

Leveraging science to enhance the quality of life

GlaxoSmithKline Pharmaceuticals Limited

Annual Report for the 15 months period ended 31st March 2015



# A word from the Managing Director

Consistent with GSK's mission to improve the quality of human life by enabling people to do more, feel better and live longer, your Company has over the years, endeavoured to bring the latest in pharmaceuticals, both from the parent company as well as through licensing opportunities. In the current year, a medicine for metastatic colorectal cancer, a difficult disease to treat was launched from one of our Licensor partners. In addition, given its expertise in the respiratory area, it has launched the Ventorlin Mini Spacer which is an add-on device for asthma and COPD patients. A face mask is to be used along with the Ventorlin Spacer and Inhaler to help paediatric and geriatric population suffering from asthma and COPD.

Your Company's other ambition is to provide access to its medicines to as many patients as possible. To this end, given the recent price drop on the flagship product Augmentin, your Company has taken a number of steps to ensure much wider access to the product. This has been responsibly done keeping in mind the problem of antibiotic resistance. Significant increase in the prescription share, a reflection of access, has been achieved. This has been done for other products which have been impacted by price control as well. This is a demonstration of a unique business model of the Company, where it strives to not only add value by leveraging science to enhance the quality of life of its patients, keeping in mind access pricing, but also adding value in the process to other stakeholders as an outcome.

Efforts have also been made to improve the diagnosis and treatment of thyroid diseases by not only educating healthcare professionals widely, but also patients. The whole focus on access has also reflected in the continuing emphasis on the rural initiatives to support patients in rural markets. It has been gratifying to note the success of the oncology business by providing state-of-the-art cancer treatments at affordable prices for the benefit of a large number of patients during the year. In the area of preventive health, your Company continues to be a leading provider of the widest range of vaccines to as many patients as possible with continued innovation to improve access. In this context, a cost effective extension of the market leading pneumococcal vaccine in the form of vials was launched to help more children.

Given its healthcare heritage, your Company's focus on CSR has been in the area of access to healthcare, preventing infant and maternal mortality, apart from other health initiatives.

A recent transaction with Novartis will, during the course of the coming year, see the transfer of the oncology business to Novartis and in return, your Company will receive a market leading vaccine for dog bites, apart from addition to its portfolio of vaccines for meningitis.

Over the last few years, an attempt has been to broad base the offerings of your Company to increase its healthcare impact footprint through entry in new therapeutic areas as well as channels. This will benefit many more patients in the time to come.

Above all, your Company remains a benchmark in terms of compliance and ethical behaviour, and in the current year, a novel incentive system for its frontline field force which is not linked to direct sales was introduced. Many initiatives in this area are planned in the time to come.



GSK is a company that puts people at the heart of everything that we do to help them do more, feel better and live longer.

However, even today, millions of people still do not have access to basic healthcare and there are thousands of diseases without effective treatments. We want to change this and are working to develop innovative new medicines and vaccines while also finding new ways to get them to everybody who needs them.

# Leveraging science to enhance the quality of life

At GSK, the aim is to improve quality of human life by putting people at the heart of everything that we do to help them do more, feel better and live longer. The Company develops and makes medicines to treat a broad range of acute and chronic diseases. GSK India continues to be a leader in many of the therapy areas in which it provides healthcare solutions to patients. By straddling the domains of preventive and curative, the Company effectively leverages the power of science to enhance the quality of life.

The year has witnessed key brands in the Mass Markets portfolio such as Zinetac, Calpol, Neosporin, Betnesol, Zyloric, Zentel, and Cetzine maintain dominant market leadership positions. In keeping with the Company's vision of improving access and reach of medicines to as many patients as possible, the Company targeted the adjacent and direct category competition to drive unit sales. The rural initiative, REACH, is being expanded further to ensure prescription leadership and support to patients in rural markets.

The Mass Specialty business continued its growth trajectory with Augmentin regaining the No. 1 position in the amoxy-clav market with a remarkable recovery despite the NLEM (National List of Essential Medicines List) impact.

To help rapid and early diagnosis of Thyroid disorders, GSK conducted around 2,600 one-to-one Scientific Promotion Meetings (SPMs) on "Maternal Thyroidism" and translated Thyroid guidelines to equip HCPs for appropriate disease management. In addition, the team also conducted disease awareness initiative on Congenital Hypothyroidism (CH) in various cities.

Apart from this, Ceftum also registered a double digit prescription growth in major specialty areas, while the new launch, Avamys showed a positive value growth and became the 6th brand among 52 brands in INCS (intranasal corticosteroids) market with a market share of 5.8%.

In the Specialty business, the Company continued to retain a strong leadership position in Dermatology. Within clinical dermatology, brands like Betnovate, TBACT, Tenovate sustained strong growth while the cosmetology portfolio of brands comprising Ansolar, Oilatum and Physiogel continued to benefit increasing number of patients requiring these therapeutic options. Creating unique platforms for patients and physicians with programmes like SKIN SENSE (aimed at enabling patients and physicians for early diagnosis of skin problems) and SPEAK campaign (aimed at spreading awareness for conditions like Psoriasis and Eczema) resonated with its strong patient focused approach. The Oncology division's vision to improve patient care in cancer management at affordable prices has benefited almost 7,000 patients during the year. Apart from innovative solutions in the form of key brands such as Tykerb, Revolade, Votrient and Hycamtin used to treat various types of cancer, the year saw the division driving unique and unstinted commitment to patient care for brands like XGEVA (indicated for Skeletal related disorders) with programmes like "SWASTI" aimed at improving patient access. This division also launched Vectibix (in licensed from AMGEN) a novel innovative monoclonal antibody for patients with certain types of metastatic colorectal cancer.

The Respiratory team made inroads into the asthma / Chronic Obstructive Pulmonary Disorder (COPD) category with products like Seretide and Ventorlin, while the Evohaler device with dose counter continued to create a new mark in the category for patients with asthma. The CNS team created unique awareness campaigns for patients and physicians in areas such as Epilepsy and Bipolar Disorders. Lamictal became the second largest prescribed brand of Lamotrigine in Epilepsy. In the Cardiology division, focus on areas like hypertension and dyslipidemia continued with brands like Benitec, Rosutec, Carzec and Volibris. The team organised screening camps across the country to enable physicians and patients to diagnose conditions like dyslipidemia early and thereby improve treatment outcomes.

In the area of preventive healthcare, GSK Vaccines continues to be the No.1 vaccines Company in the private vaccines market in India. In keeping with the Company's philosophy of offering access to vaccines to as many patients as possible, a more cost effective extension of the flagship pneumococcal vaccine in the form of vials was launched, which will help protect more kids from pneumococcal diseases (one of the leading causes of infant mortality in India).

# New Products launched in 2014-15



**Vectibix** is a fully human monoclonal antibody for the treatment of patients with metastatic colorectal cancer (mCRC). **Vectibix** is a novel anti-epidermal growth factor receptor (EGFR) drug and has been granted an approval for a controlled indication in all 3 lines of mCRC based on the RAS gene status of the patient.

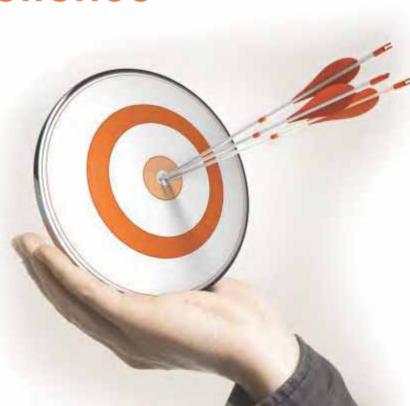
**Ventorlin mini spacer** is a device to be used along with Ventorlin Inhaler as an add-on device for asthma and COPD Patients. Face mask is to be used along with Ventorlin mini spacer and Ventorlin Inhaler especially for paediatric and geriatric population suffering from asthma and COPD.

# Mini Space

# Sustaining Excellence

Enhancing the quality of life by ensuring seamless supply of our medicines to patients is the hallmark of a responsible organisation.

The India manufacturing and supply operations undertook various global programmes to ensure smooth operations throughout the year. The Nashik site is being upgraded with a special focus on Good Manufacturing Practices (GMP), Safety and Sustainability. Further, the site has embarked on the GSK Production System (GPS) Deployment journey in line with Global Manufacturing and Supply initiative to achieve Zero Accidents, Zero Defects & Zero Waste with an ambitious target to deploy GPS to 50% of direct value stream zones in 2015.





### **Board of Directors**

(As on 18.05.2015)

Chairman D. S. Parekh

Vice-Chairman V. Thyagarajan

#### Managing Director

Dr. H. B. Joshipura

#### Directors

A. Aristidou (w.e.f. 01.12.14)
R. R. Bajaaj
Ms. A. Bansal
P. V. Bhide
S. Harford (upto 18.05.15)
M. B. Kapadia (upto 30.11.14)
N. Kaviratne CBE
R. Krishnaswamy
P. V. Nayak
A. N. Roy
R. C. Sequeira
R. Simard (w.e.f. 18.05.15)
D. Sundaram

#### Audit Committee

D. Sundaram – Chairman P. V. Bhide N. Kaviratne CBE P. V. Nayak D. S. Parekh V. Thyagarajan

#### Stakeholders' Relationship Committee D. S. Parekh – Chairman R. R. Bajaaj P. V. Bhide

Dr. H. B. Joshipura

#### Nomination & Remuneration Committee N. Kaviratne CBE – Chairman Ms. A. Bansal D. S. Parekh V. Thyagarajan

Corporate Social Responsibility Committee D. S. Parekh – Chairman Ms. A. Bansal Dr. H. B. Joshipura A. N. Roy

#### Management Team

Managing Director Dr. H. B. Joshipura

#### Executive Directors A. Aristidou – Chief Financial Officer R. C. Sequeira – Human Resources R. Krishnaswamy – Technical

**Commercial Head** 

S. Venkatesh – Pharmaceuticals Executive Vice-Presidents B. Akshikar – Pharmaceuticals R. Bartaria – Pharmaceuticals H. Buch – Pharmaceuticals K. Hazari – Legal & Corporate Affairs

#### Vice-Presidents

Dr. (Ms.) V. Desai – *Medical & Clinical Research* S. Dheri – *Biologicals* S. Khanna – *Finance* 

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Factory Ambad, Nashik

Solicitors Gagrat & Co. General Manager – Administration & Company Secretary A. A. Nadkarni

Auditors Price Waterhouse & Co Bangalore LLP

Cost Auditors R. Nanabhoy & Co.

Bankers Citibank N.A. Deutsche Bank HDFC Bank Limited Hongkong and Shanghai Banking Corporation Limited

#### **Registrars & Share Transfer Agents**

Karvy Computershare Private Limited Unit: GlaxoSmithKline Pharmaceuticals Limited Karvy Selenium Tower B, Plot No. 31 & 32 Gachibowli, Financial District Nanakramguda, Serilingampally Hyderabad, Telangana-500 032 Tel. No.: 040 67162222 Fax No.: 040-23001153 Email : einward.ris@karvy.com

#### Share Department

Dr. Annie Besant Road Mumbai 400 030 Telephone: 022-24959415/434 Fax: 022-24981526 Email: ajay.a.nadkarni@gsk.com

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Note: Members are requested to kindly bring their copy of the Annual Report to the Meeting.

# **Performance Summary**

(Amounts in Rupees Lakhs)	15 Months Ended	2013 *	2012 *	2011 *	2010	2009	2008	2007	2006	2005
	March 2015 *									
PROFIT AND LOSS ACCOUNT										
Sales	3358,54	2593,39	2669,97	2391,73	2155,08	1912,77	1751,56	1712,84	1677,57	1575,89
Profit before tax	800,51	703,17	994,78	921,60	867,27	758,48	679,90	606,73	555,95	477,91
Tax	(278,10)	(226,19)	(317,59)	(290,24)	(285,89)	(253,59)	(231,54)	(209,94)	(194,23)	(171,63)
Profit after tax and before exceptional items	522,41	476,98	677,19	631,36	581,38	504,89	448,36	396,79	361,72	306,28
Exceptional items (net of tax)	(50,76)	24,90	(99,93)	(200,76)	(17,69)	7,40	128,21	140,87	183,79	195,80
Net Profit	471,65	501,88	577,26	430,60	563,69	512,29	576,57	537,66	545,51	502,08
Balance brought forward	1099,94	1142,95	1110,59	1164,53	1049,23	882,41	759,89	632,75	441,19	259,75
Dividends	(529,39)	(423,51)	(423,51)	(381,16)	(338,81)	(254,11)	(338,81)	(304,93)	(262,58)	(237,17)
Tax on distributed profit	(107,77)	(71,19)	(63,66)	(60,32)	(53,21)	(40,13)	(57,58)	(51,82)	(36,82)	(33,26)
Transfer to General Reserve	(47,16)	(50,19)	(57,73)	(43,06)	(56,37)	(51,23)	(57,66)	(53,77)	(54,55)	(50,21)
Balance carried forward	887,27	1099,94	1142,95	1110,59	1164,53	1049,23	882,41	759,89	632,75	441,19
BALANCE SHEET										
Equity Capital	84,70	84,70	84,70	84,70	84,70	84,70	84,70	84,70	84,70	84,70
Reserves	1766,96	1932,49	1925,31	1835,23	1846,11	1674,45	1456,39	1276,21	1110,01	863,91
Borrowings	3,12	4,14	4,59	4,91	5,16	5,42	5,65	5,77	5,54	4,85
-	1854,78	2021,33	2014,60	1924,84	1935,97	1764,57	1546,74	1366,68	1200,25	953,46
Fixed Assets	238,28	161,93	133,19	115,32	117,65	114,17	100,35	92,90	94,46	96,94
Investments	47,67	57,67	102,58	159,80	160,35	190,91	751,87	1333,32	1139,41	913,06
Net Deferred Tax	82,91	92,11	86,54	61,47	56,40	44,69	29,60	20,14	24,61	29,76
Net Assets (Current and Non-Current)	1485,92	1709,62	1692,29	1588,25	1601,57	1414,80	664,92	(79,68)	(58,23)	(86,30)
	1854,78	2021,33	2014,60	1924,84	1935,97	1764,57	1546,74	1366,68	1200,25	953,46
* 15 Months Ended March 2015, and Years 2013, 2012 and 2011 based on Revised Schedule VI										
OTHER KEY DATA										
Rupees per Rs.10/- Equity Share										
DIVIDENDS	62.50	50.00	50.00	45.00	40.00	30.00	22.00	18.00	17.00	14.00
SPECIAL ADDITIONAL DIVIDEND		_		_		—	18.00	18.00	14.00	14.00
TOTAL	62.50	50.00	50.00	45.00	40.00	30.00	40.00	36.00	31.00	28.00
EARNINGS PER EQUITY SHARE	55.68	59.25	68.15	50.84	66.55	60.48	68.07	63.48	64.40	58.51
BOOK VALUE	218.61	238.16	237.31	226.67	227.96	207.69	181.95	160.67	141.05	112.00
Number of employees	4657	5034	4706	5055	4338	4006	3722	3620	3850	4016

NO

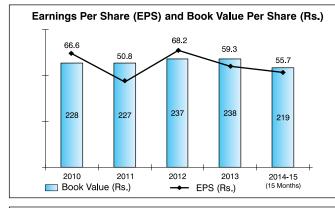
ES The Company has divested its Fine Chemicals business on 30<sup>th</sup> September, 2007 and its Animal Health business on 31<sup>st</sup> July, 2006. The Company has bought back and extinguished 26,19,529 equity shares during 2005. 1.

2.

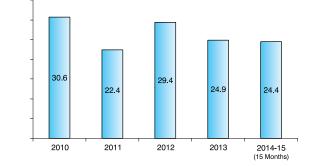
The accounting year of the Company has been changed from January-December to April-March with effect from the current year. Consequently, the current year's financial statements are for the 15 months from 1<sup>st</sup> January, 2014 to 31<sup>st</sup> March, 2015. The current year's figures therefore, are not comparable with those of the previous year. Figures have been adjusted/regrouped wherever necessary in line with the financial statements, to facilitate comparison. 3.

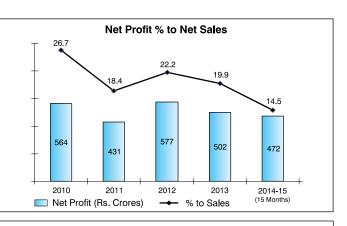
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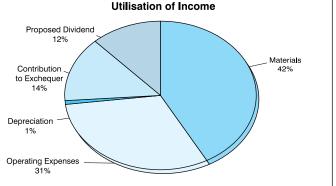
## Charts













## **Directors' Report**

The Directors have pleasure in submitting their Report for the fifteen months period ended 31<sup>st</sup> March 2015. The Accounting year of the Company has been changed from January-December to April-March in line with the provisions of the Companies Act, 2013, which prescribe a uniform financial year. Accordingly, current year's Annual Accounts and Report of the Company are for a period of fifteen months from 1<sup>st</sup> January 2014 to 31<sup>st</sup> March 2015. These figures, therefore, are not comparable with those of the previous year ended 31<sup>st</sup> December 2013.

#### 1. Financial Results & Dividend for the fifteen months ended 31st March 2015

			15 months ended 31 <sup>st</sup> March 2015 Rs. in lakhs	Year ended 31 <sup>st</sup> December 2013 Rs. in lakhs
Sale of Products (Net of Excise Duty)			3253,40.98	2520,17.24
Other Operating Revenue			34,16.82	25,97.50
Revenue from Operations			3287,57.80	2546,14.74
Profit before Exceptional Items and Tax			800,50.43	703,16.57
Less: Exceptional Items			(51,88.14)	26,15.46
Profit before Tax			748,62.29	729,32.03
Less: Tax expense			276,97.71	227,43.79
Net Profit for the year			471,64.58	501,88.24
Add: Opening Surplus brought forward from	1142,94.60			
Less: Appropriations:				
Proposed Dividend (including tax on	distribut	ed Profits)	637,16.78	494,70.75
Transfer to General Reserve			47,16.46	50,18.82
Closing Surplus carried forward			887,24.61	1099,93.27

#### 2. Dividend

The Directors recommend a Dividend of Rs. 62.50 per Equity Share for the fifteen months period (previous twelve months period: Rs. 50 per Equity Share). If approved by the Shareholders at the Annual General Meeting, the Dividend will absorb Rs. 529 crores. The Dividend Distribution Tax borne by the Company will amount to Rs. 108 crores.

#### 3. Management Discussion and Analysis

#### (a) Finance and Accounts

Sale of Products (net of Excise Duty) increased by 29% for the fifteen months period 31<sup>st</sup> March 2015 as compared with the previous year twelve months period ending 31<sup>st</sup> December 2013. The fifteen months period was impacted by the full year effect of the Prices Control Order introduced in mid 2013. The Pharmaceuticals business continues to be affected by supply constraints mainly from local supplies during the period to meet the demands of the market.

The Gross Margin has remained flat compared to last year mainly driven by the full period absorption of the Price Control Order. Other expenses such as field force recruitment were restricted to segments that required resourcing for growth and significant investments continued to be made for the consumer brands lodex and Ostocalcium which are marketed by GlaxoSmithKline Consumer Healthcare Limited.

Profit before Exceptional items and Tax amounted to 25% of Net Sales for the fifteen months period, compared to the twelve months previous year of 28%. Profit after Exceptional items and Tax for the corresponding periods amounted to 14% of Net Sales for the fifteen months

period, as compared to 20% in 2013. This is mainly due to the profit on disposal of property in 2013 of Rs. 21.18 crores (pre-tax) as compared to Exceptional costs of Rs. 52 crores in the current fifteen months period. These costs include Rs. 21.51 crores relating to actuarial loss on employee benefits and a charge of Rs. 30.37 crores for the rationalization of capital assets for one dosage form at the Nashik facility.

Cash generation from Operations continued to remain favourable this year and is in line with business performance. Your Company continues to look for ways and means of deploying accumulated cash balances which remain invested largely in bank deposits.

Your Company has not accepted any fixed deposits during the year. There was no outstanding towards unclaimed deposit payable to depositors as on 31<sup>st</sup> March 2015.

## Key Comparable Figures for the 12 months period ending April-March 2015 as compared to April-March 2014

As mentioned above, the audited results for the fifteen months period ended 31<sup>st</sup> March, 2015 are not comparable with those of the previous year ended 31<sup>st</sup> December, 2013. However, on a memorandum basis, for comparative purposes, unaudited results for the twelve months ended 31<sup>st</sup> March, 2015 are given below:

- Net Sales at Rs. 2653.4 crores (2013-14: Rs. 2488.1 crores) grew by 6.6% with a Gross Margin improvement of 1.8% to 54% in the current period.
- Profit from operations (excluding Other Income and Exceptional items) at Rs. 499.3 crores (2013-14: Rs. 447.9 crores) grew at 11.5%, enhancing Operational profit margin by 0.8% to 18.8%.
- Profit before tax at Rs. 371.5 crores (2013-14: Rs. 418.4 crores) decreased by 11.2% mainly due to exceptional gains in 2013-14 of Rs. 21.18 crores arising from profit on sale of property and Rs. 5.78 crores from actuarial gain on employee benefits, as compared to an exceptional charge in 2014-15 towards the actuarial loss on employee benefits (Rs. 22.5 crores) as well as charge of Rs. 30.4 crores towards the rationalization of capital assets for one of the dosage forms at a manufacturing facility.

#### **Novartis Transaction**

In April 2014, GlaxoSmithKline Plc (GSK), London, UK, entered into three inter-conditional agreements with Novartis AG (Novartis), Basel, Switzerland. In one such agreement GSK agreed to acquire Novartis's Vaccines Business (excluding influenza vaccine) and manufacturing capabilities and facilities from Novartis, and in the second agreement, GSK agreed to sell the rights of its Marketed Oncology Portfolio, related R&D activities and AKT Inhibitors currently in development to Novartis. Globally, these transactions with Novartis were completed on March 2<sup>nd</sup>, 2015.

In connection to the above transactions, the GlaxoSmithKline Pharmaceuticals Limited ("Company") Board in its meeting held on 12<sup>th</sup> February 2015, approved the transactions on an Asset Sale basis with Novartis Healthcare Private Limited, a private unlisted Company incorporated under the Companies Act 1956. Pursuant to the global deal, the Company will have its distribution rights terminated for the oncology portfolio and it will acquire distribution rights for vaccines portfolio. The transaction is expected to be profit neutral for the Company.

GSK Plc and Novartis AG have obtained the approval from Competition Commission of India. The Company and Novartis Healthcare Private Limited have filed separate applications for approval with Foreign Investment Promotion Board (FIPB). The closing of the asset sales between the companies is subject to the receipt of all applicable legal and regulatory approvals, consent, permissions and sanctions as may be necessary from the concerned authorities.

#### (b) Pharmaceuticals Business performance and outlook

Your Company continues to enjoy a leadership position in the therapy areas in which it provides health care solutions to patients.

The speciality business continued to make rapid strides during the year with strong leadership position in therapy areas like Dermatology. Within the Clinical dermatology area, brands like



Betnovate, TBact and Tenovate sustained strong growth while the Cosmetology portfolio of brands like Ansolar, Oilatum and Physiogel continued to benefit increasing number of patients requiring these therapeutic options. The cornerstone of the Dermatology business continues to be a strong patient focused approach. This division created unique platforms for patients and physicians with programs like SKIN SENSE (aimed at enabling patients and physicians for early diagnosis of skin problems) and SPEAK campaign (aimed at spreading awareness for conditions like Psoriasis and Eczema).

The Oncology team articulated vision to improve patient care with affordability benefited over 7000 patients during the year. Apart from the innovative solutions in the form of key brands like Tykerb, Revolade, Votrient & Hycamtin used to treat various types of cancer, the year saw this division driving unique and unstinted commitment to patient care for brands like Xgeva (indicated for Skeletal related disorders) with programs like "SWASTI" aimed at improving patient access. This division also launched VECTIBIX (in licensed from AMGEN), a novel innovative monoclonal Antibody for patients with certain types of metastatic colorectal cancer.

The Respiratory team made new inroads for patients with asthma/Chronic Obstructive Pulmonary Disorder (COPD) with products like Seretide and Ventorlin. The "EVOHALER" device continues to create a new mark in the category for patients with asthma with dose counter. The Central Nervous System (CNS) team created new and unique awareness campaigns for patients and physicians in areas like Epilepsy and Bipolar Disorders. "Lamictal" became the 2<sup>nd</sup> largest prescribed brand of Lamotrigine in Epilepsy. The Cardiology team continued to focus on areas like hypertension and dyslipidemia with brands like Benitec, Rosutec, Carzec and Volibris. This team deployed screening camps across the country as a patient awareness initiative to enable physicians and patients to diagnose conditions like dyslipidemia early and thereby improve treatment outcomes.

The Mass Speciality business continued its growth trajectory and "Augmentin" the flagship brand of your Company regained the No. 1 position in the "Amoxy Clav" market, showing a remarkable recovery after it was bought under the NLEM (National List of Essential Medicines List) list and under DPCO 2013 with an annual prescription growth of 46%. Your Company used the opportunity of the price control induced downward correction to improve access to patients and improve outcomes as is evidenced by the growth of prescriptions. The team remains focused to enable Augmentin achieve the status of volume leader in the market and be the highest prescribed brand in the "Amoxy Clav" market. Eltroxin, the Company's flagship therapeutic solution for Thyroid management achieved an annual growth of 5%. Many recent advances in prevention and management of Hypothyrodism need to be translated into practice for Health Care Professionals (HCPs) in Tier 1 and Tier 2 cities.

To help rapid and early diagnosis of Thyroid disorders, your Company undertook several 1:1 Scientific Promotion meetings on "Maternal Thyrodism" and "Translating of Thyroid guidelines". As many as 2600 such meetings took place during the year. The 'One to One' SPMs were a good example in our pursuit of being a patient focused organisation and taking a lead to 'door deliver' knowledge to equip HCPs for appropriate disease management. The Disease Awareness initiative on Congenital Hypothyroidism(CH) was conducted in many cities during the year. Feedback from doctors was encouraging as they believed that the Company is spreading awareness in the society and thus improving the future of children with CH. Ceftum also registered a double digit prescription growth in major specialities areas. The new launch, "Avamys" showed a positive value growth and became No. 6 brand amongst 52 brands in INCS market with a market share of 5.8%.

The key brands in Mass markets like Zinetac, Calpol, Neosporin, Betnesol, Zyloric, Zentel, and Cetzine all have maintained dominant market leadership positions. Brands like Betnesol and Zinetac sell almost double the number of units as compared to total population of the country. Your Company's strategy was to expand the access opportunities to patients by targeting the adjacent and direct category competition and drive unit Sales consistent with the Company's policy of improving access to their medicines to as many patients as possible. The rural initiative is being expanded further which will ensure prescription leadership and support to patients in rural markets.

In the area of preventive healthcare, GSK Vaccines continues to be the No. 1 vaccines Company in the private vaccines market in India. Again, consistent with the Company philosophy of offering access to enable as many patients as possible to use them, a more cost effective presentation of a flagship pneumococcal vaccines in the form of vials was launched which will help protect more kids from pneumococcal diseases which is one of the leading causes of infant mortality in the country. Sudden changes in interpretation of licensing requirements coupled with constraints of supplies from the Parent's facility led to shortages of number of vaccines through the year. Notwithstanding that, the measure of the ability of your Company's vaccines to benefit children and women health is indicated in the healthy growth registered. The vaccines team is gearing up for the launch of the combined MMRV vaccine- the first of its kind to be launched in India in 2016.

Exports recorded a sales turnover of Rs. 6.3 crores for the fifteen months period ended 31<sup>st</sup> March 2015.

#### (c) Opportunities, risk, concerns and threats

The health budget of the Government saw an overall decline of 5.7 percent, however, it has announced the move towards Universal Health Assurance with a set of drugs, diagnostics and services to be made free of cost to the population. State governments are expected to play a larger role in pooling resources and taking the health agenda forward. Your Company's early initiative of having a tender focused team should help in supporting this initiative in a small way.

Importantly the Insurance Bill was approved in the Parliament replacing the previous ordinance that increased FDI in the insurance sector to 49% from 26%. The approval in the Parliament brings more certainty to the foreign investor and from a health insurance view point, the potential investment flow and the increase in foreign holding in the insurance ventures can shape the health insurance sector in a faster pace than it used to be before. The strong growth in demand for quality healthcare over the last few years has been driven by the opening of the health insurance sector. Support for this sector will continue to strengthen demand for quality healthcare of pharmaceuticals.

With the expansion of Jan Aushadhi schemes the government is also likely to explore possible legislative changes to increase generic prescription. Whilst there is a positive sentiment in the Pharmaceuticals Industry further guidance is required on formalising and implementing the schemes.

The Drug Price Control Order (DPCO) which had a significant impact on the fortune of your Company in 2013 has resulted in widening the access of medicines of your Company to a larger pool of patients then before and the outlook for continued strong growth continues to remain positive.

#### (d) Regulatory Affairs, Clinical Research, Medical Affairs and Medical Governance

During the year under review, in order to support the commercial availability of new drugs that would benefit and improve the quality of life of Indian patients suffering from various diseases, your Company submitted several applications for New Products in India to the CDSCO (Central Drugs Standard Control Organization), Ministry of Health and Family Welfare, Government of India. After a thorough review of these applications, your Company has received approval for some of these products from CDSCO, which will enable timely access to new and innovative therapeutic options to patients in our country.

Some of the innovator products approved by the regulatory agency in India during the year under review include a biological oncology product of atumumab (Arzerra) for the treatment of patients with refractory or previously untreated chronic lymphocytic leukaemia (CLL), another biological product denosumab 60 mg/ml (Prolia) for treatment of post-menopausal osteoporosis in women as well as male osteoporosis, a line extension for micafungin injection (Mycamine 100 mg) for treatment of systemic fungal infections by candida and aspergillus sp., a new combination vaccine for prophylaxis of measles, mumps, rubella and varicella (MMRV) infections (Priorix Tetra), new indication for panitumumab (Vectibix) for use in first line and second line therapy of colorectal cancer (CRC), new indication for eltrombopag (Revolade) for use in patients with Hepatitis C patients for treatment of thrombocytopenia, new indication for pazopanib (Votrient) for treatment of advanced soft tissue sarcoma, expansion of indication for use of lapatinib (Tykerb) in combination with trastuzumab for treatment of metastatic breast cancer, expansion of label of varicella vaccine (Varilrix) to include 2-dose vaccination schedule