



Cadila Healthcare Limited  
Annual Report 2013-14



***RESURGE***

This is the year of Resurge.

We are **UNLEASHING** our energies.

We are **UNLOCKING** new ideas.

We are **UNIFYING** expertise.

We are **UNEARTHING** new realms.

We are innovating **UNIQUE** therapies.

We are developing an **UNMATCHED** product pipeline.

We, with our '**U-PHORIA**' for life, are creating healthier communities, globally.

*We are resurging to optimise value for*



'U-PHORIA' is a specially coined term to capture the spirit of resurgence and euphoria of 16000 Zydans from across the globe.

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<b>ZYDUS BIOLOGICS</b>	Survey No. 40P, 23, 25P, 42, 37, Opp. Ramdev Masala, Sarkhej-Bavla N.H.No. 8A, Changodar, Ahmedabad.	
<b>SEZ UNIT</b>	Plot No. 1/1A & 2, PHARMEZ, Sarkhej-Bavla N. H. No. 8A, Village – Matoda, Taluka Sanand, District-Ahmedabad.	
<b>ZYDUS RESEARCH CENTRE</b>	S. No. 396/403, Village Moraiya, Taluka Sanand, District-Ahmedabad.	



*Mr. Ramanbhai B. Patel*

Founder Chairman, Zydus Cadila  
August 19, 1925 – September 19, 2001

It was a call for resurgence and self-sufficiency in drugs and pharmaceuticals in a newly independent India that led to the setting up of the organization in 1952. This guiding spirit and pioneering vision of the late Founder Chairman, Mr. Ramanbhai B. Patel continues to inspire us as we innovate to bridge unmet healthcare needs.



The year of Resurge, is a year of refocussing energies to aim higher and move faster. It's a year dedicated to seeking new levels of excitement through novel ideas and approaches. It's a year of commitment for 16000 Zydans who have dedicated themselves to raise the bar of performance and shine out with their contributions. It's a year full of moments that will strengthen the bond with the stakeholders as we create U-phoria by unleashing value.

It's a call for action, to make every effort count and go the extra mile. Resurge is about challenging ourselves and enabling peak performance and realising our aspirations.





India's largest, fully automated, 11000 litre state-of-the-art monoclonal antibody production facility at Changodar Ahmedabad

## Highlights of Operations - 2013-14

### Home Markets

#### India

- Launched Lipaglyn (Saroglitazar), the first New Chemical Entity (NCE), discovered and developed indigenously by an Indian pharmaceutical company.
- Maintained strong leadership positions in the represented markets of cardiology, gynaecology, gastro intestinals and respiratory therapy areas, while in the dermatology segment, gained two positions from 6<sup>th</sup> rank last year to the 4<sup>th</sup> rank this year.
- Launched over 75 new products (including over 45 line extensions) in India, of which 19 were first in India.
- Overall, the formulations business in India registered a growth of 6.1%, higher than the overall market growth and posted sales of Rs. 24,644 Mio.

#### US

- Filed a record 50 ANDAs with the USFDA during the year, taking the cumulative ANDA filings to 227.
- Launched 7 new products in the US market.
- The US business posted sales of Rs. 21,704 Mio., up by 44 %.

#### Brazil

- Undertook several initiatives in the areas of optimising the cost of operations, inventory management and sales force effectiveness.
- Overall, the Brazil operations posted sales of Rs.2,353 Mio.

#### Mexico

- Commenced commercial operations in June 2013 with launch of 7 products.
- Posted sales of Rs.109 Mio. in Mexico.

### Other Markets and Businesses

#### Europe

- Consolidated the business in France by restructuring the product portfolio and customer base which helped in improving overall profitability. Growth in Spain was almost in line with the market growth.
- Launched 8 new products in the French generic market, of which, two were Day-1 launches. In Spain, launched 12 new products, including one Day-1 launch.

- Overall, the European business posted sales of Rs. 3,902 Mio. up by 6%.

#### Emerging Markets

- Launched more than 35 new products in the key markets of Asia Pacific, Africa and Middle East during the year.

- Overall, the Emerging Markets business posted sales of Rs. 3,592 Mio. during the year, up by 15%.

#### Consumer Wellness

- Sugar Free, India's leading sugar substitute, continued to maintain dominant position with a market share of more than 93%.
- In the EverYuth category, continued thrust on new product launches to consolidate the brand position and minimise the impact of slowdown.
- In the Nutralite category, launched a lower priced variant - 'Nutralite Yummy' in North India.
- Zydus Wellness Ltd. registered sales of Rs. 4,296 Mio. up by 5% and net profit of Rs. 965 Mio.

#### Animal Health

- Introduced a range of specialty products for companion animals through a separate division 'Petz' to focus on growing pet care needs.
- Launched 11 new products in India.
- On a consolidated basis, animal health business posted sales of Rs. 2,754 Mio., with a growth of 17% during the year.

#### API

- Filed 10 DMFs with the USFDA, taking the cumulative US DMF filings to 117.
- API business grew by 13% and posted sales of Rs. 3,497 Mio.

#### JVs & Alliances

- Zydus Hospira JV successfully completed audits from the regulatory authority of Japan and the Korean FDA.
- Zydus Hospira JV also completed successful inspections from the ISO/OHSAS.

### New Technologies and NCE

- Initiated Phase III clinical trials for one of the monoclonal antibodies (mAb) and completed Phase I clinical trials for one of the mAbs.
- Received regulatory approval to conduct Phase III clinical trials for one more mAb.
- Received regulatory approval to conduct clinical trials for global development of one of the first generation biosimilars, which is currently being marketed in India.

- On the novel biologics front, completed Phase I clinical trials in India for both PEGEPO and Rabimabs.
- On the NCE front, filed a US-IND for ZYDPLA 1, a novel, next generation orally active, small molecule DPP-4 inhibitor to treat Type 2 Diabetes.
- Development of different vaccines progressed well with ten vaccines in the clinical development phase.

### Manufacturing Operations

- Moraiya formulations facility was awarded the 'Gold Award – Pharma Sector, Mega Large Business' by The Economic Times and Frost & Sullivan for achieving operational excellence.

### Financial Highlights

- Gross sales revenue was up by 15% y-o-y to Rs. 72 bn from Rs. 62.8 bn last year.
- Earnings before interest, depreciation and tax grew by 7% to Rs. 12,002 Mio. from Rs. 11,251 Mio. last year.
- Net profit was up by 23% to Rs. 8,036 Mio. from Rs. 6,535 Mio. last year.
- Return on net worth stood at 25.6%, an improvement of 2% over the last year.



## Chairman's Message

Dear Shareholders,

This was a year when we launched 'Resurge' a call to examine and explore the myriad in which we can catapult Zydus to the next phase of strategic growth. How does a company which has overcome many challenges and successfully remained on the growth path, Resurge and take its growth trajectory to a new level? This is a question we asked ourselves. We also asked ourselves the question: "How have we, as an organisation been able to achieve what we have been able to do together?" The answer was quite simple. The collective spirit of the people who make the organisation, the exciting and the differentiated ideas that they bring to their work, the processes that have enabled us to connect seamlessly, and the shared goals and legacy to achieve the impossible – all of this has scripted our journey of growth and transformation. Resurge is about taking the next leap forward, opening up the space for ideas and thoughts that are game changers, to excite people and pool in their creative energies, inviting the leadership team to go beyond and help their teams achieve more, to emerge bolder and stronger on the achievement canvas and enable an invigorating environment that challenges one's imagination.

All through these years, we at Zydus have been focussed on addressing a dual challenge: to perform in the short term while making some bold, transformative moves to realise future growth opportunities and create long-term shareholder value. Our journey of resurgence which began in 2013 was no different. We stepped up our investments in promising markets and technologies. We boosted our investment in research and development to build long-term, differentiated platforms. We focussed on making our business more efficient, and we began to align our global operating structure to fully leverage the scale of Zydus.

Our goal is to aim higher, move faster and perform better than ever before. Our strategies and the review mechanisms ensure that we remain performance-driven and goal focussed and operations remain sustainable as we accelerate our growth aspirations. The next evolution of the organisation builds on the strong record of achievement. It raises the bar on business health and profitability and puts more emphasis on profitable growth.

As we move ahead our priority will be to

Accelerate our growth agenda

Optimise our go-to-market strategies

Integrate - Collaborate – Value Add

Look at cost optimisation in all that we do

Sharpen our focus on innovation

## Bringing High Energy to Operations

Our US business was the key driver of growth. We are currently the 8th largest generic company in the US in terms of prescriptions. The most satisfying moment was when our US subsidiary won the 'Service Level Excellence' award during the year with an overall customer service level exceeding 99%. It was a record achievement with 50 ANDA filings with USFDA and it was the collaborative effort of teams across the organisation which made this happen. In Mexico, where we commenced operations, we have been understanding the market dynamics and hope to lay a strong foundation for the business in the years to come. Globally, we have been able to make inroads and look forward to building on this in the years to come.

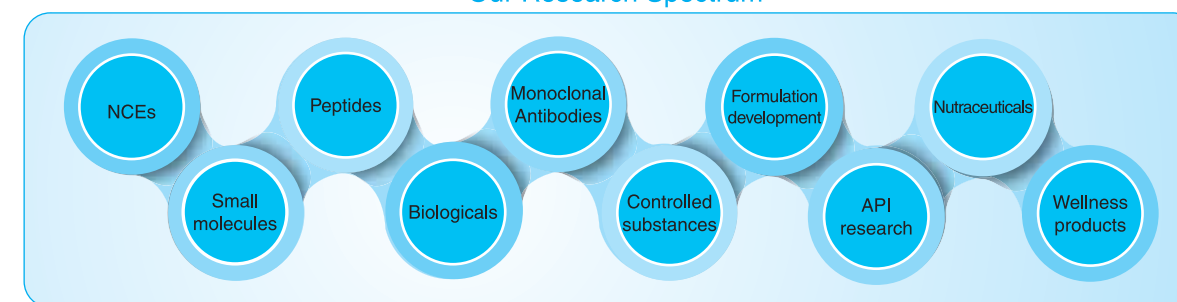
Our India formulations witnessed a historic milestone with the launch of Lipaglyn™ Saroglitazar which is the first NCE discovered and developed indigenously by an Indian pharma organisation in September 2013. We maintained leadership positions in cardiology, gynecology, gastrointestinal and respiratory therapy areas in our represented markets. In the dermatology space we improved our ranking from 6<sup>th</sup> rank last year to 4<sup>th</sup> rank. As one of the leading players in the market, we will continue to focus on therapy management, portfolio mix and brand building efforts.

Cost optimisation focus at Zydus has been relentless with each wave of it becoming more successful than the one before. The PRISM programme is well on track and has achieved its targeted savings during the first year of its implementation phase. The scope of PRISM was further expanded during the year to address all indirect spends as well.

## Nurturing an Innovation Culture

There are abundant opportunities for innovation waiting to be explored. At every level – strategies, brands, marketplace, therapies, technologies, processes, cost efficiency - there are ideas that can make a significant improvement or a difference. All we need to do is to align those with our overarching goal, add them to our canvas, and back it up every inch of the way with action. The promise of idea becomes a potential reality. The ideas that excite us most are the ones which have the power to transform our world.

### Our Research Spectrum



In January 2014, we had an Innovation forum which had 1200 researchers across 19 sites converging to look at differentiated medicines for the future. From APIs to vaccines, biosimilars and niche technologies, we looked at different ideas and concepts that can transform the marketplace. It's only a relentless flow of innovation that can set us apart and position us for success. Having already made brisk headway with our NCE research and launched our own original research product in the market, it has vetted our appetite for more.

## Engaging and Nurturing Talent

All through our journey of growth, we have been building a culture whereby people are able to leverage their talent, innovate, explore differentiated paths, engage constructively, collaborate, take appropriate risks and deliver on their commitments. Our aim is to drive higher, more enriching levels of employee engagement. A vibrant learning culture, where all Zydans are given ample opportunities to sharpen, hone and gain new capabilities and skills, has also made us an employer of choice. In 2006, we had taken a decisive step in organisation transformational programme and created a Zydus leadership model. This continues to form the basis of our leadership development programme. The organisation continuously invests in programmes which uniquely trains, supports, and selects people who can drive their business strategy and lead the way by maximising opportunities and contributing to a high performance culture.

## Well-Positioned for the Future

We firmly believe the goals that we have set for ourselves are within reach and with the proven capabilities of 16000 Zydans we are in a stronger position to leverage strengths, optimise costs, efficiently target leadership and people resources, to successfully compete in the global marketplace. Thanks in large part to your continuing support and the dedication and hard work of talented people across the organisation, our plans are well on track and moving ahead at an accelerated rate. We remain confident about the company's growth prospects and our ability to deliver significant value to stakeholders in the years ahead.

Pankaj R. Patel  
June 2014





The leadership team of the Zydus Group is seen here with the Zydus Executive Board (ZEB) members - Chairman and Managing Director, Mr. Pankaj R. Patel, Deputy Managing Director, Dr. Sharvil Patel and COO and Executive Director, Mr. Ganesh Nayak during the Company's Annual Day Celebrations held in January 2014.

## Management's Discussion & Analysis - 2013-14

### Economy and Industry Overview

#### Global Economy and Pharmaceutical Industry

The global economy appears to be on the path of revival with high income economies showing signs of firm recovery after years of low growth and/or recession. This recovery in the high-income economies is expected to be a major contributor to the projected acceleration in the global growth. In these countries, the drag on growth from fiscal consolidation and policy uncertainty is easing and private sector recoveries are gaining firmer footing. This likely acceleration in the global growth marks a significant shift from recent years when developing countries alone pushed the global economy forward. In addition to providing a sound basis for global growth, stronger high income growth and import demand are likely to be important drivers of developing countries' exports. Economic activity and business sentiments improved in the developing countries from mid-2013 on the back of strengthening high-income demand and the rebound in China. This positive development though, was partially offset by tighter financial conditions and reduced capital flows. Increase in long-term interest rates in the United States in response to the expectations of the gradual withdrawal of quantitative easing was one of the key factors responsible for this (Source: Global Economic Prospects, January 2014 by World Bank).

The growth registered by the developing countries in 2013 was almost the same as the growth registered by them in 2012. However, some of the regions and/or countries of the developing world displayed significant variation in the growth rates registered in 2013 vis-à-vis 2012. While the countries of the developing Eastern Europe, Central Asia and Sub-Saharan Africa witnessed significant increase in the GDP growth in 2013 vis-à-vis 2012, countries of Middle East and North Africa registered significant decline in GDP growth over the same period (Source: Global Economic Prospects, January 2014 by World Bank).

The global pharmaceutical industry is estimated to have grown by approximately 3% in 2013 and reached a size of over US\$ 975 bn. The growth in 2013 was lower compared to the growth of over 5% registered during the period 2007 to 2012. Healthcare spending in the US, the world's largest pharmaceutical market, as well as in Europe, declined marginally during 2013, while the Japanese pharmaceutical market grew by over 2.5% in 2013. On the other hand, developing markets of Asia, Africa, Australia and Latin America, which are termed as 'pharmerging' markets continued to grow by 10-14% in 2013, driving the overall growth of the global pharmaceutical industry (Source: IMS Health Market Prognosis Report).

Generic drugs continued to increase their share in the overall prescription for pharmaceutical drugs dispensed across the globe, though the growth in 2013 was impacted by relatively lower value of innovator drugs losing their patent protection compared to that in 2012. In the US, generic drugs now account for over 83% of the total prescriptions (Source: IMS Health Market Prognosis Report).

#### Indian Economy and Pharmaceutical Industry

The Indian economy registered a growth of 4.9% during the financial year 2013-14, marginally better than the growth of 4.5% registered during the financial year 2012-13. However, the growth rate was much lower than the recent growth rates. Among the three sectors of the economy viz. agriculture, industry and services, the industrial sector was the worst performer as it grew by only 0.7% during the year 2013-14, mainly due to the de-growth registered by the manufacturing and mining sectors (Source: Monthly Economic Report, March 2014, as published by the Ministry of Finance, Govt. of India).

Overall inflationary pressure on the economy eased during the year. The average Wholesale Price Index (WPI) inflation rate for 2013-14 was 5.93% as against 7.35% during 2012-13, although it moved from below 5% during the initial part of the year to a peak of 7.52% in November 2013, from which it started a downward trend and fell below 6% in March 2014 (Source: Monthly Economic Report, March 2014, as published by the Ministry of Finance, Govt. of India).

The financial year 2013-14 saw a steep depreciation of the Indian Rupee vis-à-vis global currencies. The exchange rate between the Indian Rupee and the US Dollar, which was at around Rs. 54 in the beginning of the financial year started an upward movement and reached a level of Rs. 68-69 in the month of August. From the month of October, the Indian Rupee started appreciating against the US Dollar but the exchange rate remained more or less in the range of Rs. 60-63 during the rest of the financial year (Source: Monthly Economic Report, March 2014, as published by the Ministry of Finance, Govt. of India).

The year 2013-14 turned out to be one of the worst phases for the Indian pharmaceutical market in the recent past as it grew by a mere 6.1% and reached a size of approximately Rs. 75,600 crores after growing well in excess of 10% during the previous few years (Source: AIOCD-AWACS Report, MAT March 2014). The Government of India notified the new Drug Price Control Order (DPCO) 2013 whereby it expanded the scope of the National List of Essential Medicines (NLEM), covering a larger number of medicines under the list and notified revised prices, mostly downward, for the same. This adversely impacted a large number of companies in the Indian pharmaceutical market as they realised lower prices as notified by the new DPCO 2013 on an increased number of products. The new DPCO, 2013 also adversely affected the volume growth during the year for the products covered under NLEM. During the year, the products covered under the NLEM saw an overall sales decline of approximately 8% whereas those out of the purview of the list grew by around 8.5% (Source: PharmaTrac MAT March 2014).





## Home Markets

### India Formulations

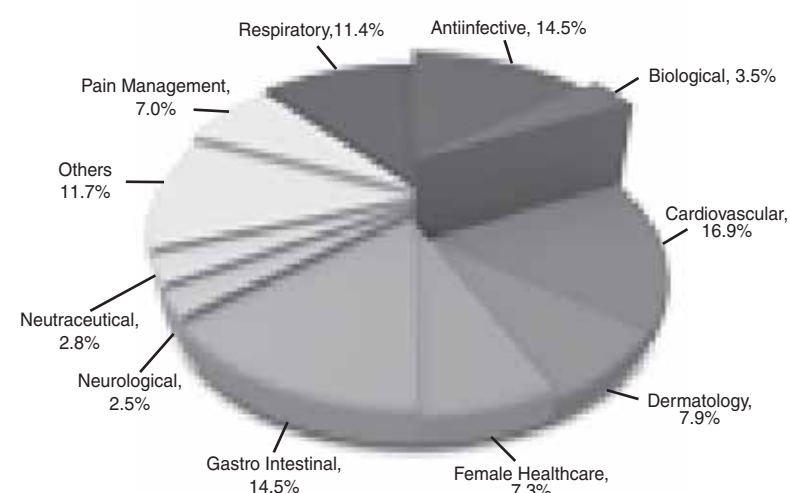
The year 2013-14 was a challenging one for the Company's formulations business in India, currently the largest contributor to the topline. The price reductions imposed by the Government of India on the products covered under NLEM impacted both the volume and the value growth of these products. Despite this, the growth registered by the Company in the India Formulations Business was a little higher than the overall market growth of 6% (Source: AIOCD-AWACS Report, MAT March 2014).

The Company retained its leading positions in the participated market segments of cardiovascular, gastro intestinal, women's healthcare and respiratory therapeutic areas. The Company also gained 2 positions in the dermatology segment, from 6<sup>th</sup> rank last year to the 4<sup>th</sup> rank this year. 16 of the Company's brands feature among the top 300 pharmaceutical brands in India (Source: AIOCD-AWACS Report, MAT March 2014).

The Company continued its drive of adding new products to the existing portfolio and launched more than 75 new products, including line extensions in India during the year. Of these, 19 were first-time launches. This included the launch of Lipaglyn (Saroglitzar), the first New Chemical Entity (NCE), discovered and developed indigenously by an Indian pharmaceutical company.

Overall, the Company's formulations business in India posted sales of Rs. 24,644 Mio. during the year, up by 6.1% from Rs. 23,232 Mio. last year.

The therapeutic area-wise break-up of branded formulations sales in India during FY 2013-14 is given below:



### US Formulations

The US remains the world's largest pharmaceutical market accounting for more than 30% of the global market. The Company's operations in the US are spearheaded by its wholly-owned subsidiary Zydus Pharmaceuticals (USA) Inc.

The Company is now ranked 8<sup>th</sup> amongst the US generic companies based on scripts (Source: IMS), moving two positions from the 10<sup>th</sup> rank last year.

The Company's business in the US completed yet another year of successful operations and posted sales of Rs. 21,704 Mio., up by 44%. The Company launched 7 new products in the US during the year.

The Company filed a record 50 ANDAs with the USFDA during the year, taking the cumulative ANDA filings to 227.

The Company's continuous endeavour to improve service levels coupled with a focus on quality has helped achieve high levels of customer satisfaction. The Company received the 'Service Level Excellence' award from a large US wholesaler with an overall customer service level exceeding 99%.

Going forward, the Company's focus will continue to be on launching complex, difficult-to-make oral solids and formulations of other dosage forms like injectables, nasals, creams and ointments to further strengthen its position in the US generic market.

### Brazil

Brazil, which is the largest pharmaceutical market in Latin America and one of the promising 'pharmerging' markets, has been undergoing the process of consolidation in the recent past. Entry of large distributors, big retail chains buying the smaller ones and the increased competition have posed new challenges for the existing companies. In 2013, the Brazilian pharmaceutical market grew by approximately 3% (Source: IMS Retail Drug Monitor – February 2014).

The overall market scenario and the lack of new product approvals posed several challenges to the Company during the year. Despite this, the Company continued its focus on brand building initiatives with an aspiration to be a leading player in the women's healthcare, respiratory, cardiovascular, diabetes and neuropsychiatry therapy segments. During the year, the Company took several initiatives in the areas of optimising the cost of operations, inventory management and sales force effectiveness.

The Company posted sales of Rs. 2,353 Mio. in Brazil during the year.

### Mexico

The Mexican pharmaceutical market, valued at around US\$ 10 bn., is the second largest pharmaceutical market in Latin America after Brazil. The Company is present in the Mexican pharmaceutical market through its subsidiary Zydus Pharmaceuticals Mexico S.A. de C.V.

The Company commenced commercial operations in Mexico in June 2013 and launched 7 products. During the year, the Company posted sales of Rs. 109 Mio. in Mexico.

Going forward, the Company intends to expand its focus on the cardiovascular and the primary care specialty area by aggressively launching new products in the Mexican market.





## Other Markets and Businesses J

### Europe

The Company is present in the generic market of France through its subsidiary, Zydus France SAS, while in the Spanish generic market, its presence is marked by its subsidiary, Laboratorios Combix S.L. During the year, the French generic market grew by about 6%, reflecting a fall in the Government-led initiatives to increase generic penetration towards the later part of the year. The French generic market is likely to remain challenging as the French government introduces price cuts to keep the healthcare costs down. The Spanish generic market, which is highly competitive, grew by 12% during the year. Going forward, this market is expected to continue strengthening as the fiscal crisis has started to ease.

During the year, the Company consolidated its business in France by restructuring the product portfolio and customer base which helped in improving overall profitability. The Company launched 8 new products in France, including two Day-1 launches. The Spanish business registered growth mostly in line with the market growth rate. The Company launched 12 new products, including one Day-1 launch in the Spanish market during the year. In both these markets, the focus now is on improving the profitability further by increasing the proportion of products supplied from India.

Overall, the Company's business in Europe posted sales of Rs. 3,902 Mio. up by 6% during the year.

### Emerging Markets of Asia Pacific, Africa and the Middle East

During the year, the Company continued to strengthen its branded generics business in the key markets of Asia Pacific, Africa and the Middle East. The Company launched over 35 new products in these markets during the year, including several firsts in these markets. The Company posted sales of Rs. 3,592 Mio. in these markets during the year with a growth of 15% over the previous year.

### Japan

During the year, the Company decided to discontinue its existing business in Japan, which was operated through its subsidiary Zydus Pharma Japan Co. Ltd.

### APIs

The Company's APIs and intermediates' business continued to provide support to the formulations business by providing key input materials in a timely and cost efficient manner for the Indian as well as the developed and emerging markets across the world and also contributed to the launch of new formulations in these markets. The API business also fulfilled the requirements of the external customers by supplying them APIs and intermediates in a timely manner and at the most competitive prices. During the year, the Company filed 10 more DMFs with the USFDA, taking the cumulative filings to 117.

During the year, the Company's API business grew by 13% and posted sales of Rs. 3,497 Mio.

## Consumer Wellness

The Company is present in the consumer wellness space through its subsidiary, Zydus Wellness Limited, which has three established brands viz. Sugar Free, a low calorie sugar substitute, EverYuth, a range of skincare products and Nutralite, a cholesterol free table spread.

During the year 2013-14, Sugar Free maintained its leadership position in the low calorie sugar substitute market with a market share of more than 93%, which virtually represents the entire low calorie sugar substitute market in India (Source: AC Nielsen).

The skincare category witnessed a slowdown primarily due to reduced discretionary spending on personal care products by consumers driven by high inflation, which has impacted all the three categories in which EverYuth has a presence viz. face wash, scrub and peel-off. The Company continued its thrust on new product launches with the launch of several variants in the existing categories.

Despite strong competition from lower priced regional brands, Nutralite continued to maintain its leadership position in the margarine category due to the focus on superior quality, high standards of customer service and launch of a lower priced variant of Nutralite called 'Nutralite Yummy' in North India.

During the year, Zydus Wellness Ltd. registered a sales of Rs. 4,296 Mio. up by 5% and a net profit of Rs. 965 Mio. marginally down by 1%.

