



UNLEASHING THE POWER of SCIENCE

Cadila Healthcare Ltd. Annual Report 2018-19

CORPORATE INFORMATION

FOUNDER

Late Ramanbhai B. Patel

BOARD OF DIRECTORS

Pankaj R. Patel *Chairman*

H. Dhanrajgir

Nitin R. Desai

Mukesh M. Patel

Dharmishtaben N. Raval

Apurva S. Diwanji

Bhadresh K. Shah (w.e.f. December 6, 2018)

Dr. Sharvil P. Patel Managing Director

Ganesh N. Nayak *Executive Director*

Nitin D. Parekh Chief Financial Officer

Upen H. Shah Company Secretary (upto February 7, 2019)

Dhaval N. Soni Company Secretary (w.e.f. February 7, 2019)

Registered and Corporate Office

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

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

REGISTRAR AND SHARE TRANSFER AGENTS

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

FORMULATION UNITS

Plot No. 1/1A & 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

Plot No. 203-213, Kundaim Industrial Estate, Ponda, Goa - 403 115

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

Plot No. 254-255, Sarkhej-Bavla N.H.No. 8A, Village: Changodar, Taluka: Sanand, District: Ahmedabad - 382 210

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

Plot No. 26-29,31, Dabhasa - Umraya Road, Taluka Padra, District: Vadodara.

BIOLOGICS AND VACCINES 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-I/I, Sector 6B, IIE SIIDCUL, Haridwar - 249 403

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.

"Innovation is never an end in itself. It must be purposeful... creating the foundations for a better life. The future advances in pharmaceutical sciences lies in our ability to imagine a world free of what is plaguing us and the determination to create this world."



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

This belief of 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.

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'Whatever it takes'

That was the resolve with which the first steps were taken on the path of innovation, 67 years ago. Over the decades, the resolve strengthened and became the overarching goal. To be an innovation-driven company, taking novel concepts and ideas all the way from lab to market became the raison d'être. From new chemical entities to novel biologics, vaccines and novel drug applications, it's all happening at Zydus. It's a research pipeline that's deep, complex and plugging some of the urgent global healthcare needs that are still unmet. Each of the programmes that the team is working on could throw up novel solutions that significantly address the healthcare burden that the diseases pose, it also builds a sustainable future based on innovation.





ENGAGED IN DRUG DISCOVERY & DEVELOPMENT



In search of a therapy for NASH, a disease of global epidemic proportions

Non-alcoholic Steatohepatitis (NASH) is caused by the accumulation of liver fat, which could lead to fibrosis over time.

Nonalcoholic Fatty Liver Disease (NAFLD) is expected to become the most common chronic liver condition globally in relation to obesity and type 2 diabetes in the coming years.

A peak NASH market opportunity of **\$35-40B** by 2025

Around **6.5mn adults** in both the US & Big5 EU have advanced NASH

Normal Liver 1 Fatty Liver 2 Liver Fibrosis 3 Cirrhosis 4

STAGES OF

LIVER DAMAGE



Source - Deutsche Bank Markets Research

EVIDENCES Trials

(EValution In NAFLD/NASH of Saroglitazar magnesium)

Since 2010, Zydus Researchers have been working on a therapy to treat this global unmet need. Across 20 clinical sites in the United States of America, patients with Non-Alcoholic Fatty Liver Disease (NAFLD), including Non-Alcoholic SteatoHepatitis (NASH) are undergoing Phase 2 clinical trials with Saroglitazar Magnesium* for NASH and is in Phase 3 clinical trials in Mexico for the same indications. In India, the molecule is in Phase 3 clinical trials for NASH, Type 2 diabetes and lipodystrophy.

*Saroglitazar Mg is a molecule under development





A potential treatment for PBC

PBC (Primary Biliary Cholangitis) is a long-term, auto-immune condition which affects the liver.

Patients with PBC also have an increased incidence of pruritus.

EPICS trials (Evaluation In Primary Biliary Cholangitis of Saroglitazar)

Saroglitazar Mg is being tested in Phase 2 trials in USA to develop a drug that can reduce Alkaline Phosphatase (ALP) without causing Pruritius or increasing LDL-c



PBC is one of the most common autoimmune diseases, affecting nearly I in 1000 women over the age of 40.

WHAT'S UNIQUE

Saroglitazar Mg, because of its unique mechanism of engaging PPAR alpha and PPAR gamma, favourably affects all components of NASH including steatosis, ballooning, inflammation and fibrosis.

UNMET NEED

There are currently no treatments approved by the U.S. Food and Drug Administration (USFDA) for the treatment of NASH.

A safer, oral therapy to treat Anemia in CKD

Anemia commonly occurs in people with chronic kidney disease (CKD)—the permanent, partial loss of kidney function. Anemia might begin to develop in the early stages of CKD, when someone has 20 to 50 percent of normal kidney function.

In a CKD condition, the kidneys fail to produce Erythropoietin (EPO) and this leads to low levels of hemoglobin (Hb) in the blood or anemia.



Chronic Kidney Disease is a **Serious medical condition** involving gradual loss of functioning of kidneys eventually leading to kidney failure.

More than **200 million** people worldwide are estimated to be living with CKD.







Single dose cure in Malaria to aid patient compliance

Malaria is one of the most severe public health problems worldwide. It is a leading cause of death and disease in many developing countries, where young children and pregnant women are the most affected groups.

Nearly half the world's population lives in areas at risk of malaria transmission in 91 countries and territories.

In 2016, malaria caused an estimated **216 million** clinical episodes, and **445,000 deaths.**



(World malaria report 2017. Geneva: World Health Organization; 2017)



Stage**5**

Kidney failure need treatment to live The GFR number represents kidney function. As the kidney gets worse, the GFR number goes down.

DREAM trials (Desidustat oRal Evaluation in Anemia Management)

Desidustat is a novel, oral, HIF-PH inhibitor being developed for treating anemia in Chronic Kidney Disease (CKD) patients. The molecule has completed Phase II clinical trials in India and the company has announced Phase III clinical trials in India for CKD patients not on dialysis

► WHAT'S UNIQUE

This innovation has the potential to bring about a paradigm shift in the management of CKD patients with anemia. An **HIF-PH** inhibitor could provide an oral, safer alternative to currently available erythropoietin-stimulating agents (ESAs), which are associated with increased risk of cardiovascular events and have to be given via injections and a cold chain has to be maintained.

UNMET NEED

Improve renal anemia safely and conveniently, as compared to injectable EPO that also requires a cold chain to be maintained.

Less than 15

ZY3278

being developed in collboration with MMV

Researchers at Zydus are working on a novel compound, ZY3278 for treating malaria in collaboration with Medicines for Malaria Venture (MMV).

► WHAT'S UNIQUE

ZY3278 has the potential to be a single-dose cure for P. falciparum malaria due to its novel mechanism of action, rapid parasites killing activity across all intra-erythrocytic stages and a long half-life.

UNMET NEED

Artemisinin resistance is seen as a mounting challenge to the global fight against malaria. ZY-3278 is being developed to provide an effective alternative to the current front-line antimalarial drugs for the treatment of P. falciparum malaria and artemisinin-based combination therapies (ACTs), which are under threat of resistance.

Addressing the rabies menace

Rabies is an infectious viral disease which can be fatal following the onset of clinical symptoms. In upto 99% of cases, domestic dogs are responsible for transmission of rabies virus to humans. It is spread to people through bites or scratches, usually via saliva.

Although effective human vaccines and immunoglobulins exist for rabies, they are not readily available or accessible to those in need.

Every year, more than 15 million people worldwide receive a post-bite vaccination. This is estimated to prevent hundreds of thousands of rabies deaths annually.



Developing a novel biologic for treating AMD

Age-Related Macular Degeneration (AMD) is a common eye condition and a leading cause of vision loss among people age 50 and older. It causes damage to the macula, a small spot near the centre of the retina and the part of the eye needed for sharp, central vision, which lets us see objects that are straight ahead.

In some people, AMD advances so slowly that vision loss does not occur for a long time. In others, the disease progresses faster and may lead to a loss of vision in one or both eyes.

As AMD progresses, a blurred area near the centre of vision is a common symptom.