing technologies at a commercial scale. Regarding APIs, our focus continues to be on developing commercially competitive, intellectual property compliant, robust and eco-friendly technologies. Our Radiopharmaceuticals business has a small focused R&D team with Radiochemical expertise, based in Montreal, Canada. This team supports existing products and leads the development of new products using its own resources and also collaborating with our R&D team in India. In Radiopharmaceuticals, we are continuously engaged in the development of new products that have yielded a pipeline of products that can be introduced in the future.
Since our LSI segment faces significant competition from Chinese and other competitors, the R&D team has taken a pro-active approach to introduce new products in Pyridine chemistry and also in non-Pyridine chemistry, by deploying our various technological platforms and capabilities. New products continue to get developed by experienced and talented R&D teams which work in alignment with the marketing strategy by developing new cost effective processes/products. Further, in order to ensure that cost competitiveness is maintained along with minimal environmental impact, R&D is working on the improvement of existing processes, their carbon efficiency and atom economy. Initiatives are also being taken to develop alternative green processes involving fewer manufacturing steps with reduced consumption of utilities and increased manufacturing efficiency. R&D also has a dedicated team which works on Homogenous and Heterogeneous catalysis for process intensification and reducing the synthetic steps.

The focus is on development of processes within the deadlines at optimum cost with effective and efficient scalability. We have institutionalised robust processes and proven R&D methodologies to ensure successful commercialisation of the products for which research has been conducted to avoid any unpleasant surprises during the scale-up. The R&D function keeps itself updated with the regulations, upcoming technological changes and trends and proactively aligns with pharmacopoeia methods and industry best practices.

In Drug Discovery & Development Solutions, we have a mixed business model that delivers small molecule drug discovery services to our clients and also have a portfolio of proprietary discovery programs that is used to initiate drug discovery collaborations with our clients through out-licensing or partnerships. Drug discovery is inherently a risky venture with a high failure rate. To mitigate this, we maintain a pipeline of client programs that can help offset attrition of client programs. For our own portfolio of internal proprietary drug discovery programs to help offset attrition risk, we have 1) built a pipeline of early and late stage discovery programs and 2) are developing select relationships with academic groups as a source for new targets which allows us to replace programs where the science does not deliver an asset that is fit for out-licensing. We create small molecule assets through Intellectual Property (IP) filing in a time bound manner. This enables us to out-licence the asset to clients to jump start their efforts through the integrated outsourcing model and earn an upfront payment. IP rights which create any assets leading to Investigational New Drug Application (IND) filing will enable us to maximise returns. Hence, creating and protecting our IP portfolio for these assets is a risk mitigation strategy for the Drug Discovery & Development Solutions business. Further risk mitigation is achieved by developing growth plans for our research sites and investing in new technologies such as Flow chemistry, Surface Plasmon Resonance (SPR) testing and digitization of Critical Processes to drive both speed and efficiency.

Innovation, speed-to-market and a robust and diverse product pipeline are critical factors in ensuring success for an integrated global pharmaceutical and life sciences company. Failure of R&D to provide innovative and cost effective products would result in non-achievement of top line or bottom-line goals. Similarly, an R&D function which fails to meet the expectations of the business, such as, meeting target product costs and minimising product cost deviations between R&D and operational phase will adversely impact our ability to launch products competitively and hence, diminish market penetration and/or diminish our market share. Risk of failing to develop products which are compliant with accepted standards documentation will significantly dent the Company’s reputation in addition to the financial loss associated with the failed launch. Further, emergence of new cost effective methods for producing core products supplied by us can pose a risk to the Company’s competitive position.

R&D set up at various plant locations continuously works on cost reduction of existing products and development of new products using the same assets.
Supply Interruptions due to Single Source Supplier

In our Pharmaceuticals segment which includes Solid Dosage Formulations, APIs, Radiopharmaceuticals and commercial Radiopharmacy businesses, we must ensure a regular and secure supply of the raw materials required to produce our products. For some of our key raw materials in this segment, we have only a single or a few external sources of supply, and alternative sources of supply may not be readily available. If we are unable to maintain our relationships with our suppliers or find alternative suppliers on commercially acceptable terms, our financial condition, results of operations and profitability could be materially and adversely affected in the event of any supply shortage or disruption. In addition, if we are unable to obtain such raw materials, or if we are unable to obtain them at a competitive cost, the Company’s competitiveness would be affected and we may lose market share.

For both our Radiopharmaceutical and our commercial Radiopharmacy businesses, a critical ingredient is Tc99m, used for a majority of cold-kit preparations. Tc99m is generated through the decay of Molybdenum, which is the parent Radioisotope contained in the Technetium generator. Molybdenum is produced by a limited number of nuclear reactors, all of which are located outside the United States. These limited Molybdenum processing sites supply generator manufacturers with the needed parent isotope to manufacture generators, thus providing the Tc99m in North America. Any prolonged disruption of supply from the Molybdenum reactors or processors could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We require Radioisotopes such as Strontium-82 (‘Sr-82’) and I-131, which are procured from third party isotope processing companies. According to Frost & Sullivan, there are only three major suppliers globally for I-131 Radioisotopes, of which we have entered into supply contracts with two such suppliers. If the available supply of Radioisotopes is insufficient to meet the demand of our Radiopharmaceutical business or there is any interruption of supply from any one or both of our suppliers, including any unanticipated outage, shutdown and/or suspension of production of Radioisotope producers, it could lead to sudden shortages of Radioisotopes in the market and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

For our Allergy Therapy Products, in connection with manufacturing of venom products for the treatment of allergies, we must source venom for its production. Venom products are made from venom gathered by hand from individual insects. A scarcity of venom could lead to backorders and affect our reputation among customers.

In our APIs and Solid Dosage Formulations businesses, we must ensure a regular and secure supply of the raw materials required to produce our products. The principal raw materials for our APIs are fine chemical products and other advanced intermediate compounds, almost all of which we purchase from third party sources. China has recently tightened implementation of environmental regulations, which had an impact on the chemical and pharmaceutical industries. In addition, for our Solid Dosage Formulations, we currently use one supplier for one of the raw materials used to produce Methylprednisolone.

Any failure to source any of our key raw materials required to produce our products, even on a temporary basis, could affect our ability to deliver some products to our customers in required quantities, within the required timeframe or at all, which could result in order cancellations and decrease in revenues.

Also, in the light of strong regulations on pollution, the chemical industry has seen a lot of outages in China. In
view of this, we need to evaluate suppliers outside China so that we are adequately protected.

We have an effective strategy to mitigate these risks by developing alternative suppliers on a continuous basis that minimises any order cancellations and decrease in revenues.

**Limited Product Pipeline**

In the Pharmaceuticals segment, if we are unable to maintain a sufficiently large portfolio of pharmaceutical products and services and manage their development and approval processes so as to bring them to market on a timely basis, our growth strategy may not be successful and our business operations would be adversely affected. Our future success will depend to a significant degree on our ability to continue to develop and commercialise new pharmaceutical products in a timely and cost-effective manner. The success of any product offerings will depend upon several factors, including our ability to properly anticipate and respond to customer needs, to obtain timely regulatory approval for new products, identify available suppliers and create manufacturing capacity for such products. To that end, it is important that we maintain a sufficiently large portfolio of products and a product pipeline to manage their development and approval processes so as to bring products to market on a timely basis.

As mitigating steps, our R&D team strives to create new, innovative processes and new knowledge-driven products that allow us to capitalise on opportunities for growth in competitive markets. We have R&D centres located in India and North America and employ a large team of research scientists with expertise in the development of non-infringing products for APIs, Solid Dosage Formulations, Radiopharmaceuticals and other products.

**Failure to Supply to Customers**

In the Pharmaceuticals segment, if we are unable to supply our products to customers as per the agreed timelines or specifications or other conditions, we may face penalties from our customers as per the terms of the agreement and the Company’s financial condition, results of operations and profitability could be materially and adversely affected. It may also adversely affect our reputation and our competitiveness and we may lose market share. Such failures can have a far-reaching adverse impact on the reputation of our business and brand value. We ensure that such risks are monitored and mitigated on a continuous basis to avoid customer dissatisfaction, order cancellations and decreased revenues.

**Human Resources – Acquire and Retain Talent**

We have committed substantial resources and strategies to acquire, retain and develop talent, given the size, complexity and geographic reach of our businesses because of competition for qualified and experienced professional personnel. Job enrichment along with timely and appropriate job training is provided to employees at all levels. To execute its ambitious growth and diversification plans, the Company continues to hire and retain highly skilled scientific and technical personnel. Employees get evaluated under reward and recognition programs based on performance.

We realise that an insufficient or minimal focus on human resources processes (e.g. recruiting, talent management, talent retention, labour management, development and training) threatens our ability to recruit and retain the qualified personnel required to maintain desired operational standards. Further, given the nature and complexity of the regulatory regime of the pharmaceutical industry and our dependence on R&D activity, it is imperative that we recruit and retain high quality R&D specialists and Quality Control personnel. Lack of credible, talented successors or effective knowledge transition mechanism may adversely affect the Company’s financial condition in case of unexpected departures from key positions.

As a part of our strategic talent and succession management process, the leadership invests valuable time in identifying high potential candidates and planning their development for succession to critical positions. The leadership development program and the 360-degree feedback are conducted by us for these employees based on the leadership competency framework, helping the human resources department to perform gap analysis followed by capability development activities.

The gap analysis is used to create individual development program to develop the next line of managers. In certain businesses, sales trainees recruited from campuses, are being groomed for future sales positions. We also recruit management trainees and graduate engineer trainees to build a strong talent pipeline.

As talent development is imperative for the success of businesses, training need identification is done during annual performance appraisal. This is included
in the Company’s training calendar and courses are designed to help employees to perform their roles at their highest potential. Senior management employees at critical positions are also sent for customised general management programs at premier institutes to prepare them for larger roles and also build cross-functional capability in the organisation. We have launched a Learning Management System (LMS), which comprises an extensive collection of training and learning resources and can be accessed by all employees through the online portal of LMS.

We also understand the need to create a culture of high employee engagement as a method to retain talent in the organisation. Regular communication forums are organised in the form of town hall, skip meeting and new joiner assimilation program to understand employee concerns and a structured mitigation process is developed for effective redressal.

Today’s fast paced business changes make it imperative to focus on forward looking and futuristic systems and applications. As a step in this direction, we have integrated a PeopleSoft based Human Resource Information Systems (HRIS) across all our locations and entities across the globe. The HRIS system is designed to cover all key human resource processes – performance management, recruitment, training and development, profile and position management, career and succession planning, compensation and benefits. We continue to make improvements in this system.

We ensure that there is full adherence to the code of conduct and fair business practices are followed.

Compliance and Regulatory

Our business operates within a highly regulated environment and regulatory affairs play a vital role in the development of all businesses. Due to constantly increasing regulatory obligations, new requirements as well as globalisation of market, the demands and responsibilities of business in terms of regulatory readiness are becoming stringent, especially in some countries/regions, such as US, Europe and Japan. We have to comply with the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations in 28 member countries of the European Union and REACH like regulations in all major countries for Company’s business, like China, Korea, Japan, Malaysia, Taiwan, Turkey etc. These regulations require registration and extensive data submission without which we cannot enter the market. We have established systems and controls to monitor and upgrade the registrations as per business needs. There are also other major challenges in terms of meeting the requirements of other compliances like United Nations Globally Harmonised System (GHS), Classification, Labelling and Packaging (CLP) and other country specific GHS requirements.

We expect the regulatory requirements to continue to trend upward globally. Although we have adopted measures to address these stricter regulations, such as increasing the efficiency of our internal R&D process in order to reduce the impact of extended testing on the time-to-market for our products, stricter regulatory regimes may increase our compliance costs, delay our product development and hinder our marketing and sales and we may, therefore, not be able to recover our investment in R&D in a timely manner or at all. If we fail to comply with regulatory requirements, or if allegations are made that we fail to comply, our financial condition and results of operations could be adversely affected.

In addition, failure to achieve regulatory approval of new products in a timely manner or at all can mean that we do not recoup our R&D investment through sales of that product. Regulatory agencies may at any time change regulations or reassess the safety and efficacy of our products based on new scientific knowledge or other factors. Such reassessments could result in the amendment or withdrawal of existing approvals to market our products, which in turn could result in a loss of revenue. This may occur even if regulators take action falling short of actual withdrawal. In addition, if we fail to comply fully with such regulations, then civil or criminal actions could be brought against us.

Any change in the regulations, enforcement procedures or regulatory policies set by regulatory agencies could increase the costs or time of development of our products and delay or prevent sales of our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted, may have on our business in future. Such changes or new legislation, could increase the costs or delay or prevent sales of our products and our revenues may decline and we may not be able to maintain profitability. In addition, increases in the time that is required for us to obtain required approvals could delay the commercialisation of our new products.

Besides, there are other specific regulatory requirements that pertain to end use applications like biocides, pesticides, food and feed applications etc. which have various parameters depending upon the geography.
These are being complied with for all businesses proactively.

Over the last few years, various regulators and law enforcement agencies are adopting a zero tolerance approach towards non-compliance. We need to comply with a broad range of regulatory controls on testing, manufacturing and marketing of our products in the pharmaceuticals and life sciences space. Besides, there are laws of many countries that we need to comply with. In some countries, including the US, regulatory controls have become increasingly demanding leading to increased costs and reduced operating margins for our line of products and services. Failure to achieve regulatory approval for new products can mean that we do not recoup our R&D investment through the sale of final products. Any change in regulations or reassessment of safety and efficacy of products based on new scientific knowledge or other factors could result in the amendment or withdrawal of existing approvals to market our products, which may adversely affect the Company’s financial condition, results of operations and profitability. This may occur even if regulators take action falling short of actual withdrawal.

We have adopted measures to address these stricter regulations by increasing the efficiency of our R&D process, reducing the impact of extended testing, timely submission of dossiers and ensuring timely product availability. We are proactively following-up with regulatory authorities regarding pending approvals and queries raised by authorities are addressed promptly. Further, estimation of risks on account of failure/delay in obtaining approvals is duly considered while designing business plans. We have also put in place a compliance management system to ensure compliance with all applicable laws and regulations. We have a dedicated team of experts whose knowledge ensures that the global regulatory compliances are met and we can build competitive advantage. We also undertake training and orientation programs to keep the relevant process owners updated on new regulations and changes in the existing laws.

**Environment, Health and Safety (EHS)**

Our operations are spread across different geographical regions and are subject to a wide range of Environmental, Health and Safety (EHS) laws and regulations. For North America, we are regulated by various environmental agencies and authorities including the United States Environmental Protection Agency (US EPA), and Environment and Climate Change Canada. In India, we are also regulated by various environmental agencies and authorities including the Central Pollution Control Board and State Pollution Control Boards. As such, we require certain statutory and regulatory permits and approvals to operate our business, including environmental clearances. Any failure to procure, renew or maintain the required permits or approvals or any violations of EHS requirements may result in substantial fines or penalties, the imposition of other civil or criminal sanctions, clean-up costs, claims for personal injury or property damages, restrictions on the suspension of operating permits or activities. Any such resulting violation may lead to the interruption of our operations and may have a material adverse effect on the Company’s financial condition, results of operations and profitability.

We are aware of the rapid changes in the business environment such as increased global competition; more rigorous customer and societal demands; and extensive investor pressure. To face these challenges and ensure sustainability, excellence in cost, quality, services, and Environment, Health and Safety is of paramount importance. We are committed to protecting the environment and ensuring the health and safety of our employees, customers and the public. We take pride in managing our operation with a high concern for EHS.

Over the years, EHS excellence has been extensively promoted as a part of our culture. It is also clearly reflected in our policies on sustainability, EHS, responsible care, climate change and green supply chain. The Company does the right things right so that its employees, the community at large, and the environment, including natural resources, are protected. Leaving minimal environmental footprint is integral to our EHS
philosophy. On the road to achieving EHS excellence, we have adopted a top down approach and have been enhancing the impact of EHS initiatives by making it a line function responsibility through active employee consultation and participation.

Caring for the environment is a core corporate promise and as a part of this commitment, high capital expenditure is being incurred on process improvements as well as up-gradation of environmental management facilities using the latest technologies that have helped to reduce environmental footprint. While end-of-the-pipe solutions are implemented, we are also making progress on initiatives for reduction of waste at source. Efforts to process more by-products and waste to make them reusable are paying off in terms of ecological and economic impact.

The Government of India has rightly been focusing on the environmental issues and making the environmental laws appropriately stringent for industry to follow. With the initiatives of cleaning the river Ganges, these laws and guidelines are expected to get even more stringent and industries in India will have to be more disciplined in adhering to the same. We are extremely sensitive to these externalities and strive to pro-actively adhere to all latest guidelines laid out by Government of India from time to time for all our locations.

Investments were made for the up-gradation of process safety and enhanced process controls at our sites. Safety culture in terms of safe behaviour is being aggressively promoted and propagated at workplace through Sanchetna – a platform for encouraging identification and 360-degree correction of unsafe acts and conditions. Safety knowledge of the technical personnel is constantly updated through various external and in-house training programs, including special training programs by external experts and consultants.

All our manufacturing sites are equipped with an Occupational Health Centre (OHC) run by an occupational health physician. We run a comprehensive health assessment program in our manufacturing sites, wherein the occupational health of the employees is assessed on a periodic basis. The OHC provides curative, advisory and health promotion services to the employees.

We proactively engage with government, industry forums and academia to support creation of responsible and practicable EHS regulations.

We have a full-fledged EHS team which is continuously addressing the issues of environmental safeguards by conducting periodical safety audits and training programs.

**Protecting Intellectual Property Rights (IPR)**

Companies in the pharmaceutical industry commonly assert patent and other IPR claims in order to delay or prevent competition. In the normal course of business, we
are sometimes subject to lawsuits. The ultimate outcome of any such litigation could adversely affect our financial condition, results of operations and cash flow. Regardless of regulatory approval, should anyone commence a lawsuit against us with respect to any alleged patent infringement by us, whether because of the filing of an application for governmental approval, such as an ANDA, or otherwise, the expense of such litigation and the resulting disruption to our business, whether or not we are successful, could harm our business. The uncertainties inherent in patent litigation make it difficult for us to predict the outcome of any such litigation. If we are unsuccessful in defending ourselves against these suits, we could be prevented from selling our products, resulting in a decrease in revenues, or to damages, which may be substantial. Either event could adversely affect our consolidated financial position, results of operations or liquidity. Furthermore, in order to sell our API products in regulated markets, we are required to submit DMFs, which among other things, provide information regarding the production site, the API product, the manufacturing process and input materials. If the DMF for a particular API product is determined by a regulatory authority to be inaccurate and cancelled as a result, we could lose access to regulated markets. Similarly, in order to sell our solid dosage formulations, we require ANDAs or dossiers, which provide information on, among others, manufacturing process and facility, stability data, input material, and make reference to the DMF of APIs used. If the ANDA or dossier is found to be incorrect, launches of our Solid Dosage Formulations may be delayed and we could fail to capitalise on related business opportunities. Historically, in addition to patents, we have relied on trade secrets, know-how and other proprietary information. To protect such information, we require our employees, vendors and suppliers to sign confidentiality agreements. However, these confidentiality agreements may be breached and we may not have adequate remedies for any breach. If our IPRs are infringed or if our trade secrets are compromised by third parties, competitive advantages deriving from our usage or access of such rights and information may be revealed to our competitors, compromising our competitiveness and adversely affecting our business. Third parties that obtain our proprietary information may procure IPR on such information, or on substantially equivalent proprietary information that they develop based on our proprietary information, which could affect the validity of our own IPR claims on the revealed proprietary information. Our development of products may be limited to the extent that their manufacturing processes are considered to infringe existing third party IPRs, although the Company is not aware of any such infringements in the past. In particular, an ANDA for a generic formulation utilising APIs that we have developed will not be approved by the USFDA if our APIs infringe on a third party’s IPR. We cannot be certain our APIs do not infringe on the IPRs of other parties. In addition, patent applications are currently pending for some of the technologies currently being utilised by us. If the patent application is rejected or challenged, any aspect of our business reliant on such technologies would be disrupted. Any such disruption would harm our business.

Our efforts have helped us avoid any intellectual property issues by developing designed around research strategies, better understanding of emerging challenges, identifying newer opportunities and creating intellectual property which is well protected in defined geographies of our business interests. Our efforts have been rewarded, resulting in growth of our intellectual property over the years.

We protect our products with patents in major markets. Depending on the jurisdiction, patent protection may be available for individual active ingredients; specific compounds, formulations and combinations containing active ingredients; manufacturing processes; intermediates useful in the manufacture of products; and new uses for existing products. The protection that a patent provides varies from country to country, depending on the type of claim granted, the scope of the claim’s coverage and the legal remedies available for enforcement. The Company has filed intellectual property applications in various countries for innovations. The Company has trademarks primarily in India, US, Canada, Europe, Nigeria, South Africa, Mexico, Columbia, China and Australia.

We have a dedicated team of scientists whose primary task is to ensure that the products are manufactured using only non-infringing processes and compliance requirements are met by reviewing and monitoring IPR issues continuously.

There has been substantial patent related litigation in the pharmaceutical and medical device industries concerning the manufacture, use and sales of various products. We take all reasonable steps to ensure that our products do not infringe valid third-party IPRs. Any material litigation or other communications alleging such infringements could delay the sale of or prevent us from selling our products. In the normal course of business, we are sometimes subject to litigation. Further to our launch of RUBY-FILL®, an innovative technology for PET Myocardial Perfusion Imaging (MPI), Bracco
In the ordinary course of our business, we collect and store sensitive data in our data centres and on our networks, including intellectual property, proprietary business information (both ours and that of our customers, suppliers and business partners) and personal identifiable information of our employees. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union (‘EU’), including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices. Despite our efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European activities.

Risk of Changes in Tax Legislation

The Company’s activities are subject to tax at various rates around the world computed in accordance with local legislation and practice. Actions by governments to increase tax rates or to impose additional taxes may reduce our profitability. Revisions to tax legislation or to its interpretation (whether with prospective or retrospective effect) may also affect our results and significant judgment is required in determining our provision for income taxes. Likewise, we are subject to audit by tax authorities in various jurisdictions. In such audits, our interpretation of tax legislation might be challenged and tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions. Although we believe our estimates are reasonable, the ultimate outcome of such audits and related litigation could be different from our provision for taxes and might have a material adverse effect on our financial statements. In addition, we may become subject to various tax litigation and claims. Any consequent rulings against us could materially and adversely affect our business, financial condition and results of operations.

We have a dedicated team of tax professionals whose primary task is to ensure that the tax liabilities are correctly computed and any revision in the tax legislation is monitored continuously.

Mergers & Acquisitions

In the Pharmaceuticals segment, we may expand our business through selective, targeted mergers or acquisitions of businesses and assets we believe to be complementary to our existing business. We may also
seek to expand our business through complementary or strategic acquisitions of other businesses, products, or assets, or through joint ventures, strategic agreements or other arrangements. Mergers and acquisitions may involve a number of risks, including that our management’s attention may be diverted due to integration efforts; we may have cultural differences; we may fail to retain key personnel and clients of the acquired business; future developments may impair the value of our purchased goodwill or intangible assets; we may face difficulties or delays establishing, integrating or combining operations and systems; we may assume liabilities related to legal proceedings involving the acquired business; or we may encounter unforeseen internal control, regulatory or compliance issues some or all of which could harm our results of operations and financial condition. We may overpay for a business or if we are not able to successfully integrate other businesses we may acquire or merge with in the future, with the rest of our business, we may be unable to realise the anticipated benefits of such mergers or acquisitions, or our existing business may be harmed. We have adopted measures to address these issues by increasing the efficiency and reducing the impact, if any. Further, estimation of risks on account of failure/delay in integration is duly considered while designing business plans. We have a dedicated team of experts whose knowledge ensures that the requirements are met and we can build competitive advantage.

**Political or Economic Instability or Acts of Terrorism**

Jubilant Life Sciences is an integrated global pharmaceutical and life sciences company with worldwide operations and one of its strategic objectives is to continue to expand its geographic outreach. We derive sales and procure materials from countries/regions that may be adversely affected by political or economic instability, major hostilities or acts of terrorism. Any such events may adversely affect the Company’s financial condition, results of operations and profitability. Moreover, as we export and import a substantial number of products and raw materials, we may be denied access to customers or suppliers of our raw materials. We may also be denied the ability to ship products from any of our sites if the borders of some countries are closed due to political or economic instability or acts of terror, in such countries.

**Duties by Export Destination Countries**

A substantial part of the Company’s revenue is derived from exports and our products are sold in various countries across the world. Export destination countries impose varying duties on our products, which may adversely affect our ability to compete with the local manufacturers and other competitors on cost. There can be no assurance that the duties or other levies imposed on our products by such destination countries will not change or increase, or that a change or increase will not adversely affect the Company’s financial condition, results of operations and profitability.

**Acceptance of Our Products in Market**

In the Pharmaceuticals segment, our ability to market our products successfully depends, in part, upon the acceptance of the products not only by customers, but also by independent third parties including wholesalers, distributors, physicians, hospitals, pharmacies, government representatives and other retailers, as well as patients. Unanticipated side effects or unfavourable publicity concerning any of our products or brands, could have an adverse effect on our ability to achieve acceptance by prescribing physicians, managed care providers, pharmacists and other retailers, customers and patients.

If our products are approved by the regulatory authorities but do not achieve an adequate level of acceptance by independent third parties, we may be unable to generate any or sufficient revenue from these products to make them profitable. If our products fail to maintain significant market acceptance, it could have a material adverse effect on our projected business, financial condition and results of operations.

**Policies Regarding Returns, Allowances and Chargebacks in the United States**

In the Pharmaceuticals segment, consistent with the industry practice in US, our US subsidiary, Jubilant Cadista Pharmaceuticals Inc., like many other generic product manufacturers, has liberal return policies and has been willing to give customers post-sale inventory allowances in our Solid Dosage Formulations business. Under these arrangements, from time to time, this subsidiary may give customers credits on generic products that customers hold in inventory after it has decreased the market prices of the same generic products. Therefore, if new competitors enter the marketplace and significantly lower the prices of any of their competing products, we may reduce the price of our product. As a result, this subsidiary may be obligated to provide significant credits to customers who are then holding inventories of such products, which could reduce sales revenue and gross margin for the period the credit is provided.
Like our competitors, this subsidiary also gives credits for chargebacks to wholesale customers that have contracts with us for their sales to hospitals, group purchasing organisations, pharmacies or other retail customers. A chargeback represents an amount payable in the future to a wholesaler for the difference between the invoice price paid to us by our wholesale customer for a particular product and the negotiated contract price that the wholesaler’s customer pays for that product. As a mitigation strategy, the Company establishes reserves based on prior experience and best estimates of the impact that these policies may have in subsequent periods. However, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates, which could have material adverse effect on our financial condition, results of operations and cash flows.

Labour Unions

If the Company experiences labour union issues, our production capacity and overall profitability could be adversely affected. Although we generally enjoy cordial relations with our employees, the Company may experience a strike over wages and other matters. This may be resolved amicably through a voluntary negotiation and mediation process. However, if any such negotiation in future regarding wages with our employees or any of the labour unions is not concluded quickly, our relations with employees could suffer, which may adversely affect our financial condition, results of operations and profitability.

Consolidation of Customer Base

In the Pharmaceuticals segment, sales of our products may be adversely affected by the continuing consolidation of its customer base. A significant part of our Generics sales is made to the relatively few retail drug chains and pharmaceutical wholesalers in the US and in other geographical markets. These customers are continuing to undergo significant consolidation. Such consolidation (e.g. the joint venture of Walgreen Company and Alliance Boots forming a long-term partnership with AmerisourceBergen Corporation) has provided and may continue to provide them with additional purchasing leverage or negotiating power, and consequently may increase the pricing pressure that we face. We expect that consolidation of drug wholesalers and retailers will increase pricing pressures and competition, including product price erosion on generic drug manufacturers, including those in the US. The consolidation resulting from the merger of CVS Health Corporation and Aetna Inc. is expected to create a vertically integrated organisation with increased control over the physician and pharmacy networks and, ultimately, over which medicines are sold to patients. In addition, several major hospital systems in the United States announced a plan to form a non-profit company that will provide US hospitals with a number of generic drugs. In January 2018, Amazon Inc., Berkshire Hathaway Inc. and JPMorgan Chase & Co., announced that they plan to join forces by forming an independent healthcare company for their combined one million US employees. This initiative is expected to further increase competition and enhance price erosion. These changes to the traditional supply chain could lead to our customers having increased negotiation leverage as well as additional pricing pressure which could have a material adverse effect on our business, financial condition and results of operations. This dual effect of increased competition and increased purchasing power has resulted in a downward trend for prices of our Solid Dosage Formulations & APIs products. If these trends continue or worsen, or if we experience further difficulty in this market, this may continue to adversely affect our revenues and profits from the Solid Dosage Formulations and/or APIs products.

We are able to manage pricing pressure by taking initiatives to continuously redefine production processes to control cost. For some of our generic formulations, we have captive manufacturing of APIs to ensure effective cost control to focus on improving profit margins.

Business Interruption

A significant invasion, interruption, destruction or breakdown of our information technology systems and/or infrastructure by persons with authorised or unauthorised access could negatively impact our business and operations. In the ordinary course of our business, we collect and store sensitive data in our data centres and on our networks, including intellectual property, proprietary business information (both ours and that of our customers, suppliers and business partners) and personally identifiable information of our employees. We could also experience business interruption, information theft, legal claims and liability, regulatory penalties and/or reputational damage from cyber-attacks, which may compromise our systems and lead to data leakage either internally or at our third party providers. Our systems may be the target of malware and other cyber-attacks.
Absence of a response plan or delays in response may adversely affect the business in the event of anticipated or unanticipated disruption due to internal and external factors. We have dedicated teams (including for EHS, supply chain and IT) which are responsible to monitor and manage an event of disruption on account of a disaster, supply issues and network/IT breakdown. Emergency response plan exists for each location with individually assigned roles and responsibility for responding to an emergency. Extensive training programs focusing on EHS are conducted annually. For the Radiopharmaceuticals business, we have a dedicated Radiation and Safety officer at the manufacturing sites with the responsibility of monitoring radiation levels and emission to environment as per the prescribed levels. Our maintenance and EHS teams ensure periodic maintenance and safeguarding of assets and environment. Our IT team ensures internet and plant level connectivity, data back-up, restoration plan and security of data centre.

**Dependence on Third Parties to conduct our Clinical Trials**

We may depend upon third parties to conduct our clinical trials under agreements with universities, medical institutions, Clinical Research Organisations, strategic partners and others. For example, we have a contract with a third party Clinical Research Organisations for our MIBG (Metaiodobenzylguanidine) clinical trial. We depend on our industry partners, including medical institutions and in particular Clinical Research Organisations, to conduct clinical trials in compliance with Good Clinical Practice (GCP), and in compliance with other applicable regulatory and technical requirements. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for potential product candidates or be able to commercialise them.