



Registered Office: D-4, MIDC, Chikalthana Chhatrapati Sambhajinagar 431006, India

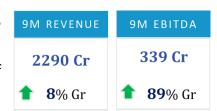
Tel.: +91-22-2653 4444 CIN: L24230MH1999PLC120720

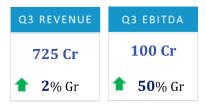
Mumbai, February 7th, 2025

# 9MFY25 EBITDA at Rs.339 crore; growth by 89%

Wockhardt Limited, the Pharmaceutical and Biotechnology major, reported its 3<sup>rd</sup> Quarter Results for Financial Year 2024-25, today.

YoY growth of 8% in revenue in 9MFY25, Revenue for 9MFY25 of INR 2,290 Cr compared to INR 2,129 Cr in the previous year. YoY growth of 89% in EBITDA in 9MFY25, EBITDA for 9MFY25 of INR 339 Cr compared to INR 180 Cr in the previous year.





QoQ growth of 2% in revenue in Q3FY25, Revenue for Q3FY25 of INR 725 Cr compared to INR 709 Cr in the previous year. QoQ growth of 50% in EBITDA in Q3FY25, EBITDA for Q3FY25 of INR 100 Cr compared to INR 67 Cr in the previous year.

## **Novel Antibiotics:**

ZAYNICH® (Zidebactam/Cefepime, WCK 5222): Following the completion of the Global, pivotal, registration-enabling, Phase III study in hospitalized complicated urinary tract infection (cUTI) patients, Wockhardt's Zaynich® has demonstrated the highest-ever efficacy achieving a clinical cure rate of 96.8%.



The study enrolled 529 patients with complicated urinary tract infection (cUTI) and Acute Pyelonephritis (AP) and was conducted in US, Europe, LATAM, China, India, spanning 64 sites.

In this study, Zaynich® demonstrated superiority over gold standard meropenem, achieving a composite clinical and microbiology cure rate of 89.0% vs 68.4% respectively. These results were based on primary endpoints defined by both the US FDA and EMA.

The combined efficacy of Zaynich® is the highest ever recorded among recently approved novel antibiotics developed in more than a decade. The outcome of this study reflects the





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impact of Zaynich's novel β-lactam enhancer mechanism of action. Additionally, Zaynich® was well-tolerated and showed a safety profile consistent with β-lactam class of antibiotics, comparable to meropenem.

This study is NDA-enabling, based on which marketing authorization applications will be made to global health authorities including India, US, EMA and MHRA.

Clinical Trial in seriously ill patients with meropenem-resistant infections: This study was conducted in India based on recommendation from the DCGI, India

**MEROPENEM** RESISTANT SERIOUS **GRAM NEGATIVE INFECTION** 

CLINICAL

100% BSI, cIAI HABP/ VABP

In this study, Zaynich® demonstrated over 98% Efficacy in treating seriously ill patients with infections caused by carbapenem-resistant (including meropenem-resistant) Gram-negative pathogens. The study including patients with Hospital Acquired Bacterial Pneumonia (HABP), Ventilator Associated Bacterial Pneumonia (VABP), Blood Stream infections (BSI), complicated intra-abdominal infections (cIAI) and complicated Urinary Tract Infections (cUTI). The study was conducted across 15 top-rated tertiary care hospitals nationwide.

While the overall clinical efficacy of Zaynich® across indications was 98%, it was 100% for BSI, HABP/VABP & cIAI and 97.3% for cUTI. This study underscores the potential of Zaynich as a life-saving antibiotic, particularly in carbapenem-resistant infections.

**Compassionate Use:** We have treated 45 patients, including two



Success Rate

US Patients, under compassionate use, after receiving approval from DCGI. Use of Zaynich resulted in 100% cure and was found to be safe even when administered up to 95 days.



Considering the results from the Meropenem Resistance Clinical Trial as well as several patients successfully treated under compassionate use in India and US, lives of more than 100 critically ill patients, infected with life threatening XDR Gram-negative infections have been saved with the administration of Zaynich®





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MIQNAF® (WCK 4873): The Indian drug regulator, Central Drugs Standard Control

INDIAN DRUG REGULATOR (CDSCO)

APPROVES MIQNAF®

FOR THE TREATMENT OF

COMMUNITY ACQUIRED

BACTERIAL PNEUMONIA

Organization (CDSCO) has approved MIQNAF® as a new treatment for the Community-Acquired Bacterial Pneumonia (CABP).

MIQNAF® offers a compliance friendly, ultrashort course, Once-a-day 3-day treatment for CABP including those caused by multi-drug resistant (MDR) pathogens.

In the Phase 3 comparative trial involving patients with CABP, Nafithromycin demonstrated a clinical cure rate of 96.7% at the test of cure (TOC), compared to the gold standard Moxifloxacin.



In India, antibiotic resistance is a burning issue including in community pneumonia cases. A key feature of MIQNAF® is its coverage of entire range of community respiratory pathogens including pneumococci resistant to azithromycin and amoxicillin/clavulanate. Current oral

antibiotics such as azithromycin face significant resistance challenges, while amoxicillin/clavulanate lack the coverage of atypicals, as a result, patients often require hospitalization for intravenous treatment, which imposes higher cost. MIQNAF® is designed to obviate the need of such hospitalization.



**ERTAPENEM-ZIDEBACTAM** (WCK 6777): WCK 6777 is a once-a-day,  $\beta$ -lactam enhancer-based combination being developed for outpatient parenteral antimicrobial therapy (OPAT) in ambulatory settings. WCK 6777 is the only drug in the global antibiotic pipeline designed for OPAT.

WCK 6777 is active against entire range of meropenem-resistant Gram-negative pathogens generally encountered in community as well as in hospital urinary tract infections (UTI) and intra-abdominal infections (IAI). Such a therapeutic option is expected to cut hospital admissions, facilitate early patient discharge and thus offer patient-centred care for MDR infections.



Recognizing its potential to meet significant unmet medical needs, the US FDA has granted Fast Track designation to WCK 6777 for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, and complicated intra-abdominal infections (cIAI).





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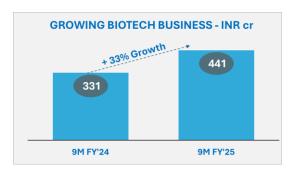
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Results from Phase I study (52 subjects) conducted by National Institutes of Health, US, demonstrated a promising safety profile, with WCK 6777 being well-tolerated, and no serious or unexpected adverse events reported. This study paves the way for advancement of WCK 6777 into Phase II trial.

**EMROK/ EMROK O**: Emrok has successfully treated nearly >93,000 patients to date. It is currently undergoing the registration process in 10 countries within emerging markets and anticipates receiving approvals within the next 6 to 12 months.



# **Biosimilars Business Highlights:**



Our Insulin and Glargine business has demonstrated remarkable and sustainable growth driven by increasing volumes accelerating our presence and reach across Emerging Markets. Likewise in India, our domestic biotech business is poised for substantial growth. Additionally, our entry into newer emerging markets, positions us well for scaling the Biotech

business growth to the next level strengthening our commitment to meeting global healthcare needs and advancing our leadership in diabetes care.

## **Business Highlights**

UK Business: Global Contribution in Q3 is 41% and 9M FY'25 is 38%





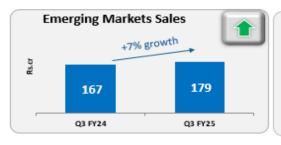




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## Emerging Markets Business: Global Contribution in Q3 and 9M 25 is 25%





**India Branded Business** stood at Rs.114 crore in Q3FY25 and for 9MFY25 the revenue was Rs. 361 crore.

**Irish Business** stood at Rs.46 crore in Q3FY25 and for 9MFY25 the revenue was Rs. 134 crore. **US Business** stood at Rs.25 crore in Q3FY25 and Rs. 85 crore in 9MFY25.

## **New Products Launch:**

- 1 Filing and 5 New launches in Ireland
- 4 Filings and 6 Launches in Wockhardt UK
- India 4 NCE Patents Granted till Dec'24
- EMROK/EMROK O Registration has been filed in 10 countries of ROW & other Markets



# **Intellectual Property Update:**

- 2 patents were filed during the quarter ended 31<sup>st</sup>
   December 2024 and the cumulative filings till date are 3269.
- The company was granted 1 patent during the quarter and now holds 844 patents.

PATENTS
Filings till Date: 3269
Patents held: 844





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## **Financial Performance:**

Particulars	Q3 FY25	Q3 FY24	Q2 FY25	9MFY25	9MFY24
	Oct - Dec	Oct - Dec	Jul - Sep	Apr - Dec	Apr - Dec
	2024	2023	2024	2024	2023
Total Revenue	725	709	818	2,290	2,129
EBITDA before R&D	131	97	167	424	279
EBITDA % to Sales	18.1%	13.6%	20.4%	18.5%	13.1%
R&D	31	30	28	85	99
R&D % to Sales	4.2%	4.2%	3.4%	3.7%	4.7%
EBITDA	100	67	139	339	180
EBITDA Margins %	13.8%	9.5%	17.0%	14.8%	8.5%
Exceptional Items	-	-	-	_	(14)
Loss on sale of property, plant & equipment #	-	(7)	-	-	(7)
РВТ	21	(87)	(9)	6	(240)
Profit After Tax	20	(86)	(16)	(12)	(295)
PAT Margins %	2.8%	-12.1%	-2.0%	-0.5%	-13.9%

# In Q3FY24 the company had incurred a loss of Rs. 7 crore on the sale of property, plant, and equipment attributable to the restructuring of the company's US operations.

### **About Wockhardt**

Wockhardt is a research based Global Pharmaceutical and Biotech company. Wockhardt's New Drug Discovery programme has focussed on unmet need of Anti-bacterial drugs that are effective against the menace of untreatable superbugs. Wockhardt is the only company in the world where USFDA has given QIDP Status



(Qualified Infectious Disease Product) for 6 of our Anti-bacterial discovery programmes – 3 of them are Gram Negative and 3 Gram Positive effective against untreatable "Superbugs". It has a comprehensive Drug Discovery team and clinical organisation.

Wockhardt is employing around ~2600 people and 27 nationalities with presence in USA, UK, Ireland, Switzerland, France, Mexico, Russia and many other countries. It has manufacturing and research facilities in India, USA & UK and a manufacturing facility in Ireland. Wockhardt has a significant presence in USA, Europe and India, with 79% of its global revenues coming from international businesses.