Over the past 5 years, Lupin’s endeavour has been to strengthen its presence in the U.S., the largest pharmaceutical market globally that accounts for more than 45% of global pharmaceutical sales.

During FY20, the U.S. contributed 38% to the company’s revenues, aggregating US$ 800 Million. This is a 3% growth over FY19, largely supported by the ramp up of our Levothyroxine generic during the year. Price erosion in our legacy product portfolio was largely contained to mid-single digits. During the year, we filed 21 ANDAs in the U.S., two of which were confirmed exclusive First-to-Files (FTFs). We now have over 158 ANDAs pending approval with the U.S. FDA, a rich pipeline that includes inhalation, FTF and injectable products.
commercial formularies in the U.S., the successful conclusion of our phase 3 study in trichomoniasis, as well as our ongoing business development activities and internal pipeline assets give us confidence of a significant future ahead for this business.

U.S. Generics

Our base U.S. generics business was robust in FY20, helping us deliver even amidst challenges. Our track record with customers remains strong. Our focus on strengthening our already agile supply chain backed by unparalleled customer service helped us capitalize on seasonal product opportunities like gTamiflu®. Lupin’s product portfolio (including those pending approval) includes many of the products related to the treatment of COVID-19 such as Azithromycin and Albuterol as well as other flu, antibiotic and antiviral products.

During the year, we continued to work toward reinforcing our quality systems and processes across our manufacturing network ensuring compliance with regulatory standards. In the last quarter of FY20, the intensive efforts of our team began to bear fruit with successive positive outcomes for inspections at several of our facilities. This will help us deliver on new product launches whilst consolidating our position in our existing portfolio. These measures will now accelerate our U.S. generics growth trajectory.

Throughout the year, we proactively resolved challenges around supply chain issues, channel consolidation and ongoing U.S. FDA discussions that affected new product launches. During the last quarter of the year, we ramped up these efforts substantially in sync with our global efforts to fight COVID-19. Our agile supply chain and meticulous planning ensured continuity of product supply in the market. We also exhibited responsible stewardship in our communities by contributing substantial quantities of product, PPEs and meals to frontline workers and the needy.

In the coming year, we look forward to delivering the promise of our pipeline products including our first Metered Dose Inhaler (MDI) launch in the U.S. — Albuterol (gProAir®), which would mark an inflection point for our complex generics evolution. We remain on track for our biosimilar Pegfilgrastim U.S. filing in FY21. We are confident that as we move ahead, an improved pricing environment, resolution of U.S. FDA issues at certain facilities, and ramp-up of our recent niche product launches will accelerate our growth.

U.S. Specialty

Early in FY20, we triggered a deep introspection on our Specialty strategy as our lead women’s health product, Solosec® witnessed lower than expected traction. We moved swiftly to put in place a set of focused initiatives. We have strengthened the leadership team with experienced executives led by a new President of the U.S. Specialty business, Jon Stelzmiller, who comes with extensive experience in building women’s health brands. Led by Jon, the Specialty team executed a host of transformational efforts, which prior to COVID-19, was set to build a formidable and durable franchise.

We remain committed to building a world class Women’s Health franchise in the U.S.

However, with the sharp reduction in prescriptions for acute medicines and the continued impact of COVID-19 in FY21, we have now implemented a new operating structure. A smaller team carries forward our ambition in U.S. Specialty, but we believe it will best position us to respond to the market, patient needs, and achieve sustainable growth, going forward.

Securing preferred formulary status for Solosec® with Express Scripts, one of the largest

123 of our products, out of a total of 174, rank amongst the top three products in their segment. Our marketed products have an average market share of 30%

During the year, we continued to work toward reinforcing our quality systems and processes across our manufacturing network ensuring compliance with regulatory standards.
Lupin’s India business is a crucial growth driver and continues to lead the way with greater profitability and value by consistently delivering best-in-class results. In FY20, our Domestic Formulations business crossed the milestone revenue figure of INR 50,000 Million and registered double-digit growth.

The India business continues to be the second largest business unit for Lupin, contributing 34% to the topline and significantly to the bottomline.

Lupin’s branded generics sales grew by 13.6% in FY20. Lupin's branded generic business is currently placed at 6th position in the Indian Pharmaceutical Market (IPM). The branded generics business has consistently outpaced the IPM with a four-year CAGR of 11.7% vs. IPM CAGR of 9.4%. Importantly, over the last four years, we have improved our market share from 3.46% in FY16 to 3.61% in FY20.

Overall, Lupin retains the 4th position in the high growth chronic segment. The chronic segment has improved in salience to 62% of total revenues and the acute segment contributes the balance 38%.

Our top five therapies, cardiology, anti-diabetes, respiratory, anti-infective and gastrointestinal contribute more than 74% of total sales. We continue to lead in the anti-TB segment and maintain 2nd position in the respiratory and 3rd position in the anti-diabetes and cardiology segments. We have grown significantly in the anti-diabetes segment with growth of 18.4% versus IPM’s growth of 11.8%, resulting in improved market share from 7.9% in FY19 to 8.4% in FY20. We now have 10 Lupin brands that feature in the Top 300 brands of the IPM. In FY20, Lupin successfully launched three new divisions focused on the urology, dermatology and pediatric respiratory therapy areas. We also launched ‘Adhero,’ a first of its kind Bluetooth-Enabled Smart Device in India to support treatment of respiratory disease. We continue to demonstrate our commitment to driving innovation and excellence in our business.
Our top five therapies, cardiology, anti-diabetes, respiratory, anti-infective and gastrointestinal contribute more than 74% of total sales. We continue to lead in the anti-TB segment and maintain 2nd position in the respiratory and 3rd position in the anti-diabetes and cardiology segments. We have grown significantly in the anti-diabetes segment with growth of 18.4% versus IPM’s growth of 11.8%, resulting in improved market share from 7.9% in FY19 to 8.4% in FY20. We now have 10 Lupin brands that feature in the Top 300 brands of the IPM.

In FY20, Lupin successfully launched three new divisions focused on the urology, dermatology and pediatric respiratory therapy areas. We also launched ‘Adhero,’ a first of its kind Bluetooth-Enabled Smart Device in India to support treatment of respiratory disease.

We continue to demonstrate leadership in launching new products and rank 3rd in the IPM in the 12 months New Product Introduction Index.

We are focused on building therapy-specific scientific platforms to enable long-term and meaningful association with focused specialties. In FY20, Lupin associated with the American College of Gastroenterology (ACG) to create a platform for gastroenterologists and similarly with Mayo Clinic for Orthopedics.

Lupin has been at the forefront of digital transformation and technology adoption. ‘AnyA,’ Lupin’s Health Chatbot launched in FY20, can answer queries on respiratory ailments, Hypertension and Diabetes. It can even respond in Hindi and Tamil for the latter two conditions. Through our social media channels, we continue to engage with health care professionals through live webinars and content focused on therapeutic advancement.

Lupin has also partnered with new-age startups to leverage their digital prowess and reach patients for educating them on developing healthy habits and improving adherence.

Therapy-Wise Share of Revenue

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Rank FY20</th>
<th>Market Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTI-TB</td>
<td>1</td>
<td>56.6%</td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>2</td>
<td>5.8%</td>
</tr>
<tr>
<td>CARDIOLOGY</td>
<td>3</td>
<td>6.6%</td>
</tr>
<tr>
<td>ANTI-DIABETES</td>
<td>3</td>
<td>8.4%</td>
</tr>
<tr>
<td>CNS</td>
<td>6</td>
<td>2.6%</td>
</tr>
<tr>
<td>GYNAECOLOGY</td>
<td>10</td>
<td>2.8%</td>
</tr>
<tr>
<td>GASTROINTESTINAL</td>
<td>11</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

Lupin’s Therapy-Wise Ranking

Owing to our innovative product development and aggressive marketing, Lupin has been able to achieve a market leadership in the ANTI-TB, RESPIRATORY, CARDIOLOGY, ANTI-DIABETES and CNS categories. We also have a strong presence in the GASTROINTESTINAL and GYNAECOLOGY categories.

Outlook

Lupin’s India business is a sustainable growth story for Lupin. We continue to work on business imperatives and key drivers while engaging with our key stakeholders, doctors, patients and consumers.

Our expertise in brand building, focus on gaining market leadership in key therapies, and agility to adopt digital initiatives will continue to propel our India business towards newer milestones and a promising future.

Data Source: IQVIA MAT March 2020

Therapy-Wise Share of Revenue
Laying the Foundation
Latin America (LATAM)

In FY20, the pharmaceutical market in LATAM region grew by 12%, driven by innovation in select therapeutic areas and sale of branded generics. Overall, our LATAM business recorded growth of 8.6% and contributed 4% to our overall revenues in FY20.

While there has been continued improvement in healthcare access and budgetary allocation by successive governments through the course of the last decade, it still remains a constraining factor to overall growth prospects. In FY20, the two biggest markets in the region, Brazil and Mexico, represented 64% of LATAM market in size and witnessed a growth of 9%. The region also includes exports from India. We have now expanded our presence into Chile, Peru and Colombia by signing distribution agreements with key players in these markets.

Mexico

Mexico is one of the world’s largest pharmaceutical markets, with a size of US$ 7.5 Billion. The market witnessed robust growth of 8% in FY20, albeit affected by currency devaluation due to macroeconomic headwinds.

Laboratorios Grin (Lab Grin), Lupin’s subsidiary in Mexico, recorded a growth of 3.6% in secondary sales and continues to be ranked 2nd in the ophthalmic reference market (by units). In FY20, we launched important products like hyaluronic acid in preservative free presentations. This launch further strengthened our presence in the dry eye segment.

Lab Grin’s portfolio consists of 50 ophthalmic products and 10 primary care products. We intend to now leverage our global product pipeline and grow in areas beyond the ophthalmic segment by launching products in the respiratory, pain management and CNS segments. We are committed to transforming Lab Grin’s portfolio to one that is balanced with innovative and branded generics products, across therapy areas.

Brazila

The Brazilian pharmaceutical market is US$ 14.9 Billion and is the most important pharmaceutical market in LATAM, accounting for about 42% of the region’s sales. It is ranked as the 13th largest pharmaceutical market worldwide. In FY20, the Brazilian pharmaceutical market recovered with a growth rate of approximately 10% largely led by robust volume growth. However, price pressures coupled with higher input costs weighed on profitability.

MedQuimica, Lupin’s Brazilian subsidiary, now ranks 14th in value and is the 5th largest in terms of volumes (in reference market), commanding a 2.1% market share. During the year, MedQuimica launched 10 new generic and dermatology products. MedQuimica outpaced industry growth, delivering 28.1% and 14.2% growth in value and volumes respectively, per IQVIA. Leveraging our strong manufacturing platform and efficient commercial structure, we are aligned to emerge stronger in the quarters to come. Whilst in the short term there are significant headwinds in terms of lower footfall in clinics, increase in input and logistic costs, specific supply shortages and unfavourable forex rates, we continue to believe in the potential of Brazil as a growth market for the pharma industry. Our strategy to leverage our global pipeline assets in the CNS, Ophthalmology and Respiratory segments and build innovation capabilities in both Specialty and OTC, will pay dividends from the region in the years to come.

Data Source: IQVIA MAT Dec 2019 & March 2020
The APAC region accounts for more than 20% of the global pharmaceutical market with an estimated market size of US$ 230 Billion. Lupin is present in the major markets of Japan, Australia and Philippines in the region, and the region accounts for 4% of our global sales. In FY20, we recorded a growth of 8.4% in the region, while the market grew at 6%.

**Building Rank**

**Asia Pacific (APAC)**

- **Markets Served in the Region**: 10
- **4th Largest Generic Company in Australia**
- **5th Largest Branded Generic Company in Philippines**

**Japan**

The pharmaceutical market of Japan is pegged at US$ 79 Billion. The market has significantly evolved since we entered in 2007. Kyowa Pharmaceutical Industry Co. Ltd, acquired in 2007 was our main subsidiary in Japan. Its acquired Kyowa Criti Care focused on the injectables business. We believe that Japan's intense cost-containment regulations with regular price cuts present significant headwinds for growth, and led us to exit our on-shore presence in the market in FY20. We remain interested in the Japanese market. Lupin continues to supply its existing products, APIs and select new products in Japan through a licensing agreement with Kyowa Pharmaceutical Industry Co. Ltd. We are also committed to our partnership with Nichi-Iko for biosimilar Etanercept, which was successfully launched in Japan in H2 FY20. We will continue to selectively bring our portfolio of complex generics and rare diseases to the Japanese market, partnering with the right partners to maximize value for the company.

**Data Source**: IQVIA MAT March 2020

**Australia**

The Australian pharmaceutical market is valued at US$ 11.7 Billion with a growth rate of 6.8% in FY20. The generics segment in Australia has witnessed consolidation in recent times and grew at a faster rate of 13.2%, backed by government support. Lupin’s Australian subsidiary, Generic Health ranks 4th in the region amongst generic players and supplies generic prescriptions and OTC medicines to pharmacies and hospitals in Australia. Generic Health reported a strong FY20, with revenues of AUD 48 Million.

As we move ahead, we plan to introduce our complex injectable and respiratory products to the Australian market, in addition to select niche products with limited competition.

**The Philippines**

The Philippines pharmaceutical market is valued at US$ 4.4 Billion, and grew by 8.3% in FY20. Multicare Pharmaceuticals Philippines Inc. (Multicare), Lupin’s subsidiary in the country, is a premium branded generics company with a strong presence in the rheumatology, gastrointestinal and diabetes segments. We rank 5th among branded generic companies in the country. Multicare generated total revenues of PHP 1,760 Million, recording a growth of 13% compared with the previous year. Our strategy for the region focuses on increasing our market share by launching a mix of in-house and in-licensed products. The in-house inhalation and injectable pipeline is expected to be launched in the Philippines in the near future.

**Data Source**: IQVIA MAT March 2020
Bringing new Solutions
Europe, Middle East and Africa (EMEA)

The Europe, Middle East and Africa (EMEA) region accounts for 26% of the global pharmaceutical market with an estimated market size of US$ 292 Billion. Lupin is present in the major markets of U.K., Germany and South Africa, with the region contributing 8% to the company’s global sales.

The region offers significant opportunity to Lupin for further growth in the complex generics segment, especially with our unique range of long-acting injectables, biosimilars and inhalation products. In addition to our diverse generics portfolio, Lupin has entered the Specialty segment with the neurology orphan drug NaMuscla®.

NaMuscla® is our proprietary product prescribed for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders, a severely debilitating neuromuscular condition. We plan to comprehensively address Europe and the Middle East with this product before taking it to other geographies.

Europe

The pharmaceutical market in Europe is valued at US$ 267 Billion. In FY20, Lupin's business in Europe registered a growth of 13% with sales of INR 6,414 Million. The key contributors to growth include the portfolio expansion of Hormosan Pharma, our German subsidiary, new product launches and scaling NaMuscla® across U.K., Germany and France.

The restructuring of our sales and marketing strategy in Germany along with our cost optimization measures and implementation of centralized finance shared services, delivered cost savings which further boosted the bottomline for the region.

During the year, Hormosan entered into a partnership with Eli Lilly to promote their migraine product Emgality®, further strengthening Hormosan’s position as a market leader in the cluster headache and migraine segment. We also increased promotion of our key products including Oxycodone, Sumatriptan Pen and NaMuscla®. In the U.K., we launched Valproate Semisodium and several ARVs. Negotiations for NaMuscla® reimbursement remain on track, paving our growth path in existing markets while we continue exploring partnerships to expand reach beyond the EU5 markets.

FY21 is poised to be a milestone year as we prepare to launch our first inhalation product (generic Fostair® MDI), our first biosimilar (Etanercept), and continue the expansion of NaMuscla®

GIVE YOUR NDM PATIENTS MOVEMENT WHEN IT MATTERS
South Africa

The pharmaceutical market in South Africa is valued at US$ 3.6 Billion. While the market grew by 1% YoY, Lupin's South African subsidiary, Pharma Dynamics, registered a growth of 4.9% with sales of ZAR 1,219 Million driven by continued strength in key pharma segments, including CVS and CNS. In FY20, Pharma Dynamics achieved Broad-Based Black Economic Empowerment (BBBEE) compliance. This ensures the continued access for our products and puts us in a preferred status.

While the new regulatory body, South African Health Products Regulatory Authority (SAHPRA) works towards strengthening its presence, we anticipate some delays in product approvals. In addition, the benchmark-pricing band structures being used by medical aid funding agencies have been driving prices down. Growth rate during the year was constrained by the minimal price increase approved by the government.

Despite these hurdles, Pharma Dynamics was the 3rd fastest growing pharma company overall and the fastest growing company in the OTC segment in South Africa. The company also maintained its leadership in the CVS space, led by key brands including Amloc (Amlodipine), Fedaloc (Nifedipine) and Bilocor (Bisoprolol). The complementary medicines franchise and OTC segment was augmented by cough and cold brands, further fuelled by COVID-19, especially the EfferFlu product range.

Our growth in FY21 will be driven by our strong market position, a robust portfolio in the CVS space, and launch of new products. In addition, we target to expand our product offering in the OTC, Self-Help (CAMS) category and also enter the medical cannabidiol market with a complimentary (non-scheduled) product.

In the backdrop of the COVID-19 pandemic, we have revisited our commercial approach and focused on de-risking our supply chain. We have built contingencies into our new product launches, focused on leveraging digital to market our products and connect with customers, while accelerating our pace towards digital transformation.

Data Source: IQVIA MAT March 2020
Lupin’s API business contributes to both captive consumption as well as external sales across 70 countries. For FY20, it constituted 9% of consolidated revenues driven from six manufacturing sites at Tarapur, Ankleshwar, Dabhasa, Mandideep, Indore and Visakhapatnam.

In addition to sale of API, the business is forward integrated into the Principal to Principal (P2P) business which aims to provide access to new molecules for first-to-market opportunities in developing countries and the Global Institutional Business (GIB) which partners with governments and organizations to help eradicate diseases like Tuberculosis (TB), HIV and Malaria.

In addition to a very strong marketed product portfolio, we have a valuable development pipeline of new products across select therapy areas of interest.
Our P2P business leverages our rich expertise in API research and formulation development. The business entails launching several first-to-market products in India and other developing geographies, providing partners with a strong and reliable product supply.

Our P2P product pipeline is focused on developing new fermentation technology required to manufacture products like Rifampicin, which forms the backbone for treating TB.

**Opportunity landscape in ARV**

Our antiretroviral (ARV) portfolio is comprehensive and has evolved in line with current treatment guidelines. With a comprehensive development pipeline, meaningful filings and select approvals to date, we are geared to address the ARV segment, with an overall market size of US$ 1.8 Billion.

**Facilitating access to the newest molecules**

Our P2P business leverages our rich expertise in API research and formulation development. The business entails launching several first-to-market products in India and other developing geographies, providing partners with a strong and reliable product supply.

Our P2P product pipeline is focused on developing new molecules and combinations attuned to market needs. In line with this, we are strengthening our gastroenterology portfolio with unique combination drugs for the management of dyspepsia, while in the cardiac segment we are strengthening our product range with complex extended release formulations for the management of heart failure.

**The battle against Tuberculosis**

Lupin has always been at the forefront of the global fight against TB and we are the largest supplier of first-line anti-TB drugs in the world. Our API plants operate in compliance with all applicable standards, including WHO GMP, and our products are prequalified by WHO, signifying high quality standards. We are the largest supply partners to governments of high TB burden countries across Africa and Asia, including India.

We are strengthening our anti-TB portfolio with the development of key products recommended for the treatment of multi-drug resistant (MDR) TB. Our expertise in fermentation technology required to manufacture products like Rifampicin, which forms the backbone for treating TB.

**Share of API revenues**

Data Source: IQVIA MAT March 2020
With 7 R&D centers employing over 1,500 personnel, Lupin has pursued a single goal in all its research endeavors – bringing affordable, quality medicines to market that address unmet patient needs. Our Research and Development efforts are primed to utilize the best technologies, superior competencies and strategic partnerships, helping us do truly global cutting-edge work.
Generic API and finished product research

We continue to invest ahead of the curve to advance our global Generic R&D pipeline with significant investments in complex generic platform technologies. The guiding principles are appropriate capital allocation, productivity and profitability improvement. Our Generic R&D pipeline is aimed at developing a comprehensive portfolio of high entry barrier products in the inhalation, injectable, ophthalmic and oral space with complexities linked with API, delivery systems, device design or clinical trial requirements.

Highlights FY20

- Filed 21 ANDAs* comprising oral, injectable, ophthalmic, inhalation and dermatology dosage forms and 2 NDAs
- ANDA filings for the year include 2 confirmed exclusive First-to-File (FTF) and 6 shared FTF products
- Received approval for 14 ANDAs from U.S. FDA; launched 18 products in the U.S. market
- Filed 11 generic products in other advanced markets including EMEA (Europe, South Africa and Russia), APAC (Japan and Australia), LATAM (Mexico and Brazil) and Canada; received 10 approvals in these geographies
- Filed 2 Marketing Authorization Approvals (MAA) for anti-TB and antiretroviral institution sale products, including one PEPFAR filing

* Includes 2 external filing through partner organizations
**Biosimilari research**

FY20 saw significant developments on our biosimilar Etanercept front with its launch in Japan in partnership with Yoshindo and Nichi-Iko. In June 2020, the European Commission (EC) granted marketing authorization for our biosimilar Etanercept (branded as Nepexto®), for all indications of the reference product (Enbrel®). The regulatory approval follows the adoption of a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) in March 2020, which was based on a biosimilarity assessment including preclinical and clinical studies demonstrating bioequivalence to Enbrel®. In addition, a global phase 3 clinical study in patients with moderate-to-severe active rheumatoid arthritis confirmed equivalence of Nepexto® to Enbrel® in terms of efficacy, safety and immunogenicity. The centralized marketing authorization applies to all member countries of the European Union. This milestone reflects the strong scientific program behind Nepexto® and commitment by our team and our partner, Mylan, to commercialize the product as soon as possible.

Our biosimilar pipeline is a rich portfolio of diverse products at various stages of development, with the potential for us to be there in the first wave of biosimilar launch.

**Ongoing developments include:**

- **Pegfilgrastim**: Successfully conducted U.S. FDA-centric clinical studies and achieved positive results.
- **Ranibizumab**: Phase 3 clinical study ongoing in India and global clinical trial initiated.
- **Aflibercept**: Received grant of US$ 6.5 Million under the National Biopharma Scheme of the Department of Biotechnology, Government of India.

**Novel Drug Discovery & Development (NDDD)**

Our NDDD team has developed a pipeline of highly differentiated and innovative New Chemical Entities in focused therapy areas of Oncology, Immunology and Metabolic Disorders. During the year, we successfully partnered with Boehringer Ingelheim to advance our clinical stage MEK inhibitor LNP3794 for the treatment of difficult-to-treat cancers.

**AbbVie/MALT1 Partnership (FY19)**

AbbVie licensed Lupin’s MALT1 (Mucosa-Associated Lymphoid Tissue Lymphoma Translocation Protein 1) Inhibitor Program.

Lupin received US$ 30 Million upfront + milestone payments up to US$ 947 Million and royalty on sales.

**Boehringer Ingelheim (BI)/MEK Partnership (FY20)**

BI licensed Lupin’s MEK inhibitor compound for clinical development in combination with its KRAS inhibitor pipeline.

Lupin received US$ 20 Million upfront + milestone payments more than US$ 700 Million and royalty on sales.
**Bioclinical research**

Lupin Bioresearch Centre (LBC) conducts both in-vivo and in-vitro bioequivalence studies as part of regulatory dossier submission for regulatory agencies across the globe. LBC has managed 74 studies in FY20 and established cumulatively over 300 validated analytical methods to date.

**Intellectual Property Management Group (IPMG)**

Lupin was First-to-File in FY20 with respect to generic versions of Juluca® Tablets, Entresto® Tablets, Rexulti® Tablets, Odefsey® Tablets, Descovy® Tablets, Vemlidy® Tablets, and Bridion® Intravenous Solution, with the cumulative FTF products pending launch now standing at 43.

We settled 8 pending U.S. patent litigations and received a favorable U.K. court decision in the Truvada® SPC challenge. We secured a total of 65 patents in FY20.

**Complex injectables platform, Nanomi**

Nanomi, Lupin’s Netherlands subsidiary, has unique capabilities in the field of microspheres and nanoparticle manufacture for the development of long-acting injectables. Nanomi’s expertise relies on its proprietary Microsieve technology. Post a successful meeting with the U.S. FDA, Nanomi is now set to embark on a clinical program for its lead Long Acting Injectable asset.

**Inhalation Research Center, Coral Springs**

Lupin’s Inhalation Research Center at Coral Springs, Florida, is a specialized R&D facility focused on research and development of inhalation products for the treatment of asthma, chronic obstructive pulmonary diseases and other respiratory ailments.

**Highlights FY20**

**Generic Fostair®**: Successfully completed pivotal PK study; MAA submitted to U.K. MHRA

**Generic Spiriva®**: Targeting approval in FY21

**Generic Dulera®**: ANDA submitted to the U.S. FDA

**Generic ProAir®**: Successfully addressed all regulatory queries in line with recent U.S. FDA guidance

**Generics of Qvar® and Ellipta® franchise**: Developed functioning prototypes of generic Redihaler® and Ellipta® devices with Lupin owned IP

In FY20, we made significant progress in the development of complex generic formulations, in progressing our biosimilars pipeline and in our new drug development portfolio. This ongoing delivery from our R&D is a critical part of our strategy to bring to market a strong pipeline of complex products that bolster our revenues.
Building Greatness
Global Manufacturing & Supply Chain

With a manufacturing footprint of 15 sites spread across India, United States, Brazil and Mexico, Lupin’s technical operations are its powerhouse to globally deliver high quality and affordable products.

In FY20, we continued our thrust on expanding capacities and automation to support growth in existing businesses and commercialization of our pipeline of complex generics and biotechnology products. We enhanced existing capacities significantly and created capacities for several new areas:

The high-potency product manufacturing block at Indore Unit I that was commissioned at the end of FY19 for commercial production of products such as Levothyroxine, has been stabilized in the current fiscal. Another facility for high potency products is under commissioning.

We completed the construction of the Pyrazinamide API block in our Vizag facility.

Our state-of-the-art plant for Metered Dose Inhalers (MDI) in Indore Unit III is now nearing completion. Commercial production has commenced in this Unit for other products this fiscal.

Project work on our new hi-tech facility for Oral Solid Dose (OSD) formulations and a dedicated sterile facility for injectables in our Nagpur SEZ facility was completed. Commercial production commenced from the OSD facility at the beginning of the year. The sterile injectable facility is equipped with the latest technologies involved in injectable manufacturing and includes a Prefilled Syringe (PFS) filling line, Vial filling line and Lyophilizers under aseptic isolators.

Project work for the multi-fold expansion of our Biotech Drug Substance facility at Pune is ongoing to support the future demand and pipeline of our biosimilars, including Etanercept.
Supply Chain

The supply chain function at Lupin has been built on a framework of agility, business continuity, service standards and optimizing on inventory carrying costs. The model has always been found to be robust with accolades from multiple channel partners. We carry out periodic ‘supply risk assessments’ to absorb supply shocks. This was especially put to test in the COVID-19 outbreak and related lockdown in India and other parts of the world, which impacted distribution networks across the country as well as the availability of key raw materials. Through the resilience built into our supply chain and concerted and collaborative efforts with supply partners, the team ensured continuity of production and supply of our products.

**Highlights FY20**

<table>
<thead>
<tr>
<th>Built a future-ready procurement operations engine through the centralized Shared Services function leading to automated procurement operations</th>
<th>First blockchain initiative implemented to build transparency with Contract Manufacturing Operations (CMO)</th>
<th>Maintained an industry leading OTIF (On-Time In-Full) score of 95% + for all procurement categories</th>
</tr>
</thead>
</table>

**Site highlights**

**MANDIDEEP**
- Installed roof top solar power panels (capacity 500 KW) as an alternate source of power. These will generate annualized savings of INR 3.4 Million
- Installation of Emulsification unit to improve steam fuel ratio by 2.3% will give substantial savings annually

**TARAPUR**
- Centralized Data Acquisition System implemented for real time data capture in manufacturing operations to reduce human errors
- Quality Control (QC) lab improvement implemented leading to transcription error reduction; ‘5S’ project helped in reduction of lab incidents
- Received the Government of Maharashtra Health Department award

**GOA**
- Implemented Centralized Data Acquisition System and 200 KW solar power project for clean, renewable energy
- Engineering team was the 2nd runner up in the CII All Goa Kaizen Competition

**ANKLESHWAR**
- Future Ready Factory of the Year Platinum Award received from Frost & Sullivan
- Par-Excellence Award received from Quality Circle Forum of India – HQ for Cefadroxil Yield Improvement
- Gold Award received from American Society of Quality (ASQ) for Cefadroxil Yield Improvement

**AURANGABAD**
- New, state-of-the-art building constructed for Quality Control

**NAGPUR**
- Won the prestigious Engineering News Record Global Best Project Award of Merit in the Manufacturing category. The award was given to Lupin’s Oral Solid and Sterile Injectable units at Nagpur
Operational Excellence Awards

Received the International Sustainability Rating System (ISRS 8th edition) certification for Mandideep, Tarapur, Ankleshwar and Dabhosa sites. The first three sites achieved a rating of 7 which is the highest score in the pharmaceutical sector globally.

Received award for Best Operational Excellence in Manufacturing at the India Pharma Awards for the third time in last four years.
Putting Quality First

Quality and Compliance

Our unwavering commitment to sustainable Quality and Compliance remains deeply rooted in our core values and is a part of our Quality First commitment. Lupin’s continued engagement through global benchmarking and collaboration with regulatory bodies, industry working groups and subject matter experts continues to shape our Quality Governance Model.

Putting Quality First is not only a mandate coming from the outcome of regulatory inspections but also a strategic decision to examine and revamp our core manufacturing operations so that they are in line with our aspirations. With this in mind, we initiated the Global Quality Action Plan (GQAP), an integrated plan and a roadmap driving global standardization under a single quality system across Lupin’s manufacturing entities. We have further strengthened our Quality and Compliance team by bringing in Johnny Mikell as head of Quality and Compliance, a seasoned leader with significant experience in global quality operations and compliance in the generics, branded and API segments.

In an effort to minimize errors arising out of manual interventions, we have embraced technology and automation across all our sites. In FY20, we have introduced several automated processes like advanced robotic equipment for preparing analytical samples at our Indore site. There are several other enterprise-wide systems being implemented that will bring Lupin to being best-in-class in both our Manufacturing and Quality operations. These include electronic Batch Production Records, Laboratory Information Management System and a Quality Assurance Management System. We recognize that we also have to continuously upskill our team and have completely overhauled our training program for technical personnel. Measures like Gemba Walkthroughs instituted across our manufacturing facilities ensure continuous assessment and true ownership of our sites by our team.

Quality outcomes

The effectiveness of our Quality remediation measures can be seen in the outcomes of recent inspections conducted by the U.S. FDA and other regulatory agencies, across our sites.

We place the highest priority on the safety, efficacy and reliability of our products, the safety of our patients, and towards maintaining the highest data quality.

Recent inspection history

- **Indore (Unit I, II, III)**
  - GMP certificate received from U.K. MHRA in May 2020
- **Nagpur**
  - EIR received from the U.S. FDA in April 2020
- **Vizag**
  - EIR received from the U.S. FDA in May 2020
- **Aurangabad**
  - EIR received from the U.S. FDA in April 2020
- **Lupin’s Inhalation Research Center, Florida**
  - EIR received from the U.S. FDA in March 2020
As a leading pharmaceutical player supplying medicines to over 100 countries across the globe, our sites are certified by all relevant regulatory bodies. Through our Environment, Health and Safety measures we ensure that our procedures and practices in manufacturing our products meet the highest international benchmarks. We continue to upgrade and invest in infrastructure to create a greener footprint of our operations whilst investing in our employees’ health and safety through training, process overhauls and technology deployment.

**Energy consumption and conservation**

In FY20, our consumption of energy from both renewable and non-renewable sources was 2,981,239 GJ. Of the total energy used in our manufacturing plants and R&D center, 10.3% comes from renewable sources. We have also started switching over from furnace oil to cleaner fuel for several of our facilities. To further reduce dependency on fossil fuels, we have installed solar power panels at almost all our facilities.

**Steps taken to reduce energy consumption**

- 2,175 GJ energy was saved by replacing conventional sodium vapour and fluorescent lights by LED lights at five of our API sites.
- Replacement of pumps and motors with high efficiency models.
- Installation of variable frequency drives.
- Installation of motion sensors in offices and warehouses to optimize energy utilization.

**Water management**

Our total water consumption for FY20 was 2,648,232 KL, including both fresh and recovered water. Of this, over 30% is recovered water. The primary source of the freshwater is municipal/industrial bodies and this is further supplemented by groundwater and surface water.

**Steps taken to reduce freshwater consumption**

- Steam condensate recovery and reuse in the boiler.
- About 68% of the wastewater generated in our plants is recycled and reused directly for utilities, flushing, etc. after recovery.
- Rainwater and AHU condensate to the tune of 7,740 KL was collected and used in place of freshwater.

**Roof-top solar panels at Aurangabad site**

**Wastewater recovery plant at Nagpur site**
Wastewater management

At Lupin, we continuously improve our wastewater management and output. We have installed wastewater treatment plants and water recovery plants consisting of state-of-the-art reverse osmosis units (RO), multiple-effect evaporators (MEEs) and agitated thin film dryers (ATFD) to recover water from the wastewater.

Waste management and recycling

All hazardous and non-hazardous wastes generated from our facilities are segregated, recovered, recycled and disposed as per their individual characteristics, in compliance with all regulations. In FY20, our plants generated biodegradable wastes amounting to 3,942 MT which was either sent to piggeries or composted to convert it into usable organic fertilizer.

Employee health & safety

Like any responsible corporate entity, Lupin is committed towards the goals of sustainable growth, employee health and safety along with shareholder value creation. Our measurement on various environmental parameters has matured over the years and will enable us to gauge our performance even better.

Navigating COVID-19

Environment, Health and Safety are at the center of all decision-making in our response to the COVID-19 pandemic.

Lupin ensured that its sites and employees could continue work without disruption by implementing numerous procedures and protocols such as regular deep sanitization of premises and employee transport/buses.

We have implemented measures to ensure social distancing is practiced across shop floors, QC laboratories and canteens.

Robust screening procedures are in place and all employees are mandatorily screened.

We have implemented Self-declaration through a daily health monitoring app to track employee health.

Employees, contractors and visitors are provided masks and sanitizers regularly.

Mock drills are carried out at each facility to prepare for any emergency and check the efficacy of our COVID-19 response protocols.

We have used the Emission Factors of Central Electricity Authority (CEA), 2018, India and United States Environmental Protection Agency (USEPA), 2020, Greenhouse Gas Inventories for the estimation of direct and indirect emissions from scope 1 (71,967 tCO2) and scope 2 (325,562 tCO2) energy use. We have reduced 7,490 tCO2e by using solar and wind power.
A Strong Core

Financial Review

The current year saw us making several notable strides on the Finance front that set us on a stronger footing for the future – stronger capital return ratios, lower balance sheet leverage and lowered effective tax rates. With regards to Business performance, we closed the year with solid growth across key markets and a strong compliance record across facilities in recent audits. In light of the COVID-19 crisis, the last quarter tested our leadership, endurance and adaptation skills, and I am delighted to share that we excelled in the way we responded.

Ramesh Swaminathan
Executive Director, Global CFO and Head Corporate Affairs

Financial highlights

- Recorded consolidated sales (from continuing operations) of INR 151,428 Million in FY20 compared to INR 143,181 Million in FY19; a growth of 5.8%

- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) from continuing operations was INR 28,386 Million; 18.7% of sales

- Profit before Tax (PBT) before Exceptional items (from continuing operations) was INR 15,054 Million; 9.9% of sales

- Exceptional items for the year amounted to INR 7,521 Million and included:
  - Profit on divestment of Japan operations of INR 12,164 Million
  - Impairment of intangibles of INR 15,893 Million
  - Settlement with State of Texas of INR 3,792 Million

- Profit before Tax and after Exceptional items (from continuing operations) was INR 7,533 Million

- Net Profit before Exceptional items (from continuing operations) was INR 9,088 Million in FY20 as compared to INR 8,521 Million in FY19; growth of 6.7%

- Net Debt as on March 31, 2020 stands at INR 15,118 Million as compared to INR 52,438 Million as on March 31, 2019; growth of 6.7%

- Net Debt-Equity for the company stands at 0.12:1 on March 31, 2020 as compared to 0.38:1 as on March 31, 2019

- The Board recommended a Dividend of 300% for FY20

- Current ratio in FY20 stood at 1.7 compared to 2.3 in FY19 due to increase in the current portion of long term debt by US$ 267 Million relating to the Gavis acquisition

- Interest coverage ratio in FY20 stood at 5.5 compared to 7.8 in FY19 due to increase in reported finance costs on implementation of IND-AS 116 (Leases) in FY20

Research and Development

R&D investment (from continuing operations) for FY20 was INR 15,538 Million, 10.3% of revenue versus 10.5% in FY19. The accent on cost optimization and productivity improvement without impacting product delivery of our pipeline of complex generics, biosimilars and differentiated products is paying off.

We made solid progress on several key products during the year – we received European approval for Nepexto®, a biosimilar to Enbrel® (Etanercept). We advanced our inhalation pipeline with the filing of another MDI with the U.S. FDA, and received tentative U.S. FDA approval for gBrovana. We have now filed five major inhalation products in the developed markets, with collective sales of almost US$ 6 Billion (IQVIA MAT Mar 2020). We are committed to bringing gProAir® to the U.S. market shortly.
Cost optimization

With the changing dynamics of the generics market, we believe that cost optimization and prudent capital allocation will continue to be a key business imperative. We aim to continue creating a leaner and more efficient organization. In FY20, we made significant strides in our cost optimization initiatives encompassing value engineering, procurement efficiencies and R&D productivity. However, input price rises on other molecules and sales mix changes eroded visibility of the same, to some measure. These initiatives have however created a strong foundation and our cost optimization momentum will continue with increased rigor in FY21.

Capital allocation and balance sheet strengthening

In FY20, we divested our Japanese subsidiaries Kyowa CritiCare Co., Ltd. (KCC) and Kyowa Pharmaceutical Industry Co., Ltd. (Kyowa). The net proceeds were utilized to pare long-term debt by ~US$ 300 Million. This divesture coupled with debt repayment is expected to improve our return on capital employed by ~72 bps. We also recognized a non-cash impairment of US$ 225 Million (INR 15,893 Million) as a result of erosion in the value of our Gavis acquisition. Erosion in the value of pipeline products and increased competition on existing products were key reasons for the impairment.

Capital expenditure

We continue to invest in upgrading of our existing manufacturing facilities to aid efficiencies as well as build capacities to meet future demand. We have significant enhancements of our Biosimilar and Inhalation facilities underway. We invested INR 5,710 Million toward capex requirements during the year.

Internal control systems & Information Technology

We continue to invest in automation of business processes and operations in order to improve efficiencies, drive down costs and for driving business. Automation of processes including Laboratory Information Management, Batch Process Records, Document Management, Acquisition & Consolidation of shop floor data, and HR processes have made significant progress and are being scaled across the company. Our medical representatives are equipped with the best digital tools to engage with doctors. Infrastructure harmonization and heightened emphasis on information security have been focus areas. Our newly created Finance Shared Service Center aided by Robotic Process Automation supports markets around the globe, ushering in greater efficiencies and savings. The robustness of these initiatives is being tested in the COVID-19 crisis, but I am happy to share that we have come out with flying colours to date, having crafted agile solutions to remotely manage continuity and carry on business.

A strong internal audit framework is key to ensuring compliance. Our audit framework monitors and controls all systems and processes and business groups ensuring compliance to financial norms and procedures, building financial control and accountability within our business ecosystem. We are ably assisted by Ernst & Young (EY) and PricewaterhouseCoopers (PwC) who support our Internal Audit function.

Risk, concerns and threats

We witnessed huge volatility in commodity prices and foreign currencies towards the end of the fiscal year due to the COVID-19 outbreak. This was further accelerated by a stringent lockdown in China, a key source of raw material and intermediates for the Pharmaceutical industry, leading to a significant supply chain disruption. Our investment in building a global supply chain leveraging business intelligence, reporting and forecasting systems has helped us ensure business continuity at this time. In addition, our deep customer relationships coupled with agile supply chain helped us in ensuring high service levels across markets.

Our forex strategy for the short, mid and the long-term through appropriate forecasting and hedging tools helped minimize forex volatility. We rely on risk management and forecasting frameworks and a strong compliance ethic to manage competitive, economic, financial, geopolitical and social risks.

We are conscious of the headwinds being faced by the industry. However, we see the emergence of an improved business environment, especially in the second half of FY21 and are confident that the measures taken by us in recent times would help us to come out stronger than ever.
The Spirit of Lupin
Human Resources

Great Place to Work™ Certified Company

Innovation, transformation and continuous improvement are the bedrock of all great companies. These traits are the pillars of our people philosophy and help us build our functional capabilities to embrace technology and best-in-class practices, allowing us to create greater value for the organization and our stakeholders. This also enables us to attract the best talent, develop skills, enhance roles and shape careers that contribute to the fulfilment of Lupin’s vision. All this goes into accolades such as being recognized as a Great Place to Work™, a ‘Gold Standard’ in workplace culture assessment and recognition.
New HR model

In FY20, we migrated to a new Human Resources (HR) model comprising Business Partners (HRBPs) and Centre of Expertise (CoE). The new model allows HR to collaborate with our businesses on aspects such as strategy design and execution, workforce planning, talent management and organization development. The CoEs in turn, continuously update and improve our core HR processes.

In line with this transformation, we introduced EmployeeKonnect, an integrated and globally deployed digital platform to ensure seamless availability of employee data across different services and systems. Additionally, we launched an automated Recruitment Management Module which streamlines our recruitment lifecycle.

Leadership development

The fiscal also witnessed the launch of our Senior Leadership Development Program, an intense nine-month learning journey for our senior leadership participants to self-assess, learn and develop themselves with support from top-notch faculty, coaches and our business leaders. The debut of the program saw 35 leaders undergo a five-day classroom training in Naples, Florida.

Corporate Values awards

After receiving an overwhelming response from 1800 nominees across the globe, we were delighted to announce the first recipients of the Dr. Desh Bandhu Gupta Spirit of Lupin Awards. The DBG Spirit of Lupin Awards recognize those employees amongst us, who embody Lupin’s core values and are role models.

COVID-19 response

HR has played a critical role in ensuring business continuity through the COVID-19 disruption by ensuring the health and safety of our employees. Even as corporates were grappling to come to terms with the pandemic, we designed and executed on a blueprint for site and office operations teams, working collaboratively with functions such as Manufacturing, Environment Health and Safety, R&D, our India Fieldforce and IT to ensure last mile connectivity for each employee and providing them support through the crisis.

We launched LIBERATE, a medical helpline for our employees to address their concerns around COVID-19 symptoms and queries. We also doubled the medical and life insurance coverage for all our employees to provide relief during this time of unprecedented stress. During the lockdown, we have offered multiple learning programs in order to upskill employees and support their mental well-being. Close to 200 online programs with over 15,000 enrollments have been conducted.

We are committed to doing all that is needed to ensure the safety and well-being of our employees during these uncertain times.
Serving Communities Everywhere
Corporate Social Obligation

The Lupin Human Welfare and Research Foundation (LHWRF) works towards creating holistic and sustainable growth for rural communities across India. Our programs are of meaningful scale and are focused around economic development, social development, natural resource management, and infrastructure development.
Economic development

Rural development has been at the core of LHWRF’s efforts since its inception in 1988. LHWRF undertakes economic upliftment activities in the areas of agriculture, animal husbandry and rural industrialization, with special emphasis on enhancing farm productivity and income. This is primarily done through measures like crop diversification, introducing technology interventions in agriculture, breed improvement in farm animals, and support for commercial dairies and fisheries.

Social development

LHWRF’s social development programs are focused on women empowerment, community health management, education and skill training via creation of self-help groups for women, organizing health camps, and efforts aimed at increasing student retention in rural schools.

Natural Resource Management (NRM)

Through the natural resource management interventions, the Foundation aims to insulate rural communities from the impact of droughts and uncertain weather-related issues. Efforts are aimed at increasing water access and land productivity.

Infrastructure development

LHWRF has been assisting development of rural infrastructure through measures such as strengthening of civic infrastructure in rural schools, sanitation and low-cost housing. These initiatives have improved the quality of life of rural communities multi-fold.

COVID-19 and rising to the occasion

LHWRF has carried out unparalleled work during the unprecedented COVID-19 crisis. The Foundation provided timely support to affected communities, assisting transiting migrants and quarantined people. From coordinating with district administration and authorities, distributing food packets to migrants, organizing food camps and grain distribution centers, to distributing masks and sanitizers for frontline workers and officials, the Foundation stood in support of all those affected by the pandemic.

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