Realizing the Promise of Asia-Pacific:
The Strategic Shift from Outsourcing to Innovation

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For more than a decade, the emerging markets of the Asia-Pacific region have held special promise for the global biopharmaceutical industry. Driven by a combination of low per-capita consumption, rapidly expanding economies, technological innovation and a talented workforce, the region has seen explosive growth in both economic and political power during the past ten years.

From a biopharmaceutical development perspective, such growth has hardly gone unnoticed. In recent years, Western companies have set up shop in the entire region, eager to capture a portion of the region’s comparative advantages in talent costs, patient pools and disease demographics. Faced with declining R&D productivity, increasing development costs, decreasing pipelines and lower earnings, these companies are turning to Asia for greater efficiency, lower costs and increased speed to market in clinical development operations.

The Strategic Shift
In meeting these needs, the region has more than matched its promise as a low cost, higher
value service provider. Yet, as the industry continues to grapple with its challenges, the potential sought by many Western companies as part of their Asian strategy is also changing. In order to operate effectively in an increasingly competitive economic and commercial landscape, they are searching for new partners and new strategies to help navigate risks and seize opportunities.

In this regard, Asia as a whole may be poised to assume the mantle of leadership as the strategic partner of choice for global pharmaceutical companies; a partnership that goes beyond simply providing patients and data. As pressure on biopharma’s development pipelines continues to grow, companies are setting their strategic sights on a future world where Asia is not just a market and support powerhouse for the industry, but a provider of key contributions to drug discovery and research innovation as well.

Increasingly, Western biopharma companies are turning to research-based partnerships as a way of sourcing high-end expertise and building up drug discovery investment in Asia. For example, in 2009, Pfizer announced a joint initiative with the Shanghai Institutes for Biological Sciences (SIBS) to support fundamental research geared toward drug discovery and development programs in China. The impetus for innovation is also coming from other sources. A mixture of collaborative research, contract research, outsourcing and co-development is sprouting all over Asia, fueled by organizations such as CROs that are seeking to enhance revenue streams and expand market opportunities. India-based biopharma companies such as Dr. Reddy’s that have specialized in generic drug manufacturing are also seeking to compete in new drug discovery. Many private equity funds located in the developed world are investing in a range of higher end activities by Asian biopharma companies.

With such widespread innovation occurring across the region, the possibility exists for Asia-Pacific to become a prime proving ground for the notion of “virtual drug development,” in which nearly every step in the development lifecycle is provided by a network of nimble partners. This could involve partnering with innovative companies or research centers to access intellectual property – with or even without capital – to develop and commercialize promising drug candidates. A flexible, global partner could prove to be a valuable ally in such a construct due to its efficient cost structure and regional focus.

Governments across the region are also stepping up. The Indian government, for example, has started offering incentives to domestic and multinational drug makers to encourage new drug discovery and turn the country into one of the top five pharma innovation hubs by 2020. South Korea, Singapore and Malaysia have all identified the biopharmaceutical industry as a strategic sector worthy of public infrastructure investment and support. Singapore, for example, continues to attract attention with two flagship R&D centers operated by the Agency for Science and Technology Research (A*STAR), including Biopolis, opened in 2003 to develop biomedical sciences, and Fusionopolis, an interdisciplinary research center designed to bring technology experts from A*STAR and those from the private sector together under one roof. The government also offers a number of research and development grants that can subsidize a company’s capital expenditure, depending on what type of skills and expertise it brings to Singapore.

In Malaysia, the development, testing and production of biopharmaceutical products are entitled to High Technology Pioneer Status, which offers significant tax incentives. Malaysia is also a participant to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which helps to protect innovative patents. To bolster clinical trials, the Clinical Research Centre (CRC) functions as the clinical research arm of the Ministry of Health to operate a network of 17 centers around the country. CRC serves as a single point of contact to access all Ministry of Health hospitals and clinics to carry out clinical trials in Malaysia.

For its part, South Korea’s biotechnology and pharmaceutical industry has been rapidly growing, due to government support. The Korean government has set forth Bio-Vision 2016, a national plan to promote biotechnology aimed at strengthening the core infrastructure necessary to develop and commercialize original biotechnologies.

**A More Uniform Approach**

The stage is set for Asia to take the next step up the value ladder in helping the global biopharmaceutical industry increase productivity, accelerate timelines and manage complexity. But in order for the region to fully realize its potential, some final pieces of the puzzle must be addressed.

For one, Intellectual Property Protection (IPP) remains a significant barrier to real innovation. In the past, the majority of outsourced clinical
activity in Asia has focused primarily on relatively inexpensive areas such as biology and chemistry, driven by pharma’s desire to keep higher-value, more patent-heavy activities under direct control. Today, however, an increasing number of CROs across the entire region – both local and foreign-owned – are moving into more lucrative stages of the drug development chain. These offerings include integrated drug discovery capabilities that encompass the drug discovery spectrum, from lead identification to lead optimization, supporting biology, process chemistry, formulations, preclinical toxicology and more6.

As Western companies begin to feel more confident about outsourcing discovery research projects to Asia – a vital step in creating the critical mass necessary to foster innovation – they must believe patents are safe. Fortunately, significant progress has been made by some key Asian territories to enforce IPP and implement patent laws. Singapore has established a strong track record for IPP, South Korea’s 2007 Free Trade Agreement with the United States includes an improved patent system, and China and India have also placed the need to address IPP issues near the top of their agendas7.

Harmonization of government regulatory schemes is also an urgent issue. While some countries such as India may fare better than Eastern Europe or China in terms of a regulatory environment, the situation is hardly uniform across the region. A more uniform approach to regulation of clinical studies and results could, over time, help create a pan-Asian pharmaceutical market large enough to encourage a range of biopharma companies to find their niches without having to reinvent the wheel in each new geography.

Beyond state responsibilities and legal protections, the region’s culture of innovation is further hampered by legacy issues surrounding a lack of educational infrastructure and effective collaboration between industry and academia. To innovate, scientists are best served when able to draw from different disciplines like mathematics, biology and chemistry. In Asia, however, educational systems often create scientists with strong focus on specialization but minimal opportunity to change disciplines. Moreover, despite a steady rise in the number of doctorates in natural sciences and engineering awarded throughout the region, sufficient linkage has not been established between key innovation centers such as universities, public institutions and private industry facilities, further hampering drug discovery by minimizing interdisciplinary processes.

Finally, the most powerful force in enhancing innovation throughout the region may be a simple change in thinking. For the most part, the R&D business models of Western biopharma companies are still heavily skewed toward a developed markets perspective. To fully engage in the processes that lead to innovation, the region as a whole must re-examine its priorities to include placing its own unmet healthcare needs in line with its vast potential for drug discovery and development.

Whether addressing tuberculosis, diabetes, Hepatitis C or any of a range of Asian-specific disease manifestations or characteristics, the desire to effectively leverage lower cost, higher value processes and infrastructure to pilot novel drug development methods may, in the end, be harnessed most effectively when the end user resides across town rather than across the world.

A New Center of Gravity
Although significant challenges remain, a culture of innovation is poised to take root today across Asia, as the infrastructure for world class R&D is developed, the level of technical and leadership talent grows and a renewed emphasis on regulatory harmonization takes place in countries big and small. As the center of gravity for the industry shifts from developed to developing geographies, the balance of pharmaceutical investment and innovation will also shift toward a future where high-end drug discovery in Asia will play an increasingly significant role.

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Dr. Tharmaratnam joined Quintiles in April 1997 as a Clinical Pharmacologist at Guys Drug Research Unit, having spent the previous five years working in anesthesiology and critical care medicine in London.

In 1999, he was appointed Medical Director for Quintiles Europe. Two years later, Dr. Tharmaratnam was tasked with setting up the Quintiles ECG lab in Mumbai, India - the first global ECG lab outside Europe or the U.S. In 2003, he joined Quintiles Japan and was instrumental in setting up international alliances for the business in Hawaii, Brazil and Peru. In August 2004, Dr. Tharmaratnam moved to Singapore and was appointed Chief Executive Officer of Quintiles Southeast Asia, Taiwan and Korea. He was most recently Head of Core Clinical Operations Asia-Pacific.

Dr. Tharmaratnam earned his medical degree from University College London, UK, where he specialized in anesthesiology. He is also a member of the Royal College of Anesthetists, UK.

References: