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“We anticipate starting sales of India’s first invented antibiotic drug combination of Cefepime and Enmetazobactam by the next quarter”

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Orchid Pharma, based in Chennai, has recently received Drugs Controller General of India (DCGI) approval for the manufacturing and marketing of its invented New Chemical Entity Active Pharmaceutical Ingredient (API), Enmetazobactam, and to manufacture and market Finished Dosage Form (FDF) of Cefepime and Enmetazobactam as a dry powder injectable, to improve the treatment landscape for serious infections in India such as antimicrobial resistance (AMR). To discuss more about this development, and to find out about the company’s growth plans this year and beyond, BioSpectrum spoke to Manish Dhanuka, Managing Director, Orchid Pharma in detail.

What are the major plans in store for FY 24-25? How much growth is expected?

We have recently received DCGI approval for India’s first invented Antibiotic Drug Combination of Cefepime and Enmetazobactam (NCE). We look forward to expanding access to advanced and affordable treatment options for patients. For the Indian market, Orchid will partner with a third party with comprehensive hospital coverage while also utilising our own Antimicrobial Solutions (AMS) division for product distribution.

Enmetazobactam has already received approval from both the US FDA and the European Medicines Agency. These approvals are a significant step forward for Orchid Pharma, opening doors to royalties from lucrative markets. In India, we have also been granted waiver for Phase III clinical trials and we will be conducting a Phase IV post-launch.

Our initial expectations for launching in mid-2025 have now been advanced, and we anticipate starting sales by the next quarter. This accelerated timeline will enhance our revenue streams substantially.

Besides this our new capacities coming online will lead to a healthy growth for the coming year in line with the past trend of 2-3 years.

How much revenue do you expect to add up through this product?

This will depend on the price elasticity, but we should be able to capture ~3 per cent of the market in the medium term.

How much revenue was generated by the company during FY 23-24?

For the full year FY2024, we achieved sales of Rs 819 crore, a significant jump from Rs 666 crore last year. Our full-year EBITDA stood at Rs 142 crore, up from Rs 103 crore in FY2023. This growth is reflected in our strong Compound Annual Growth Rate (CAGR) of 22 per cent in sales and 30 per cent in EBITDA over the past three years. These figures highlight our continuous progress and ability to adapt to market demands.

Are you exploring new partnerships with global pharma companies?

As an enterprise, we are always on a look-out for expansion and collaborations. We do see a massive need for our innovations globally. Several such deals are under discussions but due to confidentiality cannot be shared. One such outcome was the Orchid-GARDP-Shionogi partnership to tackle the growing menace of antimicrobial resistance. Orchid has received the license to make this product for 135 LMICs (Low and Middle Income Countries).

Are you planning new investments, or facility expansions in India?

Orchid is committing close to Rs 800- Rs 1000 crore of capital investments in next 2-3 years.

How do you view the growing burden of AMR globally? What needs to be done?

Antimicrobial resistance (AMR) isn't just a scientific challenge; it's a growing threat to public health and has severe economic impact. The World Health Organization (WHO) considers AMR one of the top ten global health threats, highlighting its potential to send us back to a pre-antibiotic era. We may soon be returning to the pre-antibiotic era because antibiotics are losing their power. AMR is declared as the silent pandemic by the UN and WHO and it has contributed to almost 5 million deaths in 2019. In addition to death and disability, AMR has significant economic costs. The World Bank estimates that AMR could result in $1 trillion additional healthcare costs by 2050, and $1 trillion to $3.4 trillion gross domestic product (GDP) losses per year by 2030.

Combatting AMR requires more than just scientific advancements; it demands a shift in mindsets and behaviours. We see some steps that can support and build a future resilient to AMR:

- **Antimicrobial Stewardship Programmes** that promote responsible antibiotic use in human and veterinary medicine is paramount. These programmes champion responsible prescribing practices, track resistance patterns, and advocate for rapid diagnostics.
- **Global Surveillance Networks**: Establishing robust surveillance networks to monitor AMR trends across different regions is essential. This data will guide targeted interventions and inform research priorities.
- **Investing in Innovation:** Increased investment in R&D for new antimicrobials, diagnostics, and alternative therapies is crucial. Public-private partnerships can accelerate innovation and ensure a steady stream of solutions.
- **Dedicated Funding for Innovation**: Creating a dedicated "AMR and Innovation Fund" can incentivise continued research and development.

What are your views on pharma innovation in India? What are the gaps and challenges that need to be addressed?

Pharma innovation is progressing rapidly and is making strides in India, with significant advancements in drug discovery and development. However, there are still significant gaps and challenges to be addressed. Insufficient funding for research and development, limited collaboration between academia and industry, plus navigating regulations can feel like a maze.

Additionally, we need to invest in better facilities and skilled workforce. By addressing these issues and challenges, India can truly become a global leader in innovative medicines.

What are major expectations from the government to strengthen the pharma sector in India, in terms of R&D, innovation and quality?

Orchid Pharma is committed to developing life-saving medications, that's our passion and purpose. However, it is always better and efficient to have partnerships and support especially from government functionaries, it can accelerate this mission in India.

First, increased R&D funding will empower our scientists to develop cutting-edge treatments. Second, streamlining the process for approving new drugs that will get them to patients faster. Protecting intellectual property is also essential, inventors need to be rewarded for their hard work to encourage continuous innovation. Finally, fostering stronger ties between universities and drug companies, along with creating a conducive environment for startups, will get everyone working together to create the next big breakthrough and drive growth in the Indian pharma sector.

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