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Ã¢â?¬Å?Asian IVD market is in urgent need of more open technologies, support from government schemes and regulationsÃ¢â?¬Â•

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China-headquartered Fapon Biotech Inc. has fostered partnerships with many top notch Indian in-vitro diagnostics (IVD) companies over the years, and has contributed to more than half of the IVD raw materials in the Indian market. The company has recently announced its innovative chemiluminescence one-stop solution strategy in India to help local in-vitro diagnostics (IVD) partners quickly extend their product portfolio and streamline their production processes, as well as accelerate their business in the chemiluminescence immunoassay industry. In conversation with BioSpectrum Asia, Kevin Liu, Global Sales Director, Fapon Biotech shares his perspective on the growth and challenges of the Asian, particularly Indian IVD industry.



How would the domestic IVD manufacturers benefit from Fapon's new Chemiluminescence one-stop solution strategy launched in India? Are similar such solutions not already available in India by other domestic or global companies?

The world has been observed great growth in the Chemiluminescence Immunoassay (CLIA) market these years. It is known that the Asia-Pacific CLIA analysers market is expected to grow at the fastest CAGR, due to the increasing awareness about early disease diagnosis, rising healthcare expenditure, and increasing demand for advanced medical technologies, as well as the prevalence of chronic diseases in developing economies like India. India CLIA analysers market is the fastest growing market in the Asia-Pacific region. Rooted in IVD industry for over 20 years, Fapon actively responds to industry trends and challenges, hope to unite the vast number of industry partners, spare no effort to provide IVD solutions to meet the needs of the industry.

Fapon’s chemiluminescent immunoassay (CLIA) analysers are open systems, which enables the IVD manufacturers to develop and commercialize their CLIA kits without spending any additional time, efforts, resources and money on the development of a new analyser that takes multiple years. So the Indian IVD manufacturers can directly start development of their CLIA kits.

To the best of our knowledge, there are not much choices for open CLIA analyzers available in the Indian market, all the CLIA analyzers are closed systems, which are restricted to the use of CLIA kits developed by the big IVD manufacturers. Chemiluminescent immunoassay (CLIA) analyzers open systems removes restrictions and accelerated local self-development of reagents. The introduction of the open system and CLIA reagent technology enables Indian local IVD manufacturers to develop IVD kits for disease biomarkers, and also provide the desired opportunity to clinical experts and scientists who would like to develop automated CLIA tests for new disease biomarkers; Combining high quality core raw materials, reagents technology and affordable analyzers caters business localization and further reducing Indian local healthcare cost.

What objectives are to be achieved with this new launch in India? Are you establishing new partnerships with Indian IVD companies with this launch? What is Fapon's current share in the Indian IVD market?

This launch is mainly targeted to empower the local Indian IVD manufacturers so that they can develop the desired IVD kits that are needed by India to enable the rapid, accurate and affordable clinical diagnosis of the diseases prevailing in India. The early-stage diagnosis leads to better health outcomes as the healthcare professionals can intervene earlier and start the treatment of the disease preventing the costly late-stage complications. Therefore, early-stage diagnosis by developing local IVD kits in India can critically reduce the total healthcare costs making healthcare more sustainable for the country. Fapon is serving the Indian IVD market from the last 15 years, empowering the local IVD players in India through continuous iteration of the IVD technology platform, reagent service and excellent core raw materials.

What is your view about the current IVD market in India- its growth opportunities & challenges?

Indian IVD market is growing at a significant pace and there are multiple growth opportunities. The increased outreach of the healthcare and diagnostics in India is further leading to better healthcare outcomes as it enables the healthcare professionals to start the treatment and medical invention much earlier, thereby preventing the costly and life-threatening late-stage complications.

The challenges are the evolving regulations in India, which is making it more stringent and hard for the entire IVD industry to develop the local IVD products and solutions faster. Besides, insurmountable technical difficulties can also pose challenges to industrial development. Therefore, bringing advanced technologies to the lab testing industry from outside India can be crucial. Introducing cutting-edge technology platforms and breaking down local technology limitations can effectively help iterate technology and reduce product costs for Indian local manufacturers.

What are the current challenges facing the Asian IVD market? How is Fapon addressing those challenges?

The Asian IVD market is in urgent need of more open technologies, support from government schemes and regulations to further evolve the industry. A positive competitive landscape for both import players and indigenous manufacturers to boost local IVD industry is also very encouraging. The lack of the open CLIA analyzers has prevented many local IVD companies from developing their own IVD kits. Fapon is addressing this challenge by democratizing the CLIA analyzer and enabling the local IVD players to develop their own reagents.

Are you planning to launch or develop new analysers for the global IVD market? Please share your future plans. What other products are in the pipeline?

Yes. Fapon is working on the development of a very high throughput CLIA analyzer that will be officially launched in the global market by next year. Further, Fapon is working on total lab automation solution for very high throughput clinical labs, which we will be launching in the coming years. Additionally, we are working on the development of new CLIA panels targeting both the commodity and high specialty biomarkers.

Any new partnerships or investments in the pipeline this year or later?

Fapon has forged multiple partnerships with the IVD companies globally and we are empowering them to develop timely, accurate and affordable diagnostics. We are continuously investing our sales revenue in R&D and have further invested in

opening our global R&D sites in Boston, USA and Munich, Germany this year. Over years, Fapon achieves continuous iteration of products and technologies on chemiluminescence immunoassay.

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