Driving sustainable growth

Annual Report 2014-15

AUROBINDO

AUROBINDO PHARMA LIMITED

PRESENCE WORLDWIDE

Aurobindo strengthened by its manufacturing facilities approved by US FDA, UK MHRA, Japan PMDA, Health Canada, MCC South Africa and ANVISA Brazil for both APIs & formulations and with a global presence with its own infrastructure, strategic alliances with about 55 subsidiaries & joint ventures, features among the top 10 pharma companies from India in terms of consolidated revenues. The Company exports to over 150 countries across the globe with more than 86% of its revenues derived out of international operations. The customers include premium multi-national companies.

FORMULATIONS 77.9%

ACTIVE INGREDIENTS 22.1%

CONSOLIDATED REVENUES

FORMULATIONS SALES

50.5% US

33.4% EUROPE

16.1% EMERGING MARKETS & ARVs

INTERNATIONAL 86%

DOMESTIC 14%

CONSOLIDATED REVENUES

MANUFACTURING FACILITIES
(INCLUDING WHOLLY OWNED SUBSIDIARIES)

INDIA	15
US	3
BRAZIL	1

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WHO WE ARE

USD 2 BILLION
CONSOLIDATED REVENUES

We are a global pharmaceutical company producing oral and injectable generic formulations and active pharmaceutical ingredients with several large manufacturing facilities approved by leading regulatory agencies such as US FDA, UK MHRA, Japan PMDA, Health Canada, MCC South Africa and ANVISA Brazil.

Aurobindo Pharma Limited, headquartered at Hyderabad, India, has a robust product portfolio spread over six major therapeutic/product areas encompassing antibiotics, anti-retrovirals, CVS, CNS, gastroenterologicals, and anti-allergics, supported by an outstanding R&D set-up. Aurobindo has been ranked as #9 generics supplier as per IMS total prescriptions dispensed for the 12 months ending September 2014.

The Company, with 28 years of experience, has products that benefit people worldwide across 150+ countries and has recorded revenues of almost USD 2 billion in 2014-15.

WHAT WE DO

11,500
PROFESSIONALS WORLDWIDE

Aurobindo's strength lies in vertically integrating its active pharmaceutical ingredients (APIs) with finished dosages to yield quality generic formulations based on extensive pharmaceutical research. We couple non-infringing processes and chemistry challenges for drug substances with non-infringing and complex drug products developed by using innovative technologies.

In the process, the vast scientific pool at Aurobindo creates intellectual wealth for the Company and commercializes cost effective, quality generic finished dosages for people across the globe. The competitive advantage of the Company is to launch high-end quality products, in time to meet unmet demands of customers across the world.

Aurobindo employs more than 11,500 professionals across various divisions - Research & Development, manufacturing, quality assurance, marketing, supply chain, commercial and HRD.

WHAT WE STAND FOR

150 COUNTRIES
MARKETING PRESENCE

Aurobindo aims to be a leader in global generics formulations both in oral and injectables, nutraceuticals and over-the-counter products. The Company is building a large portfolio of differentiated and niche products to add value to customers and ensure robust value creation for shareholders.

We will build leadership positions in the businesses we are active in and shall be distinguished for technical excellence, expertise in quality assurance, compliance with regulatory standards, and be recognized for cost competitiveness and customer focus.

The brand value of the Company is its people who shall be well-known for delivering on promises. Our success will be based on the performance of each individual and what we do as a team, from research through manufacturing right up to marketing and deliveries.

The Company aims to achieve USD 3 billion in revenues by 2017-18.

MESSAGE FROM THE VICE CHAIRMAN

Driving sustainable growth

2014-15 was a landmark year for Aurobindo. We executed on our core strategies, delivered financially and accelerated on our way to long-term growth. In fact, we feel reassured that we are driving sustainable growth.

The challenges were plenty and competition was engaging. We made successful inroads into the injectables market and deployed our resources to gain presence in the demanding markets of Western Europe. We acquired the nutraceutical company Natrol in the US, which manufactures and sells nutritional supplements. The acquisition is strategic for us, to gain an entry into the growing nutraceutical segment.

We grossed revenues of almost USD 2 billion. We did larger volumes, set a new high in revenues and closed the year with EPS of ₹54. The dividend for the year has been raised to ₹4.50 per share as compared to ₹3 in the previous year. The Board of Directors has recommended issue of bonus shares in the ratio of one share of ₹1 for every share held. Members' approval is being sought separately for the issue.

I must hasten to thank our employees, who combine as a family, for the passion with which they work together, advance meaningfully the performance capabilities of Aurobindo and deliver value to all the stakeholders. The reliability, dedication and service of our employees translate into quantifiable improvements.

We are proud of our employees. They are indeed aligned with the Company's philosophy of 'Committed to healthier life' and are making it happen by delivering a larger volume of good quality drugs. Together we are performing better, demonstrating our agility and resilience in a competitive environment and, in the face of challenges, driving growth.

There are several examples which exemplify the employee commitment. Every day, at each facility, we are reviewing our quality and assurance standards and are seeking to constantly improve every process, transaction, competitive edge and effectiveness towards our goal of operational excellence. There is increasing process discipline, focus on results and motivation to be better at execution capabilities.

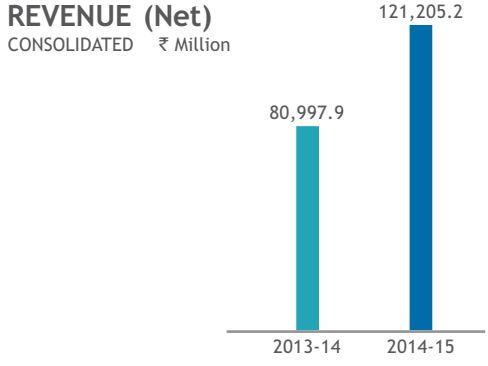
Due primarily to the efforts over several years, we have a strong presence in most of the markets in which we operate thanks to the relationships that we have built in matured and emerging markets alike. Our customers have been encouraging us to do better and we shall continue to reciprocate their trust in us.

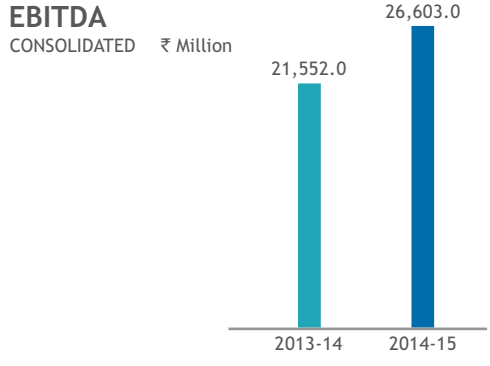
During the year, we successfully launched several products, especially injectables in the US. We stepped up our presence in West European countries with both active pharmaceutical ingredients and generic formulations. We gained momentum in France, Germany, Netherlands, UK, Spain, Italy, Portugal and several RoW markets. At the year end, Europe accounted for 33.4% of our formulations revenues and emerging markets & ARVs totaled 16.1%. US market continued to lead with 50.5% of the formulations business.

Generic formulations business saw a growth of 77.7% across all global markets with US growing by 42% and Europe rising by 375%. Market expansion was through increased penetration of several products. Triple combination drugs are giving traction to our ARV business. I am gratified that our ARV products addressed the treatment needs of 2.2 million patients.

Sales of active ingredients at ₹27,062 million were marginally lower by 5.5% year-on-year, primarily due to the significant demand for our in-house formulations business. There is a growing external demand for our active ingredients which is being met by expanding our Pydibhimavaram facility (Unit XI). Shipments will commence from the new block in latter half of 2015.

In 2014-15, we are proud of the progress we made in our safety and environmental performance. We believe running a safe business is a critical facet of running an excellent business and hence invested in a culture of continuous improvement. We will do whatever it takes to keep our employees and the environment safe and healthy.





Our CSR activities were tailored to provide drinking water, good health, sanitation and education in villages in the neighborhood of our facilities. During the year, we have undertaken social activities such as promoting education, hygiene, preventive health care, eradicating hunger, poverty & malnutrition, making available safe drinking water, environment sustainability, ecological balance & conservation of natural resources, rural sports and setting up of old age homes etc. At the end of the day, we witnessed several smiles and improved in a small way, the quality of life of a few hundred families.

Going ahead, as a priority, we shall deepen the integration of the recent acquisition of over 1,250 dossiers in Western Europe as well as Natrol. Our strategy is to grow the businesses profitably through a combination of cost and growth synergies. Several initiatives have been taken to enhance operational leverage, increase volumes and optimize costs.

We shall be anchored by fundamental execution disciplines to deliver on customer expectations. We are learning, changing, growing, making things happen and committed to make our growth sustainable. Team Aurobindo is working day in, day out to make the Company even more efficient, even more profitable and has set ambitious targets for the coming months and years, including crossing revenues of USD 3 billion in 2017-18.

I am gratified that we have several levers to gain traction with a robust business model: a large differentiated product portfolio that addresses six key therapeutic areas, with growing presence in over 150 countries; a sizeable pipeline of filings for niche products that await regulatory approval; a state-of-the-art vertically integrated manufacturing infrastructure that adds to our competitive edge; strict monitoring of compliance standards and data governance; a first-rate business relationship with our customers and business associates; and a young and vibrant team of managers and employees who showcase accountability and take pride in delivering on promises.

We have the template to do better in the future anchored by our strong balance sheet, healthy cash flow and an exciting revenue stream. We therefore are seeking incremental growth by creating a dash board of key priorities for the year ahead.

We are investing time and effort on each of these priorities to enhance our competitive position and climb the value chain. In the process, we shall ensure that we are synonymous with customer focus, outstanding reliability and expertise. We will minimize our business risks and keep revisiting our assurance standards to upgrade our reliability benchmarks. A track record of consistent, cost-efficient offerings will continue to underpin our competitive edge and strengthen the predictability of earnings. That is how we will deliver maximum value to our stakeholders.

K. Nithyananda Reddy
Vice Chairman

Dash board of key priorities for the year ahead

- add bandwidth to manage growing businesses;
- augment further on our differentiated portfolio;
- quicken the time to commercialize product approvals;
- improve reliability in our deliverables;
- automate and simplify our processes;
- grow revenues faster than cost increases;
- deliver strong and consistent cash flow; and
- re-invest to grow our businesses.

New Initiatives

Aurobindo has calibrated its growth over the years. After creating a few landmarks in active ingredients and generic formulations, the Company is now making a mark in the niche injectables segment with quick to launch initiatives and rising market share. On the strength of the in-house expertise, the Company is taking several initiatives to make an impact on a few more product segments. Each of the following product groups is likely to improve the business mix, enhance revenues and add traction to the continuing momentum of the Company.

NUTRACEUTICALS

The Company is exploring opportunities in the nutraceutical market. R&D activities have been initiated to identify and develop synthetic nutraceutical products. During 2013-14, process development work to manufacture a few products has been completed.

The Company completed the acquisition of the assets of nutritional supplement maker Natrol Inc, which was acquired for a consideration of USD 132.5 million. Natrol manufactures and sells quality nutritional supplements in the US and select international markets. It offers branded products including vitamins, minerals, and supplements; diet and weight management products; sports nutrition products; and products for hair, skin, and nails. This acquisition is a strategic move to gain an entry for Aurobindo into the growing nutraceutical segment.

The US based Natrol is a leading 35 year old nutraceuticals manufacturer with established brands and was acquired with all the manufacturing assets, personnel, commercial infrastructure including the well established brands of Natrol along with an agreement to take on certain liabilities. The due approval was obtained from authorities and the acquisition was completed on December 4, 2014. In the consolidated financial statements, the financials of the acquired entity have been integrated effective that date.

All the products are being manufactured in US and the capacity utilization is being ramped up to its potential. The focus areas for the medium term are to enhance the product portfolio, be cost competitive, increase the revenue and improve the market share.

Nutraceuticals industry itself is moving towards the pharmaceutical industry in terms of the regulatory standards and stringent needs are to be implemented. Aurobindo will strive to take advantage since the Company has the necessary expertise to ensure that regulatory requirements are met.

It is estimated that nutraceuticals business is valued at USD 30-35 billion currently and is expected to reach around 55 billion in 2020. There is enough opportunity for growth not only within US but also elsewhere globally. Aurobindo would play an active role in the industry's growth trajectory.

PEPTIDES

Peptides are naturally occurring biological molecules. They are short chains of amino acid monomers linked by peptide (amide) bonds. Aurobindo has started investing in peptide technology and is building a commercial facility with two modules commensurate with cGMP standards. Necessary equipment have been commissioned and we have developed technologies for more than ten products.

Validation batches have been completed for three peptides and sample shipments have commenced to customers for their development work. Drug Master Files are being prepared and we propose to seek a few product filings before the end of 2015-16.

The peptides presently being developed include four microsphere and liposomal injectable products for which we are working towards filing these products in 2016-17. The addressable market for the four products is about $3 billion.

On the whole, there are over 30 peptides which are available globally and Aurobindo is capable of making each of these peptides and aspires to be an important player in the premium markets. Considering the capability that we have in terms of technology as well as competency in our experienced and talented resources, Aurobindo can compete with the best players in the industry, in the near future. The revenue streams are planned to commence in 2015-16.

OVER-THE-COUNTER (OTC)

The Company develops, manufactures, markets and distributes store brand Over-the-Counter (OTC) products. The mission is to develop as many OTC products for the US retail market as possible, providing a consistent and reliable supply, at a fair price and of the highest quality.

The plans are to include Rx to OTC switch molecules, ANDA & Monograph OTC products in various dosage forms/formats - solids (tablets, capsules, soft gels), liquids, semi solids & nasal sprays. The manufacturing sites are located at New Jersey, US at Lawrenceville with facility to make liquids, semi solids & nasal sprays (about 52 million units per year); another manufacturing site is at Dayton with facility to make solids including Drug Enforcement Administration (DEA) controlled products (about 3 billion doses per year); and the third facility is set up at Jedcherla, near Hyderabad, with facility to manufacture solids (about 8 billion doses a year). This business is supported with adequate infrastructure including 200,000 sq ft of packaging & distribution facilities for solids & liquids.

70 liquid products have been developed, exhibit batches have been made for a few solids and some are undergoing stability tests. The Company has also commenced marketing a few products through well-established chain stores in the US.

Aurobindo will work hard to get a strong foothold in this competitive but attractive market.

PENEMS

Aurobindo has developed and made penem filings for four products in injectable portfolio that are administered in the pre-operating process. These are products that would be used as neuromuscular blockers while under anesthesia reversal.

We are selecting difficult to develop penem products and have expanded the capacity for lyophilised penems which is being made ready to take exhibit batches. We are working towards filing one more product within the next 12 months. The addressable market for all five products is USD 400 million in the US. Initially, the products are likely to be launched in Brazil and Mexico in 2015-16.

The Company is also exploring entering Nanospheres (in the penems segment) which have a much larger market, where the products have an addressable market of about USD 3 billion in the US.

VACCINES

Aurobindo is entering the vaccines business with a joint venture for developing pneumococcal conjugate vaccine (PCV). Presently development work is on-going on PCV through use of novel vaccine technology compressing time and cost, thereby making such vaccine available at an affordable cost. Vaccines segment is another addition to the differentiated portfolio where there are unmet needs and limited competition.

Pneumococcal conjugate vaccine is a commercially available vaccine with limited competition and a global branded market of more than USD 5 billion. Aurobindo will hold a majority stake in the JV and will fund the product development in a phased manner spanning over three years.

Development work for a few more products has commenced towards building a sizable vaccines portfolio.

ONCOLOGY & HORMONAL PRODUCTS

The Company is also in the process of developing a wide range of oncology and hormonal products. Our product capabilities would include vials, prefilled syringes and softgel capsules & tablets that are used in the hospital as well as in oncology and renal clinics.

A new R&D Centre dedicated for generic research in the field of oncology and hormones was set up in October 2013 at Hyderabad to develop anticancer drugs and hormonal products, both for solid and parenteral dosage forms. We have done our first exhibit batches for five hormone products and the dossiers are expected to be filed in 2015-16.

The tablet part of the oncology facility is completed and commissioned and we have started to run our exhibit batches. The injectable part of the oncology facility is planned to be commissioned in the later part of 2015. We are working on 15 oncology products and the plans are to prepare exhibit batches for injectables in the last quarter of 2015-16.

MESSAGE FROM THE MANAGING DIRECTOR

Making things happen

It was a high energy year for Aurobindo. As a team, we worked hard, on our strategies. We achieved what we set out to do. I am glad that the business gained further momentum with volumes on the rise, higher revenues across all geographies and despite challenges, we grew the bottom line.

We achieved record revenues, enhanced our efficiencies, met our cost reduction targets, reached higher operating profits and profit after tax. Thus, we demonstrated Aurobindo's underlying strength and ability to execute.

The consolidated revenues at ₹121,205.2 million were higher by 49.6% over the previous year; material cost to revenues was higher at 45.4%; EBIDTA at ₹26,603.0 million was 23.4% higher; profit before tax was increased by 41.4% to ₹21,678.5 million; profit after tax was higher by 34.4% at ₹15,757.7 million; and, the diluted EPS climbed to ₹54.00 from ₹40.22 in the previous year. Cash flow generated from operations was ₹12,368.1 million compared to ₹6,462.8 million in the previous year.

Every indicator demonstrates that we delivered financially. Equally, we made the long-term investments necessary to transform the Company to the next level, globally.

All our major initiatives are working to plan:

- Volumes of high-end injectables are growing with rising market share;
- Acquisition of new products from Actavis is adding to the competitive strength of Aurobindo in the West European markets;
- Natrol acquisition is fast tracking our progress in to the nutraceuticals markets;
- Existing product pipeline is robust with niche and differentiated products;
- Research is increasingly being done on more difficult to develop, complex products;
- OTC products were commercialized from our US facility;
- The portfolio of oncology and hormonal products are at an advanced stage with potential to launch in 2017-18;
- Considerable progress is being made on the development work on vaccines & inhalers, penems and peptides; and,
- The Company's products are now made available in over 150 countries.