#### **ANNUAL REPORT 2016-17**

# Investing in reliability





#### **Auro Mission**

Aurobindo's mission is to become the most valued pharmaceutical partner to the world pharma fraternity by continuously researching, developing and manufacturing a wide range of pharmaceutical products that comply with the highest regulatory standards.

Auro Values					
BUSINESS CARE  Operational excellence Stakeholder orientation Quality	PEOPLE CARE  Fairness, humility and respect for individuals  Teamwork  Applied learning	ORGANIZATION CARE Accountability Integrity Achievement			

On the cover: Our office at New Jersey, USA



## CONTENTS

2	Aurobindo at a glance		
6	Investing in reliability		
8	On a runway to growth	30	Board of Directors
		_ 32	Regulatory Filings
10	New Initiatives	33	Notice of AGM
11	Biosimilars	38	Board's Report
12	Oncology & hormonal products	47	Management Discussion & Analysis
13	Dermatology, inhalers & nasal products	53	Management of Risks
14	Specialty injection products	57	Business Responsibility Report
15	Vaccines	96	Report on Corporate Governance
16	Peptides, Penems, Biocatalysts		
		<del>-</del> 109	Independent Auditors' Report
17	Investing in people	114	Balance Sheet
20	Dedicated to customers	115	Statement of Profit and Loss
22	Climbing the value chain	117	Cash Flow Statement
24	Environmental savings and improved safety	163	Consolidated Financial Statements
26	Creating societal wealth	221	Proxy Form
		223	Attendance Slip



#### **AUROBINDO AT A GLANCE**

Aurobindo is a leading global pharmaceutical company producing oral and injectable generic formulations and active pharmaceutical ingredients.

Development and growth of Aurobindo stretches over three decades, only made possible by its intense focus on productivity, operational efficiency and commitment to highest standards of quality.

Strengthened by several large manufacturing facilities approved by US FDA, UK MHRA, MCC-SA, ANVISA Brazil for both APIs & formulation, Aurobindo markets in over 150 countries, with a critical mass in US and Europe.

Aurobindo's robust product portfolio is spread over seven major therapeutic/product areas including antibiotics, anti-retrovirals, cardiovascular (CVS), central nervous systems (CNS), gastroenterologicals, anti-diabetics and anti-allergics, supported by an outstanding R&D set-up. The in-house scientific pool creates intellectual wealth for the Company and commercializes cost effective, quality generic finished dosages.

The competitive advantage of the Company is the broad portfolio of diversified dosage forms including Rx and OTC oral solids & liquids, injectables, ophthalmics, specialty products and controlled substances. The focus is on complex molecules, differentiated technology platforms and specialty products.

₹150,899

CONSOLIDATED REVENUE

27% CAGR
CONSOLIDATED REVENUE
FOR PAST 5 YEARS

88% REVENUE

INTERNATIONAL OPERATIONS

CONSOLIDATED 2016-17

#### THE WAY FORWARD

The Company is building leadership position in the business with its technical excellence, expertise in quality assurance, compliance with regulatory standards, and being recognized for cost competitiveness and customer focus.

Aurobindo aims to gain market share for existing products and by the introduction of new launches (presently 115 ANDAs under review). Products under review include 38 ANDA filings for injectables, inhalation and ophthalmics.

We are future proofing value creation for Aurobindo with new initiatives which include gaining entry into complex R&D products in differentiated technology platforms such as biosimilars, depot injections, inhalers, nasal and dermatology products.

Plans are to expand penetration of OTC products and capitalize on OTC conversions and enhance nutraceutical business profitability through a combination of cost and growth synergies.

In Europe, the strategy is to ramp up own filings and gain market share, with focus on enhancing profitability.

Forward plans in ARV business are to launch new products including combinations, as well as grow the existing market. New geographies are being explored in the emerging markets.

API capacities are being augmented to support growth in advanced markets.

Top 3

In India among pharmaceutical companies<sup>1</sup>

Top 6

In the US generic company by volume<sup>2</sup>

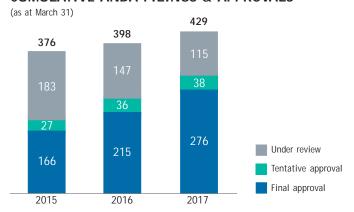
Top 15

In Europe generic company by sales<sup>3</sup>

- <sup>1</sup> As per 2016-17 revenues.
- <sup>2</sup> IMS National Prescription Audit, Total prescriptions dispensed, twelve months ending April 2017.
- <sup>3</sup> Market Reports.



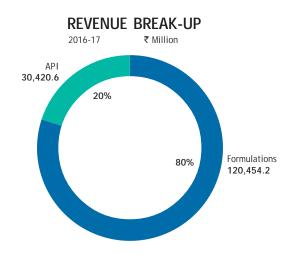
#### **CUMULATIVE ANDA FILINGS & APPROVALS**



As per IMS MAT, addressable market is USD 61.1 billion for products under review and tentatively approved ANDAs as at March 31, 2017  $\,$ 

(Tentative as at March 31, 2017 include 10 ANDA approved under PEPFAR).

PORTFOLIO MIX	Products	Addressable market size (USD Billion)		
Cardiovasculars	69	27.4		
Neurosciences	82	25.7		
Anti-retrovirals*	39	8.0		
Anti-diabetics	13	5.4		
Gastroenterologicals	27	5.0		
Controlled substances	16	2.3		
SSP & Cephalosporin	30	1.0		
Oncology	2	0.6		
Ophthalmics	10	0.6		
Respiratory	10	0.6		
Penems	4	0.5		
Others	127	14.0		
Total	429	91.1		
*Does not include the addressable market of the products approved under PEPFAR.				



FORMULATIONS REVENUE (%)

US 57

Europe 27

Emerging markets & ARVs 16

70% in-house API VERTICALY INTEGRATED FOR FORMULATIONS MANUFACTURE

16,000+

EMPLOYEES from over 30 countries March 31, 2017

#### **STRUCTURE**

Corporate office in Hyderabad, India.

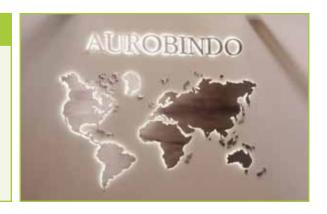
Manufacturing facilities (including wholly owned subsidiaries)
India 19
US 3
Brazil 1

Research & Development Centers

India 5 US 2

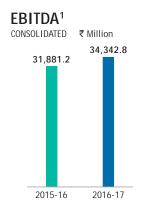
housing 1,400 + professionals.

Marketing offices in 30 countries.





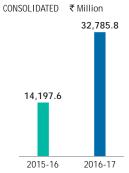
# REVENUE CONSOLIDATED 7 Million 150,898.6 139,552.2



2015-16

#### CASH FLOW FROM OPERATIONS

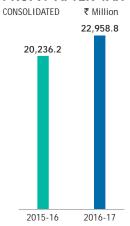
2016-17



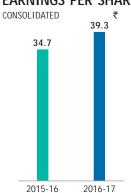
### FORMULATIONS REVENUE 2016-17 ₹ Million



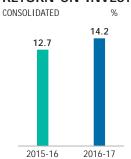
#### **PROFIT AFTER TAX**



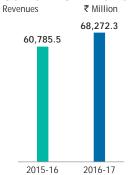
#### **EARNINGS PER SHARE**



#### RETURN ON INVESTMENT



#### **US FORMULATIONS**



# Investing in reliability

I am pleased to report that 2016-17 was another satisfactory year for Aurobindo with solid growth in sales in all major geographies. New benchmarks were recorded in gaining market presence in US, Europe and emerging markets, in a continuing story of exemplary growth.



The year witnessed an incremental sales of 8.1% over the previous year at ₹150,899 million, at the consolidated level. The Company's diversified product portfolio in oral solids including controlled substances and injectables made all the difference in a challenging and competitive market. We are continuing to build a strong pipeline and are confident that we shall ensure sustainable growth, well into the future.

Earnings before interest, depreciation and tax before forex and other income (EBITDA) for the year at ₹34,343 million reflected a 7.7% growth. We faced head winds, but maintained the EBITDA margin for the year at 22.8%, the same as in the previous year. Profit after tax at ₹22,959 million was higher by 13.5% over 2015-16. Earnings per share for the year were healthy at ₹39.3.

This extraordinary financial achievement is the result of the

talent, resiliency and resourcefulness of our 16,000+ employees across the globe. Because of their dedication and commitment demonstrated every working day, our products are presently marketed in 150+ countries, and are growing in all geographies.

All the manufacturing facilities were streamlined and optimized to increase throughput, add to our reliability levels and maintain profitability. They improved on their process efficiencies to deliver exceptional performance, while meeting aggressive goals in product launches and market presence. Our experienced professionals, supported by continued investment in state-of-the-art manufacturing equipment, are an enormous competitive strength.

There was unrelenting focus to raise the bar. We redefined our project timelines, made marked progress in supply chain performance and material planning, augmented alternate source of supplies, fine tuned production scheduling, asset utilization and productivity, all of which have worked together to enhance our reliability quotient with our customers. We have further supplemented our manufacturing infrastructure, to add to our market presence and value creation. Going ahead, one more large manufacturing facility - Unit X at Nayudupeta - and a biosimilars manufacturing unit are being commissioned in 2017-18.

Our organizational structure ensures sharp focus and accountability, leveraging on our inherent capabilities. We have been ramping up our operations to generate continuous and sustainable improvement, to enhance the quality of our processes, ensure that we comply with all the



So far what we have achieved is only the beginning of things to come. We expect robust growth to continue for the foreseeable future. Actually, we are building a moat around us.

standard operating procedures and pare down our costs. This now is the mindset of our team.

I am excited to share with you that we have forayed into biosimilars development, to continue with our strategy of investing in complex portfolio. New initiatives into oncology, dermatology, inhalers, nasal products, specialty injection products, peptides, vaccines etc are progressing to schedule.

I am equally excited that during the year, Aurobindo acquired Generis Farmacêutica S.A., a generic pharmaceutical firm that focuses on both the retail and hospital segments. Generis has a wide portfolio of products with major share in the therapeutic areas of cardiovascular (CVS), central nervous system (CNS), anti-infectives and genito-urinary system ailments.

Generis is the most sold pharmaceutical brand in Portugal, and is the 2nd largest generic group in Portugal and would establish Aurobindo as the leading generics group in that country. We also acquired the rights, title and interest in products Calcium and Calcium Vitamin D3, including the use of the Orocal trademark for the France market. This is in-line with our corporate plan to ramp up our presence in Europe, to generate a strong revenue stream from those developed markets.

So far what we have achieved is only the beginning of things to come. We expect robust growth to continue for the foreseeable future. Actually, we are building a moat around us. Increasingly, we will be seen working on newer technologies and more complex product range. We have

further strengthened our competitive position by enhancing our product development capabilities. I must assure all our stakeholders that we have the necessary expertise, while some of the infrastructure is being made ready, in time.

We work beyond business. As a responsible corporate, we are committed to achieving economic success; our stakeholders expect it of us. Yet, we believe that key to the business success lies in finding a balance between the social, environmental and economic responsibilities that we face.

We have done considerable work to foster positive relationships in the communities where our facilities exist, as well as minimized consumption of resources especially water and fossil fuel. We believe strong safety performance contributes to our competitive strength and benefits our employees. These are of course, a continuing effort; ongoing up gradation is hence, a work-in-progress.

I appreciate the strong support of our shareholders and business partners and the reliable counsel of our Board including our newest Director Mr. Rangaswamy Rathakrishnan Iyer who joined the Board and Dr. Rajagopala Reddy who stepped down, both in February 2017. We welcome Mr. Rangaswamy and wish Dr. Reddy all the very best in his pursuits.

I am deeply thankful to all our stakeholders for their encouragement and support. In particular, I am grateful to our inherent strength - all our employees. I am extremely proud of them.

K. Nithyananda Reddy

Vice Chairman

# On a runway to growth

We did well on all counts. Revenues, EBITDA, earnings per share were increased. Our product pipeline was enhanced and we were able to launch several complex products. Challenges were many, but the entire organization stood up to reinforce the core of our business, optimized the value of our portfolio and increased our commitment to long-term value creation.



On an everyday basis we dedicated ourselves to compliance, quality and a healthier life for our customers. Overall, we invested in reliability in whatever we do and are working to ensure, we are on a runway to continual growth.

US formulations business contributed 57% to the overall formulations revenue during the year, as against 55% in the previous year. The revenue generated from the US business grew by 12.3% at ₹68,272 million in 2016-17 over the previous year sales of ₹60,785 million.

In the highly competitive US market, we have become the 6th ranked Rx supplier of prescriptions dispensed (as per IMS National Prescription Audit, April 2017).

We launched 35 products in the US market during the year under review. In 2016-17, we received approvals for 61 ANDAs and filed 31 ANDAs. With our increasing product pipeline, we believe we can further strengthen our market position in 2017-18 and set the course for future growth prospects.

In Europe, we witnessed a growth of 4.7%, to reach revenues of ₹32,771 million, during the year. The focus continues to achieve improved synergies between the acquired businesses at Western Europe with the Company's existing product pipeline.

In all the addressable European markets, there was volume growth, improved market presence as well as enhanced profitability, supplemented by increased manufacturing in India for larger number of products. With the commissioning of Unit XV at Parawada in Visakhapatnam, the exercise of transferring the manufacturing base to India is on-going to streamline and integrate the operations, optimize costs, improve information flow, facilitate decision making and enable better supervision and control. All of these initiatives are work-in-progress, to enhance profitability.

We have reinforced our presence in Western Europe with both manufacturing and marketing footprint with the acquisition of Generis as well as branded products, to expand our presence in those developed markets. We shall optimize resources and stay, as always, focused on profitability.

