BioSpectrum
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ASIA EDITION

â??Looking beyond science, it is execution and capital discipline that ultimately determine which biotech companies will surviveâ?•

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More than 300 million people worldwide are impacted by over 10,000 rare diseases, i.e. more than cancer and AIDS combined. Although biotech research has transformed the treatment of many common illnesses, thousands of rare diseases still lack effective therapies. Companies working at the intersection of biotech innovation and rare disease research are increasingly focused on addressing these gaps, including US-based Soligenix. Amidst this scenario, World Rare Disease Day, celebrated every year on 28 February, encourages biotech research and innovation, including the development of orphan drugs and specialised therapies. In conversation with BioSpectrum, Dr Christopher J. Schaber, President and Chief Executive Officer of Soligenix shares his perspective on the current rare disease market and biotech research funding challenges.



What are Soligenix's major plans for 2026? Are you planning to launch any new products this year? Please share the details.

Our top priority for 2026 is completing our confirmatory Phase 3 clinical trial of HyBryte (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL), which is a rare and chronic skin cancer. We expect an interim analysis for this study in 2Q 2026 and top-line results in 2H 2026. We will not be launching any commercial products in 2026. Our growth expectations and the potential for revenues will come with our lead product candidate HyBryte in CTCL, where we expect peak sales in the US to exceed $90 million and $250 million globally.

What are your views on the global growth of the rare diseases market?

Over my 35 + years in the biotech and pharma industry, I have seen the global growth of the rare disease market explode and I do not see that growth slowing down any time soon. Although rare diseases affect small patient populations, they collectively impact more than 300 million people worldwide, and approximately 90 per cent still lack approved therapies.

How does rare disease development present unique operational and financing challenges as compared to broader therapeutic areas?

In rare disease development, a comprehensive pre-study evaluation is critical, not only for designing the clinical study, but also for accurately estimating enrollment and planning around key financial milestones. Without a deep understanding of the disease and patient landscape, teams often underestimate how complex rare disease enrollment can be, and how many sites may ultimately be required. Strict inclusion and exclusion criteria can significantly reduce the number of eligible patients, sometimes requiring far more study sites than originally anticipated to meet enrollment targets. Carefully analysing the patient landscape, including disease characteristics, geographic distribution, and enrollment criteria, before launching a study is essential. Building a lean team with deep operational expertise further increases the likelihood of success in rare disease drug development.

In today's funding environment, what separates biotech companies that survive from those that stall?

Biotech companies that demonstrate clear programme progress and positive data are far more likely to secure continued funding. Strong science and technology are important, but the ability to execute and achieve key milestones on schedule is just as critical. Leaders must also understand their studies in detail, including realistic enrollment rates and how far their capital will carry them toward the next key inflection point. Without that level of discipline, programmes often become too costly to sustain or fail to reach the milestones needed to attract additional capital investment.

How should companies think about capital allocation when managing multiple late-stage programmes?

When managing multiple programmes, companies must weigh which ones have the greatest likelihood of success, and ideally, require a reasonable amount of capital to reach key inflection points. It's also critical to operate within your means. In challenging markets, demonstrating that you can achieve milestones efficiently builds confidence with investors.

What advice would you give biotech leaders navigating prolonged market uncertainty?

First, determine the minimum capital required to reach your next key inflection points. That requires a detailed understanding of your programme, realistic timelines, and the funding needed to achieve meaningful milestones that will support future financing.

It’s also important to pursue non-dilutive funding sources, such as government grants and contracts, and explore creative capital-raising strategies, even though these options may be more limited in the U.S. currently.

Finally, maintain visibility with both existing and prospective investors through public relations, investor outreach, and regular program updates. Staying visible helps ensure that when capital is needed, investors are already familiar with your progress and story.

What role do clinical inflection points play in shaping financing strategy?

Clinical inflection points play a central role in shaping financing strategy, which is why study design must be carefully aligned with both scientific goals and capital constraints. Blinded or placebo-controlled trials often take significant time before meaningful outcomes become clear. While larger trials may provide more statistical confidence, they can also be difficult to fund in smaller biotech settings.

For that reason, it's often important to design studies that can deliver meaningful signals as efficiently as possible. Generating credible data quickly can help companies reach the next key inflection point and secure the capital needed to continue development.

How can non-dilutive funding mechanisms, such as government support, shape a biotech company's long-term strategy and capital efficiency?

There are several important considerations when leveraging non-dilutive funding.

First, identify which funding sources, such as government grants and contracts, are available for your specific therapeutic area, since access can vary significantly. Next, stay informed about evolving government priorities and align programs accordingly, as funding focus areas can shift with changing administrations. Maintaining a diversified portfolio can help mitigate some of that risk.

Finally, closely monitor the availability of funding for specific programmes. For example, we made the decision to pause a heat-stable vaccine segment due to the changing funding landscape for vaccines in the US. Engaging experienced mentors or consultants can also provide valuable guidance in navigating these complexities. Having the right expertise around you makes a significant difference.

How do you balance scientific ambition with financial discipline in volatile markets?

A strong scientific understanding of your molecule and the regulatory requirements for your program is essential, but financial management, budgeting, and capital strategy are equally important. Together, these skills allow companies to manage studies efficiently and demonstrate value while using capital responsibly.

The choice of CRO also matters more than many executives realise. Large CROs can add significant overhead by managing the entire study infrastructure, while smaller organisations may operate more efficiently and help keep costs under control while still providing the expertise required.

Ultimately, long-term success in biotech depends on building a team with deep operational expertise and making disciplined financial decisions that reflect the realities of today's funding environment. Looking beyond science, it is execution and capital discipline that ultimately determine which biotech companies will survive.

Could you please share your thoughts on the growing use of AI in the field of drug discovery and development?

Artificial intelligence (AI) is increasingly transforming drug discovery by accelerating target identification, molecular design, and early candidate optimization, largely through the ability to analyse vast biological datasets and predict protein structures. AI platforms are helping generate and prioritise drug candidates faster and with improved predictions of toxicity and pharmacologic properties. However, while AI is improving efficiency in early discovery, its ultimate impact is still constrained by the complexity of human biology and the need for clinical validation. As a result, the most effective model emerging in the industry is AI augmenting human expertise, enabling faster hypothesis generation and better-informed decision-making throughout the drug development process.

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