BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Ã¢â?¬Å?The cancer diagnostics industry is on the cusp of substantial growth, attributed to an ageing populationÃ¢â?¬Â•

December 2, 2023 | News

Headquartered in California, USA, Harae Dx, a medical diagnostics company is all set to introduce the next generation Artificial Intelligence (AI) enabled automated multi-cancer early detection system in India, China and the US in three years-time period. Harae Dx has already secured seed funding from global investor SOSV and is in the process of securing Series A funding of $12 million. The company holds strategic patents in its core technology platform, and the development and manufacturing of the entire diagnostics system will be executed through strategic partnerships using an outsourced model. In an exclusive interview with BioSpectrum, Dr Nitin Malekar, Director, Harae Dx Inc., shared his views on the effectiveness of the new technologies being offered and regulatory challenges.

What are the new technologies you are offering?

Our game-changing, non-invasive, portable rapid cancer diagnostic system delivers reliable test results in just 30 minutes. The heart of our innovation lies in a multi-application platform, harnessing proprietary lab-in-the-box centrifugal microfluidic technology, expressly designed for the early and precise detection of an extensive array of protein and genetic biomarkers present in blood, each pertinent to various cancer types.

Harae Dx Corp.'s visionary project overcomes the inadequacies that have plagued traditional cancer screening methodologies. First and foremost, it offers a safe, non-invasive, and cost-effective alternative, abolishing the need for

cumbersome procedures that often invoke anxiety and discomfort.

Secondly, our system incorporates AI-powered algorithms that have demonstrated unparalleled accuracy, dramatically reducing the prevalence of false positives and negatives that have plagued conventional screenings.

Moreover, our solution is not just cutting-edge; it's accessible and scalable, ensuring that a broader population can benefit from the tremendous advantages of early detection. In doing so, it has the potential to save countless lives.

The Harae Dx System is more than just a medical innovation; it's a catalyst for transformative change in cancer care. It offers the essential tools to bridge existing healthcare gaps, making mainstream and portable cancer diagnostics the new standard. Physicians, hospitals, and laboratories now have a dependable ally, enhancing decision-making, diagnostic efficiency, and screening accuracy, all while keeping costs at a minimum.

Together, we can reshape the future of healthcare, one breakthrough at a time. We stand at the precipice of a new era in cancer detection, by leading the change, being united in our mission to improve the lives of countless individuals battling this relentless disease. Let this be a New Dawn in Cancer Detection.

How cost effective are these new technologies?

When it comes to cutting-edge diagnostic technologies, cost-effectiveness is not just a measure; it's a game-changer. The surging demand for rapid and precise biomarker diagnostics is propelled by the global increase in infectious diseases, the growing embrace of personalised medicine, heightened focus on biomarker research, and a rising need for non-invasive diagnostics. Leading this charge is cancer biomarker testing, which stood at the forefront of the biomarker test market in 2019.

Are there any regulatory challenges associated?

Regulatory challenges are part of our journey, and we embrace them as we work tirelessly to save lives and improve healthcare worldwide. Harae Dx is fully aware of the hurdles that lie ahead as we embark on our mission to revolutionise cancer diagnostics, starting with a particular focus on breast cancer—the world's most prevalent cancer among women, causing 2.3 million new cases and 1.2 million deaths each year. It's a sobering fact that in India, every second woman diagnosed with breast cancer succumbs to this disease.

While navigating Regulatory Challenges, we are committed to provide Safe, Innovative Cancer Testing. As a cancer research and technology organisation, Harae Dx is unwavering in its commitment to adhere to regulatory requirements in the United States, India, and other target countries. We understand that the future of healthcare hinges on both innovation and compliance.

Our initial focus centres on detecting cancer biomarkers for specific anatomical sites, and we have ambitious plans to develop specific cancer tests, including those for breast, prostate, lung, cervical, colorectal, and others. We will do this through strategic collaborations with biopharmaceutical companies and medical laboratories in subsequent phases of our business plan.

Transparency and rigorous validation are at the core of our operations. Our project undergoes extensive testing and clinical trials to ensure its reliability, efficacy, and safety. We are committed to actively collaborating with global regulatory authorities, notably seeking the highest regulatory clearances, including approval from the US FDA.

Our pledge is to not only revolutionise cancer diagnostics but to do so with the highest standards of safety and effectiveness.

Please highlight the value and opportunity it brings by investing in this project.

At this juncture, we are currently designing the prototype which will pass through a rigorous validation. Our project will undergo extensive testing and clinical trials to guarantee its reliability, efficacy, and safety. We are committed to actively collaborating with global regulatory authorities, including seeking the highest regulatory clearances, such as from the US FDA.

Now, let's delve into the value and opportunity that investing in Harae Dx represents. The demand for rapid and accurate biomarker diagnostics is soaring, driven by the global increase in infectious diseases, the adoption of personalized medicine,

and a growing focus on biomarker research. Cancer biomarker testing stood at the forefront of the biomarker test market in 2019, underscoring the transformative power of such diagnostics.

The cancer diagnostics industry is on the cusp of substantial growth, attributed to an aging population susceptible to disease and the proliferation of technologically advanced products delivering precise test results.

What sets Harae Dx apart is our portability, affordability, and efficiency. Our AI-enabled, automated multi-application platform rapidly analyses protein and genetic biomarkers for a wide range of cancers at an early stage. While prominent players exist in the liquid biopsy early cancer detection field, none offer our unique automated portable Lab in a box technology. This distinctive advantage positions us as potential partners for the future.

Current offerings in the next-generation diagnostics market are scarce, creating a void in early cancer detection, progression management, and post-treatment recurrence monitoring. Harae Dx plans to seize this opportunity as an early mover in the market, potentially establishing an unparalleled brand in the global healthcare community.

From a funding perspective, investing in Harae Dx isn't just an opportunity; it's a chance to be part of a healthcare revolution that can save lives and transform the industry. It's a call to action, an invitation to join us in reshaping the future of healthcare.

Bhagwati Prasad