

# WHAT NEXT

# WHAT NEXT?

**The answer to this all important question is ensconced in our vision and embedded in our strategy for tomorrow.**

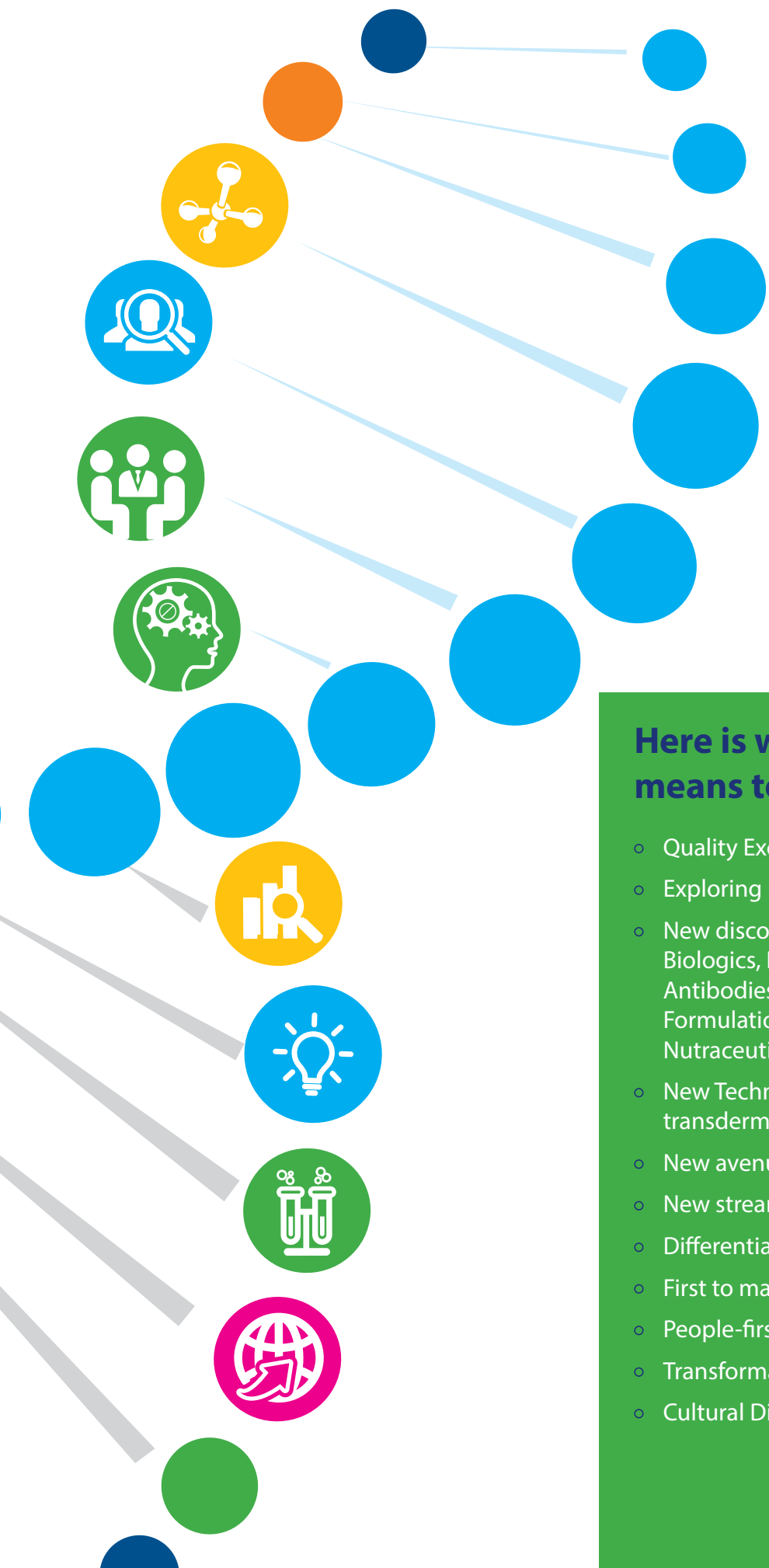
At Cadila Healthcare, we have always believed in being future ready. The future has already begun and tomorrow has already started.

## OUR ANSWER TO WHAT NEXT IS



ZyNext 2020 is all about being future ready. It is both our roadmap and our blueprint for the next strategic horizon and goal. It details the steps of our journey over the next four years.





## Here is what ZyNext 2020 means to us :

- Quality Excellence
- Exploring new markets
- New discoveries and Innovation (Vaccines, Biologics, NMEs, Peptides, Monoclonal Antibodies, Controlled Substances, Formulation Development, API Research, Nutraceuticals and Wellness Products)
- New Technologies (New Dosage Forms - transdermals, aerosols, inhalables)
- New avenues for growth
- New streams of business
- Differentiated strategies
- First to market
- People-first approaches
- Transformational journeys
- Cultural Diversity



**Mr. Ramanbhai B. Patel**

Founder Chairman, Zydus Cadila  
August 19, 1928 - September 19, 2001

"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."

As the Company prepares itself for the leap into the future, it explores innovative pathways guided by its Founder's vision.



# CORPORATE INFORMATION

## FOUNDER

Late Ramanbhai B. Patel

## BOARD OF DIRECTORS

Pankaj R. Patel

*Chairman & Managing Director*

Dr. Sharvil P. Patel

*Deputy Managing Director*

## DIRECTORS

Mukesh M. Patel

Humayun Dhanrajgir

Nitin Raojibhai Desai

Dharmishta N. Rawal

Apurva S. Diwanji\*

\* [w.e.f. May 13, 2016]

## CHIEF FINANCIAL OFFICER

Nitin D. Parekh

## COMPANY SECRETARY

Upen H. Shah

## REGISTERED AND CORPORATE OFFICE

"Zydus Tower", Satellite Cross Roads,  
Sarkhej-Gandhinagar Highway,  
Ahmedabad - 380 015

## STATUTORY AUDITORS

M/s. Mukesh M. Shah & Co.  
Chartered Accountants  
Ahmedabad

## REGISTRAR AND SHARE TRANSFER AGENTS

Link Intime India Private Limited,  
No. 303, 3rd Floor, Shoppers Plaza-5,  
Nr. Government Society,  
Opp. Municipal Market,  
Behind Shoppers Plaza II,  
Off C. G. Road, Navrangpura,  
Ahmedabad - 380 009

## WORKS FORMULATION UNITS

Survey No. 417, 419 & 420,  
Sarkhej Bavla N. H. No. 8A  
Village - Moraiya, Taluka - Sanand,  
District - Ahmedabad - 382 210

Kundaim Industrial Estate,  
Ponda, Goa - 403 115

Village - Swaraj Majra, Baddi,  
District - Solan,  
Himachal Pradesh - 173 205

## API UNITS

Block No. 265/266, Village: Changodar,  
Sarkhej Bavla N. H. No. 8A, GIDC Estate,  
Ankleshwar, Gujarat

Dabhasa, Taluka - Padra,  
District - Vadodara

Block No. 162, Ekalbara Umraya Road,  
Village - Dabhasa, Taluka - Padra,  
District - Vadodara

## TOPICAL UNIT

Plot No. 254-255, Opp. Laxmi Narayan  
Petrol Pump, Sarkhej Bavla N. H. No. 8A,  
Changodar Road, Taluka - Sanand,  
District - Ahmedabad - 382 210

## BIOLOGICS UNIT

Survey No. 40P, 23, 25P, 42, 37.  
Opp. Ramdev Masala,  
Sarkhej-Bavla N. H. No. 8A,  
Changodar, District - Ahmedabad

## SEZ UNIT

Plot No. 1 / 1A & 2,  
"PHARMEZ"  
(Special Economic Zone),  
Matoda, Sarkhej-Bavla N. H. 8A,  
Taluka - Sanand,  
District - Ahmedabad - 382 213

## RESEARCH CENTRE

Survey No. 396 / 403,  
Sarkhej Bavla N. H. No. 8A,  
Moraiya - Ahmedabad - 382 213

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# HIGHLIGHTS OF OPERATIONS - 2015-16



## FORMULATIONS BUSINESS - KEY MARKETS

### US Formulations

- Crossed US\$ 600 Mio. in sales for the first time during the year. In INR terms, the business posted sales of Rs. 40,215 Mio., up by 19%.
- Filed 30 ANDAs with the USFDA during the year, taking the cumulative ANDA filings to 269.
- Received approval for 10 ANDAs (including the first ANDA approval from the formulations facility located in Ahmedabad SEZ and the first ANDA approval from own filings made from the Nesher facility in the US) during the year, taking the cumulative ANDA approvals to 103.
- Launched 3 new products in the US market, including one from the Nesher facility.

### India Formulations

- Ranked among the top 3 players in the market in the Cardiology, Gynecology and Pain Management therapy areas while in the Gastro Intestinal, Respiratory and Dermatological space, ranked among the top 5 players in the market.
- Launched over 40 new products, including line extensions, of which 10 were first in India. These included the launch of Vaxiflu S, an H1N1 vaccine and Tenglyn (Teneligliptin 20 mg tablets), the most affordable gliptin for diabetics in India.
- Posted sales of Rs. 29,732 Mio., up by 11.1%.

### Latin America Formulations

- Launched 2 new products both in Brazil and Mexico during the year.
- In Brazil, filed 5 new product dossiers and received approval of 4 new product dossiers from the regulatory authority ANVISA during the year.
- In Mexico, received approval for 12 dossiers during the year, taking the cumulative number of approvals to 36.
- Registered sales of Rs. 2,177 Mio.

### Emerging Markets Formulations

- Launched 8 new products in different markets of Asia Pacific, Africa and Middle East during the year. This included the launch of "Pegihep" (Pegylated Interferon alpha 2b) in Myanmar, the first biosimilar launch in the emerging markets.
- Posted sales of Rs. 4,760 Mio. during the year, up by 17%.

## OTHER BUSINESSES AND ALLIANCES

### Europe Formulations

- Rationalized the product portfolio both in France and Spain by expanding the business of in-house products.
- Launched 3 new products in France (2 from India) and 4 new products in Spain (all from India).
- Posted sales of Rs. 2,956 Mio.

### Consumer Wellness

- Sugar Free maintained leadership position in the artificial sweetener category with a market share of 93.7%, an increase of 120 basis points over the last year.
- In the skincare category, both EverYuth peel off and EverYuth scrub maintained leadership position with a market share of 92.1% and 30.7% respectively.
- Registered sales of Rs. 4,570 Mio., up by 3% and net profit of Rs. 1,017 Mio., up by 10% on a like-to-like basis.

### Animal Health

- Acquired select brands and manufacturing operations in India from the Indian subsidiary of Zoetis Inc., a global animal healthcare company.
- Received the "Animal Pharm Award for the best company in India/Africa/Middle East 2015" from the world's leading pharma news publication, Animal Pharma, UK.

- Launched 8 new products in India.
- Posted sales of Rs. 3,199 Mio., with a growth of 3% during the year.

#### API

- Filed 6 DMFs with the USFDA, taking the cumulative US DMF filings to 122.
- Posted sales of Rs. 3,647 Mio.

#### JVs & Alliances

- Zydus Takeda JV received the Best Energy Efficient Unit Award at the national level from the Confederation of Indian Industry.
- Zydus Hospira JV successfully completed inspections by the regulatory authorities of Japan and Korea.
- Received approval from the USFDA for 2 ANDAs and 1 NDA which were filed on behalf of the partners.
- Posted sales of Rs. 5,342 Mio., up by 13%.

#### NEW INITIATIVES

#### Biosimilars

- Initiated Phase III clinical trials for one more monoclonal antibody (mAb) and received the regulatory approval to initiate Phase III clinical trials for one more biosimilar product.
- Continued to file the dossiers of first generation biosimilars in the emerging markets.
- On the novel biologics front, initiated the next phase of clinical trials for Rabimabs.

#### Vaccines

- Received marketing authorization from DCGI for two vaccines, out of which, one has been launched in India.
- Successfully completed the last stage of clinical testing for four vaccines and submitted them to DCGI for marketing authorization in India. Apart from this, thirteen vaccines are in different stages of clinical trials.

#### NCE

- Received approval from the USFDA to initiate Phase II clinical trials for Saroglitazar in patients with severe hypertriglyceridemia.

- Completed Phase I clinical trials in United States for ZYDPLA 1, a novel, next generation, orally active small molecule DPP-4 inhibitor to treat Type 2 diabetes.
- Completed Phase I clinical trials in Australia for ZYAN 1, a HIF-PH for treating anaemia.
- Filed an IND with DCGI for ZYTP 1, a novel Poly (ADP-ribose) Polymerase (PARP) inhibitor. This was the first IND filed in the oncology segment.

#### MANUFACTURING OPERATIONS

- Four formulations facilities viz. oral solid dosage facility, oncological injectable facility (of Alidac Pharmaceuticals Ltd., a 100% subsidiary of the Company) and transdermal facility (of Zydus Technologies Ltd., a subsidiary of the Company) located in Ahmedabad SEZ and oral solid dosage facility located at Baddi received Establishment Inspection Report (EIR) from the USFDA.
- Moraiya formulations facility successfully completed the ANVISA inspection.
- Moraiya formulations facility received the India Pharma Award from UBM India for EHS Excellence.
- Sikkim formulations facility received "Silver Certificate of Merit" from Frost & Sullivan at India Manufacturing Excellence Awards 2015.

#### FINANCIAL HIGHLIGHTS

- Total income from operations was up by 14% y-o-y to Rs. 98.4 bn., from Rs. 86.6 bn., last year.
- Earnings before interest, depreciation and tax grew by 36% to Rs. 23.8 bn., from Rs. 17.6 bn., last year. The EBIDTA margin as % to total income from operations improved by 3.9% to 24.2% from 20.3% last year.
- Net profit was up by 32% to Rs. 15.2 bn., from Rs. 11.5 bn., last year. The net profit margin as % to total income from operations improved by 2.2% to 15.5% from 13.3% last year.
- Return on net worth improved to 31.7% during the year compared to 30.1% registered in last year.



# CHAIRMAN'S MESSAGE





*"The theme of this year's report 'What's Next' captures the Company's overriding objective: to continually look ahead and build a sustainable and ethical Company that, through its initiatives and contributions, generates enduring value for the communities that it is a part of."*

Dear Shareholders,

Your Company continued to make progress and delivered strong results in the year under review which has been detailed out in various sections of this report. In this section, I'd like to share with you why the year was important for us and how it will have a bearing on our future.

### Planting the seeds for future growth

FY16 was a pivotal year when we looked at the enterprise of the future and took stock of where we wish to be in the next four years and what we need to do to get there. So quite simply, we asked ourselves, "What Next?" This was the start of a new growth journey and we set out to explore a Prism of Possibilities. We continue to believe that our Company has the diversity and mix of skills, experience, independence and knowledge required in order for the Company to be able to reach its goals successfully.

Over the past few years, the pace of progress has accelerated and we have introduced effective new technologies for improving accessibility of healthcare therapies across geographies. As we continue to add value through innovation and optimise our resources, we remain committed to our goal of bridging unmet healthcare needs and providing therapies that address both accessibility and affordability.

### We asked ourselves -



We asked ourselves all these questions and more in our overarching goal of ZyNext 2020.

To be better positioned to do this, we will need to look at differentiated strategies, think creatively, move with agility and stay in the action mode.

There is a clear understanding at Zydus of how important it is to grow, evolve and continuously raise the bar of excellence at the marketplace and that is why the quest for ongoing improvement is integrated into our business strategy.

We will continue to strengthen our ability to meet our goals - a reflection of our people's commitment to harness their energies and passion to create a better tomorrow.

As we look ahead, the strategy is clear and our goal is to execute it well. With a strong management team and more than 19,000 people - we believe that we can make this possible.

### The future belongs to those who can innovate

Innovation has been the core of our being. The journey of discovery and innovation that began with our Late Founder Chairman, Mr. Ramanbhai B. Patel, has become one of the most important pillars of our organisation. We at Zydus, have been putting innovation and technology to work to make our growth journey more meaningful.

In keeping with our vision to become a research-driven pharma company by 2020, we have stayed invested in research and have been making brisk progress with a robust pipeline of innovative medicines, including small molecule NCEs, biosimilars, novel biologics vaccines and novel formulations.

Lipaglyn, our NCE and a first-in-class medicine to treat diabetic dyslipidemia, has been delivering excellent results and has benefitted more than 300,000 patients since its launch in September 2013. We are also looking at developing this product globally for several other indications and data on these studies have been presented at prestigious scientific and medical conferences like American Association of Clinical Endocrinologists (AACE) and American Diabetes Association (ADA). Recently, our group received approval from the USFDA to initiate a Phase 2 clinical trial of Saroglitazar in patients with Non-Alcoholic Steatohepatitis (NASH) of the liver and additional Phase III trials are ongoing in non-alcoholic steatohepatitis (NASH), lipodystrophy, severe hypertriglyceridemia and a few additional indications. A post-marketing Phase-IV study is also currently underway in patients suffering from hypertriglyceridemia in India.

Our research programme is also aimed at finding better cures for people living with various kinds of inflammation, like rheumatoid arthritis, Ankylosing spondylitis, psoriasis, ulcerative colitis, Crohn's disease

as well as chronic pain. We remain committed to increasing patient access to high-quality biosimilars at affordable costs. It is this commitment that spurred the launch of Exemptia, the world's first biosimilar for Adalimumab, the largest selling therapy worldwide for inflammatory arthritis. We have built one of the largest biosimilars pipelines in India and currently market eight biosimilars products in India and have 20 biosimilars in various stages of development.

Our Vaccine Technology Centre (VTC) has been developing vaccines for the basic vaccine programmes such as Diphtheria, Pertussis, Tetanus, Haemophilus Influenzae type B, Hepatitis B, Measles, Mumps, Rubella, Varicella, Influenza and Typhoid fever. In addition, VTC is developing new vaccines such as Human Papilloma Virus, Leishmaniasis, Malaria, Haemorrhagic Congo Fever, Ebola and Japanese Encephalitis and many such vaccines which are not yet produced either in India or elsewhere in the world.

### Quest: Institutionalising a Culture of Quality

At various stages of our growth, we have been looking at key elements that will become leitmotif or a recurrent theme in our journey. PRISM, our cost optimisation is one such programme which continues to run successfully since its launch in 2002. SLIM - a Strategic, Lean and Integrated Manufacturing initiative, which started off in a small way in 2007 is today a power engine of continuous improvement with nearly 3000 ideas and 700 members powering it across 20 locations. In 2015, we looked at how Quality in its various dimensions can become a part of our being at Zydus. Thus began Quest - an exploration that will change the way we think and work. With nearly 50 circles across three manufacturing locations, covering 4500 people and a bank of over 500 ideas prioritised for implementation, the programme is well entrenched in the organisation. QUEST - Quality Excellence by Sustainable Transformation is an all important step towards the larger cause of making Quality a way of life at Zydus.