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# Resilience & Innovation: Navigating The Current Biotech Landscape

INSIGHTS FROM CHRIS SMYTH, PRESIDENT, ICON BIOTECH

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# Resilience & Innovation: Navigating The Current Biotech Landscape

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The biotech industry has become a great source of new talent and robust methods in healthcare, addressing unmet needs and redefining standards of practice. In recent years, however, the industry has been impeded by a lack of funding, increased R&D complexity and digital transformation. This has been particularly acute for smaller biotechs, where financing and commercialization challenges have proven more difficult to overcome. As large pharmaceutical companies lead in sales and clinical development, biotechs are battling to scale operations with limited infrastructure and resources.

Innovation is the driving force that keeps this vital industry moving forward. Biotechs are using targeted and combination therapies to generate positive real-world outcomes and increase patient access to treatments, with the oncology therapeutic area having the largest share of the global biotech sector as of 2021.<sup>1</sup> Not to mention, advancements in artificial intelligence (AI) and machine learning (ML) are accelerating innovation through new platform-based therapeutics and other automated models for breakthrough modalities.

As biotechs adapt to the evolving landscape, partnerships have proven to be a key factor in optimizing cost and timelines across development phases. Outsourcing has become a way for companies to leverage specific expertise and technology provided by clinical research organizations (CROs) in a time when regulation and talent pools continue to be challenging. Despite an increasingly complex industry, Chris Smyth, President of ICON Biotech, expects to see stronger biotech growth in coming years.

## Barriers To Success In Biotech

The largest barrier in biotech today is the lack of funding, says Smyth. “In 2022 we saw an 80% drop in initial public offerings (IPOs) and, similarly, a large decrease in crossover rounds and venture capital investment was also down nearly 25%,” he says. It seems that the industry is returning to pre-pandemic levels of funding, which are hurting companies as access to digital technologies is becoming more imperative for survival. Implementation of AI and automation, though potentially positive when looking at the big picture, requires large investment, in addition to constant costly updates on technology. For small biotechs, this is hard to achieve, he adds.

The complexity of R&D is another challenge for biotechs as new therapies and novel clinical trial designs are introduced. “Clinical trials are costly, time-consuming, hard to recruit patients into, and require significant expertise and coordination,” Smyth stresses. On top of that, it is becoming more difficult to secure talent with appropriate experience as competition rises. In 2022, life, physical and social science occupations had the second lowest unemployment rate of all US occupations—0.6%.<sup>2</sup>

While innovation is at an all-time high, regulation continues to be an obstacle for biotechs. “It’s hard for a small company to operate in a macro environment where the pace and complexity of change, especially with these regulatory requirements, is so rapid, and the regulations also vary across different regions of the world,” says Smyth. “To operate in an environment like this, biotech companies need talent with the required skillset and appropriate access to regularly updated databases of regulations as well.”

The landscape is completely different from that of large pharma. While biotechs are the source of most life science innovation, it is rare for them to commercialize their own products. Oftentimes, small biotechs need to wear many hats and experience different pressures than large pharma companies, as budgets and manpower are limited. Therefore, they are focused on near-term milestones rather than long-term goals. “Those milestones are usually value inflection points which are going to allow them to generate positive news flow and support the next tranche of funding or support an IPO,” says Smyth.

### New & Ongoing Biotech Trends

The good news is that R&D spend is projected to increase, according to a sector survey conducted by Citeline and ICON in 2023. Based on the survey’s results, six in ten respondents expect their R&D spend to increase within the next one to two years.<sup>3</sup> The biotech market size is also expected to grow at a compound annual growth rate (CAGR) of 13.96% from 2023 to 2030. It was estimated at \$1.37 trillion in 2022.<sup>4</sup>

The biotech industry is also seeing companies use pipeline prioritization as a method of optimization, says Smyth. “Biotechs are tending to narrow their focus and progress their best lead candidates to commercial milestones rather than trying to build a broad pipeline,” he explains. With more funding directed towards cutting-edge science, there has been a revolution in advanced therapies and precision medicines. Cell and gene therapies (CGTs), for example, are emerging as stars in the space, with the FDA predicting that by 2025

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they would be approving 10 to 20 new CGTs a year. “Without a doubt we’re on track for that prediction to be proved true,” he adds.

Furthermore, excitement around clustered regularly interspaced short palindromic repeats (CRISPR) technology is increasing as the FDA approved the two first-ever CRISPR-based gene editing therapies for sickle cell disease in the US on December 8, 2023—a modality that had been previously approved in the UK in mid-November 2023.<sup>5</sup> “This is the first CRISPR-based medicine available in the US and if successful, I think we’re also going to see further indications being approved next year,” says Smyth.

A less surprising trend is exhibited in the global share of the biotech market, where the US remains on top. As of 2021, the US holds almost 60% of the global biotech sector.<sup>6</sup> “The US biotechs are receiving significantly more private funding, certainly more than the European biotechs,” says Smyth. “And when it comes to the public markets, we’re also seeing the IPOs being much larger on NASDAQ than the exchanges elsewhere.” Mergers and acquisitions (M&A) are one way to expand successfully in global markets to combine resources and reduce costs, he adds.

### Advantages Of Strategic Partnerships

Whether big or small, biotechs today are facing the critical issue of supporting clinical trials in new markets. “It’s tough to find sites with the required capabilities,” says Smyth. “Those are limited. The logistical considerations are critical and what we’re finding is not every biotech company is going to have that experience and expertise in-house. A sensible way to have a presence in the new market is to partner with a CRO like ICON, which has a global footprint.”

Partnering with CROs who have the necessary experience, can act as a consultative partner and provide the necessary drug development advice is key. Biotech is expected to drive CRO market growth the most, with a CAGR of 11% between 2020 and 2025.<sup>7</sup> In terms of regulation, keeping pace with global requirements and guidance can be tricky. “Partnerships can be beneficial if the partner has the geographic footprint and the qualified resources to advise and

help the company navigate the various regulations,” says Smyth.

ICON offers full-service, trusted partnerships that deliver a clearly defined set of shared goals, tracked with key performance indicators as well as transparency and clear communication. Its biotech division consists of more than 8,000 people who are “dedicated to serving the unique needs of biotech companies and thereby understand the pressures that companies are facing as they look to develop their life changing treatments,” Smyth emphasizes.

### The Future Of Biotech

As changes continue in the biotech landscape, future innovation is expected to bring forward never-before-seen treatments. Combination modalities are taking advantage of CAR-T cells, as “CRISPR technology for genetic editing is allowing us to overcome some of the limitations of the CAR-T therapies and producing something that’s a bit more affordable, has better efficacy and certainly less off-target toxicities,” says Smyth. Innovation in the APAC markets specifically has a lot of potential, he adds, with China’s big players, WuXi Biologics and Beigene, making waves in the East.

The future of biotech is bright and the reliance on CRO partnerships will continue, Smyth concludes, due to the nature of the current landscape. Companies

have already shown tremendous resilience after the pandemic, during high rates of inflation, interest rate rises and talent shortages. Outsourcing is one way for them to ease the burden of managing competing factors along with partnering with large pharma. “It’s large pharma that has real strength in commercialization, so that’s a good partnership within the industry – the innovation coming from biotech and the commercial strength from large pharma,” Smyth notes.

“I’m optimistic that we’re seeing green shoots of recovery. It’s encouraging to see that not only did biotech companies expect their own R&D spending to increase in the next couple of years, but the proportion of that outsourced R&D spending is also expected to increase. So, companies that are outsourcing strategically to CROs like ICON are benefiting from our industry-leading therapeutic and clinical trial experience.”

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