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â??There is a pressing need for enhanced eye health research in Indiaâ?•

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World Sight Day 2023 on October 12 recently reminded us to realign our focus on eye healthcare and research. The increasing prevalence of vision-related issues in India presents a significant concern and a formidable challenge for pharmaceutical companies in the region. Recent estimates indicate that there are approximately 62 million visually impaired individuals in India, with a staggering 8 million among them suffering from total blindness. Among a few key players in the eye healthcare space, Mumbai-based Entod Pharmaceuticals is pioneering advancements in ophthalmic super-specialty solutions by introducing new divisions to focus on glaucoma management and ophthalmic surgical products. BioSpectrum interacted with Nikkhil K Masurkar, Chief Executive Officer, Entod Pharmaceuticals to know more about the contribution of the company and the pharma industry in the eye healthcare sector.



What are the key highlights at Entod Pharma for FY 23-24? What are the revenue & growth projections as compared to the previous fiscal? Are there any new launches, investments, partnerships in the pipeline in the coming months?

The company's brand new state-of-the-art The Department of Scientific and Industrial Research (DSIR) approved ophthalmic R&D centre will engage in new molecular discovery, formulation development, personalised ophthalmic medicine and focus on areas such as biologicals, stem cell based therapies and gene therapies. The company is expecting a growth of over 35 per cent year-on-year (YoY) with a growth rate more than twice that of its covered market.

We intend to launch several new speciality medicines in the ophthalmic, ENT and derma segments. These are innovative solutions to be born out of our completed R&D projects.

The company is also actively investing in generative AI-led drug discovery, quality analysis and clinical trials, and intends to be a pioneer in robotic process automation in sterile manufacturing.

Entod Pharmaceuticals' ongoing phase 3 clinical trials for Atropine 0.05 per cent and Pilocarpine 1.25 per cent eye drops are expected to complete by the end of this calendar year, which should allow them to hopefully commercialise these by April 2024.

At the same time the company is rapidly expanding its sales field force for stronger sales promotion on the ground and penetration right from metros to rural areas. Furthermore, the company will soon launch a new ophthalmic veterinary division focusing on quality eye care for pets.

What are the major challenges facing the pharma companies in the eye care market in India? How is Entod addressing those challenges?

According to the National Blindness and Visual Impairment Survey, cataracts are responsible for 66.2 per cent of cases of blindness in individuals over the age of 50. Following cataracts, diabetic retinopathy emerges as a major source of ocular morbidity and potential blindness if not promptly addressed.

India holds the unenviable title of the world's diabetes capital, and diabetic retinopathy is evolving into a condition of significant public health concern. Recent research reveals that 16.9 per cent of individuals with diabetes are afflicted by diabetic retinopathy. Moreover, the World Health Organisation (WHO) forecasts that in 2010, nearly two billion people were affected by myopia — a quarter of the global population. By 2030, they anticipate myopia to afflict a staggering 3.3 billion individuals.

To combat these pressing issues, we are steadfast in our commitment to introducing innovative vision care products in India. A recent milestone is the launch of Cyclo Tears eye drop, the world's first dry eye therapy incorporating self-emulsifying drug delivery systems (SEDDS) technology. This heralds a novel therapeutic approach for addressing inflammatory dry eye disease in India. Furthermore, we are in the final stages of introducing an eye drop that promises relief for individuals, predominantly those over 40, grappling with presbyopia. This product has garnered approval from the US Food and Drug Administration (FDA) and is already available in the market.

What are your views on the R&D, innovation taking place in India to combat various eye diseases? Where are the gaps, and what more needs to be done?

While the industry is making commendable strides in developing solutions for eye health concerns, there is a pressing need for enhanced eye health research in India. Allocating greater resources and fostering a genuine research culture within our medical colleges is essential for a more promising future. Investment in Research and Development (R&D) holds the potential to refine design and manufacturing processes, ultimately elevating the quality and effectiveness of products. Moreover, it can facilitate the creation of advanced testing and regulatory frameworks, ensuring the safety and efficacy of medicines.

Furthermore, there is a critical demand for a well-trained cadre of ophthalmologists to address these issues comprehensively. A substantial endeavour is warranted to elevate the quality of residency training nationwide and augment funding for robust research. Only through these measures can we cultivate a pool of professionals equipped to provide comprehensive ophthalmic care and adeptly incorporate emerging ideas and technologies. Until then, challenges like myopia, cataracts, glaucoma, age-related macular degeneration, and others will persist as ongoing hurdles into the future.

How do you foresee the implementation of stem cell therapy in curing certain eye diseases in India?

Disorders or ailments affecting the eye arise from damage or dysfunction in one or more of its integral components. The specific disorder that develops is contingent upon which component(s) are affected. The challenge in addressing these issues lies in the fact that, unlike the replaceable electronic components of a camera, obtaining new biological components for the eye is a complex endeavor. This is where stem cell technology holds promise. Stem cells serve as a wellspring of fresh, specialised cells and offer a potential avenue for replacing impaired cells within the eye. Various types of stem cells can be utilised in diverse ways, tailored to the specific disorder being addressed.

Recent advancements in preclinical research have bolstered the belief that stem cells possess the potential to regenerate degenerated cells or take the place of cells in numerous significant diseases, including ocular disorders. In experimental trials, the introduction of healthy stem cells in lieu of deteriorated retinal cells has spurred cell regeneration, facilitated the establishment of new intercellular connections, and contributed to the enhancement of visual function. Stem cells exhibit the capacity to differentiate into various cell types within their environment, including retinal neural cells and photoreceptors. Prior experimental studies have demonstrated the remarkable compatibility of stem cells with retinas, enabling seamless integration with Müller, amacrine, bipolar, horizontal, and glial cells, as well as photoreceptors.

What are your major expectations from the government to improve eye care in India, in terms of new policy announcements or collaborations with the industry?

Increased Funding for Research and Development (R&D): I believe that the government should allocate more resources towards R&D in the field of ophthalmology. This would facilitate the development of innovative treatments, drugs, and technologies that can address a wide spectrum of eye-related disorders.

Support for Stem Cell Research: Given the promising potential of stem cell technology in eye care, I would encourage the government to provide incentives and funding for research in this area.

Streamlined Regulatory Processes: It is crucial for the government to work in tandem with the industry to establish efficient and transparent regulatory processes. This would accelerate the approval and market entry of new and advanced eye care products, ensuring that they reach patients in need in a timely manner.

Encouraging Public-Private Partnerships: Collaboration between the government, private sector, and non-profit organisations can greatly amplify the impact of eye care initiatives. By fostering partnerships, we can collectively work towards improving access to quality eye care services across the country.

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