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Syngene forays into commercial manufacturing of new molecules

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In 2013, the company achieved revenues close to $100 million. Going forward, it aspires to touch the $250 million mark by 2018, through strengthening its current discovery and development platforms. He also elaborately discusses on the company's future goals and collaborations between industry-academia.

Importantly, Dr Nerurkar charts out recent trends and major shifts seen among the Indian and global CROs. He also touches on the sensitive topic of clinical trials regulation in the country and how the company strategically plans to navigate through the turbulent times. Excerpts:

Are there any differences in your collaboration with Baxter and others like Endo Pharmaceuticals and BMS?
Dr Manoj Nerurkar: Syngene Baxter collaboration is strategic in nature similar to many of our other collaborations.

The Baxter Global Research Center (BGRC) that we inaugurated at Syngene earlier this year, is a part of Baxter's global strategy of building R&D collaborations with strategic partners. This collaboration will support Baxter in the Research and Development of medical products and devices to serve patients both in India and around the world.

A team of over 100 multidisciplinary Syngene scientists will be based at this dedicated Center of Excellence at Syngene in Biocon Park, Bangalore.

The Syngene team, working closely with Baxter scientists, will engage in a wide range of R&D activities centered on product and analytical development and pre-clinical evaluation in parenteral nutrition and renal therapy.

What is the progress of your collaboration with Endo and BMS?

The success of a discovery-based company is measured at early stages by number and quality of drug candidates that they are able to introduce into clinical development. Our partners have made a tremendous progress in this direction through strategic collaboration with Syngene.

I am proud to say that our scientists have made significant contributions to the drug discovery and development efforts of these leading global pharma companies.

What are the trends that you see in contract research outsourcing in and outside India?
There are several trends that we have observed over the past few years which have affected the CRO landscape to a significant extent.

The first trend I would like to talk about is in the way large pharma companies are selecting their drug candidates today. Along with their internal discovery efforts, today large pharma companies are relying heavily on smaller boutique biotech companies for in-licensing the drug candidates. These smaller, discovery-based companies have limited infrastructure and bandwidth to carry out end-to-end discovery and development and hence they are heavily dependent on reliable partners like Syngene for their discovery efforts.

This is an important trend that we see which has evolved in the last 5-10 years. Since the needs of these companies are different than the large pharma companies, CROs like Syngene need to adopt to the ways of doing things that will support their R&D. Today we work with a significant number of small discovery-based companies in their pursuit of selecting a clinical candidate.

Another important trend that has emerged over past several years is the emphasis on large molecules or biologics in the pipelines of all major pharma companies. This is an important trend from outsourcing perspective since CROs will have to develop this skill-set if they want to participate in this shift in R&D focus. Syngene is well-poised to take on R&D of biologics since it has well-developed discovery and development biologics platform with a globally experienced team of scientists in this area.

We are also witnessing another trend, which is the change of mindset of the big pharma companies in the way they leverage the external R&D. Previously, CROs were considered as an 'extra pair of hands'. However, with significant knowledge, expertise and experience that CROs have developed over past several years, these companies are working with CROs as strategic partners.

Since CROs work with multiple partners simultaneously, one of the benefits they have, is the knowledge of best practices across the pharma industry. This non-confidential knowledge can be effectively leveraged by our strategic partners to their benefit.

Another shift that we see is in the consolidation of partners by large pharma companies. Back then, pharma companies would tie-up with multiple partners for outsourcing of their R&D. This would require significant hand-offs between various activities resulting in an overall loss of productivity and time. However, with companies like Syngene offering end-to-end discovery and development services, pharma companies have embraced this model of a 'one-stop-shop' by consolidating outsourcing of majority of services under one roof.

Today, the R&D budgets of pharma companies are either shrinking or at best remain flat. Therefore, in research including contract research outsourcing, the focus is more on bringing down the unit cost of R&D. The only way to achieve that is by improving productivity, decreasing cycle times and by working with CROs from the emerging markets due to the cost arbitrage that they offer.

Companies are also looking for differentiators and they are diligent in selecting their partners.

What are Syngene's key differentiators?
At Syngene, our business is governed by 3 core values: integrity, excellence and professionalism. These three values reflect in everything we do.

For us, our people are the biggest value differentiators. We have 2000+ employees, about 300 of them have doctorate degrees, and 10-15% of the total population has global education or experience from US, Europe and Japan, bringing in global perspectives.

This is important because they not only bring global experience and standards of doing R&D, but are able to speak the same 'R&D language' of our partners. So when we work with these global companies, they feel that we are an extension of their own research labs. Collaboration flourishes well with that degree of comfort.

Our infrastructure is cutting-edge and is similar to that of our global partners. We also have robust systems in place which allow efficient and timely sharing of information while protecting confidential information that we generate for our partners. Quality is also a key differentiator at Syngene and it reflects in everything we do. We carry out work under cGMP and GLP, ensuring strict adherence to global quality standards.

Customer-centricity is another key differentiator at Syngene. We take pain-staking efforts in understanding our customers' needs and expectations and provide customized solutions rather than using a 'cookie-cutter, one-size-fits-all' approach. This has allowed us to make foray into other industrial sectors outside pharma such as nutritional, agrochemical, cosmetic and even electronics.

We have been successful in strengthening integration of our discovery and development platforms across small and large molecules and empower innovation. Today we offer innovative and cutting-edge platforms in various areas including Antibody-Drug-Conjugates (ADCs), High Potency API development and manufacture, innovative xenograft models for oncology research to name a few.

What are the company's goals and targets moving forward?
Last year, we crossed about $100 million in revenues. By 2018, we aspire to be close to $250 million. To do this we are strengthening our current discovery and development platforms.

We are also making a foray in to commercial manufacturing of molecules. Over past few years, we have been working closely with many of our global partners in discovery and development of novel molecules. These molecules have been largely successful through clinical development and will require manufacture of large quantities for commercial launch by our partners.

Since Syngene has intimate knowledge of the process of manufacturing them, we become an obvious partner of choice. Planning for these requirements, we have been expanding our scale and capacity to support manufacturing of these large quantities. This is a significant step forward for Syngene since it allows us to support our partners in discovery, development and commercialization of their novel assets.

This we believe will give us tremendous impetus and growth. Our success comes from our partners' success, and we grow with their success.

How are you collaborating with universities and institutions?
We work with universities outside India. Today every university in the US and Europe has IP CELL, where universities come up with ideas but do not have the necessary infrastructure or expertise to develop those ideas in to molecules. We offer them that infrastructure and expertise. In India we have not tasted much success, but we are actively seeking out academic partners.

Now that India is at crossroads in clinical trials. How do you intend to navigate through such turbulent times?
The regulatory scenario around clinical trials in India is a big concern and we certainly hope that the situation improves quickly. The lack of clear regulatory pathway has forced a lot of clinical CROs to fold.

At Clinigene, which is a subsidiary of Syngene, we are looking at this differently. While we wait for the clinical trial situation to improve, we are focusing on strengthening other supportive services such as bioanalytical, data management etc. In fact, for bioanalytical services, we have been able to establish a 'Center of Excellence' for some of our large pharma partners, where the samples from global clinical studies are shipped to us for bioanalysis.

We are focusing on these types of strategies to reinvent ourselves under these difficult circumstances so that we come out strong when the regulatory scenario improves.