





## CORPORATE INFORMATION

**Founder** 

Late Ramanbhai B. Patel

**Board of Directors** 

Pankaj R. Patel

Chairman

Dr. Sharvil P. Patel

Managing Director

Ganesh N. Nayak

Executive Director

Mukesh M. Patel

Bhadresh K. Shah

Nitin R. Desai

Dharmishtaben N. Raval

Apurva S. Diwanji

Nitin D. Parekh

Chief Financial Officer

Dhaval N. Soni

Company Secretary

#### **Statutory Auditors**

Deloitte Haskins and Sells LLP Chartered Accountants Ahmedabad

#### **Zydus Research Centre**

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

Ahmedabad - 382 213

## Pharmaceutical Technology Centre (PTC):

Plot No. A-106, 107, Road Number 21, Nehru Nagar, Wagle Industrial Estate, Thane West, Thane-400604, Maharashtra

#### Registrar and Share Transfer Agents

Link Intime India Private Limited 506-508, Amarnath Business Centre-1 (ABC-1), Besides Gala Business Centre, Off. C G Road, Ellisbridge, Ahmedabad - 380 006

#### **Formulation Units**

Plot No. 1, 1A, 1B and 2 'PHARMEZ' (Special Economic Zone) Matoda, Sarkhej-Bavla N.H. No. 8A

Taluka: Sanand

District: Ahmedabad - 382 213

Survey No. 417, 419 & 420 Sarkhej-Bavla N.H. No. 8A

Village: Moraiya Taluka: Sanand

District: Ahmedabad - 382 210

Survey No. 434/6/B and 434/1/K Village Jarol, Taluka: Waghodia

Vadodara - 391510.

Plot No. 254-255, S.G. Highway N.H. No. 8A, Changodar

Taluka: Sanand, Ahmedabad - 382210.

Plot No. 203-213

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 Ahmedabad - 382 210

GIDC Estate

Ankleshwar 393 002, Gujarat

Dabhasa, Taluka: Padra 391 440

District: Vadodara

Block No. 162

Ekalbara Umraya Road

Village: Dabhasa Taluka: Padra 391 440 District: Vadodara

#### **Biologics Unit**

Survey No. 40P, 23, 25P, 42, 37 Opp. Ramdev Masala, Sarkhej-Bavla

N.H. No. 8A, Changodar District: Ahmedabad - 382 213

#### Animal Health Unit

Plot No. F-1/1, Sector 6B IIE SIIDCUL, Haridwar - 249 403

#### **Registered and Corporate Office**

Zydus Corporate Park, Scheme No. 63, Survey No. 536, Near Vaishnodevi Circle Khoraj (Gandhinagar) S.G. Highway, Ahmedabad - 382481.

Forward-looking statement: In this Annual Report, we have disclosed forward-looking information to enable investors to comprehend our prospects and take informed investment decisions. This report and other statements – written and oral – that we periodically make, contain forward-looking statements that set out anticipated results based on the management's plans and assumptions. We have tried wherever possible to identify such statements by using words such as 'anticipates', 'estimates', 'expects', 'projects', 'intends', 'plans', 'believes' and words of similar substance in connection with any discussion on future performance. We cannot guarantee that these forward-looking statements will be realised, although we believe we have been prudent in assumptions. The achievement of results is subject to risks, uncertainties and even inaccurate assumptions. Should known or unknown risks or uncertainties materialise, or should underlying assumptions prove inaccurate, actual results could vary materially from those anticipated, estimated or projected. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.



**Mr. Ramanbhai Patel** Founder Chairman August 19, 1925 - September 19, 2001

"The world is in the throes of an unprecedented healthcare challenge. The spread of the novel Coronavirus across the globe brought the healthcare fraternity together in this most difficult period for humanity. As the infection mounted and we lost many lives, medical professionals, scientists, researchers, pharmaceutical companies and policy makers have grappled to stop it's advance.

We at Zydus, have resolved to fight this pandemic in every way that we can, with therapeutics, vaccines and diagnostics.

Our mission of contributing to healthier communities globally, has taken on a new meaning and purpose. In this, the 25<sup>th</sup> year of our existence as an organisation, we remain dedicated to bring innovations to life and do all that we can to care, cure and nurture, good health."

Our Founder Chairman, a seeker, an explorer and innovator, continues to inspire us and forms the founding pillar of the innovation journey at Zydus as we live our mission of creating healthier, happier communities by bridging unmet healthcare needs.

## Contents

### **Company Overview**

Fighting the Pandemic **02** 

Chairman's Message 04

Highlights of the year *06* 

#### **Statutory Reports**

Management Discussion and Analysis **10** 

Business Responsibility Report **37** 

Board's Report 43

Corporate Governance Report 73

#### **Financial Statements**

Standalone 92

Consolidated 158

Notice 232



# ZYDUS' **MULTI-PRONGED APPROACH TO COMBAT THE PANDEMIC OF** COVID-19



08 March COVID-19 cases reported in 100 countries of the world, with more than 100,000 cases worldwide.

#### 20 March

One of the largest manufacturers of Hydroxychloroquine, Zydus ramps up production to meet the global demand.







11 March

The World Health Organization declared that the "COVID-19 can be characterized as a pandemic".



25 March

A nation-wide lockdown was announced in India.



#### Cases reach 1 million

02 April

The number of confirmed COVID-19 cases around the world hits 1 million.

**APRIL** 

2020

#### 20 April

Zydus explores the biologicals route to treat novel coronavirus with long acting Pegylated Interferon alpha-2b.



#### 21 May

Zydus to manufacture "COVID KAVACH ELISA" - the first indigenously developed IgG test for antibody detection in collaboration with ICMR-NIV Pune.



Supplied first batch of 30,000 COVID KAVACH ELISA tests to ICMR, free of cost.

> MAY 2020

#### **FEBRUARY** 2020



WHO announced that the new coronavirus disease will be known by the official name of COVID-19.



#### 15 February

Zydus launches a fast tracked programme to develop a vaccine for COVID-19.



## **MARCH** 2020

### ZYDUS' MULTI-PRONGED APPROACH

Diagnostic Prophylactic Therapeutic Wellness **NCEs Products** Vaccines **Products Products** 

India's first

coronavirus

patient tests positive.

**JANUARY** 

2020

#### 28 May

Zydus launches Immunity Booster **CIMUNE**, combination of Vitamin C (Ascorbic Acid) and Elemental Zinc in India.



#### Range of sanitizers launched.

Zydus launches a range of Alcohol based Sanitizing/ Cleansing Wipes and Sanitizers in India.



Preponed the launch of sanitizer range under the Nycil brand in India.

Launch originally planned for 2021. Launched in a record time and it has provided a great impetus to overall Zydus Wellness portfolio.



MAY 2020



\*Timeline till 23 July, 2020

#### JUNE 2020

#### 12 June

Zydus signs a non-exclusive licensing agreement with Gilead Sciences Inc., to manufacture and market Remdesivir.

#### 16 June

Oxford University trial indicates that Dexamethasone may reduce deaths by up to one third in hospitalised patients with severe respiratory complications of COVID-19. Zydus is one of India's



leading manufacturers of

Dexamethasone.

#### 28 June

Zydus launches Supermune, an immuno-booster,



comprising a unique combination of Herbs multiminerals and multivitamins. A one-of-its-kind product in India.

#### 03 July

Zydus' vaccine for COVID-19 (ZyCoV-D) successfully completes preclinical development and receives permission to initiate human clinical trials.

#### 06 July

Zydus receives approval from COFEPRIS, Mexico to study Desidustat in the management of COVID-19.

#### 11 July

Zydus launches ZyUV –UV sanitizer, which provides 99.9% surface disinfection. Ideal for home, small and big offices with built-in safety measures.



#### 15 July

'ZyCoV-D vaccine' -Human dosing starts. 

#### 17 July

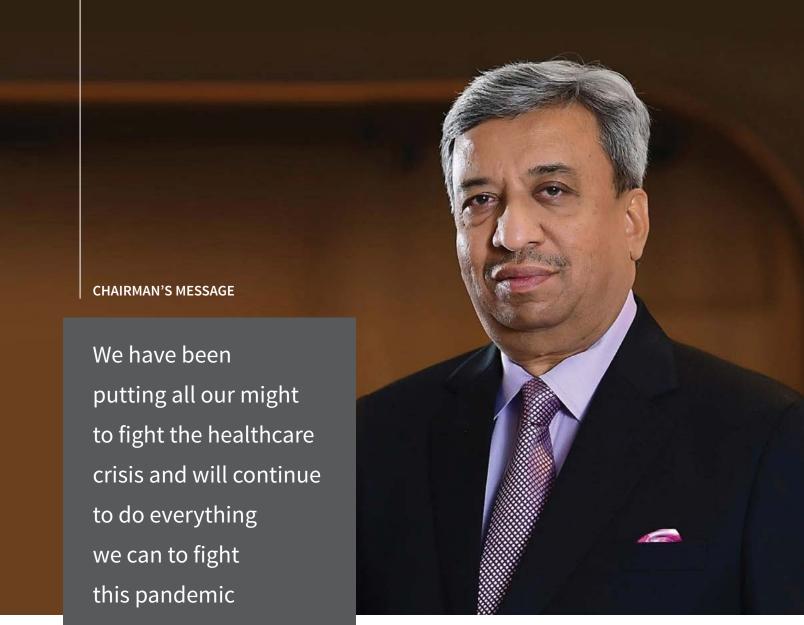
Zydus receives approval from COFEPRIS to conduct clinical trials in Mexico with Pegylated Interferon alpha-2b to treat novel Coronavirus.

......

#### 23 July

Zydus launches ZyOxy - Portable oxygen cylinder with medical grade oxygen for home use.

> **JULY** 2020



Pankaj R. Patel | Chairman

Dear Shareowners.

We are passing through some difficult times. Families, communities, neighbourhoods and economies have all been impacted by this unprecedented healthcare crisis of COVID-19. The pandemic has shaken up the very core of our existence and reminded us of how precious good health is and how we must do everything we can to safeguard it. In this 25<sup>th</sup> year of our existence as an organisation it has only reinforced our resolve to continue working towards the mission of creating healthier communities through innovation, making therapies accessible and bridging unmet healthcare needs.

The deep expertise and capabilities that we have developed through the year have enabled us to support the nation and the world in the fight against COVID-19. Our Company has been at the forefront, contributing with therapeutics, vaccines and diagnostics.

Our vaccine research team swung into action in February 2020, working on a vaccine in which the plasmid DNA would be introduced into the host cells. Once this is done, it would be translated into the viral protein and elicit a strong immune response mediated by the cellular and humoral arms of the human immune system, which play a vital role in protection from disease as well as viral clearance. After a crucial pre-clinical stage, where the vaccine ZyCoV-D was found to be safe, immunogenic and well tolerated, we have received the permission from the Drug Controller General of India (DCGI) and Central Drugs Standard Control Organisation (CDSCO) to initiate the Adaptive Phase I/II human clinical trials. We are extremely thankful for the support extended by National Biopharma Mission (BIRAC), Department of Biotechnology, Government of India and

regulatory agencies ICMR and DCGI, in this journey. With the human dosing underway, we hope that our quest to provide a safe and efficacious vaccine to prevent COVID-19 is a fruitful one.

Even as the country wide lockdown was first announced, pharmaceutical manufacturing was placed under essential services as it was necessary for uninterrupted supplies of medicines. In these early days when the world at large was in search of a cure, a team of French researchers produced clinical evidence of hydroxychloroquine (HCQ) proving to be successful in the treatment of COVID-19 and some European and South Korean hospitals included HCQ as a part of the treatment protocol for the treatment of COVID-19. As one of the largest producers of HCQ in the world, we knew that we had to support the call for this therapy. Our teams swung into action and took the call of ramping up the production from 3 metric tonnes to 20 metric tonnes and subsequently scalable to 30 metric tonnes. We ensured supplies to the Government in India and also to the other countries as mandated. With our robust manufacturing infrastructure, agile working capabilities and a dedicated workforce we were ready to face the challenges and devote all our resources to navigate through these difficult circumstances.

Tracking every possibility of a cure, our team found interesting research data in the two non-peer reviewed research articles at bioRxiv and medRxiv, the COVID-19 pre-print servers hosted by Cold Spring Harbor Laboratory. The first one by the University of Texas Medical Branch, Galveston, showed an evidence of a direct anti-viral effect of Interferon alpha against novel Coronavirus in vitro. The study demonstrated around 10,000 fold reduction in virus titre in cells that were pre-treated with Interferon alpha 48 hours earlier. The second by a group of universities in China, Australia and Canada retrospectively analysed 77 moderate COVID-19 subjects in Wuhan and observed that those who received Interferon alpha-2b showed a significant reduction in the duration of virus shedding period and even in levels of the inflammatory cytokine, IL-6. This suggests that if a long-acting molecule like Pegylated Interferon alpha is given early on in the infection, the patient suffering from COVID-19 will have a significant benefit as the viral load is reduced, lesser IL-6 is produced and virus eliminating specific immune response is generated. Following up on this, we approached the USFDA to open an Investigational New Drug (IND) filing for Pegylated Interferon alpha-2b and explore possibility for Compassionate Use Programme and also approached the Department of Biotechnology, Government of India to investigate the role of Pegylated Interferon alpha-2b for COVID-19. Even as the clinical trials get underway in India, we have received permissions from COFEPRIS to conduct clinical trials in Mexico. Pegylated Interferon alpha 2b is already being manufactured by our Company and we have the capabilities to manufacture this in a large scale.

While grappling to cope with a pandemic, testing and surveillance

are most critical tools. Our Company collaborated with ICMR-NIV, Pune to manufacture Covid Kavach Elisa test kits which are the first indigenously manufactured kits for COVID-19. The test was found to have high sensitivity and specificity and also have the advantage of testing 90 samples together in a single run of 2.5 hours. In all 30,000 test kits were manufactured and supplied to ICMR free of cost.

As we study the disease patterns and more findings come to the fore, newer pathways are being explored. To study the Novel mechanism of targeting 'hypoxia' through HIF-PH inhibitor in COVID-19 for the very first time, we approached COFEPRIS to conduct clinical trials in Mexico. These trials are now underway and we are conducting a Phase 2b, Multicenter, Open-label, Randomized, Comparator - Controlled Study to Evaluate the Efficacy and Safety of Desidustat Tablet for the Management of COVID-19 patients. Desidustat, is currently undergoing Phase III clinical development, is a novel oral HIF-PH inhibitor for treating Anemia.

A well experienced team to closely assess scenarios and actively monitor situation on the ground across geographies and our ability to rally around in a crisis and look for solutions helped us make positive contributions in this fight. We have been putting all our might to fight the healthcare crisis and will continue to do everything we can to fight this pandemic.

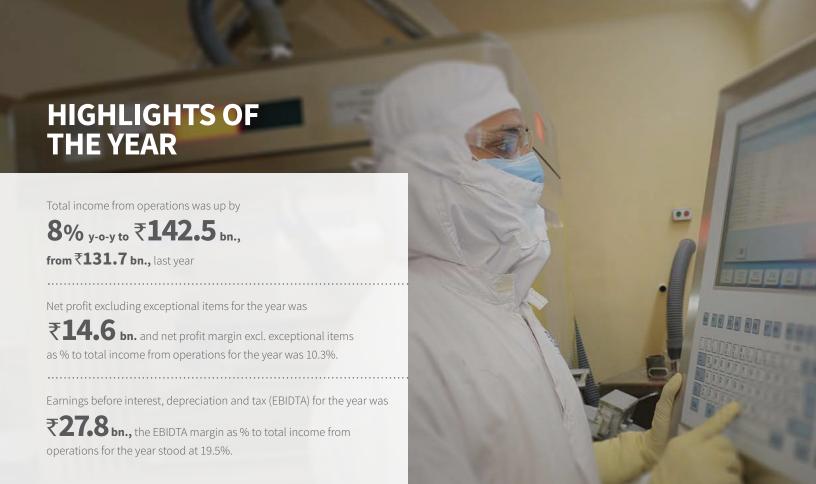
We are grateful to all the stakeholders - our customers, partners, suppliers, vendors who supported us in this fight. Our team of 25,000 Zydans who have worked tirelessly through these months to resolve concerns and ensured that we are able to deliver medicines in India and across the world. I am especially proud of these champions at work who showed steely resolve and courage and defied the odds to continue their critical work in these times. Their dedication to serve deserves our heartfelt thanks.

I also want to thank all the medical professionals and the medical fraternity at large for their selfless work in caring for those infected with the virus. Your care has given a new lease of life to many who survived the health scare.

In this financial year that has been dripped with the scare of the pandemic, there has also been a silver lining. The search for the elusive cure for Non Alcoholic Steato Hepatitis or NASH, an unmet healthcare need globally, ended with Saroglitazar becoming the first drug in the world to be approved for this indication. The Drug Controller General of India granted approval for the drug to be used for the treatment of NASH ranks as one of the major causes of cirrhosis, behind hepatitis C and alcoholic liver disease and is a leading cause of liver transplant.

Bringing more innovation to life and commitment to create healthier communities with patient-centric approaches, will be our overarching purpose as we move beyond our silver years to a new decade.

> Pankaj R. Patel Chairman July 17, 2020



#### INNOVATION

## New Chemical Entity (NCE) Research

 Received the approval from the Drug General Controller of India (DCGI) for a New Drug Application (NDA) of Saroglitazar Magnesium for the treatment of Non-Cirrhotic Non-Alcoholic SteatoHepatitis (NASH) in India.

The drug becomes the first ever drug anywhere in the world approved for the treatment of NASH.

- Saroglitazar Magnesium was also approved by the DCGI in the treatment of Type II Diabetes Mellitus as an add-on therapy with Metformin during the year.
- · Successfully completed EVIDENCES IV Phase II clinical trials of Saroglitazar Magnesium in the US in patients with NAFLD and NASH as the molecule achieved the primary efficacy end-points.
- Initiated Phase III clinical trials of Desidustat in India, an Investigational New Drug (IND), targeted at treating anemia both in dialysis and non-dialysis dependent CKD patients.
- Desidustat is also being evaluated in moderate COVID patients. Novel coronavirus causes less and less hemoglobin that can carry oxygen and carbon dioxide. Iron dysregulation is also noticed in the subjects with COVID-19. Desidustat regulates HIF which, in turn, results into increase in EPO and inhibition of hepcidin thereby relieving the symptoms in COVID patients.

## **Biologics**

- · In a bid to provide the treatment option against the novel coronavirus COVID-19, explored multiple options from the portfolio of biological products and based on the available evidence, selected the long-acting biological therapy Pegylated Interferon alpha-2b as an arrow head product for treatment of COVID-19.
  - The treatment has emerged after the recent research conducted in the US which shows that Interferon alpha significantly reduces novel coronavirus titers in vitro. A clinical study in China shows shortened duration of viral shedding in patients.
- · Achieved a significant milestone in the field of novel biologics with the receipt of marketing authorization in India for the first novel biologics Rabimabs.
- · Initiated Phase III clinical trials in India for two more biosimilars during the year.

#### **Vaccines**

- · Initiated a fast-tracked research programme with multiple teams in India and Europe for developing a vaccine for the novel coronavirus COVID-19 based on two approaches.
  - The first approach deals with development of a DNA vaccine against the major viral membrane protein responsible for entry

- of virus into the cell while the second approach deals with development of a live attenuated recombinant measles virus vectored vaccine against COVID-19.
- Hepatitis B vaccine received the marketing authorization in India while Pentavalent vaccine successfully completed Phase II/ III clinical trials in India during the year. Phase II/ III clinical trials for Td vaccine are going to start soon.
- Completed Phase I clinical trials of Inactivated Hepatitis Avaccine during the year while Phase I clinical trials for Recombinant Hepatitis E vaccine is currently under progress.

#### **INDIA BUSINESS**

#### **India Formulations**

- Restructured the product portfolio of 100% subsidiary Zydus Healthcare Limited, Mumbai, bifurcating it into mass and specialty cluster so as to drive the marketing and promotion efforts in a focused manner.
  - In the case of a mass cluster, the focus will be to improve market penetration by expanding the reach of the products and in the case of a specialty cluster, the focus will be on intensified engagement efforts with Key Opinion Leaders (KOLs).
- · Successfully completed nation-wide implementation of "new sales force effectiveness initiative" which has been developed for second line sales managers and above.
  - The focus of the initiative is on demand generation by improving the sales planning cycle and also improve the quality of interactions between field business officers and business managers.
- Posted sales of ₹37,141 Mio., up 6%. Branded formulations (i.e. total business excluding generic products) business posted a growth of 7% during the year. Excluding the impact of COVID-19 on sales during March 2020, the growth in branded formulations business would have been approximately 10%.

#### **Consumer Wellness**

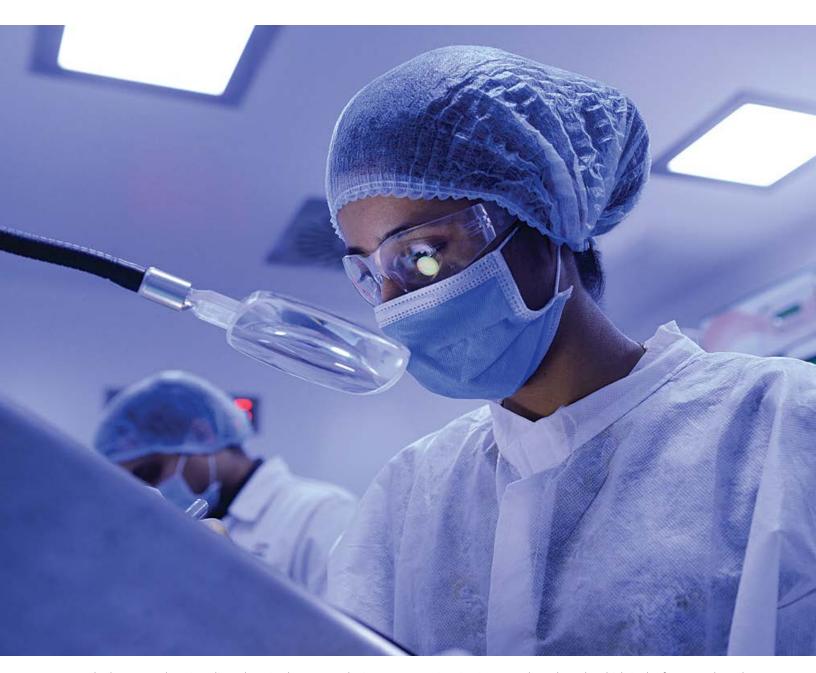
- Successfully completed the integration of newly acquired entity Heinz India Pvt. Ltd. The integration progressed better than what was planned in the beginning of the year.
- Continued to invest behind the brands through various modes such as sustained media presence and competitive consumer and trade offers to drive the growth and increase the market share of the brands.
- On the Sugar Free front, re-launched Sugar Free Green with an improved formulation and new packaging. Re-launched Sugarlite with a superior product formulation which addresses any questions of taste being a barrier to adoption.
- Nycil brand ended the year with first ever brand extension in the space of hand sanitizers during the month of March, 2020.
- In terms of market share, Glucon-D, Nycil, EverYuth Scrub and Peel-Off maintained their leadership position in their respective categories.

• Posted sales of ₹17,379 Mio., up 116% and net profit of ₹1,417 Mio. Excluding the impact of COVID-19 related disruptions and adjusting the base of the previous year on account of Heinz acquisition, the business would have grown by 10% during the year.

#### **Animal Health**

• Transferred Animal Health Business which comprise of 2 undertakings viz. Animal Healthcare Established Markets Undertaking (AHESTM, comprising of animal healthcare business carried out primarily in India and rest of the world excluding USA and Europe) and Animal Healthcare Emerging Markets Undertaking (AHEMGM, comprising of animal healthcare business carried out outside India, primarily in USA and Europe) to its wholly owned subsidiary Zydus Animal Health and Investments Limited (ZAHL) on a going concern basis, in exchange of 8% Non-cumulative Non-convertible Redeemable Preference Shares of ₹10/- each issued at face value ("ZAHL Preference Shares") on a lump sum basis.





- Launched 3 new products in India and received 11 new marketing authorizations for the exports business during the year.
- Posted sales of ₹5,149 Mio. Excluding the impact of COVID-19 related disruptions, the business would have grown by 5%.

#### **US FORMULATIONS BUSINESS**

- Ranked 4<sup>th</sup> among US generic companies based on prescriptions with an increase in market share by 0.62% (Source: IQVIA, NPA Audit, MAT March 2020 TRx), which is a gain of three positions from last year.
- Received 28 ANDA approvals (including 5 tentative approvals) from the USFDA during the year.
- Launch 30 new products during the year. New launches include

- Rivastigmine Transdermal Patch, which is the first transdermal patch launched from the Company's own pipeline.
- Filed 30 additional ANDAs with the USFDA during the year, taking the cumulative number of filings to 390.
- Posted sales of ₹62,514 Mio.

## **EMERGING MARKETS OF ASIA, AFRICA AND LATIN AMERICA**

• Continued to perform well in some of the key geographies of Asia Pacific and Africa region with double digit growth registered in several countries driven by volume expansion of pillar brands. However, the performance in some of the counties was impacted

on account of sudden increase in generic competition, rapid