JUBILANT PHARMA

Pharmaceuticals

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Leading market positions across business lines, with high barriers to entry for specialty pharmaceuticals

JUBILANT PHARMA

COMPANY OVERVIEW

Jubilant Pharma Limited is a global integrated pharmaceutical company offering a wide range of products and services to our customers across geographies. We organise our business into three segments, namely, **Specialty Pharmaceuticals**, comprising Radiopharma (including Radiopharmacies) and Allergy Therapy Products; **CDMO**, comprising Contract Manufacturing of Sterile Injectables & Non-sterile products and Active Pharmaceutical Ingredients; and **Generics**.

We supply our products and services to customers in over 85 countries. We have four manufacturing facilities in North America and two in India, coupled with Research and Development centers in North America and India. In addition, we have a distribution network of more than 50 radiopharmacies in the United States.

Revenue FY 2019 USD 761 million

Distribution network of more than 50 radiopharmacies in the United States

BUSINESS SEGMENTS

- **Pharmaceuticals**
  - Radiopharma (including radiopharmacies)
  - Allergy Therapy Products
- **CDMO**
  - Contract Manufacturing of Sterile Injectables and Non-sterile products (CMO)
  - Active Pharmaceutical Ingredients (APIs)
- **Generics**

GLOBAL FOOTPRINT

Operations in following countries

- USA
- Canada
- India
- Singapore
- Belgium
- China
- South Africa

LEADERSHIP POSITIONS

Radiopharma

- **Third largest** radiopharmaceutical manufacturer in the nuclear medicine industry in the United States based on revenue
- **Second largest** centralised commercial radiopharmacy network in the United States with a national footprint of more than 50 radiopharmacies across 22 states

Active Pharmaceutical Ingredients

- **One of the global suppliers** for several key 'API' products based on market share

Allergy Therapy Products

- **One of the top three** players in the allergenic extract market in the United States and are currently the **sole producer and supplier** of venom products for the treatment of allergies in the United States

Generics

- **One of the market leaders** in the United States, based on market share of several key products

6 US FDA Inspected/Accredited Manufacturing Facilities
(4 in North America and 2 in India)

MANUFACTURING FACILITIES

Kirkland, Montreal, Canada

Health Canada and the US FDA inspected/accredited facility for Radiopharmaceuticals

Kirkland, Montreal, Canada

US FDA, Health Canada inspected/accredited facility for Sterile Injectables and Non-sterile products

Spokane, Washington, USA

US FDA, MHRA, Health Canada, PMDA Japan inspected/accredited facility for Sterile Injectables

US FDA and Health Canada inspected/accredited facility for Allergy Therapy Products

Salisbury, Maryland, USA

Health Canada, US FDA and DEA inspected/accredited facility for Generics

Nanjangud, Karnataka, India

US FDA, PMDA Japan, KFDA Korean and COFEPRIS Mexico inspected/accredited facility for Active Pharmaceutical Ingredients

Roorkee, Uttarakhand, India

US FDA, EU, PMDA Japan, Health Canada, ANVISA Brazil and SAPHRA South Africa inspected/accredited facility for Generics

- **Research and Development** centers in North America and India
- Team of **over 450 R&D professionals**

PHARMACEUTICALS
BUSINESS OVERVIEW

We offer products and services across the pharmaceuticals value chain. We have three business segments,

(i) Specialty Pharmaceuticals, comprising Radiopharma (including radiopharmacies) and Allergy Therapy Products;

(ii) CDMO, comprising Contract Manufacturing of Sterile Injectables & Non-sterile products and Active Pharmaceutical Ingredients; and

(iii) Generics.

RADIOPHARMA

Jubilant DraxImage Inc (JDI) develops, manufactures and commercializes Radiopharmaceuticals used for the diagnosis and treatment of diseases. The company serves markets globally, and is the market leader in North America in three Nuclear Medicine segments.

Jubilant DraxImage Radiopharmacies (JDR), is focused on delivering patient specific doses of radiopharmaceuticals to local Nuclear Medicine Department across the United States.

Nuclear Medicine market leader in North America for lung and bone scintigraphy and I-131 thyroid disease therapy

Strong portfolio of differentiated products including RUBY-FILL® - Rb-82 Generators and I-131 Sodium Iodine, MAA and DTPA

New product pipeline includes I-131 MIBG (Iobenguane)- an ultra-orphan drug used for paediatric treatment of neuroblastoma and other key imaging agents in nuclear medicine

Regulatory approvals in US, Canada, Central & South America, Europe and South Asia

Clinical applications include diagnostic imaging for Cardiology, Oncology, Pulmonary, Kidney, Brain and Skeletal, as well as Radiotherapy for Thyroid and other Cancers

Worldwide Exports- North America, Latin America, European and Asian Markets

Strong new product development pipeline with a series of key generic products used widely in general nuclear medicine diagnostics and therapy

Serving nearly 4 million patients each year, making JDR the second-largest nuclear pharmacy network in the United States

JDR's network of specialized radiopharmacies provide single photon emission computed tomography (SPECT) and positron emission tomographic (PET) prescriptions to local hospitals and outpatient imaging centers across the national US market

Manufacturing Facility

Kirkland, Montreal, Canada

Health Canada and the US FDA inspected/accredited facility for Radiopharmaceuticals

Over 50 Radiopharmacies

Across 22 states in US

Employing over 700 highly skilled professionals

CONTRACT MANUFACTURING OF STERILE INJECTABLES AND NON-STERILE PRODUCTS

Jubilant HollisterStier is an integrated contract manufacturer of sterile injectables, ophthalmics, otics and sterile and non-sterile products - ointments, creams and liquids.

- **Leading contract manufacturer** of Clinical to Commercial Sterile injectables
- Broad range of capabilities including **sterile injectables (vials and ampoules), ophthalmics and otics (tubes and bottles) and non-sterile products - ointments, creams, and liquids (bottles, tubes, and pumps)**
- Serving global leaders in pharmaceutical & biopharmaceutical industries
- Offering turn- key services including full testing, regulatory support, supply chain support, secondary packaging, cold chain management, stability, CMC support and serialization

Manufacturing Facility

Kirkland, Montreal, Canada
US FDA, Health Canada inspected/accredited facility for Sterile Injectables and Non-sterile products

Spokane, Washington, USA
US FDA, MHRA, Health Canada, PMDA Japan inspected/accredited facility for Sterile Injectables

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.

We are **one of the top three players*** in the allergenic extract market in the United States and are currently the sole producer and supplier of venom products for the treatment of allergies in the United States.

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 and New Zealand 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.

Manufacturing Facility

Spokane, Washington, USA

US FDA and Health Canada inspected/accredited facility for Allergy Therapy products

*Ranking as per Frost & Sullivan

GENERICS

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 generics for CVS, CNS, GI and Anti-allergy therapeutic categories. The business derives benefit from vertically integrated into our APIs business.

Experienced in developing over 100 molecules across therapeutic categories of CVS, CNS, Antiinfective, Pain, Respiratory, Antidiabetic and Urology

- Multiple dosage forms / containment capabilities
  - Immediate release oral solids
  - Modified release oral solids
  - Steroids
  - Potential for liquids, ointments, powders, ophthalmics and injectables
  - Experience in developing formulations for veterinary business
- **A leading formulations player -** Development, manufacture and sale of proprietary Formulations
- Creating differentiated dosage forms with MUPS based products, ODT, chewable tablets, Powder For Oral Solutions & Suspensions etc.
- Capable of developing multiple products for various geographies including **USA, EU, Canada, Japan, China, Australia, Brazil and RoW Markets**
- In-house BA/BE unit audited by US FDA and other key regulatory agencies
- In the United States market, till June 30, 2019, we have made a total of **96 ANDA filings** for generics of which 35 are pending approval
- In non-US markets, till June 30, 2019, we have made a total of **900 filings** for generics, of which 636 are approved
- As at June 30, 2019, we had **55 commercialised generic products** across the United States, Europe, Canada, Australia and the Rest of the World.
- Our in-house APIs capability provides us stable source of APIs supply for availability of these products at competitive prices

Manufacturing Facility

Salisbury, Maryland, USA

Health Canada, US FDA and DEA inspected/ accredited facility for Generics

Roorkee, Uttarakhand, India

US FDA, EU, PMDA Japan, ANVISA Brazil and MCC South Africa inspected/accredited facility for Generics

ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)

Jubilant is a preferred partner of choice across the globe for innovator and generic pharmaceutical companies. Jubilant APIs business has prominent presence in markets such as North America, South America, Europe, Japan, APAC (Asia Pacific) and Middle East.

Jubilant offers one of the **broadest portfolio comprising of more than 90 different APIs** from various therapeutic categories like **CNS, CVS, Anti-infective, Anti-diabetic** etc.

- Proven expertise to operate large scale chemical operations, which is key to better cost efficiencies
- **Global leaders in Carbamazepine, Oxcarbazepine, Pinaverium, Risperidone, Valsartan etc.**
- Diversified & large external customer base to drive growth across multiple regions
- Business sustainability & supply assurance from backward integration of key APIs
- Best in Class quality compliance, with excellent track record on successful multiple inspections by various regulatory bodies such as **US FDA, Health Canada, ANSM-France, ANVISA- Brazil, TGA-Australia, PMDA- Japan, COFEPRIS-Mexico and KFDA**
- APIs manufacturing site spans over an area of 2,67,000 square mts. with 33% built-up area; 6 large scale manufacturing blocks and a pilot plant; 170 reactors having volumetric capacity of 760 KL and 18 clean rooms
- World class APIs R&D team comprises of more than **150 synthesis & analytical scientists including PhDs;** Expertise in complex chemistries such as Chiral separation, Low Temp reactions, Bio-transformation, Stereo-selective synthesis, continuous flow reactions; equipped with latest analytical instruments such as LC HRMS, NMR, XRD, LCMS, etc. Analytical expertise in polymorphic characterization and contamination, Genotoxic & Carry over studies, Impurity profiling etc.
- Dedicated DoE/QbD cell for bringing quality and process robustness during the product development.

Manufacturing Facility

Nanjangud, Karnataka, India

US FDA, PMDA Japan, KFDA Korean and COFEPRIS inspected/ accredited facility for Active Pharmaceutical Ingredients

MANUFACTURING

Global competitive edge due to integrated and efficient manufacturing operations

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 starting materials and helps to insulate us from significant volatility in raw materials prices.

The APIs from our manufacturing facility are used for our generics business. Such integration between our Generics and APIs 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.

Additionally, our radiopharmaceutical products are distributed through more than 50 radiopharmacies.

We operate our plants in accordance with cGMP and/or other applicable requirements. We currently operate four US FDA inspected/accredited manufacturing facilities in North America and two US FDA inspected/accredited manufacturing facilities in India.

MANUFACTURING FACILITIES

NORTH AMERICA

Kirkland, Montreal, Canada

Health Canada and the US FDA inspected/accredited facility for Radiopharmaceuticals

Kirkland, Montreal, Canada

US FDA, Health Canada inspected/accredited facility for Sterile Injectables and Non-sterile products

Spokane, Washington, USA

US FDA, MHRA, Health Canada, PMDA Japan inspected/accredited facility for Sterile Injectables

US FDA and Health Canada inspected/accredited facility for Allergy Therapy Products

Salisbury, Maryland, USA

Health Canada, US FDA and DEA inspected/accredited facility for Generics

INDIA

Nanjangud, Karnataka, India

US FDA, PMDA Japan, KFDA Korean and COFEPRIS Mexico inspected/accredited facility for Active Pharmaceutical Ingredients

Roorkee, Uttarakhand, India

US FDA, EU, PMDA Japan, Health Canada, ANVISA Brazil and SAPHRA South Africa inspected/accredited facility for Generics

RESEARCH & DEVELOPMENT AND INTELLECTUAL PROPERTY

Strong product pipeline with deep R&D capabilities

In radiopharmaceuticals (till June 30, 2019), we are focused on high value niche products with diagnostic and/or therapeutic uses like successful 505(b)2 NDA inspection/accredition by US FDA DraxImage® Exametazime and RUBY-FILL®. Another 505(b)2 NDA filing process for I-131 MIBG is ongoing along with 4 other products under development. We have our own in-house radiopharmaceutical distribution capabilities, thereby reducing our reliance on third party radiopharmaceutical distributors.

We also have a strong pipeline in our Generics and APIs business segment and since we commenced operations (through to June 30, 2019): for generics we have filed 96 ANDAs in the United States, of which 35 ANDAs are pending approval; For APIs, we have filed 94 DMFs in the United States. In addition, as on June 30, 2019, we have 15 sterile filings, of which two ANDAs are pending approval in the United States.

We have R&D centers located in North America and India and we employ a team of over **450 R&D professionals** with expertise in the development of novel, robust and non-infringing processes for APIs and generics, as well as specialized and/or niche formulations and designs for radiopharmaceuticals and other products, which have been taken to commercialisation. Our R&D continues to lead to new, innovative processes and new knowledge-driven products that increase the efficiencies of our production and allow us to capitalise on opportunities for growth in competitive markets. As on June 30, 2019, we have been granted patents for intellectual property in various countries for innovation, including 12 active patents granted relating to APIs in a number of different countries, 4 active access patents granted relating to generics in a number of different countries, 81 active patents granted relating to radiopharmaceutical products in a number of different countries and 01 active patent granted relating to allergy therapy products in the United States.

BUSINESS EXCELLENCE

In Jubilant Pharma, Business Excellence function is proactively creating the framework for new improvement strategies which drives the competitive advantage backed by a strong execution mechanism & capability. These improvement strategies pertain to all three critical pillars of the organisation – CUSTOMER, PROCESS & PEOPLE.

During the journey of continual improvement, we have adopted various improvement methodologies in line with organisation priorities Lean Six Sigma, Total Productivity Maintenance (TPM), Business Intelligence Framework backed with Business Intelligence (BI) Tools etc.

Highlights:

- Lean Six Sigma tools are used for capacity debottlenecking and process simulation tools backed by statistics is used for APIs, Generics, Supply Chain process optimisation.
- QbD (Quality by Design) is an approach followed in new product development for generating a robust design space which in turn helps developing Right First Time products.
- Lean Lab as a concept is followed for optimizing efficiencies in Quality Lab area where by speed of execution without any error is key driver for improvement.
- Cash to Cash cycle time reduction and working capital improvements are driven across all businesses by following best in class Lean and Supply Chain practices.
- EBITDA maximization approach is followed for improvement project selection.

SUPPLY CHAIN

Customer delivery through effective and efficient logistics and supply chain management

The goal of Supply Chain Management (SCM) at Jubilant is to provide a substantial and sustainable value contribution to its customers for the success of our businesses.

Jubilant strives to play an integral role in all geographies where we operate. The guiding principles for our supply chain have been set under our Green Supply Chain Policy. To fulfil our Green Supply Chain commitments, the evaluation criteria cover clauses on compliance to EHS, human rights and social requirements relevant laws of the land.

Highlights:

- Jubilant emphasises and invests in Life Cycle Management (LCM) of all its products consistently to be a reliable and a sustainable supplier meeting **global quality standards**.
- Partners in progress meet to collectively innovate & optimise a sustainable value chain.
- **Paperless Sourcing:** Jubilant uses an e-procurement tool that enables paperless buying. It ensures greater efficiency and transparency in procurement process and information flow by use of tools like reverse auction.
- **Supplier Audits** are conducted annually to cover critical vendors at least once in three years. It include performance assessment against parameters such as environment, labour practice, human rights and social impact.
- **Local Sourcing:** The Company sources its material, machinery, spares stores etc. from across the globe without compromising on quality and value. Preference is given to local suppliers if they satisfy the requisite specifications.
- **Training Programs:** Road safety during transportation of its products and raw materials is of prime concern to the Company. In order to improve transporter safety, 'Behavioural Safety Training with focus on defensive driving' is imparted to transport service providers.
- All domestic tanker **movement are tracked through GPS** for safety & timely delivery, going forward all export shipments will also be tracked online to ensure timely delivery to customers.

SUSTAINABILITY

Jubilant's Promise of Caring, Sharing, Growing finds life in each of the many sustainability endeavours of the Company. We take pride in our long and momentous journey by creating long term value for our stakeholders.

Jubilant follows Triple Bottom Line approach towards sustainability and is reporting sustainability performance of the Company following Global Reporting Initiative (GRI) Guidelines since 2003.

Jubilant is signatory to United Nations Global Compact principles. Jubilant is also GRI Gold Community Member and a Member of GRI South Asian Consortium in Chemicals Sector.

The Company through stakeholder engagement identified focus areas and set Sustainability Targets 2020 on environment, safety and community services.

Climate Change

- Jubilant is aware about business implications and responsibilities arising out of Climate Change across the globe. In response the Company has adopted Climate Change Mitigation Policy which aims to reduce its climate change impact through reduced carbon footprint.
- Jubilant participates in Carbon Disclosure Project to publicly demonstrate its Greenhouse Gas emission performance and commitments.
- The Company uses renewable energy sources like solar, bio-diesel etc. in its energy mix to reduce company's carbon footprint.
- There is dedicated team to identify, plan, budget, implement, monitor and report resource efficiency improvement projects.

Environment, Health and Safety (EHS)

- The Company's approach towards best-in-class EHS standards is articulated in the EHS Policy.
- Dedicated EHS teams at manufacturing facilities & corporate office effectively manage the EHS performance of the Company.
- Safety culture in terms of safe behaviour is being aggressively promoted and propogated at workplace
- EHS & sustainability performance of the Company is reviewed by sustainability and CSR committee at Board level regularly.

Customer Health and Safety

- Strong team involving R&D, QA, QC, sales and marketing to take care of product safety
- Good Manufacturing Practices (GMP), US FDA, Health Canada, PMDA (Japan), KFDA (Korea), COFEPRIS (Mexico) and other inspections/ accreditions are there for exporting products to relevant countries.

Corporate Social Responsibility (CSR)

- Jubilant' s CSR initiatives thrust on creating value in the lives of the communities around the area of operations of the Company
- Jubilant CSR initiatives are focused in the realm of Education, Health, Livelihood and Social Entrepreneurship
- The Company is aligning its sustainability efforts along with UN SDGs (Sustainable Development Goals) and refer these SDGs while planning/ adopting any new / existing community development projects.

Jubilant Pharma Limited is a global integrated pharmaceutical company offering a wide range of products and services to our customers across geographies. We organise our business into three segments, namely, Specialty Pharmaceuticals, comprising Radiopharma (including Radiopharmacies) and Allergy Therapy Products; CDMO, comprising Contract Manufacturing of Sterile Injectables & Non-sterile products and Active Pharmaceutical Ingredients; and Generics.

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