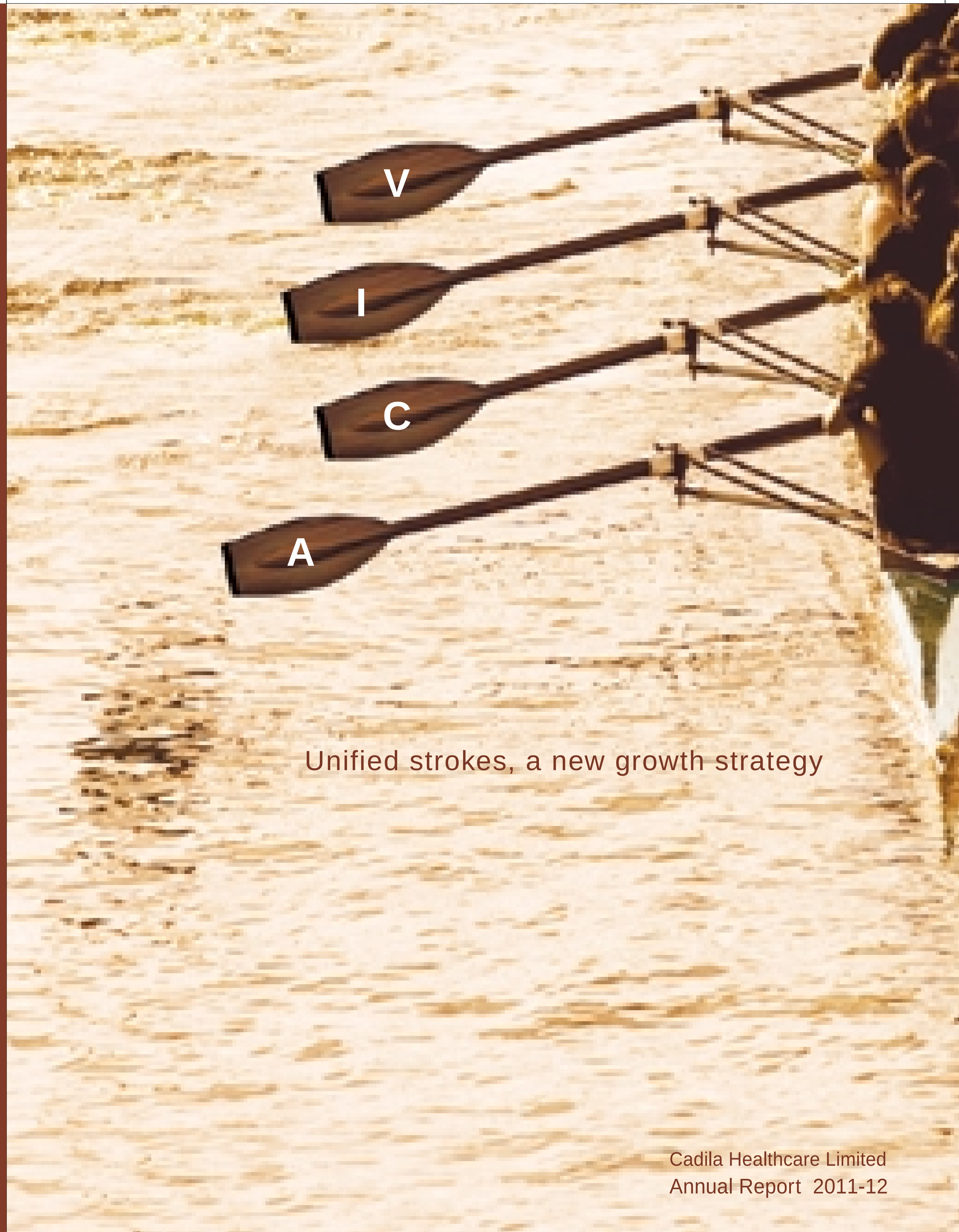


# Unified strokes, a new growth strategy

Cadila Healthcare Limited
Annual Report 2011-12

Zydus
dedicated to life

www.zyduscadila.com

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| | |
|---|---|
| **FOUNDER** | Late Mr. Ramanbhai B. Patel |
| **BOARD OF DIRECTORS** | Pankaj R. Patel<br>Chairman & Managing Director<br><br>Dr. Sharvil P. Patel<br>Deputy Managing Director |
| **DIRECTORS** | Humayun Dhanrajgir<br>Mukesh M. Patel<br>Nitin Raojibhai Desai<br>Apurva S. Diwanji |
| **CHIEF FINANCIAL OFFICER** | Nitin D. Parekh |
| **CHIEF ACCOUNTS OFFICER** | Jyotindra B. Gor |
| **COMPANY SECRETARY** | Upen H. Shah |
| **BANKERS** | Bank of Baroda<br>BNP Paribas<br>Credit Agricole Corporate and Investment Bank<br>Citibank N. A.<br>Exim Bank<br>HDFC Bank Limited<br>ICICI Bank Limited<br>IDBI Bank<br>State Bank of India<br>Standard Chartered Bank |
| **AUDITORS** | Mukesh M. Shah & Co.<br>Chartered Accountants |
| **REGISTERED AND CORPORATE OFFICE** | "Zydus Tower", Satellite Cross Roads,<br>Ahmedabad - 380 015.<br>www.zyduscadila.com |
| **REGISTRAR AND SHARE TRANSFER AGENTS** | M/s. Sharepro Services India Private Limited<br>13 AB, Samhita Warehousing Complex,<br>Sakinaka Telephone Exchange Lane,<br>Off. Andheri-Kurla Road, Sakinaka,<br>Mumbai-400 072. |
| **WORKS FORMULATION UNITS** | S. No. 417, 419 & 420, Village Moraiya,<br>Taluka Sanand, District Ahmedabad.<br><br>Kundaim Industrial Estate, Ponda,<br>Goa-403 401.<br><br>Village Saraj Mujra<br>P.O. Baddi<br>Tehsil-Nalagarh<br>District Solan (HP) |
| **API UNITS** | GIDC Estate, Ankleshwar, Gujarat.<br>Dabhasa, Tal. Padra, District Vadodara. |
| **ZYDUS RESEARCH CENTRE** | Zydus Research Centre<br>S. No. 396/403, Village Moraiya, Taluka Sanand,<br>District Ahmedabad. |



### Important Communication To Members

The Ministry of Corporate Affairs has taken a "Green Initiative in Corporate Governance" by allowing paperless compliances by the Companies and has issued circulars allowing service of notices / documents including Annual Report by e-mails to its members. To support this green initiative of the Government in full measure, members who have not registered their e-mail address so far, are requested to do the same immediately.


V

### I AM VALUE CREATION

I like action
It's my basic nature to grow, to expand
I like to get stretched
I like to step into new roles
So let me put in my best in all that I do
Let me take special care of my health and fitness profile
How can I expect to win the race without it?

I

### I AM INNOVATION

People say I am brilliant, I can light up anything
I can make things look different
I don't like to be in a box
I can be a change agent
But like the bulb I need power to switch on
I need the power of new thoughts and ideas

C

### I AM COLLABORATION

I can't exist alone
You give your best, I give my best
Together we complement each other
Together we are unbeatable
Together we are unstoppable
Together, the universe is ours
So, let's join hands

A

### I AM ACCOUNTABILITY

I stand by whatever I promise, come what may
If I have said it will be done, it will be
I will deliver, everytime, as agreed
You can always count on me

The newly inaugurated, state-of-the-art QA/QC centre located within the global manufacturing hub at Moraiya

# Highlights of Operations – 2011-12

## Home Markets

### India

- Acquired 100% stake in Biochem Pharma, one of the top 40 pharma companies in India, having presence in the antibiotics, cardiovascular, anti-diabetic and oncological segments, to capitalise on the growth of the acute segment and in turn, further strengthen presence in the Indian pharmaceutical space.
- Maintained strong leadership positions in the cardiology, gynaecology, gastrointestinal and respiratory segments.
- Launched over 90 new products (incl. over 40 line extensions) in India, of which 29 were first in India.
- Overall, the India formulations business posted sales of Rs. 18,954 Mio., up by 17%.

### US

- Entered the $ 7 bn generic controlled substances market in the US, with the acquisition of the assets of Nesher Pharmaceuticals Inc., which has the capability to manufacture controlled release medications or DEA-controlled substances.
- Launched 6 new products in the US market.
- During the year, the US business posted sales of Rs. 12,431 Mio., up by 29%.

### Brazil

- Launched 7 new products during the year, with an aspiration to be a leading player in the chronic therapy segments like cardiovascular, diabetes and neuro psychiatry.
- Overall, the Brazil operations posted sales of Rs. 2,473 Mio., up by 10% during the year.

## Steady Growth Businesses

### Europe

- Launched 16 new products in the French generic market, of which, 6 were Day-1 launches.
- Launched 12 new products in the Spanish generic market.
- Overall, the Company's European business posted sales of Rs. 2,983 Mio., registering a growth of 8%.

### Japan

- Launched 2 in-licensed products and received the PMDA approval for 3 new products, including one for Day-1 launch.
- During the year, the Japanese business registered a growth of 24% with sales of Rs. 522 Mio.

### Emerging Markets

- The Company's business continued progress in the markets of Asia Pacific, Africa and the Middle East, gaining market share in Philippines, Vietnam and Sri Lanka.
- Over 30 new products were launched in the focussed markets of Asia Pacific and Africa during the year.

### Consumer Wellness

- Sugar Free, India's leading sugar substitute, achieved a milestone market share of more than 90% in the category.
- 'ActiLife' – a nutritional milk additive for adults, which was launched last year, progressed on expected lines during the year.
- During the year, Zydus Wellness Ltd. registered sales of Rs. 3,446 Mio., up by 3% and net profit of Rs. 677 Mio., up by 14%.



### Animal Health

- The company continued its thrust on new product launches with 11 new product introductions during the year.
- Zydus Animal Health Ltd. (ZAHL), acquired 100% stake in Bremer Pharma GmbH, Germany – a global animal health company. This will help ZAHL expand its animal health business and gain strategic access to the key markets across Europe, South America, Asia and Africa.
- On a consolidated basis, ZAHL posted sales of Rs. 1,944 Mio., with a growth of 40% during the year.

### APIs and Intermediates

- The company's API business continued to provide strong support in the form of backward integration to cater to the demand for finished formulations across markets.
- During the year, 10 DMF filings were made in the US, taking the cumulative US DMF filings to 107.

## JVs & Alliances

- Zydus Nycomed JV commenced commercial production and supply of 7 generic APIs to Nycomed.
- Zydus Hospira JV commenced commercial production and supply of 2 products for Europe and 1 product for the US market.
- Bayer Zydus Pharma, the JV with Bayer Schering Pharma commenced commercial operations in India during the year.
- Added 7 products and 3 markets in the out-licensing deal with Abbott Labs.
- Overall, the JVs reported sales of Rs. 4,230 Mio., up by 16%.

## New Technologies

- 5 biosimilar products were launched in the Indian market, developed and manufactured in-house. 3 more products are in the advanced stages of development.
- On the novel biologics front, filed clinical trial applications for both PEGEPO and Rabimabs.
- Filed 2 ANDAs for transdermal patches with the USFDA.

## NCE Research

- ZYOG1, a novel, orally acting GLP-1 agonist completed Phase I(a) clinical trials. The Company applied for permission to conduct Phase I(b) trials during the year.
- ZYD1, a novel GLP-1 agonist for treating diabetes and ZYGK1, a novel Glucokinase activator are currently in Phase 1 clinical trials.
- The Company also received Phase I clinical trial permission for ZYPH0907, a novel oral PTH agonist for treating osteoporosis, and ZYG19, a novel GPR-119 agonist for treating diabetes.

## Manufacturing Operations

- Baddi formulations manufacturing plant received an approval from the USFDA during the year, opening up an additional resource to cater to the growing needs of the US business.
- Commenced commercial production from the Ointments facility during the year.

## Financial Highlights

- Total income from operations was up by 14% y-y to Rs. 52.6 bn from Rs. 46.3 bn last year.
- Profit before interest, depreciation and tax, excluding the impact of exchange rate fluctuation loss on operating transactions, was up by 14% y-y to Rs. 11,772 Mio. from Rs. 10,287 Mio. last year. PBIDT margin was up by 0.2% to 22.4% from 22.2% last year.
- Net profit, excluding the impact of exchange rate fluctuation loss on the operating transactions and forex loans was up by 7% y-y to Rs. 7,468 Mio. from Rs. 6,992 Mio. last year.

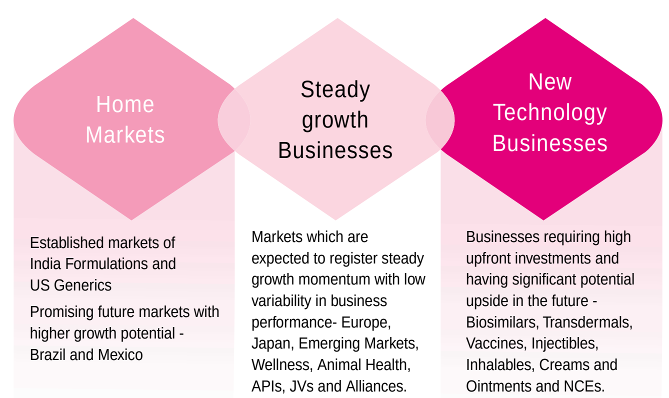

Chairman and Managing Director, Mr. Pankaj R. Patel at
the launch of VICA during the Chairman's Annual Meeting, January 2012

# Chairman's Message

The Year 2011-12 was a launchpad in many ways for our journey ahead - Beyond the Billion (BtB). It began with an extensive dialogue process that included key stakeholders across the organisation. In the weeks and months that ensued, we asked ourselves questions related to our business model, strategies, markets, operations and our review mechanisms. Along the way, we also looked at the success factors that had helped us achieve our growth and how they could be the levers for our growth as we move ahead. All these discussions and insights culminated into a strategic blueprint for the road ahead that was different, refreshing and opened the door to new possibilities.

## New Paths, New Approaches

Your Company has never believed in waiting for favourable tailwinds to achieve its goals. We have always believed in seizing opportunities and pursuing aggressive plans to capture them. This phase of our growth will be no different. We are moving ahead with a well thought out strategy. The vision, objectives and detailed road-map for each of these businesses have been defined and strategic initiatives have been identified along with an execution plan to ensure that each business achieves its own vision and BtB objectives. We identified 15 markets and 13 therapies which would be our core areas of focus. The clusters that emerged are home markets, steady growth businesses and new technology businesses. Our accomplishments in our journey of growth so far, have been the result of six core strengths : clear vision, superior performance and execution, strong leadership, unrivalled collaboration with partners, innovation and a successful acquisition track record. Apart from this, our operational excellence, robust review mechanism and ownership of the goals set, have also helped us achieve successive milestones and unleash value for our stakeholders. I am confident that we will continue with this winning stride as we head towards our goal of 2015 and beyond.




## Beyond the Billion and VICA

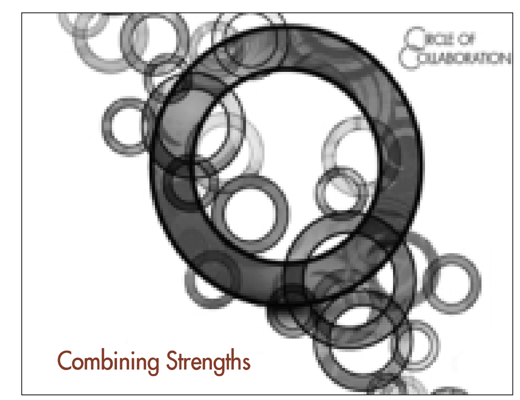
With the blueprint in place to achieve sales of over $3bn by 2015, we also looked at the key elements that will have help us achieve this overarching goal. Our collective thinking zeroed in on the four pillars of Value Creation, Innovation, Collaboration and Accountability (VICA). Under each of these pillars, several initiatives and ideas have been identified which can support our big leap forward.



**Accelerating Value Creation:** A sustainable value creation process begins with looking at value accruing points and embedding them in our products, technologies, processes and services. It's a like a kaleidoscope that reflects many hued images, each different from the other. The value creation initiative under VICA looks at different initiatives to build value by optimising resources, creating new talent pools and leveraging existing talent resources, creating new knowledge platforms, honing leadership capabilities and connecting and engaging with people globally, to create a unified, concerted thinking on sustainable value creation. Over the past few years, we have been successfully institutionalising several best practices in the organisation. One such initiative was PRISM 1– a landmark programme launched in 2002 which encouraged an organisation-wide ideation process on how we can generate savings through innovative, out-of-the-box thinking. Another successful initiative was the Strategic Lean Integrated Manufacturing programme or SLIM. It established a Zydus Way of Manufacturing of looking at lean manufacturing practices with significant increase in efficiency while lowering costs. At the start of this year, we launched PRISM 2 which has a core team of 63 members who are exploring creative ideas to optimize savings in procurement costs. Spread over 24 months, an important feature of PRISM 2 will be to institutionalise the ideas so the impact becomes a sustainable one on a year-on-year basis.

**Instituting a culture of Innovation:** In the current business environment, the need to innovate stretches far beyond the purely research and technological spheres. Now, more than ever, innovation is critical to our competitiveness and at another level, simply adding zest to our worklife by building in freshness and creating new experiences. So, how are we preparing our innovation processes for these challenges?


We've recently adopted a new innovation programme called the 'Zydus Innovation Farm', calling for three definite actions of planting ideas, nurturing ideas and harvesting ideas in consistent and measureable ways that brings in yields, year after year. First, we want to come up with innovations that improve our existing business initiatives and processes. The second goal of the programme is to develop more of the groundbreaking innovations that open up new markets. Third, to spur Open Innovation that connects all Zydans across the organisation and drawing on ideas from the grassroot level which can impact our business, operations and services. With local farm committees fanning out and building a momentum, we can expect the Zydus Innovation Farm to deliver a rich harvest in the coming year.




**Creating the Circles of Collaboration:** Collaboration at Zydus is more than just team work. It's about networking and integrating efforts and being able to reach out for information and expertise, or engage with people from different teams for critical decision making. An integrated and energised organisation is one in which collaboration networks enable teams and individuals across functions, departments, distance and technical specialities to side step bottlenecks. Under VICA, we have been able to study collaboration challenges across functions and geographies, address gaps to enhance connectivity and leverage solutions in targeted ways. Circles of Collaboration aims at helping teams, leverage diverse cross functional expertise and drive adoption of new ideas across geographies. Service Level Agreements and Cross Functional Teams will look at effectively serving the needs of business stakeholders and fast tracking processes.

**Gearing up with Accountability:** The fourth pillar of VICA is also closely linked to the performance culture that has taken root in the organisation over a period of time. We are fortunate to have forged a team of like-minded individuals with high aspirations, a bias for action, passion and energy to drive results and possessing the ability to turn commitment into strong performance. These characteristics have evolved a winning paradigm that helps us excel over and over again. The pillar of Accountability reinforces this and encourages Zydans across the organisation to take ownership for the overall business performances and celebrate in meaningful outcomes of it. It's about examining all the performance parameters at an individual, team and the organisational level and see how they can be supported adequately so that the expectations against performance commitments are understood and widely shared.

## On the path of sustained growth

Over the last 17 years, we have been building for the future, that looks at excellence and opportunities that create new horizons in healthcare. We'd like to thank all those who have shared our optimism and conviction, especially the talented team of over 15000 Zydans spread across the world and our Partners in Progress, who help us achieve our mission of creating healthier communities globally. As we continue to explore new vistas, we remain dedicated to the company's core values of being adaptable to change, being people-driven, commitment to deliver, and being humble, value-driven and innovative in what we do. In the years ahead, our aim will be to maintain our growth focus, drive our business strategy to produce successful results, provide innovative healthcare solutions and deliver increasing shareholder value.

Pankaj R. Patel
June 30, 2012

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 Chairman's Annual Meeting held in January 2012

# Management's Discussion & Analysis - 2011-12

## Global economy and Pharmaceutical Industry

The global economy has passed through a challenging phase in 2011-12, characterised by significant risks and instability. The intense financial crisis prevailing in Europe has had a ripple effect in both the developing and high-income countries, and has generated significant headwinds. Capital flows to developing countries have declined by almost half as compared to last year. While Europe seems to be in recession, several major developing countries like Brazil, India, and to a lesser extent Russia, South Africa and Turkey have witnessed decceleration in economic growth owing to a variety of factors including domestic policies. This has resulted in a sharp slowdown in the global economic growth. As against a growth of 4.1% in 2010, the global economic growth, measured by GDP, is expected to have slowed down to 2.7% in 2011. Also, the outlook for 2012 looks muted with expected growth of 2.5% as against 3.6% projected earlier (Source: Global Economic Prospects 2012 by World Bank).

The global pharmaceutical industry, particularly the branded innovator drugs segment, is also facing pressure due to a number of factors like patent expiry of a large number of high revenue molecules, a diminishing R&D pipeline of new drugs, regulatory challenges and pricing pressures from governments across the globe, apart from ballooning costs of doing research. There has been a shift of focus towards the emerging markets of Asia, Africa and Latin America, which are growing three times faster than the leading markets of North America, Japan and Europe. In 2011, while the leading pharmaceutical markets of North America and Europe continued to grow at a matured market rate of less than 3%, the emerging markets are expected to have grown by more than 15% (Source: IMS Health). The generics segment growth continued to outpace branded drugs, with several drugs losing patent protection in 2011, including ‘block-busters’ like Atorvastatin in the USA.

## Indian Economy and Pharmaceutical Industry

The financial year 2011-12 was a year of slow growth for the Indian economy. The GDP is estimated to have grown at less than 7% during 2011-12 after it grew by more than 8% during the two preceding financial years. Agriculture and industry showed slower growth during the year as compared to the growth that was registered in the previous year, resulting in slower overall growth.



Inflation remained high, with the Wholesale Price Index (WPI) remaining at over 9% for the most part of FY 2011-12, although it showed signs of moderating towards the later part of the fiscal year. The average WPI inflation rate for 2011-12 was 8.79% as against 9.56% during 2010-11. The global economic slowdown and the crisis in European economies, especialy Greece and now Spain, have resulted in currency movement from Euros to US Dollars and Pound Sterling, and a clamour for USD, which has gained in strength. This in turn, has led to a sharp depreciation of currencies of developing economies, including the Indian Rupee vis-à-vis the US Dollar and other currencies. The exchange rate for the Indian Rupee vs. the US Dollar, which was below Rs. 45, has shown a steady rise from August 2011 and reached a peak of Rs.53.7 in December 2011, before closing at Rs. 50.9 in March 2012 (Source: Monthly Economic Report, March 2012, as published by the Ministry of Finance, Govt. of India).

The Indian pharmaceutical market is on the path of becoming a major global market and is one of the biggest drivers of growth in the Asian subcontinent, apart from China. The year 2011 was yet another year of robust growth for the Indian pharmaceutical industry as it grew by 15%, reaching a market size of more than Rs. 60,000 crores (Source: AIOCD Market Intelligence Report 2012). This high growth can be attributed to the increase in investment by market players, high penetration into the rural areas, increasing purchasing power of the consumers and improving availability of healthcare facilities. Rural markets, now termed as the 'Extra Urban' markets, offer high growth potential for the Indian pharmaceutical industry. The anti-infectives therapy is the highest contributor to the Indian pharmaceutical market, in terms of sales.

## 2011-12: Journey Beyond the Billion begins

While the year 2010-11 marked the achievement of an important milestone of $ 1 bn in consolidated revenues by the Company, the year 2011-12 marks the beginning of the journey Beyond the Billion in pursuit of its next milestone of $ 3 bn in 2015.

During the year, the Company carried out a detailed exercise to work out the strategy for this journey Beyond the Billion(BtB). After a detailed study of various therapies and markets, the Company has identified 15 markets / countries and 13 therapies as key focus areas. Different markets / therapies have been classified into different clusters. They are home markets, steady growth businesses and new technology businesses.

Home markets comprise the two established markets of India Formulations and US generics and the two promising future markets of Brazil and Mexico. While the established home markets are expected to continue sustainable and profitable growth with significant revenue contribution, the future home markets offer a high growth potential with a large revenue contribution in times to come. The steady growth businesses comprise Europe, Japan, the Emerging Markets, Consumer Wellness, Animal Health, APIs, JVs and Alliances. These markets are expected to continue a steady growth momentum with low variability in business performance.

The new technology businesses comprise Biosimilars, Transdermals, Vaccines, Injectibles, Inhalers, Creams and Ointments and NCEs. While these businesses require high upfront investments, which the Company has already initiated, they have a very large potential upside in the future.

The vision, objectives and detailed road-map for each of these businesses have been defined. Several strategic initiatives have been identified for each of the businesses, alongwith their execution plans to ensure that each business achieves its own vision and BtB objectives. Key risks and their mitigation plans have also been identified for each business.

To ensure better review and monitoring process, greater accountability and better focus, the Company has also revamped the internal governance architecture. Key initiatives and implementation plans have been laid out for improving overall organisational health in the areas of Value Creation, Innovation, Collaboration and Accountability. These four pillars of VICA have been identified as the growth drivers in the journey Beyond the Billion.

Highlights of operations of the different businesses and markets in FY 2011-12 are as follows.


The new products launched during the year which were first in India

# Home Markets

## India Formulations

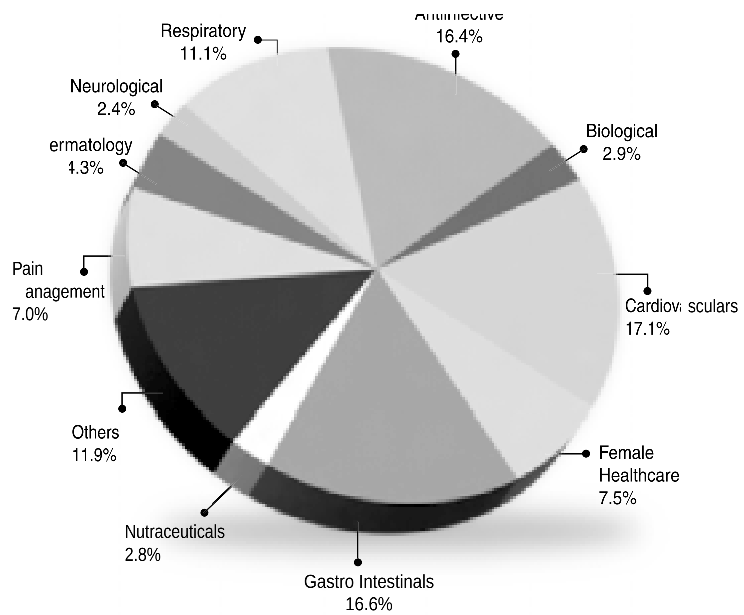
The Company's formulations business in India is of strategic importance in the journey Beyond the Billion. It is currently the largest contributor to the Company's revenues, and is expected to remain one of the largest contributors in the BtB journey.

During the year, the Company acquired 100% stake in Biochem, one of the top 40 pharma companies in India. A well-integrated pharma player, Biochem has a presence in the antibiotics, cardiovasculars, anti-diabetics and oncological segments. It has over 1100 employees (including a field force of 900) and a manufacturing facility at Daman. This acquisition is aimed at strengthening the Company's presence in the Indian pharmaceutical space by capitalising on the growth of the acute segment where it has a relatively smaller presence.

The Company continued to maintain its strong position in the participated market segments of cardiovasculars, gastro intestinals, respiratory and women's healthcare during the year. 20 of the Company's brands now feature amongst the top 300 pharmaceutical brands in India. (Source: AIOCD AWACS Report, MAT March 2012). During the year, the Company made a foray into a new therapy segment of opthalmology with the launch of the division, Zydus Occucare. The Company continued its thrust on new product introductions and launched over 90 new products, including over 40 line extensions, of which, 29 were first in India. The new products launched during 2011-12 contributed to about 3% in the growth of the formulations business in India.

During the year, the Company's formulations business in India posted sales of Rs.18,954 Mio., up by 17% from Rs.16,208 Mio. last year.

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






## US Oral Solids

The US pharmaceutical market remains the world's largest pharmaceutical market accounting for more than 40% of the market share. The Company's business in the US is spearheaded by its 100% subsidiary, Zydus Pharmaceuticals (USA) Inc. It ranks amongst the top three players in the market for nine out of the top ten products marketed by it in the US and has also recently been ranked 11th amongst the top US generic companies based on scripts (Source: IMS).

During the year, Zydus Pharmaceuticals (USA) Inc., through its subsidiary Nesher Pharmaceuticals USA LLC, acquired the assets of the US based pharmaceutical company, Nesher Pharmaceuticals Inc. Nesher has capabilities to manufacture controlled release medications or DEA-controlled substances. With this, the Company will now be able to manufacture and distribute generic controlled substances in the US market, which otherwise cannot be imported. The market for controlled substances medications in the US is estimated at $7 bn.

The Company's business in the US continued to grow and posted sales of Rs.12,431 Mio., up by 29% during the year. The Company launched 6 new products in the US market. This performance reflects the capabilities of the Company to offer high quality low cost generic products, making it a trusted and preferred supplier. The Company's continuous endeavour to improve service levels has helped it achieve close to 100% service level satisfaction of the customers. Going forward, the Company's growth momentum in the US market will continue with the launch of value added generic products that will drive incremental sales and margins.

## Brazil

Rated as one of the most promising 'pharmerging' countries across the world, the Brazilian pharmaceutical market has been continuously growing for the last few years and offers significant potential. Several factors such as strong Government support and high healthcare demand, amongst others are propelling the Brazilian healthcare market to grow at a faster pace.

The company is present in both the branded and generic segments of the Brazilian pharmaceutical market. With an aspiration to be a leading player in chronic therapy segments like cardiovascular, diabetes and neuro psychiatry, the Company launched 7 new products in Brazil during the year. Overall, the Company posted sales of Rs. 2,473 Mio., up by10% during the year.

## Mexico

The Company is present in Mexico, the second largest pharmaceutical market of Latin America, valued at $11 bn, through its 100% subsidiary, Zydus Pharmaceuticals Mexico S.A. de C.V. The Mexican market is expected to show an upward trend, with prescription medicines continuing to dominate the market, representing about 85% of its total value (Source: IMS and BMI). During the year, the organisational structure at Mexico including the basic regulatory, finance and marketing were put in place. Going forward, the Company expects to continue its aggressive product development and filing strategy and commence commercial operations in 2013.


# Steady Growth Businesses

## Europe

The Company has its presence in Europe through its subsidiaries in the generic markets of France and Spain. During the year, the French generics market grew by approximately 3% to reach €2.8 bn. Market growth showed a decline as compared to the previous years, mainly due to lower than expected generic substitution rates. The Spanish generic market, on the other hand, grew by about 30% and reached €1.4 bn, led by the increase in generic penetration, combined with some key patent expiries.

The Company's business in France maintained its progress during the year, despite the slowdown in the overall French market. The Company launched 16 new products in France, including 6 Day-1 launches. In Spain, the Company registered a robust growth backed by the launch of 12 new products. More than half of the products launched in France and Spain were manufactured and supplied from India.

During the year, the Company's business in Europe posted sales of Rs. 2,983 Mio., up by 8%.

## Japan

The Company is present in Japan, the world's second largest pharmaceutical market, through its subsidiary Zydus Pharma Japan Co. Ltd. (ZPJ). Japan continues to face the challenge of a rapidly ageing population and increasing healthcare costs, forcing the government to intervene by promoting generics. This offers a promising opportunity for the generic players to expand and grow. During the year, the Company launched two in-licensed products and received the PMDA approval for three new products including one Day-1 launch.

The Company's sales in Japan grew by 24% and reached Rs. 522 Mio. during the year.

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

During the year, the Company's business continued to perform well in the participated markets of Asia Pacific, Africa and the Middle East despite a slowdown in some of the markets due to political imbalances, regulatory changes and adverse currency fluctuations. The Company expanded its market share in the Philippines, Vietnam and Sri Lanka. With the launch of over 30 new products, the Company posted sales of Rs. 1,889 Mio. during the year in the Emerging Markets.



## API & Intermediates

The Company's APIs and Intermediates business continued to provide support in the form of backward integration to cater to the demand for finished formulations across markets. The Company filed 10 US DMFs during the year, taking the Company's cumulative filings to 107.

The year 2011-12 saw a decline in the sales of APIs at Rs. 2,854 Mio., down by 18% primarily on account of price erosion in the key international markets and higher capacity allocation to internal requirements for manufacturing of finished formulations.

## Consumer Wellness

The health and wellness market in India is a niche segment, which has been growing rapidly as in the recent past there has been an increased awareness and concern for health and wellness. The Company is present in this segment through its subsidiary, Zydus Wellness Ltd., which has become a significant player in this growing market with its portfolio of health care brands such as Sugar Free, EverYuth, Nutralite and the recently launched Actilife.

During the year 2011-12, Sugar Free, India's leading sugar substitute achieved a milestone market share of over 90%, through its multi-product presence. The year witnessed an intense competition in the skincare category from new entrants. In EverYuth skincare range, the scrubs and peel-off segments continued to grow, despite stiff competition. The last quarter of the FY 2011-12 saw a rapid revival in the market share backed by the strong marketing support. Nutralite also faced competition in the margarine space, as there have been multiple launches from low priced competitors, especially in the institutional segment. Despite this, Nutralite has successfully maintained its position through high service levels that complement strong brand equity.

Actilife, a nutritional milk additive for adults, launched last year, has seen steady progress during the year. Being a new concept, the Company has invested in creating awareness, not just through theme advertising but also through large scale consumer contact programs involving education and sampling. This brand will be in focus for the next few years as it has a potential to become an additional pillar of growth for the Company.

During the year, Zydus Wellness Ltd. registered sales of Rs.3,446 Mio., up by 3% and net profit of Rs. 677 Mio., up by 14%.

## Animal Health Business

Zydus Animal Health Ltd., (ZAHL), a 100% subsidiary of the Company, is one of India's leading animal healthcare providers with its wide range of drugs, feed supplements and vaccines for livestock, companion animals and poultry. During the year 2011-12, ZAHL continued its prowess in launching new products with the introduction of 11 new products in India.

During the year, ZAHL expanded its operations globally with the acquisition of a 100% stake in Bremer Pharma GmbH, Germany. This acquisition will help ZAHL, expand its animal health business and gain strategic access to the key markets across Europe, South America, Asia and Africa.

On a consolidated basis, ZAHL posted sales of Rs. 1,944 Mio, with a growth of 40% during the year.

## JVs and Alliances

### A. Zydus Nycomed Healthcare Pvt. Limited

Zydus Nycomed is a 50:50 JV between Nycomed and Cadila Healthcare Ltd., for manufacturing of Key starting materials (KSMs) for Pantoprazole and also a hub for supplying various APIs of Nycomed's generic portfolio and in future for Takeda, following the acquisition of Nycomed by Takeda .

During the year, the Zydus Nycomed JV commenced the commercial production and supply of 7 generic APIs to Nycomed. The JV was successful in getting approvals from the Danish Medicine Agency after their regulatory audits for different products.

### B. Zydus Hospira Oncology Pvt. Ltd.

Zydus Hospira Oncology Pvt. Ltd. (ZHOPL), the 50:50 JV between Cadila and Hospira Inc., USA, successfully completed its third year of operations. During the year, the JV successfully completed audits by the Korean and Saudi FDA. With this, the JV has received approvals from the regulatory authorities of US, Europe, Canada, Australia, Brazil, Uganda, Korea and Saudi. The JV commenced commercial production and supply of 2 additional products for Europe and 1 for the US market during the year.

### C. Bayer Zydus Pharma Pvt. Ltd.

Bayer Zydus Pharma Pvt. Ltd., the joint venture with Bayer Schering Pharma, commenced commercial operations in India during the year. The JV aims at operating in key segments of the Indian pharmaceutical market with a focus on women's healthcare, metabolic disorders, diagnostic imaging, cardiovascular diseases, anti-diabetic treatments and oncology.

### D. Zydus BSV Pharma Pvt. Ltd.

Zydus BSV Pharma Pvt. Ltd. (ZBSV), the 50:50 JV set up in alliance with Bharat Serums and Vaccines Ltd., owns rights to a novel and patented product for use in oncology. ZBSV also operates in the generic oncology segment by way of contract manufacturing. The JV's novel and patented product progressed well in the Indian market. This clearly indicates the superior benefits, this product offers to cancer patients and further supports the Company's plans for developing the product for global markets. The Company's ongoing clinical trial in breast cancer is progressing as per schedule and will assist in gaining market share in India as well as approvals in various other markets.

### E. Strategic out-licensing deal with Abbott Laboratories

During the year, the company expanded its alliance with Abbott Laboratories to 3 more countries taking the total number of countries to 18. Further, 7 more products were added to the existing portfolio of 24 products, taking the number of out-licensed products to 31.

Overall, the Company's share in the sales from the JVs was Rs. 4,230 Mio. during the year, up by 16%.



# New Technologies

## Biologics

The Company is developing a pipeline of 19 biologics, comprising 17 biosimilars and 2 novel biological products. During the year, the Company launched 5 biosimilar products in the Indian market, developed and manufactured in-house. 3 more products are in an advanced stage of development. On the novel biologics front, the Company filed clinical trial applications for PEGEPO, which is being developed in collaboration with Prolong Pharma, USA and Rabimabs, which is being developed in collaboration with WHO.

## Transdermals

The Company's initiatives to develop a niche portfolio of technologically complex and advanced new drug delivery systems have progressed well during the year, with filings with the USFDA for 2 ANDAs for transdermal patches.

## NCE Research

The Company's state-of-the-art Zydus Research Centre (ZRC) spearheads the Company's NCE and Biologics research activities. The company currently conducts basic new drug discovery research in cardio-metabolic, inflammation, pain and oncology therapeutic areas, with a portfolio of 8 candidates in various stages of development.

During the year, ZYOG1, the Company's novel, orally acting GLP-1 agonist completed Phase I(a) clinical trials in healthy human volunteers and the Company applied for permission to conduct Phase I(b) trials in diabetic patients. ZYD1, a novel GLP-1 agonist for treating diabetes and ZYGK1, a novel Glucokinase activator are currently undergoing Phase 1 clinical trials. The Company also received Phase I clinical trial permission for ZYPH0907, a novel oral PTH agonist for treating osteoporosis and ZYG19, a novel GPR-119 agonist for treating diabetes.

## 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 150 patents in the US, Europe and other countries during the year, taking the cumulative number of filings to over 800.

# Manufacturing Operations

The Company's state-of-the-art facilities for manufacturing formulations and APIs are considered to be the backbone of the Company's global operations and would be one of the important pillars for success in the BtB journey.

During the year, the formulations manufacturing plant at Baddi, Himachal Pradesh received an approval from the USFDA. This opens up an additional resource to cater to the growing needs of its US business. Further, commercial production was started from the Ointment facility during the year for the Indian market.

# Environment, Health and Safety

The company is aiming for sustainable development, specially focussed on EHS by recognising, understanding and addressing EHS related matters, right from the stage of development to delivery. During the year, the EHS portal was launched to bring in information asymmetry across various manufacturing units on techno-legal aspects in the field of EHS. All the manufacturing units in India completed the fire safety audit through the expert committee. By integrating various treatment options in API units, the Company was successful in treatment and utilisation of treated effluent as a boiler feed. Two of the Company's units received the safety award from the Gujarat Safety Council for the second consecutive year in a row. At present, 11 of the Company's manufacturing facilities are accredited by ISO 14001 and OHSAS 18001.



# Consolidated Financial Highlights*

* In the consolidated financial statements, the Company's share in incomes, expenses, assets and liabilities of Joint Ventures (JVs) have been shown at the end of the schedule of such incomes, expenses, assets and liabilities. However, for financial analysis, share in each head of income, expense, asset and liability of the JV has been considered for better understanding.

## Sales

The gross sales revenue grew by 15% to Rs. 51,807 Mio., in 2011-12 from Rs. 45,211 Mio., in 2010-11. Sales growth was driven largely by the US oral solids business and the Indian formulations business, which grew by 29% and 17% respectively.

## Gain / loss on account of foreign exchange rate fluctuations

The Company has an exposure in foreign currencies, mainly US Dollar and Euro. The company is a net foreign exchange earner due to its higher export earnings compared to imports. However, the steep depreciation of the Indian Rupee vis-à-vis the US Dollar, particularly in the second half of the year has resulted in a negative impact on the earnings due to the large foreign currency denominated borrowings, while hedge contracts entered in the earlier periods to protect export receivables have restricted the upside available during the depreciation of the Indian Rupee.

The Company continued to recognise the gain / loss on account of foreign exchange rate fluctuations ("forex gain/loss") arising on translation of foreign currency long term loans under "Foreign Currency Monetary Items Translation Difference Account" (FCMITDA) and amortize the same during the tenure of the loan, but not beyond 31st March 2020. Such forex gain/loss is adjusted to the cost of fixed asset, in case the foreign currency loan is taken for funding fixed assets.

During the year, the Company has adopted the provisions of Accounting Standard 30 on "Financial Instruments: Recognition and Measurement" issued by ICAI for accounting of derivatives and hedge instruments. Accordingly, any changes in the fair value of such instruments which are designated and effective as hedges are recognised in "Hedge Reserve" and ineffective portion is charged to Profit & Loss account.

During the year, the total forex loss was Rs.1,177 Mio., as against gain of Rs.148 Mio., last year. Of this, the loss on foreign currency loans was Rs. 776 Mio., which includes loss of Rs. 138 Mio. reclassified as interest cost as per Accounting Standard 16 on "Borrowing Costs".

## Profits and margins

The PBIDT (Profit before Interest, Depreciation and Tax) grew by 9% to Rs. 11,370 Mio., from Rs. 10,393 Mio., last year. PBIDT excluding the impact of forex loss on operating transactions was up by 14% y-y to Rs. 11,772 Mio. from Rs. 10,287 Mio. last year. The PBIDT margin excluding such forex loss was up by 0.2% to 22.4% from 22.2 % last year.

Net profit, excluding the impact of exchange rate fluctuation loss on operating transactions and forex loans was up by 7%, y-y to Rs. 7,468 Mio. from Rs. 6,992 Mio. last year.

## Net Worth

The consolidated net worth increased to Rs. 25,736 Mio., at the end of March 2012, up by 19% from Rs. 21,715 Mio., at the end of March 2011.

The reserves and surplus increased by Rs. 4,021 Mio., to Rs. 24,712 Mio., at the end of the year 2011-12, from Rs. 20,691 Mio., last year. The book value per share increased to Rs.125.85 as on 31st March 2012 from Rs. 106.06 last year.

The return on adjusted net worth (RONW = Net profit excluding exceptional items net of tax/Average net worth adjusted for deferred expenses and exceptional items) stood at 27.5% for the year.

### Debt

Consolidated debt of the Company stood at Rs. 22,951 Mio., as on 31st March, 2012 as against Rs.10,973 Mio., last year. This includes long term borrowings, short term borrowings and current maturities of long term borrowings classified as current liability as per the requirements of the revised Schedule VI of the Indian Companies Act.

There was, however, cash and bank balance of Rs.4,666 Mio., as on 31st March 2012 as against Rs. 2,952 Mio., last year. Net debt (adjusted for cash and bank balances) as on 31st March, 2012 was at Rs. 18,285 Mio., against Rs. 8,021 Mio., last year. The increase in debt was mainly to fund the capex, increased working capital and other opportunities. Net debt-equity ratio stood at 0.71:1 as on March 31, 2012 as against 0.37:1 as on March 31, 2011.

### Fixed Assets and Capital Expenditure

The consolidated gross block (including capital work in progress) at the end of the year was Rs. 45 bn, up by over Rs. 12.4 bn from Rs. 32.6 bn last year. Net capital expenditure (excluding goodwill, but including capital work in progress) during the year was Rs. 6,495 Mio., which was incurred mainly for upgradation and expansion of the capacity of existing facilities for formulations and API manufacturing, expansion of research facilities, building of new facilities for new dosage forms and acquisition of assets of Nesher Pharma. This also included capital expenditure on R&D of Rs. 423 Mio.

### Capital employed and operating efficiency

The total Capital Employed (CE), adjusted for exceptional items and deferred expenses, at the end of the year was Rs. 49.9 bn, up from Rs. 33.8 bn at the end of the previous year. The increase in capital employed was mainly due to the increase in the Debt, which has increased by Rs.12 bn during the year from Rs.11 bn to Rs. 23 bn. Return on Capital Employed (ROCE = Adjusted earnings before interest net of tax / Average CE) stood at 19.1% during the year.

## Risk Identification, Risk Mitigation and Internal Controls

Various risks identified by the Company in the ever changing economic, commercial, regulatory and political scenarios across the globe are explained below.

### Risk related to economic and political environment across the world

The Company has a global presence with its operations spanning 15 countries and 5 continents. Different countries of the world today face different political and economic challenges and in today's era of globalisation, policies of countries that the Company operates in are reviewed periodically to evaluate risks.

### Risk of competition, price pressure and Government controls on prices

The Company's business in the developed as well as emerging generic markets across the globe faces stiff competition as the generic markets are characterised by a number of players competing with each other to grab market share, creating pricing pressures. The company's strategies in such markets are tailored to mitigate such risks.

### Risk of litigation related to quality of products, intellectual properties and other litigation

The pharmaceutical products and their manufacturing and supply chain processes are subject to stringent regulations and quality standards.



Any deviation from prescribed regulations or any variation in quality from standards laid down by regulatory authorities can lead to actions from these authorities or litigation from the customers. The Company also faces the risk of litigation from the competitors and multinational pharmaceutical companies holding patents for products and processes, in case the Company's products or processes are claimed to be infringing their intellectual property rights.

The company does take out 'Product Liability Insurance' wherever necessary, as a safeguard against unrealistic claims. It also maintains constant vigilance on quality standards of shipments, to ensure the high standards of the Company, often superior to those required.

### Risk of international operations including foreign exchange risk

The Company's international operations in various countries and funding of its operations through foreign currency debt exposes it to the risk associated with fluctuation in the currencies of these countries vis-à-vis its functional currency viz., the Indian Rupee.

### Risk of efforts on Research and Development proving to be unproductive

The Company invests about 6 to 7% of its revenues on research and development activities (both revenue and capital expenditure) every year. NCE and NDDS research require significant investment and a longer gestation period, with chances of success being determined by many factors. This exposes the Company to the risk of its drug discovery efforts, proving to be unproductive at any phase. However, as a global player, this risk is a necessity as the Company aspires to be a research-driven player by 2020.

### Risk Management and Internal Control Systems

The Company has established a well-defined process of risk management, wherein the identification, analysis and assessment of the various risks, measurement of the probable impact of such risks, formulation of risk mitigation strategies and implementation of the same takes place in a structured manner. The process of evaluation and validation of business-specific risks and risks affecting overall organisation is carried out regularly. The review of the risk management policy and framework is also carried out at regular intervals by the Risk Management Committee as well as the Board of Directors. Requisite internal control mechanisms have been put in place by the Company on various activities across the board to minimise the impact of various risks. A well-defined and established system of internal audit has also been set up to independently review and strengthen these control measures. The Audit Committee of the Company regularly reviews the reports of the internal auditors and recommends actions for further improvement of the internal controls.