

# **Contents**

| Laurus Labs at a glance                    |          |
|--|----------|
| Who we are                                 | 02       |
| Business overview                          | 04       |
| Facilities                                 | 07       |
| lourney                                    | 08       |
| COVID-19 response                          | 09       |
| Year in review                             |          |
| Key performance indicators                 | 10<br>12 |
| CEO's message                              | 12       |
| We promise. We deliver through             |          |
| Strong product portfolio                   | 14       |
| Modern manufacturing facilities            | 16       |
| Robust R&D and unwavering focus on quality | 18       |
| Our approach to value creation             |          |
| Business model                             | 20       |
| Operating context                          | 22       |
| Stakeholder engagement                     | 24       |
| Our value creation strategy                | 26       |
| ESG focus                                  |          |
| Environment                                | 28       |
| Social                                     | 30       |
| Governance                                 | 34       |
| Risk management                            | 40       |
| Awards and recognitions                    | 42       |
| Management commentary                      |          |
| Management discussion and analysis         | 44       |
| Statutory reports                          |          |
| Board's Report                             | <br>53   |
| Report on Corporate Governance             | 72       |
| Business Responsibility Report             | 89       |
| Financial statements                       |          |
| Standalone                                 | 94       |
| Consolidated                               | 143      |
|  |          |
| Notice                                     | 197      |

# 2020-21 highlights

# Financial

₹4,814cr ₹1,573cr **EBITDA** Revenue

**1** 70%

176%

₹984 cr Profit after tax

1 286%

y-o-y growth

page 10

Waste recycled

2,273 мт 12,23,192 кг

Water consumed

1,80,522 Mwh

**Energy consumed** 

page 28

# Social

Average rate of

₹5.82cr

training for employees

page 30

Customers served

Independent Directors on the Board 89%

attendance rate in Board meetings

Median Director age

→ page 34

# We promise. We deliver.

Ever since we began our journey, we at Laurus Labs have consistently leveraged opportunities to build a sustainable and value-creating enterprise. The result is that we have now emerged as a leading integrated research and development ('R&D') driven pharmaceutical and biotechnology company in India.

We have been moving up the value chain into formulations, and have invested in developing products and building facilities to meet the most stringent regulatory expectations. We expect the formulation business to gain further momentum led by higher capacity/ANDA pipeline build-up for the US market.

Our strong presence in the different therapies, consistency in compliance,

and forward integration into formulations business have cemented the position as an integrated niche pharma player. Moving forward, we are convinced that with the right people, coupled with a culture of innovation, we will continue to deliver sustainable and balanced growth. With our core strengths reinforced, we stand reaffirmed to our promise to deliver on our purpose of building long-term value.

We deliver on our promise of quality healthcare through:



A strong product portfolio

page 14



Modern manufacturing facilities

page 16



Robust R&D and unwavering focus on quality

→ page 18

We are passionate. We exceed quality benchmarks. We transform patients' lives.

# Who we are

# Improving health outcomes globally

Laurus Labs is a fully integrated pharmaceutical and biotechnology company, with a leadership position in generic Active Pharmaceutical Ingredients (APIs) and major focus on anti-retroviral, Hepatitis C, and oncology drugs. Today, we are one of the leading suppliers of APIs in the ARV therapeutic area for multinational pharmaceutical companies across different parts of the globe.

We also develop and manufacture oral solid formulations, provide contract research and manufacturing services (CRAMS) to other global pharma companies, and produce specialty ingredients for nutraceuticals, dietary supplements and cosmeceuticals. With our strong R&D and innovation capabilities, we work towards improving manufacturing process efficiencies and backward integration strategy to maintain cost competitiveness. Our aim is to improve access to quality and affordable healthcare globally, while conducting our business ethically and with utmost respect for the environment and communities.

We completed 15 years of offering integrated solutions, and helped thousands of people globally to lead a healthy life.

# & LAURUS

# **Business** areas

At Laurus Labs, we operate under four business units covering a wide range of therapeutic applications



Laurus Generics - API -Development, manufacture and sale of APIs and advanced intermediates



Laurus Generics - Finished Dosage Form (FDF) -Development and manufacture of oral solid formulations



**Laurus Synthesis -** Key starting materials, intermediates and APIs for New Chemical Entities (NCEs)



Laurus Bio - Recombinant products - animal origin free products for safer and viral free bio manufacturing

# Vision

To become a leading player in offering integrated solutions to global pharmaceutical needs in creating a healthier world.

# Mission

We constantly strive for innovation to enhance quality and to provide affordable integrated pharmaceutical solutions to facilitate wellness and well-being across the globe.

## **Values**



**Knowledge:** Seek to learn constantly to stand out from the crowd



**Innovation:** Strike out on new paths to go farther



**Excellence:** Scale new peaks in everything we do



**Integrity:** Stand up always for what is right



Care: Be diligent, safe and sensible



# Key strengths

# Robust R&D capabilities and process chemistry skills

Our advanced process chemistry skills, manufacturing process efficiencies and backward integration strategy set us apart from our peers. Our research-first approach has been critical to our success and a differentiating factor in the industry. Our strong R&D competencies enable us to improve our existing products and make inroads in areas with significant growth potential.



# Cutting-edge facilities

We have seven modern manufacturing facilities in Visakhapatnam, one API facility in Bibinagar near Hyderabad and a Kilo Lab facility in R&D Centre, Hyderabad. Our facilities have been certified and approved by USFDA, WHO, NIP Hungary, KFDA, COFEPRIS, PMDA, ANVISA, and JAZMP. They allow us to develop high-quality, affordable cures to challenging diseases. We are also able to adopt uniform manufacturing standards across all our facilities to achieve standardised product quality for all our markets.



# Extensive collaboration and longstanding partnerships

Our expanding product portfolio, cost-effective healthcare solutions and technical expertise have won us long-standing relationships with multinational pharmaceutical companies. Our top 5 customers have been with us for several years and contribute to a major share of our revenue – which has been growing annually over the last three years.



# Robust compliance

We have progressively reinforced our compliance with the demanding standards in regulated markets. We continue to strengthen our compliance culture through consistent investments in people, technologies and processes.



# Strong leadership at the helm

The team at Laurus Labs is led by qualified and experienced promoters and key managerial personnel, who have extensive knowledge and understanding of the global generic pharmaceutical and bio-pharma business.



# Numbers that define us

292
Patents filed

150 Patents granted /50+ Scientists at our R&D centres

61 Drug Master Files (DMFs) 60+
Products commercialised since inception

Global generic pharmaceutical companies served

4,638 KL

Reactor volume

27
ANDAs

# **Business overview**

# Leveraging integration to create value across businesses

We offer a broad and integrated portfolio of products and services to the global pharmaceutical industry. The journey from APIs to formulations to synthesis businesses is the outcome of our integrated strategy, which we have successfully executed in all these years. Our four business units cover a wide range of therapeutic applications across the product value chain.

# Laurus Generics – API

- Development, manufacture and sale of APIs and advanced intermediates
- Leaders in various high-value and high-volume APIs with a sizeable global market share
- High potent manufacturing units

54% Revenue contribution



- Anti-retroviral (ARV)
- Anti-diabetic
- Cardiovascular
- Proton Pump Inhibitors (PPIs)
- Oncology



- Commercialised 60+ products
- Filed 61 DMFs



- Four manufacturing facilities, (4,186 KL) (1) (2)
- ~1,000 KL under expansion

# 2020-21 highlights

- Filed 292 patent applications and 150 patents granted
- Strong ARV API sales and market share gain in first line treatment

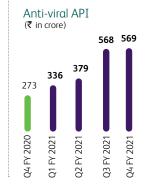
## Performance review

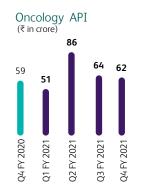
The Generic API division showcased a robust growth of 61% y-o-y due to increased focus of diversifying into new therapy areas. The anti-viral API business recorded a healthy growth of 70% with ₹1,852 crore sales. The growth was led by

higher volumes for all key first-line APIs. Second-line ARV APIs continued to see healthy sales. Due to the demand increase from third-party API sales, we are expanding capacities for key APIs in the coming year.

Oncology APIs showed 25% growth y-o-y increased by ₹52 crore with a total sales ₹263 crore.

Other API sales stood at ₹506 crore, marking a sales growth of 56% over 2019-20 due to higher contract manufacturing orders from Europe.







- (1) Includes ingredients products, excluding Unit 2 API and Kilo lab capacity
- (2) APIs, Ingredients and Synthesis (other than Aspen supplies) are manufactured at Units 1, 3, 4 and 6

# Laurus Generics – FDF

- Development and manufacturing of oral solid formulations for low and middle-income countries (LMIC), North America and European Union (EU) markets
- Backed by in-house API strengths

35% Revenue contribution



- Anti-retroviral (ARV)
- Anti-diabetic
- Cardiovascular
- Proton Pump Inhibitors (PPIs)
- Central nervous system (CNS)



# **Filings**

- Filed 27 ANDAs with USFDA, and nine final approvals and eight tentative approvals
- Completed validation of two products
- Filed 12 dossiers in Canada, nine in Europe, eight with WHO, two in South Africa, two in India and 14 in rest of the world (RoW)



# Infrastructure

- Capacity of 5 billion units/year
- Capacity enhancement to 10 billion units/year in progress

# 2020-21 highlights

- Commenced marketing of in-licensed products in the US by leveraging our frontend
- Completed three product validations for formulation
- Strong demand in ARV segment for LMIC region

# Performance review

During the year, this division achieved sales of ₹1,664 crore showing a growth of 102% y-o-y backed by a higher quantum of launches in the US as well as opportunities from in-licensing of products. The business witnessed growth in LMIC, in the developed markets of North America and EU, as well as in RoW markets.

Strong order book in all geographies



# **RoW Markets**

Launched TLE400 in the LMIC market



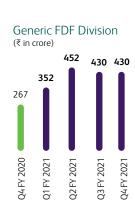
### North America

Sales were driven by increased volumes in the US



# **Europe**

Entered into a long-term partnership with a leading generic player in EU region for contract manufacturing opportunities



# **Business** overview

# Laurus Synthesis

- Contract development and manufacturing services for global pharmaceutical companies and several late-stage projects
- Steroids and hormone manufacturing capability
- Sale and manufacture of specialty ingredients for use in nutraceuticals, dietary supplements and cosmeceutical products with natural extraction capability

11%
Revenue contribution



- Commercial scale contract manufacturing
- Clinical phase supplies
- Analytical and research services
- Nutraceuticals, dietary supplements and cosmeceutical products



# **Filings**

- API validation planned in Unit 5
- Custom development of ophthalmic portfolio initiated
- Laurus Synthesis Pvt. Ltd. (LSPL) API validations planned



- Dedicated manufacturing (Unit 5) 137 KL capacity for steroidal and hormonal intermediates
- A dedicated block set up in Unit 4 for high-potent phytochemical APIs
- LSPL 147 KL capacity

# 2020-21 highlights

- 50 active projects in the Contract Development and Manufacturing Organisation (CDMO) division
- State-of-the-art cGMP facilities to manufacture new chemical entities (NCEs) and Intermediates
- Commercial supplies on-going for four products
- Expanded client base Added two big pharma companies



## Performance review

We recorded a growth of 35% during the year, achieving sales of ₹519 crore due to client additions and increasing commercialisation of products.

# 

**Note:** During the year, we acquired 72.55% stake in Richcore Lifesciences from two private equity funds and the company has been renamed Laurus Bio Private Limited. We closed the transaction in the month of January 2021.

# **Facilities**

# Delivering quality at scale

Our state-of-the-art facilities enable us to develop quality and affordable medicines. We currently have seven manufacturing facilities in Visakhapatnam, Andhra Pradesh, one API facility in Bibinagar near Hyderabad and a Kilo Lab at our R&D centre, Hyderabad. At seven of these facilities, we manufacture drug substances and one facility is well-equipped to manufacture both drug products and drug substances.

| IKP Knowledge Park, Genor  | me Vallev Turkanally                               | Function   | Capacity   | Approvals granted   |  |  |  |
|--|--|--|--|---|--|--|--|
|  | Kilo Lab   | Commercialised in 2006,<br>this facility deals in<br>pre-commercialisation activities for<br>APIs, ingredients, custom synthesis<br>and contract manufacturing | 43 reactors and<br>4.3 KL capacity   | USFDA, KFDA and PMDA  |  |  |  |
| Jawaharlal Nehru Pharma City, Visakhapatnam  |  |  |  |   |  |  |  |
|  | Unit 1   | Commercialised in 2007,<br>this facility deals with API<br>and includes capacity for<br>ingredients, synthesis and<br>contract manufacturing                   | 328 reactors and<br>1,226 KL capacity  | USFDA, WHO – Geneva,<br>NIP – Hungary, KFDA,<br>COFEPRIS, PMDA, ANVISA                                |  |  |  |
|  | Unit 3   | Commercialised in 2015, this facility deals with APIs and includes capacity  | 259 reactors and<br>1,982 KL capacity  | USFDA, WHO – Geneva,<br>NIP – Hungary, COFEPRIS,<br>KFDA, ANVISA and<br>JAZMP – Slovenia              |  |  |  |
|  | Unit 5   | Commercialised in 2017, this is a dedicated hormone and steroid facility for Aspen   | 46 reactors and<br>137 KL capacity   |   |  |  |  |
|  | Laurus<br>Synthesis<br>Private Limited             | API manufacturing facility<br>and includes capacity for<br>ingredients, synthesis and<br>contract manufacturing  | 50 reactors and<br>156.73 KL capacity  | CDSCO, WHO GMP by<br>CDSCO, PMDA, EDQM,<br>FAMHP and MFDS   |  |  |  |
| APIIC, Atchutapuram, Visakhapatnam   |  |  |  |   |  |  |  |
|  | Unit 2   | Commercialised in 2017,<br>this facility deals with FDFs<br>and APIs   | FDF – 5 billion tablets/capsules;<br>capacity expansion initiated and will<br>be operational by the end of FY 22<br>API – 12 reactors and 83 KL capacity | BVG Hamburg Germany,<br>USFDA, WHO – Geneva,<br>and JAZMP – Slovenia and<br>various African countries |  |  |  |
| The state of the s | Unit 4   | Commercialised in 2018,<br>this facility deals with APIs<br>and includes capacity for<br>ingredients, synthesis and<br>contract manufacturing                  | 54 reactors and<br>221 KL capacity   | WHO, USFDA and<br>COFEPRIS – Mexico   |  |  |  |
|  | Unit 6   | Commercialised in 2018, this facility deals with APIs (largely manufacturing intermediates for captive consumption)  | 68 reactors and<br>758 KL capacity   | USFDA   |  |  |  |
| Bibinagar, Yadadri Bhuvan  | Bibinagar, Yadadri Bhuvanagiri District, Telangana |  |  |   |  |  |  |
|  | Sriam Labs<br>Private Limited                      | API manufacturing facility<br>and includes capacity for<br>intermediates and contract<br>manufacturing   | 32 reactors and<br>81.63 KL capacity   | WHO GMP by CDSCO  |  |  |  |

# Journey

# 15 years of patience, diligence, and perseverance

We started our journey in 2005 and have yielded promising progress in this one-and-half decade. Today, we are among the world's leading manufacturers of active pharmaceutical ingredients (API) for anti-retroviral (ARV), oncology, cardiovascular, antidiabetics, anti-asthma, and gastroenterology. We cater to the requirements of several Indian and global pharmaceutical companies.

| Capabilities                       | 2006-11         | 2011-16     | 2016-21                |
|------------------------------------|-----------------|-------------|------------------------|
| Description of Company 🛭           | ARV API Company | API Company | Pharmaceutical Company |
| Team strength                      | 883             | 2,266       | 4,808                  |
| Manufacturing units                | 1               | 2           | 8                      |
| Reactor volume (KL)                | 220             | 1,870       | 4,638                  |
| Formulations OSD billion           | -               | 2           | 5                      |
| DMFs                               | 12              | 28          | 61                     |
| ANDAs - Total filed                |                 |             | 27                     |
| - Para IV                          |                 |             | 2                      |
| - First to file                    |                 |             | 7                      |
| Patents – Filed                    | 48              | 218         | 292                    |
| Granted                            | -               | 25          | 150                    |
| USFDA approved manufacturing sites | 1               | 2           | 5                      |

