Laurus Labs Limited Corporate Office

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January 31, 2019

To

The Corporate Relations Department BSE Limited Phiroz Jeejeebhoy Towers, 25<sup>th</sup> Floor, Dalal Street Mumbai – 400001

Code: 540222

To

The Listing Department
National Stock Exchange of India Limited
Exchange Plaza,
Bandra Kurla Complex, Bandra (East)
Mumbai – 400 051

**Code: LAURUSLABS** 

Dear Sirs,

Sub: Investors/Analysts Presentation

Please refer to our letter dated January 28, 2019, wherein we have intimated the schedule of Investors/Analysts call to be held on February 01, 2019. In this connection, we enclose herewith the presentation to the Investors/Analysts on the Unaudited Financial Results of the Company for the Quarter and Nine Months period ended December 31, 2018.

The presentation is also being uploaded on the website of the Company – www.lauruslabs.com.

Please take the information on record.

Thanking you,

Yours sincerely, For Laurus Labs Limited

G. Venkateswar Reddy

Company Secretary





## **LAURUS LABS LIMITED**

Q3 & 9M FY19
RESULTS PRESENTATION
January 31, 2019

BSE: 540222 NSE: LAURUSLABS

### Disclaimer



Certain statements in this document may be forward-looking statements. Such forward-looking statements are subject to certain risks and uncertainties like regulatory changes, local political or economic developments and many other factors that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statements.

Laurus Labs Limited (Laurus) will not be in any way responsible for any action taken based on such statements and undertakes no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances.

## **Business Snapshot**



Overview	LAURUS Generics     Active Pharmaceutical Ingredients & Intermediates      Development, manufacture and sale of active pharmaceutical ingredients (APIs) and advanced intermediates	LAURUS Generics Finished Dosage Forms  • Developing and manufacturing oral solid formulations	LAURUS Synthesis     Contract Development & Manufacturing Services     Contract development and manufacturing services for global pharmaceutical companies	Sale and manufacture of specialty ingredients for use in nutraceuticals, dietary supplements and cosmeceutical products
Product and Service Offerings	<ul> <li>Anti-retroviral (ARV)</li> <li>Hepatitis C</li> <li>Oncology</li> <li>Anti-diabetic</li> <li>Large volume APIs for cardiovascular, anti-asthmatic, gastroenterology therapeutic areas</li> <li>Small volume APIs for the ophthalmic therapeutic area</li> </ul>	<ul> <li>ARVs</li> <li>Anti-diabetic</li> <li>Cardio Vascular</li> <li>Proton Pump Inhibitors</li> <li>CNS</li> </ul>	<ul> <li>Commercial scale contract manufacturing</li> <li>Clinical phase supplies</li> <li>Analytical and research services</li> <li>Several projects executed</li> </ul>	<ul> <li>Nutraceuticals, dietary supplements and cosmoceutical products</li> <li>Set up a dedicated block in Unit 4 for global partner, C2 Pharma</li> </ul>
Filings	<ul> <li>Commercialized 50+ products</li> <li>51 DMFs filed</li> </ul>	<ul> <li>Filed 18 ANDAs with USFDA</li> <li>3 dossier in Canada, 5 dossiers in Europe, 6 dossier with WHO, 2 dossier in South Africa, 2 dossier in India &amp; 81 in ROW. In addition, completed 1 product validations.</li> <li>3 ANDAs Approved</li> </ul>	Commenced commercial supplies from Unit 5	• NA
Infrastructure	4 Manufacturing facilities, (2,847 KL) (1) (2)	• 5 bn Units / year capacity.	<ul> <li>Dedicated manufacturing (Unit – 5) Capacity (125 KL) for Aspen.</li> </ul>	Manufacturing facilities <sup>(2)</sup>



### **Strategy in Motion**



#### **ARV**

- Significant increase in HIV patient population with revised WHO guidelines
- New opportunities in Second Line therapies
- ARV drugs patent expiry in US & European markets
- Lamivudine and DTG DMFs got approval from WHO and will initiate generation of revenue from Q4 FY 19.
- Backward integration for few of API completed

Capitalize on our Leadership Position in APIs in Select, High-Growth Therapeutic Areas . Foray into regulated markets



Hep C, Oncology & Other APIs

- Leadership in select
   Oncology API. Launching
   few more products in FY19
   & beyond in regulated
   markets
- Leverage process chemistry skills to expand API product portfolio in other growing therapeutic areas
- Strong opportunity in Hepatitis C in emerging markets
- Contract manufacturing of generic APIs

Further expand our API
Portfolio in key therapeutic

areas such as Oncology,

Hep C, CVS, Anti-Diabetic & Ophthalmology



**FDFs** 

- Leverage API capabilities backed up by backward integration
- 2 Partnerships in place for commercialization of FDFs in US market.
- In Place own front end in the US market and partnering for Europe markets
- Geared up for emerging markets by participating through tenders. First product launched and TLD combination product to be launched based on the approval
- Contract manufacturing for European customer

Leverage API Cost Advantage for Forward Integration into Generic FDF Therapeutic Focus Areas –

ARV, CVS, CNS, PPI & Anti



**Synthesis** 

- Focus on supply of key starting materials and intermediates for new chemical entities
- Completed several projects in various stages from pre clinical to commercial with development & Manufacturing. And many more in pipeline
- Contract with Aspen for supply of hormonal intermediates

Ingredients

 Leverage process chemistry skills to strengthen presence in nutraceutical and cosmeceutical sectors as they adopt quality standards at par with pharma industry

Develop our Synthesis Business through various global Innovators including Aspen



Expanding from Synthetic process to Natural Extraction



### Formulations Business – Global Approach



- Extensive Manufacturing capabilities across markets with commitment to maintain highest quality standards "One Quality Standard for All Markets"
- Current FDF Manufacturing Capacity 5 bn tab/caps with total Capex investment of ~INR 4,280 mn
- Tenofovir (TDF) ANDA rights transferred to CASI Pharma for a consideration of ~\$3 mn of which ~\$2 mn received in Q3 FY19 Milestone Payments. Laurus continues to sell TDF in other countries.

#### Dossier Filings

Therapy	US ANDA	Europe	Canada	Africa	Asia
ARV	10	3	2	68	6
Anti- Diabetic	3	1	-	3	2
CVS	1	-	-	-	-
CNS	1	1	-	2	-
Autoimmune	1	-	1	-	-
Pulmonary (IPF)	2	-	-	-	-
Total	18*	5	3	73	8

<sup>\*</sup> Have 2 Para IV opportunities and ~7 FTF opportunities in US market with addressable current market size of \$10 bn

Inspection status for Formulations manufacturing Unit (Unit 2)

Region	Agency	Audit Status
USA	USFDA	EIR Received
Europe	JAZMP – Slovenia, and BGV Hamburg	Certificate Received
ROW	WHO – Geneva	Certificate Received
Europe	JAZMP – Slovenia, and BGV Hamburg	Certificate Received
Africa	Tanzania FDA, National Drug Authority – Uganda, PMPB – Malawi, and Pharmacy & Poisons Board – Kenya	Approvals Received

## **Formulations Strategy for Developed Markets**



Overview	US, EU, Canada remains our key focus markets by focusing on the combination of commercialised high volume products, first to file, Para IV opportunity based on IP to address short, medium and long term strategy.	
Target Markets	USA, Europe and Canada	
Key Therapeutic Areas	ARV, Anti Diabetic, CVS, CNS and others	
US Filings	<ul> <li>Cumulatively filed 18 ANDAs</li> <li>Have filed 2 Para IV and 7 FTFs with opportunities worth over \$ 10 Billion* annual sales in US</li> <li>Targeting ~10 ANDA Filings per year</li> </ul>	
US Approvals	3 Final Approvals and 1 tentative approval received	
US Partnerships	<ul> <li>Re negotiated partnerships with DRL and Rising Pharma by reducing products under partnership from 18 to 7 products. 11 products will be developed by Laurus which was concluded in the second quarter by paying necessary development fees back to the partner</li> <li>Exploring possibility of marketing in-licensed products by Laurus.</li> </ul>	
EU Overview	Followed with partnering model for supply of FDF products and also contract manufacturing. Incremental expenditure incurred for filings in 2 <sup>nd</sup> quarter	
EU Filings	Filed 5 Dossiers for ARV & Anti Diabetic products	
Approach	<ul> <li>To participate in various country specific tenders and partnering for marketing</li> <li>Commercial supplies under Contract Manufacturing for an European Customer commenced in Q3 FY19</li> </ul>	

\* Source: IMS Q3 CY 2017



## **Formulations Strategy for Emerging Markets**

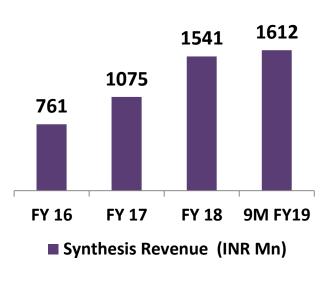


Overview	Emerging Markets of Africa & ARV Tender business remains the forefront of our Formulations Strategy. Integrated approach is key to success and Laurus is well positioned to garner this opportunity			
Target Market	Emerging Markets – Global fund tenders, WHO Tender, PEPFAR Tender, Various African In-Country Tenders			
Therapeutic Areas	ARV			
Addressable Market Size	<ul> <li>~\$ 2 Billion in Generic Accessible markets</li> <li>Commenced Tenofovir (TDF) Sales in Africa and awaiting participation in tenders for TLD (Tenofovir, Lamivudine, Dolutegravir) Combination</li> </ul>			
Filings	TLE <sub>600</sub> & TLE <sub>400</sub> (Tenofovir, Lamivudine, Efavirenz) combinations filed in October 2018 and January 2019 respectively.  Over 50 product registrations filed in various African & Asian Countries			
Approvals	<ul> <li>Have received approval for TLD under Global Fund-ERP which enables us to participate in various In-Country Tenders. TLD Approval from USFDA expected in 1st week of February 2019 and from WHO before March 2019.</li> <li>Tenofovir approved by WHO and USFDA and also in several EU countries.</li> </ul>			
Future Filings	<ul> <li>Development of other combinations for first line and second line therapy is active and expected to be ready for filing before Dec 2019.</li> </ul>			
Growth Potential	Three out of four major combination drugs [TLD, TLE <sub>600</sub> , TLE <sub>400</sub> ] are filed with the regulatory authorities. Total patients growth is expected to be in high single digit and treatment to reach about 25 mn patients by 2022			

## Synthesis Business Strategy



Overview	<ul> <li>State-of-the-art cGMP facilities to manufacture NCEs</li> <li>Can support early stage, late stage and commercial launch supply requirements</li> <li>Working with Global Innovator Companies</li> <li>Around 50% of the business revenue comes from ASPEN &amp; the rest from CDMO services</li> </ul>
Target Market	USA, Europe and Japan
Approvals	Units Approved by key regulatory agencies of US, EU, Japan
Growth Potential	<ul> <li>Commencement of commercial supplies from Unit 5 to ASPEN</li> <li>New business opportunities for manufacturing from several global companies</li> </ul>



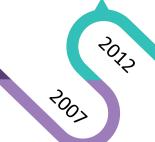
### **Transformation of Business Model**



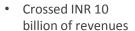
- Set up the R&D Centre at IKP, Knowledge Park, Hyderabad
- Investment of INR 600 mn by FIL Capital Management and Promoters.
- Incorporated First Subsidiary in USA, Laurus Inc.
- Investment of INR 3000 mn by Warburg Pincus
- Successfully listed on BSE & NSE
- Filed first ANDA for US market\*
- Acquired 100% stake in Sriam Labs Pvt Ltd.

2016

- Crossed INR 20 billion of revenue
- Commenced commercial operations from Unit 4
- Incorporated a subsidiary in Germany
- Unit 2-Formulations EIR received from USFDA
  - Launched maiden FDF product Tenofovir in USA, Canada and emerging markets.
  - Certified as Great Place to Work for the year 2018
- Unit 6 USFDA inspection completed successfully with 1 observation



Commenced commercial operations at Unit 1



2013

 Commenced commercial operations at Unit 3,

2015

 Forged partnership with NATCO



- Commenced commercial operations at Unit 2
- Commenced commercial supplies from Unit 5 for Aspen
- Launched Velpatasvir in the HEP - C segment
- Received EIR from USFDA for Units 1,2 & 3
- Incorporated subsidiaries in UK & USA



### **Strong R&D Capabilities**





"Research-first" approach – Set up dedicated R&D center in Hyderabad in 2006 prior to commissioning API manufacturing facility in 2007 and further expansion completed in 2017.

R&D team comprising 800 plus scientists (~24% of total employee strength) including over 55 PhDs

Kilo Lab at R&D center accredited by international regulators

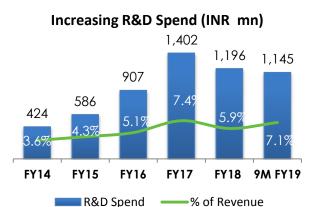
Currently setting up new R&D center in Visakhapatnam













R & D spent includes OPEX, CAPEX and RMC of FDF validation batches
FY 17 numbers are high due to additional CAPEX and initial FDF validation batches



### **Quality Focus & Regulatory Audits**





We maintain consistent quality, efficiency and product safety.

We have adopted uniform manufacturing standards across all facilities to achieve standardized quality for all markets. Good manufacturing practices across all the manufacturing facilities, encompassing all areas of business processes right from supply chain to product delivery.



# Regular Inspection at different manufacturing units

2018	USFDA, ANVISA (Brazil)
2017	WHO, USFDA, EU (Germany)
2016	USFDA
2015	WHO, USFDA, EU (Germany)
2014	WHO, USFDA, CDSCO
2013	WHO
2012	USFDA
2011	KFDA, USFDA, WHO
2010	MHRA
2009	TGA, USFDA

### Manufacturing Facilities at Parawada, Vizag





- Located at Jawaharlal Nehru Pharma City, Vishakhapatnam, India.
- API manufacturing facility and includes capacity for ingredients, synthesis and contract manufacturing.
- Commenced operations in 2007.
- 316 reactors with 1,142 Kilo Liters capacity.
- Received approvals from US FDA, WHO-Geneva, NIP Hungary, KFDA, COFEPRIS & PMDA.



- Located at Jawaharlal Nehru Pharma City, Vishakhapatnam, India.
- API manufacturing facility and includes capacity for ingredients, synthesis and contract manufacturing.
- Commenced operations in 2015.
- 195 reactors with 1,360 Kilo Litres capacity.
- Received approvals from USFDA, WHO Geneva, & NIP Hungary.



- 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 Kilo Litres capacity .

### Manufacturing Facilities at Achutapuram, Vizag





- Located at APIIC, Achutapuram, Visakhapatnam, India. (SEZ)
- FDF and API manufacturing facility
- Commenced operations in 2017.
- FDF capacity of 5 bn tablets/capsules per year.
- API block with 12 reactors with 83 Kilo Liters capacity.
- Received approvals from BVG Hamburg Germany, USFDA, WHO Geneva



- Located at APIIC, Achutapuram, Visakhapatnam, India. (SEZ)
- API manufacturing facility and includes capacity for ingredients, synthesis and contract manufacturing.
- Commercial operations in 2018
- 32 reactors with 85 Kilo Liters capacity
- Received approval from COFEPRIS Mexico



- Located at APIIC, Achutapuram, Visakhapatnam, India.
- API manufacturing facility.
- Commercial operations in 2018
- 44 reactors with 260 Kilo Liters capacity.
- Successful completion of USFDA inspection with 1 observation

## Business Highlights – Q3 & 9M FY 19



### **Overall**

- Total Income at INR 16,568 mn during the 9M FY19 (Y-o-Y) grown by 11 % and INR 5,295 mn during quarter grown by 11% Y-o-Y.
- R & D spent of INR 1,145 mn and 7.1 % as percentage of sales during 9M FY19.

### **Generic API**

- Filed 234 patent applications and 73 patent granted as on Dec 31, 2018
- Capacity expansion completed for Lamivudine.
- USFDA inspection of Unit VI completed with 1 procedural observation

## Synthesis & Ingredients

• New Business opportunities from Innovator/Pharma companies will accelerate further growth.

### **Generic FDF**

- TLD Approval from USFDA expected in 1<sup>st</sup> week of February 19 and from WHO before March 19.
- TLE600 filed in October -18 with USFDA & WHO
- TLE<sub>400</sub> filed in January -19 with USFDA & WHO
- 1 product validation completed for formulation apart from filling of 18 ANDAs & NDA
- FDF Opex of INR 941 mn which includes INR 395 mn related to the R&D during 9MFY19.

### **Performance Highlights - Abridged Profit & Loss statement**



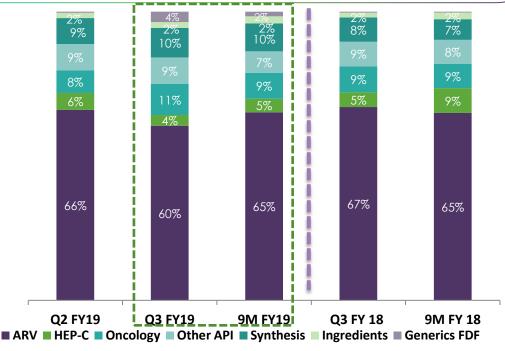
Particulars (Rs. mn)	Q3 FY19	Q3 FY18	Growth % (Q3 FY19 Vs. Q3 FY 18)	Q2 FY19	Growth % (Q3 FY19 Vs. Q2 FY 19)	9M FY19	9M FY18	Growth % (9M FY19 Vs. 9M FY 18)
Total Revenues from Operations (Net)	5,295	4,789	10.6%	5,883	-10.0%	16,568	14,959	10.8%
Total Expenditure	5,081	4,403		5,770		16,041	13,467	,
EBITDA	891	972	-8.3%	862	3.4%	2,578	3,198	-19.4%
Margins	16.8%	20.3%		14.7%		15.6%	21.4%	
PBT	228	486	-53.1%	218	4.6%	672	1,733	-61.2%
Margins	4.3%	10.1%		3.7%		4.1%	11.6%	
PAT	178	349	-49.0%	162	9.9%	506	1,225	-58.7%
Margins	3.4%	7.3%		2.8%		3.1%	8.2%	
EPS (Diluted)	1.7 (Not annualised)	3.3 (Not annualised)		1.5 (Not annualised)	10,0,0	<b>4.8</b> (Not annualised)	11.5 (Not annualised)	

- Exchange rate per US\$ stood at INR 65.04 by 31st Mar 18, INR 72.55 by 30th Sep 18, INR 69.79 by 31st Dec 18 and appreciated by INR 2.76 (3.80%) comparing to Q2 resulted a forex gain of INR 113 mn in Q3 and depreciated by INR 4.75 (7.30%) comparing to Mar 18 resulted INR 110 mn loss for FY 19 YTD.
- There is no significant price increase of raw materials in Q3, based on overall backward integration/alternative sourcing for a few intermediates already implemented and some are in pipeline.
- Cost of borrowing has increased by 0.5% due to increase in base lending rates.

### **Drivers of Revenue – Division wise revenue breakup**



- Total Revenues grew by 11% for the quarter (Y-o-Y) and 11% for 9M (Y-o-Y)
- Generic API
  - ARV Segment registered a healthy growth of ~11% in 9M (Y-o-Y) on the back of improved volumes. Q3 Revenue stood at INR 3,202 mn due to lower off take from couple of customers. We are on track for delivering high single digit growth for FY19.
  - HEP-C business continues to remain muted. The segment recorded sales of INR 197 mn for Q3 FY19 & INR 782 mn for 9M FY19, registering de-growth. However, we are confident of improved sales in Q4 FY19.
  - Oncology business showed robust growth of 31% for the quarter (Y-o-Y) & 18% for 9M (Y-o-Y) on the back of new capacity additions
  - Other API sales grew over 20% for the quarter (Y-o-Y). Sales remained flat for 9M (Y-o-Y) because of lower sales in Q1 FY19.
- Synthesis Business continues to report robust revenue growth growing by 34% for the quarter (Y-o-Y), and 51% in 9M (Y-o-Y), with increase in revenue from Unit 5 and also with improved contribution from CMO business.
- Generic FDF business recorded sales of INR191 mn in Q3FY19, resulting in 9M FY19 sales of INR 264 mn. On the back of ANDA Sale to CASI Pharma
- Ingredients revenue grew 14% for 9M(Y-o-Y)



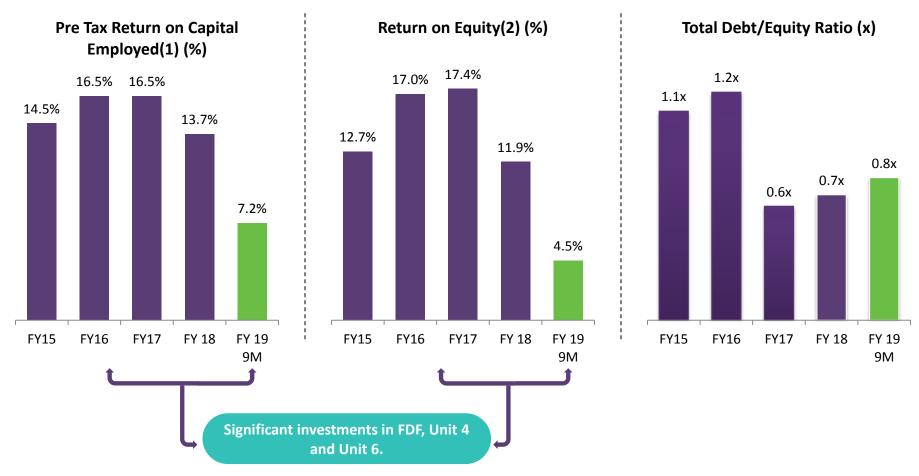
Segments (INR mn)	Q2 FY19	Q3 FY19	9M FY19	Q3 FY18	9M FY 18	Growth Q3 (Y-o-Y)	Growth 9M (Y-o-Y)
ARV	3,882	3,202	10,794	3,208	9,709	-0.2%	11%
HEP-C	344	197	782	244	1,288	-19%	-39%
Oncology	465	569	1,474	433	1,254	31%	18%
Other API	533	489	1,239	406	1,250	20%	-1%
Synthesis	530	541	1,612	404	1,067	34%	51%
Ingredients	107	106	403	79	353	34%	14%
Generics FDF	22	191	264	15	38	1,173%	595%
Total Revenue	5,883	5,295	16,568	4,789	14,959	11%	11%



### **Established Track Record Of Delivering Growth**

Efficient Use of Capital and Prudent Leverage





FY 19 9M ratios are calculated based on 9M annualized.

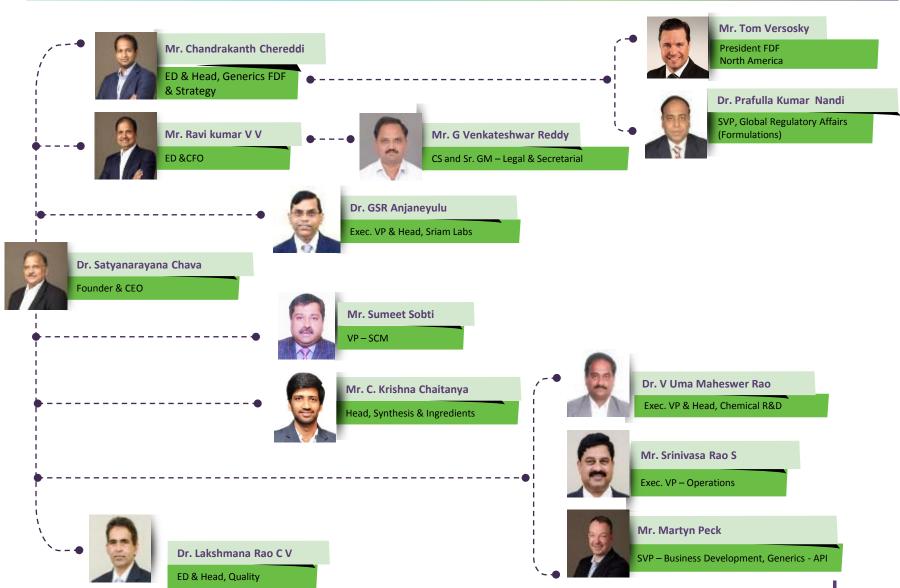
Note: Based on consolidated financials as per Ind AS



<sup>(1)</sup> Pre-tax RoCE is calculated as EBIT/Average Capital Employed. Capital employed is defined as Net Worth + Long Term and Short Term Borrowings + Current Portion of Long Term Borrowing - Cash

<sup>(2)</sup> RoE is calculated as PAT/Average Net Worth

### **Management Team**



## **Corporate Governance**



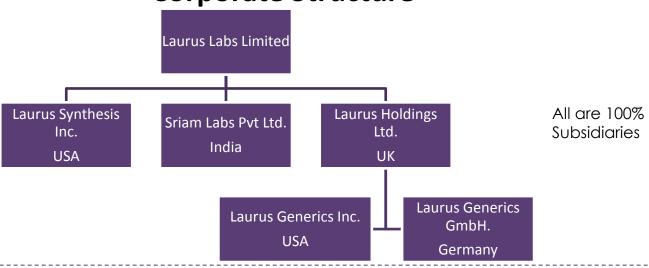
Executive Directors				
Name	Background			
Dr Satyanarayana Chava	Whole-time Director, Founder and Chief Executive Officer			
Ravi Kumar V V	Whole-time Director and CFO			
Chandrakanth Chereddi	■ Whole-time Director and Head of Generic FDF and Strategy			
Dr Lakshmana Rao C V	Whole-time Director and Head, Quality			

Non-Executive Directors				
Name	Background			
Dr. M. Venu Gopala Rao	Non Executive Chairman and Independent Director			
Narendra Ostawal	Managing Director of Warburg Pincus India Private Limited			
Aruna Rajendra Bhinge	<ul> <li>Independent Director; Former Head of Food Security Agenda, APAC at Syngenta India Limited</li> </ul>			
Dr. Rajesh Koshy Chandy	<ul> <li>Independent Director; Professor of Marketing at the London Business School</li> </ul>			
Ramesh Subrahmanian	<ul> <li>Independent Director; Founder and Director of Alchemy Advisors</li> </ul>			
Dr. Ravindranath Kancherla	<ul> <li>Independent Director and Founder-Member and Treasurer of ELSA of Asia in Singapore and Chairman of Global Hospitals</li> </ul>			

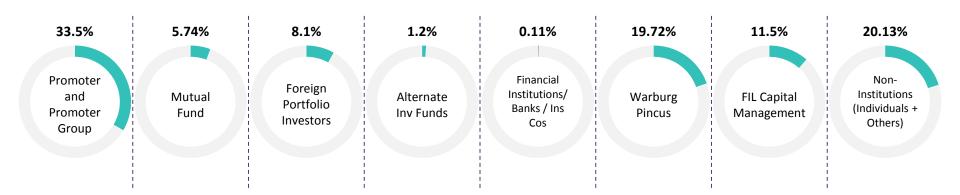
### **Ownership Structure**







## **Shareholding pattern \***



# Laurus Labs is a Fortune 500 Company, Great Place To Work and one of the India's Best Workplace in 2018



Laurus Labs is listed in the Fortune 500 Companies List in India

FORTUNE

FORTUNE

INDIAS LARGEST CORPORATIONS

THE CHINA SOO -- THE BRIC 5 CIVETS 100

Laurus Labs is certified as "Great Place to Work" for the year 2018.



Laurus Labs is recognized as one of the Best Work Places in Biotechnology,
Pharmaceuticals & Health
Care sector for the year 2018



### **Results Conference Call**



### Results conference call on Friday February 01, 2019 at 4:00 PM IST

### Details of the conference call are as follows:

Timing	4:00 PM IST on Friday, February 01, 2019
Conference dial-in Universal Dial-In	+91 22 6280 1214 +91 22 7115 8115
India Local access Number	+91 7045671221 Available all over India
Singapore Toll Free	8001012045
Hong Kong Toll Free	800964448
USA Toll Free	18667462133
UK Toll Free	08081011573

### **Contact us**



### **About Laurus Labs Ltd.**

Laurus Labs is a leading research and development driven pharmaceutical company in India. The Company has grown consistently to become one of the leading manufacturers of Active Pharmaceutical Ingredients (APIs) for anti-retroviral (ARV) and Hepatitis C. Laurus also manufactures APIs in Oncology and other therapeutic areas. Its strategic and early investments in R&D and manufacturing infrastructure have enabled it to become one of the leading suppliers of APIs in the ARV therapeutic area. Laurus Labs also forayed into Finished Dosages Forms capabilities on the back of existing strengths in APIs. The Company is also driving growth opportunities in the Synthesis and Ingredients businesses. **Corporate Identification No: L24239AP2005PLC047518.** 

### For more information about us, please visit **www.lauruslabs.com** or contact:

Monish Shah Pavan Kumar N

Tel: +91 040 3980 4366 Tel: +91 040 3980 4380

Email: <a href="mailto:investorrelations@lauruslabs.com">investorrelations@lauruslabs.com</a> Email: <a href="mailto:mediarelations@lauruslabs.com">mediarelations@lauruslabs.com</a>

# Thank You