



A first for the nation...



Cadila Healthcare Limited
Annual Report 2012-13

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REGISTRAR AND SHARE TRANSFER AGENTS	M/s. Sharepro Services India Private Limited 13 AB, Samhita Warehousing Complex, Sakinaka Telephone Exchange Lane, Off. Andheri-Kurla Road, Sakinaka, Mumbai-400 072.	51	Statement of Profit and Loss
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Topical Plant	Plot No.254/255, Behind Zyfine Chemicals, Sarkhej Bavla.N.H.No.8A, Changodar Road, Tal. Sanand, District-Ahmedabad.		
Zydus Biologics	Survey No. 40P, 23, 25P, 42, 37, Opp. Ramdev Masala, Sarkhej-Bavla N.H.No. 8A, Changodar, Ahmedabad.		
SEZ Unit	Plot No. 1/1A, & 2, PHARMEZ, Sarkhej-Bavla N. H. No. 8A, Village – Matoda, Tal. Sanad, District-Ahmedabad.		
ZYDUS RESEARCH CENTRE	S. No. 396/403, Village Moraiya, Tal. Sanand, District-Ahmedabad.		



Mr. Ramanbhai B. Patel
Founder Chairman, Zydus Cadila
August 19, 1925 – September 19, 2001

What others perceived as challenges, transformed into possibilities for him. He worked around problems, solutions excited him.

Innovation was not an output of work but an outcome of his explorations.

Our Founder Chairman was a seeker, an explorer and an innovator.

*The discovery of Lipaglyn, our first New Chemical Entity
is a tribute to his pioneering spirit.*

“ *For my part, I had a dream to contribute to the process of nation building, becoming an innovator and a successful entrepreneur. Over the years, I put my heart and soul into realising this dream and was also fortunate to have people join me and share this vision. I am happy to have been able to give a concrete shape to my dreams and build the edifice of an enterprise, which I am sure will continue to transform itself in response to the changing times.* ”

Excerpts from the acceptance speech delivered by Mr. Ramanbhai B. Patel
on receiving the Gujarat Businessman Award 1999-2000.



The new state-of-the-art Oral Solids Oncology Formulation Plant at Pharmez in Ahmedabad

Highlights of Operations – 2012-13

Home Markets

India

- Maintained leadership positions in the Cardiology, Gynecology, Gastro Intestinal and Respiratory therapy segments (represented markets) and outpaced the overall market growth of 12% (Source : AIOCD AWACS MAT Mar-13).
- Restructured operations at Biochem to establish a strong foundation for achieving mid and long term growth plans.
- Launched over 90 new products (including more than 50 line extensions) in India, of which, 21 were first in India.
- Overall, formulations business in India posted sales of Rs.23,232 Mio., up by 23%.

US

- Launched 7 new products, including one controlled substance product from Neshier, in the US market.
- US business posted sales of Rs.15,068 Mio., up by 21 %.

Brazil

- Continued focus on brand building initiatives in keeping with the aim to be a leading player in chronic therapy segments like cardiovascular, diabetes and neuro psychiatry and launched 2 new products in Brazil.

- Overall, the operations in Brazil posted sales of Rs.2,384 Mio.

Mexico

- Undertook several initiatives to launch commercial operations in 2013.



Other Businesses

Europe

- Continued to progress well in France on the back of high growth of the French generic market. In Spain, continued to outperform the market growth rate.
- Launched 13 new products in the French generic market, of which, 5 were Day-1 launches.
- Overall, European business posted sales of Rs.3,697 Mio., up by 24%.

Emerging Markets

- Launched more than 30 new products in the key markets of Asia Pacific, Africa and Middle East during the year.
- Overall, Emerging Markets business posted sales of Rs.3,134 Mio., up by 66%.

Consumer Wellness

- Sugar Free, India's leading sugar substitute, continued to maintain its leading position with a market share of more than 92%.
- Revamped EverYuth brand with the launch of new variants of face washes, scrubs and premium range of soaps. EverYuth Menz was also revamped and re-launched during the year.
- In the Nutralite category, launched the premium variant namely Omega 3 in order to enhance the health offerings of the brand. This new variant was declared as the 'Product of the Year'.
- During the year, Zydus Wellness Ltd. registered sales of Rs.4,100 Mio., up by 19% and net profit of Rs.971 Mio., up by 43%.

Animal Health

- Strengthened position as a leading animal health player in India by launching 13 new products.
- On a consolidated basis, animal health business posted sales of Rs.2,370 Mio., registering a growth of 22% during the year.

API

- Filed 7 DMFs with the USFDA, taking the cumulative US DMF filings to 114.
- API business grew by 9% and posted sales of Rs. 3,099 Mio.

JVs & Alliances

- Zydus Takeda JV (formerly known as Zydus Nycomed JV) started the commercial supplies of 2 generic APIs to Takeda Pharma.
- Zydus Hospira JV successfully completed re-audits by the USFDA, MHRA and new audits from Egypt and Tunisia during the year. The JV commenced commercial production and supply of 2 more products for the US and 1 more product for the EU market during the year.
- During the year, the US FDA audited and approved the manufacturing facility of Zydus BSV JV and also approved the first ANDA submitted from the site.
- Commenced the commercial supply of products under an out-licensing deal with Abbott and shipped 2 products during the year.

New Technologies and NCE

- Completed the construction of India's largest state-of-the-art manufacturing facility for monoclonal antibodies during the year.
- Initiated dossier submission of first generation biosimilars for the emerging markets.

- Received the regulatory approval to conduct clinical trials for one mAb during the year.

- On the novel biologics front, Phase I clinical trials have been initiated in India for both PEGEPO and Rabimabs.

- Completed the construction of a new live viral vaccines manufacturing plant during the year.

- Phase I clinical trials have been successfully completed for one of the viral vaccines.

- Filed the NDA with the DCGI for novel NCE, Saroglittazar, for treating Diabetic Dyslipidemia and Hyper Triglyceridemia. It is the first NCE discovered and developed indigenously by an Indian pharma company.

Manufacturing Operations

- During the year, the formulations facility at Moraiya got the USFDA approval for new dosage forms like Injectibles and Nasal sprays in addition to oral solids.

- Inducted an organization wide programme on cost optimization through multiple levers, under project PRISM-II, which is expected to improve the overall profitability going forward.

Financial Highlights

- Gross sales revenue went up by 21% y-o-y to Rs.62.8 bn from Rs.51.8 bn last year.

- Earnings before interest, depreciation and tax, excluding the impact of one-time dossier income received in the previous year, grew by 9% to Rs. 11,251 Mio. from Rs. 10,326 Mio. last year.

- Net profit, excluding one-time income, grew by 7% to Rs. 6,535 Mio.





Chairman's Message

It's the dream of any research-driven pharma enterprise to launch its own New Chemical Entity (NCE) in the market. This has been a pivotal year in which we realized this dream; the dream of putting the first NCE from an Indian Pharma company in the market. The unrelenting focus on research capabilities that we developed internally at every stage of the research programme and groundbreaking teamwork has resulted in this pioneering effort. As a result of this milestone achievement your Company is today a stronger, innovation-led company - with a clearer promise of the future.

The foundation of our successes

This is perhaps the most apt moment in our corporate history to remember our Founder Chairman, the Late Mr. Ramanbhai B. Patel and his vision that had first sown the seeds of innovation. He believed that innovation was the key to build a differentiated standing in the market. To be able to offer what didn't exist – was a simple maxim but it created a strong edifice of a company that made innovation its cornerstone. Early successes with innovation in therapies for pernicious anemia (Livivubra), incompatible neurotropics Vitamin B1, B6 and B12 in a single vial, a derivative of INH tuberculosis and many other ailments created a niche in the marketplace. At the heart of it all, was a dream, a vision that has continued to guide the Company in its quest, ever since. It all began with a steadfast belief that the magnitude of research can never be greater than the human will to make it succeed.



Setting out on the path of innovation

The Lipaglyn story

Among the many chronic diseases that we are grappling with, diabetes is the one that confounds us with new findings, each one more alarming than the one before. Nearly 90% of people suffering from diabetes also suffer from dyslipidemia or lipid disorders. This discovery is significant because the world finally has found an answer to the problem which we recognize as 'Metabolic Syndrome' or 'Syndrome X' – a highly complicated medical condition where one underlying disorder leads to other multiple disorders.

For a person suffering from diabetes who is struggling to keep his or her blood sugar levels down, there is another battle he/she constantly needs to fight, of keeping a check on the cholesterol levels, especially the triglyceride levels. The question is how does one do it in a safe and efficacious manner in which both the conditions are controlled?

This novel drug offers the dual benefit of controlling lipid levels as well as blood sugar levels in one single pill, in one single dosage form. It is for the first time that the problem of diabetic dyslipidemia has been distinctly identified and a treatment has been specifically approved for it. For the millions of people suffering from diabetes and grappling with the problem of dyslipidemia – here is a new way forward.

From a long term patient care point-of-view this is a remarkable discovery as Lipaglyn has been found to be safe on the heart, liver, kidneys and the gastrointestinal tract. Right from the concept stage to the final approval – this is entirely an indigenous effort and we are extremely proud of it. Lipaglyn shows that India has what it takes to successfully launch its own patented molecules for chronic diseases such as diabetes and other metabolic disorders. India's innovation has always been anchored to cost effectiveness. But I think what's far more important, is that we also have the capabilities required in the entire spectrum of drug discovery. This is the belief and conviction that has made Lipaglyn possible. This is an important milestone for the entire healthcare fraternity in India and for the world of drug discovery as well and I'd like to dedicate this achievement to all the Indian research scientists.

Innovation and technology leadership

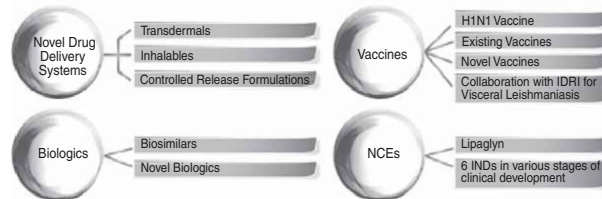
During the journey of 12 years from concept to the New Drug Application, there were several opportunities to outlicense the drug. We chose not to do so and embarked upon a more challenging and differentiated path. There were phases in the clinical development programme which were new and an uncharted territory for us. At such times, it's our steely resolve to learn and acquire capabilities that helped us the most. Today, we are richer in our learnings. As we go about creating a unique portfolio of Zydus Discovery Products, we bask in a newly gained confidence that the ability to learn can open up new paths where none exist.

It has been opined that the ability to anticipate trends that will shape the future of technology, customers, society and the marketplace will determine the survival of an enterprise. Across the world, the healthcare fraternity continues to be engaged in exploring the critical role of new medicines in the prevention, treatment and management of diseases and improving the overall quality of life. The critical questions shaping our world are : How can innovation lead to new ways of tackling the enormous disease burden and improve healthcare outcomes? How do we bring innovation to the frontline? How do we equip ourselves and more importantly, are we equipped to ride the next wave of innovation which may not just be restricted to products but extend to our business as well?

Sustaining and furthering this innovation culture is our priority. Between now and 2020, we hope to bring more therapies from our research pipeline to the market. There are a dedicated group of research scientists at the Zydus Research Centre working on NCE research inspired by Lipaglyn's success. Continuing with our quest to be an innovation-led, research-driven enterprise, the thrust of our discovery research is in the areas of cardio-metabolic disorders, inflammation, pain and oncology.

It's not just in NCE research, but our scientists are also doing exemplary research work in vaccines, biologics and niche and complex technologies. The vision as always is a broad and expansive one. At Zydus Biologics, our focus is on Novel Biologics and Biosimilars. The team is working on a strong pipeline of 17 biosimilars and 2 novel biologics. At our fully approved Vaccine Technology Centre, the team is working on existing vaccines as well as developing novel vaccines. Here's where India's first indigenously developed H1N1 vaccine – Vaxiflu, was developed as a response to a health threat of endemic proportions. Today, our scientists are developing the world's first vaccine to prevent visceral leishmaniasis or Kala Azar with Infectious Diseases Research Institute (IDRI). Aspiring to be one of the leaders in complex technologies, a dedicated team of scientists are working on next-gen technologies and Novel Drug Delivery Systems (NDDS). This includes a robust portfolio of products such as transdermals, inhalables and controlled release formulations.

While research is always associated with high risk and challenges, it also presents us with a major opportunity to realize the purpose with which the Company was founded in 1952 ; to create a company that will enrich lives by providing innovative contributions in healthcare.



A moment in time

These are exciting times for us. With a blueprint of strategies, a strong team for execution, a commitment to innovation and an aspiration to post new milestones, we are poised for significant and sustained growth that will carry us to new frontiers. By being guided by our vision and long term goals, investing in the development of capabilities and infrastructure to excel, and by continuing to do things differently—the Zydus way—we will hold our own as a value creator. The discovery and launch of our first NCE is what we have been working towards for many years. I am happy to be a part of this endeavour, and I look forward to delivering on the promise of the future.

We wish to thank our employees, partners in progress, the healthcare fraternity and the shareholders for their unstinted support. Working together, we will create healthier communities through novel ideas, innovation and quality healthcare solutions.

Pankaj R. Patel



Management's Discussion & Analysis - 2012-13

Global Economy and Pharmaceutical Industry

Four years after the onset of the global financial crisis, the world economy continues to struggle for growth. The year 2012 turned out to be another year of very slow growth when the global economy grew by just 2.3%. Although the developing economies continue to be the main drivers of global growth, their growth at an estimated 5.1% during 2012 was amongst the lowest in the last 10 years. The high income countries registered a very modest growth of 1.3% on the back of very weak consumer and business confidence, high unemployment and fiscal consolidation with no signs of dramatic improvement in the next year either. Although the growth was sluggish during the most part of 2012, financial market conditions have improved globally since June 2012. This improvement was the result of the cumulative effect of the national and Eurozone measures that the key European Governments took to improve fiscal sustainability, and the augmentation of measures that the European Central Bank was willing to take in defense of the Euro. The improvement was felt in the developing countries as well, where the international capital flows, which fell by between 30-40% in May-June 2012, reached new highs thereafter. The stock markets of developing countries went up by nearly 13% between June-December 2012.

While signals from the financial markets were encouraging, those emerging from the real-side of the global economy were mixed. Overall, the global economic environment remained fragile and prone to further disappointment, although the balance of risks is now less skewed to the downside than it has been in recent years (Source: Global Economic Prospects, January 2013 by World Bank).

The global pharmaceutical market is estimated to have expanded at the rate of 3-4% during 2012 and reached the size of over US\$ 980 bn. The growth in 2012 was lower compared to the earlier years. The developed markets of North America, Europe and

Japan grew in the range of just 1% to 2%, thus, reducing the overall growth of the pharma market globally. On the other hand, the markets of Asia Pacific, Africa and Latin America, termed as the 'pharmerging' markets, are estimated to have grown by 10-14% during the same period. In terms of size, the US still remains the largest market in the world. Moving forward, the pharmerging markets are expected to gain a larger share in the global pharma market as they are expected to grow three to five times faster than the developed countries of the world (Source: IMS Health Market Prognosis Report).

The year 2012 was an important year for the generic drugs industry, as it saw some of the largest products losing their patent protection. This included the world's largest selling drug, Lipitor (atorvastatin calcium, for lowering cholesterol). An accelerated shift to the use of generic medicines is expected to continue, both from an unprecedented level of patent expiries of innovator drugs and from volume-driven growth in the largely generic pharmerging markets.

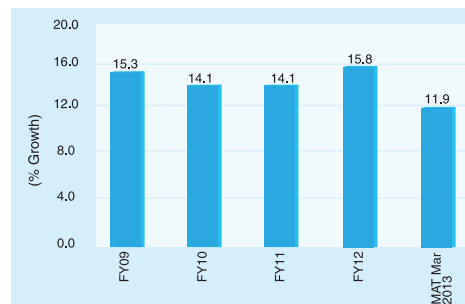
Indian Economy and Pharmaceutical Industry

The financial year 2012-13 was one of the worst phases the Indian economy has seen in the recent past. The GDP is estimated to have grown by just 5%, the lowest growth in the last 10 years. All three sectors of the economy viz. agriculture, industry and services registered lower growth rates compared to the last year resulting in the dismal overall growth of the economy.

Inflation, a concern, remained in the range of 7-8% during most part of the financial year, although it showed signs of significant moderation in the later part of the year with wholesale price index (WPI) touching a low of 5.96% in March 2013. Average WPI inflation rate for 2012-13 was 7.34% as against 8.94% during 2011-12.

The exchange rate between the Indian Rupee and the US Dollar, which was at around Rs. 51 in the beginning of the financial year started spiraling upwards from the month of May and remained in the range of Rs. 54-56 during most part of the year (Source: Monthly Economic Report, March 2013, as published by the Ministry of Finance, Govt. of India). However, post March 2013, the Rupee started depreciating sharply vis-a-vis global currencies and crossed Rs. 65 per US Dollar in August 2013, a level unheard of before. This is likely to impact the economy adversely despite prospects of exports surging.

The Indian pharmaceutical market, which had been continuously growing at around 15% for the last few years slowed down, registering a growth of 11.9% during the financial year 2012-13, and crossed Rs. 70,000 crores. The key reasons for this slow growth was the strong base of the previous year, lower discretionary spending and deferring of treatments. Chronic segments registered a higher growth as compared to the acute segments. Diabetics, urology, anti-malarial and CVS therapeutic areas registered a higher growth during the year (Source: AIOCD AWACS report).



A five year snapshot of the Indian Pharma Industry's growth



The group's global manufacturing hub at Moraiya, Ahmedabad

Home Markets

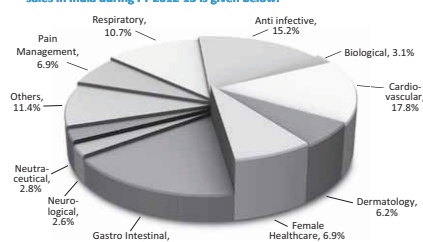
India Formulations

The Company's India formulations business, currently the largest contributor to the Company's revenues completed yet another year of successful operations outpacing the market growth in almost all the therapeutic areas in which the Company has its presence. The growth registered by the Company in the India formulations business was higher than the overall market growth of 12% (Source: AIOCD, AWACS Report, MAT March 2013).

The Company continued to maintain its strong position in the cardiovascular, gastro intestinal, respiratory and women's healthcare segments during the year. 17 of the Company's brands now feature amongst the top 300 pharmaceutical brands in India (Source: AIOCD AWACS Report, MAT March 2013). The Company continued its focus on new product introductions and launched over 90 new products, including over 50 line extensions, of which, 21 were first-time launches in India. The Biochem operations were restructured during the year to establish a strong foundation in the acute segment for achieving the mid and long term growth plans.

Overall, the Company's formulations business in India posted sales of Rs.23,232 Mio. during the year, up by 23% from Rs.18,950 Mio. last year.

The therapeutic area-wise break-up of branded formulations sales in India during FY 2012-13 is given below:



US Oral Solids

The US pharmaceutical market, the world's largest pharmaceutical market, accounts for around 40% of the global market share. Zydus Pharmaceuticals (USA) Inc. spearheads the Company's operations in the US.

It is ranked tenth amongst the US generic companies based on scripts (Source: IMS). For about two thirds of the products marketed in the US, the Company is ranked amongst the top three players.

The Company's business in the US continued to grow despite several challenges in the form of stiff competition, price erosion and lack of sufficient new product approvals by the USFDA and posted sales of Rs.15,066 Mio., up by 21% during the year. The Company launched 7 new products, including one controlled substance product from the Neshet facility.

This performance reflects the capability and determination of the Company to offer high quality, reasonable cost generic products making Zydus a trusted and preferred supplier. The Company's continuous endeavours to improve service levels have helped it achieve high levels of customer satisfaction. The company aspires to occupy a significant place in the US market and make its position firmer with the launch of value added generic products that will drive incremental sales and margins. The initiatives in the form of filing ANDAs for other dosage forms like nasals, creams and ointments and injectable products are also expected to take the Company on a higher growth path.

Brazil

The Brazilian pharmaceutical market, the largest pharmaceutical market in Latin America and one of the most promising 'pharmerging' markets, has been continuously growing at a fast pace for the last few years and offers significant opportunity for growth. In 2012, the Brazilian pharmaceutical market registered a growth of 16% (Source: IMS Retail Drug Monitor – February 2013).

The Company is present in both the branded and generic segments of the Brazilian pharmaceutical market. The Company continued to focus on brand building initiatives with an aspiration to be a leading player in the cardiovascular, diabetes and neuro psychiatry therapy segments. The Company launched 2 new products in Brazil during the year.

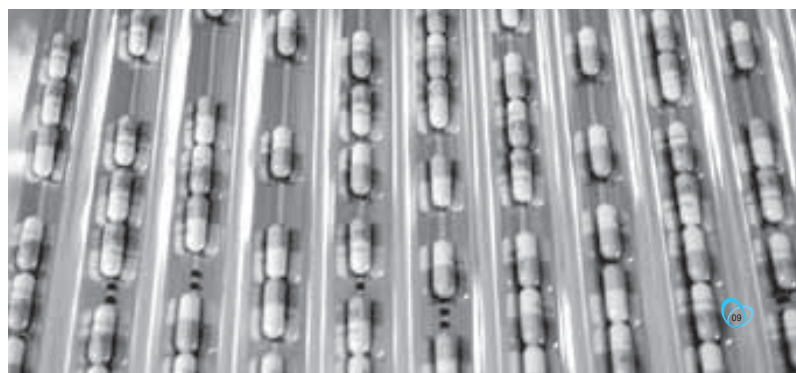
Overall, the Company posted sales of Rs. 2,384 Mio. in Brazil during the year.

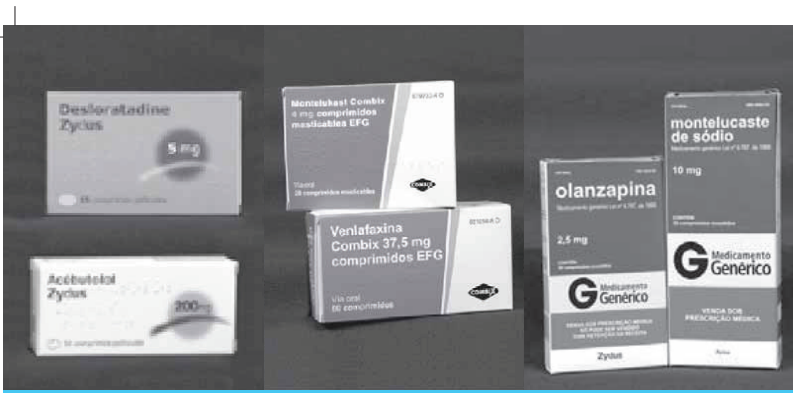
Mexico

The second largest pharmaceutical market in Latin America after Brazil is the Mexican pharmaceutical market, which is valued at around US\$ 10 bn. It offers a significant opportunity to the generic players on account of several government initiatives.

The Company is present in Mexico through its 100% subsidiary Zydus Pharmaceuticals Mexico S.A. de C.V. During the year, the Company received the first product approval from the regulatory authority COFEPRIS, which has paved the way for launching commercial operations in the country.

The Company expects to commence commercial operations in 2013 and continue its aggressive product development and filing strategy with the aim to become a significant market player in the Mexican pharmaceutical market.





Other Businesses

Europe

The Company is present in Europe through its subsidiaries in the generic markets of France and Spain. During the year, the French generics market grew by approximately 22% to reach € 3.5 bn. Market growth showed a strong recovery from the low single digit growth witnessed in the previous year. This is credited mainly to a number of Government-led initiatives to increase generic substitution rates. The Spanish generic market, on the other hand, grew by about 10% and reached € 1.5 bn, which represented a significant deceleration, compared to the previous year and reflected the emphasis that the Government had placed on restricting healthcare spending in response to the economic crisis in the country.

The Company's business in France was able to benefit from the high level of growth in the market. The Company launched 13 new products in France, including 5 Day-1 launches. The Spanish business continued to out-perform the market growth rates, backed by the launch of 24 new products, including 5 Day-1 launches. More than half of the products launched in France and Spain were manufactured in and supplied from India.

During the year, the Company's business in Europe posted sales of Rs. 3,697 Mio., up by 24%.

Emerging Markets of Asia Pacific, Africa and the Middle East

During the year, the Company consolidated its branded generics business in the key markets of Asia Pacific, Africa and the Middle East. The Company launched more than 30 new products in these markets, including several Firsts in the market, which resulted in the gain of market share in the Philippines, Sri Lanka and Vietnam. The Company posted sales of Rs. 3,134 Mio. in these markets with a growth of 66 % over the previous year.

APIs

The Company's APIs and intermediates' business continued to perform well on both the fronts viz. providing continued support to internal customers in the form of backward integration to cater to the demand for finished formulations across markets and satisfying the demand of external customers by supplying them the APIs and intermediates at the most competitive prices. During the year, the Company filed 7 more US DMFs with the USFDA, taking the cumulative filings to 114.

During 2012-13, the Company's API business grew by 9% and posted sales of Rs. 3,099 Mio.



Consumer Wellness

The Company is present in the consumer wellness segment through its subsidiary, Zydus Wellness Ltd., which has been a niche and significant player with its portfolio of wellness brands viz. Sugar Free, EverYuth, Nutralite and Actilife.

During the year 2012-13, Sugar Free maintained its leading position in the low calorie sugar substitute market with a market share of more than 92% and remained the driving force for the overall category growth.

In the EverYuth category, the Company continued to maintain its leadership position in the scrubs and peel-off category, while the face wash category continued to experience stiff competition. Reflecting the aspirations of the modern Indian consumer and with a view to being relevant and contemporary, the brand was re-launched with new exciting packaging and improved formulations for superior performance and with a powerful new marketing programme. Apart from this, the Company launched several new variants in the face wash and scrub categories and re-launched the Menz line. The Company also ventured into the soap category and launched its first range of transparent soaps during the year.

In spite of growing competition from low priced brands, Nutralite maintained its leading position through its commitment to quality and service. The Company expanded its product portfolio in the retail segment with the launch of a premium variant, Nutralite with Omega 3, in order to strengthen the health positioning of the brand. It was voted 'Product of the Year 2013' based on an independent survey conducted amongst 18,000 consumers in India undertaken by global research agency AC Nielsen. This prestigious award is reserved for products which have excelled in innovation and in delivering consumer satisfaction.

Investments continued in creating awareness amongst the consumers about Actilife, a nutritional milk additive for adults.

During the year, Zydus Wellness Ltd. registered sales of Rs. 4,100 Mio., up by 19% and net profit of Rs. 971 Mio., up by 43%.



Animal Health Business

The Company is one of India's leading animal health players, with a strong market share in several therapeutic areas, offering a wide range of drugs, feed supplements and vaccines for livestock, companion animals and poultry. The international business is driven by its subsidiary, Bremer Pharma GmbH, Germany.

During the year 2012-13, the Company strengthened its position and continued with its ability to launch new products by introducing 13 new products in India.

On a consolidated basis, the Company's animal health business posted sales of Rs. 2,370 Mio., with a growth of 22% during the year.

JVs and Alliances

A. Zydus Takeda Healthcare Pvt. Ltd.

Zydus Takeda (formerly known as Zydus Nycomed) is a 50:50 JV between Takeda Pharmaceuticals Co. Ltd. and Cadila Healthcare Ltd. for manufacturing of Pantoprazole and its key starting materials. The JV is also a hub for supplying various APIs of Takeda's generic portfolio.

During the year, the JV started commercial supply of 2 generic APIs to Takeda. Apart from this, the production and supply of 3 more generic APIs to Takeda were started for validation batches.

B. Zydus Hospira Oncology Pvt. Ltd.

Zydus Hospira Oncology Pvt. Ltd. (ZHOPL), the 50:50 JV between Cadila Healthcare Ltd. and Hospira Inc., USA, successfully completed its fourth year of operations. During the year, the JV also successfully completed re-audits by the USFDA, MHRA, and new audits from Egypt and Tunisia.

The JV commenced the commercial production and supply of 2 more products for the US and 1 more product for the EU market during the year. Apart from this, additional products are being added to the scope of the JV.

C. Bayer Zydus Pharma Pvt. Ltd.

Bayer Zydus Pharma Pvt. Ltd., the joint venture with Bayer Schering Pharma, successfully completed the second year of commercial operations. The JV has a strong portfolio in the areas of women's healthcare, metabolic disorders, diagnostic imaging, cardiovascular diseases, anti-diabetic treatments and oncology where it focusses on increasing its market share.

D. Zydus BSV Pharma Pvt. Ltd.

Zydus BSV's novel and patented product for use in oncology continues to enjoy confidence of the Indian oncologist fraternity. The clinical trial for breast cancer product has been completed and the outcome has been a favourable one. The JV has also finalised design of pivotal clinical trials and applications were submitted to the Drug Controller General of India (DCGI) during the year.

The JV has also made considerable progress in the contract manufacturing business. During the year, the USFDA audited and approved the manufacturing facility and also approved the first ANDA submitted from the site.

E. Strategic out-licensing deal with Abbott Laboratories

The Company, for the first time, commenced the commercial supply of products under an out-licensing deal with Abbott and shipped 2 products during the year. Apart from this, approvals were received for 2 more products during the year.



New Technologies & NCE

Biologics

The Company is developing a pipeline of 19 biologics, comprising 17 biosimilars and 2 novel biological products. During the year, the Company launched one more first generation biosimilar product in the Indian market, taking the cumulative number of such launches to 6. Dossier submission of first generation biosimilars for the Emerging markets was also initiated during the year.

The Company completed the construction of India's largest state-of-the-art manufacturing facility for monoclonal antibodies during the year. Apart from this, the construction of the new fill and finish facility for the production of drug product in multiple formats was also commissioned. The Company received the regulatory approval to conduct clinical trials for one mAb during the year.

On the novel biologics front, Phase I clinical trials have begun in India for PEGEPO, which is being developed in collaboration with Prolong Pharma, USA and Rabimabs, which is being developed in collaboration with WHO.

Vaccines

The Company completed the construction of a new live viral vaccines manufacturing plant during the year. Phase I clinical trials have been successfully completed for one of the viral vaccines. The Company has several vaccines in different stages of development viz. pre-clinical toxicity and clinical studies.

NCE Research

The Company's state-of-the-art Zydus Research Centre (ZRC) spearheads the Company's NCE research activities. The company currently conducts basic new drug discovery research in cardio-metabolic, inflammation, pain and oncology therapeutic areas, with a portfolio of 7 candidates in various stages of development.

During the year, the Company filed the NDA with Drug Controller General of India (DCGI) for the novel NCE, Saroglitazar, for treating Diabetic Dyslipidemia and Hyper Triglyceridemia. It is the first NCE discovered and developed indigenously by an Indian pharma company. In June 2013, the Company received the DCGI's permission to market the product in India.

Intellectual Property Rights

The Company's efforts in the development of new molecules, newer delivery systems, processes and technologies have continued. The Company's research and development centres have filed over 120 patents in the US, Europe and other countries during the year, taking the cumulative number of filings to over 950.