Resilient Growth Amidst Funding Fluctuations: How Syngene's Strategic Vision Outperformed the Market

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CXOToday has engaged in an exclusive interview with **Mr Sibaji Biswas, ED & CFO, Syngene International**

1. Even with the recent Biotech funding scenario, Syngene has still shown growth. Did you foresee this? What was your strategy?

The biotech sector funding has experienced significant fluctuations, culminating in a return to baseline conditions by the end of the last fiscal. Between FY23 and FY24, there was a noticeable decrease in biotech funding within the USA, which can be seen as a temporary deviation following a substantial increase in funding during the pandemic years, rather than an underlying problem with the biotech sector or innovation. This reduction inevitably impacted the demand for R&D services from the US biotech segment.

Despite these challenging market conditions in FY24, Syngene managed to achieve a 9% growth rate, outperforming many competitors in the industry. We not only delivered growth and expanded our market share but also made strategic investments in new capabilities, successfully passed numerous client and regulatory audits, and solidified our position for future success.

Sibaji Biswas
ED & CFO, Syngene International

Tracing back to our origins, Syngene started as a research services company dedicated to meeting the R&D demands of the global pharmaceutical industry. Recognizing the value our clients placed on comprehensive services, we strategically expanded to include development and manufacturing (CDMO), enhancing our CRO offerings. This approach has proven successful, establishing us as a provider of complete solutions across the drug development value chain and allowing us to benefit from diverse market dynamics, ranging from the immediate effects of biotech funding on research to the long-term operational models that govern development and manufacturing contracts.

Last year was a milestone for Syngene, marking our inaugural year in commercial manufacturing and the advancement of our enduring partnership with Zoetis. A significant highlight was the acquisition of a biologics manufacturing facility from Stelis Biopharma, which, once operational later this year, will enhance Syngene's bio-manufacturing capabilities threefold and incorporate a state-of-the-art, high-capacity fill-finish line.

Our commitment to innovation continued unabated, with investments in cutting-edge modalities like PROTACs and Antibody Drug Conjugates, alongside increased funding in artificial intelligence, automation, and digitization. These strategic investments are anticipated to be pivotal in boosting efficiency, ensuring high quality, and shortening delivery times for our customers. The distinction in the quality of science is increasingly becoming the primary differentiator for outsourcing partners. In this domain, Syngene's unwavering focus on innovation and our capacity to deliver scientific expertise at scale distinctly sets us apart.

Looking to the future, the trends are encouraging, with biotech funding showing signs of a rebound. This resurgence is expected to translate into increased spending by biotech clients as the year progresses. Moreover, in the large-cap biopharma segment, there is a noticeable shift as companies diversify their operations away from China, aiming to mitigate geopolitical and geographical risks.

In summary, the long-term outlook for Syngene and the broader sector remains optimistic. With positive indicators in place, I am confident in our ability to sustain strong performance over the long term.

2. How is Syngene leveraging AI and ML in its drug discovery and development processes to accelerate timelines and improve success rates? / Can you elaborate on specific applications of AI and ML within Syngene, such as in molecule design, clinical trial simulations, or data analysis? / How is Syngene integrating automation and robotics into its laboratories and manufacturing facilities to improve efficiency, accuracy, and scalability?

Syngene is at the forefront of innovation, harnessing the power of cutting-edge technologies to revolutionize research and development in the pharmaceutical industry. Our strategic investment in artificial intelligence (AI), machine learning (ML), automation, and robotics significantly accelerates project timelines, enhances success rates, and boosts operational efficiency across drug discovery and development.

Our transformative digital journey is encapsulated in our two-year comprehensive digital transformation program, meticulously designed to elevate our operating model. By integrating multiple systems through a seamless digital layer, we ensure data harmony and system integration. The incorporation of AI across various enterprise processes, including customer order responses, contract writing, materials planning, and finance, streamlines operations, enabling auto-responses, optimizing material planning, and improving overall efficiency.

Syngene's proprietary platforms, Syn. AITM and SarchitectTM, are pivotal in expediting data-driven drug discovery. These platforms refine molecular properties, evaluate toxicity, and design molecules with the ideal balance for success. Syn.AI™'s expanded capabilities now include enhanced target identification and validation, pinpointing the most promising drug targets for a range of diseases. Our HepTox™ computer model, a sophisticated simulation of the human liver, allows scientists to foresee potential liver damage risks, leading to the development of safer drugs with minimal side effects.

Our commitment to advanced data engineering, analytics, and visualization equips our scientists with the necessary tools to speed up the R&D processes, nurture innovation, and catalyse breakthroughs in the pharmaceutical sector. Syngene's dedication to digital excellence is unwavering, as we continue to set industry benchmarks and deliver superior outcomes through technological prowess and scientific acumen.

Syngene is enhancing its laboratories and manufacturing facilities with a strategic integration of automation and robotics. The implementation of Electronic Batch Manufacturing Records (EBMR) has successfully transitioned all manufacturing setups to a paperless environment, ensuring that data is electronically captured, stored, and easily retrievable. The gradual rollout of Manufacturing Execution Systems (MES) is a testament to our commitment to achieving fully automated manufacturing in the future, while maintaining strict adherence to GMP processes and regulatory standards.

In the realm of research, the deployment of robotic systems has been a game-changer, significantly boosting productivity and efficiency. Our state-of-the-art robotic compound management system exemplifies this advancement, capable of storing, retrieving, weighing, and dispensing compounds autonomously, thereby eliminating the need for manual intervention.

Syngene's vision extends beyond automation, as we actively integrate Information Technology (IT) and Operational Technology (OT) systems across our campuses. This integration enhances safety and operational efficiency, with IT-OT systems meticulously monitoring critical parameters such as temperature, movement, and air flows. The establishment of a centralized digital monitoring hub at our Biocon Park campus, equipped with advanced digital monitors, allows for comprehensive tracking of campus operations. Moreover, our enterprise asset management solution digitally oversees every asset within our facilities, streamlining asset verification and ensuring precise tracking and maintenance. This digital foresight not only optimizes asset management but also reinforces our commitment to safety and efficiency.

3. How is Syngene ensuring the responsible use of AI and ML to mitigate bias and ensure ethical considerations in its research?

Syngene has been able to build trust with over 450 clients, including 11 out of the 15 top biopharma companies in the world because integrity is part of our DNA, it shapes our operations and actions.

At Syngene, our approach to ethics is fundamental to everything we do. We are committed to ensuring transparency, accountability, and traceability in our research and manufacturing practices. To this end, we continuously invest in cutting-edge technologies. We leverage Electronic Lab Notebooks (ELNs) and Electronic Batch Manufacturing Records (EBMRs) to ensure data integrity and maintain rigorous quality standards. ELNs create a permanent, auditable record of all research activities, including data collection, analysis, and results, which helps prevent errors and fraud while ensuring data can be traced back to its source. Similarly, EBMRs electronically capture all data associated with a drug batch, ensuring consistency and adherence to quality standards while providing an auditable trail. These technologies not only enhance efficiency but also uphold our ethical standards.

We are in the middle of implementing a digital transformation program which would have a layer of intelligence built into it. A significant aspect of mitigating bias in AI and ML applications involves removing human biases from decision-making processes. For instance, in materials planning, algorithms can neutralize biases by relying on statistical data rather than subjective judgments. By using historical data and statistical models, our AI-driven platforms make logical and unbiased decisions, such as determining the optimal amount of raw materials needed for a process without the 'play safe' tendency to over-order.

We absolutely ensure that client data is never used to train our AI systems. This practice is a cornerstone of our trust with clients and is crucial to our business model. We depend on publicly available global information for our AI training, avoiding the use of proprietary client data.

We understand the value of technology in delivering efficient services, but we also remain committed to information security. Robust systems, policies, and governance are in place to maintain the security, confidentiality, and integrity of our IT systems and the data they contain. Our risk management framework includes regular reviews by our Risk Committee to ensure compliance with ethical standards and client data protection.

4. Can you provide examples of how automation has transformed specific processes at Syngene, such as high-throughput screening or formulation development?

Our commitment to integrating automation into processes has significantly transformed various areas of operations, thus enhancing efficiency, accuracy and overall product quality. By modernizing and expanding our facilities, we can deliver tangible benefits to customers.

Last year, we commissioned a state-of-the-art, digitally enabled, Quality Control laboratory to complement our new biologics manufacturing facility. We also commissioned a state-of-the-art centralized compound management facility in Hyderabad. This highly sophisticated set-up will be the storage and dispensing central hubs for all the compounds we synthesize.

Another notable example is the use of automation in our custom-built sterile fill-finish facility. Here, we employ automated liquid handling systems for precise dispensing of drugs and excipients into vials or syringes. This automation ensures accuracy and consistency, while minimizing human error. Additionally, automated aseptic filling processes are crucial in maintaining sterility, significantly reducing human intervention and the risk of contamination.

The facility is also equipped with machine vision systems to automate the inspection of filled vials or syringes. These systems efficiently identify any defects, ensuring that only high-quality products proceed through the production line. The increased throughput facilitated by automation allows us to handle larger volumes efficiently, ensuring consistent filling volumes and reducing human error, thereby enhancing the quality of our products.

Furthermore, the implementation of robotics in DMPK (Drug Metabolism and Pharmacokinetics) and other areas has brought about remarkable improvements. DMPK involves repetitive biological processes, and automation simplifies these tasks, reduces effort, and improves clarity. The use of robotics in such areas not only streamlines operations but also enhances the overall integrity and reliability of the system.

In line with enhancing integrity, Syngene also captures and stores data digitally, without manual intervention. This robust data management system is trusted by auditors and regulators, simplifying the validation and approval processes of our facilities. The transition from manual to automated data capture has also eliminated the need for extensive processes to protect paper-based data from manipulation, making the entire system more reliable and efficient.

5. How does Syngene envision the future of the CRDMO industry in terms of technological advancements and its impact on drug development timelines and costs?

We envision a future where technological advancements, particularly AI integration, play a pivotal role in transforming the CRDMO industry. Recent reports indicate that a large share of pharma executives are incorporating expected savings from generative AI into their 2024 budgets, reflecting strong confidence in AI's potential to boost productivity and reduce costs (Pharm Exec).

Operational excellence is part of Syngene's culture, enabling long-term relationships with leading pharmaceutical companies based on innovation, trust, and commitment to quality. Our clients value our ability to intellectually match their thoughts, engage in scientific debates, and add value to their advancements. This collaborative foundation uniquely positions Syngene to lead the integration of cutting-edge technologies in the CRDMO industry.

At Syngene, our AI-driven analytics is significantly reducing drug discovery timelines by narrowing down targets and accelerating early-stage discovery. AI's ability to quickly and accurately analyze vast amounts of data is in the process of transforming drug discovery and clinical trials. By leveraging AI, CRDMOs can expedite early-stage discovery and reduce the time required to identify new molecules. Additionally, AI's potential to design new drugs using previously learned knowledge opens new avenues for treating diseases that were previously untreatable.

Another significant improvement we've witnessed through the adoption of AI and machine learning, at Syngene, is the reduction or elimination of errors across all our processes. By minimizing manual programming and input errors through pre-programmed, validated operations, we ensure accuracy and significantly reduce human error, thereby increasing yield, throughput, and reliability.

Syngene's leadership in adopting these technologies positions us to lead the technological evolution in the CRDMO and pharmaceutical industries, ensuring we drive forward innovation rather than being absorbed by industry changes.

https://cxotoday.com/interviews/resilient-growth-amidst-funding-fluctuations-how-syngenes-strategic-vision-outperformed-the-market/