LAURUS Labs

Knowledge . Innovation . Excellence

BUILT FOR THE LONG-TERM

2018-19

Annual Report

Laurus Labs Limited

CONTENTS

A Foundation for the Future

Read more about Laurus Labs on Page 2

Building for the Future

Read more about Dr. C. Satyanarayana's views on Page 14

Delivering on our Strategy

Read more about Laurus's strategy on Page 18

Explore Online

For further information, log on to **www.lauruslabs.com**

Social Media

Follow us and join the conversation

Forward-looking Statement

In this Annual Report, we have disclosed forward-looking information to enable investors to comprehend our prospects and take investment decisions. This Report and other statements – written and oral – that we periodically make contain forward-looking statements that set out anticipated results based on the management's plans and assumptions. We have tried, wherever possible, to identify such statements by using words such as 'anticipate', 'estimate', 'expects', 'projects', 'intends', 'plans', 'believes', and words of similar substance in connection with any discussion of future performance. We cannot guarantee that these forward-looking statements will be realised, although we believe we have been prudent in our assumptions. The achievements of results are subject to risks, uncertainties and even inaccurate assumptions. Should known or unknown risks or uncertainties materialise, or should underlying assumptions prove inaccurate, actual results could vary materially from those anticipated, estimated or projected. Readers should keep this in mind. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Building on Our Core Strengths

Laurus Labs is using its expertise in offering a broad and integrated portfolio of research and manufacturing services spanning the entire drug development continuum to the global pharmaceutical industry.

Our overarching focus is to help improve the quality of life for millions around the world through affordable medicines.

We are building on our core strengths by expanding capacities, enriching our portfolio by entering the formulations cycle of the value chain and following global best practises. We have made long-term strategic decisions in key areas to drive faster growth and create better outcomes for stakeholders around the world.

We have committed significant investments in infrastructure and facilities for almost all our businesses to support potential revenue scale-up in the foreseeable future and also for the long term.

We are further building on our API strengths to forward integrate into FDF. We have several formulation dossiers under development for the US, Europe and other emerging markets and we intend to selectively pursue Paragraph IV filing opportunities in the US. The recently awarded formulation contracts provide significant scope for future growth. We have also commenced commercial supplies from Unit 5 to Aspen and have received new orders.

We are excited about the opportunity landscape that is unfolding around us. Our decade-and-a-half-rich experience and expertise uniquely position us to build on the foundation that we have created with a long-term perspective and to help improve access to quality and affordable healthcare worldwide.

2018 - 19 Highlights

Net Sales

₹22,919 million

11.5% ↑

(y-o-y growth)

Profit after Tax

₹938 million

44% ↓

(y-o-y)

Dividend per Share

₹1.50

(Face value of ₹10)

INTRODUCING LAURUS LABS

A Foundation for the Future

Laurus Labs is a leading developer and manufacturer of generic APIs with focus on products where it has cost leadership, led by innovation in process chemistry and manufacturing efficiencies.

Apart from manufacturing APIs, we develop and manufacture oral solid formulations, provide Contract Research and Manufacturing Services (CRAMS) services to other global pharmaceutical companies, and also produces specialty ingredients for nutraceuticals, dietary supplements and cosmeceuticals. Innovation, people and clients are our three major focus areas.

We offer a broad and integrated portfolio of products and services to the global pharmaceutical industry. Since inception in 2005, our experience, expertise and core strengths have enabled us to help our clients reach relevant markets quicker and contribute towards improving access to quality and affordable healthcare worldwide.

Key Differentiators

Value creation through innovative science, customer-centric approach and cost effectiveness

Strong work ethics driven by sound systems and best practices, highest quality standards, emphasis on delivery and a strong focus on IP

State-of-the-art infrastructure and facilities supported by highly capable personnel

Sound business model built on being a strategic partner to the client, and not merely a service provider

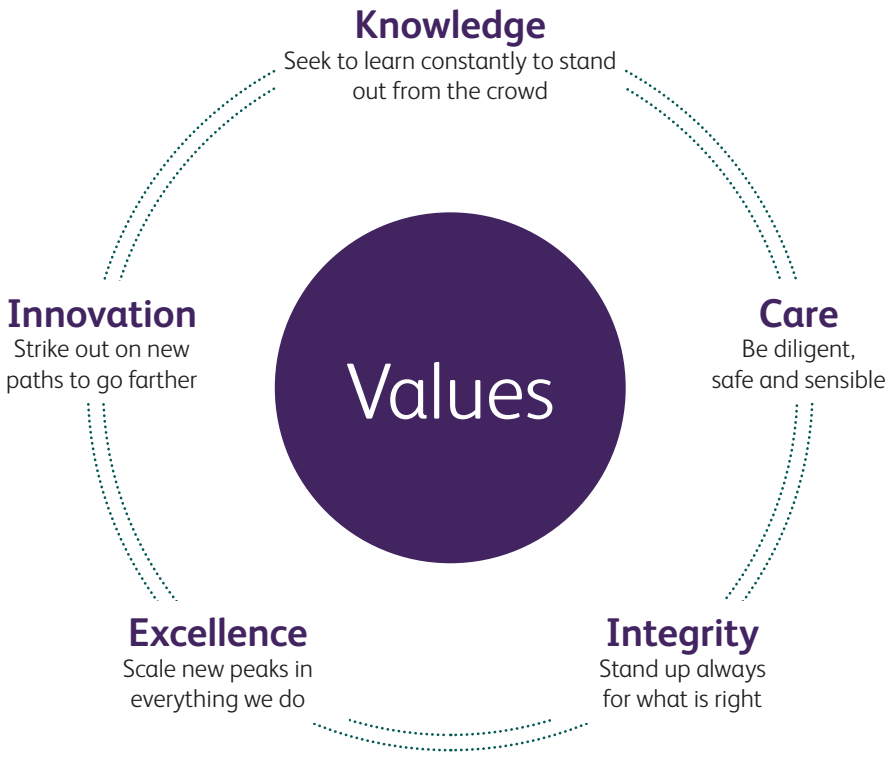
Experienced R&D team and a large differentiated pipeline

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.



Key Numbers

50+ Products commercialised since inception	**54** DMFs filed	**238** Patents filed	**81** Patents granted
19 Abbreviated New Drug Applications (ANDAs) and dossiers filed	**3,612** Employees (Consolidated)	**200+** Serving customers	**56** Countries presence

* Figures as on March 31, 2019

MANUFACTURING FACILITIES

Robust Manufacturing Presence

Built to world-class standards, our manufacturing facilities enable us to produce high-quality and affordable medicines. We currently operate six manufacturing facilities in Vishakhapatnam, Andhra Pradesh and one facility in Hyderabad.

KILO LAB

Located in R&D at Shamirpet, Telangana India.

This facility is highly suitable for pre-commercialisation activities for APIs, Ingredients, Custom Synthesis and Contract Manufacturing

43
Reactors and a capacity of 4.3 Kilo Litres (KL)

Approvals Received
USFDA, KFDA and PMDA

UNIT 1

Located at Jawaharlal Nehru Pharma City, Vishakhapatnam, India

API manufacturing facility includes capacity for ingredients, synthesis and contract manufacturing

Commenced operations in 2007

319
Reactors with 1,180 KL capacity

Approvals Received
USFDA, WHO - Geneva, NIP - Hungary, KFDA, COFEPRIS and PMDA

UNIT 2

Located at APIIC, Achutapuram, Visakhapatnam, India (SEZ)

FDF and API manufacturing facility

Commenced operations in 2017

5 billion
FDF capacity of tablets/capsules per year

12
Reactors with 83 KL capacity

Approvals Received
BVG Hamburg Germany, USFDA, WHO - Geneva, JAZMP - Slovenia and various African countries

Scope for expansion
More than double the current capacity of drug product and drug substance

UNIT 3

Located at Jawaharlal Nehru Pharma City, Vishakhapatnam, India

API manufacturing facility and includes capacity for ingredients, synthesis and contract manufacturing

Commenced operations in 2015

227

Reactors with 1,752 KL capacity

Approvals Received
USFDA, WHO - Geneva and NIP - Hungary

UNIT 4

Located at APIIC, Achutapuram, Visakhapatnam, India

API manufacturing facility and includes capacity for ingredients, synthesis and contract manufacturing

Commercial operations in 2018

32

Reactors with 85 KL capacity

Approvals Received
COFEPRIS - Mexico

Scope for expansion
Significant capacity expansion possible

UNIT 5

Located at Jawaharlal Nehru Pharma City, Vishakhapatnam, India (SEZ)

A dedicated hormone and steroid facility for Aspen

Commenced operations in 2017

46

Reactors with 125 KL capacity

Scope for expansion
Capacity can be expanded by almost 100%

UNIT 6

Located at APIIC, Achutapuram, Visakhapatnam, India

API manufacturing facility

Commenced commercial operations in 2018

45

Reactors with 261 KL capacity

Received approval from USFDA

Scope for expansion
More than three times of current capacity

BUSINESS REVIEW

Our Value-creating Business

1 Generics APIs

Comprises the development, manufacture and sale of APIs and advanced intermediates in the Antiretroviral (ARV), hepatitis C, oncology, cardiovascular, antidiabetic, anti-asthmatic, gastroenterology and ophthalmic therapeutic areas.

Product and Service Offerings

- ARV
- Hepatitis C
- Oncology
- Antidiabetic
- Large-volume APIs for cardiovascular, anti-asthmatic, and gastroenterology therapeutic areas
- Small-volume APIs for the ophthalmic therapeutic area

2018-19 Highlights

- Completed validation of all second-line ARV APIs and can now offer a complete basket of APIs
- Received DMF approvals from WHO for Dolutegravir and Lamivudine
- Lamivudine production capacity is now operational
- Completed FDA inspection of Unit 6
- Validation completed for key APIs in the diabetes segment

Filings

- Commercialised 50+ products
- Filed 54 DMFs

Revenue Contribution

84%

(Consolidated)

2 Generics FDFs

Comprises developing and manufacturing oral solid formulations; building on API strengths to forward-integrate and become a leading FDF player in the global pharmaceutical market

Product and Service Offerings

- ARVs
- Antidiabetic
- Cardiovascular
- Proton Pump Inhibitors (PPIs)
- Central Nervous System (CNS)

2018-19 highlights

- Began commercial supplies of FDFs to European markets
- Started shipping Metformin tablets to the US markets
- USFDA approval for Hydroxychloroquine ANDA
- USFDA tentative approval and South Africa SAHPRA for triple drug combination of TLD (Tenofovir/Lamivudine/Dolutegravir)
- Commenced commercial supplies of TLD under Global Fund contract
- Filed two major products in antiretroviral segment – TLE_{600} and TLE_{400}
- Transferred ANDA of Tenofovir to CASI Pharma and received $2 million
- Formulations Unit 2 successfully completed regulatory inspections from various countries like USA, UK-MHRA, WHO-Geneva,Tanzania, Uganda, Kenya, Zimbabwe and Malawi
- Significant number of Paragraph IV (PIV) and first to file ANDA
- Entered into a strategic partnership with Global Fund for a three-and-a-half year period for ARV supplies

Filings

- Filed 18 ANDAs with the USFDA
- 3 dossiers in Canada, 5 dossiers in Europe, 6 dossiers with WHO, 2 dossiers in South Africa, 2 dossiers in India and 81 in ROW. In addition, completed 1 product validations
- 3 ANDAs approved

Revenue Contribution

2%

(Consolidated)

BUSINESS REVIEW

Our Value-creating Business

3 Synthesis

Comprises contract development and manufacturing services for global pharmaceutical companies

Product and Service Offerings

- **Commercial scale contract manufacturing**
- **Clinical phase supplies**
- **Analytical and research services**

2018-19 Highlights

- **Completed several projects in various phases from pre-clinical to commercial, with development and manufacturing**
- **New orders from existing Contract Manufacturing Organisation (CMO) partners and business opportunities for manufacture from several global companies**

Filings

Commenced commercial supplies from Unit 5

Revenue Contribution

11%

(Consolidated)