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## BUSINESS

### Overview

We are a global integrated pharmaceutical company offering a wide range of products and services to our customers across geographies. We organize our business into two segments, namely, Specialty Pharmaceuticals, comprising radiopharmaceuticals (including radiopharmacies), contract manufacturing of sterile injectables and non-sterile products (“**CMO**”) and allergy therapy products, and Generics & APIs, comprising solid dosage formulations and active pharmaceutical ingredients (“**APIs**”). Specialty Pharmaceuticals accounted for close to two-thirds of our total revenue from operations for the financial year ended March 31, 2018, and Generics & APIs accounted for the remainder. As at December 31, 2018, we supplied our products and services to customers in over 80 countries. North America, where a majority of our customers are based, accounted for a significant portion of our total revenue from operations for the financial year ended March 31, 2018. We have four manufacturing facilities in North America and two in India, coupled with research and development (“**R&D**”) centers in North America and India. In addition, we have a distribution network of more than 50 radiopharmacies in the United States. All of our manufacturing facilities are registered with the USFDA and Health Canada, among other regulatory bodies, and all of our radiopharmacies are licensed by state boards of pharmacy in each applicable jurisdiction.

A summary of our business segments is outlined below:

- *Specialty Pharmaceuticals*
  - *Radiopharmaceuticals*—We develop, manufacture, distribute and market diagnostic imaging and therapeutic radiopharmaceutical products. According to Frost & Sullivan, we are the third largest radiopharmaceutical manufacturer in the nuclear medicine industry for the United States based on revenue. We have a strong portfolio of differentiated products used in the diagnosis, treatment and monitoring of various diseases. Clinical applications for our radiopharmaceutical products include cardiology, oncology, endocrinology (thyroid diagnostic imaging and therapy), pulmonology (lung perfusion and ventilation scans), renal (kidney), neurology (brain), infection imaging (leukocyte labeling) and bone imaging. Our radiopharmaceuticals business has a well-established base in North America and is also expanding in Latin America, Europe and Asia. In North America, we have JDI Montreal Facility, a USFDA and Health Canada approved manufacturing facility located in Kirkland, Montreal, Canada for production of our radiopharmaceutical hot products as well as cold products, and a nationwide commercial radiopharmacy distribution network in the United States. We acquired the network in September 2017 to strengthen our radiopharmaceutical distribution capabilities. According to Frost & Sullivan, our distribution network is the second largest centralized commercial radiopharmacy network in the United States with a national footprint of more than 50 radiopharmacies across 22 states. Our radiopharmaceutical customers include third party commercial radiopharmacy networks and our own radiopharmacies, GPOs and regional networks, standalone imaging centers, hospitals and cardiologists in the United States, leveraging our radiopharmaceutical capabilities for end-to-end customer service in the United States.
  - *Contract Manufacturing of Sterile Injectables and Non-Sterile Products (CMO)*—We are an integrated contract manufacturer with a broad range of capabilities, which includes developing and producing sterile injectables and non-sterile products. We believe we have predictability and stability in our CMO business underpinned by long-term contracts we have entered into with such customers. We focus on the delivery of clinical and commercial fill and finish services for sterile parenteral pharmaceuticals, utilizing both liquid and lyophilization capabilities. Additional capabilities include the manufacture of sterile and non-sterile ophthalmics, ampoules, creams, ointments and liquids. Our key markets for sterile injectables and non-sterile products are North America and Europe. Our CMO manufacturing facilities, Spokane Facility and CMO Montreal Facility, have obtained USFDA and Health Canada certifications for their manufacturing processes. Our customer base includes leading innovative pharmaceutical companies in the United States, as well as other companies and organizations in the pharmaceutical and biotechnology industries in North America, Europe and Asia. We contract manufacture cold kits at our CMO Montreal Facility to support our radiopharmaceutical products.
  - *Allergy Therapy Products*—We provide allergy therapy products to the allergy specialty industry with a product offering range of over 200 different allergenic extracts and standard allergy vaccine mixtures as well as six different insect venom products for the treatment of allergies to insect stings. According to Frost & Sullivan, we are one of the top three players in the allergenic extract market in the United States with a market share of 17.6% and are currently the sole producer and supplier of venom products for the treatment of allergies in the United States. We produce and market a number of products under the “HollisterStier” brand. Our allergy therapy products business line has traditionally focused on North America as our key

market, where we believe we have generated significant brand loyalty due to the quality of our products and long-standing operating history. We also market some of our key products such as allergenic extracts and venom extracts in Canada, Europe, Australia, New Zealand and South Korea through distributors. Our allergy therapy products are manufactured at our Spokane Facility. The primary target user base of our allergy therapy products are allergists; ear, nose and throat physicians; general physicians and hospital-based clinics across North America.

• *Generics & APIs*

- *Solid Dosage Formulations*—We are engaged in the development, manufacture, sale and distribution of prescription generic pharmaceutical products principally in the United States, and with a growing presence in Europe, Canada, Japan, Australia, as well as the rest of the world. We focus primarily on the manufacture and sale of solid dosage formulations for CVS, CNS, GI and anti-allergy therapeutic categories. According to Frost & Sullivan, we are one of the market leaders in the United States, based on our market share of several key products. As at December 31, 2018, in the United States, we had 28 commercialized solid dosage formulations available. We also have a strong pipeline of products pending approval in a number of jurisdictions. For example, in the United States, since we commenced operations through to December 31, 2018, we have made a total of 96 ANDA filings for solid dosage formulations, of which 35 are pending approval. Our solid dosage formulations business derives benefit from backward integration into our API business and we have two manufacturing facilities for solid dosage formulations, our Salisbury Facility and our Roorkee Facility, both of which are registered with the USFDA and Health Canada.
- *Active Pharmaceutical Ingredients (APIs)*—We develop and produce APIs in the therapeutic areas of the CVS, CNS, GI, anti-infectives and anti-depressants. According to Frost & Sullivan, we are one of the global suppliers for several key API products based on market share. Approximately 80% of our commercialized portfolio is in lifestyle driven therapeutic areas such as CVS and CNS, catering to an increasing incidence of lifestyle-related medical conditions or non-communicable diseases including cardiac ailments and seizures. Our APIs are produced at manufacturing plants in our Nanjangud Facility. As at December 31, 2018, we had 39 commercialized APIs available globally and had filed 94 DMFs in the United States. Our APIs are exported worldwide, into emerging as well as developed markets. Our key markets are North America, South America, Europe, Japan, Korea, Commonwealth of Independent States (CIS) countries, the Middle East and Australia. According to our internal estimates, we believe approximately 60.0% of our sales are to regulated markets, namely, the United States, Europe and Japan. Our APIs are primarily sold to manufacturers of formulations of generic drugs and used in our solid dosage formulations business line. Approximately 15% of our APIs we produce are used in-house for the manufacturing of solid dosage formulations by the Group.

The following table sets forth a breakdown of our revenue from operations by business lines for the periods indicated:

	Financial Year Ended March 31				Nine Months Ended December 31			
	2017		2018		2017		2018	
	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)
<b>Specialty Pharmaceuticals</b>								
Radiopharmaceuticals . . . . .	121,602.4	26.4	265,060.6	42.8	176,663.2	41.4	267,944.6	47.6
Contract Manufacturing of Sterile Injectables and Non-Sterile Products (CMO) . . . . .	88,740.6	19.3	100,863.4	16.3	66,847.6	15.7	81,630.6	14.5
Allergy Therapy Products . . . . .	36,350.9	7.9	43,598.8	7.0	32,421.5	7.6	38,066.5	6.8
<b>Sub-total Specialty Pharmaceuticals . . . . .</b>	<b>246,694.0</b>	<b>53.6</b>	<b>409,522.9</b>	<b>66.1</b>	<b>275,932.3</b>	<b>64.7</b>	<b>387,641.6</b>	<b>68.9</b>
<b>Generics &amp; APIs</b>								
Solid Dosage Formulations . . . . .	121,992.8	26.4	123,540.8	20.0	88,854.7	20.8	109,629.9	19.4
Active Pharmaceutical Ingredients (APIs) . . . . .	91,885.4	20.0	86,101.9	13.9	61,973.4	14.5	65,587.4	11.7
<b>Sub-total Generics &amp; APIs . . . . .</b>	<b>213,878.1</b>	<b>46.4</b>	<b>209,642.7</b>	<b>33.9</b>	<b>150,828.2</b>	<b>35.3</b>	<b>175,217.2</b>	<b>31.1</b>
<b>Revenue from operations (net) . . . . .</b>	<b>460,572.1</b>	<b>100.0</b>	<b>619,165.6</b>	<b>100.0</b>	<b>426,760.4</b>	<b>100.0</b>	<b>562,858.8</b>	<b>100.0</b>

## Competitive Strengths

### *Leading market positions across business lines, with high barriers to entry in specialty pharmaceuticals*

We enjoy global and regional leading market positions across our business lines as follows:

*Radiopharmaceuticals.* According to Frost & Sullivan, we are one of the leading integrated players in the U.S. market that develops, manufactures, distributes and markets radiopharmaceutical products and are the third largest radiopharmaceutical manufacturer in the nuclear medicine industry for the United States based on revenue. We believe we are well-positioned in the high value niche segment of radiopharmaceuticals, offering quality diagnostic imaging and therapeutic radiopharmaceutical products. We specialize in lung, thyroid, bone and cardiac imaging products as well as thyroid disease therapy. For diagnostics, our key products include MAA and DTPA, both of which we have a 100% market share in the United States, according to Frost & Sullivan. For therapeutics, our key products include I-131, of which we are one of only three manufacturers globally, according to Frost & Sullivan.

In order to strengthen our centralized commercial radiopharmaceutical distribution network, we acquired a radiopharmacy network in the United States with a national footprint of more than 50 radiopharmacies across 22 states in September 2017. As a result, according to Frost & Sullivan, we operate the second largest centralized commercial radiopharmacy network in the United States. We believe this pharmacy distribution network and expanded geographic coverage enhances our ability to secure contracts with customers because the short half-lives of products and customers' preference for just-in-time ordering, compared to bulk orders, make it otherwise difficult for radiopharmaceutical manufacturers to distribute directly from manufacturing facilities. Our nationwide U.S. footprint with direct access to hospital networks allows us to better deliver end-to-end customer service in the United States.

*Contract Manufacturing of Sterile Injectables and Non-Sterile Products (CMO).* We are fully integrated, providing a broad range of capabilities including sterile liquids and lyophilized products, ointments, creams and lotions (OCL) and biologics. We serve seven of the top 20 pharmaceutical companies globally (based on revenue, according to Frost & Sullivan). We have an established market position in the sterile injectables and non-sterile products markets globally, with deep and long-term relationships with our top 10 customers who include some of the leading innovative pharmaceutical companies. For example, as at December 31, 2018, our top 10 customers have been with us for at least five years, and six of our top 10 customers have been with us for over 10 years. We believe we have predictability in our CMO business as supported by our consistently strong order book with recurring orders from long-standing customers and as a result of long-term contracts we have entered into with certain customers. With our North American-based manufacturing operations, we benefit from being geographically close to our customers, a majority of which are located in North America. 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. Accordingly, we expect to be able to continue to increase our market share for sterile injectables and non-sterile products as a result of our proven regulatory track record with the USFDA, Health Canada, UKMHRA, KFDA Korea, ANVISA Brazil and PMDA Japan, our expertise in multi-mode contract manufacturing and our broad range of capabilities.

*Allergy Therapy Products.* We are one of the leading allergenic immuno therapy companies in the United States according to Frost & Sullivan, 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. According to Frost & Sullivan, we are one of the top three players in the allergenic extract market in the United States with a market share of 17.6% 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 U.S. allergen extract market and most products in this market are biological products with grandfather status requiring a BLA from the USFDA for any new approval for manufacturing and commercialization. Our allergy therapy products business line has traditionally focused on North America as our key market, where we believe we have generated significant brand loyalty in respect of the "HollisterStier" brand, due to the quality of our products and long-standing operating history.

*Solid Dosage Formulations.* We believe we have a strong product portfolio. According to Frost & Sullivan, we are one of the market leaders in the United States based on market share of several key products, namely, prochlorperazine, methylprednisolone, prednisone, olanzapine ODT, donepezil and, pantoprazole. We focus primarily on the manufacture and sale of solid dosage formulations for CVS, CNS, GI and anti-allergy

therapeutic categories. As at December 31, 2018, we had 54 commercialized generic solid dosage formulations products across the United States, Europe, Canada, Australia and the rest of the world. We have capabilities in multiple dosage forms and our solid dosage formulations business derives benefit from backward integration into our API 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. In the United States, since we commenced operations through to December 31, 2018, we have made a total of 96 ANDA filings for solid dosage formulations, of which 35 are pending approval. Additionally, our in-house API capability allows us to better control the development of certain products from formulation through commercialization and provides a stable source of API supply for these products at competitive prices.

*APIs.* We develop and produce APIs in the therapeutic areas of the CVS, CNS, GI, anti-infectives and anti-depressants. We have a diverse customer base and our APIs are exported worldwide. According to Frost & Sullivan, we are one of the global suppliers based on market share for several key API products, namely, oxcarbazepine (global market share at approximately 30.0%), carbamazepine (global market share at approximately 20.0%), risperidone (global market share at approximately 33.0%), pinaverium (global market share at approximately 20.0%), citalopram (global market share at approximately 18.0%), donepezil (global market share at approximately 16.0%), and meclizine (global market share at approximately 20.0%). 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. In addition, manufacturers of APIs are subject to strict regulation worldwide. For example, regulated markets like the United States and Europe, have high entry barriers in terms of intellectual property rights and regulatory requirements, including facility approvals, which lead to increased time, cost and efforts by our customers in order for them to manufacture and sell their products in such markets. We believe our strong presence and extensive experience operating in highly regulated markets help with customer retention and price realization of our API products.

#### ***Diverse sources of revenue with a de-risked business model***

We generate 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 and which offer opportunities for us to achieve higher revenue and margins, while minimizing concentration risk.

*Products and Product Supply.* As at December 31, 2018, 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, 54 commercialized generic solid dosage formulations and 39 commercialized APIs sold across markets globally. As a result of our diversified product portfolio, we benefit from diversified revenues between two differentiated business segments. Our Specialty Pharmaceuticals business segment, largely catering to the U.S. market, contributed 66.1% of our total revenues from operations for the financial year ended March 31, 2018, while our Generics & APIs business segment, which focuses on developing limited competition products, contributed 33.9% of our total revenue from operations for the financial year ended March 31, 2018. Our top 10 products by revenue contributed 39.4% and 39.4% of our total revenue from operations for the financial year ended March 31, 2018 and the nine months ended December 31, 2018, respectively, and our top product contributed 13.6% and 11.6% to our total revenue from operations for the financial year ended March 31, 2018 and the nine months ended December 31, 2018, respectively. No other product represented more than 10% of total revenue from operations for the financial year ended March 31, 2018 and the nine months ended December 31, 2018.

*Customers.* We have a broad and diversified customer base across each of our five business lines. For the financial year ended March 31, 2018 and the nine months ended December 31, 2018 we derived 33.8% and 31.1%, respectively, of our total revenue from operations from our top 10 customers (excluding GPOs but including customers purchasing goods and services through such GPOs). For the financial year ended March 31, 2018 and the nine months ended December 31, 2018, save for one customer, none of the top 10 customers of the Group contributed more than 5% of the total revenue.

*Geographic diversification.* We had sales in over 80 countries as at December 31, 2018. Revenues from North America, Europe, Asia and rest of the world contributed 82.0%, 8.9%, 5.6% and 3.6%, respectively, of our revenue from operations for the nine months ended December 31, 2018. 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 which share a plot of land located in Kirkland, Montreal, Canada, being our JDI Montreal Facility, which produces radiopharmaceuticals, and our CMO Montreal Facility which produces sterile injectables and non-sterile products. Our Salisbury Facility and Spokane Facility produce solid dosage formulations and sterile injectables, respectively. 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 Spokane, Washington, United States, Montreal, Canada, Nanjangud, India and Noida, India, 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. In radiopharmaceuticals, we are focused on high value niche products with diagnostic and/or therapeutic uses. As at December 31, 2018, 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 Exametazime™ 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 mIBG for which we plan to make an NDA filing. In addition, we have eight 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 USDA, we plan to register our venom products and allergenic extracts for use in animals. We also have a strong pipeline in our Generics & APIs business segment and since we commenced operations through to December 31, 2018, for solid dosage formulations we have filed 96 ANDAs in the United States, of which 35 ANDAs are pending approval, and for APIs, we have filed 94 DMFs in the United States. As at December 31, 2018, for solid dosage formulations, we have made a total of 23 product filings in Canada, of which one is pending approval, 34 product filings in Europe, of which two are pending approval and 42 product filings in the rest of the world, of which seven are pending approval. In addition, as at December 31, 2018, for sterile injectables, we have filed 15 ANDAs (inclusive of 11 ANDAs for radiopharmaceuticals), of which two ANDAs are pending approval in the United States, 16 product filings in Canada, four product filings in Europe, of which one is pending approval and nine product filings in the rest of the world.

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 capitalize on opportunities for growth in competitive markets. We have R&D centers located in North America and India and, as at December 31, 2018, we employed 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 specialized and/or niche formulations and designs for radiopharmaceuticals and other products, which have been taken to commercialization. As at December 31, 2018, we have been granted patents for intellectual property in various countries for innovation, including 19 active patents granted relating to APIs in a number of different countries, five active patents granted relating to solid dosage formulations in a number of different countries, 123 active patents granted relating to radiopharmaceutical products in a number of different countries and one active patent granted relating to allergy therapy products in the United States giving us in-house radiopharmaceutical distribution capabilities, thereby reducing our reliance on third party radiopharmaceutical distributors.

### ***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 utilization 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, by virtue of our integrated operations, we believe that we enjoy competitive advantages in the form of cost efficiencies by producing across the value chain, thereby reducing 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. For the financial year ended March 31, 2018 and the nine months ended December 31, 2018, approximately 15% of our APIs we produce are used in-house for manufacturing of solid dosage formulations, which accounts for approximately 35% of the APIs used in such solid dosage formulations manufactured by the Group. Such integration between our solid dosage formulations and API business lines, allows us to continuously

improve our cost of production. Multiple products in our radiopharmaceuticals and allergy therapy products business lines 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 DRAXIMAGE® MAA and DRAXIMAGE® MDP-25 for our radiopharmaceuticals business line, and our Spokane Facility is used to manufacture products for our allergy therapy products business line. Additionally, our radiopharmaceutical products are distributed through our network of more than 50 radiopharmacies.

We operate our plants in accordance with cGMP and/or other applicable requirements. We currently operate four USFDA registered manufacturing facilities in North America and two USFDA registered 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. As at December 31, 2018, we employed over 700 quality control employees, over 60 regulatory employees and over 50 technical services employees to support our production of quality products. Three out of six of our manufacturing facilities were inspected by the USFDA in the financial year ended March 31, 2018. Of the remaining sites, the Salisbury Facility was inspected in April 2018, the CMO Montreal Facility was inspected in May 2018 and the Roorkee Facility was inspected in August 2018. Most recently, our Spokane Facility was inspected by the USFDA and the CBER USFDA in October 2018, and our Nanjangud Facility was jointly inspected by the USFDA and Health Canada in December 2018. In addition to inspections by the USFDA, in the financial year ended March 31, 2018, we were inspected by a number of other regulatory agencies, including, Health Canada (CMO Montreal Facility and Nanjangud Facility), CDSCO in India (Roorkee Facility), ANVISA Brazil (Spokane Facility) and RP Darmstadt Germany (Roorkee Facility), and in the nine months ended December 31, 2018, we were inspected by Health Canada (JDI Montreal Facility and Nanjangud Facility (joint inspection with the USFDA as described above)).

#### ***Demonstrated financial track record with strong revenue growth and attractive profitability profile***

Our revenue from operations was US\$460.6 million and US\$619.2 million, respectively, for the financial years ended March 31, 2017 and 2018. Our profit for the year was US\$50.3 million and US\$49.1 million, respectively, for the financial years ended March 31, 2017 and 2018. From the financial year ended March 31, 2017 to the financial year ended March 31, 2018, our Adjusted EBITDA has grown at a CAGR of 9.0% and our Adjusted EBITDA and Adjusted EBITDA Margin for the financial year ended March 31, 2018 was US\$151.5 million and 24.5%, respectively. Our share of revenues and Segmental Adjusted EBITDA attributable to Specialty Pharmaceuticals has increased, accounting for 53.6% and 66.1% of our total revenue from operations, and 72.4% and 91.0% of our total Adjusted EBITDA, in the financial years ended March 31, 2017 and 2018, respectively.

Our focus is on leveraging free cash flows generated from our operations to further strengthen our ability to grow. We believe our business model enables us to benefit from various segments in the pharmaceutical industry and value chain, from R&D, manufacturing through to distribution and sales. We also have synergies within our business lines which arise from our coordinated efforts across businesses and among our business leaders, functional leaders and management, which we believe helps us grow our business and profitability. Due to our long-standing customer relationships, we believe we have predictability and stability in our business underpinned by long-term contracts we have entered into with such customers.

#### ***Strong acquisitions and integration capabilities with a proven track record***

We have differentiated ourselves by building niche businesses especially in the specialty injectables space and have built our capabilities through successful integration of our past acquisitions. For example, beginning in 2003, we acquired our Nanjangud Facility followed by multiple acquisitions in the United States, Canada and Europe. These have included significant acquisitions over time to establish our various business lines, including Cadista Holdings Inc., a generic pharmaceutical company in 2005, which enabled us to expand our solid dosage formulations capabilities in North America. Our acquisitions in 2008 of HollisterStier Laboratories, a CMO service provider, and HollisterStier Allergy's allergy facility in Spokane helped us leverage an existing brand to gain a foothold in two new business lines, being contract manufacturing of sterile injectables and allergy therapy products. We further expanded our footprint in 2009 by entering into radiopharmaceuticals through our acquisition of Draxis Pharma, Inc.'s radiopharmaceuticals business. In 2015, to further consolidate our ownership and control, we acquired the balance minority stake in Cadista Holdings Inc. Most recently, we acquired substantially all of Triad's assets which comprised its radiopharmacy business in the United States. As a result, according to Frost & Sullivan, we now have the second largest centralized commercial radiopharmacy network in the U.S. comprised of more than 50 radiopharmacies across 22 states. Growth-related acquisitions and investments in facilities, capacity and capabilities across our businesses have positioned us for future growth in areas aligned with anticipated future demand. Each of our significant acquisitions were intended to help us



diversify and differentiate our business. We have put together a specialist in-house strategy team, which works with the Promoters and senior management team to support expansion, identify potential acquisition and investment opportunities in the market and evaluate the same on an ongoing basis.

***Highly qualified, experienced and dedicated Board of Directors and management team with in-depth industry knowledge and support from listed Parent***

Our pharmaceutical business has been built by the Promoters and JLL from 2003 through a series of organic initiatives as well as acquisitions of assets and businesses, including the APIs business in 2003, solid dosage formulations business in 2006, allergy therapy products business in 2008, radiopharmaceuticals business in 2009 and radiopharmacy business in 2017. The Promoters have been in senior positions in JLL and the Company for more than 35 years, and have played and continue to play an active role in driving the long-term strategy and the day-to-day business of JLL and the Company. We also benefit from support from our listed Parent. For example, as part of JLL's effort to increase efficiency and negotiate for better pricing across its group companies, JLL may from time to time enter into contracts with third parties, the cost of which is shared within the JLL Group on an actual cost basis. In addition, we have a distinguished Board of Directors with an average of over 30 years of industry experience as well as science and industry expertise. Our senior management team has an average of 20 years of work experience in the pharmaceutical industry. Our management team comprises professionals from diverse backgrounds including engineering, radiochemistry, pharmacy, nuclear medicine, legal, regulatory and health and safety, many of whom hold advanced educational degrees in their area of expertise. These professionals have generally worked at other pharmaceutical, healthcare or chemical companies, including large global companies and companies listed in the United States. Our management team is supported and guided by prudent financial policies with respect to leveraging and capital structure, investments, dividends and hedging in addition to corporate governance policies. We believe our experienced management team has contributed to our past success.

**Business Strategies**

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:

***Continue to strengthen leadership positions in our key business segments***

We have established leadership positions throughout our diversified portfolio in both our business segments, namely (i) Specialty Pharmaceuticals, comprising radiopharmaceuticals (including radiopharmacies), CMO and allergy therapy products and (ii) Generics & APIs, comprising solid dosage formulations and APIs. We intend to continue to strengthen our leadership positions by focusing on the following:

*Radiopharmaceuticals.* According to Frost & Sullivan, 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. Our goal is to achieve market leadership in the nuclear medicine industry by increasing our market share of RUBY-FILL<sup>®</sup> generators and RUBY Rubidium Elution System<sup>™</sup>—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. According to Frost & Sullivan, we are the second largest centralized commercial radiopharmacy network partner in the United States comprised of more than 50 radiopharmacies across 22 states. We aim to build the nation's premier centralized radiopharmacy network. We continue to seek opportunities to expand or enhance the efficiency of our radiopharmaceuticals business by optimizing the coverage of our radiopharmacy network including through further additions and improvements or consolidation of locations. This may include geographic expansion of our radiopharmacies in the United States and Canada by opening new pharmacies, as well as through investments in R&D to introduce new products in radiopharmaceuticals. In this regard, we are working on making the “Jubilant” brand a well-known and respected brand among hospital networks in the United States and Canada. Combined with our radiopharmaceutical manufacturing capabilities, we believe by continuing to build out a wider distribution network of radiopharmacies, including through acquisitions, we create synergies within our radiopharmaceuticals business line. We believe we are a strong partner to major U.S. healthcare providers and have deep relationships with our current customers and organizations (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.

*Contract Manufacturing of Sterile Injectables and Non-Sterile Products.* Due to consolidation activities across the 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 unutilized production capacities and establishing new lines within our current capabilities, including lyophilization. In addition, we plan to expand capacities through debottlenecking. De-bottlenecking and operating our Spokane Facility on a 3-shift, 7-day basis enables us to increase capacity to achieve greater sales volume. In this regard, we have initiated plans to increase available capacity at our Spokane Facility by approximately 25% based on currently identified initiatives, including running our production lines 24/7. Our production efficiency measures are also aimed to increase our product filing yield and reduce the time cycle between product releases.

*Allergy Therapy Products.* 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 U.S. 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 and into new markets.

*Solid Dosage Formulations.* 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 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 U.S. filings. Our focus is also on cost leadership with increased integration in our portfolio mix and of in-house APIs into our solid dosage formulations. We believe such integration will facilitate the efficient development and manufacturing of our products and provide a competitive advantage for pursuing product improvements independent of third party sources. We believe integration may also help us maintain higher overall product quality.

*APIs.* Our strategy is to continue to be a preferred supplier to our customers and our expansion in this business line is based on streamlining our product selection to ensure that some of our DMF filings are first to file opportunities in the U.S. market, 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 optimization 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 utilization. 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.

### ***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 capitalize on the strength of these relationships to create and pursue additional growth opportunities. As at March 31, 2018, approximately 70% of our assets, including our four manufacturing facilities in North America (Spokane Facility, CMO Montreal Facility, JDI Montreal Facility and Salisbury Facility), our network of more than 50 radiopharmacies and the Group’s non-current assets, were based in North America in order to better serve our customers, a majority of which are based in North America. North America accounted for 80.1% and 82.0% of

our total revenue from operations for the financial year ended March 31, 2018 and the nine months ended December 31, 2018, respectively. We will continue to leverage the insights we have gained from successfully bringing products to market in the highly regulated U.S. 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 North America.

***Develop a diverse product and service portfolio through differentiated and complex offerings***

We believe our success is derived from our ability to select attractive product candidates and increase capacity utilization. We expect to grow our diverse product and service portfolio both by increasing penetration in existing markets and expanding our product portfolio by utilizing market expertise globally. We believe that we will have a higher likelihood of increasing our penetration in our existing markets by offering new product innovations to our customers to meet their demands. We also intend to expand our product portfolio by utilizing 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.

We will continue to look to create a strong pipeline of products in both of our key business segments. In Specialty Pharmaceuticals, our primary focus is to develop differentiated products with an objective to cater to the North American market by focusing on a niche product development strategy highlighted by differentiated products in the radiopharmaceuticals and specialty injectables segments. In Generics & APIs, our focus is on developing complex products with limited competition and to file products that can be integrated with our in-house API manufacturing, where we are able to leverage integration synergies and benefit from enhanced cost competitiveness.

***Offer an integrated business model that provides products and services which are cost-effective***

We expect to continue to optimize 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 business lines are supported by our CMO operations. We are also able to utilize our network of radiopharmacies to distribute our radiopharmaceutical products in the United States. Our multi-site manufacturing capabilities in the United States 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 API 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 optimize 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 utilization 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.

***Continue to pursue strategic acquisitions to further consolidate leadership positions and accelerate growth***

We have historically grown our business 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 business lines, and achieve higher than industry growth. These opportunities may include, among others: (i) expanding the radiopharmacy sales and distribution network in the United States and Canada through strategic and selective acquisitions, (ii) expanding manufacturing capacity and capabilities through the addition of new sites to further strengthen the radiopharmaceutical product portfolio focused on the North American market, and (iii) acquiring manufacturing sites in India to support our Generics & APIs business segment. We have a dedicated team in place to identify these opportunities and a rigorous and financially disciplined process for evaluating, executing and integrating such acquisitions. At this time, we have not entered into any agreement or commitment with respect to any material acquisitions or investments but we continue to explore suitable opportunities.

## **Business Segments**

We offer products and services across the pharmaceuticals value chain. We have two business segments, namely (i) Specialty Pharmaceuticals, comprising radiopharmaceuticals (including radiopharmacies), CMO and allergy therapy products and (ii) Generics & APIs, comprising solid dosage formulations and APIs.

### **Specialty Pharmaceuticals**

Our Specialty Pharmaceuticals business segment comprise radiopharmaceuticals, CMO and allergy therapy products. The United States is the most significant market for our Specialty Pharmaceuticals business segment, particularly after our acquisition of substantially all of the assets which comprised Triad's radiopharmacy business in September 2017. As a result, we also operate the second largest centralized commercial radiopharmacy network in the United States with a national footprint of more than 50 radiopharmacies across 22 states, according to Frost & Sullivan. We believe the acquisition is a strong strategic fit with our niche radiopharmaceutical business and will help us better serve healthcare providers and their patients with quality radiopharmaceutical products. According to Frost & Sullivan, there are significant growth opportunities in the distribution of radiopharmaceuticals to end-user customers in the United States. According to Frost & Sullivan, the radiopharmaceutical market will experience a 6.3% CAGR 2018-2023. The growth will be driven by increasing prevalence of disease and focus on therapeutic radiopharmaceuticals.

### ***Radiopharmaceuticals***

Our radiopharmaceuticals business comprises of radiopharmaceutical manufacturing and our network of centralized commercial radiopharmacies, which we acquired in September 2017. We manufacture and distribute our own radiopharmaceutical products, which generally consists of a radioactive element (isotope) either standalone or attached to a chemical compound. According to Frost & Sullivan, we are the third largest radiopharmaceutical manufacturer in the nuclear medicine industry for the United States based on revenue. Our products are used in the diagnosis, treatment and monitoring of various diseases. We specialize in cardiology, pulmonology, oncology and endocrinology as well as bone, brain and renal imaging. We operate a network of commercial radiopharmacies, currently under the Triad Isotope brand. Our radiopharmacies prepare and deliver radiopharmaceuticals for use in nuclear imaging at standalone imaging centers, cardiologists and hospitals in the United States, leveraging our radiopharmaceutical capabilities for end-to-end customer service in the United States.

Our radiopharmaceuticals business generated revenues of US\$265.1 million for the financial year ended March 31, 2018 (inclusive of the revenues generated by our radiopharmacies during the seven-month period from the time of acquisition on September 1, 2017 through March 31, 2018) and US\$267.9 million for the nine months ended December 31, 2018, which comprised 42.8% and 47.6%, respectively, of our revenue from operations for the year/period.

### ***Products and Services***

***Radiopharmaceuticals.*** We manufacture and market radiopharmaceuticals used in nuclear medicine imaging procedures and a line of radioactive therapeutic products. Our radiopharmaceutical product offerings include both "hot" radioisotopes (manufactured as an active radioactive product) and "cold" kits (tracer agents that are paired with "hot" radioisotopes (most commonly with Tc99m Technetium) for a final injectable product for targeted diagnostic imaging procedures). Two common forms of nuclear imaging procedures are single photon emission computed tomography ("SPECT"), which measures single-photon gamma rays emitted by a radiopharmaceutical, and PET, which measures positrons emitted by a PET radiopharmaceutical. In therapy applications, radiopharmaceuticals are used to treat or ablate certain types of cancer and other diseases.

We have a strong portfolio of differentiated products used in the diagnosis, treatment and monitoring of various diseases. In the SPECT market, our products include HICON<sup>®</sup> Sodium Iodine I-131 Solution USP for thyroid disease and thyroid cancer management (used in combination with SMART-FILL<sup>™</sup> Dispensing System for safer and more accurate dosage administration), DRAXIMAGE<sup>®</sup> MAA for lung perfusion imaging, DRAXIMAGE<sup>®</sup> DTPA for lung ventilation, brain and renal imaging and DRAXIMAGE<sup>®</sup> MDP-25 used in bone scanning. Additionally, we market DRAXIMAGE<sup>®</sup> I-131 Diagnostic Capsules and solutions used in the assessment of thyroid function and imaging, Sodium Iodide I-131 Therapeutic Capsules and solutions for thyroid-related treatments and thyroid carcinoma, DRAXIMAGE<sup>®</sup> Sestamibi used in the imaging of myocardial perfusion imaging and Drax Exametazime<sup>™</sup> used in white blood cell-labeled imaging to identify intra-abdominal infection and inflammatory bowel disease.

In the PET market, pursuant to our Section 505(b)(2) NDA filing, we obtained USFDA approval for RUBY-FILL<sup>®</sup> Rubidium Rb82 Generator and Elution System in September 2016, bringing to the PET market, a newly

developed innovative technology for PET MPI. RUBY-FILL® Rubidium Rb82 Generator and Elution System is comprised of a Rubidium-82 (“**Rb-82**”) generator and an elution system, Ruby Rubidium Elution System™ (“**RbES**”), which we believe is novel in the cardiac nuclear medicine industry. We believe RUBY-FILL® offers overall improved diagnostic sensitivity, specificity and accuracy in cardiac PET by enabling improved image quality, higher dosing accuracy and infusion consistency and reliability. Certain features of RUBY-FILL® Rubidium Rb82 Generator and Elution System include automated quality control and reports, automated safety alerts aimed at detecting Sr-82 breakthrough and flexible patient dosing, among other things. We believe PET imaging with RUBY-FILL® Rubidium Rb82 Generator and Elution System can provide significantly lower patient radiation doses as compared to current SPECT MPI procedures. In March 2018, two legal challenges were filed by Bracco against the Jubilant Defendants in the United States District Court for the District of New Jersey and with the USITC in connection with alleged patent infringement relating to RUBY-FILL® Rubidium Rb82 Generator and Elution System. See “—*Legal Proceedings—RUBY-FILL® Proceedings*” for further details.

We developed I-131 mIBG, which is undergoing Phase II and Phase III clinical trials in the United States in collaboration with key pediatric oncologists, the NIH, selected academic centers and neuroblastoma consortiums. I-131 mIBG has received orphan drug status with eligibility for accelerated approval in the United States. In clinical trial, we have observed that when I-131 is attached to mIBG, the mIBG directs the I-131 radiation to the neuroblastoma cells to kill such cells. We believe I-131 mIBG is the first product candidate of its kind targeted at treating high-risk neuroblastoma in infants and young children, and is currently not available commercially. We have however, provided I-131 mIBG for use in the treatment of neuroblastoma, a neuroendocrine pediatric cancer, to hundreds of patients under an Investigational New Drug (“**IND**”) Expanded-Access Program approved by the USFDA and for other investigational clinical trials since 2007. Subject to positive outcomes of these initial clinical trials, we plan to further advance our therapeutic I-131 mIBG program, and submit an NDA to the USFDA. In addition to I-131 mIBG, we have four additional products in the pipeline intended to expand and strengthen our medical imaging portfolio.

*Commercial Radiopharmacies.* As a result of our acquisition of substantially all of the assets which comprised Triad’s radiopharmacy business, we operate the second largest centralized commercial radiopharmacy network in the United States, according to Frost & Sullivan. We compound and distribute radiopharmaceuticals to national GPOs and regional networks, standalone imaging centers, cardiologists and hospitals in the United States, leveraging our radiopharmaceutical capabilities for end-to-end customer service in the United States, among others. Our radiopharmacies also prepare both SPECT and PET doses for diagnostic imaging and therapeutic purposes. Our operations consist of direct distribution activities and outsourced deliveries made by contracted third party distributors within the United States, including serving as an integrated distribution partner for our radiopharmaceutical product pipeline and our generics & APIs products. The products we manufacture and distribute include DRAXIMAGE® Sestamibi, DRAXIMAGE® MDP-25, Drax Exametazime™, DRAXIMAGE® DTPA and DRAXIMAGE® MAA kits. Other products which we distribute but do not manufacture include Tc99m-Tetrofosmin, Tc99m Sodium Pertechnetate, In-111 Octreoscan, Tc99m Sulfur Colloid, Tc99m Mertiatide (MAG-3) and In-111 Oxine.

#### *Market and Customers*

*Radiopharmaceuticals.* Our radiopharmaceuticals business has a well-established base in North America, and is currently expanding in Latin America, Europe and Asia. Our radiopharmaceuticals customers include third party commercial radiopharmacy networks and our radiopharmacies (doing business as Triad Isotopes), and hospitals, free-standing imaging centers and cardiologists. We supply 14 USFDA or Health Canada approved diagnostic and therapeutic products to nuclear medicine departments in 18 different countries.

Radiopharmaceutical products contain radioactive isotopes that decay at a predictable rate. Tc99m, which we use in a number of our radiopharmaceutical products, has a half-life of six hours. This short half-life presents certain logistical challenges as customers have to be in a certain proximity to the radiopharmacy to use Tc99m product before it decays or expires. See “*Risk Factors—Risks Relating to Our Business—Our dependence on a limited number of third party suppliers for some of our key raw materials such as Molybdenum could prevent us from delivering some of our products, including radiopharmaceutical products, to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues*”.

JDI has entered into a number of long-term contracts in the United States for JDI to supply such distribution networks with products used for diagnostic and therapeutic procedures for thyroid, myocardial perfusion, lung, kidney, brain and bone scans. Pursuant to the contracts, JDI will supply the agreed products over a period of 39 months effective from January 2017.

Centralized Commercial Radiopharmacies. Handling, preparation, and storage of radiopharmaceutical agents require specialized training and specially-equipped facilities, resulting in comparatively high fixed and staffing costs for the commercial radiopharmacy industry. Further, the short half-lives of radioactive diagnostic and some therapeutic agents make it cost prohibitive for hospitals and other medical providers to maintain in-house nuclear preparation and dispensing capabilities. A market for radiopharmacies has arisen because hospitals and medical recognized the value in utilizing the central radiopharmacy services to decrease costs, reduce headcount, and gain better utilization of both radioactive materials and prepared drugs. Radiopharmacies that have several hospitals and medical providers as customers are able to achieve economies of scale and offer radiopharmaceutical agents to hospitals and other medical providers at a relatively lower price. The short half-lives of products and customers' strong preference for just-in-time ordering, compared to large bulk orders, make it difficult for radiopharmaceutical manufacturers to distribute directly from the manufacturing facilities to the end customers and a key factor in obtaining contracts with national GPOs is for radiopharmacies to have the geographic capability to service a majority of the members of each GPO we negotiate with.

We distribute nuclear medicine products that are manufactured in-house as well as products from other manufacturers through our commercial radiopharmacy network to standalone imaging centers, cardiologists and hospitals in the United States. We also contract with national GPO's and regional networks, supplying our products to their hospital and institutional members, nationally. We maintain strong relationships with major national GPOs in the United States and continue building relationships with regional networks as they emerge. JDR prepares unit doses of radiopharmaceuticals and deliver these preparations to such institutional customers directly for administration to patients. We currently deliver approximately three million patient doses annually to approximately 1,700 customers across national GPOs, regional networks, local hospitals and physician groups.

#### *Sales, Distribution and Marketing*

Radiopharmaceuticals. Our radiopharmaceuticals business has a sales force that caters to customers in the United States, Canada, South America, Asia and Europe. We are continuing our efforts to obtain registration for select products in select markets. We are currently also seeking to expand our distribution network for our radiopharmaceutical products in India and other emerging markets in Asia and the Middle East. In all countries or regions where we are seeking commercialization, we are required to have each product approved by the relevant health authorities to actively market our products. Furthermore, in the United States, we are also required to be licensed by each state to meet specific state requirements for the sale of products in specific states. While some of these licenses are pending approval or filing with the state authorities, any delay or denial of such state licenses is not expected to have a material impact on our results of operations.

Commercial Radiopharmacies. Our radiopharmacies have an experienced and patient-centric sales force that caters to institutional customers in the United States. We have multi-year agreements with GPOs, most of which are multi-source agreements. In conjunction with the GPOs we maintain direct customer contracts over multiple years. We also utilize the JDR sales force as a contracted sales organization to market and contract for RUBY-FILL<sup>®</sup> to customers on a separate contract basis originating with JDI. In addition, we believe our radiopharmacy network provides a highly scalable distribution platform for distribution of our products with relatively marginal increases in expenses.

#### *Research and Development*

Radiopharmaceuticals. Our radiopharmaceuticals business has a specialized R&D team, based in Montreal, Canada, with extensive expertise in developing radiopharmaceutical generators, radiolabeled small molecules/biomolecules and stable lyophilized kits. Our R&D team in Montreal, Canada, supports existing products and leads development of new products using its own resources, and also collaborates with our R&D team in India, which is capable of handling products in various presentations, ranging from solutions to lyophilized kits to pre-filled syringes. Our R&D team in Montreal has sound understanding of developing generic and innovative products using a Quality by Design (QbD) approach and up-scaling the manufacturing processes which align with current regulatory expectations. We believe we have end-to-end integration within our R&D team in Montreal and in collaboration with our R&D team in India, covering all facets of the development cycle, starting from API synthesis to finished product development, filing and approval.

R&D development at our JDI Montreal Facility is critically supported by in-house analytical capabilities, including an animal testing facility, and intellectual property creation and protection. In addition, we believe our ongoing technological landscaping and networking help us design sustainable and effective solutions for the future. We believe our radiopharmaceutical R&D capabilities, enables us to continually engage in the development of new products.

Commercial Radiopharmacies. The commercial radiopharmacies generally do not engage in new product development. However, to remain competitive in the commercial radiopharmacy space we recognize a need to innovate and re-define the commercial radiopharmacy operating model and footprint. We continuously seek opportunities to expand or enhance the efficiency of our radiopharmaceuticals business by optimizing the coverage of our radiopharmacy network including through further additions and improvements or consolidation of locations.

#### *Fleet*

Radiopharmaceuticals. JDI does not maintain a fleet of drivers or vehicles within its operation, but maintains a small team of service professionals to support the devices provided to customers with the RUBY-FILL® RUBY Rubidium Elution System (RbES) for rubidium-82 (Rb-82 chloride) infusion and the Smart-Fill™ Dispensing System for HICON® Sodium Iodine I-131 Solution USP.

Commercial Radiopharmacies. JDR maintains a fleet of drivers and leased vehicles delivering radiopharmaceuticals from our radiopharmacies directly to our customers on a daily basis. As at December 31, 2018, we have commissioned over 350 leased vehicles operated by approximately 400 JDR-employed drivers for the distribution and delivery of our products. JDR also engages delivery services with third party commercial couriers when required to supplement delivery requirements and fleet services.

#### *Facilities*

Radiopharmaceuticals. Our radiopharmaceutical hot products are manufactured in our JDI Montreal Facility. Our facility is approved by Health Canada and the USFDA. The JDI Montreal Facility maintains Class 100 cGMP sterile production capabilities for the production of rubidium-82 Generators. The last USFDA inspection of our JDI Montreal Facility was in September 2017 and the EIR was received in January 2018. The most recent Health Canada inspection was completed in April 2018.

The two key products for our radiopharmaceuticals division are cold kits, being DRAXIMAGE® MAA and DRAXIMAGE® DTPA, manufactured by JHS, JDI's contracted CMO. Our radiopharmaceutical hot products include any product that is radioactive at the time of shipment from the manufacturing location, including HICON® Sodium Iodine I-131 Solution USP, I-131 therapeutic capsules and solutions, I-131 diagnostic capsules and solutions, I-131 mIBG, and our RUBY-FILL® generators. We do not consider our lyophilized kit products as hot products as they are reconstituted at radiopharmacies. These products do not ship from our JDI Montreal Facility as a radioactive hot product but rather are prepared with Tc99m at a radiopharmacy to form the final radiopharmaceutical product.

We continue to manage and minimize supply interruptions and have secured multi-source coverage for raw materials for our key products. We have entered into contracts with leading suppliers of I-131 radioisotopes, while JHS is currently our partner-of-choice for our cold kit manufacturing and supply. Under the current supply agreement with JHS, JHS supplies us with cold kits on commercial terms, which includes all JDI cold kit products, such as DRAXIMAGE® MDP-25, DRAXIMAGE® Sestamibi, DRAXIMAGE® Gluceptate, DRAXIMAGE® DTPA, DRAXIMAGE® MAA, and others. We engage in multi-sourcing for Sr-82 and I-131. For Sr-82, we have supply contracts with three key suppliers of six, and for I-131, we have supply contracts with two of the three suppliers globally. See *“Risk Factors—Risks Relating to Our Business—Our dependence on a limited number of third party suppliers for some of our key raw materials such as Molybdenum could prevent us from delivering some of our products, including radiopharmaceutical products, to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues”*.

Commercial Radiopharmacies. The supply of radiopharmaceutical agents is highly regulated and affected by several factors. For nuclear imaging agents, the primary radioactive ingredient is Tc99m, which has a half-life of about six hours and is generated through the decay of Molybdenum, its parent radioisotope using a Molybdenum/Technetium generator. Molybdenum-99 has a half-life of approximately 66 hours and is produced by a limited number of nuclear reactors, all of which are located outside the United States. For PET, the primary radioactive ingredient is F-18 Fluorine, which is cyclotron-produced. Once activated, F-18 Fluorine has a half-life of approximately 110 minutes. PET radiopharmacies therefore need to have access to a cyclotron within their facilities. In addition, PET agents need to be synthesized, packaged and delivered quickly in order to reach physicians prior to the expiration of the radioactive agents. Not all PET agents can be produced within a PET radiopharmacy and transported to a customer, which is the case for Rubidium (Rb-82) and ammonia (N-13). As part of our acquisition of Triad's assets, we acquired a total of 51 SPECT nuclear pharmacies and three PET manufacturing sites operating from a total of 52 physical locations in the United States, as well as seven cyclotrons, of which three remain operational. The premises for these 52 locations were assigned to us by Triad

Isotopes Inc. with the consent of the respective landlords. While certain leases provide for an option to renew, substantially all of these leases expire in the future including within the next 12 months. Depending on our business needs and strategies, we may not extend or renew certain leases upon their respective expirations and/or may lease premises in different locations. As at December 31, 2018, we had a distribution network of 51 radiopharmacies.

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

Our CMO business line develops and produces sterile injectables, ampoules, ophthalmic and sterile/non-sterile ointment cream and lotions (OCL). We believe both the Spokane and Montreal facilities are leading service providers to the pharmaceutical industry, serving seven out of the top 20 pharmaceutical companies globally (based on revenue, according to Frost & Sullivan) and providing manufacturing product development and laboratory analytical services. Our CMO business services the spectrum of pharmaceutical industry requirements, from large-scale leading pharmaceutical companies to biotechnology organizations. We follow a partnership approach to this business, working closely with our customers to provide comprehensive solutions with utmost flexibility and customer service.

Our CMO business generated revenues of US\$100.9 million for the financial year ended March 31, 2018 and US\$81.6 million for the nine months ended December 31, 2018, which comprised 16.3% and 14.5%, respectively, of our revenue from operations for the year/period.

### ***Products and Services***

We have two product segments under our CMO business line: (i) sterile injectables, accounting for approximately 80.0% of CMO revenues, is the primary product segment; and (ii) non-sterile products, accounting for the remaining 20.0% of CMO revenues.

We offer services for a broad range of sterile injectables, including vial and ampoule liquid fills, freeze-dried (lyophilized) injectables, biologics, suspensions and water for injection diluents. The size of the vials we are currently able to produce ranges from two milliliters to 100 milliliters and batch sizes range up to 2,000 liters. We are also able to manufacture products in quantities suitable for clinical trials as well as for large-scale commercial requirements. We also offer products that include sterile ointments, creams and liquids and have a growing presence in topical and ophthalmic areas. The services we offer for non-sterile products include semi-solid dosage formulations, including antibiotic ointments, dermatological creams and liquids (syrups and suspensions). Further, we offer a full suite of services to our customers including supply chain support, lab testing services, regulatory submission support, manufacturing process refinement and project management.

As a fully integrated contract manufacturer of sterile injectables with in-house R&D capabilities, we believe we are well positioned to become a leading, cost effective CMO. We have relationships with several global pharmaceutical companies and have the ability for captive consumption through integration with our other business lines, particularly our allergy therapy and radiopharmaceuticals businesses. We will continue to focus our efforts in strengthening our industry position by enhancing and expanding our capacity, focusing on consistent and “first time right” customer service, building new customer relationships and finding opportunities to strategically extend our product portfolio.

### ***Market and Customers***

We believe that the global pharmaceutical contract manufacturing market is fragmented and there are only a few leading operators with combined sterile injectables and non-sterile products capabilities and competencies required to serve large pharmaceutical and biotechnological customers. The markets for sterile injectables and other sterile/non-sterile dosage forms have been among the fastest growing business lines with significant barriers to entry such as complex manufacturing processes, stringent USFDA and other regulatory compliance requirements which can take between three and five years and high capital investment. Furthermore, the market is going through a phase of large-scale consolidation with large pharmaceutical companies acquiring CMOs and thereby limiting their capacity to service their customers, USFDA regulatory violations that have led to import alerts and/or bans of certain manufacturers and changing market trends among others. We believe such consolidation has led to a demand-supply disequilibrium and presents an opportunity for us to grow our CMO business.

We have an established market position in the sterile injectables and non-sterile products markets globally. Our key markets for sterile injectables and non-sterile products are North America and Europe. We also distribute to other markets such as the Middle East, Africa and Asia. We expect to be able to continue to increase our market share in the market for sterile injectables and non-sterile products as a result of our proven regulatory track record with the USFDA, Health Canada, UKMHRA, KFDA Korea, ANVISA Brazil and PMDA Japan, our expertise in multi-mode contract manufacturing, the quality of our products and our execution capabilities.



We utilize a number of marketing channels to target key pharmaceutical and biotechnological customers such as advertising in trade publications, participation in tradeshow, social media, targeted email communications, direct mail, print media and other content marketing. We serve seven out of the top 20 pharmaceutical companies globally (based on revenue, according to Frost & Sullivan). We have deep and long-term relationships with our top 10 customers. For example, as at December 31, 2018, our top 10 customers have been with us for at least five years, and six of our top 10 customers have been with us for over 10 years. We also contract manufacture cold kits at our CMO Montreal Facility to support our radiopharmaceutical products.

#### *Facilities*

Our sterile injectables manufacturing facility located in Spokane, Washington, United States is focused on the delivery of clinical and commercial fill and finish services for sterile parenteral pharmaceuticals, utilizing both liquid and lyophilization capabilities. It is able to support manufacturing from a Phase I trial stage through to commercial manufacturing. The Spokane Facility has obtained MHRA, Health Canada, PMDA Japan and other certifications for its manufacturing processes. The last USFDA inspection of the Spokane Facility was in October 2018. The inspection resulted in the issuance of Form-483 inspectional observations. We have responded to these observations and believe the findings have been corrected. The EIR is pending.

Our sterile and non-sterile manufacturing facility in Kirkland, Montreal, Canada has multi-dosage form capabilities ranging from sterile parenteral (vial and ampoule liquid and lyophilization), to sterile and non-sterile semisolid manufacturing of OCL. The CMO Montreal Facility has obtained USFDA, Health Canada and other certifications for its manufacturing processes. The last USFDA inspection of the CMO Montreal Facility was in May 2018 and the EIR was received in July 2018.

#### *Allergy Therapy Products*

Our allergy therapy products business provides products to the allergy specialty industry with an offer range of different allergenic extracts and standard allergy vaccine mixtures, including insect venom products for the treatment of allergies to insect stings. We are one of the leading allergenic immuno therapy companies in the United States according to Frost & Sullivan, with 90 years of experience, and a service provider to allergists and the medical community. Our allergy therapy products business generated revenues of US\$43.6 million for the financial year ended March 31, 2018, which comprised 7.0%, of our revenue from operations for the year.

#### *Products*

Our allergy therapy product range includes over 200 different allergenic extracts, six insect venom products and exclusive skin diagnostic testing devices. We are currently the sole producer and supplier of venom products for the treatment of allergies in the United States. The majority of our therapeutic and diagnostic vaccines are extracted from pollens, animal pelt/hair and stinging insects (for our venom products) and are produced in a unique phenol-free format, which yields better potency and stability compared to our competitors' products which contain phenol. Our main products are our extensive line of pollens, Venomil<sup>®</sup> which is a venom product and line of acetone-precipitated extracts, such as AP Dog and AP Cat; and its QUINTIP<sup>®</sup> and ComforTen<sup>®</sup> lines of skin testing diagnostic devices.

#### *Market and Customers*

The primary target user base of our allergy therapy products are allergists; ear, nose and throat physicians; general physicians and a few hospital-based clinics across North America. Our allergy therapy products business line has traditionally focused on North America as our key market, where we believe we have generated significant brand loyalty in respect of the "HollisterStier" brand, due to the quality of our products and long-standing operating history. We also market some of our key products such as allergenic extracts and venom extracts in Canada, Europe, Australia, New Zealand and South Korea through distributors. JHS has also entered into partnerships to further deepen the penetration of our allergy therapy products in Canada and Europe, specifically France and Germany. We also look to explore adjacencies or vertical integration such as supplier and distribution agreements or diagnostic testing services. According to Frost & Sullivan, we are one of the top three players in the allergenic extract market in the United States with a market share of 17.6%.

#### *Sales, Distribution and Marketing*

Our allergy therapy products are sold primarily in bulk and then mixed in the office/clinic environment. We have a dedicated sales force in the United States and distributors in Europe, Canada and South Korea for our allergy therapy products.

### *Facility*

Our allergy therapy products are manufactured at our Spokane Facility. Our Spokane Facility maintains registration with the USFDA and Health Canada approval for manufacturing allergy therapy products. As part of our long-term facility upgrade, we plan to add a second lyophilizer and a second filler to our venom line. We believe this will provide redundancy in the case of equipment failure, and minimize interruptions to our supply of venom to the market. The last Center for Drug Evaluation and Research (“CDER”) USFDA inspection of our Spokane Facility was in September 2017 and the EIR is pending. The last CBER USFDA inspection of our Spokane Facility was in October 2018 and the EIR is pending.

### **Generics & APIs**

Generic pharmaceutical products, or “generics”, are the pharmaceutical and therapeutic equivalents of brand-name drug products whose patents have either expired or been successfully challenged in their respective markets and are usually marketed under their established non-proprietary drug names, rather than under a brand name. Generics are typically more affordable in comparison to their brand-name equivalents. Generics are required to meet similar governmental regulations as their brand-name equivalents offered or sold by the originator such as those relating to manufacturing processes and health authorities’ inspections, and must receive local regulatory approval prior to their sale in any given country.

We have a robust generics & APIs product portfolio, comprehensive R&D capabilities, focused generics & APIs product pipeline and a global operational network, which collectively we believe will enable us to execute key generics & APIs launches to further expand our generics product pipeline and diversify our revenue stream. We use these capabilities to mitigate price erosion arising from our Generics & APIs business segment. When considering whether to develop a generic medicine, we take into account a number of factors, including our overall strategy, regional and local patient and customer needs, R&D and manufacturing capabilities, regulatory considerations, commercial factors and the intellectual property landscape. We believe our position in the generics market is supported by our global R&D function, as well as our APIs business line, which provides significant integration for our products.

### ***Solid Dosage Formulations***

We are engaged in the development, manufacture, sale and distribution of prescription generic pharmaceutical products in the United States, Europe, Canada, Japan, Australia and the rest of the world. We are one of the market leaders in the United States based on our market share of several key products.

Generic formulation pharmaceuticals contain the same active ingredient and are of the same route of administration, dosage form, strength and indication(s) as brand-name pharmaceuticals already approved for use by the regulatory authorities. The 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. We focus primarily on the manufacture and sale of solid dosage formulations for CVS, CNS, GI and anti-allergy therapeutic categories.

Our solid dosage formulations business generated revenues of US\$123.5 million for the financial year ended March 31, 2018, which comprised 20.0%, of our revenue from operations for the year.

### ***Products and Services***

Our solid dosage formulations business develops generic drugs. As at December 31, 2018, we had 54 commercialized generic solid dosage formulations products across the United States, Europe, Canada, Australia and the rest of the world. One of the solid dosage formulations products that we manufacture for our CMO customers is sold in Japan under a third party’s brand. In the oral solid dosage formulations business, our product portfolio spans CNS products such as lamotrigine, oxcarbazepine, cyclobenzaprine, donepezil, anti-histamine products such as meclizine and GI products such as pantoprazole in the United States market. Our range of products also includes value-added formulations and special formulations such as taste masking, flash tablets, oral dispersible forms, chewable tablets and modified release forms.

We also offer turnkey products and services to generic pharmaceutical companies by undertaking the supply of solid dosage formulations and APIs based on dossiers developed by us and arrange market authorizations and release for facilitating sales of solid dosage formulations in EU countries and the United States. We also provide regulatory affairs services, formulation development, licensing of marketing authorizations and supply solid dosage formulations to generic pharmaceutical companies in Europe.

According to Frost & Sullivan, within the United States, we are one of the market leaders based on market share for several key products, namely, prochlorperazine (largest market share at approximately 52.0%), terazosin

(largest market share at approximately 51.9%), methylprednisolone (largest market share at approximately 38.0%), prednisone (third largest market share at approximately 9.0%), olanzapine ODT (second largest market share at approximately 22.0%), donepezil (fourth largest market share at approximately 8.0%), and pantoprazole (fourth largest market share at approximately 13.0%). We develop dossiers for our products in accordance with regulatory and registration procedures for various countries, most of which incorporate our APIs, which we license to European generic pharmaceutical companies in addition to selling our own products in selective countries within Europe. In the United States, since we commenced operations through to December 31, 2018, we have made a total of 96 ANDA filings for solid dosage formulations, of which 35 are pending approval. We have also made ANDA filings in other jurisdictions, including Canada and Europe. As at December 31, 2018, for solid dosage formulations, we have made a total of 23 product filings in Canada, of which one is pending approval, 34 product filings in Europe, of which two are pending approval and 42 product filings in the rest of the world, of which seven are pending approval.

We believe we have a strong product portfolio, focused on developing products for which we can be one of a few reliable suppliers in the market. We are registered to distribute products in more than 50 countries, directly and indirectly. In particular, for non-U.S. markets, we plan to become a leading supplier of esomeprazole through cost leadership and capacity enhancement. Esomeprazole is a proton-pump inhibitor used in the treatment of gastroesophageal reflux disease (“GERD”) and other conditions involving excessive stomach acid. Currently, we distribute esomeprazole to seven countries with sales contracts in place for 16 additional countries. In line with our strategy to provide predictable and reliable service to our customers, we engage in dual-sourcing of our raw materials, including APIs, and dual-qualification of our manufacturing and/or packaging sites. Dual-sourcing and dual-qualifications also help to lower our cost base.

#### *Market and Customers*

In recent years, the market for generic pharmaceuticals has grown dramatically. We believe this growth has been driven by several factors, including:

- efforts by governments, employers, third party payers and consumers to control healthcare costs;
- increased acceptance of generic pharmaceutical products by physicians, pharmacists and consumers;
- the aging of the population and the resulting greater utilization of prescription pharmaceutical products at affordable prices;
- increased access to healthcare for the local population in developing countries; and
- the increasing number of pharmaceutical products whose patents have expired or will expire over the next several years and are or will be subject to competition from generic equivalents.

We believe these factors will continue to increase demand for generic pharmaceuticals and accelerate the growth of the generic pharmaceuticals industry in future years.

We have also increasingly focused on diversification of the markets we sell to, particularly emerging markets. Outside the United States, we have subsidiaries in Europe and Australia and partnerships with local companies across the globe.

#### *Sales, Distribution and Marketing*

We sell our solid dosage formulations products in more than 50 countries. Sales are driven by new product launches and launches of existing products in new countries, sales are driven by capacity, product cost and supply chain efficiency enhancement in addition to consolidation of existing partners and identification of new partners. For the financial year ended March 31, 2018, our solid dosage formulations business accounted for 20.0%, of our total revenue from operations. In the United States, we have established our presence as a generic pharmaceutical company and we market our own products through a distribution network and supply solid dosage formulations directly to the United States. We also supply to the U.S. Federal Government through our Salisbury Facility in the United States. In addition, we also make filings for our solid dosage formulations products in other markets such as Europe, Japan, Canada, South Africa, Australia, China and United Arab Emirates and typically sell our products through local partners. In many European countries and in other countries such as Japan, South Africa, Canada, Australia and Philippines, we have partnered with the largest pharmacy chains and/or distributors of the region in addition to local generic pharmaceutical companies. We have also filed products within countries in Asia (including Philippines, Malaysia, Taiwan, Singapore, Hong Kong and Vietnam), Africa (including Ethiopia, Zimbabwe, Uganda, Kenya and Nigeria), Middle East (including Israel, Jordan, Iraq), certain CIS countries (including Ukraine, Uzbekistan, Belarus and Russia) and Latin America (including Chile, Colombia and Peru). We have also partnered for filings in key new markets like Saudi

Arabia and Brazil. We typically partner with local pharmaceutical companies, distributors, retail pharmacy chains or local pharmaceutical marketing companies for sale of our products in those countries and such arrangements are usually long-term supply agreements extending up to five years.

#### *Facilities*

We have two manufacturing facilities for solid dosage formulations — one located in Salisbury, Maryland in the United States and the other, located in Roorkee, Uttarakhand, India. The Roorkee Facility has been inspected by, among others, the USFDA, FAMHP Belgium, PMDA Japan, ANVISA Brazil and MCC South Africa. The two sites collectively have an annual capacity of producing over 3.5 billion doses. The last USFDA inspection of our Salisbury Facility was in April 2018 and the EIR was received in September 2018. The last USFDA inspection of our Roorkee Facility was in August 2018 and resulted in four Form-483 observations. We have responded to the Form-483 inspectional observations for the Roorkee Facility. We have not yet received the EIR from this inspection. Subsequently, the USFDA has classified the inspection at the facility as “Official Action Indicated” through a letter dated November 27, 2018. While we have responded to the USFDA and contested this classification pursuant to our letter dated December 14, 2018, an “Official Action Indicated” classification can result in further regulatory action and the USFDA may also withhold approval for any pending applications in which the Roorkee facility is listed. In addition, following the inspection of our Roorkee Facility, which is owned by JGL, in August and September 2018, the USFDA issued Complete Response Letters (the “CRLs”) to JGL in respect of two of its ANDAs previously filed with the USFDA in March 2014 and March 2017. The CRLs reaffirmed the observations identified during the recent inspection of the Roorkee Facility in August 2018, but did not cite concerns with the ANDAs themselves, including with respect to their clinical safety, bioequivalence or efficacy data. The FDA noted in the CRLs, among other things, certain outstanding inspection issues identified at the Roorkee Facility, and requested communications submitted to, or held with, the USFDA to facilitate resolution of such conditions or deficiencies, noted at the Roorkee Facility. The USFDA indicated in the CRLs that it cannot grant final approval of these ANDAs in their present form until there is satisfactory resolution of such observations.

We plan on increasing the solid dosage formulations capacity at our Roorkee Facility. The first phase of our expansion plan was recently completed and is expected to increase the solid dosage formulations capacity by one billion doses to meet increasing demand. The next phase would involve expanding our product manufacturing lines in oral solids and certain niches in Novel Drug Delivery System (“NDDS”) with a view to increasing the contribution to revenues as we grow beyond the traditional regulated markets.

#### *Raw Materials, Inputs and Suppliers*

The primary raw material input for our generic solid dosage formulations are APIs which we produce as well as purchase from third party sources. Of the APIs which we use for our solid dosage formulations, more than 35.0% is produced by the Group. We are currently working on finding alternative sources for critical APIs, which we believe will help to further mitigate supplier concentration risks on the availability of critical APIs, for both for APIs which we produce in-house and APIs sourced from third party suppliers.

#### *Research and Development*

We currently have a team of more than 130 scientists at our R&D facility in Noida, Uttar Pradesh, India, developing solid dosage formulations. The facility is equipped for laboratory scale tablets and capsules manufacturing. Our finished dosage development center based in Noida, Uttar Pradesh, India, also has capabilities to develop oral solid products, including immediate release oral solids formulation, modified release formulation, chewables and orally disintegrating tablets, as well as injectables, powder for oral suspensions and ophthalmic products.

#### *APIs*

We develop and produce APIs, which are the principal ingredients for pharmaceutical formulations, and are also known as bulk active substances or bulk drugs. APIs become formulations when the dosage is prepared for human consumption in the form of a tablet, capsule or liquid using additional inactive ingredients. Our APIs are primarily sold to manufacturers of formulations of generic drugs or used in-house by our solid dosage formulations business line. We sell only development quantities of APIs to manufacturers of formulations of generic drugs prior to the patent expiry as permitted by the local laws of the importing country and commercial quantities only upon patent expiry or prior to patent expiry for our customers to prepare for launch upon patent expiry. In all cases, our approach is governed by the local laws of the importing country.

Our API business generated revenues of US\$86.1 million for the financial year ended March 31, 2018, respectively, which comprised 13.9%, of our revenue from operations for the year.

## *Products*

As at December 31, 2018, we had 39 commercialized APIs available globally through commercial scale plants, of which carbamazepine, oxcarbazepine, citalopram, donepezil, pinaverium, valsartan, risperidone and meclizine are the most significant. According to Frost & Sullivan, we are one of the global suppliers based on market share for several key API products, namely, oxcarbazepine (global market share at approximately 30.0%), carbamazepine (global market share at approximately 20.0%), risperidone (global market share at approximately 33.0%), pinaverium (global market share at approximately 20.0%), citalopram (global market share at approximately 18.0%), donepezil (global market share at approximately 16.0%), and meclizine (global market share at approximately 20.0%). We are focused on the development of APIs in the following therapeutic categories: CVS, CNS, GI, anti-infectives and anti-depressants. Approximately 80% of our commercialized portfolio is in lifestyle driven therapeutic areas such as CVS and CNS, catering to an increasing incidence of lifestyle-related medical conditions or non-communicable diseases including cardiac ailments and seizures. As at December 31, 2018, in the United States, we had filed 94 DMFs in the United States. We have also made DMF filings in other jurisdictions, including Canada, Europe, Japan and Australia.

We continuously evaluate opportunities for API product development to build our product pipeline. Product launch will depend on a number of factors, including market conditions and relevant regulatory approvals.

## *Market and Customers*

The global API market is witnessing a period of stable growth, supported by both outsourced and captive segments. According to Frost & Sullivan, the global API market is forecasted to increase from approximately US\$164.3 billion in 2018 to US\$219.1 billion in 2022, at a CAGR of 5.9%, of which captive production accounts for approximately 58.0%. We manufacture APIs for captive consumption in our solid dosage formulations business line as well as for external sales. Sartans (angiotensin II receptor blockers), used primarily for the treatment of hypertension, continue to be a key focus area for us.

Our APIs are exported worldwide, into emerging as well as developed markets. Our key markets are North America, South America, Europe, Japan, Korea, Commonwealth of Independent States (CIS) countries, the Middle East and Australia. Our API customers include leading global generic pharmaceutical companies. We are also forward integrated with our solid dosage formulations business line, supplying APIs for use in the manufacturing processes of our solid dosage formulations products. See “—*Solid Dosage Formulations—Raw Materials, Inputs and Suppliers*”. For the financial year ended March 31, 2018 and the nine months ended December 31, 2018, third party customers accounted for more than 88.1% and 86.9% of our API revenues, respectively.

Manufacturers of formulations that use our APIs are subject to strict regulation globally. The global API market can broadly be divided into regulated and less regulated markets. According to our internal estimates, we believe approximately 60.0% of our sales are to regulated markets. We believe our strong presence in highly regulated markets help with customer retention and price realization of our API products. The less regulated markets offer low entry barriers in terms of regulatory requirements and intellectual property rights. The regulated markets, like the United States and Europe, have high entry barriers in terms of intellectual property rights and regulatory requirements, including facility approvals, which lead to increased time, cost and efforts by our customers in order for them to sell their products in such markets. As a result, there is a premium for quality and regulatory compliance along with relatively greater stability for both volumes and prices. Generally, only a single source of API is qualified for use in each product due to costs and time required to validate a second source of supply. Changes in API suppliers must typically be approved through a prior approval supplement by the USFDA. As such, we believe our customers are less likely to switch their API source frequently.

## *Sales, Distribution and Marketing*

Due to the long development and approval lead times, typically the development of an API for generic use starts a number of years prior to patent expiry. However, we also develop a number of soon to be generic or already generic APIs where we seek to be an alternate supplier for the customer rather than the primary supplier. Our sales and marketing team interacts with our customers’ technical teams in R&D, quality control and manufacturing, as well as with our customers’ procurement personnel, in order to identify such opportunities. Change of API source or alternate development can take between three months and two years depending upon the regulations for alternate API supplier qualifications in a particular country and the regulatory approval status of the supplier. Our teams continuously look for customer development opportunities and follow up on potential leads.

We rely primarily on our existing relationships with leading generic pharmaceutical companies in markets such as the United States, Europe, Canada, Japan and Brazil to explore opportunities to obtain regulatory approval for

and sell our APIs. We also employ agents who act as a link between ourselves and drug manufacturers interested in sourcing APIs to meet their requirements. Such arrangements are customized and we implement such arrangements selectively for certain countries or with customers where the local language, knowledge of regulations, customs and/or payment follow-up requirements necessitate the use of such services of a local entity as an intermediary. These contacts may be initiated by us, the manufacturer, or the distributor/agent if it is aware of mutual interest in outsourcing arrangements for a particular API.

#### *Facility*

Our APIs are produced at manufacturing plants in our facility in Nanjangud, Karnataka, India. There are currently six multi-purpose, multi-product commercial production plants at this facility. Our production plants are capable of conducting sophisticated manufacturing and chemical processes, particularly high-temperature or high-pressure reactions. Our Nanjangud Facility is approved by key regulatory agencies including the USFDA, PMDA Japan, KFDA Korean and COFEPRIS Mexico. The last inspection of our Nanjangud Facility was carried out jointly by the USFDA and Health Canada in December 2018. At the conclusion of this joint inspection, the USFDA issued a Form-483 with 12 observations on December 18, 2018. We have responded to the Form-483 observations in a timely manner and are yet to receive the EIR. As this was a joint inspection, Health Canada issued to us the same observations as the USFDA as part of their inspection exit notice on December 21, 2018. We responded to Health Canada on January 22, 2019 with details of our corrective and preventive actions. On January 16, 2019, the Nanjangud Facility received a letter from Health Canada indicating a NC rating and with an opportunity to appeal within 10 business days. We submitted our appeal on January 25, 2019 with a justification to reconsider the NC rating. We are currently in the process of engaging with Health Canada to remediate the concerns with our corrective and preventive actions.

We continue to invest in the expansion of our manufacturing capacity utilization. Such expansion is driven by continuous de-bottlenecking of our manufacturing plants/streams and by value engineering through the application of lean six sigma and other value-added tools for productivity enhancement. In addition, we also build new capacities as per our commercialization plans based on customer approvals and patent expiry of various molecules. We intend to continue to increase production capacity for several of our API products. For example, we expanded production capacity of our API products such as lamotrigine, citalopram, oxcarbazepine and tramadol through de-bottlenecking and line balancing of our existing plants at Nanjangud to increase production capacity.

We believe having large capacities in select products provides us with certain advantages, including:

- *Reduced changeover time leads to higher utilization:* We save approximately three production days per month for a line with two products;
- *Larger batch sizes:* Producing larger batches reduces our costs due to efficiencies in sources as well as reduces quality control cost for customers due to testing of a lower number of batches; and
- *Better customer service:* Shorter lead times enable us to get products to customers more quickly.

We have recently added a third stream to one of our existing plants at our Nanjangud Facility. We are currently also exploring options to increase our API production capacity including expanding the capacity of our existing Nanjangud Facility by debottlenecking, building a new API facility at a new location and/or acquiring an existing API facility, among other things.

#### *Raw Materials, Inputs and Suppliers*

The primary raw material input for our APIs are fine chemicals, bulk chemicals, solvents, catalysts, and basic and advanced intermediates. Some of the fine chemicals and advanced intermediates we use are designated under DMFs as Key Starting Materials (“KSMs”) for manufacturing of APIs. Such KSMs are subject to regulatory compliance and are sourced from manufacturers who are cGMP compliant in the manufacturing of these KSMs. For regulated markets such as the United States and Europe, KSM sources are specified in the process and DMFs and EDMFs, respectively. If a KSM supplier is changed in a regulated market, the relevant DMF or EDMF, associated ANDAs and dosage dossiers have to be updated to reflect the new KSM supplier. The prices of these raw materials generally fluctuate in line with commodity cycles, demand supply situations and changes in government policies. We evaluate and manage our commodity price risk exposure through periodical supply contracts as well as primary and responsive sourcing procedures. For most APIs we produce, we are not dependent on any single supplier for raw materials used in API production and have at least two or more approved sources for KSMs and other critical raw materials for most of our APIs.

## Research and Development

Our API development centers in India have more than 150 scientists, focusing on the development of non-infringing processes for markets including the United States, Europe, Japan and Canada. These scientists focus exclusively on the R&D of new APIs in order to develop non-infringing processes facilitating the first-to-file advantage in ANDAs and dossiers in regulated markets. For example, we have developed difficult to synthesize complex molecules such as Aliskiren, Ticagrelor, Rosuvastatin, Lurasidone and Dabigatran. We also have an in-house R&D center at our Nanjangud Facility, including a kilo lab and pilot plant, which are used to develop processes for the production of APIs from laboratory test amounts to larger commercial quantities.

We have chemistry expertise in complex chemistries such as chiral separation, low temperature reactions, bio-transformation and stereo-selective synthesis as well as other technical expertise. The API R&D team is organized according to specific functionalities, including chemical synthesis, analytical research, IPR, and technology transfer. Our IPR group also monitors the patent status of our API products and coordinates patent filing and patent infringement issues worldwide.

In accordance with our strategy to expand our R&D efforts in complex formulations and differentiated formulations we have increased our R&D spending, leading to a large number of DMFs filed. See “—Generics & APIs—APIs—Products”. To manage our costs, we have implemented cost improve programs for Oxcarbazepine, Valsartan, Pinaverium Bromide, Risperidone, Citalopram HBr and Olmesartan Medoxomil. For these products, we have reduced raw material costs in our API manufacturing by improving yields and solvent recovery rates.

## Sales

As at December 31, 2018, we supplied our products and services to customers in over 80 countries. North America, where a majority of our customers are based, accounted for 80.1% and 82.0% of our total revenue from operations for the financial year ended March 31, 2018 and the nine months ended December 31, 2018, respectively. Our other customers based in Europe, Asia and the rest of the world accounted for 19.9% and 18.0% of our total revenue from operations for the financial year ended March 31, 2018 and the nine months ended December 31, 2018, respectively.

We intend to focus on strengthening our presence in the key developed markets of North America, Europe and Japan as well as in certain emerging markets. We intend to continue strengthening our United States marketing efforts for CMO, solid dosage formulations and APIs. We also have in place an extensive international logistics and distribution network to effectively cater to our international customers.

The following table is a breakdown of our revenue from operations (net) by geographic region, including the percentage contribution by such regions to our total revenue from operations for the periods indicated.

	Financial Year Ended March 31				Nine Months Ended December 31			
	2017		2018		2017		2018	
	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)
North America . . . . .	325,091.8	70.6	495,649.5	80.1	340,782.5	79.9	461,301.2	82.0
Europe . . . . .	80,225.3	17.4	57,794.6	9.3	42,632.7	10.0	49,882.1	8.9
Asia . . . . .	31,977.3	6.9	39,502.5	6.4	28,000.4	6.6	31,518.9	5.6
Rest of the world . . . . .	23,277.7	5.1	26,219.1	4.2	15,344.8	3.6	20,156.7	3.6
<b>Revenue from operations (net) . . .</b>	<b>460,572.1</b>	<b>100.0</b>	<b>619,165.6</b>	<b>100.0</b>	<b>426,760.4</b>	<b>100.0</b>	<b>562,858.8</b>	<b>100.0</b>

## Customers

For the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2018, our top 10 customers (excluding GPOs but including customers purchasing goods and services through such GPOs) contributed approximately 39.6%, 33.8% and 31.1% of our total revenue. For the financial year ended March 31, 2018 and the nine months ended December 31, 2018, save for one customer, none of the top 10 customers of the Group contributed more than 5% of the total revenue.

We have agreements with GPOs that act as agents to negotiate vendor contracts on behalf of their members. Sales to members of our GPO relationships (based on member revenue) under various contracts across our businesses, collectively accounted for 13.1%, 26.8% and 35.7%, respectively, of our total revenue from operations for the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2018.

## Suppliers

For the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2018, our top 10 suppliers accounted for approximately 28.9%, 39.7% and 47.2% of the total payments to suppliers, and save for one supplier for the financial year ended March 31, 2018 and two suppliers for the nine months ended December 31, 2018, none of our top 10 suppliers accounted for more than 5% of the total payments for such year and period, respectively.

## Seasonality

Sales of individual products in individual markets may be subject to fluctuations from quarter to quarter. However, our consolidated results of operations have not been subject to any significant seasonality.

## Facilities and Offices

As at December 31, 2018, we had four North American manufacturing facilities comprising one manufacturing facility for solid dosage formulations located in Salisbury, United States, one sterile injectables manufacturing facility in Spokane, United States for the contract manufacturing of sterile injectables and allergy therapy products, one sterile manufacturing facility for radiopharmaceuticals, and one sterile injectables and non-sterile products manufacturing facility for CMO, both located at Kirkland, Montreal, Canada, and two manufacturing facilities located in India, in Nanjangud and Roorkee, for APIs and solid dosage formulations, respectively. All our facilities in the United States (at Spokane and Salisbury), Canada (at Kirkland, Montreal) and India (at Nanjangud and Roorkee), are registered as establishments with USFDA. Our Nanjangud Facility has obtained ISO9001:2015, ISO 14001:2015 and BS OHSAS 18001:2017 certifications. Our central R&D center is located in Noida, Uttar Pradesh, India. Our Nanjangud Facility has also been granted the good manufacturing practices certificate by the Drugs Controller & Licensing Authority, Karnataka, India. Such certificate is granted for manufacturing activities for tablets (non beta lactum) and capsules (non beta lactum).

The following table sets forth certain information concerning our manufacturing facilities and principal locations:

<u>Location</u>	<u>Primary Use/Products</u>	<u>Certifications (as at December 31, 2018)</u>	<u>Nature of Interest</u>
Nanjangud, Karnataka, India	R&D center	—	Freehold
	Production facility for APIs (CNS, CVS and antibiotics)	ISO 9001:2015, ISO 14001:2015, BS OHSAS 18001:2017, USFDA, Health Canada, ANVISA Brazil, TGA Australia, PMDA Japan, EMA, KFDA Korea, ANSM France, COFEPRIS Mexico, WHO-cGMP	
Roorkee, Uttarakhand, India	Production facility for solid dosage formulations (oral solid dosage)	USFDA, Health Canada, TGA Australia, PMDA Japan, WHO-cGMP, SAHPRA, MCC South Africa, MOH (Belarus), MOH (UAE), FDA (Jordan), MCAZ (Zimbabwe), FDA (Tanzania), DRU (Botswana), GMP (DLCA, India), WHO (India), CDSCO <sup>(1)</sup> , RP Darmstaaft Germany, FAMHP Belgium, FDA (Philippines), Ministry of Health (Yemen and Vietnam)	Freehold
Kirkland, Montreal, Canada.	Colony Land	—	Freehold
	Contract manufacturing of sterile injectables (lyophilized and sterile injectable ointments, creams and liquids)	USFDA, Health Canada, ANVISA Brazil	Freehold
	Production facility for radiopharmaceuticals (radioactive cold kits)	ISO 13485, USFDA, Health Canada	
	R&D center—radiopharmaceuticals	—	



<u>Location</u>	<u>Primary Use/Products</u>	<u>Certifications (as at December 31, 2018)</u>	<u>Nature of Interest</u>
Spokane, Washington, United States	Sterile injectables and allergy therapy products (lyophilized and sterile injectables)  R&D center	USFDA  —	Freehold
Salisbury, Maryland, United States	Production facility for solid dosage formulations (oral solid dosage)	USFDA	Freehold
Noida, Uttar Pradesh, India	R&D center—API   R&D center—Solid dosage formulations	DSIR (India)  —	Leasehold under license from the Parent  Leasehold under license from the Parent
Yardley, Pennsylvania, United States	R&D center clinical research Corporate office	— —	Leasehold 63 month leasehold
Orlando, Florida, United States	Corporate office	—	Leasehold expiring on January 31, 2019 with two three-year renewal options
Merelbeke, Belgium	Office	—	Small office leasehold
Singapore	Registered Office	—	Leasehold expiring on October 14, 2021

*Note:*

(1) No separate certification from CDSCO as such certification is valid through the WHO (India) certification.

In addition to the facilities and offices described above, we have 51 SPECT nuclear pharmacies and three sites that manufacture PET products operating from a total of 51 physical locations in the United States. These physical locations are all leased. These radiopharmacies supply radioactive diagnostic doses to end-user customers and have been obtained approvals from the U.S. Department of Transportation (“US-DOT”), the NRC and the relevant state board of pharmacy. We consider our radiopharmacy network adequate to meet our present needs. However, we regularly evaluate our radiopharmacy leases and may make further additions and improvements or consolidate locations as we seek opportunities to expand or enhance the efficiency of our radiopharmaceuticals business.

## Capacity and Utilization

The following table shows the production capacity as at March 31, 2017 and 2018 and as at December 31, 2018 and utilization rates of our facilities for the years ended March 31, 2017 and 2018 and the nine months ended December 31, 2018:

Facilities	Units	Installed Capacity <sup>(1)</sup>			Utilization rate <sup>(2)(3)(%)</sup>		
		As at March 31,		As at	For the nine		For the nine
		2017	2018	December 31,	years ended	months	
				March 31	ended	ended	
		2017	2018	2018	2017	2018	2018
Nanjangud Facility . . . . .	Metric tonnes (MT)	874	874	874	83	82	79
Roorkee Facility . . . . .	Doses (MM)	1,320	1,320	990	86	99	90
CMO Montreal Facility . . . . .	Batches (Lyo) <sup>(4)</sup>	122	122	122	99	93	98
	Batches (SPD) <sup>(4)</sup>	265	265	265	51	42	51
	Batches (OCL) <sup>(4)</sup>	200	200	200	4	1	1
JDI Montreal Facility . . . . .	Ci for I-131	70,000	70,000	70,000	7.1	6.3	6.3
	Units for RUBY-FILL <sup>®</sup>	700	700	700	6.6	13	17
Spokane Facility (CMO) . . . . .	Batches	367	367	367	92	89	91
Spokane Facility (Allergy) . . . . .	Vials	270,000	270,000	270,000	99	94	94
Salisbury Facility . . . . .	Doses (MM)	2,200	2,200	2,200	65	72	59

### Notes:

- (1) Represents total production capacity assuming 100% utilization.
- (2) Represents utilized capacity for the trailing twelve month period prior to the date indicated except in the case of the nine-month period ended December 31, 2018.
- (3) Exclusive of down time.
- (4) Lyo refers to lyophilization line, SPD refers to sterile product department (ophthalmics, ampoules), and OCL refers to ointments, creams and liquids.

## Regulatory Inspections and Quality Control

The pharmaceutical industry is highly regulated and pharmaceutical manufacturers are required to comply with cGMP's and applicable regulatory requirements. Our six facilities undergo periodic inspections from various regulatory agencies including the USFDA, Health Canada, PMDA Japan, CDSCO, ANVISA, RP Darmstaft Germany and UKMHRA. Our radiopharmacies are also subject to periodic inspections from state authorities and the USFDA. Such inspections for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon pharmaceutical manufacturers, may be unannounced. The USFDA may present a company with a Form-483 if an investigator has observed any conditions that in such investigator's judgment may constitute violations of the FDCA and applicable regulations. The Form-483 is then discussed with the company's senior management at that inspected facility. Companies are encouraged to respond to the observations in Form-483 in writing with their corrective and preventative action plan within 15 days and then implement that action plan expeditiously. A Form-483 does not constitute a final USFDA determination of whether any condition is in violation of the FDCA or any of its relevant regulations. A Form-483 is considered, along with a written report called an EIR and all evidence or documentation collected on-site. The USFDA considers all of this information and then determines what further action, if any, is appropriate to protect public health.

In addition, manufacturers of pharmaceutical products are subject to reporting requirements. For example, we are required to report certain adverse reactions, stability failures, market complaints or manufacturing problems impacting the quality of the distributed products to the USFDA within three business days. We also provide updated efficacy information and comply with requirements concerning advertising and promotional labeling requirements. From time to time, we may determine that products we manufacture or market do not meet approved specifications, regulatory requirements or published standards. When we or a regulatory agency identify a quality or regulatory issue, we are required to investigate and take appropriate corrective action, which may include recalling the product, correcting the product at the customer location, revising product labeling and notifying customers. As a precautionary measure, we have conducted voluntary recalls and market withdrawals of products manufactured by the Group in the United States, Canada and the rest of the world. For example, in 2017, we voluntarily recalled 744 bottles of meclizine hydrochloride tablets. The bottles manufactured were part of the process validation batch for process change requiring a 30-day waiting period for USFDA approval, and such bottles were inadvertently released prior to final approval from the USFDA. In May 2018, we voluntarily

recalled two lots of Valsartan due to the potential inclusion of a coarser grade of excipient during the manufacturing process. The USFDA designated these voluntary recalls as Class III recalls and efforts relating to the latter two of these Class III recalls remain ongoing. Further to the recall in May 2018, in August 2018, we voluntarily recalled 10 additional lots of Valsartan which were prepared using excipient from the same shipment as the two lots of Valsartan recalled in May 2018. In August 2018, we completed an internal investigation for one lot of Methylprednisolone tablets for failing a stability test at 18 months and initiated a voluntary product recall. The USFDA designated these voluntary recalls as Class III and efforts relating to these voluntary recalls remain ongoing. In October 2018, we voluntarily recalled 13 batches of Pantoprazole due to discolored tablets, which has been designated by the USFDA as a Class II recall and efforts relating to this Class II recall remain ongoing. In addition, some recalls may involve markets outside of the United States. For example, in 2016, we completed a voluntary Type I product recall of two lots of DRAXIMAGE® MDP-25 kits for preparation of Tc99m Medronate Injection distributed to Canada because a glass particle was found in one of the vials distributed to Canada. Most recently, in August 2018, we voluntarily recalled certain batches of Esomeprazole enteric coated tablets in 20mg and 40mg dosage form, Levofloxacin 500mg film coated tablets, Oxcarbazepine 300mg tablets and Valsartan capsules in 80mg and 160mg dosage form distributed to Europe due to the potential use of a coarser grade of excipient during the manufacturing process. See *“Risk Factors—Risks Relating to Our Business—As the manufacture of our products is technically complex and highly regulated, product recalls, regulatory inspection failures or shortcomings at our manufacturing facilities or other problems may reduce sales, adversely affect our business, financial condition and results of operations and delay the launch of new products, and in some cases may lead to closures of our facilities”*.

The Class III recalls we have experienced in the past as well as the Class II recall we recently experienced were initiated by us through a voluntary notice submitted by us to the USFDA indicating our intent to initiate a voluntary recall of the relevant product. In such voluntary notice, we designate the recall classification. Upon receipt of such voluntary notice, the USFDA will review and may or may not respond if it agrees or disagrees with our classification of the recall. We notify our customers of a recall with the example letter supplied by us to the USFDA. For both Class II and Class III recalls, the Company typically incurs costs related to assessment and evaluation of the product being recalled, logistics costs of bringing any remaining recalled products back to our warehouse, administrative fees to distributors and costs relating to the destruction of recalled products, if any.

We have established an independent global corporate-level quality function that reports to the Senior Vice President Global Head of Quality (“**Sr. VP Global Head of Quality**”), who is based at our corporate office in the United States. While the Sr. VP Global Head may update our Board of Directors and Chief Executive Officer, our Sr. VP Global Head of Quality is responsible for the decision-making in relation to the quality of our products. At all our manufacturing facilities (site level) located in Montreal, Spokane, Salisbury, Nanjangud, and Roorkee, we have one designated quality head. The site-level quality heads of the facilities report to designated quality heads at the corporate-level and quality-related matters may then be further escalated to the Sr. VP Global Head of Quality. We believe we place a strong emphasis on implementing quality systems, training, quality by design, patient safety and data integrity compliance measures that are aligned with current guidelines applicable to us. We have in-house pharmacovigilance operations for our business lines except for Solid Dosage Formulations, for which we rely on an external vendor that is supervised by our in-house team.

We have in the past, received Warning Letters and untitled letters from the USFDA regarding certain operations. For example, our CMO facilities at Montreal and Spokane received Warning Letters from the USFDA in February 2013 and November 2013, respectively. Our response was to voluntarily shutdown the CMO section of the Spokane Facility until the USFDA’s concerns had been addressed. Actions we took to address the USFDA’s concerns in relation to the Montreal and Spokane facilities included (i) providing corrective action commitments to the USFDA regarding the respective Warning Letters each facility received; (ii) having in-person meetings at the relevant USFDA District Office to discuss the commitments and progress towards completion; and (iii) engaging the assistance of an external consulting firm specializing in USFDA inspections and Warning Letters to assist with the development of corrective action and provision of resources to implement such corrective actions. In addition, for the Spokane Facility, we committed to 16 specific quality enhancement plans/projects that reviewed and improved many of the facility’s quality systems. These quality enhancement plans/projects were reviewed with the USFDA, which we committed to complete during follow-up inspections. Further to the subsequent USFDA inspection of the Spokane Facility in November 2014, the USFDA granted the Spokane Facility approval for pending regulatory supplements, clients’ NDA applications and recommendation of an NDA for a client product. The USFDA formally confirmed that the violations identified in the Warning Letter to the Montreal Facility were resolved in September 2014 by way of a close-out letter and EIR for the Spokane Facility was received in June 2015. While we believe the violations identified in these Warning Letters have been adequately addressed, the Company’s revenues were negatively impacted as a result of the Montreal Facility and Spokane Facility Warning Letters due to the disruption to our production from the shutdown of the

CMO section of the Spokane Facility and our reputation amongst customers was negatively affected. See *“Risk Factors—Risks Relating to Our Business—As the manufacture of our products is technically complex and highly regulated, product recalls, regulatory inspection failures or shortcomings at our manufacturing facilities or other problems may reduce sales, adversely affect our business, financial condition and results of operations and delay the launch of new products, and in some cases may lead to closures of our facilities”*.

Our radiopharmacy in Kansas City, United States, which we acquired in September 2017 as part of our acquisition of Triad’s assets, received a Warning Letter in March 2016 prior to our acquisition. Triad Isotopes, Inc., the owner and operator of such radiopharmacy at the time of the inspection took a number of corrective steps which included the training of key site personnel on investigation and root cause analysis tools and technique, as well as implementing aseptic practice training, developed by a sterility assurance third party consultant on an annual basis. The USFDA indicated in a letter dated November 8, 2016 that Triad Isotopes, Inc.’s response to the Warning Letter appeared to be sufficient and would be verified during a subsequent inspection.

We have placed a strong emphasis on implementing quality systems, training, quality by design, patient safety and data integrity compliance measures that are aligned with current guidelines applicable to our business. We aim to continue investing in quality and quality systems as well as implementing electronic systems such as enterprise resource planning systems to ensure robust compliance across all entities. Further, we are focused on improving the quality “on-the-floor” and resolving Corrective Action/Preventive Action (CAPA) deficiencies in a timely manner, and have invested in training which we believe will contribute to our efforts to deliver on our “first time right” customer service initiative.

Notwithstanding the above, our business is heavily regulated by governmental health authorities around the world and involves technically complex manufacturing processes, which may require strict environmental controls. If we or our third party suppliers fail to comply with regulations, there could be shutdowns or disruption of our manufacturing activities. There is also no guarantee that we will be able to successfully manage such issues if and when they arise.

### **Research and Development**

Research & Development (R&D) is essential for innovation and plays a vital role in developing and adopting new technologies in the technologically intensive pharmaceutical industry. We have a team of well-qualified and experienced professionals in R&D centers spread across multiple locations that is specialized across the value chain of pharmaceutical research.

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. We believe our strong R&D capabilities are demonstrated by complex and niche product filings in our APIs, solid dosage formulations and radiopharmaceuticals business lines.

We have R&D centers located in North America and India and, as at December 31, 2018, we employed 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 specialized and/or niche formulations and design for radiopharmaceuticals and other products, which have been taken to commercialization. As at December 31, 2018, we have filed 111 ANDAs, of which 37 ANDAs are pending approval in the United States.

During the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2017 and 2018, we incurred US\$38.8 million, US\$33.5 million, US\$23.3 million and US\$25.5 million, respectively, on R&D, representing 8.4%, 5.4%, 5.5% and 4.5%, respectively, of our total revenue from operations in those periods.

### **Intellectual Property Rights**

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.

As at December 31, 2018, we have been granted patents for intellectual property in various countries for innovations, including 19 active patents granted relating to APIs in a number of different countries, five active patents granted relating to solid dosage formulations in a number of different countries, 123 active patents granted relating to radiopharmaceutical products in a number of different countries and one active patent granted relating to allergy therapy products in the United States. Five patents for APIs and one patent for solid dosage formulations are registered in India and held in the name of JGL.

We have trademarks in the United States, India, Canada, Europe and other jurisdictions worldwide. As at December 31, 2018, we held 94 registered trademarks across these jurisdictions, of which 32 registered trademarks in India are held by JGL, and two trademarks are held by JLL, which have been duly assigned to JGL and applications have been made to the Indian regulatory authorities for change in ownership. We use the corporate name and trademark “Jubilant” which is held by Jubilant Enpro Private Limited (“JEPL”), an entity owned by the Promoters. JEPL has registered the “Jubilant” trademark and logo, either individually or jointly, in a number of jurisdictions, including India.

## **Competition**

The pharmaceutical industry is highly competitive and is affected by new technologies, new developments, government regulations, healthcare legislation, availability of capital or financing and other factors. Many of our competitors have longer operating histories and substantially greater financial, R&D, marketing and other resources than us. We compete with numerous other companies that operate, or intend to operate, in the pharmaceutical industry, including companies that are engaged in the development, manufacturing and distribution of radiopharmaceutical, allergy therapy, generics & APIs products. We also compete with numerous companies that engage in the contract manufacturing of pharmaceutical products.

As a generic pharmaceutical supplier, we compete with branded products, as well as generic pharmaceutical companies supplying other bioequivalent products. Competing manufacturers of generic pharmaceutical products may create value for our customers by offering substitutes for branded pharmaceutical products at significantly lower prices. Some of our principal generic competitors are Par Pharmaceuticals, Inc., Sandoz Laboratories, Inc., Teva Pharmaceutical Industries Ltd., Mylan, Inc. and Amneal Pharmaceuticals Inc. Our key competitors in India include Cipla Limited, Aurobindo Pharma Limited, Camber Pharmaceuticals, Inc. and Unichem Laboratories. By focusing on our differentiated medicines with limited reliable competition, as well as taking advantage of our integration of products with dual sourcing of API, we aim to manufacture more profitable products relative to our competition. For our API business, the majority of our competition is from other Indian players, including Ipca Laboratories, Dr. Reddy’s, Aurobindo Laboratories, Lupin Limited, Glenmark Pharmaceuticals and Cipla Limited. We also face competition from Chinese manufacturers such as Hisun, Huahai and Tianyu and players from Italy and Spain.

The market for diagnostic medical imaging agents is highly competitive and continually evolving. Large pharmaceutical, specialty pharmaceutical, radiopharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are commercializing or pursuing the development of products that aim to diagnose and treat serious conditions affecting patients. The diagnostic and therapeutic products and product candidates that they develop and/or produce may target the same conditions and cancers our products and product candidates aim to diagnose and/or treat. Our principal competitors in existing diagnostic modalities include large, global companies such as Curium, GE Healthcare, Cardinal Health and Bracco, as well as other competitors. We compete with such companies both in terms of efficacy and product portfolio across SPECT, PET and generics. While we believe our therapeutic approaches have significant advantages compared to conventional approaches, we still face significant competition from conventional approaches for reasons of cost or familiarity of hospitals and doctors with existing treatments. According to Frost & Sullivan, the vertical integration of our radiopharmaceutical products manufacturing with our commercial radiopharmacy business provides us with competitive advantages in manufacturing, pre-commercialization of products and product delivery.

With respect to our CMO business line, the market is competitive, where companies often use pricing as a differentiator from their competitors. In addition, many competitors offer similar experience and expertise, including in the area of regulatory compliance. Supply base consolidation is expected to favor large, well-capitalized companies with broad capabilities, global scale and a good regulatory track record. We believe that our competitive strengths of sterile manufacturing expertise across solid dosage formulations, expertise in unique manufacturing requirements for lyophilization, ampoule, sterile ointment, ophthalmic, our market lead in North America in sterile vial manufacturing our technical expertise across our Spokane and Montreal manufacturing locations and expertise in semi-solid manufacturing and active relationships with global pharmaceutical companies allow us to compete effectively against our competitors.

## **Environmental Matters**

Solid waste at our facilities is disposed, recycled or reused in accordance with applicable regulatory standards. Our facilities are also equipped with the necessary air pollution control equipment to keep emissions below applicable regulatory standards.

In the United States, we continue to invest resources to reduce or eliminate waste effluents and other hazardous materials produced by our facilities. We have secured all necessary licenses and permits under the relevant United States environmental regulations and we believe we are in compliance with all applicable United States environmental regulations in all material respects. As at December 31, 2018, both our Spokane Facility and Salisbury Facility held valid permits for waste water, air and hazardous waste as applicable under local regulations. The Salisbury Facility submitted an application for industrial surface water discharge in September 2015 to the Maryland Department of Environment (“MDE”) pursuant to the notification from the MDE dated August 31, 2015. On December 1, 2017, the MDE issued the permit for industrial surface water discharge to the Salisbury Facility, which expires on November 30, 2022.

In 2017, the USEPA had cited our subsidiary, Jubilant Cadista, for violating the Resource Conservation and Recovery Act, which is a federal law governing the treatment, storage and disposal of hazardous waste, including lab solvents and corrosive cleaner wastes. We provided a satisfactory action plan to comply with the observations of the USEPA and after discussions with the USEPA, Jubilant Cadista paid a US\$35,000 penalty. Such penalty imposed did not have a material impact on our business and/or operations, and as at June 30, 2018, we have not received any notification of alleged violations or penalties imposed further to the 2017 notice.

In Canada, we have also implemented waste management initiatives for all of our facilities. We have secured all necessary consents and authorizations under the relevant Canadian environmental regulations and we believe we are in compliance with all applicable Canadian environmental regulations in all material respects. We have not received any previous citation of violation during environmental inspections conducted either by the Canadian authorities or by our customers. As at December 31, 2018, both our CMO Montreal Facility and JDI Montreal Facility held valid permits for wastewater, air and storm water as required under local regulation.

In our Indian facilities, we have undertaken significant efforts to reduce and manage effluents by investments in incinerators in certain facilities and waste treatment facilities and improvements in production processes to reduce the quantity of effluents or increase recycling of materials, and upgrading of waste storage facilities. Our Indian manufacturing facilities have achieved zero discharge norms, meaning that the plants do not discharge any effluent outside of their premises, and the effluent that is discharged on the premises is treated and recycled within the premises. Our Nanjangud Facility and Roorkee Facility comply with IFC EHS guidelines in addition to local regulatory requirements. Both our Nanjangud Facility and Roorkee Facility hold valid consents under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981.

## **Occupational Health and Safety**

We have first-aid rooms in our manufacturing facilities. In addition, our Indian manufacturing facilities have set up occupational health centers, which are appropriately staffed by trained medical officers, medical technicians and other trained personnel. The medical facilities are equipped with the necessary equipment required for healthcare, first aid and other medical emergencies. We also conduct mandatory pre-employment and regular medical check-ups for all the employees.

We strictly follow safety norms at our manufacturing locations, including institution of safety permit systems and standard operating procedures. Our target is to achieve a zero incident record at all of our facilities. During the financial year ended March 31, 2018 and the nine months ended December 31, 2018 there were no reportable lost time incidents at our Nanjangud Facility and Roorkee Facility. At our North American facilities there were a total of 13 and 19 lost time incidents during the financial years ended March 31, 2017 and 2018, respectively, and 10 lost time incidents during the nine months ended December 31, 2018. We have undertaken precautionary safety measures following such incidents or accidents in the past. As at December 31 2018, we did not have any contingent liabilities relating to such incidents, however future occurrences of such incidents may subject us to liabilities.

## **Sustainability**

In line with the Parent’s continued focus on the sustainability of its business, we aim to improve stakeholder value through improved eco efficient use of capital and natural resources. The Company’s approach to sustainable development focuses on economics, the environment and social performance. We are committed to working towards energy conservation and climate change mitigation.

## Employees and Employee Benefits

As at March 31, 2017 and 2018 and December 31, 2018, we had approximately 3,443, 4,320 and 4,385 full time employees, including our management team, respectively.

Our approximate employee headcount by geographic region and function, as at March 31, 2017 and 2018 and December 31, 2018, is set out below:

Region	Approximate headcount by region <sup>(1)</sup>		
	As at March 31		As at December 31
	2017	2018	2018
North America	1,367	2,178	2,231
Europe <sup>(2)</sup>	9	7	5
Asia <sup>(3)</sup>	2,067	2,135	2,149
<b>Total</b>	<b>3,443</b>	<b>4,320</b>	<b>4,385</b>

### Notes:

- (1) The increase in approximate headcount as at March 31, 2018 as compared to March 31, 2017 was due to the acquisition of substantially all of the assets which comprised Triad's radiopharmacy business.
- (2) Comprises our employees in Belgium and Germany.
- (3) Comprises our employees in China and India.

Function	Approximate headcount by function <sup>(1)</sup>		
	As at March 31		As at December 31
	2017	2018	2018
Accounts / Finance	83	97	97
Administration	8	11	11
Business Excellence & Six Sigma	13	14	14
CEO Office	6	4	5
EHS / Sustainability	20	28	24
Human Resources	45	56	62
Info & Tech	40	50	53
Manufacturing	1,676	2,344	2,402
Medical & Scientific Affairs	1	9	15
Legal	4	9	9
Pharmacovigilance	8	8	6
Program / Business Management	19	24	36
Projects	21	29	31
Quality	654	703	752
R&D	422	468	409
Regulatory Affairs	66	65	65
Sales & Marketing	113	146	135
Security	11	12	11
Supply Chain	186	189	195
Technical Services	47	54	51
<b>Total</b>	<b>3,443</b>	<b>4,320</b>	<b>4,383</b>

### Note:

- (1) The increase in approximate headcount as at March 31, 2018 as compared to March 31, 2017 was due to the acquisition of substantially all of the assets which comprised Triad's radiopharmacy business. Further, since Triad did not have the same breakdown by function as we do, all of Triad's employees that were part of pharmacy operations (pharmacists, technicians and drivers) became our employees are categorized under "Manufacturing".

As at December 31, 2018, some of our employees at our Nanjangud Facility, CMO Montreal Facility and JDI Montreal Facility, representing less than 10% of our employees, were members of unions, works committees, or otherwise had collective bargaining capability. We enjoy cordial relations with our employees and there have been no instances of major strikes, lockouts or other disruptive labor disputes with the exception of a 10-day strike in July 2016 over wages during the renewal of JDI's union contract. The strike was resolved amicably through a voluntary mediation process. We have entered into a settlement agreement with our employees union

at our Nanjangud Facility. There is no union of employees at our Roorkee Facility and we have not entered into any collective bargaining agreements with our employees at the Roorkee Facility.

JHS GP and Jubilant DraxImage Inc. have each entered into collective bargaining agreements. The JHS GP agreement expired in April 2018 and has been re-negotiated for a six-year term ending April 30, 2024. Jubilant DraxImage Inc.'s collective bargaining agreement is due to expire on March 31, 2019 and we expect it will continue to be in effect during the negotiation period.

We are currently in the process of negotiating the collective bargaining agreements with our employees at our facilities situated at Nanjangud, Karnataka, India and Montreal, Canada.

We provide various benefits to our employees, such as healthcare coverage. We fund a provident fund for employees' retirement. We also provide a superannuation plan for certain of our employees. The wages and benefits of our unionized employees are generally established pursuant to such collective bargaining agreements described above.

We have several initiatives to train and develop employees in building skills and capabilities. The training activities focus on functional requirements or generic skills enhancements, including marketing skills, behavioral skills, information technology, environmental awareness training, health and safety, and manufacturing or technical skills enhancement training.

In order to promote performance culture and individual performance, we have also introduced various initiatives, including introducing a variable pay component to senior management levels. In addition, we also award major milestones and recognize the small achievements at the individual level and at the team levels through our "Reward & Recognition Program". To further integrate our operations and to streamline our human resource automated processes, we have also implemented a human resource information system globally.

## **Insurance**

We maintain insurance policies on all of our production facilities, including buildings, plants and machinery and inventories, covering fire and other contingencies such as riot, strike, flood, storm, earthquake and other natural and accidental risks (including burglary). All of our manufacturing facilities have industrial all-risk insurance coverage, including fire and burglary coverage for certain facilities in India, a commercial package policy, boiler and machinery breakdown coverage, earning and extra expense coverage and business interruption coverage for overseas facilities. We also maintain insurance on products in transit, such as imports, international sales, and inland transport. We also maintain global commercial general / product liability insurance for the majority of the products we manufacture. Besides this, we also maintain a clinical trial policy for our Indian operations.

We also maintain insurance policies, including commercial automobile, commercial umbrella, personal accident, worker compensation and group medical insurance, which we believe to be relevant to our business. In addition, we also maintain directors' and officers' liability insurance. We do not maintain key man life insurance on our executive officers.

We maintain public liability insurance policies for our industrial units in India and Environmental Impairment Liability policy for overseas operations, to cover risks that may include explosions, lapses in safety, industrial accidents, bodily injury, pollution liability, property damage or loss caused by the direct or indirect action of any of our facilities.

In the financial year ended March 31, 2018 and in the nine months ended December 31, 2018, we paid an aggregate of US\$1.9 million (insurance income US\$1.2 million) and US\$1.7 million (insurance income US\$0.8 million), respectively, in insurance premiums, net of recoveries / adjustment in CTC under all of our insurance policies. We believe that our insurance coverage is reasonably sufficient to cover all normal risks associated with our operations and is in accordance with industry standards.

## **Legal Proceedings**

We and our subsidiaries are from time to time involved in legal or arbitration proceedings in the ordinary course of business. The material proceedings in which we and/or our subsidiaries are currently involved in are set out below. Except as set out below, we are not currently a party to any material legal or arbitration proceedings. Regardless of outcome, legal or arbitration proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.



## ***RUBY-FILL® Proceedings***

### *New Jersey District Court*

Bracco filed a complaint in the New Jersey District Court against us, the Parent and JDI (collectively, the “**Jubilant Defendants**”) on March 27, 2018 in connection with RUBY-FILL®, JDI’s product. The complaint was a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 9,814,826, 9,750,869, 9,750,870, 9,299,467 and 9,299,468 (collectively, the “**patents-in-suit**”).

JDI manufactures RUBY-FILL®, comprising a rubidium-82 generator and an elution system, which it sells under the trade name RUBY-FILL®. Prior to the launch of RUBY-FILL®, JDI had filed a 505(b)(2) NDA (NDA No. 202153) to market and sell a strontium-rubidium radioisotope infusion system, being RUBY-FILL® in the United States. On September 30, 2016, JDI received USFDA approval for RUBY-FILL®.

Bracco is the holder of NDA No. 19414 for CardioGen-82, a rubidium-82 generator with a closed system used to produce rubidium Rb-82 chloride injections for intravenous administration. Rubidium Rb-82 chloride injections are indicated by the USFDA for PET imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary disease.

In the complaint, Bracco alleges that the Jubilant Defendants infringe, contribute to the infringement of, and/or induce infringement of the five patents-in-suit under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by making, using, selling, offering for sale, and/or importing into the United States products covered by one or more claims of such patents including, but not limited to, the RUBY-FILL® system. As a result of such infringement, Bracco has alleged that it has suffered actual and consequential damages of an amount that cannot be determined without discovery and special accounting. Bracco requested the court to, among other things, award damages in favor of Bracco including but not limited to lost profits, reasonable royalties, unjust enrichment, and/or benefits received by the Jubilant Defendants as a result of the alleged use of Bracco technology, interest, costs, enhanced damages, reasonable attorneys’ fees as well as other damages to which Bracco claims it is entitled under law or in equity. The complaint also requests a permanent injunction prohibiting the Jubilant Defendants from further infringement of the five patents.

We have carefully reviewed the allegations made by Bracco and are vigorously defending our legal positions. On June 27, 2018, before the Jubilant Defendants’ answers to the complaint were due to be filed, the New Jersey District Court stayed this action pending final resolution of the USITC Proceeding (discussed below). No schedule has been set in this action. The Jubilant Defendants’ response to the complaint will not be due until after the USITC Proceeding has completed and the stay in the New Jersey District Court action is lifted.

Legal proceedings of this nature can take a long time to resolve. We cannot predict when these legal proceedings will be completed and we cannot assure you that the New Jersey District Court will dismiss the claims or rule in our favor. The New Jersey District Court could grant temporary or permanent injunctive relief against us (which could result in the suspension and/or cessation of our manufacture and sale of RUBY-FILL®), deliver a ruling in favor of Bracco and/or award substantial monetary damages against us. The process for obtaining relevant governmental approvals to market our products is rigorous, time-consuming and costly. RUBY-FILL® took around 12 years to develop and get to market, requiring significant investment, including R&D, for which we have yet to generate returns. RUBY-FILL® is a standalone radiopharmaceutical product and is not required for any of our other product lines; however it is distributed through our radiopharmacy distribution network in the United States. We are expecting synergies through the integration of RUBY-FILL® with our radiopharmacy services. Should we be unsuccessful in our defense, we would not only lose our investment but could be subject to large damages and/or heavy penalties. We may also incur significant costs and expenses because of these legal proceedings. Further, if the court does not find in our favor, we may be required to implement alternative technology, which could lead to delays or result in difficulties in meeting some of our contractual commitments. This could result in difficulties in our relationships with some customers and could lead to complaints and disputes with them. We do not know the total amount of possible damages and/or other costs that may result from this litigation, and the complaint did not quantify the relief sought by Bracco. Any award for monetary damages or other costs or any interruption of our operations could materially and adversely affect our business, financial condition, results of operations and prospects. See “*Risk Factors—Risks Relating to Our Business—If we are unable to defend ourselves in challenges related to intellectual property rights, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or we could be subject to substantial liabilities that would lower our profits and adversely affect our financial condition*”.

### *United States International Trade Commission*

On April 3, 2018, the USITC issued a Notice of Receipt of Complaint stating that it had received a complaint pursuant to § 210.8(b) of the USITC’s Rules of Practice and Procedure filed on behalf of Bracco on March 27,

2018 (the “**Bracco USITC Complaint**”). In its notice, the USITC also solicited comments on any public interest issues raised by Bracco’s filing pursuant to the USITC’s Rules of Practice and Procedure.

On April 25, 2018, the USITC announced that it had voted to institute an investigation, entitled “*Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators*”, Inv. No. 337-TA-1110, based on the Bracco USITC Complaint.

The Bracco USITC Complaint alleges violations of section 337 of the Tariff Act (19 U.S.C. §1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of JDI’s RUBY-FILL® systems and components thereof including generators, based on alleged infringement of United States Patent Nos. 9,814,826, 9,750,869, and 9,750,870. Bracco requested the USITC issue a limited exclusion order and cease and desist orders. The USITC has identified us, the Parent and JDI as respondents in this investigation. The three Bracco patents asserted in the Bracco USITC Complaint are also asserted in the New Jersey District Court matter.

The institution of an investigation by the USITC is not a decision on the merits of the case. The USITC’s Chief Administrative Law Judge first assigns the case to one of the USITC’s ALJs, who presides over the case and holds an evidentiary hearing. After the hearing, the ALJ makes an initial determination as to whether there is a violation of section 337 of the Tariff Act and, if a violation is found, a recommended determination as to remedy. The ALJ’s initial determination is then subject to review by the USITC which will make a final determination in the investigation. If a violation is found, the USITC issues remedial orders unless it finds such orders would be against public interest. USITC remedial orders in section 337 cases are effective when issued and become final 60 days after issuance unless disapproved for policy reasons by the U.S. Trade Representative within that 60-day period. Final determinations of the USITC may be appealed to the U.S. Court of Appeals for the Federal Circuit.

The USITC referred the investigation to the ALJ to conduct an evidentiary hearing. The evidentiary hearing had been scheduled for January 11, 2019, but was postponed due to the partial U.S. government shutdown. A new schedule for the remaining proceedings has not been entered, but the ALJ has indicated the hearing is likely to occur in April 2019. We have carefully reviewed the allegations made by Bracco and are vigorously defending our legal positions. On May 31, 2018, the Jubilant Defendants filed their response to the Bracco USITC Complaint, denying any unlawful activities and noting that the remedial orders that Bracco requests, if issued, would harm public welfare and health, competitive conditions, consumers, and manufacturing in the United States. Additionally, the Jubilant Defendants are implementing changes to the RUBY-FILL® products to design around the three asserted patents. These design changes have been introduced into the USITC proceeding. On February 8, 2019, the ALJ entered an order that the currently approved RUBY system infringes the three patents, but that the new redesigned RUBY systems do not infringe any of the three patents. The ALJ’s order concerning these issues is subject to review by the full Commission of the USITC. The ALJ has not yet ruled on our other defenses in the action, which will be presented at the upcoming evidentiary hearing. The final USITC decision is expected in or around November 2019. We cannot predict the outcome of the investigation and may be faced with exclusionary remedies against us (which could result in the suspension and/or cessation of our manufacture and sale of RUBY-FILL® in the U.S.) if the USITC determines we are in violation of section 337 of the Tariff Act. If we suspend or cease the manufacture and sale of RUBY-FILL®, we could lessen or lose the potential growth that RUBY-FILL® is expected to bring to our business. See “*Risk Factors—Risks Relating to Our Business—If we are unable to defend ourselves in challenges related to intellectual property rights, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or we could be subject to substantial liabilities that would lower our profits and adversely affect our financial condition*”.

On August 22, 2018, JDI filed three petitions at the USPTO challenging the validity of certain claims of U.S. Patent Nos. 9,299,467 and 9,299,468, which are asserted against the Jubilant Defendants in the Bracco New Jersey District Court complaint but are not asserted in the Bracco USITC complaint (Nos. IPR2018-01448, -1449, -1450). The petitions request the USPTO to conduct IPRs of the two patents and to cancel all claims asserted in the New Jersey District Court action as invalid over prior art. On November 29 and 30, 2018, Bracco filed its preliminary responses to JDI’s petitions, arguing that the USPTO should deny institution of the IPR proceedings. On February 8, 2019, the USPTO issued its decisions instituting all three IPRs. Under the current schedule, Bracco’s response is due May 8, 2019, JDI’s reply is due August 8, 2019, the oral hearing is scheduled for November 6, 2019, and a final decision is expected in February 2020.

### ***USFTC Investigation***

In May 2017, JPL and one of our subsidiaries were notified that the USFTC had begun a non-public investigation into certain competition law matters relating to our sales and distribution practices in our radiopharmaceuticals business and our then-pending acquisition of substantially all of the assets of Triad consisting of its radiopharmacy business in the United States. In February 2018, our Company and Triad received two CIDs from

the USFTC requesting certain information about our business and operations. The investigation is ongoing and we have produced documents and information in response to the CIDs, further to which we have not received further responses from the USFTC. To date, the USFTC has not alleged any wrongdoing by JPL or any of our subsidiary companies; however, no assurance can be given as to the timing or outcome of the investigation. If this investigation were to result in further inquiries or enforcement proceedings, we may incur substantial costs, be exposed to unanticipated civil liabilities and be subject to changes to our sales and distribution practices, in each case in a manner that may be materially adverse to our business. Moreover, the investigation and its outcome could expose us to negative publicity, which could materially and adversely affect our brands, reputation and customer preference for our product. See *“Risk Factors—Risks Relating to Our Business—We are subject to certain competition and antitrust laws throughout the world, including federal and state antitrust laws in the United States”*.

Notwithstanding the above, from time to time, we may settle or otherwise resolve legal proceedings, investigations and other matters on terms and conditions that we believe to be in our best interest. Resolution of any or all claims, legal proceedings or investigations could have a material adverse effect on our results of operations and/or cash flow in any given accounting period, or on our overall financial condition.

In addition to the above, our controlling shareholders, JLL and the Promoters, are involved in proceedings initiated by SEBI, the Indian securities regulator.

### ***Adjudication Order***

Pursuant to an adjudication order dated January 31, 2018, (the **“Adjudication Order”**), our controlling shareholder, JLL, Jubilant Stock Holding Private Limited (**“JSHPL”**), the Promoters, and a former employee of JLL who is now employed by our Group (the **“Employee”**) were each fined INR1,000,000 by SEBI. The Adjudication Order stated that JLL had violated the applicable Indian regulations with respect to corporate disclosure requirements by making delayed disclosures to the Indian stock exchanges on (a) receipt of Warning Letters from the USFDA in 2013 by a subsidiary entity and a subsidiary of JLL, namely, JHS GP and JHS, respectively in respect of the Montreal Facility and the Spokane Facility; (b) receipt of an inspection report in 2014 from the USFDA by JHS GP classifying the Montreal Facility as ‘acceptable’; and (c) announcement of a levy of provisional duties against JLL in 2013 by the Ministry of Commerce, China. JSHPL (of which the Promoters were both directors) and the Promoters were fined for purchasing equity shares of JLL while they were in possession of certain unpublished price sensitive information pertaining to the sale of a hospital business of one of JLL’s subsidiaries. The Employee was fined for selling and purchasing equity shares of JLL while in possession of unpublished price sensitive information with respect to the receipt of one of the USFDA Warning Letters and the inspection report referred to above. JLL, JSHPL, the Promoters and the Employee have filed an appeal against the Adjudication Order on April 24, 2018 before the Securities Appellate Tribunal, Mumbai, India. As at this date, the matter is pending before the SAT. We have adopted a code for the prevention of insider trading and a policy to ensure prompt reporting is made internally. See *“Risk Factors—Risks Relating to Our Business—We, our directors and controlling shareholders are and may from time to time be involved in legal proceedings from time to time”*.

## RISK FACTORS

*The risks described below are not the only ones faced by us. Our business, prospects, financial condition, cash flows and results of operations could be materially adversely affected by any of these risks.*

### **Risks Relating to Our Business**

*As the manufacture of our products is technically complex and highly regulated, product recalls, regulatory inspection failures or shortcomings at our manufacturing facilities or other problems may reduce sales, adversely affect our business, financial condition and results of operations and delay the launch of new products, and in some cases may lead to closures of our facilities.*

The manufacture of our products is technically complex and subject to regulation by various governmental authorities throughout the world. For instance, we must comply with requirements of the USFDA, Health Canada, UKMHRA, European Medicines Agency (“EMA”), CDSCO and Drugs Controller & Licensing Authority in India and other healthcare regulators with respect to the research, development, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, storage, approval, labeling, sale, distribution, marketing, advertising, promotion, import and export of pharmaceutical products. In addition, because our operations include the manufacture and distribution of medical radioisotopes and other medical products, we are subject to regulation by the U.S. Nuclear Regulatory Commission (the “NRC”), the departments of transport of each state and the departments of health of each state in which we operate and the applicable state boards of pharmacy. The USFDA is also involved in the regulation of cyclotron facilities where PET products are produced in compliance with cGMP requirements and U.S. Pharmacopeia requirements for PET drug compounding. Failure to comply with these requirements may lead to delays in the submission or approval of potential new products for commercialization and marketing, financial penalties, compliance expenditures, the recall or seizure of products, total or partial suspension of production and/or distribution, closure of affected facilities, suspension of the applicable regulator’s review of our submissions, enforcement actions, injunctions and criminal prosecution.

For example, we completed a voluntary Class III recall of batches of Bupropion in June 2018 due to quality issues. In 2016, we voluntarily conducted a Class III recall of over 1,500 bottles of glucocorticoid methylprednisolone tablets in the United States and Puerto Rico due to incorrect labelling (i.e. the incorrect expiration date of “02/0218” was printed on the container label instead of the correct expiration date of “02/2018”). In 2017, we voluntarily recalled 744 bottles of meclizine hydrochloride tablets. The bottles manufactured were part of the process validation batch for process change requiring a 30-day waiting period for USFDA approval, and such bottles were inadvertently released prior to final approval from the USFDA. In May 2018, out of abundance of caution and risk to patient safety, we voluntarily recalled two lots of Valsartan due to the potential inclusion of a coarser grade of excipient during the manufacturing process. The USFDA designated these voluntary recalls as Class III recalls and efforts relating to the latter two of these Class III recalls remain ongoing. Further to the recall in May 2018, in August 2018, we voluntarily recalled 10 additional lots of Valsartan which were prepared using excipient from the same shipment as the two lots of Valsartan recalled in May 2018. In August 2018, we completed an internal investigation for one lot of Methylprednisolone tablets for failing a stability test at 18 months and initiated a voluntary product recall. The USFDA has designated these voluntary recalls as Class III and efforts relating to these voluntary recalls remain ongoing. In October 2018, we voluntarily recalled 13 batches of Pantoprazole due to discolored tablets, which has been designated by the USFDA as a Class II recall and efforts relating to this Class II recall remain ongoing. In addition, we have experienced voluntary market withdrawals in the past, including for example, 13,152 bottles of Pantoprazole Sodium Delayed-Release tablets USP, 40mg due to discolored tablets in December 2016 and 2,016 blisters of Olanzapine OD tablets, 15mg due to an incorrect National Drug Code (“NDC”) on the shipper label in April 2018. Further, some recalls may involve markets outside of the United States. For example, in 2016, we completed a voluntary Type I product recall of two lots of DRAXIMAGE® MDP-25 kits for preparation of Technetium 99m (“**Tc99m**”) Medronate Injection distributed to Canada because a glass particle was found in one of the vials distributed to Canada.

We must register our facilities, whether located in the United States or elsewhere, with the USFDA as well as regulators outside the United States, and our products must be made in a manner consistent with cGMPs or similar standards in each territory in which we manufacture. In addition, the USFDA and other agencies periodically inspect our manufacturing facilities. Following an inspection, the USFDA or other regulatory authorities may issue a Form-483 listing conditions that are observed to violate cGMP or other regulations, a Warning Letter for violations of “regulatory significance” that may result in enforcement action if not promptly and adequately corrected and/or observations which we are required to respond to. For example, our CMO Montreal Facility and Spokane Facility received Warning Letters from the USFDA in February 2013 and

November 2013, respectively. Our radiopharmacy in Kansas City, United States, which we acquired in September 2017 as part of our acquisition of Triad's assets, received a Warning Letter in March 2016 prior to our acquisition. The Warning Letter in respect of the CMO Montreal Facility cited, among other things, (i) inadequate investigation and root cause analysis of batch failures, (ii) inadequate procedures for production and process control, (iii) inadequate procedural controls to address disposition of material and (iv) failure to establish criteria for sampling and testing of drug product. The Warning Letter in respect of the Spokane Facility cited, among other things, (i) inadequate written procedures and safety operating procedures, (ii) inadequate documentation of work orders, (iii) poor investigations regarding root cause analysis and (iv) failure to assure an adequate system for cleaning and disinfecting aseptic processing areas and equipment. The Warning Letter in respect of the Kansas City radiopharmacy cited, among other things, that drug products were prepared, packed or held under unsanitary conditions. Our response with respect to the Spokane Facility was to voluntarily shutdown the CMO section of the Spokane Facility until the USFDA's concerns had been addressed. The USFDA formally confirmed that the violations identified in the Warning Letter to the CMO Montreal Facility were resolved in September 2014 by way of a close-out letter and Establishment Inspection Reports ("EIRs") for the Spokane Facility was received in June 2015. See "*Business—Regulatory Inspections and Quality Control*" for further details. While we believe the violations identified in these Warning Letters have been adequately addressed, the Company's revenues were negatively impacted as a result of the CMO Montreal Facility and Spokane Facility Warning Letters due to the disruption to our production from the shutdown of the CMO section of the Spokane Facility and our reputation amongst customers was negatively affected.

Furthermore, the USFDA or other regulatory authorities may identify other regulatory violations in our operations at these or our other manufacturing facilities from time to time. One or more of our significant manufacturing facilities may be the subject of further warning letters, untitled letters, inspectional observations or other adverse notices or enforcement action from regulators, who may impose restrictions on or withhold necessary authorizations for their operations. If we are required to cease or limit production at such facilities, we could experience disruptions or delays to their production, which could materially and adversely affect our business. We may not succeed in mitigating the impact of such disruptions or delays if we do not remedy the violations identified, fail to do so in a timely manner, or if we are unable to reallocate our production to our other facilities.

Three out of six of our manufacturing facilities were inspected by the USFDA in the financial year ended March 31, 2018. Of the remaining sites, the Salisbury Facility was inspected in April 2018, the CMO Montreal Facility was inspected in May 2018 and the Roorkee Facility was inspected in August 2018. Most recently, our Spokane Facility was inspected by the USFDA and the CBER USFDA in October 2018, and our Nanjangud Facility was jointly inspected by the USFDA and Health Canada in December 2018. Several of these recent inspections resulted in the issuance of Form-483 inspectional observations, including inspections of our Roorkee Facility, Nanjangud Facility, Spokane Facility and CMO Montreal Facility. Our radiopharmacy in Kansas City was also inspected in June 2017, before we acquired it in September 2017, for which Form-483 inspectional observations were issued.

Historically, we have received and continue to receive Form-483 observations in connection with inspections of all of our manufacturing facilities. Upon receipt of a Form-483, we work to address any inspectional observations in a timely manner to obtain the EIRs from such inspections, which indicate formal closure of the inspections as of the date of the respective EIRs. As of this date, we have not received the EIRs from the most recent inspections of the Spokane Facility, the Roorkee Facility, the Nanjangud Facility or the Kansas City radiopharmacy. We believe the findings from both the Spokane Facility and the Kansas City radiopharmacy inspections have been corrected and are awaiting verification by the USFDA. We have responded to the Form-483 inspectional observations for the Roorkee Facility. Subsequently, the USFDA has classified the inspection at the facility as "Official Action Indicated" through a letter dated November 27, 2018. While we have responded to the USFDA and contested this classification pursuant to our letter dated December 14, 2018, an "Official Action Indicated" classification can result in further regulatory action and the USFDA may also withhold approval for any pending applications in which the Roorkee Facility is listed. Further in respect of our Nanjangud Facility, we have responded to the Form-483 observations from the USFDA in a timely manner. We are of the view that these Form-483 inspectional observations will not affect our current commercial business. In addition to inspections by the USFDA, in the financial year ended March 31, 2018, we were inspected by a number of other regulatory agencies, including, Health Canada (CMO Montreal Facility and Nanjangud Facility), CDSCO in India (Roorkee Facility), ANVISA Brazil (Spokane Facility) and RP Darmstadt Germany (Roorkee Facility), and in the nine months ended December 31, 2018, we were inspected by Health Canada (JDI Montreal Facility and Nanjangud Facility (joint inspection with the USFDA as described above)). Health Canada, has pursuant to its joint inspection with the USFDA of the Nanjangud Facility, issued to us the same observations as the USFDA as part of their inspection exit notice on December 21, 2018. We responded to Health Canada on

January 22, 2019 with details of our corrective and preventive actions. On January 16, 2019, the Nanjangud Facility received a letter from Health Canada indicating a Non-Compliant (“NC”) rating and with an opportunity to appeal within 10 business days. We have submitted our appeal on January 25, 2019 with a justification to reconsider the NC rating. We are currently in the process of engaging with Health Canada to remediate the concerns with our corrective and preventive actions.

***Regulatory controls and changes in regulations and public policy in the geographies in which we operate may reduce the profitability of new or current products.***

Our business operates within a highly regulated environment. We must comply with a broad range of regulatory controls on the testing, manufacture and marketing of many of our products. In some countries, including the United States, Europe and Japan, regulatory controls have become increasingly demanding. We expect this trend to continue 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. See also “—*A heightened public or regulatory focus on the radiation risks of diagnostic imaging could have an adverse effect on our business*”. 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.

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.

In March 2010, the U.S. Congress (“**Congress**”) enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “**ACA**”). The ACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA is likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017 that authorizes the implementation of legislation that would repeal portions of the healthcare reform legislation. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the healthcare reform legislation to waive, defer, grant exemptions from, or delay the implementation of any provision of healthcare reform legislation that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. We are subject to certain competition and antitrust laws which may affect the way we conduct our business. See “—*We are subject to certain competition and antitrust laws throughout the world, including federal and state antitrust laws in the United States*”. We expect both federal and state governments in the United States and foreign governments to continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of healthcare while expanding individual healthcare benefits. Existing regulations that affect the price of pharmaceutical products may also change which could impact the sales of our products. Cost control initiatives and political pressure could decrease the price that we receive for any product we develop in the future. Price escalation of pharmaceutical products may also lead to the risk of implementation of price controls in the future, which could have a material adverse effect on our business, financial condition, results from operations, particularly if such price controls affect products for which we have a high market share, including our radiopharmaceutical products.

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 the 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 commercialization of our new products.

***Our business is subject to rigorous licensing requirements.***

We are subject to rigorous and extensive licensing and permit requirements. To lawfully operate our businesses, we are required to obtain and hold licenses, permits, product registrations and other regulatory approvals from, and to comply with operating and security standards of, numerous governmental bodies. These licensing and permit requirements are imposed by regulators at both a national and local level, and cover all aspects of our business, including without limitation, our manufacturing facilities, our products and product development and handling, distribution and sales of products. Failure to maintain or renew necessary licenses, permits, product registrations, licenses or approvals, or to comply with required standards, could have an adverse effect on our business, financial condition and results of operations, and in some cases may lead to closures of our facilities. See also “—*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 would be adversely affected.*”

***Our dependence on a limited number of third party suppliers for some of our key raw materials such as Molybdenum could prevent us from delivering some of our products, including radiopharmaceutical products, to our customers in the required quantities, within the required timeframe, or at all, which could result in order cancellations and decreased revenues.***

For some of our key raw materials, including certain radioactive isotopes that are used in our radiopharmaceutical and commercial radiopharmacy business, we have only a single or a few, external sources of supply, and alternate sources of supply may not be readily available. If our supply of certain raw materials or finished products is interrupted from time to time, or proves insufficient to meet demand, our results of operations could be adversely impacted. In addition, if we are unable to obtain such raw materials, or if we are unable to obtain them at a competitive cost, our 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 has a half-life of about six hours and is generated through the decay of Molybdenum. Molybdenum 99 is the parent radioisotope contained in the Molybdenum/ Technetium generator. Molybdenum has a half-life of approximately 66 hours and is produced by a limited number of nuclear reactors, all of which are located outside the United States. We purchase our generators from two generator suppliers. These generators produce the Tc99m necessary for the operation of our commercial radiopharmacies. Maintaining adequate supply of Tc99m to all nuclear pharmacies is a critical process for generator manufacturers who source Molybdenum. Molybdenum processing sites obtain Molybdenum from five of the six main Molybdenum producing reactors in the world, namely, OPAL in Australia, BR2 in Belgium, LVR-15 in the Czech Republic, HFR in The Netherlands and SAFARI in South Africa. These limited 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 from 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 demands of our radiopharmaceutical business, our ability to manufacture, sell and distribute certain products could be limited and result in a material adverse effect on our business, financial condition, results of operation, and cash flows. For example, due to regulatory issues, one of our supplier’s processing facility has been off-line since late November 2017, and is currently not producing Molybdenum or I-131. 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 could lead to sudden shortages of radioisotopes in the markets and could have a material adverse effect on our businesses, financial condition, results from operations and cash flows.

Further, because a number of our radiopharmaceutical products rely on radioisotopes with limited half-lives, we must prepare, conduct quality testing and distribute these products on a strict schedule and timely basis, because the underlying radioisotope is in a constant state of decay. For example, Tc99m generators are constantly decaying and impacting the availability of Tc99m for the preparation of cold kits for customers. Tc99m requirements are highly controlled and any delay in us receiving our generators from our suppliers or being able to have finished products delivered to customers when requested for patients, or because of weather or other unforeseen transportation issues could have a negative effect on our business, financial condition, results of operation, and cash flows.

With the general instability in the global supply of Molybdenum, directly impacting cost of Tc99m and other radioactive isotopes we require for our radiopharmaceutical business, we may from time to time face increases in

the cost of Tc99m generators or other radioactive isotopes in comparison to historical costs. We expect these cost increases to continue in the future as the suppliers of such radioactive isotopes move closer to a full cost recovery business model. The Organization of Economic Cooperation and Development (“OECD”) defines full cost recovery as the identification of all of the costs of production and recovering these costs from the market. We fully expect our generator suppliers to pass cost increases on to us in our supply contracts, and if we are not able to pass such costs along to our customers in the future, our margin may decline with respect to our radiopharmaceutical products that require the input of such isotopes, which could have a material adverse effect on our business, financial condition, results of operation, 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 Generics & APIs business segment, we must ensure a regular and secure supply of the raw materials required to produce our products. The principal raw material input 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. We cannot assure you that such or future regulations will not affect our ability to maintain our supply sources in China and margins in this business segment. 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.

***Our revenues and profits from generic pharmaceutical products may, and often do, decline as a result of pricing pressures and the continuing consolidation of our customer base and commercial alliances among our customers.***

As patents for branded products and related exclusivity periods expire or are ruled invalid, the first generic pharmaceutical manufacturer to receive regulatory approval for a generic version of the reference product is generally able to achieve significant market penetration and higher margins on that product. As competing generic pharmaceutical manufacturers receive regulatory approval on a product, market share, revenue and profit typically decline for the original generic entrant. Prices of generic drugs typically decline, often dramatically, often within a few months from commercialization, especially as additional generic pharmaceutical companies (including low-cost generic producers based in China and India) receive approvals and enter the market for a given product and competition intensifies. Consequently, our ability to sustain our sales and profitability on any given product over time is affected by the number of new companies selling such product and the timing of their approvals.

In addition, intense pressure from government healthcare authorities seeking to reduce their expenditures on prescription drugs, particularly in highly regulated European and North American markets, has resulted in lower pharmaceutical pricing, causing decreases in revenues and profits. See “*Management’s Discussion and Analysis of Financial Condition and Results of Operations—Significant Factors Affecting our Results of Operations—Pricing and Government Regulation*”.

In the recent past, the barriers to entry for new entrants to the APIs and/or generics industry have reduced due to global competition arising from generic manufacturers located in emerging countries such as India and China, which have low-cost production capabilities, cheaper labor, a highly skilled workforce and infrastructure, thus resulting in a larger competitive field. In addition, the USFDA has taken steps towards reducing drug prices, including publishing a list of off-patent, off-exclusivity branded drugs and enhancing the efficiency of certain aspects of the submission process for generic drug applicants, that have increased competition. Pursuant to The Generic Drug User Fee Act (“GDUFA”), all companies that manufacture human generic drug products, and active ingredients for human generic drug products, that are distributed in U.S. commerce are subject to USFDA user fees. One of the objectives was to increase predictability and timeliness in the review process for generic drugs. We believe as a result of the imposition of such fees by the USFDA, the lead time for approval from the USFDA has reduced thereby increasing the competitive intensity within our industry. At the same time, the customer base for APIs and/or generics manufacturers has seen significant consolidation at the purchasing level, resulting in increased purchasing power for the customer. For example, a significant proportion of our generics sales are made to relatively few retail drug chains and pharmaceutical wholesalers in the U.S. and in other geographic markets. These customers have undergone and may continue to undergo significant consolidation (such as the partnership of Walgreens, Alliance Boots and Amerisource Bergen). Such consolidation has



provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face. Additionally, the emergence of large buying groups representing independent retail pharmacies, and the prevalence and influence of managed care organizations and similar institutions, enable those groups to extract price discounts on our products. Certain of these GPOs had in the past, made aggressive requests for pricing proposals and established commercial alliances resulting in greater bargaining power. We expect the trend of increased pricing pressures from our customers and price erosion in the U.S. generics market to continue. We expect that consolidation of drug wholesalers and retailers will increase pricing and other competitive pressures on generic drug manufacturers, including those in the United States. This dual effect of increased competition and increased purchasing power has resulted in a downward trend for prices for our generics & 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 APIs and/or generics industry.

The traditional model for distribution of pharmaceutical products is also undergoing disruption as a result of the entry or potential entry of new competitors and significant mergers among key industry participants. Also, the consolidation resulting from the merger of CVS Health Corporation and Aetna Inc., if consummated, is expected to create a vertically integrated organization 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 nonprofit company that will provide U.S. 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 U.S. 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.

Furthermore, brand pharmaceutical companies continue to defend their products vigorously. For example, brand companies often sell or license their own generic versions of their products, either directly or through other generic pharmaceutical companies (so-called “**authorized generics**”). No significant regulatory approvals are required for authorized generics, and brand companies do not face any other significant barriers to entry into such market. Brand companies may also seek to delay introductions of generic equivalents, by:

- obtaining and enforcing new patents on drugs whose original patent protection is about to expire;
- filing patent infringement suits that automatically delay the approval of generic versions by the USFDA;
- filing citizens’ petitions with the USFDA contesting generic approvals on alleged health and safety grounds;
- questioning the quality and bioequivalence of generic pharmaceuticals;
- developing controlled-release or other slightly modified versions, which often reduce demand for the generic version of the existing product for which we are seeking approval;
- making arrangements with managed care companies and insurers to reduce economic incentives to purchase generic versions;
- changing product claims and product labelling; and
- developing and marketing over-the-counter versions of brand products that are about to face generic competition.

These actions may increase the costs and risks of our efforts to introduce generic products and/or delay or prevent such introduction altogether, and materially and adversely affect our business, financial condition, results of operations and prospects.

***If we are unable to defend ourselves in challenges related to intellectual property rights, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or we could be subject to substantial liabilities that would lower our profits and adversely affect our financial condition.***

There has been substantial patent related litigation in the pharmaceutical and medical device industries concerning the manufacture, use and sale of various products. We take all reasonable steps to ensure that our products do not infringe valid third party intellectual property rights (“**IPRs**”). However, further to our launch of RUBY-FILL<sup>®</sup>, an innovative technology for PET myocardial perfusion imaging (“**MPI**”), Bracco Diagnostics Inc. (“**Bracco**”) filed two legal challenges against us, the Parent and Jubilant DraxImage Inc. (“**JDI**” and collectively, the “**Jubilant Defendants**”) in the United States District Court for the District of New Jersey (the “**New Jersey District Court**”) and with the United States International Trade Commission (“**USITC**”). These challenges, if not adjudicated in our favor, may result in monetary damages, the exclusion of certain systems and

components from importation as well as suspension and/or cessation of our manufacture and sale of RUBY-FILL® in the United States, which could materially and adversely affect our business, financial condition, results of operations and prospects.

Bracco filed a complaint in the New Jersey District Court against the Jubilant Defendants on March 27, 2018 in connection with RUBY-FILL® for patent infringement arising under the patent laws of the United States, Title 35, United States Code. In the New Jersey District Court complaint, Bracco alleges that the Jubilant Defendants have infringed and continue to infringe five U.S. patents that Bracco owns by assignment. We have carefully reviewed the allegations made by Bracco and are vigorously defending our legal positions. However, legal proceedings of this nature can take a long time to resolve, and we cannot predict when the New Jersey District Court proceeding, which has been stayed pending the final resolution of the USITC proceeding, will be completed. Further, we cannot assure you that the New Jersey District Court will dismiss the claims or rule in our favor. The New Jersey District Court could grant injunctive relief against us (which could result in the suspension and/or cessation of our manufacture and sale of RUBY-FILL® in the United States) and/or award substantial monetary damages against us. The process for obtaining relevant governmental approvals to market our products is rigorous, time-consuming and costly. RUBY-FILL® took around 12 years to develop and get to market, requiring significant investment, including R&D, for which we have yet to generate returns. RUBY-FILL® is a standalone radiopharmaceutical product and is not required for any of the Group's other product lines; however it is distributed through the Group's radiopharmacy distribution network in the United States. We are expecting synergies through the integration of RUBY-FILL® with our radiopharmacy services. Should we be unsuccessful in our defense, we could not only lose our investment but be subject to large damages and/or heavy penalties. We may also incur significant costs and expenses because of these legal proceedings. Further, if the court does not find in our favor, we may be required to implement alternative technology, which could lead to delays or result in difficulties in meeting some of our contractual commitments. This could result in difficulties in our relationships with some customers and could lead to complaints and disputes with them. We do not know the total amount of possible damages and/or other costs that may result from this litigation, and the complaint did not quantify the relief sought by Bracco. Any award for monetary damages, royalty payments or other costs or any interruption of our operations could materially and adversely affect our business, financial condition, results of operations and prospects.

On the same date Bracco filed its complaint in the New Jersey District Court, Bracco also filed a complaint with the USITC alleging violations of section 337 of the Tariff Act of 1930 (the "**Tariff Act**") by the Jubilant Defendants for the importation into the United States, the sale for importation, and the sale within the United States after importation of JDI's RUBY-FILL® products based on alleged infringement of three U.S. patents that Bracco owns by assignment. The three Bracco patents asserted in the USITC complaint are also asserted in the New Jersey District Court matter. On April 25, 2018, the USITC announced that it had voted to institute an investigation. If the USITC finds a violation of section 337, it issues remedial orders barring importation and sale in the United States of the products found to infringe unless it finds such orders would be against public interest. USITC remedial orders in section 337 cases are effective when issued and become final 60 days after issuance unless disapproved for policy reasons by the U.S. Trade Representative within that 60-day period. The USITC referred the investigation to an administrative law judge (the "**ALJ**") to conduct an evidentiary hearing. The evidentiary hearing had been scheduled for January 11, 2019, but was postponed due to the partial U.S. government shutdown. A new schedule for the remaining proceedings has not been entered, but the ALJ has indicated the hearing is likely to occur in April 2019. We have carefully reviewed the allegations made by Bracco and are vigorously defending our legal positions. On May 31, 2018, the Jubilant Defendants filed their response to Bracco's USITC complaint, denying any unlawful activities and noting that the remedial orders that Bracco requests, if issued, would harm public welfare and health, competitive conditions, consumers, and manufacturing in the United States. Additionally, the Jubilant Defendants are implementing changes to the RUBY-FILL® products to design around the three asserted patents. However, these design changes may require significant investment and time to develop and launch, and will be subject to regulatory approval. There is no assurance we will be able to develop and implement these design changes in a timely manner or at all. These design changes have been introduced into the USITC proceeding. On February 8, 2019, the ALJ entered an order that the currently approved RUBY system infringes the three patents, but that the new redesigned RUBY systems do not infringe any of the three patents. The ALJ's order concerning these issues is subject to review by the full Commission of the USITC. The ALJ has not yet ruled on our other defenses in the action, which will be presented at the upcoming evidentiary hearing. The final USITC decision is expected in or around November 2019. We cannot predict the outcome of the investigation and may be faced with exclusionary remedies against us (which could result in the suspension and/or cessation of our manufacture and sale of RUBY-FILL® in the United States) if the USITC determines we are in violation of section 337 of the Tariff Act. While the revenue contribution from the sales of RUBY-FILL® was not material in financial year ended March 31, 2018, we expect that this will increase in the future and should we suspend or cease the manufacture and sale of RUBY-FILL®,

we could lessen or lose the potential growth that RUBY-FILL<sup>®</sup> is expected to bring to our business, and any orders against us could materially and adversely affect our business, financial condition, results of operations and prospects. On August 22, 2018, JDI filed three petitions at the United States Patent and Trademark Office (“USPTO”) challenging the validity of certain claims of U.S. Patent Nos. 9,299,467 and 9,299,468, which are asserted against the Jubilant Defendants in the Bracco New Jersey District Court complaint but are not asserted in the Bracco USITC complaint (Nos. IPR2018-01448, -1449, -1450). The petitions request the USPTO to conduct *inter partes* reviews (“IPR”) of the two patents and to cancel all claims asserted in the New Jersey District Court action as invalid over prior art. See “*Business—Legal Proceedings—RUBY-FILL<sup>®</sup> Proceedings*” for further details.

Companies in the pharmaceutical industry commonly assert patent and other IPRs 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 any 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 capitalize 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 there being any such infringements in the past. In particular, an ANDA for a generic formulation utilizing 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 utilized 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.

***Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, or if we are required to conduct additional clinical trials for certain of our product candidates, we or any industry partners involved in the conduct of such trials may be unable to obtain required regulatory approvals, and therefore may be unable to commercialize our product candidates on a timely basis or at all.***

Clinical testing, in which people volunteer to test new treatments, even when utilizing expedited approval pathways such as the 505(b)(2) pathway, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the USFDA as safe and effective. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we and/or our industry partners for such candidate typically must demonstrate through extensive preclinical and clinical trials that our product candidates are safe and effective in humans. The process for obtaining relevant governmental approvals to market our products is rigorous, time-consuming and costly. For example, our recent launch of RUBY-FILL<sup>®</sup>, an innovative technology for PET MPI we developed took around 12 years to get to market. It is also impossible to predict the extent to which this process may be affected by legislative and regulatory developments. Due to these and other factors, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential sales that we might earn from these product candidates due to the lost time before potential commercialization and potential changes in the competitive landscape by the time such product candidates are commercialized, if they are commercialized at all. We may also suffer reputational harm from such delays or failures that could affect our business more broadly.

We have a clinical program in place for I-131 mIBG comprising an Expanded-Access Program, Phase II clinical trials run by JDI and Phase III trials relating to supply and data sponsored by Children's Oncology Group and run by the National Institute of Health ("NIH"). Clinical trials must be conducted in accordance with EMA, USFDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Institutional Review Boards ("IRBs" and each, an "IRB") at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP and other requirements. We depend on our industry partners, including medical institutions and in particular Clinical Research Organizations ("CROs"), to conduct clinical trials in compliance with Good Clinical Practice ("GCP"), and in compliance with other applicable regulatory and technical requirements. See "*—We may rely on third parties to conduct our clinical trials. 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 of or commercialize any potential product candidates*". To the extent they fail to do so, we may be affected by increased costs, program delays or both, which may harm our business.

In addition, the commencement, adequate recruitment and completion of clinical trials for our product candidates may be delayed, suspended or terminated as a result of many factors, including but not limited to:

- negative or inconclusive results, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expected to be promising;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site and changes in regulatory requirements, policies and guidelines;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- delays or failure to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- delays resulting from the need to obtain regulatory approval of changes to existing trial protocols;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to ensure adequate statistical power to detect statistically significant treatment effects, including as a result of small eligible patient populations;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our third party research contractors failing to comply with regulatory requirements or to meet their contractual obligations to us in a timely manner, or at all;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;
- the quality or stability of a product candidate falling below acceptable standards;

- the inability to produce or obtain sufficient quantities of a product candidate to complete clinical trials; and
- exceeding budgeted costs due to difficulty in predicting accurately costs associated with clinical trials.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment and completion of the trials are affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

***Our facilities are subject to client inspections and quality audits and any failure on our part to meet their expectations or to comply with the quality standards set out in our contractual arrangements, could result in the termination of our contracts and adversely affect our business, financial condition and results of operations.***

Pursuant to our contractual arrangements, certain of our clients have the right to regularly examine our manufacturing processes, quality control and procedures and registers of our manufacturing facilities after reasonable notice and at a reasonable time to ensure that our services are meeting their internal standards and regulatory requirements. Most of our clients routinely inspect and audit our facilities. Any failure on our part to meet the expectations of our clients and to comply with the quality standards set out in our contractual arrangements, could result in the termination of our contracts and our clients may choose to source their requirements from our competitors. We may also incur significant costs to upgrade our facilities and manufacturing processes. The occurrence of any such event will not have an adverse effect on our business, financial condition and results of operations.

***We may not be able to hire and retain sufficient numbers of qualified professional personnel that we need to succeed because these personnel are limited in number and in high demand.***

Given the size, complexity and geographic reach of our business and our multiple business lines, we are reliant upon our ability to recruit and retain highly qualified professional personnel and other employees. Failure to hire and retain high-quality employees may delay or prevent the achievement of major business objectives. For example, it is highly important that we recruit and retain high quality R&D specialists in view of our business lines' R&D focus. We commit substantial resources to this effort given the competition for qualified and experienced scientists from biotechnology, pharmaceutical, radiopharmaceutical and chemical companies, as well as universities and research institutes globally. Given the nature and complexity of the regulatory regime of the pharmaceutical industry, we employ a significant number of quality control personnel and we also have a dedicated regulatory team. Some of the entities with which we compete for personnel have greater financial and other resources than we do or are located in geographic areas which may be considered by some to be more desirable places to live. In particular, we will need to hire significant numbers of new, highly-skilled scientific and technical personnel to staff our pharmaceutical business, including personnel with radiopharmaceuticals expertise. In addition, our increased focus on innovative and specialty pharmaceuticals, in particular our

radiopharmaceuticals business, requires more extensive use of a direct sales force than does our core Generics & APIs business segment, due to the greater complexity of our specialty pharmaceuticals products. Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. We may also need to enter into co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well-aligned to achieve maximum penetration in the market. Any failure to attract or retain qualified personnel for such R&D functions, quality, regulatory affairs and sales personnel as well as staff generally in functions such as manufacturing, finance, information technology and management, or to enter into third party arrangements on favorable terms could adversely affect our business and our financial condition and results of operations could be harmed. There can be no assurance that we will be able to successfully attract, assimilate or retain sufficiently qualified personnel. If our recruitment, retention and motivation efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

***Significant disruptions of our information technology systems and/or infrastructure or breaches of our data security could adversely affect our business.***

A significant invasion, interruption, destruction or breakdown of our information technology systems and/or infrastructure by persons with authorized or unauthorized access could negatively impact our business and operations. In the ordinary course of our business, we collect and store sensitive data in our data centers 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. Although we have not encountered any significant disruptions or breaches that have had a material impact on the Group's financial condition and/or operations and have invested in measures to reduce these risks we cannot guarantee that these measures will be successful in preventing compromise and/or disruption of our information technology systems and/or infrastructure and related data.

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. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, responding to data subject requests, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20.0 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. 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, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European activities.

***We may not be able to implement our business strategies on schedule or within our budget or at all.***

We have implemented and may from time to time implement strategies to meet strategic objectives of our business including but not limited to being closer to our customers, diverse product and service portfolio through differentiated and complex offerings, continuing to strengthen leadership positions in our key business segments, offering an integrated business model and pursuing strategic acquisitions.

The successful implementation of our business strategies is subject to significant business, economic and competitive uncertainties and contingencies, including, among others, continued growth of the pharmaceutical market in the United States, Canada and Europe, government policies, competition, compliance with environmental or other laws and regulations, delays in securing requisite government approvals and a downturn in the economy or changes in market conditions, natural disasters, labor disputes or civil unrest, any of which could delay or inhibit the implementation of our business strategies. For example, one of our business strategies is to expand our business through selective acquisitions, which involves a number of risks and uncertainties. See "*If we have difficulty in integrating companies or businesses that we merge with or acquire, we may be unable*

*to realize the anticipated benefits of such mergers or acquisitions, or our existing business may be harmed". Any delays or failure to successfully implement our business strategies could result in a loss or delayed receipt of revenue, an increase in financing costs or the failure to grow our business or increase our profitability, any of which may materially and adversely affect our business, financial condition, results of operations and prospects.*

***Compliance with increasingly stringent environmental, health and safety laws relating to our manufacturing facilities may adversely affect our business and results of operations.***

Our operations spread across different geographies and are subject to a wide range of environmental, health and safety ("EHS") laws and regulations and regulated by various environmental agencies and authorities including the United States Environmental Protection Agency ("USEPA"), the Environment and Climate Change Canada and the Ministry of Environment, Forest and Climate Change, including the state pollution control boards in India. Some of our R&D and manufacturing operations involve dangerous chemicals, processes and by-products. The manufacture of pharmaceuticals and sterile injectables and non-sterile products is also subject to stringent regulations. Such EHS regulations govern activities including the generation, storage, handling, treatment, transportation and disposal of hazardous substances and wastes, wastewater discharges, air emissions, human health and safety, process safety and the clean-up of contaminated sites. Many of our operations require permits, and these permits are subject to modification, renewal and revocation by issuing authorities. Our permits may include requirements and conditions which could result in significant additional costs or environmental obligations for us. We have incurred, and will continue to incur, substantial ongoing capital and operating expenditures to ensure compliance with current and future EHS laws and regulations. In the ordinary course of business, there may be instances where certain of our permits have expired and applications for renewal of these permits have been submitted upon expiry. If the necessary renewals are not granted or granted subject to certain restrictions, our business or operations may be adversely affected.

In 2017, the USEPA had cited our subsidiary, Jubilant Cadista Pharmaceuticals Inc. ("**Jubilant Cadista**") for violating the Resource Conservation and Recovery Act, which is a federal law governing the treatment, storage and disposal of hazardous waste, including lab solvents and corrosive cleaner wastes. We provided a satisfactory action plan to comply with the observations of the USEPA and after discussions with the USEPA, Jubilant Cadista paid a US\$35,000 penalty.

The EHS laws, regulations and permits that govern our operations tend to become increasingly stringent over time, and we could in the future assume additional obligations and therefore incur substantial incremental costs to ensure our continued regulatory compliance. Any violations of EHS requirements may result in substantial fines or penalties, the imposition of other civil or criminal sanctions, clean-up costs and other remediation or restoration requirements, claims for personal injury or property damages, the installation of costly pollution control equipment, or restrictions on, or the suspension of, our operating permits or activities.

We have environmental liability insurance coverage for some of our facilities, which is in line with industry practice. However, we could be exposed to claims that are only partially or not covered at all. For example, our environmental insurance in the United States does not cover any penalties for non-compliance with laws, regulatory fines or environmental capex, and only covers the cost of decontamination or removal of debris, subject to policy restrictions and limitations. In addition, while our all risks of physical loss or damage policy for our radiopharmacies in the United States contains a sublimit of US\$5 million for damages due to radioactive contamination at such radiopharmacies, the liabilities from nuclear or radioactive contamination is generally not covered by our insurance policies. If we incur substantial costs that we have not made adequate provisions for or which are not covered under our insurance, our business, financial condition, results of operations and cash flows could be materially and adversely affected. Such costs may increase our expenses and reduce our profit margins. Further, if we are unable to comply with environmental laws and regulations, we may lose customer orders or be subject to monetary penalties, criminal sanctions or other enforcement actions by regulatory bodies including manufacturing facility closures or product withdrawal, which could further adversely affect our business, financial condition and results of operations. See "*Business—Environmental Matters*" for further details.

***Risks from the handling or release of hazardous materials could harm our results of operations and reputation, including by causing environmental contamination.***

Our operations are subject to the operating risks associated with pharmaceutical and chemical manufacturing, including the related storage and transportation of raw materials, products and waste.

Such hazards may cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and the imposition of civil or criminal penalties. The occurrence of any of these events may subject us to litigation and/or significantly reduce the productivity and profitability of a particular manufacturing facility and harm our results of operations. We may also be the subject of protests by affected communities and our reputation could be harmed.

Although we maintain an industrial all-risk insurance policy for all our primary manufacturing facilities that we believe is in accordance with customary industry practices, we cannot assure you that this insurance will be adequate to cover fully all potential hazards incidental to our business.

Our radiopharmaceutical business as well as research and manufacturing activities also involve the use of chemical, biological, radiological or nuclear substances. We cannot eliminate the risk of accidental or man-made contamination, injury or damage from these materials. JDR maintains a fleet of drivers and leased vehicles delivering radiopharmaceuticals from our radiopharmacies directly to our customers on a daily basis. JDR also engages delivery services with third party commercial couriers when required to supplement delivery requirements and fleet services. If the radioactive materials being transported are mishandled, not securely contained during transport or released into the environment, these materials could cause substantial damage or personal injuries resulting in significant legal claims against us. In addition, evolving regulations concerning the handling and transportation of certain materials could result in increased future capital or operating costs to our business.

In the event of an accident or environmental discharge, we may be held liable for any resulting damages. We cannot assure that the amount of our insurance coverage will be sufficient to satisfy any such damages. As a result, any such accident or man-made contamination, injury or damage from these materials could have a material adverse effect on our business, financial condition, results of operation and prospects.

In addition, in the United States, as well as in many other jurisdictions, a current or previous owner or operator of real estate may be liable for contamination resulting from the presence or discharge of hazardous or toxic substances at that property, and may be required to investigate and clean up such contamination at or emanating from that property. In the United States, under the Comprehensive Environmental Response, Compensation and Liability Act (“**CERCLA**”) and related state laws, certain persons may be liable at sites where or from which release or threatened release of hazardous substances has occurred or is threatened. These persons can include the current owner or operator of any property where a release or threatened release occurred, any persons who owned or operated the property when the release occurred, and any persons who disposed of, or arranged for the transportation or disposal of, hazardous substances at a contaminated property. Liability under CERCLA is strict, retroactive and, under certain circumstances, joint and several, so that any responsible party may be held liable for the entire cost of investigating and remediating the release of hazardous substances. We or our predecessors-in-interest operate or operated at a number of sites with a history of industrial use and the potential for releases of hazardous substances. As is the case with all companies who own or operate industrial real property, we face potential exposure from future claims and lawsuits involving environmental matters, including radioactive, soil and water contamination, personal injury or property damage allegedly caused by hazardous substances that we manufactured, handled, used, stored, transported, spilled, disposed of or released.

***If we have difficulty in integrating companies or businesses that we merge with or acquire, we may be unable to realize the anticipated benefits of such mergers or acquisitions, or our existing business may be harmed.***

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, joint ventures or other business combinations may involve a number of risks, including diversion of management’s attention, failure to retain key acquired personnel and clients, unanticipated events or circumstances, cultural differences, legal liabilities, regulatory risks and amortization of acquired intangible assets and other integration challenges or operational complexities, some or all of which could harm our financial condition and results of operations. We may also incur substantial additional indebtedness and contingent liabilities relating to the businesses we acquire. Any such mergers or acquisitions, joint ventures or other business combinations may also disrupt our ongoing businesses, which may adversely affect our relationships with customers, employees, regulators and others with whom we have business or other dealings. In particular, for newly acquired businesses, we cannot assure you that we have sufficient experience and expertise with operating and managing such businesses. We may also face challenges scaling-up the business during the integration process. Further, if we are unable to realize synergies or other benefits expected to result from any acquisitions, joint ventures or other business combinations, or to generate additional revenue to offset any unanticipated inability to realize these expected synergies or other benefits, our growth and ability to compete may be impaired, which would require us to focus additional resources on the integration of operations rather than other profitable areas of our business and may otherwise cause a material adverse effect on our business, financial condition and results of operations.

In September 2017, we substantially acquired all of the assets which comprised Triad’s radiopharmacy business. If we are not able to successfully integrate the radiopharmacy business with the rest of our business or increase



the efficiency and coverage of our radiopharmacy network through repositioning of our geographic footprint, we may be unable to realize the anticipated benefits of such acquisition and/or our existing business may be harmed.

We may acquire or make strategic non-controlling investments in complementary businesses or assets, or enter into strategic partnerships or alliances with third parties in order to enhance our business. It is possible that we may not identify suitable investment, partnership or alliance candidates, or if we do identify suitable candidates, that we may fail to complete those transactions on terms commercially acceptable to us or at all, or fail to realize strategic benefits or encounter disputes with other partners in the partnerships or alliances we enter into, and our competitiveness and growth prospects could be adversely affected.

***We may need additional capital in the future to meet our financial obligations and pursue our business objectives.***

We plan to continue to look for opportunities to increase our existing production capacity, expand our product portfolio and improve the production technologies through our R&D team. Projects aimed at expansion or growth of our business require significant capital expenditure to expand, refurbish, renovate or upgrade existing facilities as well as to develop new facilities and/or business lines or make major acquisitions or investment. Our ability to successfully implement expansion or growth plans is subject to risks and uncertainties. If adequate funds are not available on acceptable terms and on a timely basis, we may be required to delay or reduce the scope of our growth plans. For example, we are in the process of expanding the solid dosage formulations capacity at our Roorkee Facility and are currently also exploring options to further increase our API production capacity including expanding the capacity of our existing Nanjangud Facility by debottlenecking, increasing the capacity of our Spokane Facility, building a new API facility at a new location and/or acquiring an existing API facility, among other things. However, there is no assurance we will be successful in increasing our capacity in a timely manner or at all. See “*Management’s Discussion and Analysis of Financial Condition and Results of Operations—Capital Expenditures*” for further details of our expected capital expenditures. Failure to meet customers’ demands in existing markets or new markets could have a material adverse effect on our business. In addition, any significant increases in raw materials costs unforeseen in the project plan and any inability to sell the products produced at volumes and/or price levels envisaged in the project plan could adversely affect the success of our projects. Due to the significant amount of capital required and the long lead time between planning and completion of such projects, project failure could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We are dependent on the success of our R&D and the failure to develop new or improved products or process improvements or production techniques could subject us to write-offs or otherwise adversely affect our business, financial condition and results of operations and have a negative impact on our competitive position.***

Our success depends on our ability to improve our existing products, develop commercially viable and sustainable new products or to develop process improvements that can improve time, quality and cost efficiency. The pharmaceutical industry is characterized by frequent advancements in technology, coupled with high R&D expenses. In addition, rapid and frequent advancements in technology and changes in market demand can often render existing technologies and equipment obsolete and could require substantial new capital expenditures or subject us to write-offs.

During the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2017 and 2018, we incurred US\$38.8 million, US\$33.5 million, US\$23.3 million and US\$25.5 million, respectively, on R&D, representing 8.4%, 5.4%, 5.5% and 4.5%, respectively, of our total revenue from operations in those periods. We cannot assure you that the investments we have made in R&D will yield satisfactory results in terms of improved products, or will yield any results at all. Despite our investments in this area, our R&D efforts may not result in the discovery or successful development of new products. In addition, even where we successfully obtain product registrations and/or market authorizations for any such new or improved products, there can be no assurance that the new or improved product will be commercially successful. Further, if our competitors develop new processes or production techniques, or improve existing processes or production techniques that may give them significant cost and marketing advantages, we may be unable to retain our customers, which would adversely affect our revenues and profitability.

***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 would be adversely affected.***

Our future success will depend to a significant degree on our ability to continue to develop and commercialize new pharmaceutical products in a timely and cost-effective manner. The development and commercialization of

new products is complex, time-consuming and costly. Due to the long lead times associated with obtaining regulatory approvals for many of these products, as well as the competitive advantage that can come from gaining early approval, it is important that we maintain a sufficiently large portfolio of products and a product pipeline and manage their development and approval processes so as to bring products to market on a timely basis.

The submission of an application to a regulatory authority does not guarantee that approval or licensure to commercialize or market a product will be granted in a timely manner or at all. Each authority may impose its own requirements and/or delay or refuse to grant approval, even when a product has already been approved in another country. In our principal markets, the approval process for a new product is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to two years from the date of application. This registration process increases the cost to us of developing new products and increases the risk that we will not succeed in selling them successfully. Additionally, if our customers fail to obtain the required approval for their drug formulations that utilize our APIs, or if such approval is delayed, our customers may decide not to launch such formulations and cancel their tie-up arrangement with us, which may adversely impact our API sales. The occurrence of any such incidents will not have a material adverse impact on our business, financial condition, results of operations and prospects.

The success of our new product offerings will depend upon several factors, including our ability to properly anticipate and respond to customer needs, to obtain timely regulatory approval of new products, identify available suppliers and manufacture such products. If we are not able to bring enough products to market, or if products are brought to market after competing products are commercialized, our growth strategy may not be successful and our business would be adversely affected.

Furthermore, if we are unable to expand our production capacity or increase utilization as needed, our business, financial condition and results of operations will be adversely impacted. We also cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products. In the event of excess production and expiry of outdated stock, we might also have to bear the cost of disposal of the excess products. We also may not be able to utilize our available capacity, which in turn could affect our ability to recover our product development investments. If market conditions change or if our operations do not generate sufficient funds or for any other reasons, we may decide to delay, modify or forego some aspects of our growth strategies. Our future results of operations may be adversely affected if we are unable to implement our growth strategies, which include proper management of our product portfolio.

***If we are unable to respond adequately to the increased competition that we may face in the future we will lose market share and our revenues or profits will go down.***

We face competition for many of the products that we currently manufacture. Our competitors may succeed in developing technologies, processes and products that are more effective and/or more cost effective than any we may develop or license. These developments could render our technologies, processes or products obsolete or uncompetitive, which would harm our business and financial condition. Increased competition may also lead to product price erosion in the future as new companies enter the market and/or novel or advanced technologies emerge.

We believe that some of our competitors have broader product ranges, stronger sales forces and better segment positioning than we do, which may enable them to compete more effectively in segments where they may have a competitive advantage. Some of our competitors may be willing to operate at lower selling prices in order to gain market share, which may put competitive pressure on the prices of our products. Additionally, some of our competitors enjoy a lower cost base for some of our raw materials due to the availability of such raw materials at low prices. Furthermore, consolidation of market participants in our industry has occurred in recent years, which may continue to occur and may challenge our competitive position and market share.

Our competitive prospects are dependent on whether we are able to, among other things:

- diversify and enhance our product lines and services in order to keep ahead of any developments by our competitors;
- achieve sufficient market penetration within a reasonable period following commercialization of our products and services;
- attract and retain qualified technical and scientific staff;
- effectively manage costs; and
- establish our products and services as equivalent or of better quality than those of our competitors.

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

### *Specialty Pharmaceuticals*

We face extensive competition in our Specialty Pharmaceuticals business 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 well-established. If competitors introduce new products or new variations on their existing products, our marketed 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, GE Healthcare, Bracco and Curium, as well Cardinal Health 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, the introduction of generic versions when our proprietary products lose their patent protection or the new entry 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.

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.

### *Generics & APIs*

We face intense competition in the market for generics, including for both APIs and solid dosage formulations. According to Frost & Sullivan, the average price erosion for generics & APIs products is expected to be between 10-12% in the U.S. markets for generic pharmaceuticals in 2018. The generic business segment of the pharmaceutical market is characterized 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, 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 capitalize on their economies of scale and 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. Once we develop these products, we need to identify and partner with a generic drug manufacturer that will use our APIs in their formulation or our solid dosage formulations to receive the required approvals. The regulatory approval process for new suppliers of APIs to generic manufacturers imposes significant timing constraints on 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.

In our solid dosage formulations business, any delays resulting from the failure in the bioavailability and bioequivalence studies or regulatory approvals may significantly reduce our capability to gain market share in this business.

Our competitors in APIs and solid dosage formulations include other pharmaceutical companies that develop or may develop products within the same therapeutic areas as our current and future products, such as major pharmaceutical and chemical companies, specialized contract research organizations, R&D firms, universities and other research institutions. Many of our competitors have greater financial resources, marketing capabilities and greater experience than we do in the testing and production of APIs and solid dosage formulations, obtaining regulatory approvals, manufacturing and marketing. If our competitors developing APIs that are coming off patent for sales in regulated markets are able to gain early approval and commercialize 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 and solid dosage formulations, 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, in particular in relation to our API business. If we are unable to obtain new customers or maintain our relationship with existing customers, we may be unable to successfully commercialize the APIs currently in the development phase.

***We are subject to certain competition and antitrust laws throughout the world, including federal and state antitrust laws in the United States.***

Our business is subject to applicable competition and antitrust laws throughout the world, including federal and state antitrust laws in the United States. For example, the federal government and most states in the United States have enacted antitrust laws that prohibit specific types of anti-competitive conduct, including price fixing, wage fixing, concerted refusals to deal, price discrimination, monopolization, and tying arrangements, as well as acquisitions that have, or may have, a substantial adverse effect on competition. In addition, we are subject to similar antitrust and anti-competition laws in countries other than the United States, and as an importer of certain products into the United States, the potential jurisdiction of the USITC.

Similarly, the Competition Act, 2002, of India, as amended (“**Indian Competition Act**”) regulates, inter alia, practices having an appreciable adverse effect on competition in the relevant market in India (“**AAEC**”). Under the Indian Competition Act, any formal or informal arrangement, understanding or action in concert, which causes or is likely to cause an AAEC is considered void and may result in the imposition of substantial penalties. The Indian Competition Act also prohibits abuse of a dominant position by any enterprise.

We may become subject to legal action or investigations and proceedings by national and supranational competition and antitrust authorities for alleged infringements of antitrust laws, which could result in sanctions, fines or other forms of liability, prompt follow-on private or putative class action claims or otherwise damage our business reputation, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Such laws and regulations could also limit or prohibit our ability to grow in certain markets. In May 2017, our Company and one of our Group companies were notified that the United States Federal Trade Commission (“**USFTC**”) had begun a non-public investigation into certain competition law matters relating to our sales and distribution practices in our radiopharmaceuticals business and our then-pending acquisition of substantially all of the assets which comprised Triad’s radiopharmacy business. In February 2018, our Company and Triad received two civil investigative demands (“**CIDs**”) from the USFTC requesting certain information about our business and operations. The investigation is ongoing and we have produced documents and information in response to the CIDs, further to which we have not received further responses from the USFTC. To date, the USFTC has not alleged any wrongdoing by the Company or any of our Group companies; however, no assurance can be given as to the timing or outcome of the investigation. If this investigation were to result in further inquiries or enforcement proceedings, we may incur substantial costs, be exposed to unanticipated civil liabilities or monetary penalties and be subject to restrictions on our activities, including but not limited to restrictions on our sales and distribution practices and the institution of monitoring obligations, in each case in a manner that may be materially adverse to our business, financial condition and results of operation. Moreover, the investigation and its outcome could expose us to negative publicity, which could adversely affect our brands, reputation and customer preference for our products.

***Supply interruptions, any shutdowns of our manufacturing facilities or other manufacturing or production problems caused by unforeseen events may reduce sales and adversely affect our business, financial condition and results of operations.***

We are dependent on our manufacturing facilities for our production, including certain radiopharmacies. We may encounter manufacturing problems or experience difficulties or delays in production as a result of any occurrence of the following events, or any other events beyond our ability to control:

- forced or voluntary closings of manufacturing plants, including as a result of regulatory inspections, see “—As the manufacture of our products is technically complex and highly regulated, product recalls, regulatory inspection failures or shortcomings at our manufacturing facilities or other problems may reduce sales, adversely affect our business, financial condition and results of operations and delay the launch of new products, and in some cases may lead to closures of our facilities”;
- problems with supply chain continuity, including as a result of weather or a natural or man-made disaster, at one of our facilities or at a critical supplier or vendor;
- manufacturing shutdowns, product shortages, including backorders and discards, and delays in product manufacturing;

- labor strikes and lock-outs that may result in temporary shutdowns or manufacturing disruptions;
- problems with manufacturing, quality assurance/quality control or supply, or governmental approval delays, due to our consolidation and rationalization of manufacturing facilities and the sale or closure of certain sites;
- the failure of a sole source or single source supplier to provide us with necessary raw materials, supplies or finished goods for an extended period of time, which could impact continuous supply;
- shortages of qualified personnel;
- changes in applicable local and international legislations, rules and regulations such as serialization;
- changes in environmental laws and regulations;
- failures or bottlenecks in production processes, especially if we are unable to obtain adequate supply of utilities such as steam, power and water, or our inability to successfully implement debottlenecking measures to reduce idle time or improve operating efficiency by reducing plant outages, wastage or yield losses or otherwise.
- the failure of a third party manufacturer to supply us with finished products on time;
- construction or regulatory approval delays related to new facilities or the expansion of existing facilities;
- product recalls or market withdrawals;
- our equipment and production facilities becoming obsolete; and
- other manufacturing or distribution problems including limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations or other business interruptions that could impact continuous supply.

Any of the above may result in reduced production, reduced sales, and adversely affect our business, financial condition and results of operations. Additionally, as our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-down, delay in the release of product batches, product recalls, spoilage or regulatory action. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. Specific to our radiopharmaceutical business, the aging and eventual retirement of our cyclotrons will involve substantial costs associated with decontaminating and decommissioning the sites where they are used and regulatory risks in the event that the decontamination and decommissioning process is not done correctly or according to applicable regulatory requirements.

Certain of our products are produced by a single manufacturing facility, such as our allergy therapy products, which currently are solely produced by our Spokane Facility and our radiopharmaceutical products, which currently are solely produced by our JDI Montreal Facility. Our key generics manufacturing sites also may have capacity constraints and, at times, we may not be able to generate sufficient supplies of finished goods. If any of the foregoing events, or any other events arise that affect the production of such products by the relevant manufacturing facility, we will be unable to reallocate production to alternative manufacturing facilities, which may affect our ability to manage our capacity utilization and product mix to the extent that our business may be materially and adversely affected.

Similarly, our Nanjangud Facility is our sole manufacturing facility for APIs. On account of this facility being located in India, it may be subject to risks that are typically applicable to developing countries, such as political instability resulting from a change in government, changes in regulatory, economic, fiscal and taxation policies, social and civil unrest, terrorist attacks, regional conflicts and other political, social and economic developments which may affect the operations or profitability of our Nanjangud Facility and our other manufacturing facility located in India. In addition, if there is a major discontinuity of operations, we may not be able to address such issues.

***Our product candidates are subject to government price controls in certain jurisdictions that may affect our revenue.***

There has been heightened governmental scrutiny in the United States, the European Union and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level,

legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

***We are subject to numerous political, economic, legal, tax, operational and other risks as a result of our international operations, including risks of possible nationalization, expropriation and other restrictive governmental actions.***

We are subject to numerous political, economic, legal, tax, operational and other risks as a result of our international operations, including risks of possible nationalization, expropriation, price controls, capital controls, exchange controls, increased taxes and levies, and other restrictive governmental actions, as well as the outbreak of hostilities or political and governmental instability which could adversely impact our business in many ways. In particular, we believe we are most susceptible to these risks in the United States, Canada and India, being jurisdictions where a substantial portion of our business and assets are conducted and/or located.

Any compulsory acquisition or expropriation of any part of our properties, including land where our manufacturing facilities are located, by any governmental authorities in the name of public interest or otherwise may cause disruptions to our production activities and could adversely affect our business. For example, a small piece of our land on which our CMO Montreal Facility and JDI Montreal Facility are situated is in the process of being acquired by the Ministère des Transports, de la Mobilité durable et de l'Électrification des transports of Québec for the construction of Réseau Électrique Métropolitain (the "REM"), a new rapid transit system, currently under planning and construction. The expropriation procedures are undertaken pursuant to the Expropriation Act respecting the Réseau électrique métropolitain, LQ 2017, c. 17, which was adopted by Quebec's National Assembly and became effective on September 27, 2017 and communicated to us by way of an expropriation notice in October 2017. We will receive compensation for the land expropriation and we do not anticipate any material disruption to our CMO Montreal Facility or JDI Montreal Facility as a result, however there is no assurance that the construction of REM near our CMO Montreal Facility and JDI Montreal Facility will not cause any disruptions at or near our the site of our facilities or that any future actions taken by governmental authorities in respect of properties will not adversely affect our business.

***Any trade or import protection policies may affect our business.***

We distribute our products to various countries internationally. In the event that any of these countries to which we export imposes trade sanctions or enforces import restrictions or tariffs in relation to our products, our business and results of operations may be adversely affected. For example, the ongoing trade war between the United States and China has resulted in the Trump Administration and China imposing tariffs on Chinese products and U.S. products, respectively. Recently, the Trump Administration imposed 25% tariffs on a variety of imports from China and subsequently implemented tariffs on additional goods from China. If the Trump Administration continues the recent China tariffs, or if additional tariffs or trade restrictions are implemented by the United States or other countries in connection with a global trade war, the cost of our products manufactured in China, or other countries, and imported into the United States or other countries could increase, which in turn could adversely affect the demand for these products or require us to raise our prices, which may result in the loss of customers and harm our business. The North American Free Trade Agreement ("NAFTA") is also currently under review by the respective signatory countries, and given our operations and manufacturing facilities in Canada, any material change in the terms to NAFTA could adversely affect our business.

***Because we have substantial international operations, our sales and profits may be adversely affected by currency fluctuations and restrictions as well as credit risks and appreciation or depreciation of other currencies against the U.S. dollar could affect the cost competitiveness of our international sales and reduce our overall profitability, increase the cost of our imports, borrowings and repayment of indebtedness and reduce our net income.***

For the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2017 and 2018, 29.4%, 19.9%, 20.1% and 18.0%, respectively, of our total revenue from operations came from sales outside North America. As a result, we are subject to significant foreign currency risks, including repatriation restrictions

in certain countries. An increasing amount of our sales, particularly in Canada, India and European countries, is recorded in local currencies, which exposes us to the direct risk of exchange rate fluctuations, devaluations or hyperinflation. 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. In particular, in the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2018, we recorded sales and expenses in various currencies such as the Indian rupee, Canadian dollar and Euro. As a result, fluctuations in exchange rates between the currencies in which such sales are generated and expenses are incurred and the functional currencies of the respective businesses may result in translation gains or losses.

We have in the past utilized certain hedging instruments and floating to fixed interest rate swap agreements. However, we do not currently use derivative financial instruments or other “hedging” techniques to cover our potential exposure, and some elements of our financial statements, such as our equity position or operating profit or borrowings, are not fully protected against foreign currency exposures. Therefore, we cannot assure you that we will be able to limit all of our exposure to exchange rate fluctuations that could affect our financial results. Failure to hedge effectively against currency fluctuations may materially and adversely affect our financial condition and results of operations.

***If we cannot maintain our position as a low-cost manufacturer in certain of our business lines, we may not be able to capture anticipated business opportunities or we may lose market share.***

We currently position ourselves as a low-cost manufacturer and compete on the basis of cost in our Generics & APIs business segment, comprising APIs and generic solid dosage formulations. We also believe that we need to provide low cost manufacturing options for our CMO customers to remain competitive. Multinational corporations have been increasing their use of contract manufacturing, entering into agreements and/or arrangements with highly regarded companies, which include certain of our competitors, which can supply products at low cost that conform to quality standards set in developed markets. Furthermore, if our competitors adopt new technology more quickly or more successfully than we to improve on the manufacturing time and cost-effectiveness of the competing low cost products they offer, they may gain market share at our expense. The emergence of substitutes to our core products may also negatively affect our sales. If we cannot establish and maintain our position as a low-cost manufacturer of high-quality products, we may not be able to capture anticipated business opportunities or we may lose market share.

The prices and availability of our raw materials and energy needs may vary with market conditions and may be highly volatile. Where feasible, we enter into multi-year contracts with our customers, with volume commitments and prices which are linked to key input material prices. However, there have been in the past, and may be in the future, periods during which we cannot pass raw material price increases on to customers due to competitive pressure. Even in periods during which raw material prices decrease; we may suffer decreasing operating profit margins if the prices of raw materials decrease more slowly than do the selling prices of our products.

***If we are unable to patent new processes and protect our proprietary information or other intellectual property, our business may be adversely affected.***

We generally rely on a combination of patents, licensing arrangements, non-disclosure agreements and non-competition agreements to protect our proprietary intellectual property. See “*Business—Intellectual Property Rights*”. As at December 31, 2018, we have been granted patents for intellectual property in various countries for innovations, including 19 active patents granted relating to APIs in a number of different countries, five active patents granted relating to solid dosage formulations in a number of different countries, 123 active patents granted relating to radiopharmaceutical products in a number of different countries and one active patent granted relating to allergy therapy products in the United States. As at December 31, 2018, we held 94 registered trademarks across the United States, India, Canada, Europe and other jurisdictions worldwide. Due to the different regulatory bodies and varying requirements globally, we may be unable to obtain intellectual property protection in certain jurisdictions for our products or processes. If third parties decide to terminate the licensing arrangements with the Company for usage of their registered trademarks, we may not be able to continue to market our products under the licensed brand name, which could adversely affect our competitive business position. Further, two trademarks are held by the Parent which have been duly assigned to our Indian subsidiary company, Jubilant Generics Limited (“JGL”) and applications have been made to the Indian regulatory authorities for change in ownership. Until the assignment of trademarks is recorded by the regulatory authorities, there can be no assurance that we would be recognized as the owner of such trademarks.

While we intend to defend against any threats to our intellectual property, we cannot assure you that our patents, trade secrets or other agreements will adequately protect our intellectual property. Our patent rights may not

prevent our competitors from developing, using or commercializing products that are functionally equivalent or similar to our products. Further, our patent applications may fail to result in patents being issued, and our existing and future patents may be insufficient to provide us with meaningful protection or a commercial advantage. We cannot assure you that patents issued to or licensed by us in the past or in the future will not be challenged or circumvented by competitors or that such patents will be found to be valid or sufficiently broad to protect our processes or to provide us with any competitive advantage. We may be required to negotiate licenses for patents from third parties to conduct our business, which may not be available on reasonable terms or at all.

We also rely on non-disclosure agreements and non-competition agreements with certain employees, consultants and other parties to protect trade secrets and other proprietary rights that belong to us. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. Any inability to patent new processes and protect our proprietary information or other intellectual property, could adversely affect our business.

***If the USFDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.***

We may develop proprietary product candidates for which we may seek USFDA approval through the Section 505(b)(2) regulatory pathway. We have received 505(b)(2) approvals for RUBY-FILL® Rubidium Rb82 Generator and Elution System and Drax Exametazime™, and also have three other NDA approvals, namely, DRAXIMAGE® MAA, DRAXIMAGE® DTPA and I-131 mIBG. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (“FDCA”). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to USFDA to rely in part on data in the public domain or the USFDA’s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain USFDA approval. If the USFDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. We take into account design, strategic planning considerations and our interactions with the USFDA to determine whether to utilize the Section 505(b)(2) regulatory approval pathway for a particular product candidate. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the USFDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the USFDA ultimately denies such a petition, the USFDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

***Our products may have unanticipated adverse effects or possible adverse effects, and if we are sued by our customers or end users for defects in our products, it could harm our reputation and thus our profits and may subject us to regulatory investigations or sanctions.***

Our products may have previously unknown safety or efficacy concerns or unknown side effects. While our products undergo clinical studies and statistical analysis during the development process prior to approval, there



are inherent limitations with regard to the design of such trials, the limited time used to measure the efficacy of the product and the limited ability to perform long-term monitoring. In the event that such unanticipated side effects are discovered, we may be required to add descriptions of the side effects as “precautions” to the packaging of our products, recall and terminate sales of products or conduct costly post-launch clinical studies. Furthermore, concerns of potential side effects could arise among consumers or medical professionals, and such concerns, whether justified or not, could expose us to negative publicity and have an adverse effect on sales of our products and our reputation. Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the USFDA may require implementation of a Risk Evaluation and Mitigation Strategy (“REMS”);
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

The performance, quality and safety of our products also depends on the effectiveness of our quality control system, which in turn depends on a number of factors, including the design of the system, our quality training program and our ability to ensure that our employees adhere to our quality control policies and guidelines.

In addition, under certain contracts we have entered into with our customers in our Generics & APIs business segment and under certain purchase orders that are issued by our customers we have provided product specification related warranties to our customers and have agreed to indemnify our customers in case of breach of such product specification warranties. Further, a majority of our customers have the right to terminate their respective contracts with us without assigning any cause, which contracts account for a majority of our consolidated revenues. If an indemnity claim is made or a contract is terminated, it may have an adverse impact on our business.

We are exposed to product liability claims in the ordinary course of business. A product liability claim could require us to pay substantial damages. Product liability claims against us, whether or not successful, are costly and time-consuming to defend. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation or adverse publicity against us;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and resources;
- compensatory damages and fines;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- exhaustion of any available insurance and our capital resources.

Additionally, from time to time, the pharmaceutical industry has experienced difficulty in obtaining desired amounts of product liability insurance coverage. We export, and also manufacture and sell, products to highly regulated markets, including the United States, which are noted for their litigious nature and high awards of damages.

Our public and product liability insurance covering the products produced by us, including defective products, and our subsidiaries is generally subject to certain limitations and a maximum liability threshold indemnifying us for bodily injury and property damage arising out of our premises, operations or products, subject to certain customary exclusions, including bodily injury to an employee of the insured arising out of and in the course of employment by the insured, workmen compensation, property damage to property owned or occupied by or rented to the insured and liabilities arising out of deliberate or willful non-compliance with statutory provisions. Our public and product liability insurance may not be adequate and, at any time, insurance coverage may not be available to mirror all our contractual obligations on commercially reasonable terms or at all. If any product liability claim was sustained against us for products not covered by existing product liability insurance or where the damages awarded exceeds the limits set on the existing insurance cover, it could harm our business and

financial condition. Even for the products where we carry the product liability insurance our claims may not be fully accepted by the insurance companies. This risk is likely to increase as we increase the number of products that we develop internally and sell internationally.

***The USFDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

If we are found to have improperly promoted off-label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The USFDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the USFDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The USFDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***We may rely on third parties to conduct our clinical trials. 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 of or commercialize any potential product candidates.***

We may depend upon other third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. For example, we have a contract with a third party CRO for our mIBG clinical trial. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We will rely heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements for clinical trials, which are regulations and guidelines enforced by the USFDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the USFDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with biologic product produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with the applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial

prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we plan to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***Certain of our product candidates are still in clinical development. Clinical trials of our product candidates may not be successful. If we are unable to successfully develop mIBG and our other product candidates, or experience significant delays in doing so, our business, financial condition and results of operations could be materially adversely affected.***

We have invested a significant portion of our efforts and financial resources into the development of mIBG and our other product candidates. The success of mIBG and our other product candidates will depend on several factors, including the following:

- successful efforts in completing clinical trials of, receipt of regulatory approval for and commercialization of such product candidates;
- for the product candidates to which we retain rights under relevant agreements, completion of preclinical studies and clinical trials of, receipt of marketing approvals for, establishment of commercial manufacturing capabilities for and successful commercialization of such product candidates; and
- acceptance of our product candidates by patients, the medical community and third party payers, effectively competing with other therapies, a continued acceptable safety profile following approval, and qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

If we or the parties with whom we partner do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize mIBG and our other product candidates, which could materially adversely affect our business, financial condition and results of operations.

***If we obtain regulatory approval of our product candidates, we remain subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive USFDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, ANDA, BLA or other marketing application, and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the USFDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

The USFDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of

previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of our products from the market, or voluntary or mandatory product recalls;
- fines, warning letters, untitled letters, or holds on clinical trials;
- refusal by the USFDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The policies of the USFDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***The loss of services of our Chairman and Managing Director, Mr. Shyam S. Bhartia and our Co-chairman and Non-Executive Director, Mr. Hari S. Bhartia, or our inability to ensure continuity of senior management could have an adverse effect on our business, financial condition and results of operations.***

Our success depends in part on the continued services of our Chairman and Managing Director, Mr. Shyam S. Bhartia and our Co-chairman and Non-Executive Director, Mr. Hari S. Bhartia, both of whom are the Promoters. Our pharmaceutical business has been built by the Promoters and JLL from 2003 through a series of organic initiatives as well as acquisitions of assets and businesses, and the Promoters have been in senior positions in JLL and the Company for more than 35 years. They have played and continue to play an active role in driving the long-term strategy and the day-to-day business of JLL and the Company. The loss of Mr. Shyam S. Bhartia or Mr. Hari S. Bhartia could impair our ability to implement our strategy, and thus have an adverse effect on our business.

In addition, from time to time, we may lose the services of certain senior management personnel and may experience periods where there is lack of continuity of senior management. We do not maintain key man insurance on our Chairman and Managing Director, Mr. Shyam S. Bhartia, and our Co-chairman and Non-Executive Director, Mr. Hari S. Bhartia or any of our senior management personnel. There can be no assurance that we would be able to find and integrate replacement personnel in a timely manner to support the needs of our business. An inability to ensure continuity of senior management could adversely affect our business.

***We are exposed to risk of changes in tax legislation and the interpretation of such legislation and a termination or expiration of governmental tax incentive programs or tax benefits in the jurisdictions in which we operate and our tax liabilities could be larger than anticipated which could adversely affect our overall effective tax rate.***

Our activities are subject to tax at various rates around the world computed in accordance with local legislation and practice. Action 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 many 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. 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.

Moreover, our tax expenses and the resulting effective tax rate reflected in our financial statements are likely to increase over time as a result of changes in corporate income tax rates, other changes in the tax laws of the various countries in which we operate or changes in the mix of countries where we generate profit. We have benefited or currently benefit from a variety of tax benefits that generally carry conditions that we must meet in order to be eligible to obtain such benefits. If we fail to meet the conditions upon which certain favorable tax

treatment is based, we would not be able to claim future tax benefits and could be required to refund tax benefits already received. Additionally, some of these tax incentive programs and the related tax benefits are available to us for a limited number of years, and these benefits expire from time to time.

Any of the following could have a material effect on our overall effective tax rate:

- some government tax incentive programs may be discontinued;
- we may be unable to meet the requirements for continuing to qualify for some tax incentive programs;
- these tax incentive programs and tax benefits may be unavailable at their current levels;
- upon expiration of a particular benefit, we may not be eligible to participate in a new tax incentive program or qualify for a new tax benefit that would offset the loss of the expiring tax benefit; or
- we may be required to refund previously recognized tax benefits if we are found to be in violation of the stipulated conditions.

In addition, we may become subject to various tax litigations and claims, for which any rulings against us could materially and adversely affect our business, financial condition and results of operations. For example, our contingent liabilities relating to claims against the Group, disputed by the Group and not acknowledged as debt increased significantly for the financial year ended March 31, 2018 and the nine months ended December 31, 2018 due to an income tax claim pertaining to a U.S. tax filing arising as a result of a delay in recording use of carry forward tax losses in May 2018. If such carry forward tax losses are not recognized, we would be subject to a tax payment of approximately US\$8.7 million (including applicable interest) for the nine months ended December 31, 2018. See “*Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Contingent Liabilities—Contingent Liabilities*”.

***We depend on certain key products for a significant portion of our total revenue from operations, cash flows and earnings, and any events that adversely affect the markets for our key products may adversely affect our business, financial condition and results of operations.***

We derive a significant portion of our revenue and earnings from a few key products. Specifically, for the financial year ended March 31, 2018, and the nine months ended December 31, 2018, our top 10 products by revenue comprised 39.4% and 39.4%, respectively, of our total revenue from operations. Due to our acquisition of Triad’s assets in September 2017, radiopharmaceuticals represent a significant portion of our financial results for the year ended March 31, 2018 and the nine months ended December 31, 2018 as compared to previous financial periods.

If the volume or pricing of our key products declines in the future or we are unable to satisfy market demand for these key products, our business, financial position and results of operations could also be materially adversely affected. Any event that adversely affects any of these key products or their markets could have a material and adverse effect on our business, financial condition and results of operations. These events could include, among other things:

- loss of patent protection;
- availability of competing products and pricing action by competitors;
- entry of new competitors into the marketplace;
- alternative or substitute products that become available;
- unanticipated changes in product quality or product modifications required by our customers;
- discovery of previously unknown side effects, product liability claims or product recalls or safety alerts;
- manufacturing or supply interruptions;
- changes in prescribing practices of physicians;
- increased competition from the introduction of new, more effective treatments; and
- increased costs associated with manufacturing which cannot be passed along to customers.

Any factor adversely affecting the sale of our key products may cause our revenues to decline, and we may not be able to maintain profitability.

***We have entered into long-term contracts with certain of our customers in our radiopharmaceuticals and CMO business lines. Any loss of business from one or more of them may adversely affect our revenues and profitability.***

A substantial portion of the revenue from operations generated by our radiopharmaceuticals and CMO business lines are derived from long-term contracts we have entered into with certain of our customers, which typically have three to five-year terms. Our radiopharmaceuticals business generated revenues of US\$265.1 million for the financial year ended March 31, 2018 (inclusive of the revenues generated by our radiopharmacies during the seven-month period from the time of acquisition on September 1, 2017 through March 31, 2018) and US\$267.9 million for the nine months ended December 31, 2018, which comprised 42.8% and 47.6%, respectively, of our revenue from operations for the year/period. Our CMO business generated revenues of US\$100.9 million for the financial year ended March 31, 2018 and US\$81.6 million for the nine months ended December 31, 2018, which comprised 16.3% and 14.5%, respectively, of our revenue from operations for the year/period. While we are not dependent on any single customer and have a broad and diversified customer base across each of our five business lines, if any of our long-term customers terminate their contracts, or delay or breach payment obligations, reduce the volume of business we receive under the contracts, or if we are unable to renew such contracts on favorable terms or at all, our revenues and profitability may be adversely affected. See “*Business—Customers*”.

***We generate revenues and procure supplies in countries that may be adversely affected by political or economic instability, major hostilities or acts of terrorism.***

We are a global integrated pharmaceutical company with worldwide operations and one of our strategic objectives is to continue to expand our geographic outreach. Although 89.4% of our revenues generated were from North America and Europe for the financial year ended March 31, 2018, we derive a portion of our sales and future growth from other regions such as Asia, the Middle East and Central and Eastern Europe, which may be more susceptible to political or economic instability. Moreover, as we often export a substantial number of products into such markets, we may, therefore, be denied access to our customers or suppliers of our raw materials or denied the ability to ship products from any of our sites as a result of a closing of the borders of the countries in which we sell our products, or in which our operations are located, due to economic, legislative, political and military conditions, including hostilities and acts of terror, in such countries.

***In certain markets, we rely on third party distributors and other agents whose anti-corruption policies may not be as robust as our own.***

In many less-developed markets, we rely heavily on third party distributors and other agents for the marketing and distribution of our products. Many of these third parties do not have internal compliance resources comparable to ours. Business activities in many of these emerging markets have historically been more susceptible to corruption. If our efforts to screen third party agents and detect and prevent cases of potential misconduct fail, we could be held responsible for the non-compliance of these third parties under applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act, which may have a material adverse effect on our reputation and our business, financial condition or results of operations.

***Export destination countries may impose varying duties on our products. Any increase in such duties may adversely affect our business and results of operations.***

A substantial portion of our products are exported and sold in various countries across the world. These destination countries may impose varying duties and other levies on our products, which may adversely affect our ability to compete with the local manufacturers and other competitors, whom due to more widespread operations, are able to coordinate delivery and supplies from strategically located production facilities in a more cost competitive manner. 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 such change or increase will not adversely affect our business and results of operations. See “*Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Contingent Liabilities—Other Commitments*” and “*—We are subject to numerous political, economic, legal, tax, operational and other risks as a result of our international operations, including risks of possible nationalization, expropriation and other restrictive governmental actions*”.

***Our sales depend on the coverage and adequacy of reimbursement from third party payers, and pricing and reimbursement pressures may affect our profitability.***

Sales of some of our products depend, in part, on the extent to which the costs of our products, or of customers’ products for which we supply APIs are paid by health maintenance, managed care, pharmacy benefit and similar

healthcare management organizations, or are reimbursed by government health administration authorities, private health coverage insurers and other third party payers, in particular in the United States and Europe. These healthcare management organizations and third party payers are increasingly challenging the prices charged for medical products and services and putting limits on reimbursement or forcing the use of low cost alternatives. Additionally, the containment of healthcare costs has become a priority of many federal and state governments, and the prices of drugs and other healthcare products have been targeted in this effort. Accordingly, our current and potential products may not be considered cost effective, and reimbursement to the consumer may not be available or sufficient to allow us to sell our products on a competitive basis. Intense public scrutiny of the price of drugs and other healthcare costs continues and greater focus on pricing and price increases may limit our ability to set or increase the price of our products based on their value, which could have a material adverse effect on our product sales, business, financial condition and results of operations. In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third party payers. Legislation and regulations affecting reimbursement for our products may change at any time and in ways that are difficult to predict, and these changes may have a material adverse effect on our business.

Payers, including healthcare insurers, pharmacy benefit managers (“PBM”) and GPOs with our products, nationally, increasingly seek ways to reduce their costs. Many payers continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients. Such measures include more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients’ use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs.) Payers also increasingly seek price discounts or rebates in connection with the placement of our products on their formularies or those they manage. Payers also control costs by imposing restrictions on access to or usage of our products, such as by requiring prior authorizations or step therapy, and may choose to exclude certain indications for which our products are approved or even choose to exclude coverage entirely. Significant consolidation in the health insurance industry has resulted in a few large insurers and PBMs exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. Further consolidation among insurers, PBMs and other payers, including through integrated delivery systems, would increase the negotiating leverage such entities have over us and other drug manufacturers. Ultimately, further discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products.

We also face risks relating to the reporting of pricing data that affects the reimbursement of and discounts provided for our products. In the United States, pricing data that we submit to the U.S. government impacts the payment rates for providers, rebates we pay, and discounts we are required to provide under Medicare, Medicaid and other government drug programs. Government price reporting regulations are complex and may require a manufacturer to update certain previously submitted data. Our price reporting data calculations are reviewed monthly and quarterly, and based on such reviews we have on occasion restated previously reported pricing data to reflect changes in calculation methodology, reasonable assumptions and/or underlying data. If our submitted pricing data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse effect on our business and results of operations. In addition, as a result of restating previously reported price data, we also may be required to pay additional rebates and provide additional discounts.

With respect to our radiopharmaceuticals, over the past several years, Medicare has implemented numerous changes to payment policies for imaging procedures in both the hospital setting and non-hospital settings (which include physician offices and freestanding imaging facilities). Some of these changes have had a negative impact on utilization of imaging services. Examples of these changes include:

- limiting payments for imaging services in physician offices and free-standing imaging facility settings based upon rates paid to hospital outpatient departments;
- reducing payments for certain imaging procedures when performed together with other imaging procedures in the same family of procedures on the same patient on the same day in the physician office and free-standing imaging facility setting;
- making significant revisions to the methodology for determining the practice expense component of the Medicare payment applicable to the physician office and free-standing imaging facility setting which results in a reduction in payment; and
- revising payment policies and reducing payment amounts for imaging procedures performed in the hospital outpatient setting.

We believe that Medicare changes to payment policies for imaging procedures applicable to non-hospital settings will continue to result in certain physician practices ceasing to provide these services and a further shifting of

where certain medical imaging procedures are performed, from the physician office and free-standing imaging facility settings to the hospital outpatient setting. Within the hospital outpatient setting, the use of many of our products is not separately payable by Medicare, although other products may be payable as an add-on payment to the procedure. Changes applicable to Medicare payment in the hospital outpatient setting could also influence the decisions by hospital outpatient physicians to perform procedures that use our products.

Outside the United States, we expect countries will continue to take aggressive actions to reduce their healthcare expenditures. Any reduction in the coverage and reimbursement available for our products or in the timeliness or certainty of payment by payers to physicians and other providers could negatively impact the ability or willingness of healthcare providers to prescribe our products for their patients or could otherwise negatively affect the use of our products or the prices we receive for any of them. Any of such changes could have a material adverse effect on our product sales, business and results of operations.

***Healthcare reform may reduce or modify reimbursement for our current or future products, which could cause our business to suffer.***

Third party payers, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, in the United States, the ACA and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our products, under the Medicaid drug rebate program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid drug rebate program, extended the Medicaid drug rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Additionally, the ACA allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, and implemented a new Patient-Centered Outcomes Research Institute. We are still unsure of the full impact that the ACA will have on our business.

Some of the provisions of the ACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of the ACA. President Trump has signed executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain ACA-mandated health insurance as part of a tax reform bill. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018 ("BBA"), among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, the Centers for Medicare and Medicaid Services ("CMS") announced that it is suspending further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress is continuing to consider legislation that would alter other aspects of the ACA. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance, beginning in 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services, or CMS, have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA and our business. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things,



included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from products and may affect our overall financial condition.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. State government actions or ballot initiatives can also affect how our products are covered and reimbursed or create additional pressure on how our products are priced. Some states have adopted, and many other states have discussed and debated and are considering, new pricing legislation, including state proposals designed to require biopharmaceutical manufacturers to publicly report proprietary pricing information, limit price increases or to place a maximum price ceiling, or cap, on pharmaceutical products. For example, in October 2017, California's governor signed into law a new drug pricing transparency bill that requires pharmaceutical manufacturers to notify health insurers and government health plans at least 60 days before scheduled prescription drug price increases that exceed certain thresholds. Existing and proposed pricing legislation could lead to the introduction and passage of additional bills or ballot initiatives in other states.

Sales of certain of our products relies on reimbursement to our customers from U.S. federal government healthcare programs and commercial insurance plans regulated by the U.S. federal and state governments. Changes to U.S. federal reimbursement policy may come through legislative and/or administrative actions. Discussions continue around a number of potential legislative changes that could affect the reimbursement and/or pricing of our products, including proposals to allow the U.S. federal government to directly negotiate drug prices with pharmaceutical manufacturers and to require manufacturers to pay higher rebates in the Medicare Part D setting. Legislation has been introduced into Congress for other proposals, including legislation designed to overhaul provisions of the ACA as well as to enable commercial-level re-importation of prescription medications from Canada or other countries. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services ("HHS") has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. While we are unable to predict if additional changes may ultimately be enacted, to the extent that these or other changes affect how our products are priced, paid for and reimbursed by government and private payers in the United States, our business could be adversely impacted. Changes in U.S. federal reimbursement policy may also arise as a result of regulations or demonstration projects implemented by the CMS, the federal agency responsible for administering Medicare, Medicaid and the Health Insurance Marketplaces. Over the past several years, Medicare reimbursement amounts for our venom immuno therapy products have not materially changed despite new product introductions with increased prices and value propositions, as well as annual consumer price increases for existing products. Any reduction in third party payer reimbursements could have a material adverse effect on our business, financial position and results of operations. CMS has substantial power to quickly implement policy changes that can significantly affect how our products are covered and reimbursed. Legislative or regulatory changes in the United States or other federal or state government initiatives that decrease the coverage or reimbursement available for our products, require that we pay increased rebates, limit our ability to offer

co-pay payment assistance to commercial patients, limit the pricing of pharmaceutical products or reduce the use of our U.S. products could have a material adverse effect on our business and results of operations.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers, which may adversely affect our future profitability.

***Any negative trends in the global macroeconomic environment may adversely affect our business, financial condition and results of operations.***

Our business and performance are influenced by local and global economic conditions. The growth of the global pharmaceutical market is tied to global economic growth. A slowdown in global economic growth could exert downward pressure on the demand for our products and services, which could reduce the size and number of available markets for our finished products and in turn adversely impact our business, financial condition and results of operations. Furthermore, a prolonged weakness in the global financial and economic situation may provide more leverage to third parties with whom we do, or may do business, in negotiating pricing and other contractual terms that are favorable to them. For example, customers may insist on increased payment period terms which affects our available working capital or they may reduce or revise the quantity of the products that they purchase from us. Any of these factors could adversely affect our business, financial condition and results of operations.

***If we are unable to gain market acceptance or develop appropriate launch opportunities for our products and services, our profitability could be negatively affected.***

Even if we are able to demonstrate sufficiently high levels of safety, quality and efficacy for our products and services and all regulatory approvals and patents have been obtained, our products and services may not gain market acceptance, which would adversely affect our revenues or profitability.

In particular, our APIs can only be commercialized as an ingredient in a customer's drug formulation. This requires us to identify a drug manufacturer that will want to utilize our APIs in its formulation, and enter into an arrangement referred to as a "tie-up" whereby the formulation and the APIs are submitted as part of a single regulatory approval process. We incur significant expenses in developing our APIs and preparing them for commercialization. If we are unable to enter into tie-up arrangements, our APIs will not be approved and we will lose the investments made in developing the APIs and will not be able to realize the benefit that we had anticipated. Similarly, in the solid dosage formulations business in the United States, even if we are successful in developing the products and receiving the necessary regulatory approvals, we may not be able to successfully market our products through the distribution network or to the United States Federal Government. The degree of market acceptance of our products and services will depend on a number of factors, including:

- publicly establishing and demonstrating the efficacy, quality and safety of our products and services, especially as compared to other similar products and services;
- the costs to potential customers of switching to our products;
- competitive performance against alternative products and services; and
- marketing and distribution support for our products and services.

Additionally, our ability to achieve continued growth and profitability through sales of generics and APIs pharmaceuticals is dependent on our success in developing products with increased complexity to provide launch opportunities with U.S. market exclusivity or limited competition. The failure to develop such opportunities in the future could adversely affect our sales and profitability.

***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.***

Our ability to market our products successfully depends, in part, on the acceptance of products by independent third parties, including wholesalers, distributors, physicians, hospitals, pharmacies, government representatives and other retailers, as well as patients. We rely to a significant extent on the strength of our brands and our reputation and acceptance by third party agents and distributors. Unanticipated side effects or unfavorable publicity concerning any of our products or brands, or the brands of its in-licensed products, could have an adverse effect on our ability to achieve acceptance by prescribing physicians, managed care providers, pharmacies 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.

***Our policies regarding returns, allowances and chargebacks in the United States, failure to supply penalties and marketing programs adopted by wholesalers, may reduce our revenues.***

Consistent with industry practice in the United States, our U.S. subsidiary, Jubilant Cadista Pharmaceuticals Inc. (“**Jubilant Cadista**”), like many other generic product manufacturers, has liberal return policies and has been willing to give customers post-sale inventory allowances in our Generics & APIs business segment. In certain cases, our other U.S. subsidiary, Jubilant HollisterStier LLC (“**JHS**”), may also provide discounts to encourage customers to purchase and promote the use of certain of our allergy therapy products. For example, JHS provides discounts from product list prices on its various allergy therapy products to its allergist customers, in line with market practices to help reduce product costs to allergists. Under certain arrangements with customers, from time to time, we may give customers credits on generic products that customers hold in inventory after decreasing 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, we 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. Such arrangements with our customers are also subject to high service quality level, including failure to supply penalties, which in the event we are unable to supply a certain product and are unable to meet the needs of our customers, for whatever reason including unavailability of raw material APIs, could lead to service level penalties, which may be significant. Such penalties typically are not passed through to our suppliers, notwithstanding that such unavailability may arise from such suppliers instead of us. Like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to hospitals, GPOs, 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. Although we establish reserves based on our prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates, which could have a material adverse effect on our financial condition, results of operations and cash flows. As we continue to experience the consolidation of our customers, which may result in changes to previous patterns of ordering and/or pricing of our products, this could disrupt our established methodologies for calculating our provisions for chargebacks and other accruals. If there is unanticipated competition or an unexpected change in one or more of our contractual relationships, our estimates may be exceeded, which could have a material adverse effect on our financial condition, results of operations and cash flows.

***Our inability to accurately forecast demand for our products and manage our inventory may have an adverse effect on our business, financial condition and results of operations.***

Our business depends on our estimate of the long-term demand for our products from our customers. If we underestimate demand or have inadequate capacity due to which we are unable to meet the demand for our products, we may manufacture fewer quantities of products than required, which could result in the loss of business. While we forecast the demand for our products and accordingly plan our production volumes, any error in our forecast could result in surplus stock, which may not be sold in a timely manner or at all. At times when we have overestimated demand, we may have incurred costs to build capacity or purchased more raw materials and manufactured more products than required. In addition, each of our products has a shelf life of a specified number of years and if not sold prior to expiry, may lead to losses or if consumed after expiry, may lead to health hazards. Our inability to accurately forecast demand for our products and manage our inventory may have an adverse effect on our business, financial condition, results of operations and cash flows.

***We have incurred significant indebtedness, and we must service this debt and comply with our covenants to avoid refinancing risk.***

We have incurred significant indebtedness in connection with our operations and have indebtedness that has exceeded our shareholders' equity. As at March 31, 2017 and 2018, our total outstanding indebtedness (comprising loans and borrowings, net of un-amortized transaction costs) amounted to US\$445.1 million and US\$408.5 million, respectively, which exceeded our shareholders' equity for the corresponding periods, which was US\$328.2 million and US\$384.2 million, respectively. Our total outstanding indebtedness (comprising loans and borrowings, net of un-amortized transaction costs) as at December 31, 2018 amounted to US\$410.3 million and our shareholders' equity as at December 31, 2018 was US\$419.8 million. Although we believe that our current levels of cash flows from operations and working capital borrowings are sufficient to service existing debt, we may not be able to generate sufficient cash flow from operations in the future and future working capital borrowings may not be available in an amount sufficient to enable us to do so.

If we are unable to comply with the restrictions and covenants in our debt agreements and our indenture (the "**Existing Senior Notes Indenture**") relating to the 4.875% senior notes due 2021 (the "**Existing Senior Notes**") that were issued in an original aggregate principal amount of US\$300 million or our current or future debt obligations and other agreements, there could be a default under the terms of these agreements. In the event of a default under these agreements, the holders of the debt could terminate their commitments to lend to us, accelerate repayment of the debt and declare all outstanding amounts due and payable or terminate the agreements, as the case may be. Furthermore, some of our debt agreements, including the Existing Senior Notes Indenture, contain cross-acceleration or cross default provisions. As a result, our default under one debt agreement may cause the acceleration of repayment of not only such debt but also other debts, including the Existing Senior Notes, or result in a default under our other debt agreements, including the Existing Senior Notes Indenture. If any of these events occur, we cannot assure you that our assets and cash flow would be sufficient to repay in full all of our indebtedness, or that we would be able to find alternative financing. Even if we could obtain alternative financing, we cannot assure you that it would be on terms that are favorable or acceptable to us.

Our ability to make scheduled payments on, or to refinance our obligations with respect to, our indebtedness, in a timely manner or at all, will depend on our financial and operating performance, which in turn will be affected by general economic conditions and by financial, competitive, regulatory and other factors beyond our control. We may not generate sufficient cash flow from operations and future sources of capital may not be available to us in an amount sufficient to enable us to service our indebtedness, including the Existing Senior Notes, or to fund our other liquidity needs. If we are unable to generate sufficient cash flow and capital resources to satisfy our debt obligations or other liquidity needs, we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, reducing or delaying capital investments or seeking to raise additional capital, or at all. Any failure to make payments of interest and principal on our outstanding indebtedness on a timely basis would likely result in a reduction of our credit rating, which could also harm our ability to incur additional indebtedness. In addition, any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. There is no assurance that any refinancing would be possible, that any assets could be sold or, if sold, of the timing of the sales and the amount of proceeds that may be realized from those sales, or that additional financing could be obtained on acceptable terms, or at all.

In the absence of such results of operations and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. Other credit facilities and the Existing Senior Notes Indenture restrict our ability to dispose of assets and use the proceeds from the disposition. We may not be able to consummate those dispositions or to obtain the proceeds which we could realize from them and these proceeds may not be adequate to meet any debt service obligations then due. Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms and in a timely manner, would materially and adversely affect our financial condition and results of operations. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Indebtedness*".

***We are subject to risks arising from interest rate fluctuations, which could adversely affect our business, financial condition and results of operations.***

We borrow funds in the domestic and international markets from various banks and financial institutions to meet the long-term and short-term funding requirements for our operations and funding our growth initiatives. A majority of our borrowings are floating rate debt and, hence, are exposed to interest rate risk on such floating rate debt. Increases in interest rates may increase the cost of any floating rate debt that we incur. In addition, the

interest rate that we will be able to secure in any future debt financing will depend on market conditions at the time, and may differ from the rates on our existing debt. If the interest rates are high when we need to access the markets for additional debt financing, our business, financial condition, results of operations and planned capital expenditures may be adversely affected.

***Our inability to obtain adequate financing to meet our liquidity and capital resource requirements in a timely manner or at all, may have an adverse effect on our business, financial condition, results of operations and cash flows.***

We expect to continue to have, substantial liquidity and capital resource requirements for meeting our working capital requirements as well as capital expenditures. In the past, we have financed these expenditures through a variety of means, primarily through internally generated cash flows, external borrowings and capital contributions. In the future, we may be required to supplement our cash flow from operations with external sources of financing to meet these requirements. There can be no assurance that financing from external sources will be available at the time or in the amounts necessary or at competitive rates to meet our requirements. Our inability to obtain such financing may impair our business, financial condition, results of operations or prospects. See “—We have incurred significant indebtedness, and we must service this debt and comply with our covenants to avoid refinancing risk”.

***Our contracts are governed by the laws of various countries and disputes arising from such contracts may be subject to the exclusive jurisdiction of courts situated in such countries.***

Most of the contracts executed with our distributors and customers are governed by the laws of the country in which the distributor or customer is incorporated. Further, any disputes related to such contracts may be subject to the exclusive jurisdiction of courts situated in such countries. Any lawsuits with respect to such disputes must be instituted in a court having jurisdiction over the contract, which may cause us difficulty to manage such suits and to obtain enforcement of awards, either or both of which may also lead to us incurring greater costs and diverting our management’s attention from carrying out our business operations.

***We, our directors and controlling shareholders are and may from time to time be involved in legal proceedings.***

We, our directors and controlling shareholders are and may from time to time be involved in legal proceedings and claims in certain of the countries where we conduct our business or are resident in. These legal proceedings are pending at different levels of adjudication before various courts and tribunals. Should any new developments arise, such as changes in applicable law of the jurisdictions relevant to us, or rulings against us by appellate courts or tribunals, we may need to make provisions in our financial statements, which could increase our expenses and our liabilities. Further, we cannot assure you that any legal proceedings will be decided in our favor and our financial liability may be enhanced in the event any court, tribunal or authority passes an adverse order against us. Any such adverse decision may have a significant adverse effect on our business, financial condition and results of operations.

India has an elaborate judicial framework with a multi-tier judicial machinery and a complex system of procedural and substantive laws, which may lead to actions and disputes in multiple fora. Litigation in India, or even the threat of litigation, can be expensive, lengthy and disruptive to normal business operations, and the results of litigation are inherently uncertain and may result in adverse rulings or decisions, including interim measures. Further, private citizens are permitted to initiate criminal complaints against companies and other individuals and we and our directors have in the past and may in the future be required to defend frivolous actions, which may not resolve in a timely manner. The Promoters are each a party to certain legal proceedings before various courts in India and, if determined against them, could have an adverse effect on our business, financial condition and results of operations. No assurances can be given as to whether these proceedings will be decided in the Promoters’ favor or have no adverse outcome, nor can any assurance be given that no further liability will arise out of these claims. See “Business—Legal Proceedings—Adjudication Order”.

***If we experience labor union problems, our production capacity and overall profitability could be adversely affected.***

As at December 31, 2018, less than 10% of our employees belong to a number of different labor unions or undertake collective bargaining. We experienced a 10-day strike in July 2016 over wages during the renewal of the JDI’s union contract. This was however resolved amicably through a voluntary mediation process and, during the absence of certain of our employees there, management personnel maintained production. JDI has since signed a three-year contract with the union and brought the matter to closure. There have been no other instances

of major strikes, lockouts or other disruptive labor disputes but if any such negotiations in future regarding wages with our employees or any of the labor unions to which our employees belong are not concluded quickly, our relations with our employees could suffer, which could have a material adverse effect on our results of operations. We are currently in the process of negotiating the collective bargaining agreements with our employees at our facilities situated at Nanjangud, Karnataka, India and Montreal, Canada. We cannot assure you that such negotiations would not result in the occurrence of any of the preceding outcomes which could have a material adverse effect on our results of operations.

*We are subject to foreign, federal, and state, anti-kickback, false claims, physician payment transparency, fraud and abuse laws, and privacy laws, which may adversely affect our business.*

We are subject to various federal, state and foreign laws pertaining to foreign corrupt practices and healthcare fraud and abuse, including anti-kickback, marketing and pricing laws (“**anti-kickback laws**”). In the United States, most of our products sold by Jubilant Cadista, JDI and JDR are reimbursed under federal and state healthcare programs such as Medicaid, Medicare, TriCare, and or state pharmaceutical assistance programs. Many patients and imaging procedures are also covered under a variety of private insurance carriers. These laws may impact, among other things, our proposed sales and marketing programs as well as any patient support programs we may consider offering. The laws that may affect our ability to operate include:

- the federal anti-kickback statute (the “**Anti-Kickback Statute**”), which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term remuneration has been interpreted broadly to include anything of value including, for example, gifts free items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are also subject to civil monetary penalties for each violation, plus up to three times the remuneration involved. Violations of the Anti-Kickback Statute may also result civil and criminal penalties, including criminal fines of up to US\$100,000 and imprisonment of up to 10 years, or exclusion from Medicare, Medicaid or other governmental programs. Violation of the Anti-Kickback Statute may also constitute a false or fraudulent claim for purposes of the federal False Claims Act (“**FCA**”);
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA which imposes criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other third party payers that are false or fraudulent, including failure to timely return an overpayment received from the federal government or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. These laws can apply to entities that provide information on coverage, coding, and reimbursement of their products and assistance with obtaining reimbursement to persons who bill payers. Private individuals can bring FCA “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers”, may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus up to three times the amount of damages sustained by the federal government and, may provide the basis for exclusion from federally funded healthcare programs;
- provisions of the federal Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”), which created new federal criminal statutes, prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. As well as provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical

supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the HHS information related to all payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members unless a specific exclusion applies. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;

- state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payer. Many U.S. states have adopted laws similar to the Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payers, including private insurers, or paid directly by the patient. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties; and
- national regulations, both the U.S. federal government and the states in which we conduct our business, and foreign laws and regulations, including the European General Data Protection Regulations, on privacy with respect to personal data, identifiable health information, sensitive information, and other data of patients and customers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, such as providing free allergy extracts, diagnostic equipment and other items to physicians, including some who may prescribe, purchase or may be in a position to influence the ordering or purchasing of our products, could be subject to challenge under one or more of such laws. In addition, if any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***Our business is subject to risk from climate change.***

Our business is subject to risk from climate change. Some of the potential impacts of climate change to our business include increased operating costs due to additional regulatory requirements and increased energy costs. Laws and regulations are in effect at the regional, national, and supranational levels to reduce greenhouse gas ("GHG") emissions to mitigate climate change, and we expect that additional, more stringent laws and regulations will be implemented in the future. In the United States, newly constructed or modified facilities with the potential to emit certain quantities of GHGs are subject to carbon efficiency standards, GHG emission concentration limits, specific technology requirements, or other measures. At the international level, many nations have agreed to limit emissions of GHGs pursuant to the United Nations Framework Convention on Climate Change, also known as the "Kyoto Protocol". Furthermore, many countries have committed themselves to GHG emission reduction targets under the Paris Agreement, which entered into force in November 2016. We face risk from these additional regulatory requirements and increased energy costs. In addition, sea level rise and more frequent and severe weather events caused or contributed to by climate change pose physical risks to our facilities and could cause disruptions to our supply chain. Climate change could also limit water availability, impacting our manufacturing operations and our supply chain.

***The amount of intangible assets and goodwill recorded on our balance sheet may lead to significant impairment charges in the future.***

We regularly review our long-lived assets, including identifiable intangible assets and goodwill, for impairment. Goodwill, finite intangible assets and indefinite life intangible assets are subject to impairment review at least

annually. Other long-lived assets are reviewed when there is an indication that an impairment may have occurred. The amount of goodwill and identifiable intangible assets on our consolidated balance may increase further following future acquisitions as a result of any changes in accounting rules and may lead to further impairment charges in the future. In addition, we may from time to time sell assets that we determine are not critical to our strategy or execution. Future events or decisions may lead to asset impairments and/or related charges. Certain non-cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Any significant impairment charges could have a material adverse effect on our results of operations. See “*Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies*”.

***A majority of our operating subsidiaries are incorporated in the United States, Canada and India, a substantial portion of our assets are located in the United States, Canada and India and certain of our Directors and Executive Officers and all or a substantial portion of their assets are located in India and the United States. As a result, Investors may have difficulty enforcing judgments from outside these jurisdictions against our subsidiaries, certain of our Directors and our Executive Officers.***

The Company is a holding company with no business operations and its assets mainly comprise the equity interests it holds in its subsidiaries, which are located in multiple jurisdictions. We conduct all of our operations through our subsidiaries. A majority of our operating subsidiaries are incorporated in the United States, Canada and India, a substantial position of our assets are located in the United States, Canada and India and certain of our Directors and Executive Officers and all or a substantial portion of their assets are located in India and the United States. As a result, it may not be possible, or it may be difficult, for Investors to effect service of process upon such persons in jurisdictions outside these jurisdictions or to enforce judgments obtained against such Directors outside India or the United States.

In particular, India has reciprocal recognition and enforcement of judgments in civil and commercial matters with only a limited number of jurisdictions, which include the United Kingdom, Singapore and Hong Kong. The United States has not been declared as a reciprocating territory for the purposes of the Indian Civil Code. In order to be enforceable, a judgment from a jurisdiction with reciprocity must meet certain requirements of the Indian Civil Code. The Indian Civil Code only permits the enforcement of monetary decrees, not being in the nature of any amounts payable in respect of taxes, other charges, fines or penalties and does not include arbitration awards. Judgments or decrees from jurisdictions which do not have reciprocal recognition with India cannot be enforced by proceedings in execution in India. Therefore, a final judgment for the payment of money rendered by any court in a non-reciprocating territory for civil liability, whether or not predicated solely upon the general laws of the non-reciprocating territory, would not be enforceable in India. Even if an investor obtained a judgment in such a jurisdiction against us, our officers or directors, it may be required to institute a new proceeding in India and obtain a decree from an Indian court. However, the party in whose favor such final judgment is rendered, may bring a fresh suit in a competent court in India, based on a final judgment that has been obtained in a non-reciprocating territory, within three years of obtaining such final judgment. It is unlikely that an Indian court would award damages on the same basis, or to the same extent, as was awarded in a final judgment rendered by a court in another jurisdiction, if the Indian court believes that the amount of damages awarded was excessive or inconsistent with public policy in India. In addition, any person seeking to enforce a foreign judgment in India is required to obtain prior approval of the RBI, to repatriate any amount outside India recovered pursuant to the execution of the judgment and any such amount may be subject to income tax in India in accordance with applicable laws. Any judgment or award in a foreign currency would be converted into Indian Rupees on the date of such judgment or award and not on the date of payment. We cannot predict whether a suit brought in an Indian court will be disposed of in a timely manner or be subject to considerable delays.

***Political instability in India or a significant change in the Indian Government’s economic liberalization and deregulation policies could adversely affect general business and economic conditions in India and our business.***

Two of our six manufacturing facilities as well as our central R&D center are located in India. Our business, and the market price and liquidity of our securities may be affected by foreign exchange rates and controls, interest rates, changes in government policy, taxation, natural calamities, social and civil unrest and other political, economic or other developments in or affecting India.

Since 1991, successive Indian governments have pursued policies of economic liberalization and financial sector reforms. The Indian government has traditionally exercised and continues to exercise influence over many aspects of the economy. The role of the Indian central and state governments in the Indian economy as producers, consumers and regulators has remained significant and we cannot assure you that such liberalization policies will continue. Additionally, corruption and protests against privatizations, which have occurred in the past, could



slow down the pace of liberalization and deregulation in India. The rate of India's economic liberalization could change, and specific laws and policies affecting foreign investment, currency exchange rates and other matters affecting investment in India could change as well. Any such significant change could disrupt business and economic conditions in India generally, and specifically ours, as some of our assets including two of our manufacturing facilities are located in India, which may adversely affect our financial condition and results of operations.

***JGL, our wholly owned Indian subsidiary, is subject to exchange control laws in India.***

There are certain restrictions on the conversion of Indian Rupees into foreign currency. In India, the Foreign Exchange Management Act, 1999 ("FEMA") regulates transactions involving foreign exchange and provides that certain transactions cannot be carried out without the general or special permission of the Reserve Bank of India ("RBI"). The FEMA has eased restrictions on most current account transactions as provided in the Foreign Exchange Management (Current Account Transaction) Rules, 2000, as amended.

However, the RBI continues to exercise significant control over capital account transactions (such as transactions which alter the assets and liabilities, including contingent liabilities outside India of persons resident in India or assets and liabilities in India of persons resident outside India). The RBI has issued regulations under the FEMA to regulate the various kinds of capital account transactions, including certain aspects of the purchase and issuance of shares of Indian companies.

The RBI, being the primary regulator with respect to exchange control laws in India issues regulations and guidelines from time to time and may review foreign exchange transactions undertaken by us, including investments made by our Company in JGL and any transaction undertaken by JLL, our parent, in the shares of our Company. We cannot assure you that we will be able to comply with the relevant requirement, in a timely manner or at all, which may adversely affect our business, financial condition and results of operations.

***We have activities in certain countries that are exposed to a higher risk of sanctions or are subject to sanctions by the United States and other countries.***

The U.S. Department of the Treasury's Office of Foreign Assets Control, or OFAC, administers and enforces trade and economic sanctions laws and regulations that restrict or prohibit U.S. persons as well as persons owned or controlled by U.S. persons and, in some instances, foreign entities, for engaging in activities or transactions with certain countries, governments, entities or individuals. In addition, there may be other sanctions legislation administered and enforced by other regulatory bodies, including the United Nations Security Council, Her Majesty's Treasury and the European Union, and we cannot predict their enforcement policies with regards to our business activities.

As an organization with global operations, we may from time to time conduct business, in accordance with applicable laws, with customers (either directly or indirectly through traders and agents) in various countries that are exposed to higher sanctions risks, such as Venezuela, Ukraine and Qatar. In the last three financial years, sales to customers located in Venezuela, Ukraine and Qatar (who have not been identified as a "Specially Designated National and Blocked Person" or "SDN") have amounted to less than US\$100,000.

In addition, while we have, from time to time, conducted business with customers in Iran, which is the target of U.S. sanctions, this trade has not been subject to U.S. jurisdiction and has not involved SDNs. The payments made for the trade did not involve U.S. persons (the Company is not a U.S. entity, there was no involvement by the Company's CEO based in the U.S. or any of the Company's U.S. subsidiaries) and the payments made did not involve the U.S. financial system (the trade was invoiced and payment was made in Rupees). In the last three financial years, sales by JGL to customers located in Iran have amounted to less than 0.1% of our total income for each such year. In each case, we believe such sales have been conducted in accordance with applicable sanctions laws and regulations.

JPL has standard operating procedures and complies with international sanctions to the extent applicable to the Company. However, if we fail to comply with current or future applicable laws we could incur significant fines and other penalties and suffer negative publicity and reputational damage, which could have a material adverse effect on our financial condition, results of operations or prospects.

***The illegal distribution and sale by third parties of counterfeit versions of our products or of stolen products could harm our patients and reputation.***

Our industry has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous

manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the API or no API at all. However, to distributors and patients, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours. Additionally, it is possible that adverse events caused by unsafe counterfeit products would mistakenly be attributed to the authentic product. In addition, there could be thefts of inventory at warehouses, plants or while in transit, which are not properly stored and which are sold through unauthorized channels. Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, financial condition and results of operations.

***A heightened public or regulatory focus on the radiation risks of diagnostic imaging could have an adverse effect on our business.***

We believe that there has been heightened public and regulatory focus on radiation exposure, including the concern that repeated doses of radiation used in diagnostic imaging procedures pose the potential risk of long-term cell damage, cancer and other diseases. For example, starting in January 2012, CMS required the accreditation of facilities providing the technical component of advanced imaging services, including PET and nuclear medicine, in non-hospital freestanding settings. In August 2011, The Joint Commission (an independent, not-for-profit organization that accredits and certifies more than 20,500 healthcare organizations and programs, including commercial radiopharmacies, in the U.S.) issued an alert on the radiation risks of diagnostic imaging and recommended specific actions for providing “the right test and the right dose through effective processes, safe technology and a culture of safety”. Revised accreditation standards issued by The Joint Commission for diagnostic imaging took effect in July 2015 and continue to evolve.

Heightened regulatory focus on risks caused by the radiation exposure received by diagnostic imaging patients could lead to increased regulation of radiopharmaceutical manufacturers or healthcare providers who perform procedures that use our imaging agents, which could make the procedures more costly, reduce the number of providers who perform procedures and/or decrease the demand for our products. In addition, heightened public focus on or fear of radiation exposure could lead to decreased demand for our products by patients or by healthcare providers who order the procedures in which our agents are used. Any of the foregoing risks could have an adverse effect on our business, financial condition, results of operations and cash flows.

***From time to time, the USFDA issues guidance that is relevant to our industry and/or business and such guidance, if finalized, may have a material impact on our operations.***

From time to time, the USFDA issues guidance that is relevant to our industry and/or business. Most recently, in June 2018, the USFDA released a draft guidance for the industry entitled “*Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations*”. The recommendations are applicable to products that are administered systemically and undergo alpha, beta, and/or gamma decay. The isotopes we use for our radiopharmaceuticals undergo gamma decay. Although adherence to USFDA guidance is not mandatory, and companies are free to use alternative approaches if such approaches satisfy the requirements of applicable laws and regulations, USFDA guidance is a strong indication of the USFDA’s “current thinking” on the topic discussed in the guidance, including its position on enforcement and hence adherence to such guidance is strongly recommended. At this time, it is difficult to determine whether the draft guidance, if finalized, would have a material impact on our operations. However, if the USFDA were to enforce the applicable statutes and regulations in accordance with the draft guidance as written, such enforcement could require us to incur additional expenses, which could be significant, and negatively impact our business in several ways, including, but not limited to, enjoining the manufacturing of our products until the USFDA determines that we are in compliance and can resume manufacturing, increasing our liability and reducing our growth prospects.

On January 1, 2018, new guidelines regarding elemental impurities in brand and generic drug products went into effect. Elemental impurities, such as arsenic and lead, pose toxicological risks to patients without providing any therapeutic benefit. These impurities may be present in drug products from a variety of sources, such as interactions with equipment during the drug manufacturing process. The new guidelines require all new and existing NDAs and ANDAs for drug products with an official U.S. Pharmacopeial (“USP”) monograph to meet the requirements in USP General Chapters 232 and 233 for the control of elemental impurities. In addition, applicants submitting NDAs and ANDAs for drug products without a USP monograph are expected to follow the recommendations in the International Council for Harmonisation (“ICH”) Q3D Elemental Impurities guideline. The new guidelines were implemented further to draft guidance entitled “*Elemental Impurities in Drug Products*” published by the USFDA in June 2016.

Changes in regulatory requirements, USFDA guidance, guidance published by the EMA or the other competent authorities in foreign jurisdictions, or unanticipated events may force us to amend our production, labeling and other processes or protocols resulting in increased costs to us. If we are not able to pass such costs to our customers in the future, our margins may decline, which could have a material adverse effect on our business, financial condition, results of operation, and cash flows.

***Amendments to USP General Chapters 797 and 825 of the USPC relating to compounding standards for the manufacture of medicine are anticipated to occur in 2019.***

Compounding is the combining, mixing or altering ingredients, in any setting, to create medication that can meet unique medical needs of individual patients. USP General Chapters 795 (*Pharmaceutical Compounding—Nonsterile Preparations*), 797 (*Pharmaceutical Compounding—Sterile Preparations*), and 800 (*Hazardous Drugs—Handling in Healthcare Settings*) of the USPC are a set of standards assisting practitioners, including radiopharmacies, to consistently produce quality compounded preparations. To provide a unified approach to quality compounding, USP intends to align the timing and content of these three chapters. USP General Chapters 795 and 797 are currently being revised. Among other content changes in the proposed revisions, hazardous drug handling sections in USP General Chapters 795 and 797 will reference USP General Chapter 800, which was completed and published in February 2016. The U.S. Pharmacopeial Convention (“USPC”), which publishes the USP, expects the three chapters to be aligned on December 1, 2019. The current published versions of these chapters are official until the revisions become official. USP General Chapter 797 is of particular relevance to our business. We cannot guarantee that any of these or other revisions to the USP General Chapters will not lead to increased costs to us or otherwise affect the way we run our business. Our inability to pass such costs to our customers in the future or adapt our business to be in compliance with any applicable revisions, could have a material adverse effect on our business, financial condition, results of operation, and cash flows.

In addition, the anticipated revisions to USP General Chapter 797 will eliminate the section Radiopharmaceuticals as Compounded Sterile Preparations and replace it with a reference to USP General Chapter 825 (*Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Re-packaging*). USP General Chapter 825 will be published for public comment between July 27 and November 30, 2018, and is anticipated to become official on December 1, 2019. At this time, it is difficult to determine whether the proposed revisions to USP General Chapter 825, if finalized, would have a material impact on our operations.

***Brexit could adversely impact our business, financial condition and results of operations.***

On June 23, 2016 the UK voted to leave the EU in a referendum (“Brexit”). Brexit could impair our ability to transact business in EU countries. Brexit has already and could continue to adversely affect European and/or worldwide economic and market conditions and could continue to contribute to instability in the global financial markets and volatility in the value of the Pound Sterling or other currencies, including the Euro. The long-term effects of Brexit will depend in part on any agreements the United Kingdom makes to retain access to EU markets following the United Kingdom’s withdrawal from the EU. We expect that Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which EU laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pharmaceutical industry, we could face unexpected new costs. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations. Altered regulations could also add time and expense to the process by which our product candidates receive regulatory approval in the United Kingdom and EU, and may affect our current drug approvals. The EMA is currently based in London and Brexit may lead to a lengthier process in the future and we may need to engage in a separate drug approval process with the UK’s Medical & Healthcare Products Regulatory Agency (MHRA). Similarly, it is unclear at this time what Brexit’s impact will have on our intellectual property rights and the process for obtaining and defending such rights. It is possible that certain intellectual property rights, such as trademarks, granted by the EU will cease being enforceable in the UK absent special arrangements to the contrary. With regard to existing patent rights, the effect of Brexit should be minimal considering enforceable patent rights are specific to the UK, whether arising out of the European Patent Office or directly through the UK patent office. Existing patent rights covering the UK could have been granted either through an application made to the European Patent Office or the UK patent office. Generally, a patent covering the UK, whether granted by the European Patent Office or the UK patent office, can be litigated in the courts of the UK. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, business opportunities, results of operations, financial condition and cash flows.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with our consolidated financial statements and financial information and operating data. This discussion contains forward-looking statements that reflect our current views with respect to future events and financial performance. Under no circumstances should the inclusion of forward-looking statements herein be regarded as a representation, warranty or prediction with respect to the accuracy of the underlying assumptions by us. Investors are cautioned not to place undue reliance on these forward-looking statements that speak only as at the date hereof. Our consolidated financial statements have been prepared in accordance with IFRS, which may differ in certain significant respects from generally accepted accounting principles in other countries, including U.S. GAAP. Our consolidated financial statements for the financial year ended March 31, 2018 and our interim consolidated financial statements for the nine months ended December 31, 2018 give effect to the completion of our acquisition of our radiopharmacy business from Triad as at September 1, 2017. As a result, the period-to-period comparison of our financial results for the financial years ended March 31, 2017 and 2018 and for the nine months ended December 31, 2017 and 2018, are not strictly comparable and you should not use such comparisons as a basis for your investment or to predict our future performance.*

### Overview

We are a global integrated pharmaceutical company offering a wide range of products and services to our customers across geographies. We organize our business into two segments, namely, Specialty Pharmaceuticals, comprising radiopharmaceuticals (including radiopharmacies), contract manufacturing of sterile injectables and non-sterile products (“**CMO**”) and allergy therapy products, and Generics & APIs, comprising solid dosage formulations and active pharmaceutical ingredients (“**APIs**”). Specialty Pharmaceuticals accounted for close to two-thirds of our total revenue from operations for the financial year ended March 31, 2018, and Generics & APIs accounted for the remainder. As at December 31, 2018, we supplied our products and services to customers in over 80 countries. North America, where a majority of our customers are based, accounted for a significant portion of our total revenue from operations for the financial year ended March 31, 2018. We have four manufacturing facilities in North America and two in India, coupled with research and development (“**R&D**”) centers in North America and India. In addition, we have a distribution network of more than 50 radiopharmacies in the United States. All of our manufacturing facilities are registered with the USFDA and Health Canada, among other regulatory bodies, and all of our radiopharmacies are licensed by state boards of pharmacy in each applicable jurisdiction.

A summary of our business segments is outlined below:

- *Specialty Pharmaceuticals*

- *Radiopharmaceuticals*—We develop, manufacture, distribute and market diagnostic imaging and therapeutic radiopharmaceutical products. According to Frost & Sullivan, we are the third largest radiopharmaceutical manufacturer in the nuclear medicine industry for the United States based on revenue. We have a strong portfolio of differentiated products used in the diagnosis, treatment and monitoring of various diseases. Clinical applications for our radiopharmaceutical products include cardiology, oncology, endocrinology (thyroid diagnostic imaging and therapy), pulmonology (lung perfusion and ventilation scans), renal (kidney), neurology (brain), infection imaging (leukocyte labeling) and bone imaging. Our radiopharmaceuticals business has a well-established base in North America and is also expanding in Latin America, Europe and Asia. In North America, we have our JDI Montreal Facility, a USFDA and Health Canada approved manufacturing facility located in Kirkland, Montreal, Canada for production of our radiopharmaceutical hot products as well as cold products, and a nationwide commercial radiopharmacy distribution network in the United States. We acquired the network in September 2017 to strengthen our radiopharmaceutical distribution capabilities. According to Frost & Sullivan, our distribution network is the second largest centralized commercial radiopharmacy network in the United States with a national footprint of more than 50 radiopharmacies across 22 states. Our radiopharmaceutical customers include third party commercial radiopharmacy networks and our own radiopharmacies, GPOs and regional networks, standalone imaging centers, hospitals and cardiologists in the United States, leveraging our radiopharmaceutical capabilities for end-to-end customer service in the United States.
- *Contract Manufacturing of Sterile Injectables and Non-Sterile Products (CMO)*—We are an integrated contract manufacturer with a broad range of capabilities, which includes developing and producing sterile injectables and non-sterile products. We believe we have predictability and stability in our CMO business underpinned by long-term contracts we have entered into with such customers. We focus on the delivery of clinical and commercial fill and finish services for sterile parenteral pharmaceuticals, utilizing both liquid

and lyophilization capabilities. Additional capabilities include the manufacture of sterile and non-sterile ophthalmics, ampoules, creams, ointments and liquids. Our key markets for sterile injectables and non-sterile products are North America and Europe. Our CMO manufacturing facilities, Spokane Facility and CMO Montreal Facility, have obtained USFDA and Health Canada certifications for their manufacturing processes. Our customer base includes leading innovative pharmaceutical companies in the United States, as well as other companies and organizations in the pharmaceutical and biotechnology industries in North America, Europe and Asia. We contract manufacture cold kits at our CMO Montreal Facility to support our radiopharmaceutical products.

- *Allergy Therapy Products*—We provide allergy therapy products to the allergy specialty industry with a product offering range of over 200 different allergenic extracts and standard allergy vaccine mixtures as well as six different insect venom products for the treatment of allergies to insect stings. According to Frost & Sullivan, we are one of the top three players in the allergenic extract market in the United States with a market share of 17.6% and are currently the sole producer and supplier of venom products for the treatment of allergies in the United States. We produce and market a number of products under the “HollisterStier” brand. Our allergy therapy products business line has traditionally focused on North America as our key market, where we believe we have generated significant brand loyalty due to the quality of our products and long-standing operating history. We also market some of our key products such as allergenic extracts and venom extracts in Canada, Europe, Australia, New Zealand and South Korea through distributors. Our allergy therapy products are manufactured at our Spokane Facility. The primary target user base of our allergy therapy products are allergists; ear, nose and throat physicians; general physicians and hospital-based clinics across North America.
- *Generics & APIs*
  - *Solid Dosage Formulations*—We are engaged in the development, manufacture, sale and distribution of prescription generic pharmaceutical products principally in the United States, and with a growing presence in Europe, Canada, Japan, Australia, as well as the rest of the world. We focus primarily on the manufacture and sale of solid dosage formulations for CVS, CNS, GI and anti-allergy therapeutic categories. According to Frost & Sullivan, we are one of the market leaders in the United States, based on our market share of several key products. As at December 31, 2018, in the United States, we had 28 commercialized solid dosage formulations available. We also have a strong pipeline of products pending approval in a number of jurisdictions. For example, in the United States, since we commenced operations through to December 31, 2018, we have made a total of 96 ANDA filings for solid dosage formulations, of which 35 are pending approval. Our solid dosage formulations business derives benefit from backward integration into our API business and we have two manufacturing facilities for solid dosage formulations, our Salisbury Facility and our Roorkee Facility, both of which are registered with the USFDA and Health Canada.
  - *Active Pharmaceutical Ingredients (APIs)*—We develop and produce APIs in the therapeutic areas of the CVS, CNS, GI, anti-infectives and anti-depressants. According to Frost & Sullivan, we are one of the global suppliers for several key API products based on market share. Approximately 80% of our commercialized portfolio is in lifestyle driven therapeutic areas such as CVS and CNS, catering to an increasing incidence of lifestyle-related medical conditions or non-communicable diseases including cardiac ailments and seizures. Our APIs are produced at manufacturing plants in our Nanjangud Facility. As at December 31, 2018, we had 39 commercialized APIs available globally and had filed 94 DMFs in the United States. Our APIs are exported worldwide, into emerging as well as developed markets. Our key markets are North America, South America, Europe, Japan, Korea, Commonwealth of Independent States (CIS) countries, the Middle East and Australia. According to our internal estimates, we believe approximately 60.0% of our sales are to regulated markets, namely, the United States, Europe and Japan. Our APIs are primarily sold to manufacturers of formulations of generic drugs and used in our solid dosage formulations business line. Approximately 15% of our APIs we produce are used in-house for the manufacturing of solid dosage formulations by the Group.

The following table sets forth a breakdown of our revenue from operations by business lines for the periods indicated:

	Financial Year Ended March 31				Nine Months Ended December 31			
	2017		2018		2017		2018	
	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)
<b>Specialty Pharmaceuticals</b>								
Radiopharmaceuticals . . . . .	121,602.4	26.4	265,060.6	42.8	176,663.2	41.4	267,944.6	47.6
Contract Manufacturing of Sterile Injectables and Non-Sterile Products (CMO) . . . . .	88,740.6	19.3	100,863.4	16.3	66,847.6	15.7	81,630.6	14.5
Allergy Therapy Products . . . . .	36,350.9	7.9	43,598.8	7.0	32,421.5	7.6	38,066.5	6.8
<b>Sub-total Specialty Pharmaceuticals . . . . .</b>	<b>246,694.0</b>	<b>53.6</b>	<b>409,522.9</b>	<b>66.1</b>	<b>275,932.3</b>	<b>64.7</b>	<b>387,641.6</b>	<b>68.9</b>
<b>Generics &amp; APIs</b>								
Solid Dosage Formulations . . . . .	121,992.8	26.4	123,540.8	20.0	88,854.7	20.8	109,629.9	19.4
Active Pharmaceutical Ingredients (APIs) . . . . .	91,885.4	20.0	86,101.9	13.9	61,973.4	14.5	65,587.4	11.7
<b>Sub-total Generics &amp; APIs . . . . .</b>	<b>213,878.1</b>	<b>46.4</b>	<b>209,642.7</b>	<b>33.9</b>	<b>150,828.2</b>	<b>35.3</b>	<b>175,217.2</b>	<b>31.1</b>
<b>Revenue from operations (net) . . .</b>	<b>460,572.1</b>	<b>100.0</b>	<b>619,165.6</b>	<b>100.0</b>	<b>426,760.4</b>	<b>100.0</b>	<b>562,858.8</b>	<b>100.0</b>

#### Financial Impact of Our Recent Acquisition of our Radiopharmacy Business

During the financial year ended March 31, 2018, we acquired substantially all of the assets of Triad’s radiopharmacy business. As a result of the acquisition, we operate the second largest centralized commercial radiopharmacy network in the United States with a national footprint of more than 50 radiopharmacies across 22 states. This distribution platform provides us with direct access to hospital networks and the ability to deliver approximately three million patient doses annually to approximately 1,700 customers. Our acquisition was effective as at September 1, 2017 and as such, our consolidated financial statements for the financial year ended March 31, 2018 and our interim consolidated financial statements for the nine months ended December 31, 2018 include the post-acquisition results of our radiopharmacy business as at September 1, 2017, which contributed significantly to our revenue from operations. As a result, the period-to-period comparison of our financial results for the financial years ended March 31, 2017 and 2018 and for the nine months ended December 31, 2017 and 2018, are not strictly comparable.

#### Consolidation of our Financial Statements

The Company’s consolidated financial statements are prepared in accordance with IFRS as issued by the IASB.

Under the process of consolidation the standalone books of accounts of the Company and its subsidiaries are maintained under their respective local GAAP, the local GAAP trial balances are converted into IFRS and our financial statements are compiled and reported in accordance with IFRS.

KPMG has audited the Company’s consolidated financial statements prepared by us. KPMG has audited the accounts of the Company and its subsidiaries and partnerships for consolidation purposes. The financial statements of the Company and its subsidiaries have been consolidated by adding together the book values of assets and liabilities, equity, income and expenses of our subsidiaries with those of the Company on a line-by-line basis after elimination of (i) the carrying amount of each parent company’s investment in each subsidiary and such parent company’s portion of equity in each subsidiary, (ii) intra-group transactions and (iii) unrealized profits. For more information, see “—Critical Accounting Policies—Basis of preparation”.

#### Operating Segments

We present our financial reporting as two reporting segments, namely: (i) Specialty Pharmaceuticals (consisting of radiopharmaceuticals, CMO and allergy therapy products) and (ii) Generics & APIs (consisting of solid dosage formulations and APIs).

#### Significant Factors Affecting our Results of Operations

##### *Products and Services Offered*

The mix of our product and services offered has changed and, we expect, will continue to change over time. Depending on the nature and magnitude, such changes can impact our profitability. We rely on our principal

products to generate a significant portion of our revenue from operations (net). For example, in the financial year ended March 31, 2018, and the nine months ended December 31, 2018, our top 10 products by revenue contributed 39.4% and 39.4%, respectively, to our revenue from operations.

The prices and profit margins of our products also vary by the types of products produced and the raw materials used. For example, the profit margin of our specialty pharmaceuticals products, which are typically sold with price premiums, is generally higher than our generics products.

The following table shows a breakdown of revenue from operations (net) by key business lines for the periods presented.

	Financial Year Ended March 31				Nine Months Ended December 31			
	2017		2018		2017		2018	
	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)
<b>Specialty Pharmaceuticals</b>								
Radiopharmaceuticals . . . . .	121,602.4	26.4	265,060.6	42.8	176,663.2	41.4	267,944.6	47.6
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Allergy Therapy Products . . . . .	36,350.9	7.9	43,598.8	7.0	32,421.5	7.6	38,066.5	6.8
<b>Sub-total Specialty Pharmaceuticals . . . . .</b>	<b>246,694.0</b>	<b>53.6</b>	<b>409,522.9</b>	<b>66.1</b>	<b>275,932.3</b>	<b>64.7</b>	<b>387,641.6</b>	<b>68.9</b>
<b>Generics &amp; APIs</b>								
Solid Dosage Formulations . . . . .	121,992.8	26.4	123,540.8	20.0	88,854.7	20.8	109,629.9	19.4
Active Pharmaceutical Ingredients (APIs) . . . . .	91,885.4	20.0	86,101.9	13.9	61,973.4	14.5	65,587.4	11.7
<b>Sub-total Generics &amp; APIs . . . . .</b>	<b>213,878.1</b>	<b>46.4</b>	<b>209,642.7</b>	<b>33.9</b>	<b>150,828.2</b>	<b>35.3</b>	<b>175,217.2</b>	<b>31.1</b>
<b>Revenue from operations (net) . . . . .</b>	<b>460,572.1</b>	<b>100.0</b>	<b>619,165.6</b>	<b>100.0</b>	<b>426,760.4</b>	<b>100.0</b>	<b>562,858.8</b>	<b>100.0</b>

Our Specialty Pharmaceuticals business segment is generally characterized by relatively high profit margins, attributable to high barriers of entry due to the capital-intensive nature of the business and the level of technical expertise required to develop, manufacture and obtain regulatory approvals for products. Competitors within the specialty pharmaceuticals space generally aim to develop differentiated and innovative products to maintain market leadership position.

In our Generics & APIs business segment, due to increased competition from other generic pharmaceutical manufacturers as they gain regulatory approvals to market generics products, selling prices and related profit margins tend to decrease as products mature. Thus, our future results of operations are dependent on, among other factors, our ability to continue to produce our products more efficiently by driving integration advantages such as by increasing the proportion of APIs developed in-house as production materials for our solid dosage formulations business line and to continue introducing new products. In addition, we believe efficiencies gained from such vertical integration help us maintain cost competitiveness and enable us to withstand pricing pressures, which are inherent in the generic pharmaceutical industry.

Accordingly, the launch of new products and services and the increase in volume of products sold has continued to have a positive impact on our overall revenues and profitability. We intend to further expand and improve our product portfolio and use innovative technologies to develop new products and improve existing products. We anticipate that future new product launches for our solid dosage formulations and radiopharmaceutical business lines, including mIBG sales, when launched, will contribute significantly to our revenue growth in the future.

### **Research and Development of New Products**

The research and development of new innovative pharmaceutical products is essential to continued positive results of operations. Accordingly, the nature of our R&D expenses and our ability to successfully launch products currently under development may have a material impact on our results of operations in a particular financial year. See “Risk Factors—Risks Relating to Our Business—We are dependent on the success of our R&D and the failure to develop new or improved products or process improvements or production techniques could subject us to write-offs or otherwise adversely affect our business, financial condition and results of operations and have a negative impact on our competitive position”.

In the United States, since we commenced operations through to December 31, 2018, we have made a total of 111 ANDA filings (of which 96 are for solid dosage formulations, four are for sterile injectables and 11 for radiopharmaceuticals), 37 of which were pending for approval (of which 35 are for solid dosage formulations two are for sterile injectables) and three of which were inactive radiopharmaceuticals. Of the 111 ANDA filings made, we have received 74 approvals, of which 61 are for solid dosage formulations, two are for sterile injectables and eight are for radiopharmaceuticals. As at December 31, 2018, we have commercialized 54 solid dosage formulations, and eight radiopharmaceuticals.

As at December 31, 2018, we have been granted patents for intellectual property in various countries for innovations, including 19 active patents granted relating to APIs in a number of different countries, five active patents granted relating to solid dosage formulations in a number of different countries, 123 active patents granted relating to radiopharmaceutical products in a number of different countries and one active patent granted relating to allergy therapy products in the United States.

While our new products are generally protected by substance patents and exclusivity periods, patents are limited to a certain number of years depending on the jurisdiction and type of patent. Notwithstanding such protection, products with potentially higher efficacy, a more favorable side-effect profile or a more convenient mechanism of delivery are constantly being developed and introduced by our competitors even during the patent protected period. Therefore, sales of a given product typically decrease upon expiration of patent protection and the exclusivity period and in some cases earlier if superior products have been introduced to the market. In order to ensure sustained revenue growth, we must be able to develop or otherwise acquire the rights to develop or market innovative new products.

### ***Production Capacity and Utilization***

Our results of operations are directly affected by our sales volume, which in turn is a function of several factors, including our production capacity and market demand. As such, a key driver of sales growth is increased production volume at our facilities. As at December 31, 2018, we operate six manufacturing facilities across India and North America (being the United States and Canada) and a network of 51 radiopharmacies across 22 states in the United States. For more information relating to our historic capacity and utilization, see “*Business—Capacity and Utilization*”. We will continue to seek opportunities to increase production volume by expanding and/or upgrading our production facilities, enhancing the overall effectiveness of our other facilities and the overall utilization of all our assets. This may include capital expenditures and investments for the following: expansion in capacity of lyophilization for our CMO business line, additions to the product portfolio and expanding capacities in our allergy therapy products business line and investment in solid dosage formulations and APIs in India to add new production capacities and/or products to the portfolio. See “*Business—Business Strategies*” and “*Business—Facilities and Offices*” for further information.

### ***Pricing and Government Regulation***

Although we consider competitive conditions, such as pricing of competing products in the markets in which we operate, in setting and revising the price of our products, government regulation also affect the pricing of our products in many of the countries in which we operate. Government policy in many other countries has emphasized, and large customers continue to seek, discounts on pharmaceutical products. Such pricing pressure has predominantly affected us in North America.

For example, our United States solid dosage formulations business sales have been adversely affected by the impact of supply chain consolidation in the United States where certain customers engage in group purchasing agreements to demand higher rebates for higher combined volume such as the partnership of Walgreens, Alliance Boots and Amerisource Bergen, as well as imposing substantial monetary penalties on suppliers for partial or delayed supply deliveries. Together with other industry suppliers, we have taken steps to amend or modify such contracts, as well as taken other steps to mitigate against exposure to such penalties arising in the future.

Governmental policies in countries outside the United States also impact the prices we set for our products sold in such countries, though only to a lesser extent. For example, in Canada, Health Canada monitors and controls prices of patented drug products marketed in Canada by persons holding, or licensed under, one or more patents. The existence of one or more patents relating to a drug product triggers a governmental price control regime that significantly affects the Canadian pharmaceutical industry’s ability to set pricing. Furthermore, in each province of Canada there is a drug benefit formulary. A formulary lists the drugs for which a provincial government will reimburse qualifying persons and the prices at which the government will reimburse such persons. Provincial governments generally will reimburse the lowest available price of the generic equivalents of any drug listed on the formulary list of a province. Consequently, provincial formulary regimes tend to encourage the sale of lower-priced versions of pharmaceutical products. In the case of Japan, the government has the authority to set retail



prices for prescription drugs, especially in the context of sales reimbursed by national health programs. In Europe, the governments of many emerging countries also have national health programs with similar price control systems. In Europe, drug prices have recently decreased due to measures implemented in countries to control drug costs, and drug prices continue to experience downward pressure due to parallel imports, increased competition in generics, increasing use of health technology assessment based upon cost-effectiveness and other factors.

While the United States does not have a general national health insurance system, there has been increasing pricing pressure from managed care groups and institutional and governmental purchasers. The enactment of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act in March 2010 has increased the amount of rebates paid by pharmaceutical companies and continues to have an effect on the prices of certain products, thus potentially adversely affecting the operating income of pharmaceutical companies, although these effects may be offset in part in the medium to long-term by the effects of an increase in individuals covered by healthcare programs, resulting in an increase in demand. The pharmaceutical industry has also experienced significant pricing pressures in certain other emerging markets.

We expect price pressure from government regulation and supply chain consolidation to continue and this may have a negative effect on our revenue and profitability.

The manufacturing process for pharmaceutical products is highly regulated. We have put in place necessary quality systems and control measures to ensure quality is maintained by process design. At the same time, continuous monitoring by our quality control team helps ensure we deliver high quality products. Notwithstanding these measures, regulators who believe manufacturing facilities are not in compliance with applicable regulations, may take one or more steps, which may include the issuance of a Warning Letter by the USFDA or an ordered shut down of manufacturing facilities. Accordingly, there is a possibility we may have to write off the costs of manufacturing any batch that fails to pass quality inspection or meet regulatory approvals.

Three out of six of our manufacturing facilities were inspected by the USFDA in the financial year ended March 31, 2018. Of the remaining sites, the Salisbury Facility was inspected in April 2018, the CMO Montreal Facility was inspected in May 2018 and the Roorkee Facility was inspected in August 2018. Most recently, our Spokane Facility was inspected by the USFDA and the CBER USFDA in October 2018, and our Nanjangud Facility was jointly inspected by the USFDA and Health Canada in December 2018. Several of these recent inspections resulted in the issuance of Form-483 inspectional observations, including inspections of our Roorkee Facility, Nanjangud Facility, Spokane Facility and CMO Montreal Facility. Our radiopharmacy in Kansas City was also inspected in June 2017, before we acquired it in September 2017, for which Form-483 inspectional observations were issued. As of this date, we have not received the EIRs from the most recent inspections of the Spokane Facility, the Roorkee Facility, the Nanjangud Facility or the Kansas City radiopharmacy. We believe the findings from both the Spokane Facility and the Kansas City radiopharmacy inspections have been corrected and are awaiting verification by the USFDA. We have responded to the Form-483 inspectional observations for the Roorkee Facility. Subsequently, the USFDA has classified the inspection at the facility as “Official Action Indicated” through a letter dated November 27, 2018. While we have responded to the USFDA and contested this classification pursuant to our letter dated December 14, 2018, an “Official Action Indicated” classification can result in further regulatory action and the USFDA may also withhold approval for any pending applications in which the Roorkee Facility is listed. Further in respect of our Nanjangud Facility, we have responded to the Form-483 observations from the USFDA in a timely manner. We are of the view that these Form-483 inspectional observations will not affect our current commercial business.

We work to address any inspectional observations in a timely manner to obtain the EIRs from these inspections, indicating formal closure of the inspections as of the date of the respective EIRs. In addition to inspections by the USFDA, in the financial year ended March 31, 2018, we were inspected by a number of other regulatory agencies, including, Health Canada (CMO Montreal Facility and Nanjangud Facility), CDSCO in India (Roorkee Facility), ANVISA Brazil (Spokane Facility) and RP Darmstadt Germany (Roorkee Facility), and in the nine months ended December 31, 2018, we were inspected by Health Canada (JDI Montreal Facility and Nanjangud Facility (joint inspection with the USFDA as described above)). Health Canada, has pursuant to its joint inspection with the USFDA of the Nanjangud Facility, issued to us the same observations as the USFDA as part of their inspection exit notice on December 21, 2018. We responded to Health Canada on January 22, 2019 with details of our corrective and preventive actions. On January 16, 2019, the Nanjangud Facility received a letter from Health Canada indicating a NC rating and with an opportunity to appeal within 10 business days. We have submitted our appeal on January 25, 2019 with a justification to reconsider the NC rating. We are currently in the process of engaging with Health Canada to remediate the concerns with our corrective and preventive actions.

### ***Patent Protection and Generics & APIs***

Generics & APIs is a key business segment for us, and we expect that pricing pressures on patented drugs will continue to shift consumer demand to generics as prices decrease. Pricing pressures on patented drugs are due to the increasing and/or high prices of patented drugs, which makes such patented drugs more susceptible to a decline in prices of generic drugs. As patented drugs are relatively more expensive as compared to generic drugs, for which the pricing trend is generally decreasing, the demand for drugs is shifting towards generic drugs, which cost relatively less. As patented drugs are relatively more expensive as compared to generic drugs, for which the pricing trend is generally decreasing, the demand for drugs is shifting towards generic drugs, which cost relatively less.

We believe that the impact of drug patent expiry can benefit us. In general, the expiry of patents benefits our business by creating opportunities to create new indications for existing drugs or develop slightly altered chemical combinations of existing drugs, although the expiry of patents may increase competitive pressure (see *“Risk Factors—Risks Relating to our Business—Our revenues and profits from generic pharmaceutical products may, and often do, decline as a result of pricing pressures and the continuing consolidation of our customer base and commercial alliances among our customers”*). In addition, we believe patent expiries can directly benefit us by leading to overall sales volume growth in the market. However, the pricing of generics and APIs has been under pressure recently due to the declining prices of solid dosage formulations in the pharmaceuticals market brought about by the supply chain consolidation in the United States.

Legal protections and remedies for intellectual property are significant factors in determining the competitiveness of and demand for, as well as the prices of, our generics & APIs products. From time to time, we may also be involved in patent disputes, claims, or proceedings or in patent infringement suits brought by third parties. Unfavorable resolution of any such claims or proceedings could have a material adverse effect on our results of operations and/or cash flow in any given accounting period, or on our overall financial condition. For more information, see *“Risk Factors—Risks Relating to our Business—If we are unable to defend ourselves in challenges related to intellectual property rights, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or we could be subject to substantial liabilities that would lower our profits and adversely affect our financial condition”* and *“Business—Legal Proceedings”*.

### ***Our Ability to Manage Cost of Materials Consumed***

Cost of materials consumed consists of the cost of raw materials used in the manufacturing of our products. Our cost of materials consumed are generally impacted by production volumes, mix of products, the prices paid for raw materials, production efficiency and cost control measures adopted. Cost of materials consumed is a significant component of our total expenses comprising 22.7%, 25.8% and 26.9% of our revenue from operations (net) in the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2018, respectively. Cost of materials consumed increased between the financial years ended March 31, 2017 to March 31, 2018 due to the additional materials consumed by our newly acquired radiopharmacies.

The prices and availability of our raw materials may vary with market conditions and may be highly volatile. Where feasible or advantageous, we enter into multi-year contracts with volume commitments and prices which are linked to key input material prices. In certain business lines and with certain customers we are able to pass increased costs to buyers gradually overtime. However, there have been in the past, and may be in the future, periods during which we cannot pass raw material price increases on to customers due to competitive pressure. To the extent we cannot pass on some or all of any increases in the price of raw materials to our customers, any such increases could have a material adverse effect on revenue and results of operations. Even in periods during which raw material prices decrease, we may suffer decreasing operating profit margins if the prices of raw materials decrease more slowly than the selling prices of our products. See *“Risk Factors—Risks Relating to Our Business—If we cannot maintain our position as a low-cost manufacturer in certain of our business lines, we may not be able to capture anticipated business opportunities or we may lose market share”*.

We have implemented various cost control measures and efficiency improvements, such as our business excellence programs, working capital management and other initiatives related to processes and systems pertaining to sourcing, manufacturing, utilities, logistics and sales across our businesses.

### ***Geographic Mix***

The mix of countries in which our products are sold, has changed, and, we expect, will continue to change over time, which impact our profitability. As at December 31, 2018, our products are sold in over 80 countries either through a dedicated sales and marketing team or, in countries where we are less established, through third party distributors.

During the financial year ended March 31, 2018, revenue generated within North America accounted for 80.1% of our total consolidated revenue, compared to 70.6% during the financial year ended March 31, 2017. The increase in contribution of revenues from North America for financial year ended March 31, 2018 was attributable, in part, to the acquisition of our radiopharmacy business, effective as at September 1, 2017. We expect revenues and profitability in North America to continue to account for a significant portion of our future consolidated revenues as we continue to focus on a strong pipeline of products and develop differentiated products in our Specialty Pharmaceuticals business segment with an objective to cater to the regulated U.S. market and as we continue to upgrade and expand our radiopharmacies across North America.

The following table is a breakdown of our revenue from operations (net) by geographic region, including the percentage contribution by such regions to our total revenue from operations for the periods indicated.

	Financial Year Ended March 31				Nine Months Ended December 31			
	2017		2018		2017		2018	
	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)	(US\$ thousands)	(%)
North America . . . . .	325,091.8	70.6	495,649.5	80.1	340,782.5	79.9	461,301.2	82.0
Europe . . . . .	80,225.3	17.4	57,794.6	9.3	42,632.7	10.0	49,882.1	8.9
Asia . . . . .	31,977.3	6.9	39,502.5	6.4	28,000.4	6.6	31,518.9	5.6
Rest of the world . . . . .	23,277.7	5.1	26,219.1	4.2	15,344.8	3.6	20,156.7	3.6
<b>Revenue from operations (net) . . .</b>	<b>460,572.1</b>	<b>100.0</b>	<b>619,165.6</b>	<b>100.0</b>	<b>426,760.4</b>	<b>100.0</b>	<b>562,858.8</b>	<b>100.0</b>

### *Our Ability to Effectively Compete with Other Market Participants*

The pharmaceutical industry is highly competitive and is affected by new technologies, new developments, government regulations, healthcare legislation, availability of capital or financing and other factors. Many of our competitors have longer operating histories and substantially greater financial, research and development, marketing and other resources than us. We compete with numerous other companies that currently operate, or intend to operate, in the pharmaceutical industry, including companies that are engaged in the development, manufacturing and distribution of radiopharmaceutical, allergy therapy, generics & APIs products. We also compete with numerous companies that currently engage in the contract manufacturing of pharmaceutical products business.

In our Specialty Pharmaceuticals business 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 to them or otherwise more well-established. If competitors introduce new products or new variations to their existing products, our marketed products may be replaced in the marketplace or we may be required to rationalize our prices by adjusting them, generally lower, to remain competitive.

In our Generics & APIs business segment, we compete with (i) the original manufacturers of the brand-name equivalents of products produced by our Generics & APIs business segment, (ii) other API and/or generic drug manufacturers (including brand-name companies that also manufacture APIs or generic drugs or license their products to other API and/or generic drug manufacturers) and (iii) manufacturers of new drugs that may compete with our generic drugs. In the recent past, the barriers to entry for new entrants to the generic and/or API industry have reduced, thus resulting in a larger competitive field. At the same time, the customer base for generic and/or API manufacturers has seen significant consolidation at the purchasing level, resulting in increased purchasing power for the customer. This dual effect of increased competition and increased purchasing power has resulted in a downward trend for prices for our Generics & APIs business segment products.

For more information on our competitors across business segments, see “*Business—Competition*” and “*Risk Factors—Risks Relating to Our Business—If we are unable to respond adequately to the increased competition that we may face in the future we will lose market share and our revenues or profits will go down*”.

### *Foreign Currency Exchange Rate Exposure*

North America, where a majority of our customers are based, accounted for 80.1% and 82.0% of our total revenue from operations for the financial year ended March 31, 2018 and the nine months ended December 31,

2018, respectively. See “—*Significant Factors Affecting our Results of Operations—Geographic Mix*”. To a lesser extent, we also manufacture and sell products to customers outside North America in multiple foreign currencies and face translation and transaction risks related to fluctuations in the exchange rates of such currencies. Our consolidated financial statements are presented in U.S. dollars, and by translating the foreign currency financial statements of our foreign subsidiaries into U.S. dollars, the amounts of our revenue from operations (net), profit for the year and total assets, on a consolidated basis, are affected by prevailing rates of exchange, in particular for Canadian dollars and Indian rupee.

We have in the past utilized certain hedging instruments, including forward contracts with respect to our exports and imports from and into India. However, due to market uncertainties, currently the Company has decided not to enter into any forward contracts for the time being. Currently, we also have not hedged our loans, and accordingly, we are exposed to the impact of fluctuations in foreign currency exchange rates. See “*Risk Factors—Risks Relating to Our Business—Because we have substantial international operations, our sales and profits may be adversely affected by currency fluctuations and restrictions as well as credit risks and appreciation or depreciation of other currencies against the U.S. dollar could affect the cost competitiveness of our international sales and reduce our overall profitability, increase the cost of our imports, borrowings and repayment of indebtedness and reduce our net income*”.

### ***Interest Rate Exposure***

Changes in interest rates affect our interest expenses on floating rate debt instruments and loans and our interest income from cash and cash equivalents. We have in the past entered into floating to fixed interest rate swap agreements. However, due to market uncertainties, currently the Company has decided not to enter into any fixed interest rate swap agreement for the time being.

As at March 31, 2018 and December 31, 2018, 3.0% and 2.1% of our total indebtedness bore interest at floating rates, respectively.

### **Critical Accounting Policies**

The consolidated financial statements of the Group have been prepared in conformity with IFRS.

The preparation of these consolidated financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting period.

Management believes that the estimates used in the preparation of the consolidated financial statements are reasonable. Although these estimates are based upon management’s best knowledge of current events and actions, actual results could differ from these estimates. Any changes in estimates are adjusted prospectively in the consolidated financial statements. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Our critical accounting policies are described below.

### ***Basis of preparation***

The Group’s consolidated financial statements have been prepared in compliance with IFRS as issued by IASB, to reflect the consolidated financial position, consolidated financial performance and consolidated cash flows of the Group. Such consolidated financial statements have been prepared under historical cost convention on accrual basis, unless otherwise stated.

### ***Principles of consolidation***

The consolidated financial statements comprise the financial statements of the Company and the entities controlled by the Company including its subsidiaries and partnerships. Subsidiaries are entities controlled by the Group. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Specifically, the Group controls an investee if and only if the Group has (i) power over the investee (i.e. existing rights that give it the current ability to direct the relevant activities of the investee); (ii) exposure, or rights, to variable returns from its involvement with the investee; and (iii) the ability to use its power over the investee to affect its returns.

Generally, there is a presumption that a majority of voting rights result in control. To support this presumption and when the Group has less than a majority of the voting or similar rights of an investee, the Group considers all

relevant facts and circumstances in assessing whether it has power over an investee, including (i) the contractual arrangement with the other vote holders of the investee; (ii) rights arising from other contractual arrangements; (iii) the Group's voting rights and potential voting rights; and (iv) the size of the Group's holding of voting rights relative to the size and dispersion of the holdings of the other voting rights holders.

The Group re-assesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of an entity begins when the Group obtains control over that entity and ceases when the Group loses control over the entity. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date the Group gains control until the date the Group ceases to control the entity.

Consolidated financial statements are prepared using uniform accounting policies for like transactions and other events in similar circumstances. If a member of the Group uses accounting policies other than those adopted in the consolidated financial statements for like transactions and events in similar circumstances, appropriate adjustments are made to that Group member's financial statements in preparing the consolidated financial statements to ensure conformity with the Group's accounting policies.

The financial statements of all entities used for the purpose of consolidation are drawn up to same reporting date as that of the parent company, i.e., financial year ended on March 31. When the end of the reporting period of the parent is different from that of a member of the Group, the member prepares, for consolidation purposes, additional financial information as at the same date as the financial statements of the parent to enable the parent to consolidate the financial information of the subsidiary, unless it is impracticable to do so. None of the members of the Group have an end of reporting period that is different from that of the parent company. If in the future a member of the Group has a different end of reporting period, such member will complete their financial information through the end of reporting period of the parent company to enable the parent company to compile consolidated financial statements.

#### ***Foreign currency translation***

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates, being the functional currency. The consolidated financial statements are presented in U.S. dollar.

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at the reporting date exchange rates are generally recognized in the consolidated statement of profit or loss and other comprehensive income.

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss. For example, translation differences on non-monetary assets such as equity investments classified as fair value through other comprehensive income are recognized in other comprehensive income.

Effective April 1, 2018, the Group adopted IFRS interpretation IFRIC 22 "Foreign Currency Transactions and Advance Consideration" which clarifies reference dates of transactions for the purpose of determining the exchange rate to be used on initial recognition of related asset, expense or income when an entity has received or paid in advance consideration in a foreign currency. The adoption of this amendment does not have any effect on our consolidated interim financial statements.

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy as of this date) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- Share capital and opening reserves and surplus are carried at historical cost.
- All assets and liabilities, both monetary and non-monetary, (excluding share capital, opening reserves and surplus) are translated using closing rates at reporting date.
- Profit and loss items are translated at the respective quarterly average rates or the exchange rate that approximates the actual exchange rate on date of specific transaction.
- Contingent liabilities are translated at the closing rates at the reporting date.
- All resulting exchange differences are recognized in "other comprehensive income".

When a foreign operation is sold, the associated cumulative exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.

The items of consolidated cash flow statements are translated at the respective average rates or the exchange rate that approximates the actual exchange rate on date of specific transaction. The impact of changes in exchange rate on cash and cash equivalent held in foreign currency is included in effect of exchange rate changes.

### **Revenue recognition**

Effective April 1, 2018, the Group adopted IFRS 15 “Revenue from Contracts with Customers” using the cumulative catch-up transition method, applied to contracts that were not completed as at April 1, 2018. In accordance with the cumulative catch-up transition method, the comparatives have not been retrospectively adjusted. There is no material effect on adoption of IFRS 15 on the consolidated interim financial statements.

Revenue from sale of products is recognized upon transfer of control of products to customers at the time of shipment to or receipt of goods by the customers. Service income is recognized as and when the underlying services are performed. The Group exercises judgement in determining whether the performance obligation is satisfied at a point in time or over a period of time.

Any fees including upfront fees received in relation to contract manufacturing arrangements is recognized on straight line basis over the period over which the Group satisfies the underlying performance obligations.

Revenues are measured based on the transaction price, which is the consideration, net of tax collected from customers and remitted to government authorities such as sales tax, excise duty, value added tax and applicable discounts and allowances including charge-backs, expected sales return and bill backs. The computation of these estimates involves significant judgment based on various factors including contractual terms, historical experience, estimated inventory levels and expected sell-through levels in supply chain.

Contract assets are recognized when there is excess of revenue earned over billings on contracts. Contract assets are classified as unbilled revenue (only act of invoicing is pending) when there is unconditional right to receive cash as per contractual terms. Deferred revenue (“contract liability”) is recognized when there are billings in excess of revenues.

Income in respect of entitlement towards export incentives is recognized in accordance with the relevant scheme on recognition of the related export sales. Such export incentives are recorded as part of other operating income.

### **Inventories**

Inventories are valued at lower of cost or net realizable value except scrap, which is valued at net estimated realizable value.

The methods of determining cost of various categories of inventories are as follows:

Raw materials . . . . .	Weighted average method
Stores and spares . . . . .	Weighted average method
Work-in-progress and finished goods (manufactured) . .	Variable cost at weighted average including an appropriate share of variable and fixed production overheads. Fixed production overheads are included based on normal capacity of production facilities
Fuel, consumables, packing material etc. . . . .	Weighted average method
Finished goods (traded) . . . . .	Weighted average method
Goods in transit . . . . .	Cost of purchase

Cost includes all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition inclusive of excise duty wherever applicable. Excise duty liability is included in the valuation of closing inventory of finished goods.

Net realizable value is the estimated selling price in the ordinary course of business, less the estimated costs of completion and the estimated costs necessary to make the sale.

The net realizable value of work-in-progress is determined with reference to the selling prices of related finished products. Raw materials and other supplies held for use in the production of finished products are not written down below cost, except in cases where material prices have declined and it is estimated that the cost of the finished products will exceed their net realizable value.

The comparison of cost and net realizable value is made on an item-by-item basis.

## ***Property, plant and equipment and intangible assets***

### *Property, plant and equipment*

Freehold land is carried at cost. All other items of property, plant and equipment are stated at cost, which includes capitalized finance costs, less accumulated depreciation and any accumulated impairment loss. Cost includes expenditure that is directly attributable to the acquisition of the items. The cost of an item of a property, plant and equipment comprises its purchase price including import duty, and other non-refundable taxes or levies and any directly attributable cost of bringing the asset to its working condition of its intended use and estimated costs of dismantling and removing the item. Any trade discounts and rebates are deducted in arriving at the purchase price.

Expenditure incurred on startup and commissioning of the project and/or substantial expansion, including the expenditure incurred on trial runs (net of trial run receipts, if any) up to the date of commencement of commercial production are capitalized. Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Advances paid towards acquisition of property, plant and equipment outstanding at each reporting date, are shown under other non-current assets and cost of assets not ready for intended use before the year end, are shown as capital work-in-progress.

### *Intangible assets*

Goodwill on acquisitions of subsidiaries is included in intangible assets. Goodwill is not amortized but it is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired, and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold. Goodwill is allocated to cash-generating units for the purpose of impairment testing. The allocation is made to those cash-generating units or groups of cash-generating units that are expected to benefit from the business combination in which the goodwill arose. The units or groups of units are identified at the lowest level at which goodwill is monitored for internal management purposes.

Intangible assets (including intangible assets under development) that are acquired and implementation of software system are measured initially at cost. Internally generated goodwill is not recognized as an asset. Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognized in the consolidated statement of profit or loss and other comprehensive income as incurred. Development expenditure including regulatory cost and legal expenses leading to product registration/market authorization relating to the new and/or improved product and/or process development capitalized only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Group intends to and has sufficient resources to complete development and to use the asset. The expenditure capitalized includes the cost of materials, direct labor, overhead costs that are directly attributable to preparing the asset for its intended use, and directly attributable finance costs (in the same manner as in the case of tangible fixed assets). Other development expenditure is recognized in the consolidated statement of profit or loss and other comprehensive Income as incurred.

After initial recognition, an intangible asset is carried at its cost less accumulated amortization and any accumulated impairment loss. Subsequent expenditure is capitalized only when it increases the future economic benefits from the specific asset to which it relates.

### *Depreciation and amortization methods, estimated useful lives and residual value*

Property, plant and equipment are stated at cost less accumulated depreciation and amortization. The Group depreciates property, plant and equipment over the estimated useful life using the straight-line method. Upon retirement or disposal of assets, the cost and accumulated depreciation are eliminated from the accounts and the resulting gain or loss is credited or charged to consolidated statement of profit and loss and other comprehensive income. Freehold land is not depreciated.

The estimated useful lives of assets are as follows:

Buildings factory and others	30-60 years
Plant and equipment	1-20 years
Office equipment	3-15 years
Furniture and fixtures	3-15 years
Vehicles owned	3-5 years
Vehicles under finance lease	Period of the lease

Intangible assets are amortized over their estimated useful lives using a method of amortization that reflects the pattern in which the economic benefits of the intangible assets are consumed or otherwise realized.

The estimated useful lives of intangibles are as follows:

Product registration/market authorization	3-20 years
Acquired patents, trademarks / trade names and customer contracts	1-12 years
Software	5 years

Depreciation and amortization methods, useful lives and residual values are reviewed at the end of each reporting period by management and adjusted if appropriate.

#### *Derecognition*

Property, plant and equipment and intangible assets are derecognized on disposal or when no future economic benefits are expected from their use and disposal. Losses arising from retirement and gains or losses arising from disposal of a tangible asset are measured as the difference between the net disposal proceeds and the carrying amount of the asset and are recognized in the consolidated statement of profit or loss and other comprehensive income.

#### ***Business Combination***

Business combinations (other than business combinations between common control entities) are accounted for using the purchase (acquisition) method. The cost of an acquisition is measured as the fair value of the consideration transferred, equity instruments issued and liabilities incurred or assumed at the date of exchange. The consideration transferred does not include amounts related to the settlement of pre-existing relationships, such amounts are generally recognized in the consolidated statement of profit or loss and other comprehensive income. The cost of acquisition also includes the fair value of any contingent consideration. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at fair value at the date of acquisition. For each business combination, the group elects whether to measure the non-controlling interest in the acquiree at fair value or at the proportionate share and the acquiree's identifiable net assets. Transaction costs incurred in connection with a business combination are expensed as incurred.

Any contingent consideration is measured at fair value at the date of acquisition. If an obligation to pay contingent consideration that meets the definition of a financial instrument is classified as equity, it is not remeasured subsequently and settlement is accounted with in the equity. Otherwise, other contingent consideration is remeasured at fair value at each reporting date and subsequent changes to the fair value of the contingent consideration are recognized in consolidated statement of profit or loss and other comprehensive income.

The excess of the consideration transferred over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the business acquired, the difference is recognized in consolidated statement of profit and loss and other comprehensive income, provided there is clear evidence of the underlying reasons for classifying the business combination as a bargain purchase.

Business combinations arising from transfers of interests in entities that are under the control of the shareholder that controls the Group are accounted for as if the acquisition had occurred at the beginning of the earliest comparative period presented or, if later, at the date that common control was established; for this purpose comparatives are revised. The assets and liabilities acquired are recognized at their carrying amounts. The identity of the reserves is preserved and they appear in the consolidated financial statements of the Group in the same form in which they appeared in the financial statements of the acquired entity. The differences, if any, between the consideration and the amount of share capital of the acquired entity is transferred to equity.



## ***Income tax***

Income tax expense comprises current and deferred tax. It is recognized in consolidated statement of profit or loss and other comprehensive income except to the extent that it relates to a business combination, or items recognized directly in equity or in other comprehensive income.

### *Current tax*

Current tax comprises the expected tax payable or receivable on the taxable income or loss for the year and any adjustment to the tax payable or receivable in respect of previous years. The amount of current tax payable or receivable is the best estimate of the tax amount expected to be paid or received after considering uncertainty related to income taxes, if any. It is measured using tax rates enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

Current tax assets and liabilities are offset only if there is a legally enforceable right to set off the recognized amounts, and it is intended to realize the asset and settle the liability on a net basis or simultaneously.

## ***Employee benefits***

### *Short-term employee benefits*

All employee benefits falling due within 12 months of the end of the period in which the employees render the related services are classified as short-term employee benefits, which include benefits like salaries, wages, short-term compensated absences, performance incentives, etc. and are recognized as expenses in the period in which the employee renders the related service and measured accordingly.

### *Post-employment benefits*

Post-employment benefit plans are classified into defined benefits plans and defined contribution plans as under:

- **Gratuity:** The Group has an obligation towards gratuity, a defined benefit retirement plan covering eligible employees. The plan provides for a lump sum payment to vested employees at retirement, death while in employment or on termination of employment of an amount based on the respective employee's salary and the tenure of employment. The liability in respect of Gratuity (applicable for Indian entities of the Group), is recognized in the books of accounts based on actuarial valuation by an independent actuary. The gratuity liability for certain employees of the Group is funded with Life Insurance Corporation of India.
- **Provident fund:** JGL makes contribution to a recognized provident fund, VAM Employees Provident Fund Trust, a multiemployer trust, for most of its employees in India, which is a defined benefit plan to the extent that the Group has an obligation to make good the shortfall, if any, between the return from the investments of such trust and the notified interest rate. The Group's obligation in this regard is determined by an independent actuary and provided for if the circumstances indicate that the Trust may not be able to generate adequate returns to cover the interest rates notified by the Indian Government. For other employees in India, provident fund is deposited with the Employee's Provident Fund Organization and such deposit is treated as defined contribution plan. The Group's contribution to the provident fund is charged to consolidated statement of profit or loss and other comprehensive income. The Group also makes contribution to various social security plans and insurance schemes as per local requirements as applicable and generally accepted practices in their respective country of incorporation. Such contributions are recorded under consolidated statement of profit or loss and other comprehensive income on accrual basis in the year in which liability to pay arise.

### *Other long-term employee benefits*

- **Compensated absences:** As per the Group's policy, eligible leaves can be accumulated by the employees and carried forward to future periods to either be utilized during the service, or encashed. Encashment can be made during service, on early retirement, on withdrawal of scheme, at resignation and upon death of the employee. Accumulated compensated absences are treated as other long-term employee benefits.
- **Termination benefits:** Termination benefits are recognized as an expense when, as a result of a past event, the Group has a present obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation.

### *Actuarial valuation*

The liability in respect of all defined benefit plans and other long-term employee benefits is accrued in the consolidated books of account on the basis of actuarial valuation carried out by an independent actuary using the

Projected Unit Credit Method. The obligation is measured at the present value of estimated future cash flows. The discount rates used for determining the present value of obligation under defined benefit plans, is based on the market yields on government securities as at the Reporting date, having maturity periods approximating to the terms of related obligations.

Remeasurement gains and losses on other long-term employee benefits are recognized in the consolidated statement of profit and loss in the year in which they arise. Remeasurement gains and losses in respect of all defined benefit plans arising from experience adjustments and changes in actuarial assumptions are recognized in the period in which they occur, directly in other comprehensive income. They are included in Remeasurements of defined benefit obligations in the Consolidated Statement of Changes in Equity and in the Consolidated Statement of Financial Position. Changes in the present value of the defined benefit obligation resulting from plan amendments or curtailments are recognized immediately in profit or loss as past service cost. Gains or losses on the curtailment or settlement of any defined benefit plan are recognized when the curtailment or settlement occurs. Any differential between the plan assets (for a funded defined benefit plan) and the defined benefit obligation as per actuarial valuation is recognized as a liability if it is a deficit or as an asset if it is a surplus (to the extent of the lower of present value of any economic benefits available in the form of refunds from the plan or reduction in future contribution to the plan).

Past service cost is recognized as an expense in the consolidated statement of profit or loss and other comprehensive income on a straight-line basis over the average period until the benefits become vested. To the extent that the benefits are already vested immediately following the introduction of, or changes to, a defined benefit plan, the past service cost is recognized immediately in the consolidated statement of profit or loss and other comprehensive income. Past service cost may be either positive (where benefits are introduced or improved) or negative (where existing benefits are reduced).

#### ***Measurement of fair values***

A number of the accounting policies and disclosures require measurement of fair values, for both financial and non-financial assets and liabilities.

Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques as follows:

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The Group has an established control framework with respect to the measurement of fair values. This includes a finance team that has overall responsibility for overseeing all significant fair value measurements, including Level 3 fair values.

The finance team regularly reviews significant unobservable inputs and valuation adjustments. If third party information, is used to measure fair values, then the finance team assesses the evidence obtained from the third parties to support the conclusion that these valuations meet the requirements of IFRS, including the level in the fair value hierarchy in which the valuations should be classified.

When measuring the fair value of an asset or a liability, the Group uses observable market data as far as possible. If the inputs used to measure the fair value of an asset or a liability fall into different levels of the fair value hierarchy, then the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire measurement.

The Group recognizes transfers between levels of the fair value hierarchy at the end of the reporting period during which the change has occurred.

Further information about the assumptions made in measuring fair values used in preparing these consolidated financial statements is included in the respective notes.

#### ***Impairment of non-financial assets***

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. The Group's other non-financial assets other than inventories and deferred tax assets, are reviewed at each reporting date to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated.

For impairment testing, assets that do not generate independent cash inflows are grouped together into cash-generating units (“CGUs”). Each CGU represents the smallest group of assets that generates cash inflows that are largely independent of the cash inflows of other assets or CGUs. Goodwill arising from a business combination is allocated to CGUs that are expected to benefit from the synergies of the combination.

The recoverable amount of a CGU is the higher of its value in use and its fair value less costs to sell. Value in use is based on the estimated future cash flows, discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the CGU.

An impairment loss is recognized if the carrying amount of an asset or CGU exceeds its estimated recoverable amount. Impairment loss recognized in respect of a CGU is allocated first to reduce the carrying amount of any goodwill allocated to the CGU, and then to reduce the carrying amounts of the other assets of the CGU (or group of CGUs) on a pro rata basis.

An impairment loss in respect of goodwill is not subsequently reversed. In respect of other assets for which impairment loss has been recognized in prior periods, the Group reviews at reporting date whether there is any indication that the loss has decreased or no longer exists. An impairment loss is reversed if there has been a change in the estimates used to determine the recoverable amount. Such a reversal is made only to the extent that the asset’s carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortization, if no impairment loss had been recognized.

## Principal Components of Statements of Comprehensive Income

### Business Segments

For our financial reporting, we classify our business activities into two segments, namely (i) Specialty Pharmaceuticals (consisting of radiopharmaceuticals, CMO and allergy therapy products) and (ii) Generics & APIs (consisting of solid dosage formulations and APIs).

The following table shows a calculation of profit for the year/ period from the business segments for the periods presented.

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
<b>Segmental Results<sup>(1)</sup></b>				
Specialty Pharmaceuticals . . . . .	85,957.4	110,670.0	82,792.5	108,285.8
Generics & APIs . . . . .	30,526.2	(2,603.9)	4,416.7	29,678.3
<b>Segment total</b> . . . . .	<b>116,483.6</b>	<b>108,066.2</b>	<b>87,209.2</b>	<b>137,964.1</b>
Un-allocated corporate expenses (net of un-allocated income) . . . . .	(8,660.5)	(12,332.9)	(9,091.9)	(12,559.6)
Finance income . . . . .	2,125.3	4,606.8	3,472.3	3,443.8
Finance costs . . . . .	(36,740.4)	(27,488.5)	(20,198.8)	(18,596.6)
<b>Profit before tax</b> . . . . .	<b>73,207.9</b>	<b>72,851.5</b>	<b>61,390.7</b>	<b>110,251.7</b>
Income tax expense . . . . .	(22,947.9)	(23,734.7)	(17,788.1)	(33,251.0)
<b>Profit for the year/ period</b> . . . . .	<b>50,260.0</b>	<b>49,116.9</b>	<b>43,602.7</b>	<b>77,000.7</b>

Note:

(1) Segmental results as shown in our consolidated financial statements are equivalent to earnings before interest and tax (EBIT) and un-allocated expenses.

### **Revenue from Operations (net)**

Revenue from operations (net) consists of the revenue from the sale of pharmaceutical goods and services by the Group as well as certain other operating revenues. The following table shows the breakdown of our revenue from operations (net).

	<b>Financial Year Ended March 31</b>		<b>Nine Months Ended December 31</b>	
	<b>2017</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>
	(US\$ thousands)			
Sale of products . . . . .	348,734.2	511,042.1	354,419.7	473,940.0
Sale of services . . . . .	104,267.2	100,768.8	67,304.6	81,788.1
Other operating revenue <sup>(1)</sup> . . . . .	7,570.8	7,354.7	5,036.2	7,130.7
	<u>460,572.1</u>	<u>619,165.6</u>	<u>426,760.4</u>	<u>562,858.8</u>

Note:

(1) Includes government grant recognized of US\$5.6 million, US\$4.0 million, US\$2.9 million and US\$3.3 million in the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2017 and 2018.

Sale of products represents revenue from the sales of our pharmaceutical products, namely radiopharmaceuticals, CMO, allergy therapy, solid dosage formulations and API products. Sale of services represents revenue from our CMO business line. Other operating revenue represents, among others, export incentives received on export of goods and services from India, insurance proceeds received for any loss of profit claims from our business interruption policy coverage, sales of scrap materials and delivery charges.

### **Cost of Materials Consumed**

Cost of materials consumed represents the price we paid for the raw materials used in the manufacturing of our products.

### **Changes of Inventories of Finished Goods, Stock-in-trade and Work-in-progress**

Changes of inventories of finished goods, stock-in-trade and work-in-progress represents the net increases or decreases of such items.

### **Employee Benefits Expense**

Employee benefits expense comprises salaries, bonus and wages paid to our employees, our contribution to employee's provident fund, superannuation and other funds, share-based payment expense and staff welfare expenses. The following table shows the breakdown of our employee benefits expense.

	<b>Financial Year Ended March 31</b>		<b>Nine Months Ended December 31</b>	
	<b>2017</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>
	(US\$ thousands)			
Salaries, wages, bonus, gratuity and allowances . . . . .	109,542.2	149,746.7	105,043.9	133,646.1
Contribution to provident fund, superannuation and other funds . . . . .	9,986.4	11,550.1	8,032.8	9,388.1
Share-based payment expense . . . . .	7.4	—	—	—
Staff welfare expenses . . . . .	12,051.2	18,627.2	13,035.2	17,241.2
<b>Total employee benefit expense . . . . .</b>	<b><u>131,587.1</u></b>	<b><u>179,923.9</u></b>	<b><u>126,111.9</u></b>	<b><u>160,275.3</u></b>

### **Depreciation, Amortization and Impairment**

Depreciation, amortization and impairment represents depreciation of property, plant and equipment and the amortization and impairment of intangible assets (including intangible assets under development).

### Other Expenses

Other expenses primarily comprise those expenses incurred in the operation of our businesses. The following table shows the breakdown of our other expenses for the periods specified.

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
Consumption of stores and spares and packing materials . . . . .	16,041.3	19,280.8	14,255.2	13,816.1
Processing charges . . . . .	659.4	1,459.5	1,189.0	1,186.8
Excise duty related to increase/(decrease) in inventory of finished goods . . . . .	5.8	470.1	127.1	—
Repairs and maintenance				
Plant and machinery . . . . .	5,505.9	6,235.8	4,571.6	5,808.1
Buildings . . . . .	3,001.5	3,893.2	2,652.5	2,963.3
Others . . . . .	1,750.1	2,818.6	2,146.0	2,030.8
Office expenses . . . . .	1,202.9	1,475.0	1,154.8	1,119.2
Communication charges . . . . .	1,169.5	2,495.5	1,667.3	2,556.3
Power and fuel . . . . .	10,897.1	14,127.3	10,418.0	12,235.0
Rental expense . . . . .	1,835.8	4,722.7	2,922.4	4,919.3
Rates and taxes . . . . .	5,455.5	6,999.0	4,375.6	6,297.6
Legal and professional fees . . . . .	14,216.2	20,308.7	15,283.0	22,202.5
Travel and conveyance . . . . .	3,705.1	5,299.3	3,650.4	5,014.6
Vehicle running and maintenance . . . . .	234.9	262.9	179.2	157.3
Advertisement, publicity and sales promotion . . . . .	3,212.4	2,907.7	2,055.5	2,243.1
Insurance expense . . . . .	1,625.0	1,906.9	1,329.9	1,749.2
Claims to customer and other selling expenses . . . . .	7,192.5	5,259.7	2,173.6	2,461.4
Commission on sales . . . . .	958.1	3,915.3	2,343.1	4,335.1
Loss on sale/disposal/discard of property, plant and equipment (net) . . . . .	99.6	121.6	—	—
Foreign exchange loss, net . . . . .	595.6	911.3	2,902.8	—
Allowance for doubtful receivables and advances (net) . . . . .	205.4	346.3	84.3	1,586.0
Staff recruitment and training . . . . .	1,831.1	1,794.9	1,394.0	1,665.6
Freight and forwarding . . . . .	3,545.2	7,458.7	5,186.0	6,263.4
Bank charges . . . . .	838.6	2,320.9	1,565.6	2,428.3
Miscellaneous expenses . . . . .	2,358.5	3,876.2	2,277.2	3,508.7
<b>Total other expenses</b> . . . . .	<b>88,142.9</b>	<b>120,667.9</b>	<b>85,903.9</b>	<b>106,547.5</b>

### Finance Income

Finance income primarily represents interest payments received from the loans we provided to our related parties and interest earned on cash held at banks. The following table shows the breakdown of our finance income for the periods indicated.

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
Finance income from:				
Loan to related parties . . . . .	1,881.0	4,295.1	3,236.9	2,990.9
Others . . . . .	244.3	311.7	235.4	453.0
<b>Total finance income</b> . . . . .	<b>2,125.3</b>	<b>4,606.8</b>	<b>3,472.3</b>	<b>3,443.8</b>

### Finance Cost

Finance cost primarily represents interest and ancillary costs incurred in relation to borrowings by the Group during each reported period. The following table shows the breakdown of our finance cost during the periods indicated.

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
Interest expense	32,505.1	25,305.2	18,316.2	17,798.6
Other finance costs	4,134.9	2,183.4	1,882.6	798.0
Exchange differences to the extent considered as an adjustment to finance cost	100.4	—	—	—
<b>Total finance costs</b>	<b>36,740.4</b>	<b>27,488.5</b>	<b>20,198.8</b>	<b>18,596.6</b>

### Income Tax Expenses

Income tax expenses primarily comprise the payments of corporate income tax on profits from our operations and provision for deferred corporate income tax on our profits, offset by any eligible tax credits. The following table shows the major components of our income tax expenses for the periods indicated.

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
<b>Income tax expense</b>				
<b>Current tax</b>				
Current tax on profits for the year/ period	28,343.5	32,264.8	24,394.3	29,504.2
Adjustment for current income tax of previous years	547.0	213.0	(159.5)	(622.9)
<b>Total current tax expense</b>	<b>28,890.5</b>	<b>32,477.8</b>	<b>24,234.8</b>	<b>28,881.3</b>
<b>MAT credit<sup>(1)</sup></b>				
MAT credit on profits for the year/ period	(7,336.9)	(1,764.0)	(3,097.6)	(4,590.2)
Adjustment in respect of MAT credit of previous years	(710.3)	(12.7)	—	—
<b>Total MAT credit tax benefit</b>	<b>(8,047.2)</b>	<b>(1,776.7)</b>	<b>(3,097.6)</b>	<b>(4,590.2)</b>
<b>Deferred tax</b>				
Origination and reversal of temporary differences	2,104.7	(5,647.1)	(3,372.8)	8,834.2
Adjustment in respect of deferred tax of previous years/ periods <sup>(2)</sup>	—	(1,319.4)	23.7	125.7
<b>Total deferred tax (benefit)/expense</b>	<b>2,104.7</b>	<b>(6,966.4)</b>	<b>(3,349.1)</b>	<b>8,959.9</b>
<b>Income tax expense</b>	<b>22,947.9</b>	<b>23,734.7</b>	<b>17,788.1</b>	<b>33,251.0</b>

#### Notes:

- (1) In India, income tax is payable by a company as the higher of (a) for companies, whose turnover exceeds approximately US\$38 million, income tax is payable at the statutory tax rate of 34.944% (inclusive of applicable surcharge and cess) on the taxable income computed after allowing various deductions, exemptions, tax incentives etc. and (b) Minimum Alternative Tax (MAT) payable on the book profits of the company at a rate of 21.5488% (inclusive of applicable surcharge and cess). In cases where tax payable under the regular provisions of the Indian Income Tax Act as per clause (a) is less than the tax payable on the book profits of the company (i.e. MAT) as per clause (b), then the company is liable to pay tax under clause (b) on a book profits basis i.e. MAT. However, the excess of MAT over tax payable under the regular provisions of the Indian Income Tax Act is eligible for "MAT credit" for set-off against tax liability in subsequent years to the extent tax liability under the regular provisions of the Indian Income Tax Act may exceed the tax liability under MAT in those subsequent years.
- (2) Following a significant improvement in trading and service sector conditions of the pharmaceutical business in Belgium, we reviewed previously unrecognized tax losses and determined that it was now probable that taxable profits will be available against which the tax losses can be utilized. As a consequence, a deferred tax asset of US\$1.3 million has been recognized as at March 31, 2018.

### Exchange Differences on Translation of Foreign Operations

Exchange differences on translation of foreign operations represents gains or losses on the translation of financial statements of our foreign operations into U.S. dollars from their respective functional currencies for the purpose of consolidation in our Group's financial statements. We have three material subsidiaries/entities which have functional currencies that are not denominated in U.S. dollars, namely, JDI and Jubilant HollisterStier General

Partnership (“**JHS GP**”), which use CAD as their functional currency and JGL, which uses INR as its functional currency. The average exchange rates for CAD to US\$1 were 1.3130, 1.2840 and 1.3061 during the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2018, respectively, and the closing exchange rates for CAD to US\$1 were 1.3350, 1.2870 and 1.3617 as at March 31, 2017, 2018 and December 31, 2018 respectively. The average exchange rates for INR to US\$1 were 67.06, 64.55 and 69.29 during the financial years ended March 31, 2017 and 2018 and the nine months ended December 31, 2018, respectively and the closing exchange rates for INR to US\$1 were 64.85, 65.17 and 69.78 as at March 31, 2017, 2018 and as at December 31, 2018 respectively.

## **Results of Operations**

The following is a discussion of our results of operations.

### ***Nine Months ended December 31, 2018 Compared with Nine Months ended December 31, 2017***

*Revenue from operations (net).* Revenue from operations (net) increased by US\$136.1 million, or 31.9%, to US\$562.9 million in the nine months ended December 31, 2018 from US\$426.8 million in the nine months ended December 31, 2017, primarily due to additional revenue from radiopharmaceutical products and services of the commercial radiopharmacy business in the United States acquired from Triad and, to a lesser extent, better market conditions in the United States for certain products in the Generics & APIs business segment.

Revenue from North America contributed 82.0% to total revenue from operations (net) in the nine months ended December 31, 2018 compared to 79.9% in the nine months ended December 31, 2017. Revenue from Europe contributed 8.9% while revenue from Asia and the rest of the world contributed 9.2% to total revenue from operations (net) in the nine months ended December 31, 2018, compared to 10.0% and 10.2%, respectively, in the nine months ended December 31, 2017.

*Specialty Pharmaceuticals business segment.* The Specialty Pharmaceuticals business segment accounted for 68.9% of our total revenue from operations (net) in the nine months ended December 31, 2018 compared to 64.7% in the nine months ended December 31, 2017. Revenues from this business segment increased by US\$111.7 million, or 40.5%, to US\$387.6 million for the nine months ended December 31, 2018 from US\$275.9 million in the nine months ended December 31, 2017. The Specialty Pharmaceuticals business segment revenue increased primarily due to the following:

- a 51.7% increase in revenue from radiopharmaceuticals to US\$267.9 million for the nine months ended December 31, 2018 from US\$176.7 million for the nine months ended December 31, 2017, primarily due to additional revenue from our radiopharmacy business acquired from Triad; while
- revenue from our CMO and allergy therapy products business lines increased to US\$81.6 million and US\$38.1 million, respectively, in the nine months ended December 31, 2018 compared to US\$66.8 million and US\$32.4 million, respectively, in the nine months ended December 31, 2017, primarily due to better capacity utilization which resulted in higher production and sales from additional batches sold by our CMO business and higher venom sales in our allergy therapy products business.

*Generics & APIs business segment.* The Generics & APIs business segment accounted for 31.1% of our total revenue from operations (net) in the nine months ended December 31, 2018 compared to 35.3% in the nine months ended December 31, 2017. Revenues from this business segment increased by US\$24.4 million, or 16.2%, to US\$175.2 million in the nine months ended December 31, 2018 from US\$150.8 million in the nine months ended December 31, 2017. The Generics & APIs business segment revenue increased primarily as a result of the following:

- a 23.4% increase in revenue from solid dosage formulations to US\$109.6 million for the nine months ended December 31, 2018 from US\$88.9 million for the nine months ended December 31, 2017, driven by improved market conditions which influence competitive intensity, including changes in supply and demand and higher volumes of valacyclovir; and
- revenue from our APIs business line increased to US\$65.6 million in the nine months ended December 31, 2018 compared to US\$62.0 million in the nine months ended December 31, 2017, driven by improved market conditions i.e. changes in supply and demand of certain products.

*Total income.* For the reasons discussed above, total income increased by US\$142.2 million, or 33.3%, to US\$569.4 million in the nine months ended December 31, 2018 from US\$427.2 million in the nine months ended December 31, 2017.

*Cost of materials consumed.* Cost of materials consumed increased by US\$41.2 million, or 37.3%, to US\$151.5 million in the nine months ended December 31, 2018 from US\$110.3 million in the nine months ended

December 31, 2017, primarily due to additional raw materials used in relation to our newly acquired radiopharmacy business along with an increase in pricing of certain raw materials due to recent tightening of environmental regulations in China, which had an impact on the chemical and pharmaceutical industries for APIs.

*Changes in inventories of finished goods, stock-in-trade and work-in progress.* Changes in inventories of finished goods, stock-in-trade and work-in progress increased by US\$6.2 million, or 85.8%, to US\$13.4 million in the nine months ended December 31, 2018 from US\$7.2 million in the nine months ended December 31, 2017, primarily due to higher production output of our Spokane Facility for our CMO business line.

*Employee benefits expense.* Employee benefits expense increased by US\$34.2 million, or 27.1%, to US\$160.3 million in the nine months ended December 31, 2018 from US\$126.1 million in the nine months ended December 31, 2017, primarily due to additional employee benefit costs related to our newly acquired radiopharmacy business and annual salary raises.

*Depreciation, amortization and impairment.* Depreciation, amortization and impairment increased by US\$4.0 million, or 15.3%, to US\$29.9 million in the nine months ended December 31, 2018 from US\$25.9 million in the nine months ended December 31, 2017, primarily due to additional depreciation in relation to our newly acquired radiopharmacy business and amortization of our newly launched product Drax Exametazime™. Depreciation, amortization and impairment for our Specialty Pharmaceuticals business segment increased by US\$3.2 million, or 26.6%, to US\$15.4 million in the nine months ended December 31, 2018 from US\$12.1 million in the nine months ended December 31, 2017. Depreciation, amortization and impairment for our Generics & APIs business segment increased by US\$0.7 million, or 5.3%, to US\$14.5 million in the nine months ended December 31, 2018 from US\$13.8 million in the nine months ended December 31, 2017.

*Other expenses.* Other expenses increased by US\$20.6 million, or 24.0%, to US\$106.5 million in the nine months ended December 31, 2018 from US\$85.9 million in the nine months ended December 31, 2017 due to increased expenses in relation to our newly acquired radiopharmacy business.

*Result from operating activities.* For the reasons discussed above, result from operating activities increased by 60.5% to US\$125.4 million in the nine months ended December 31, 2018 from US\$78.1 million for the nine months ended December 31, 2017. Result from operating activities for our Specialty Pharmaceuticals business segment (excluding un-allocated corporate expenses) increased by US\$25.5 million, or 30.8%, to US\$108.3 million in the nine months ended December 31, 2018 from US\$82.8 million in the nine months ended December 31, 2017. Result from operating activities for our Generics & APIs business segment (excluding un-allocated corporate expenses) increased by US\$25.3 million, or 572.0%, to US\$29.7 million in the nine months ended December 31, 2018 from US\$4.4 million in the nine months ended December 31, 2017.

*Finance income.* Finance income remained relatively constant in the nine months ended December 31, 2018 from the nine months ended December 31, 2017.

*Finance costs.* Finance costs decreased by US\$1.6 million, or 7.9%, to US\$18.6 million in the nine months ended December 31, 2018 from US\$20.2 million in the nine months ended December 31, 2017.

*Profit before tax.* For the reasons discussed above, profit before tax increased by 79.6% to US\$110.3 million in the nine months ended December 31, 2018 from US\$61.4 million in the nine months ended December 31, 2017.

*Income tax expense.* Income tax expense increased by US\$15.5 million, or 86.9%, to US\$33.3 million in the nine months ended December 31, 2018 from US\$17.8 million in the nine months ended December 31, 2017, primarily due to an increase in taxable income from our operations in the United States and Canada.

*Profit for the period.* For the reasons discussed above, profit for the period increased by US\$33.4 million, or 76.6%, to US\$77.0 million in the nine months ended December 31, 2018 from US\$43.6 million in the nine months ended December 31, 2017.

*Exchange differences on translation of foreign operations.* Exchange differences on translation of foreign operations decreased by US\$51.0 million, or 285.9%, to negative US\$33.2 million in the nine months ended December 31, 2018 from US\$17.8 million in the nine months ended December 31, 2017, primarily due to changes in the average and closing exchange rates between functional currencies of foreign operations and U.S. dollars for the period. See “—Principal Components of Statements of Comprehensive Income—Exchange Differences on Translation of Foreign Operations”.

*Total comprehensive income for the period.* For the reasons discussed above, total comprehensive income for the period decreased by 28.5% to US\$43.8 million in the nine months ended December 31, 2018 from US\$61.3 million in the nine months ended December 31, 2017.



### ***Financial Year Ended March 31, 2018 Compared with Financial Year Ended March 31, 2017***

*Revenue from operations (net).* Revenue from operations (net) increased by US\$158.6 million, or 34.4%, to US\$619.2 million in the financial year ended March 31, 2018 from US\$460.6 million in the financial year ended March 31, 2017, attributable primarily to an increase in revenue from the Specialty Pharmaceuticals business segment, led by our acquisition of the radiopharmacy business from Triad, which was partially offset by reduction in revenues from Generics & APIs business segment.

Revenue from North America contributed 80.1% to total revenue from operations (net) in the financial year ended March 31, 2018 compared to 70.6% in the financial year ended March 31, 2017. Revenue from Europe contributed 9.3% while revenue from Asia and the rest of the world contributed 10.6% to total revenue from operations (net) in the financial year ended March 31, 2018, compared to 17.4% and 12.0%, respectively, in the financial year ended March 31, 2017. The increase in the contribution of revenue generated in North America was largely attributable to the acquisition of the radiopharmacy business in the United States.

*Specialty Pharmaceuticals business segment.* The Specialty Pharmaceuticals business segment accounted for 66.1% of our total revenue from operations (net) in the financial year ended March 31, 2018 compared to 53.6% in the financial year ended March 31, 2017. Revenues from this business segment increased by US\$162.8 million, or 66.0%, to US\$409.5 million in the financial year ended March 31, 2018 from US\$246.7 million in the financial year ended March 31, 2017. The Specialty Pharmaceuticals business segment revenue increased primarily due to the following:

- a 118.0%, or US\$143.5 million, increase in revenue from radiopharmaceuticals business line to US\$265.1 million in the financial year ended March 31, 2018 from US\$121.6 million in the financial year ended March 31, 2017, primarily due to a contribution from seven months of revenue of US\$118.9 million from the sales of radiopharmaceutical products and services of the commercial radiopharmacy business acquired from Triad and, to a lesser extent, due to higher sales of DRAXIMAGE® MAA, DRAXIMAGE® MDP-25 and DRAXIMAGE® DTPA, driven by the full year impact of certain customer contracts which became effective from January 1, 2017;
- a 13.7%, or US\$12.2 million, increase in revenue from the CMO business line to US\$100.9 million in the financial year ended March 31, 2018 from US\$88.7 million in the financial year ended March 31, 2017, primarily driven by an increase in revenues from the Spokane Facility due to a higher sales volume to certain existing customers following the implementation of certain efficiency measures on capacity management; and
- a 19.9%, or US\$7.2 million, increase in revenue from the allergy therapy products business line to US\$43.6 million in the financial year ended March 31, 2018 from US\$36.4 million in the financial year ended March 31, 2017, primarily due to an increase in prices, in line with market rates, effected during the financial year ended March 31, 2018.

*Generics & APIs business segment.* The Generics & APIs business segment accounted for 33.9% of our total revenue from operations (net) in the financial year ended March 31, 2018 compared to 46.4% in the financial year ended March 31, 2017. Revenues from this business segment decreased by US\$4.3 million, or 2.0%, to US\$209.6 million in the financial year ended March 31, 2018 from US\$213.9 million in the financial year ended March 31, 2017. The Generics & APIs business segment revenue decreased primarily as a result of the following:

- revenue from solid dosage formulations remained relatively constant, at US\$123.5 million in the financial year ended March 31, 2018, compared to US\$122.0 million in the financial year ended March 31, 2017 primarily as a result of an increase in revenue from within the United States, offset by lower sales from outside the United States; while
- a 6.3% decrease, or US\$5.8 million in revenue from APIs to US\$86.1 million in the financial year ended March 31, 2018, from US\$91.9 million in the financial year ended March 31, 2017, largely as a result of a decrease in sales prices in some of our products such as Oxcarbazepine, Azithromycin, Valsartan and Carbamazepine due to market dynamics, including changes in competitive intensity due to actions taken by us and other market participants such as our competitors and our respective customers, which was partially offset by higher sales volume of certain products.

*Total income.* For the reasons discussed above, total income increased by US\$159.6 million, or 34.6%, to US\$620.8 million in the financial year ended March 31, 2018 from US\$461.2 million in the financial year ended March 31, 2017.

*Cost of materials consumed.* Cost of materials consumed increased by US\$55.3 million, or 52.8%, to US\$159.9 million in the financial year ended March 31, 2018 from US\$104.6 million in the financial year ended March 31, 2017, primarily due to additional raw materials consumed in our newly acquired radiopharmacy business and higher production output to meet increases in sales from our CMO business line.

*Changes in inventories of finished goods, stock-in-trade and work-in progress.* Changes in inventories of finished goods, stock-in-trade and work-in progress decreased by US\$8.2 million, or 78.6%, to US\$2.2 million in the financial year ended March 31, 2018 from US\$10.4 million in the financial year ended March 31, 2017, primarily due to an overall decrease in finished goods and work-in-progress inventory across all the businesses.

*Employee benefits expense.* Employee benefits expense increased by US\$48.3 million, or 36.7%, to US\$179.9 million in the financial year ended March 31, 2018 from US\$131.6 million in the financial year ended March 31, 2017, primarily due to a 36.7% increase in payments of salaries, wages, bonus, gratuity and allowances to our employees to US\$149.7 from US\$109.5 million and a 54.6% increase in payments of staff welfare expenses to our employees to US\$18.6 from US\$12.1 million, primarily as a result of the additional employee headcount for our acquisition of our radiopharmacy business from Triad and expansion in hiring to accommodate higher production output driven by our higher sales volume, along with annual salary increases.

*Depreciation, amortization and impairment.* Depreciation, amortization and impairment increased by US\$24.6 million, or 79.2%, to US\$55.7 million in the financial year ended March 31, 2018 from US\$31.1 million in the financial year ended March 31, 2017, primarily attributable to product development expenses due to rationalization of our product portfolio to reflect the prevailing market conditions, in particular in the United States, and additional depreciation in relation to our newly acquired radiopharmacy business. Depreciation, amortization and impairment for our Specialty Pharmaceuticals business segment increased by US\$12.6 million, or 85.8%, to US\$27.2 million in the financial year ended March 31, 2018 from US\$14.6 million in the financial year ended March 31, 2017. Depreciation, amortization and impairment for our Generics & APIs business segment increased by US\$12.1 million, or 73.6%, to US\$28.5 million in the financial year ended March 31, 2018 from US\$16.4 million in the financial year ended March 31, 2017 primarily due to a one-time charge in our profit and loss statement on account of internally generated product registrations/market authorizations and other intangibles, including intangibles under development, to reflect current global market conditions, specifically in the United States.

*Other expenses.* Other expenses increased by US\$32.6 million, or 36.9%, to US\$120.7 million in the financial year ended March 31, 2018 from US\$88.1 million in the financial year ended March 31, 2017 primarily due to increases in legal and professional fees, freight and forwarding, consumption of stores and spares and packing materials and fuel and power consumption, as well as commission on sales and an increase in rental expense, all of which are in line with an increase in our production output to meet our higher sales volume, as well as costs incurred in relation to our new radiopharmacies. These increases were partially offset by decreases in claims to customer and other selling expenses.

*Result from operating activities.* For the reasons discussed above, result from operating activities decreased by 11.2% to US\$95.7 million in the financial year ended March 31, 2018 from US\$107.8 million in the financial year ended March 31, 2017. Result from operating activities for our Specialty Pharmaceuticals business segment (excluding un-allocated corporate expenses) increased by US\$24.7 million, or 28.7%, to US\$110.7 million in the financial year ended March 31, 2018 from US\$86.0 million in the financial year ended March 31, 2017. Result from operating activities for our Generics & APIs business segment (excluding un-allocated corporate expenses) decreased to a loss of US\$2.6 million in the financial year ended March 31, 2018 from a gain of US\$30.5 million in the financial year ended March 31, 2017.

*Finance income.* Finance income increased by US\$2.5 million, or 116.8%, to US\$4.6 million in the financial year ended March 31, 2018 from US\$2.1 million in the financial year ended March 31, 2017, primarily due to an increase in interest income from a loan given by JGL to JLL to US\$4.3 million in the financial year ended March 31, 2018 from US\$1.9 million in the financial year ended March 31, 2017. Such loan was given by JGL to JLL in furtherance of part of our intended use of proceeds from our issuance of the Existing Senior Notes in October 2016.

*Finance costs.* Finance costs decreased by US\$9.2 million, or 25.2%, to US\$27.5 million in the financial year ended March 31, 2018 from US\$36.7 million in the financial year ended March 31, 2017, primarily due to a 22.2% decrease in interest expense to US\$25.3 million from US\$32.5 million, in line with a net reduction in our outstanding balances of loans and borrowings and certain costs incurred in replacement of higher interest loans with our Existing Senior Notes.

*Profit before tax.* For the reasons discussed above, profit before tax remained relatively constant at US\$72.9 million in the financial year ended March 31, 2018 compared to US\$73.2 million in the financial year ended March 31, 2017.

*Income tax expense.* Income tax expense increased by US\$0.8 million, or 3.4%, to US\$23.7 million in the financial year ended March 31, 2018 from US\$22.9 million in the financial year ended March 31, 2017, primarily due to an increase in taxable income from our operations in Canada.

*Profit for the year.* For the reasons discussed above, profit for the year decreased by US\$1.2 million, or 2.3%, to US\$49.1 million in the financial year ended March 31, 2018 from US\$50.3 million in the financial year ended March 31, 2017. In addition, net profit margin (being profit for the year divided by revenues from operations) decreased from 10.9% for the financial year ended March 31, 2017 to 7.9% for the financial year ended March 31, 2018 primarily due to (a) the acquisition in September 2017 of substantially all of the assets which comprised Triad's radiopharmacy business which had negative margins despite being a significant contributor to revenue from operations and (b) the one-time charge of product development expenses due to rationalization of product portfolio to reflect the current market conditions prevailing in the global generics markets and the United States in particular. We continuously evaluate our portfolio of products under development and decided to cease further development of certain products due to commercial and technical reasons. We reviewed the carrying value of internally generated product registration/market authorization and other intangibles (including intangible assets under development) and based on prevailing market conditions as well as technical and financial assessments, make charge offs which are included under deductions to gross carrying amount of intangible assets under development and under depreciation, amortization and impairment in our consolidated statement of profit or loss.

*Exchange differences on translation of foreign operations.* Exchange differences on translation of foreign operations increased by US\$4.2 million, or 153.5%, to US\$6.9 million in the financial year ended March 31, 2018 from US\$2.7 million in the financial year ended March 31, 2017, primarily due to changes in the average and closing exchange rates between functional currencies of foreign operations and U.S. dollars for the period. See “—Principal Components of Statements of Comprehensive Income—Exchange Differences on Translation of Foreign Operations”.

*Total comprehensive income for the year.* For the reasons discussed above, Total comprehensive income for the year increased by 5.9% to US\$55.9 million in the financial year ended March 31, 2018 from US\$52.8 million in the financial year ended March 31, 2017.

### **Liquidity and Capital Resources**

Our cash requirements primarily relate to our operating cash requirements, capital expenditures, investments and debt service and repayments. Our operating cash requirements are primarily to fund raw material costs, manufacturing costs, including research and development expenses, personnel and other expenses, as well as income tax payments.

Our primary sources of funding are cash from operating activities, bank loans, debt issuances, as well as issuances of equity and equity-linked instruments. Our total outstanding indebtedness (comprising loans and borrowings, net of un-amortized transaction costs) amounted to US\$445.1 million, US\$408.5 million and US\$410.3 million as at March 31, 2017 and 2018 and December 31, 2018, respectively.

The availability of funding from external sources and the cost of such funding is subject to a number of factors that are beyond our control, including general economic and capital market conditions, interest rates, availability of credit from banks and other lenders, lender and/or investor confidence in the Group, tax and securities laws that may be applicable to us, and political and economic conditions in the markets in which we operate and internationally.

We may from time to time incur additional indebtedness to finance our future capital expenditures. Our ability to obtain such borrowings will be affected primarily by limitations on incurring additional indebtedness under our existing loan agreements and our Existing Senior Notes, the liquidity of the financial markets and governmental policies in effect in the relevant jurisdiction at the time and other factors. See “*Risk Factors—Risks Relating to Our Business—We have incurred significant indebtedness, and we must service this debt and comply with our covenants to avoid refinancing risk*”.

Taking into account the cash flows generated from our operating and financing activities, together with our existing cash and cash equivalents and available credit facilities from financial institutions, our Directors are of the reasonable opinion that we have sufficient working capital, as at this date, for our present requirements.

## Cash Flows

The following table sets forth our consolidated cash flow statement.

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
Operating cash flow before working capital changes . . . . .	139,595.1	151,465.3	104,081.9	152,304.9
Cash generated from operations . . . . .	147,621.7	143,660.1	110,012.3	129,849.1
Net cash generated from operating activities . . . . .	128,559.1	115,762.9	83,057.8	98,817.5
Net cash used in investing activities . . . . .	(88,252.5)	(67,016.2)	(52,725.5)	(34,132.7)
Net cash used in financing activities . . . . .	(17,970.7)	(69,902.0)	(51,039.8)	(30,551.9)
Cash and cash equivalents at the end of the year/period . . . . .	<u>48,409.1</u>	<u>27,086.5</u>	<u>28,729.4</u>	<u>59,609.6</u>

### *Net cash generated from operating activities*

Net cash generated from operating activities increased by US\$15.8 million, or 19.0%, to US\$98.8 million in the nine months ended December 31, 2018 from US\$83.1 million in the nine months ended December 31, 2017. This increase was primarily attributable to:

- (i) an increase in operating cash flow before working capital adjustment to US\$152.3 million in the nine months ended December 31, 2018 from US\$104.1 million in the nine months ended December 31, 2017, and
- (ii) a lower increase in other assets including other financial assets of US\$1.4 million in the nine months ended December 31, 2018 compared to US\$20.2 million in the nine months ended December 31, 2017.

This increase was partially offset by:

- (i) a lower decrease in trade accounts receivable of US\$2.4 million in the nine months ended December 31, 2018 from US\$30.2 million in the nine months ended December 31, 2017,
- (ii) a higher increase in inventory to US\$22.0 million in the nine months ended December 31, 2018 from US\$2.1 million in the nine months ended December 31, 2017, and
- (iii) an increase in income taxes paid (net of refund) of US\$31.0 million in the nine months ended December 31, 2018 compared to US\$27.0 million in the nine months ended December 31, 2017.

Net cash generated from operating activities decreased by US\$12.8 million, or 10.0%, to US\$115.8 million in the financial year ended March 31, 2018 from US\$128.6 million in the financial year ended March 31, 2017. This decrease was primarily attributable to:

- (i) a change to an increase in other assets including other financial assets, being unbilled accrued revenue as a result of our acquisition of Triad's assets, of US\$13.6 million in the financial year ended March 31, 2018 compared to a decrease in other assets including other financial assets of US\$7.3 million in the financial year ended March 31, 2017,
- (ii) a change to a decrease in trade payables of US\$8.8 million in the financial year ended March 31, 2018 compared to an increase in trade payables of US\$2.1 million in the financial year ended March 31, 2017, and
- (iii) a higher income taxes paid in the amount of US\$27.9 million in the financial year ended March 31, 2018, compared to income taxes of US\$19.1 million paid in the financial year ended March 31, 2017.

This decrease was partially offset by:

- (i) a higher adjustments for depreciation, amortization and impairment in the amount of US\$55.7 million applied in the financial year ended March 31, 2018, compared to the same in the amount of US\$31.1 million applied in the financial year ended March 31, 2017,
- (ii) a change to a decrease in trade accounts receivable of US\$6.8 million in the financial year ended March 31, 2018 compared to an increase of the same in the amount of US\$1.8 million in the financial year ended March 31, 2017, and
- (iii) a change to a decrease in inventories of US\$1.3 million in the financial year ended March 31, 2018 compared to an increase of the same in the amount of US\$7.0 million in the financial year ended March 31, 2017.

Profit before tax remained relatively constant in the amount of US\$72.9 million in the financial year ended March 31, 2018 compared to the same in the amount of US\$73.2 million in the financial year ended March 31, 2017. Increase in other liabilities including other financial liabilities also remained relatively constant in the amount of US\$6.5 million in the financial year ended March 31, 2018 compared to the same in the amount of US\$7.4 million in the financial year ended March 31, 2017.

#### ***Net cash used in investing activities***

Net cash used in investing activities decreased by US\$18.6 million, or 35.3%, to US\$34.1 million in the nine months ended December 31, 2018 from US\$52.7 million in the nine months ended December 31, 2017. The decrease in net cash used in investing activities primarily relates to our acquisition of Triad's assets.

Net cash used in investing activities decreased by US\$21.3 million, or 24.1%, to US\$67.0 million in the financial year ended March 31, 2018 from US\$88.3 million in the financial year ended March 31, 2017. This decrease was primarily attributable to a loan given by JGL to JLL of US\$48.4 million in the financial year ended March 31, 2017, compared to the absence of such loan being made in the financial year ended March 31, 2018. Such loan was considered a deployment of surplus funds, and therefore considered as net cash used in investing activities. This decrease was partially offset by acquisition of business in the amount of US\$20.1 million in the financial year ended March 31, 2018 in relation to the acquisition of our radiopharmacy business from Triad and higher acquisition of property plant and equipment and other intangible assets in the amount of US\$52.1 million in the financial year ended March 31, 2018, compared to the same in the amount of US\$44.6 million in the financial year ended March 31, 2017.

#### ***Net cash used in financing activities***

Net cash used in financing activities decreased by US\$20.5 million, or 40.1%, to US\$30.6 million in the nine months ended December 31, 2018 from US\$51.0 million in the nine months ended December 31, 2017. This decrease was primarily attributable to a decrease in repayment of long term loans and borrowings to US\$3.3 million in the nine months ended December 31, 2018 compared to US\$34.6 million of loan repayments in the nine months ended December 31, 2017, partially offset by a repayment of short term loans repayable on demand, net, of US\$2.6 million in the nine months ended December 31, 2018, compared to proceeds received from short term loans repayable on demand, net, of US\$2.5 million in the nine months ended December 31, 2017 and dividend paid of US\$8.2 million in the nine months ended December 31, 2018 compared to US\$ nil in the nine months ended December 31, 2017.

Net cash used in financing activities increased by US\$51.9 million, or 289.0%, to US\$69.9 million in the financial year ended March 31, 2018, from US\$18.0 million in the financial year ended March 31, 2017. This increase was primarily attributable to a repayment of long-term borrowings and loans in the amount of US\$51.4 million and absence of proceeds from long-term loans and borrowings in the financial year ended March 31, 2018, partially offset by lower finance costs paid in the amount of US\$17.0 million in the financial year ended March 31, 2018, compared to finance cost of US\$33.0 million paid in the financial year ended March 31, 2017. In the financial year ended March 31, 2017, we received proceeds from the issuance of Existing Senior Notes in the amount of US\$205.6 million, which was partially offset by repayments of long-term loans and borrowings of US\$157.6 million with the proceeds therefrom, as well as repayments of short-term loans repayable on demand, net, in the amount of US\$33.0 million.

#### **Indebtedness**

Our total outstanding indebtedness (comprising loans and borrowings, net of un-amortized transaction costs) was US\$445.1 million as at March 31, 2017, US\$408.5 million as at March 31, 2018 and US\$410.3 million as at December 31, 2018.

Our long-term borrowings include certain financial covenants. We must service this debt and comply with our covenants to avoid refinancing risk. See "*Risk Factors—Risks Relating to Our Business—We have incurred significant indebtedness, and we must service this debt and comply with our covenants to avoid refinancing risk*".

In addition, a number of our long-term and short-term borrowings are secured by assets and property of the individual borrowers, including land, buildings and movable fixed assets, as well as receivables and inventory.

## Capital Expenditures

The following table sets forth the Group's capital expenditure during the years ended March 31, 2017 and 2018 and for the nine months ended December 31, 2018.

	Financial Year Ended March 31		Nine months ended December 31
	2017	2018	2018
	(US\$ thousands)		
Property, plants and equipment and others .....	50,805.6	51,071.3	40,886.2
<b>Total</b> .....	<b>50,805.6</b>	<b>51,071.3</b>	<b>40,886.2</b>

Our historical capital expenditures were primarily related to normal capital expenditure to run and maintain our operations and debottlenecking of capacities, including:

- (i) product development, addition of a third stream to one of our existing plants at our Nanjangud Facility and Systems, Applications & Products (SAP) implementation at JGL in the financial year ended March 31, 2017;
- (ii) product development, Roorkee Facility capacity expansion, plant upgrades at our existing API facilities, de-bottlenecking and Environment Management System (EMS) augmentation, serialization at our Salisbury Facility, Roorkee Facility, CMO Montreal Facility and Spokane Facility as well as fleet replacement for our radiopharmacies in the financial year ended March 31, 2018; and
- (iii) product development, Roorkee Facility capacity expansion, fleet replacement for our radiopharmacies and RUBY-FILL® scale-up for the nine months ended December 31, 2018.

Such capital expenditures were funded primarily by cash generated from operations, proceeds from the issuance of the Existing Senior Notes and other bank borrowings.

We expect future capital expenditure will primarily relate to capacity expansion, research and development on product portfolio and acquisition of complementary businesses to strengthen existing product portfolio and manufacturing footprint. See *"Business—Business Strategies"*. We expect to fund such future capital expenditures primarily by cash generated from operating activities and bank borrowings. We may re-allocate funds to be utilized on capital expenditure based on our ongoing business needs.

We cannot assure you that our capital expenditure budget will not vary or can be financed on commercially acceptable terms, or at all. Our ability to obtain adequate financing, including new facilities, to satisfy our capital expenditures, contractual obligations and debt service requirements may be limited by our financial condition and results of operation and liquidity of domestic and international financial markets. See *"Risk Factors—Risks Relating to Our Business—We have incurred significant indebtedness, and we must service this debt and comply with our covenants to avoid refinancing risk"*.

## Contractual Obligations and Contingent Liabilities

### Contractual Obligations

The following table sets forth the Company's financial contractual obligations as at December 31, 2018. The Company's other liabilities, including trade payables and other financial liabilities, are due in less than 12 months as at December 31, 2018.

	Payment Due by Period			Total
	Less than 1 Year	1-5 Years	More than 5 Years	
	(US\$ thousands)			
Loans and borrowings <sup>(1)</sup> .....	9,987.3	403,041.3	—	413,028.6
Trade payables .....	65,478.3	—	—	65,478.3
Other financial liabilities .....	11,926.3	—	—	11,926.3
Employee benefits .....	16,088.4	3,554.0	—	19,642.4
<b>Total</b> .....	<b>103,480.3</b>	<b>406,595.3</b>	<b>—</b>	<b>510,075.6</b>

Note:

- (1) Contractual cash flows exclude interest payable.

### ***Capital Commitments***

As at March 31, 2017 and 2018 and December 31, 2018 the Group had committed to spend US\$18.1 million, US\$15.0 million and US\$14.3 million, respectively, under agreements to purchase property, plant and equipment and other intangible assets.

### ***Other commitments***

The Group has certain operating lease arrangements, which are non-cancellable for a period up to five years. Such leases contain varying terms, escalation clauses and renewal rights. As at March 31, 2017 and 2018 and December 31, 2018 the Group was subject to minimum lease payments in the amounts of US\$3.2 million, US\$11.7 million and US\$10.7 million, respectively.

### ***Contingent Liabilities***

The Group may become subject to various product liabilities, consumer, commercial, environmental and tax litigations and claims, government investigations and other legal proceedings that may arise in future.

The Group accrues for contingencies to the extent that the management concludes their occurrence is probable and the related liabilities are estimable.

The aggregate amount of claims not acknowledged as debt as at March 31, 2017 and 2018 and as at December 31, 2018 was US\$0.8 million, US\$27.3 million and US\$13.2 million, respectively. Such claims not acknowledged as debt pertain to claims against the Group, disputed by the Group and not acknowledged as debt, comprising central excise, customs, service tax, income tax and others. The claim amount increased for the financial year ended March 31, 2018 due to an income tax claim pertaining to a U.S. tax filing arising as a result of a delay in recording use of carry forward tax losses in May 2018. For the claims being disputed, there are no legal or constructive present obligations to make provisions, and we believe it is not probable that future outflow of resources will be required to settle these claims.

Outstanding guarantees furnished by banks on behalf of the Group as at March 31, 2017 and 2018 and as at December 31, 2018 were US\$8.3 thousand, US\$127.1 thousand and US\$127.0 thousand, respectively.

Further to our launch of RUBY-FILL<sup>®</sup>, Bracco filed two legal challenges against us and the Jubilant Defendants in the New Jersey District Court and with the USITC. These challenges, if not adjudicated in our favor, may result in monetary damages or the exclusion of certain systems and components from importation as well as suspension and/or cessation of our manufacture and sale of RUBY-FILL<sup>®</sup> in the United States. If we suspend or cease the manufacture and sale of RUBY-FILL<sup>®</sup>, we could lose any potential growth that RUBY-FILL<sup>®</sup> is expected to bring to our business. For more details, see “*Risk Factors—Risks Relating to our Business—If we are unable to defend ourselves in challenges related to intellectual property rights, we could be subject to injunctions preventing us from selling our products, resulting in a decrease in revenues, or we could be subject to substantial liabilities that would lower our profits and adversely affect our financial condition*”.

### **Qualitative and Quantitative Disclosures about Market Risk**

The Group’s activities are exposed to a variety of financial risks: market risk, credit risk and liquidity risk. The Company’s board of directors is tasked with the overall responsibility for the establishment and oversight of the Group’s risk management framework. The Group’s overall risk management framework seeks to minimize potential adverse effects on the financial performance of the Group and is deliberated and reviewed at appropriate forums.

#### ***Foreign Currency Exchange Rate Risk***

We manufacture and sell products to customers around the world in multiple foreign currencies and face translation and transaction risks related to the fluctuation of foreign currency exchange rates in the markets where we are active. A significant portion of our costs are denominated in currencies other than the U.S. dollar, due to our international operations. These costs are affected by prevailing rates of exchange.

Our assets and liabilities and our results of operations are subject to translation risk and transaction risk. Translation risk is the risk that our results of operations for a particular period or our assets and liabilities at a particular date are affected by changes in the applicable currency exchange rates. Transaction risk arises when the currency structure of our costs and liabilities deviates from the currency structure of our sales proceeds and assets.

The functional currencies of the Group’s operations are primarily the Indian rupee, U.S. dollar, Canadian dollar and Euro. Due to our Indian and Canadian operations, any significant movement in the value of the Indian rupee

or the Canadian dollar against the U.S. dollar could have a material effect on our business, financial condition, results of operations and prospects. As at March 31, 2018 and as at December 31, 2018, if the U.S. dollar had weakened/strengthened by 1.0% against all other currencies with all other variables held constant, profit or loss (before tax) for the period would have been US\$0.7 million and US\$1.2 million, respectively, lower/higher.

We have in the past utilized certain hedging instruments, including forward contracts with respect to our exports and imports from and into India. However, due to market uncertainties, currently the Company has decided not to enter into any forward contracts for the time being. Currently, we have not hedged our foreign currency exposure, and accordingly, we are exposed to the impact of fluctuations in foreign currency exchange rates.

We may enter, from time to time in the future, into such hedging instruments for the purpose of managing the risks on our receivables/payables, managing our assets or liabilities or in connection with a line of business. We do not enter into such hedging instruments for any purpose not permitted by any applicable law.

### ***Interest Rate Risk***

Changes in interest rates affect our interest expenses on floating rate debt instruments, loans and our interest income from cash and cash equivalents. We have in the past entered into floating to fixed interest rate swap agreements. However, due to market uncertainties, currently the Company has decided not to enter into any fixed interest rate swap agreement for the time being. As at March 31, 2018 and December 31, 2018, only 3.0% and 2.1% of our total indebtedness bore interest at floating rates, respectively.

### ***Credit Risk***

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet its contractual obligations, and arises principally from the Group's receivables from customers, investments and other financial assets. The carrying amount of financial assets in the Company's consolidated statements of financial position represents maximum credit risk exposure.

To manage credit risk from trade receivables and other financial assets, the Company established a credit policy under which each new customer is analyzed individually for creditworthiness before the Group's standard payment and delivery terms and conditions are offered. The Company's review includes external ratings, to the extent available, financial statements, credit agency information, industry information, and business intelligence. Sale limits are established for each customer and reviewed annually.

Based on internal assessment and historical experience in relation to defaults and delays in collection, management believes that the Group's credit risk in relation to trade receivables is low. Management also believes that all of the Group's financial assets with contractual cash flows other than trade receivable to be high quality assets with negligible credit risk. Management is of the view that the parties from which these financial assets are recoverable, possess strong financial capacity to meet the obligations and the risk of default is negligible. Accordingly, no provision for expected credit loss has been provided for on such financial assets.

### ***Liquidity Risk***

Liquidity risk arises in situations where the Group may encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset. The Group's approach to managing liquidity is to ensure, as far as possible, that it will have sufficient liquidity to meet its liabilities when they are due, under both normal and stressed conditions, without incurring unacceptable losses or risking damage to the Group's reputation. The Group's treasury department is responsible for managing the Group's short-term and long-term liquidity requirements. See "*—Contractual Obligations and Contingent Liabilities—Contractual Obligations*" for information on the Company's financial liabilities as at December 31, 2018, classified into relevant maturities based on the remaining period to the contractual maturity date.

### **Taxation**

The Company's effective tax rates were 31.3%, 32.6% and 30.2%, respectively, in the financial years ended March 31, 2017, 2018 and the nine months ended December 31, 2018. These amounts are more than the 17% statutory corporate tax rate applicable in Singapore as substantially all of our income is generated in countries with higher tax rates than Singapore.

### **Recently Issued Accounting Pronouncements**

The Group has not early adopted the following new or amended standards in preparing the Group's consolidated financial statements.



## ***IFRS 16, Leases***

IFRS 16 replaces existing leases guidance, including IAS 17 *Leases*, IFRIC 4 *Determining whether an Arrangement contains a Lease*, SIC-15 *Operating Leases—Incentives* and SIC-27 *Evaluating the Substance of Transactions Involving the Legal Form of a Lease*.

The standard is effective for annual periods beginning on or after January 1, 2019. Early adoption is permitted for entities that apply IFRS 15 at or before the date of initial application of IFRS 16.

IFRS 16 introduces a single, on-balance sheet lease accounting model for lessees. A lessee recognizes a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. There are recognition exemptions for short-term leases and leases of low-value items. Lessor accounting remains similar to the current standard – i.e. lessors continue to classify leases as finance or operating leases.

The Group has not yet completed its assessment of the potential impact on its consolidated interim financial statements. The actual impact of applying IFRS 16 on the consolidated interim financial statements in the period of initial application will depend on future economic conditions, including the Group's borrowing rate at April 1, 2019, the composition of the Group's lease portfolio at that date, the Group's latest assessment of whether it will exercise any lease renewal options and the extent to which the Group chooses to use practical expedients and recognition exemptions.

So far, the most significant impact identified is that the Group will recognize new assets and liabilities for its operating leases of warehouse and factory facilities. As at December 31, 2018, the Group's future minimum lease payments under non-cancellable operating leases amounted to US\$10.7 million, on an undiscounted basis (refer note 32(ii) of the consolidated interim financial statements), represent 1.11% of the consolidated total assets and 1.98% of the consolidated total liabilities. Under the new standard, remaining lease payments of the operating leases will be recognized at their present value discounted using appropriate discount rates.

In addition, the nature of expenses related to those leases will now change as IFRS 16 replaces the straight-line operating lease expense with a depreciation charge for right-of-use assets and interest expense on lease liabilities.

The Group does not expect the adoption of IFRS 16 to impact its ability to comply with the loan covenants.

### *Determining whether an Arrangement Contains a Lease*

On transition to IFRS 16, the Group can choose whether to apply the IFRS 16's definition of a lease to all its contracts or apply a practical expedient measure and not reassess whether a contract is, or contains, a lease. The Group plans to apply a practical expedient measure to grandfather the definition of a lease on transition. As such, the Group will apply IFRS 16 to all contracts entered into before April 1, 2019 and identified as leases in accordance with IAS 17 and IFRIC 4.

### *Transition*

As a lessee, the Group can either apply the standard using a retrospective approach or modified retrospective approach with optional practical expedient measures. The lessee applies the election consistently to all of its leases.

The Group plans to apply IFRS 16 initially on April 1, 2019, using the modified retrospective approach. Therefore, the cumulative effect of adopting IFRS 16 will be recognized as an adjustment to the opening balance of retained earnings at April 1, 2019, with no restatement of comparative information. When applying the modified retrospective approach to leases previously classified as operating leases under IAS 17, the lessee can elect, on a lease-by-lease basis, whether to apply a number of practical expedients on transition. The Group is assessing the potential impact of using these practical expedients.

## ***IAS 19, Employee Benefits***

In February 2018, the IASB issued amendments to IAS 19 – “Employee Benefits” regarding plan amendments, curtailments and settlements. The amendments are as follows:

- If a plan amendment, curtailment or settlement occurs, it is now mandatory that the current service cost and the net interest for the period after the remeasurement are determined using the assumptions used for the remeasurement.
- In addition, amendments have been included to clarify the effect of a plan amendment, curtailment or settlement on the requirements regarding asset ceiling.

The above amendments are effective for annual periods beginning on or after January 1, 2019. Earlier application is permitted but must be disclosed. The Group is currently in the process of evaluating the impact of this change on its consolidated interim financial statements.

### ***IFRS 3, Business Combinations***

In October 2018, the IASB issued amendments to IFRS 3 – “Business Combinations” regarding the definition of a “Business”. The amendments:

- clarify that to be considered a business, an acquired set of activities and assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs;
- narrow the definitions of a business and of outputs by focusing on goods and services provided to customers and by removing the reference to an ability to reduce costs;
- add guidance and illustrative examples to help entities assess whether a substantive process has been acquired;
- remove the assessment of whether market participants are capable of replacing any missing inputs or processes and continuing to produce outputs; and
- add an optional concentration test that permits a simplified assessment of whether an acquired set of activities and assets is not a business.

The above amendments are effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after January 1, 2020. The Group is currently in the process of evaluating the impact of this change on its consolidated interim financial statements.

### ***IFRIC 23, Uncertainty over Income Tax treatments***

On June 7, 2017, the IFRS Interpretations Committee issued IFRIC 23, which clarifies how the recognition and measurement requirements of IAS 12 “*income taxes*” are applied where there is uncertainty over income tax treatments. IFRIC 23 explains how to recognize and measure deferred and current income tax assets and liabilities where there is uncertainty over a tax treatment. An uncertain tax treatment is any tax treatment applied by an entity where there is uncertainty over whether that treatment will be accepted by the applicable tax authority. For example, a decision to claim a deduction for a specific expense or not to include a specific item of income in a tax return is an uncertain tax treatment if its acceptability is uncertain under applicable tax law.

The interpretation provides specific guidance in several areas where previously IAS 12 was silent. IFRIC 23 applies to all aspects of income tax accounting where there is an uncertainty regarding the treatment of an item, including taxable profit or loss, the tax bases of assets and liabilities, tax losses and credits and tax rates. IFRIC 23 is effective for annual periods beginning on or after January 1, 2019, though early adoption is permitted. The Group is currently in the process of evaluating the impact of this change on its consolidated interim financial statements.

### **Non-IFRS Financial Measures**

We use Adjusted EBITDA to provide additional information about our operating performance. We define Adjusted EBITDA as profit before tax expense, finance cost, net and depreciation, amortization and impairment. Adjusted EBITDA and Adjusted EBITDA Margin are not standard measures, nor measures of financial performance or liquidity, under IFRS, and should not be considered alternatives to result from operating activities, profit before tax, profit for the year/ period or any other performance measure derived in accordance with IFRS or as an alternative to cash flow from operating activities. Adjusted EBITDA and Adjusted EBITDA Margin are supplemental measures of the Group’s performance that are not required by, or presented in accordance with, IFRS.

As a measure of operating performance, we believe that the most directly comparable measure to Adjusted EBITDA is profit for the year/ period. We use Adjusted EBITDA in addition to profit for the year/ period because profit for the year/ period includes many accounting items associated with capital expenditures, such as depreciation, as well as certain other non-operating transactions, such as finance income and finance costs and income tax expenses. These accounting items may vary between companies depending on the method of accounting adopted by each company. By minimizing differences in capital expenditures and the associated depreciation expenses as well as reported tax positions, goodwill amortization and finance income and costs, Adjusted EBITDA provides further information about our operating performance and an additional measure for comparing our operating performance with other companies’ results. Funds depicted by Adjusted EBITDA may not be available for debt service due to covenant restrictions, capital expenditure requirements and other commitments. Our calculation of Adjusted EBITDA may be different from other companies and hence may not be entirely comparable and may limit its usefulness as a comparative measure.

### Consolidated Adjusted EBITDA

The following table reconciles our profit for the year/ period under IFRS to our definition of Adjusted EBITDA and Adjusted EBITDA Margin for the periods indicated:

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
Profit for the year/ period	50,260.0	49,116.9	43,602.7	77,000.7
Add:				
Finance costs (net) <sup>(1)</sup>	34,615.1	22,881.7	16,726.5	15,152.8
Income tax expense	22,947.9	23,734.7	17,788.1	33,251.0
Depreciation, amortization and impairment	31,089.1	55,719.5	25,947.6	29,921.1
Adjusted EBITDA	138,912.1	151,452.8	104,064.9	155,325.6
Revenue from operations (net)	460,572.1	619,165.6	426,760.4	562,858.8
Adjusted EBITDA Margin <sup>(2)</sup>	30.2%	24.5%	24.4%	27.6%

*Notes:*

(1) Finance costs net of finance income.

(2) Adjusted EBITDA Margin is defined as Adjusted EBITDA for the period divided by total revenues for that period.

### Segmental Adjusted EBITDA

The Company reconciles segment results from operating activities to Segmental Adjusted EBITDA by adding depreciation, amortization and impairment. Segmental results from operating activities do not include un-allocated corporate expenses.

The following table reconciles our results from operating activities for the year/ period for our Specialty Pharmaceuticals business segment under IFRS to our definition of Segmental Adjusted EBITDA and Segmental Adjusted EBITDA Margin for the periods indicated:

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
Segmental Results <sup>(1)</sup>	85,957.4	110,670.0	82,792.5	108,285.8
Add:				
Depreciation, amortization and impairment	14,635.4	27,198.0	12,140.1	15,372.6
Segmental Adjusted EBITDA	100,592.8	137,868.0	94,932.6	123,658.4
Revenue from operations (net)	246,694.0	409,522.9	275,932.3	387,641.6
Segmental Adjusted EBITDA Margin <sup>(2)</sup>	40.8%	33.7%	34.4%	31.9%

*Notes:*

(1) Segmental results as shown in our consolidated financial statements are equivalent to earnings before interest and tax (EBIT) and un-allocated expenses.

(2) Segmental Adjusted EBITDA Margin is defined as Segmental Adjusted EBITDA for the period divided by total revenues for that period.

The following table reconciles our results from operating activities for the year/ period for our Generics & APIs business segment under IFRS to our definition of Segmental Adjusted EBITDA and Segmental Adjusted EBITDA Margin for the periods indicated:

	Financial Year Ended March 31		Nine Months Ended December 31	
	2017	2018	2017	2018
	(US\$ thousands)			
Segmental Results <sup>(1)</sup>	30,526.2	(2,603.9)	4,416.7	29,678.3
Add:				
Depreciation, amortization and impairment	16,394.0	28,458.4	13,760.2	14,484.5
Segmental Adjusted EBITDA	46,920.2	25,854.5	18,176.9	44,162.9
Revenue from operations (net)	213,878.2	209,642.7	150,828.2	175,217.2
Segmental Adjusted EBITDA Margin <sup>(2)</sup>	21.9%	12.3%	12.1%	25.2%

*Notes:*

(1) Segmental results as shown in our consolidated financial statements are equivalent to earnings before interest and tax (EBIT) and un-allocated expenses.

(2) Segmental Adjusted EBITDA Margin is defined as Segmental Adjusted EBITDA for the period divided by total revenues for that period.

Adjusted EBITDA increased to US\$155.3 million in the nine months ended December 31, 2018, compared to US\$104.1 million in the nine months ended December 31, 2017 and Adjusted EBITDA margin was 27.6% in the nine months ended December 31, 2018, compared to 24.4% in the nine months ended December 31, 2017. Adjusted EBITDA increased in the nine months ended December 31, 2018 primarily due to an increase in the CMO business line of our Specialty Pharmaceuticals business segment, along with impact of favorable price movement, lower discards and failure to supply penalties in the U.S. market in our generics business line, partially offset by a loss from our newly acquired radiopharmacy business. Adjusted EBITDA margin increased in the nine months ended December 31, 2018 as compared to the nine months ended December 31, 2017 primarily due to the acquisition in September 2017 of substantially all of the assets which comprised Triad's radiopharmacy business which had negative margins despite being a significant contributor to revenue from operations.

Adjusted EBITDA increased to US\$151.5 million in the financial year ended March 31, 2018, compared to US\$138.9 million in the financial year ended March 31, 2017 and Adjusted EBITDA margin was 24.5% in the financial year ended March 31, 2018, compared to 30.2% in the financial year ended March 31, 2017. Adjusted EBITDA increased in the financial year ended March 31, 2018 primarily due to better volumes and favorable prices in our Specialty Pharmaceuticals business segment, partially offset by lower volumes, downward pressure on pricing and higher discards as well as failure to supply penalties in our generics business line in the U.S. market and impact of loss (including due to acquisition related costs) from our newly acquired radiopharmacy business. Adjusted EBITDA margin decreased in the financial year ended March 31, 2018 as compared to the financial year ended March 31, 2017 primarily due to the acquisition in September 2017 of substantially all of the assets which comprised Triad's radiopharmacy business which had negative margins despite being a significant contributor to revenue from operations.

You should not consider Adjusted EBITDA or Adjusted EBITDA Margin in isolation or construe it as an alternative to profit for the year/ period, or as an indicator of operating performance or any other standard measure under IFRS. Adjusted EBITDA and Adjusted EBITDA Margin measures used may not be comparable to similarly titled measures used by other companies.