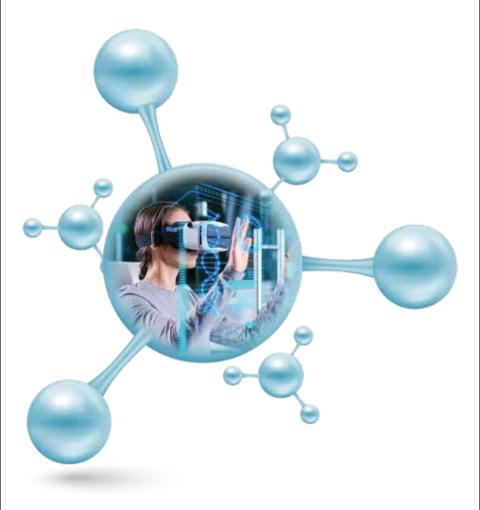
# **CHAIRMAN'S SPEECH**

# **ANNUAL GENERAL MEETING**

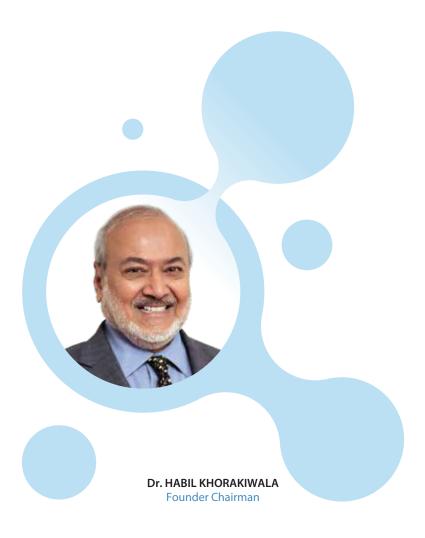
28th June, 2024

# **DISCOVERY WINS. LIFE WINS.**









My dear shareowners, friends, and distinguished guests.

I extend a very warm welcome to you all at the Annual General Meeting of Wockhardt Limited.

I would like to recognise the significant contribution and wisdom provided by our Directors, Mr. Aman Mehta, Dr. Davinder Singh Brar, and Dr. Sanjaya Baru who retired in March 2024 as per Indian regulations. Wockhardt is privileged and extremely thankful to them.

I will begin with a quote by Nobel laureate in Medicine, Har Gobind Khorana, who said, "The pursuit of science is not to be **just the pursuit of knowledge but also the pursuit of a better and more humane world."** I agree and strongly believe that Wockhardt is helping to make the **world a better place.** 

As you all know, we pride ourselves on being a research-based global pharmaceutical company, and the term 'Discovery' encapsulates the essence of Wockhardt's Research & Development (R&D) achievements and their impact on society.

FY 2023-24 has been a year of some very positive, remarkable, and heartening developments in our Research & Development (R&D) efforts. In particular, the advances we have made in the development of novel antibiotics, herald one of the most exciting and promising phases of Wockhardt's journey.



#### **DISCOVERY IN ANTIBIOTICS**

Rabindranath Tagore said, "Faith is the bird that feels the light and sings when the dawn is still dark." Over 25 years ago, we put our faith, focus, and efforts in the discovery of novel antibiotics to meet the serious global health challenge of Antimicrobial Resistance (AMR).

We put in over 25 years of efforts in building a global antibiotic scientific organisation and creating a culture of Research and Innovation, networking with over 30 global organisations for discovering a range of antibiotics for unmet medical needs and investing over US\$ 500 mn. This clearly demonstrates our resilience and belief that Wockhardt and India can do it.

Additionally, our portfolio of antibiotics to deal with anti-microbial resistance belong to different classes for diverse infections occurring in hospitals and communities which are discovered after nearly 30 – 40 years.

Allow me to update you all on the status of these novel antibiotics under development.

Our first-ever India-patented antibiotics, EMROK & EMROK O, are the only new antibiotics in their class to have been developed in over the last 30 years. These multi-spectrum anti-MRSA antibiotics have been used to treat over 65,000 patients. They are emerging as effective against multiple indications and we have successfully completed 4 new clinical studies in bloodstream infections, bone and joint infections, community-acquired bacterial pneumonia, and infections in immunosuppressed patients.

We have already completed New Drug Application (NDA) filings in 10 countries classified as Emerging Markets and are targeting 5-6 more countries in Q2 of FY 2025. These will result in significant growth in the current year.

WCK 4873 (Nafithromycin), trademarked as MIQNAF, is an ultrashort, 3-day oral course to treat community-acquired bacterial pneumonia, with 97% success rate. Existing treatments have resistance as high as 60%.

We have filed New Drug Application (NDA) with the Drug Controller General of India and expect to launch it commercially by the second half of FY 2025. We also expect to complete NDA filings in select Emerging Markets. Thereafter, we expect very robust sales in FY 26.

It is my great pleasure to share with you the promising developments of our wonder drug under development, WCK 5222 (Zidebactam/Cefepime), trademarked as ZAYNICH. It is an entirely new chemical entity, a proprietary, ground-breaking, one-of-its-kind antibiotic discovered in the last 50 years. It is designed to address all the major superbugs. Currently undergoing Global Phase 3 clinical trials, ZAYNICH was administered on compassionate grounds, with due permission from the Drug Controller General of India (DCGI), to 30 patients who weren't responding to any antibiotics available globally. You will be pleased to know that we recorded 100% success, saving the lives of all the recipients. Three of these cases were published in international journals viz. Antimicrobial Agents and Chemotherapy (US Journal), Annals of Clinical Microbiology and Antimicrobials (UK Journal) and European Journal of Clinical Microbiology & Infectious Diseases (EU Journal).

I am happy to report the fact that ZAYNICH has saved more than 30 lives. DCGI has approved a small size clinical trial protocol of carbapenem-resistant patients in India. We expect this clinical trial to be completed and hope for product approval by FY 2025 and ZAYNICH would be available in India thereafter.

You will be happy to know that the US FDA, for the first time, granted approval to use WCK 5222 under a provision termed as 'Expanded Access IND' (compassionate use) for a young cancer patient having multiple sites of infection in large wounds, at the University of California Irvine School of Medicine, Orange County.



This patient did not respond to the latest available antibiotics in the US for over 9 months. In four weeks after administration of ZAYNICH, the patient responded and was infection free and there was a complete healing of wounds. Thereafter, the doctor could start the chemotherapy to continue cancer treatment. This is an important milestone for ZAYNICH and Wockhardt.

You will be delighted to know that the globally-recognised US body, Clinical & Laboratory Standards Institute (CLSI), has granted a susceptibility breakpoint of 64 mg/L to ZAYNICH. This breakpoint is for all broader range of Gram negative resistant pathogens. The higher the break point the more effective is the drug. As you, all know Alexander Fleming first discovered Penicillin in 1928. Since then, more than 250 antibiotics have been discovered, approved and used for various antibacterial infections. It is the first time ever that a breakpoint of 64mg/L is granted for the entire range of 10-resistant Gram-negative pathogens. In other words, ZAYNICH would be clinically effective in extreme multi drug resistance organism with new mechanism driven high bacteria kill power. This is clearly demonstrated and supported by the success we have witnessed in critically ill patients treated under compassionate use as a last resort drug. A 100% clinical and microbiological success rate accompanied with safety of usage up to 70 days was established for ZAYNICH. It is extremely gratifying that ZAYNICH has been unanimously granted the investigational break point in a CLSI plenary session on 24th June 2024. This is historic and all of us who are associated with Wockhardt should be proud. This would make India proud.

Furthermore, we expect global clinical trial of ZAYNICH in Phase III world over, which will be completed by FY 2025 and thereafter we will be filing in US, Europe, and other countries for regulatory approvals. We expect sometime in FY 2026 to receive global approval for ZAYNICH launch worldwide.

From a business perspective to optimise the market value for the organisation, we have decided to have a two-pronged approach where we will market ZAYNICH in India and Emerging Markets, and license it out for US, Europe, and developed countries to one of the global pharmaceutical companies.

### **DISCOVERY IN DIABETES/BIOLOGICALS**

Our other important strategic focus is to develop business in India and Emerging Market through a portfolio of new Insulins and new diabetic products. Here we have a distinct competitive edge. We have Research, Manufacturing, and Business competitiveness and have a proven record of successfully executing and marketing these products.

Our new product pipeline will ensure a significant penetration in the Emerging Markets, which have very limited players.

The Board of Directors and I sincerely thank all Wockhardt associates, shareowners, the medical and financial communities, and our vendor associates, for their support, cooperation, and good wishes.

In conclusion, I quote A.P.J. Abdul Kalam who said, "Dream, dream, dream. **Dreams transform into thoughts and thoughts result in action."** I am sure that all of us will see that all our efforts for the last 25 years of research will culminate into a new very successful research-based Wockhardt organization.

God bless us all.

**Dr. Habil Khorakiwala**Founder Chairman



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