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Sneak Preview: BCG Study Predicts Strong R&D Focus In India; Big Pharma May Leverage India For "Niche Busters" And Stem Cells

MUMBAI - Research-related investments funnelled into India by U.S.-based pharmaceutical companies swelled by 10 times between 2002 and 2009 to reach $121 million, a number that will continue to grow in the years to come, according to an upcoming study by the Boston Consulting Group. The report, which was commissioned by the USA-India Chamber of Commerce (USAIC), will be released June 23 during the annual USA-India BioPharma & Healthcare Summit in Boston.

The BCG position paper will take an exhaustive look at the India landscape and includes findings derived from more than 40 interviews with pharma R&D heads, leading academics and government officials involved with India R&D. BCG also surveyed more than 30 R&D thought leaders to round out its findings.

Providing a sneak preview to *PharmAsia News*, leading BCG analysts said the $121 million includes both innovative research and clinical trials, but does not include payments made to Indian companies for in-licensing of new molecules. In the survey of R&D executives, over 75% of respondents expect to increase R&D activities in India in the coming years while only 3% predict a significant reduction in such allocations.

In 2009, the R&D expenditure by Pharmaceutical Research and Manufacturers of America member companies in the U.S. stood at $35.4 billion, compared to $11 billion in various research projects outside of the U.S., BCG says. Out of the $11 billion, India saw investments of about 1.1%. The amount, though marginal, has resulted in a steep climb from a negligible 0.1% budget allocated back in 2002 by big pharmaceutical companies.

During that same time, the share of R&D spend in Western Europe, Japan and Canada declined, BCG says; while areas like Latin America, Eastern Europe and other areas of Asia Pacific have seen significant growth.

"Faced with a dramatically growing R&D budget, disproportionate with discovery of new drugs, companies are relying on innovative models in India for higher productivity," said Bart Janssens, partner and director, BCG during a phone interview. Janssens and Simon Goodall, managing director, BCG, co-authored the report that dwells on ways to leverage the potential of R&D in India.

Although India R&D is on the rise, the BCG report will also explore why India has not seen an even larger explosion in research and why it doesn't yet play a larger role in global R&D programs, Goodall said. For instance, the report shows that while India is growing faster than other markets in R&D spend, its 1.1% share of ex-U.S. R&D still trails other hot emerging markets like Eastern Europe (8.3%), Latin America (3.7%) and the Middle East-North Africa (1.5%), although BCG does not break out results in those jurisdictions country by country. BCG also does not break out China, but does include "Other Asia Pacific" at 4.7%.

One factor that impacts the data is the mix between clinical and pre-clinical research, which is not something that Big Pharma generally breaks out for the public. An area like Latin America, for instance, could see higher R&D spend because it has a greater percentage of more costly clinical trials, Janssens noted.

The report is intended to be a "living document" that will evolve over time and serve as a catalyst for discussion, both during the June 23 summit and throughout the year via meetings with government and industry officials, said USAIC President Karun Rishi.

"The findings will help global R&D leaders take a fresh look at their R&D strategies to integrate and leverage India into their global drug discovery and development programs," Rishi said.

Last year's summit - which was moderated by Martin Mackay (then president of **Pfizer** Pharma Therapeutics R&D, now president of R&D for **AstraZeneca PLC**) - featured a who's who of Big Pharma R&D leaders and India pharma CEOs who engaged in a vigorous debate about how India can leverage its strengths to help spur life sciences innovation and investment ('Pre-Competitive Collaboration Would Help Pharmaceutical Productivity Crisis - If Lawyers Could Get Out Of The Way,' PharmAsia News, May 11, 2010).

R&D: Good Going, Can Get Better

The BCG study highlights that over 70% of global biopharmaceutical executives are satisfied with R&D alliances in India. Though none of the respondents in the survey were "very satisfied" with Indian alliances, a large chunk of 30% were "satisfied" and 42% were "moderately satisfied."

Another 15% of executives felt that they were "minimally satisfied" and 12% said they were not satisfied at all. Among the reasons cited for dissatisfaction, Janssens said, could be alliance management issues and whether partners are given flexibility to handle research projects. "The intentions may be all right but there may be issues with the execution models," he said, emphasizing that companies need a balanced approach where both senior management and those who operate at the ground level have bought into the partnership ('As Deals Shrink, Indian Companies Ask MNCs To Stay Open For Drug Discovery Partnerships - PharmAsia Summit,' Nov. 18, 2010).

Importantly, Janssens and Goodall also highlighted that successful partnerships are generally the ones with a close collaboration that includes "intense communication" between senior management, rather than a transactional relationship that may lead to differing expectations between the parties and poor communication.

IP, Infrastructure, Alliance Management Key To Successful Teaming Up

Among the macro-level issues described as hurdles to research in India, 61% of respondents to the BCG survey blamed an unsupportive IP regime, lack of infrastructure was singled out by another 52% and an equal percentage said that "company culture was not conducive." About 30% felt that Indian government policies were not supportive to spur R&D partnerships while 24% agreed that "partners were difficult to manage." Janssens drew attention to the views of 15% of respondents who said that India had "no big success stories" as an issue that acted as a brake to forging partnerships.

He elaborated that a few success stories of original research from India will boost possibilities of more alliances with Indian companies.

Asked if cost arbitrage was a compelling factor to build bridges with Indian companies, Janssens said costs are weighed in some cases but mostly what counts is the ability of an Indian partner to handle a project. Importantly, though, global companies can look to Indian partners to take on programs that may be too expensive to develop in the U.S. or Europe and would otherwise be de-prioritized, he explained.

Outsource, Work On Niche Busters, Stem Cells

Given a choice of R&D models in India, including partnerships, captive R&D centers, joint ventures, co-development or outsourced programs, nearly three-fourths polled thought that outsourcing is the best option. The next to receive strong support from poll participants was a JV route, while co-development agreements for a compound and captive centers were seen as least interesting.

BCG said that "niche busters," as opposed to blockbusters, could potentially save companies 40-60% if a drug is developed in India. With a vast pool of treatment-naïve patients, India could play a role in developing drugs that are aimed at smaller, niche markets.

Also, the BCG report stresses that India's capabilities in bioinformatics, data management, emerging translational centers and individualized therapies could be harnessed to improve the success rate of drugs or cut down attrition rates.

Stem cell research - where India has 22 public and seven private research institutions - could also be developed in India for an emerging success rate, said BCG in its analysis ('Regenerative Meds: Indian Drug Makers Inject New Life Through Investments In Stem Cells,' PharmAsia News, June 24, 2010).

Indian equity markets have not valued the R&D capabilities of Indian companies, Janssens said, but pointed out that the perception would change if pipelines are scaled up and cash flow issues are tackled. Traditionally, Indian companies have performed well on the stock markets after their R&D arms are spun off, Janssens noted, sharing examples of **Dr. Reddy's Laboratories Ltd.**, **Sun Pharmaceutical Industries Ltd.**, **Piramal Healthcare Ltd.**, and **Ranbaxy Laboratories Ltd.**

The BCG consultants also spoke of the emergence of "network" R&D models that will better enable smaller companies to bring innovations to market in a cost effective manner.

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